

Texas Pill Mills

The Prescription Opioid Epidemic

October 30, 2016



The United States Department of Justice
Drug Enforcement Administration

Lisa Sullivan, DPM
DEA Dallas Division





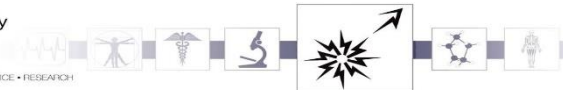
Lisa Sullivan

Ms. Lisa Sullivan is an alumna of New Mexico State University where she graduated with a Bachelor of Criminal Justice degree in 1989. She began her career with the DEA in 1990 as a Diversion Investigator in the San Antonio District Office. In 2000 she became the Diversion Group Supervisor in the San Antonio Office. The group was responsible for the dismantling and successful prosecution of one of the first internet pharmaceutical cases in the country. In 2005 Ms. Sullivan was transferred to the E-Commerce Section of the Office of Diversion Control DEA in Washington DC. There she worked on the CSOS program (the newly established controlled substance electronic ordering system), the SearchPoint prescription database, and the electronic prescriptions initiative (EPCS). She helped present and establish protocols for the Distributor Initiative which addresses the excessive or unusual sales of legitimate pharmaceuticals by distributors. In 2007 she was assigned to the office of Enforcement Pharmaceutical Section DEA HQ where she continued to establish targets for future deployments with regards to internet pharmacy investigations. In November 2007 Ms. Sullivan was transferred to the position of Diversion Program Manager for the Dallas Division where she establishes priorities and direction for the Diversion Groups in Dallas, Ft. Worth, and Tyler, Texas, as well as Oklahoma City, and Tulsa, Oklahoma.

Ms. Sullivan has no relevant financial relationships to disclose.

Texas Pain Society

PATIENT CARE • EDUCATION • SERVICE • RESEARCH





Learning Objectives

- Identify and Understand the Scope of the Prescription Drug Abuse Problem in America
- Understand the Various Schemes Utilized to Divert Pharmaceutical Controlled Substances
- Understand the Role Practitioners Play in Preventing Diversion

Public Health Epidemic





Mayo Clinic Study on Prescription Drugs

atlanta.cbslocal.com/2013/06/19/study-70-percent-of-americans-on-prescription-drugs-one-fift

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NEWS

Study: 70 Percent Of Americans On Prescription Drugs

June 19, 2013 12:59 PM

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Rochester, Minn. (CBS ATLANTA) – Researchers find that nearly 70 percent of Americans are on at least one prescription drug, and more than half receive at least two prescriptions.

Mayo Clinic [researchers report](#) that antibiotics, antidepressants and painkiller opioids are the most common prescriptions given to Americans. Twenty percent of U.S. patients were also found to be on five or more prescription medications.

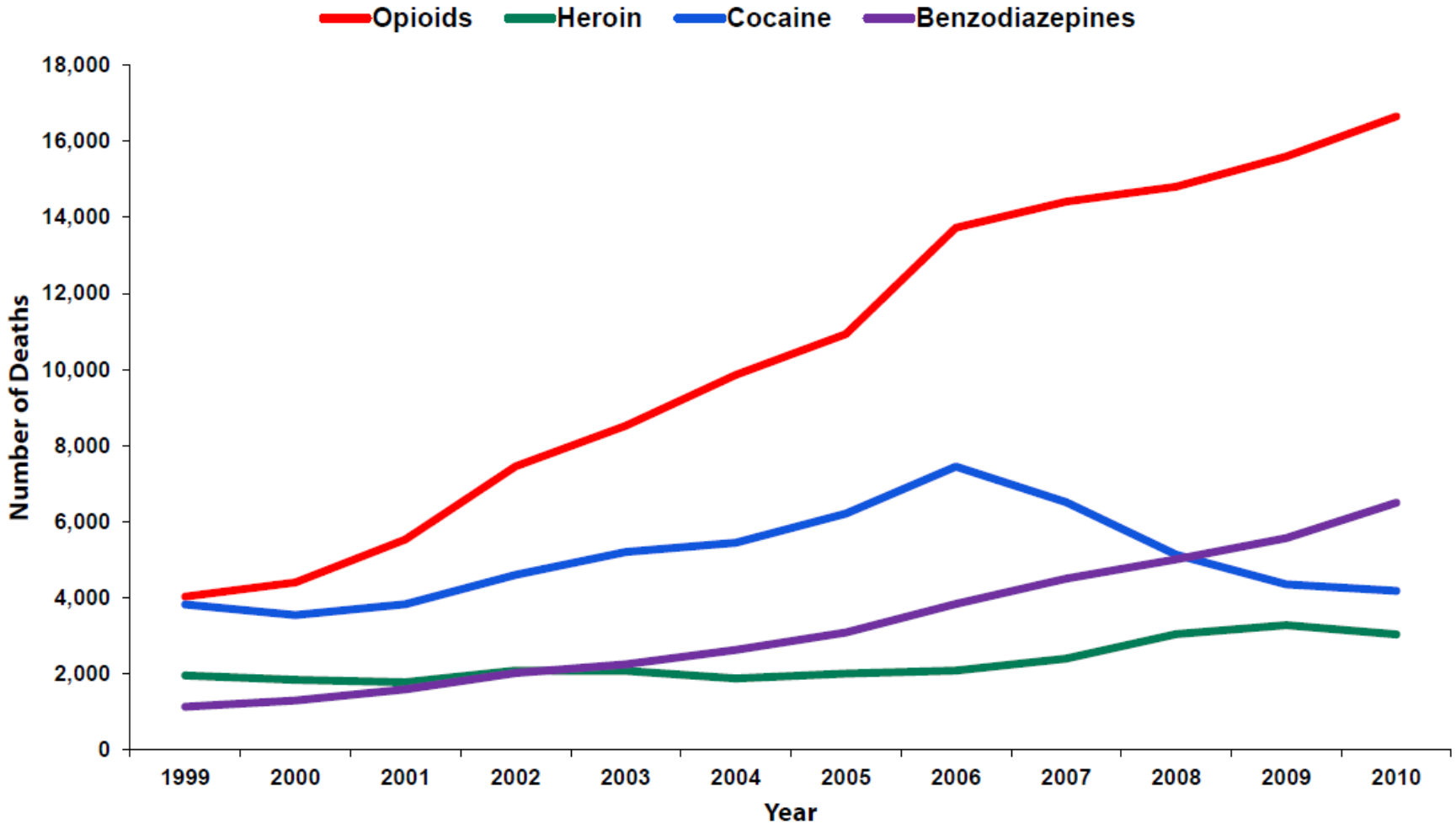
Research finds that nearly 70 percent of Americans are on at least one prescription drug, and more than half receive at least two prescriptions. (Getty Images)

The [study](#) is uncovering valuable information

- The three most common types of prescriptions are antibiotics, antidepressants, and **painkiller opioids**
- 70% of Americans are taking at least one prescription drug
- More than 50% are on at least two prescriptions



Public Health Epidemic



CDC National Center for Health Statistics/Morbidity and Mortality Weekly Report (MMWR); January 1, 2016

U.S. Drug Enforcement Administration
Office of Diversion Control



Public Health Epidemic

2000-2014:

Unintentional drug overdose deaths in the US increased 137%, which was a 200% increase in overdose deaths involving opioids.

2015:

Over **47,000** drug-related overdose deaths

28,647 deaths involved opioids, including heroin

19,000 deaths involved prescription opioid

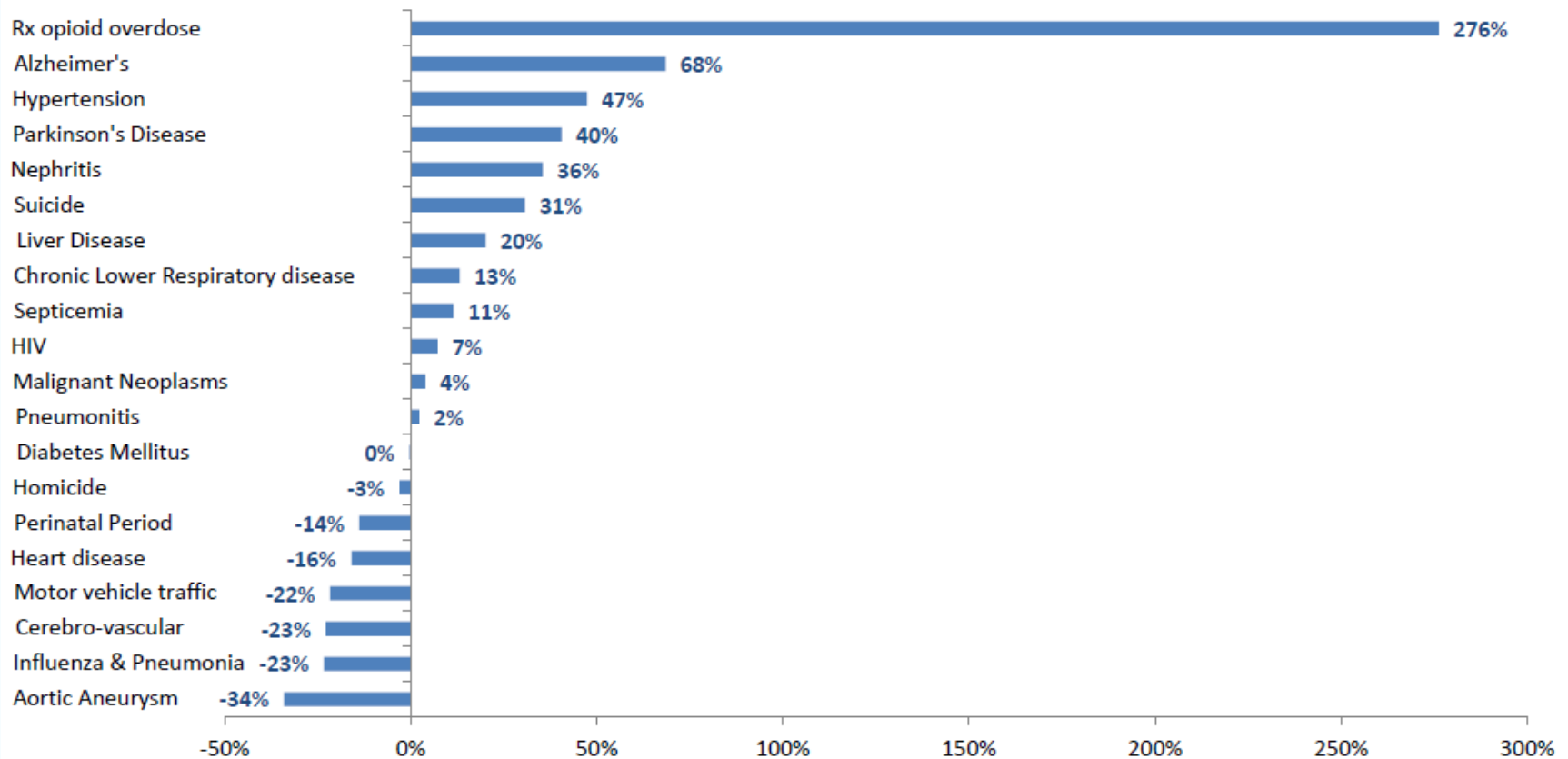
1 death every 11.16 minutes

46 deaths by end of a normal work day(8 ½ hours)

129 deaths every 24 hours

Opioid pain reliever-related overdose deaths increasing at a faster rate than deaths from any major cause

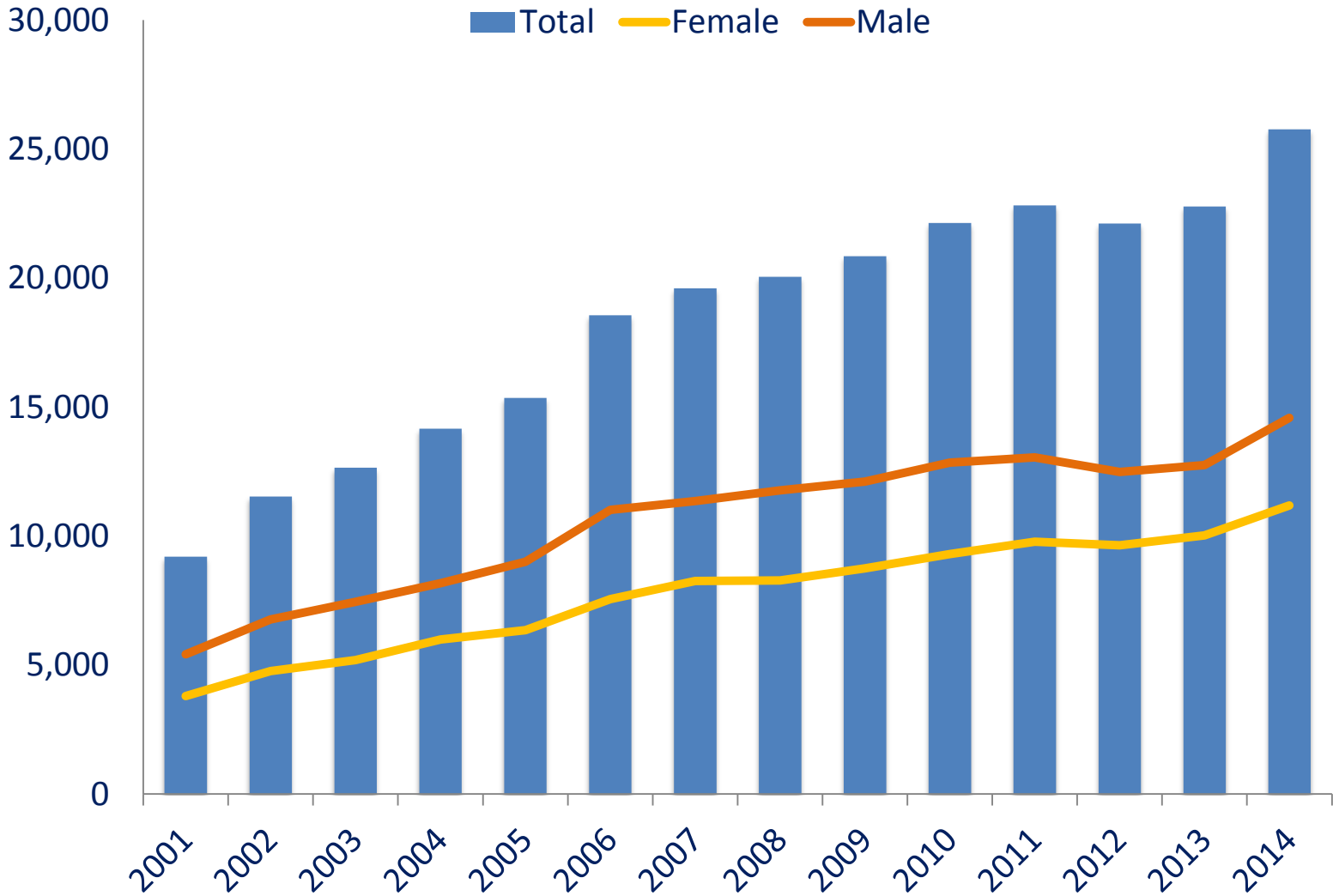
% change in number of deaths, United States, 2000-2010





National Overdose Deaths

Number of Deaths from Prescription Drugs

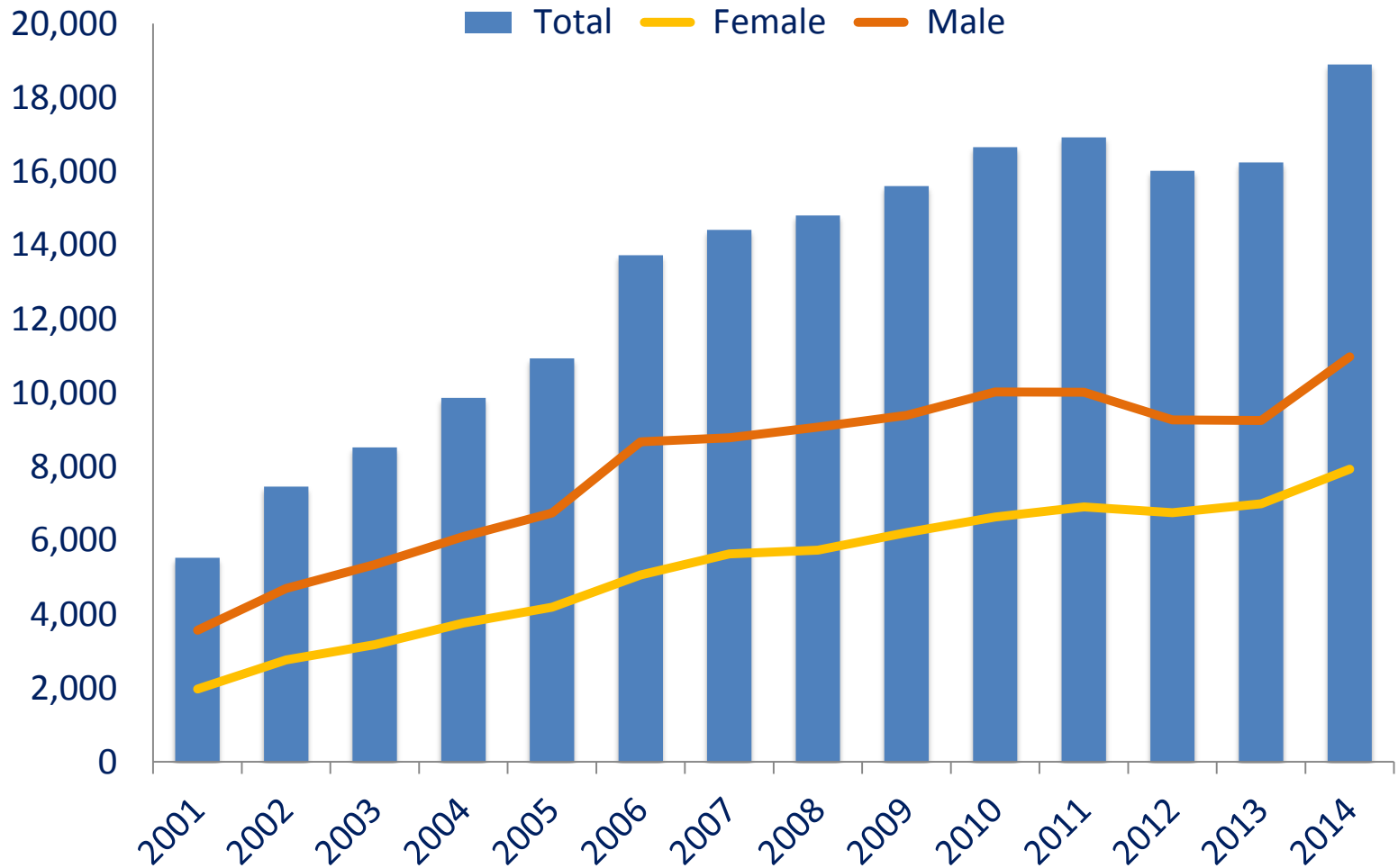


Source: National Center for Health Statistics, CDC Wonder



National Overdose Deaths

Number of Deaths from Prescription Opioid Pain Relievers

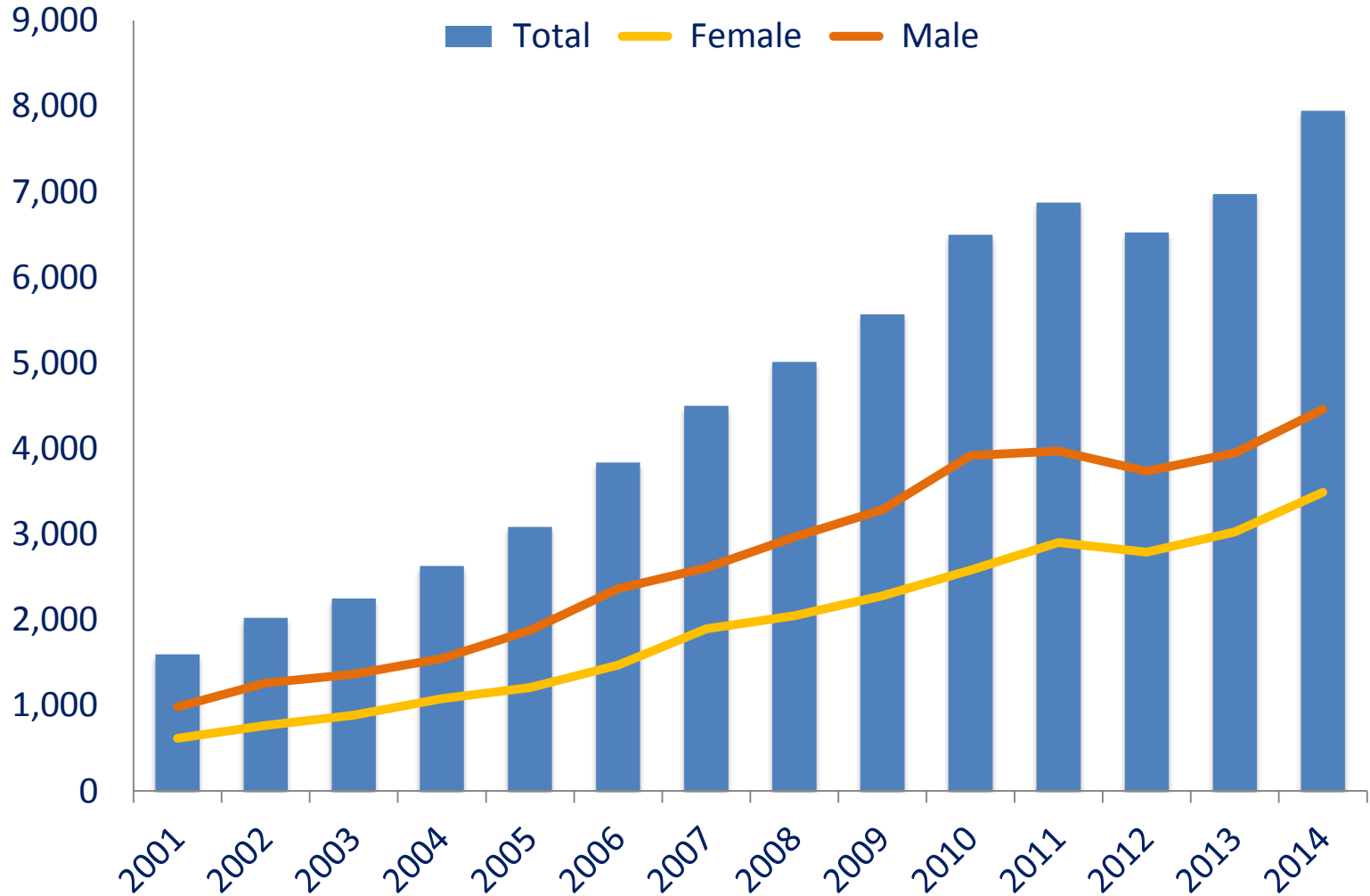


Source: National Center for Health Statistics, CDC Wonder



National Overdose Deaths

Number of Deaths from Benzodiazepines

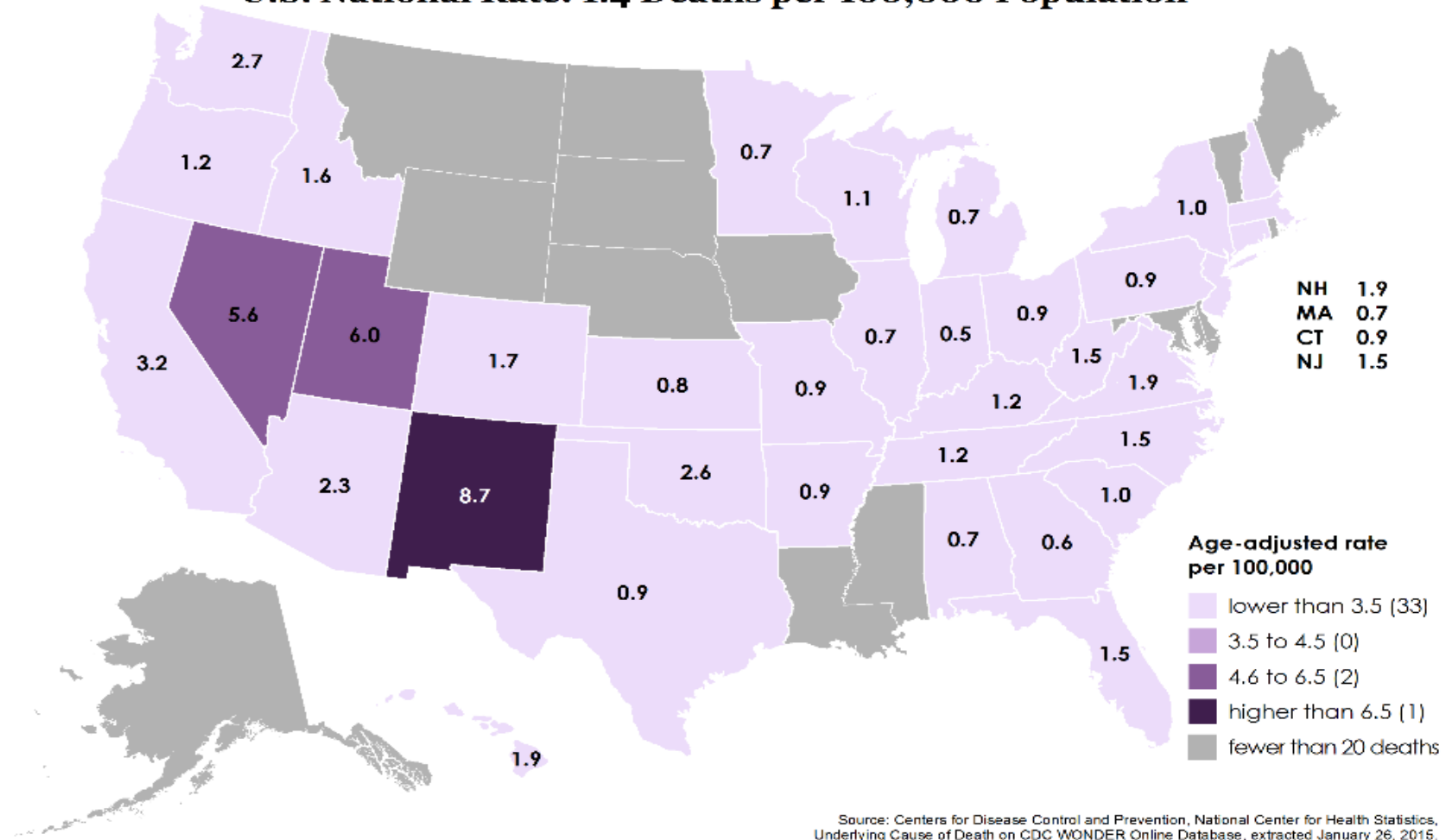


Source: National Center for Health Statistics, CDC Wonder

Prescription Opioid Analgesics Poisoning Deaths

Opioid-Involved Drug Poisoning Death Rates by State, 1999

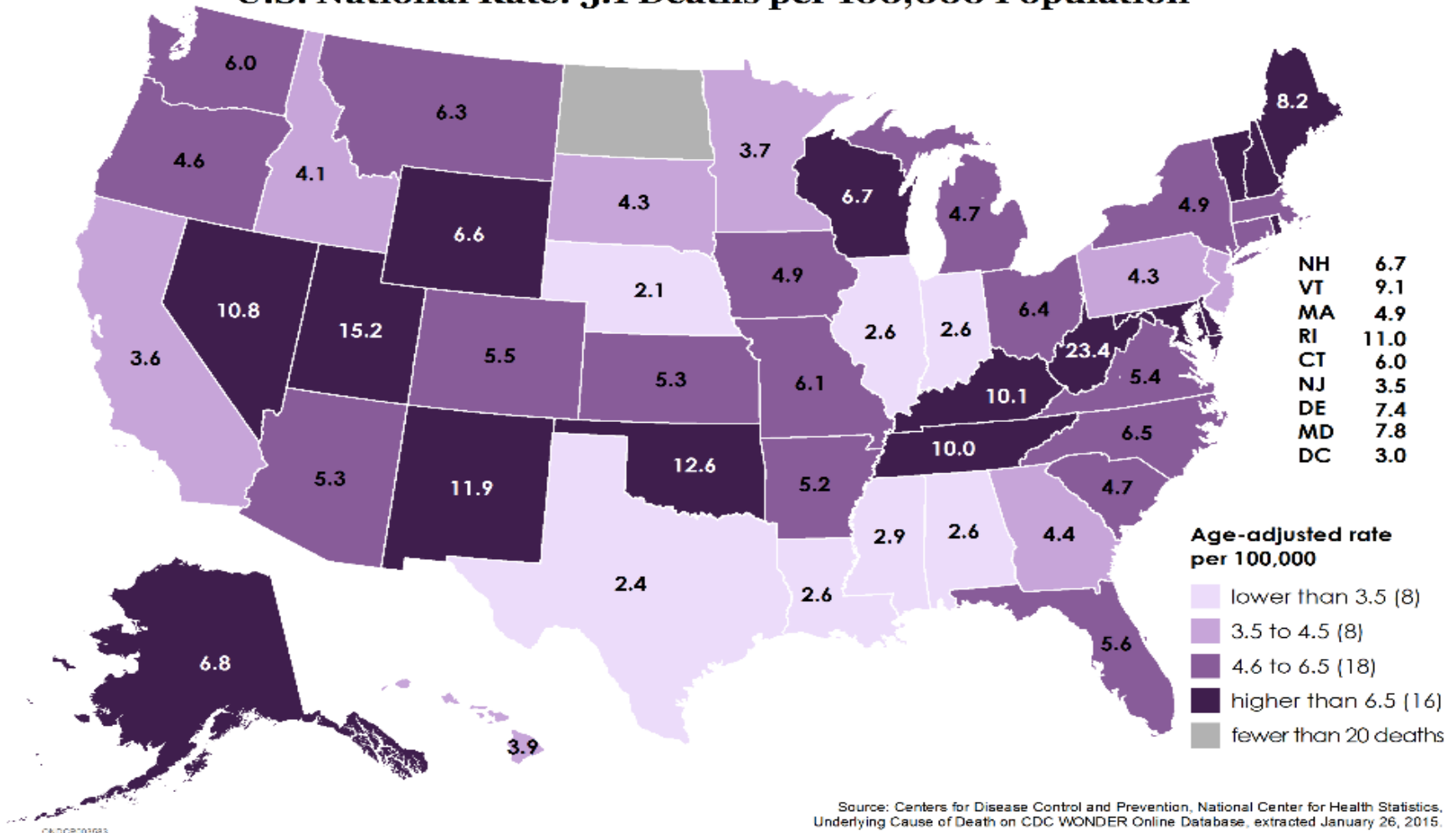
U.S. National Rate: 1.4 Deaths per 100,000 Population



Prescription Opioid Analgesics Poisoning Deaths

Opioid-Involved Drug Poisoning Death Rates by State, 2013

U.S. National Rate: 5.1 Deaths per 100,000 Population



Source: Centers for Disease Control and Prevention, National Center for Health Statistics, Underlying Cause of Death on CDC WONDER Online Database, extracted January 26, 2015.



Prescription Drug Abuse
is driven by
False Information
AND
Indiscriminate Prescribing
Criminal Activity



PAIN “THE 5TH VITAL SIGN”

- In 1996 The American Pain Society introduced the phrase “pain as the 5th vital sign”
- In the mid 1990s Purdue Pharma developed Oxycontin and launched an aggressive fraudulent marketing campaign
- In 2007 Purdue Pharma paid a 600 million dollar fine for misleading doctors and patients about the drugs risks and addiction potential
- In 2016 the CDC issues guidelines for prescribing Opioids for Chronic Pain



CDC GUIDELINES

- Opioids are not first-line or routine therapy for chronic pain
- Establish and measure goals for pain and function
- Discuss benefits and risks and availability of nonopioid therapies with patient.....
- When opioids are needed for acute pain prescribe no more than needed.....



Prescription Drug Abuse

United States 5.5% of World's Population



United States Consumes 75% of World's Prescription Medication!



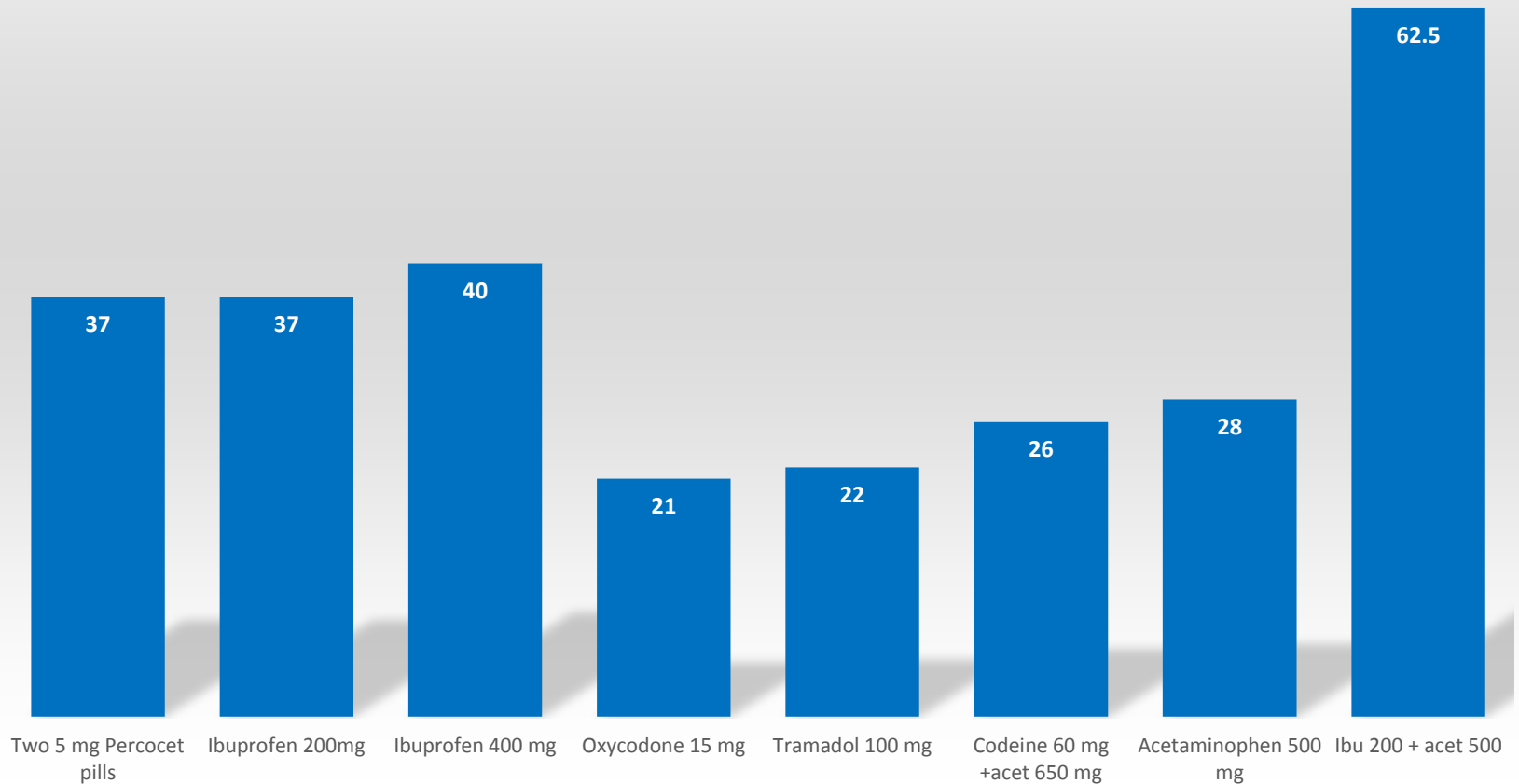
America's Love Affair with Hydrocodone

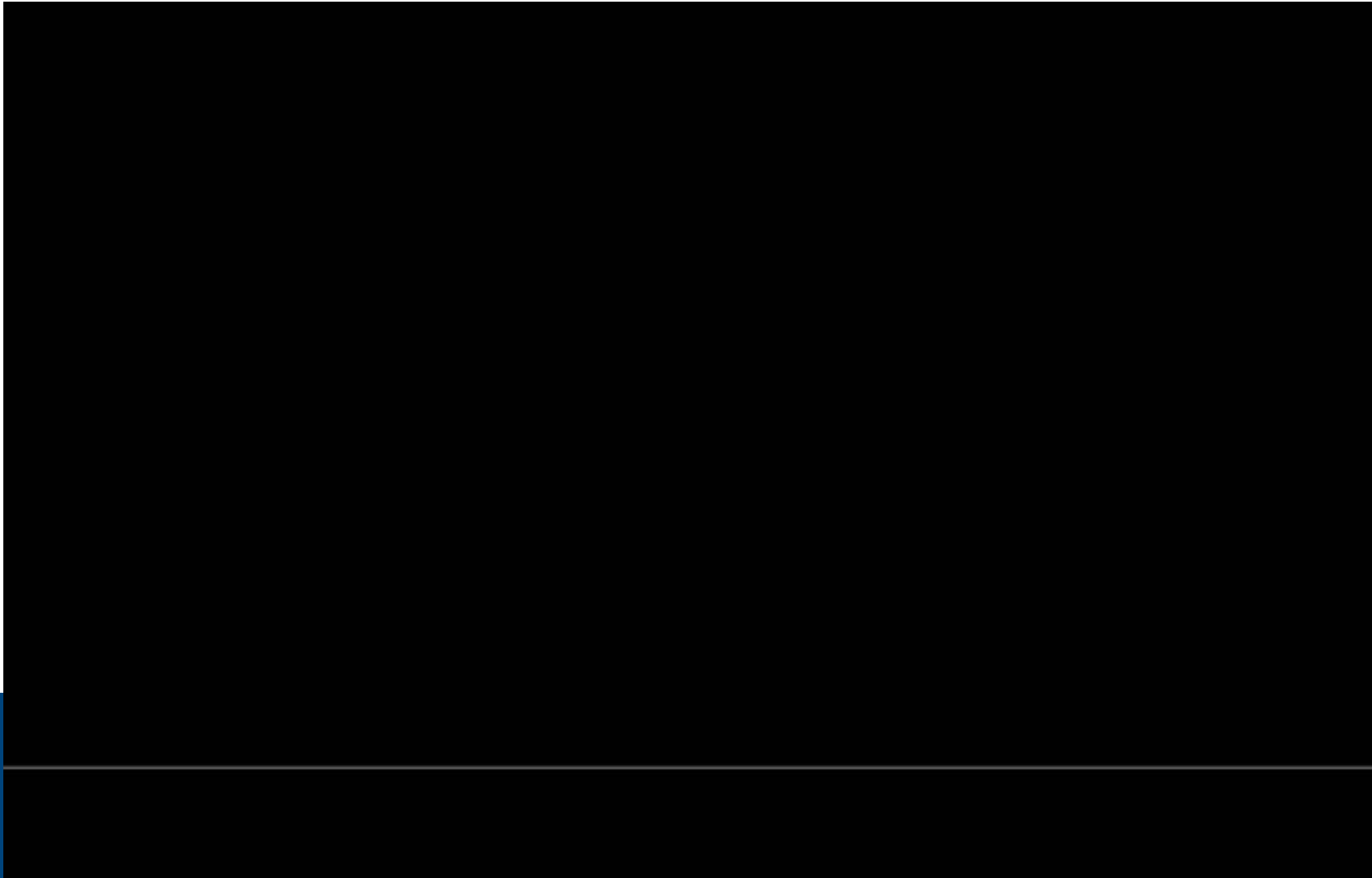
- THE UNITED STATES MAKES UP 5 PERCENT OF THE WORLDS POPULATION
- WHAT PERCENTAGE OF THE WORLD'S HYDROCODONE USAGE DOES THE UNITED STATES MAKE UP?

Hydrocodone Top 10 List

- Guatemala 10 Kilograms
- Mexico 10 Kilograms
- Vietnam 20 Kilograms
- China 20 Kilograms
- Denmark 25 Kilograms
- Syrian Republic 50 Kilograms
- Germany 60 Kilograms
- Canada 100 Kilograms
- United States 79,700 Kilograms (99.5%)

Percent of people getting 50% pain relief
(from acute postop pain)
1/NNT
From Cochrane Reviews





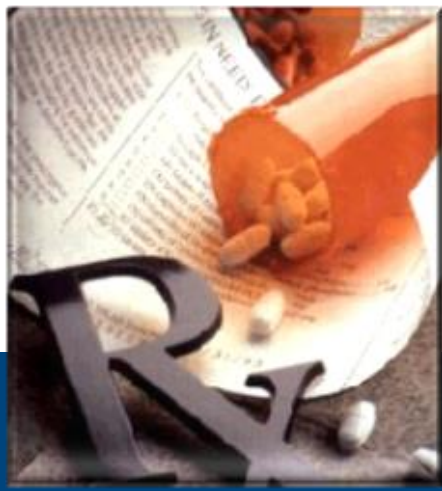


Drug Enforcement Administration/Operations
Division/Office of Diversion Control

Impact on Our Society



Drugs of Abuse





Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen

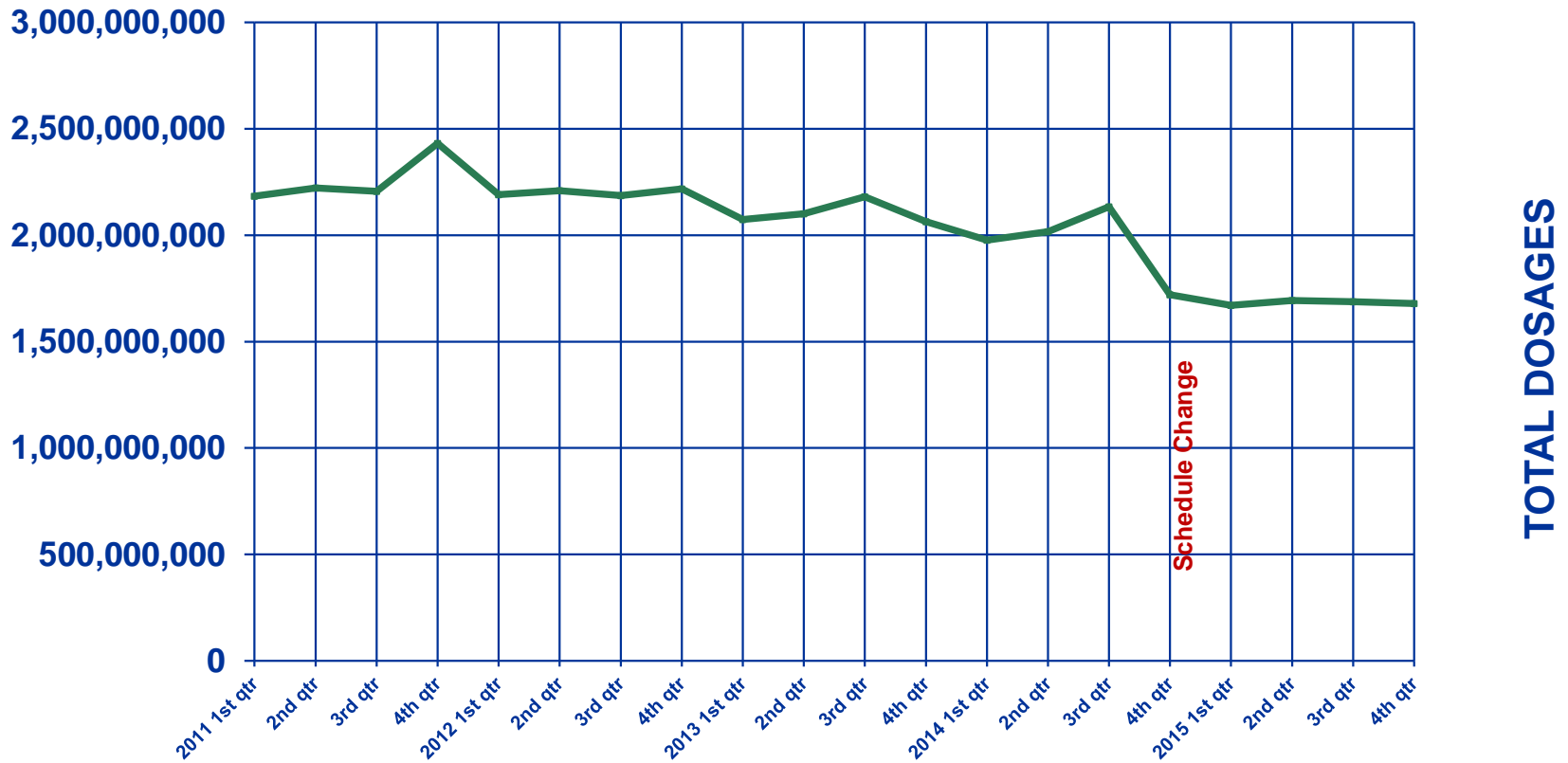
Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)
- Similarities:
 - Structurally related to codeine
 - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin[®], Lortab[®], Lorcet[®]
- **October 6, 2014 moved to SCHEDULE II**
- “Cocktail” or “Trinity”
 - Hydrocodone
 - Soma [®] / carisoprodol
 - Alprazolam / Xanax[®]



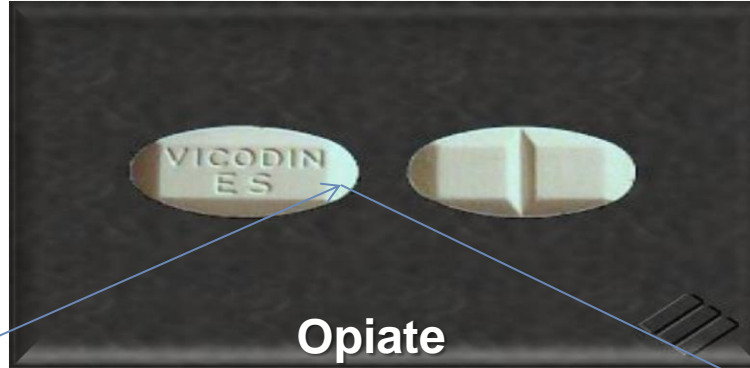
Street prices: \$2 to \$10+ per tablet depending on strength & region

Hydrocodone Distribution 2011-2015 U.S. Average

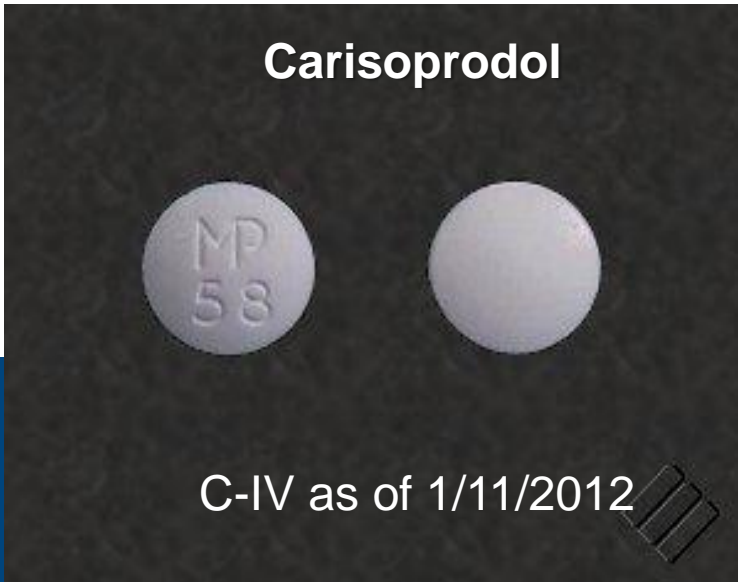


The Trinity

Hydrocodone



Carisoprodol



Muscle Relaxant



Benzodiazepine



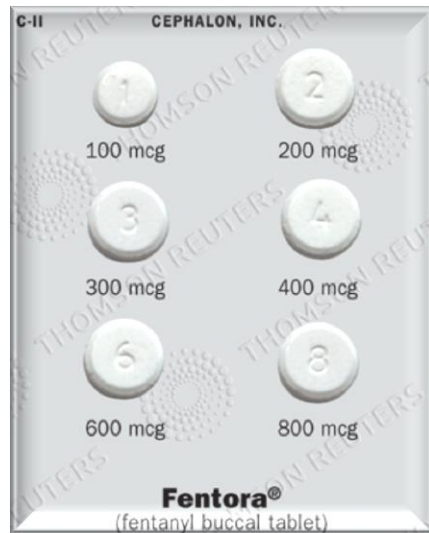
Promethazine with Codeine





“Patient” drinking “syrup” in the parking lot outside doctor’s office in Dallas, Texas

Fentanyl



Fentora®

- Fentanyl Patches
- Fentanyl Citrate dispensed in a berry flavored lollipop-type unit
- Fentanyl is 100 times more potent than morphine
- Intended to be used for chronic cancer pain & only for people who are tolerant to prescription opioid (narcotic) pain medicines
- Abused for its intense euphoric effects





Pill Presses and Fentanyl

- Mixing into the Heroin
- Mixing Fentanyl into Oxycodone or Hydrocodone powders and pressing pills
- In September of 2016 three members of the same family accidentally overdoses on what they thought were Oxycodone pills...the pills were laced with Fentanyl.
-



Hip Hop Music

- Glorified purple drank, jolly rancher, special k
- Then Macklemore took on the pharmaceutical industry
 - The following slides are from:
 - Macklemore & Ryan Lewis “Kevin”
 - Macklemore & Ariana DeBoo “Drug Dealer”



**I seen pain, I felt the losses
Attended funerals and seen
coffins
21 years old, an angel was lost
here
Wings clipped by the grip of 80
milligram sniffs of oxycontin
Everyday through the nostrils**



**And now my little brother is in
the sky
From a pill that a doctor
prescribed
That a drug dealing billion
dollar industry supplied
And the cops never go and
profile at night**



**Because a doctor with a
license played God and said
it's cool
Played God and said it's cool
But me? I don't blame Kev or
his mom freebasing while
pregnant with him I blame the
pharmacy companies**



Now he's wrapped in plastic
First dealer was his mom's
medicine cabinet
Got anxiety, better go and give
him a Xanax
Focus, give him Adderall,
sleep, give him Ambien



[Hook: Ariana DeBoo]

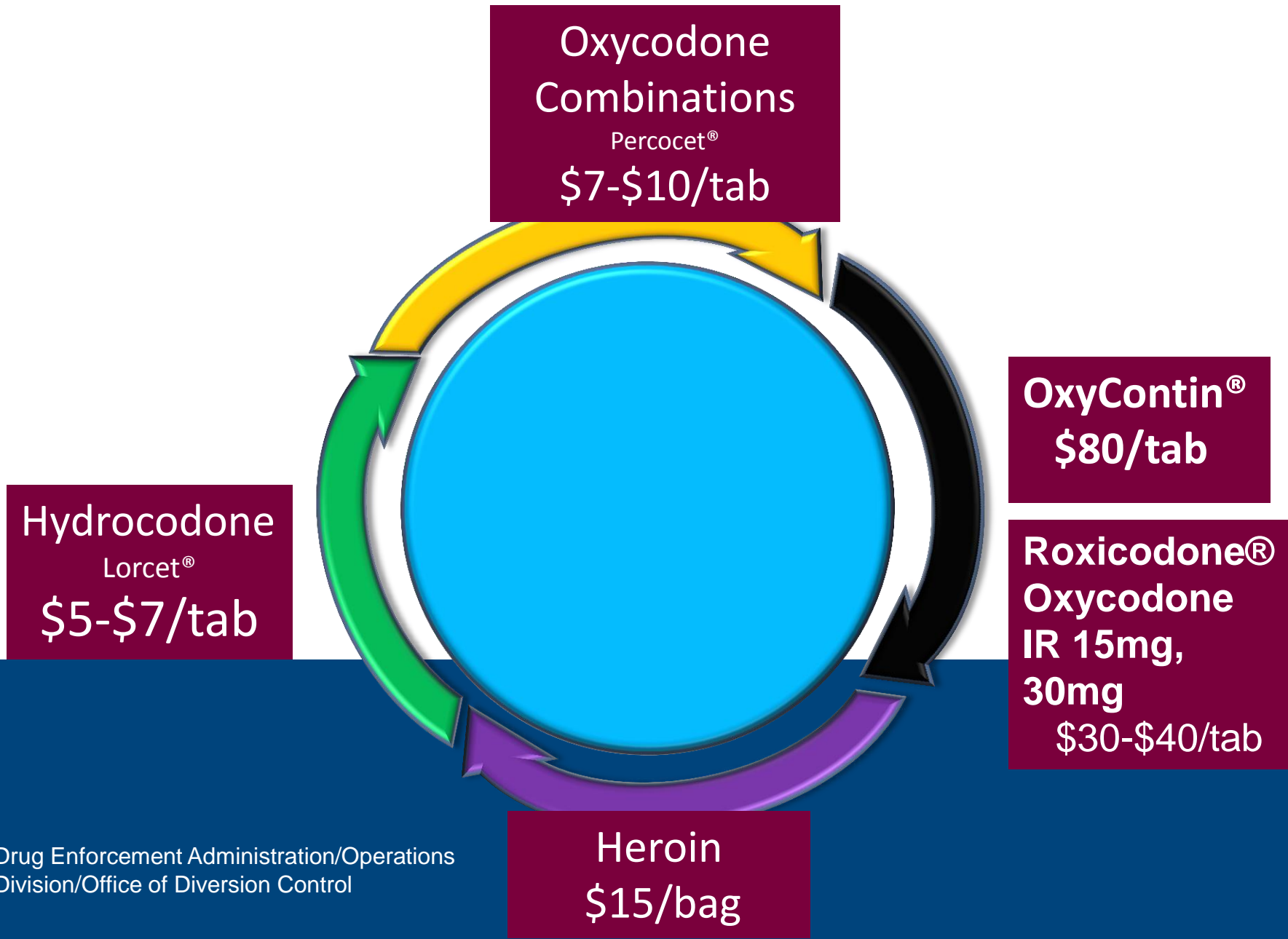
My drug dealer was a doctor, doctor
Had the plug from Big Pharma, Pharma
He said he'd heal me, heal me
But he only gave me problems, problems
My drug dealer was a doctor, doctor
Had the plug from Big Pharma, Pharma
I think he tryin' kill me, kill me
He tried to kill me for a dollar, for a dollar



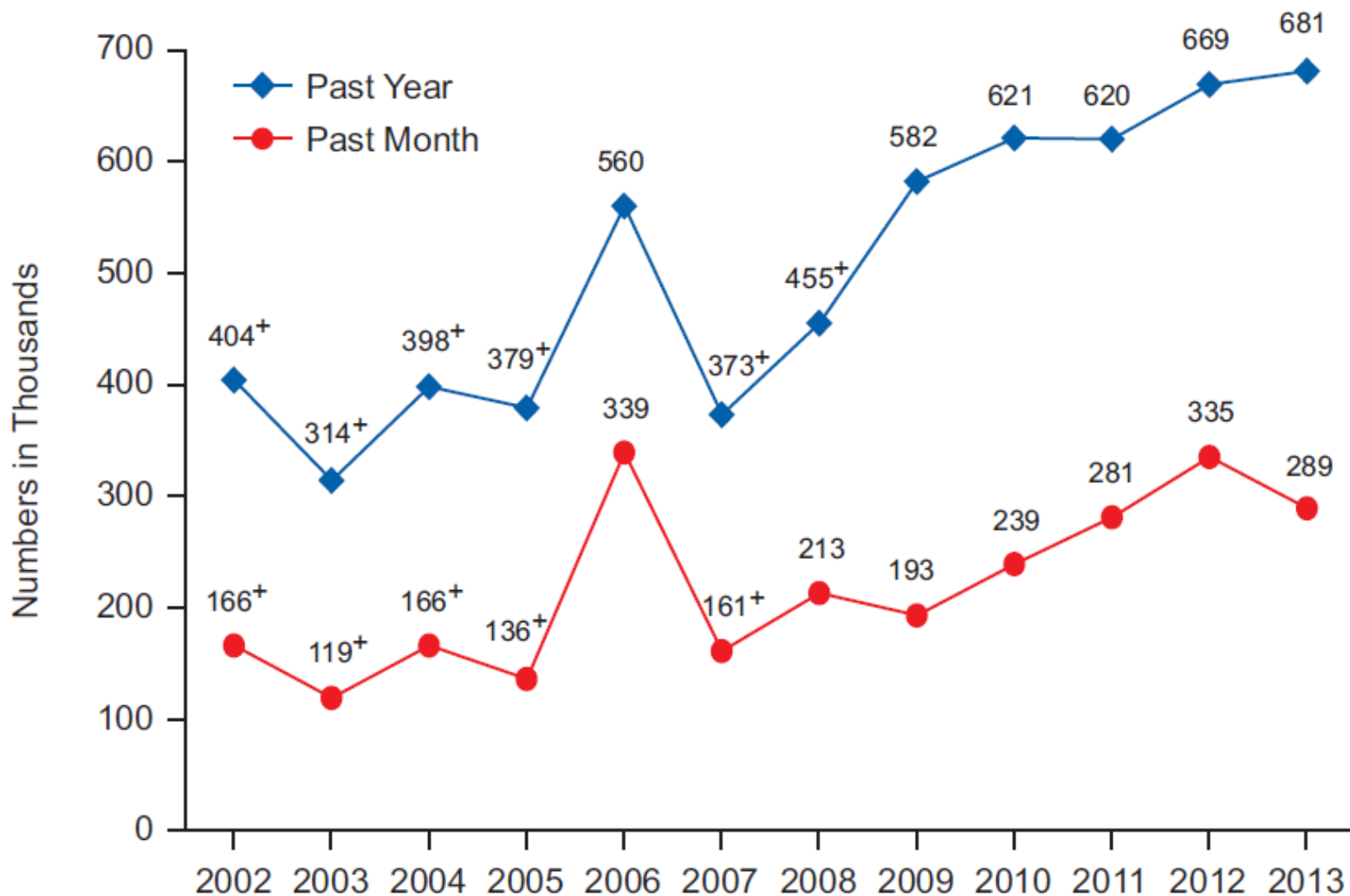
Prescription Opiates v. Heroin



Circle of Addiction & the Next Generation



Past Month and Past Year Heroin Use Among Persons Aged 12 or Older: 2002-2013



⁺ Difference between this estimate and the 2013 estimate is statistically significant at the .05 level.

HEROIN: NO LONGER CONFINED TO URBAN AREAS

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'Liaisons Dangereuses'
New approach to classic P. 19



Playoff possibilities
Schedule favors Skins P. 35

Cooling down



60° 34°
DETAILS P. 4

POLITICS

Stalemate on 'cliff'
Sides stop talking;
Obama's rate hikes
may be flexible. P. 13

LOCAL

FBI analyst busted

Heroin use spikes in area suburbs Pill addicts risk deadly drug

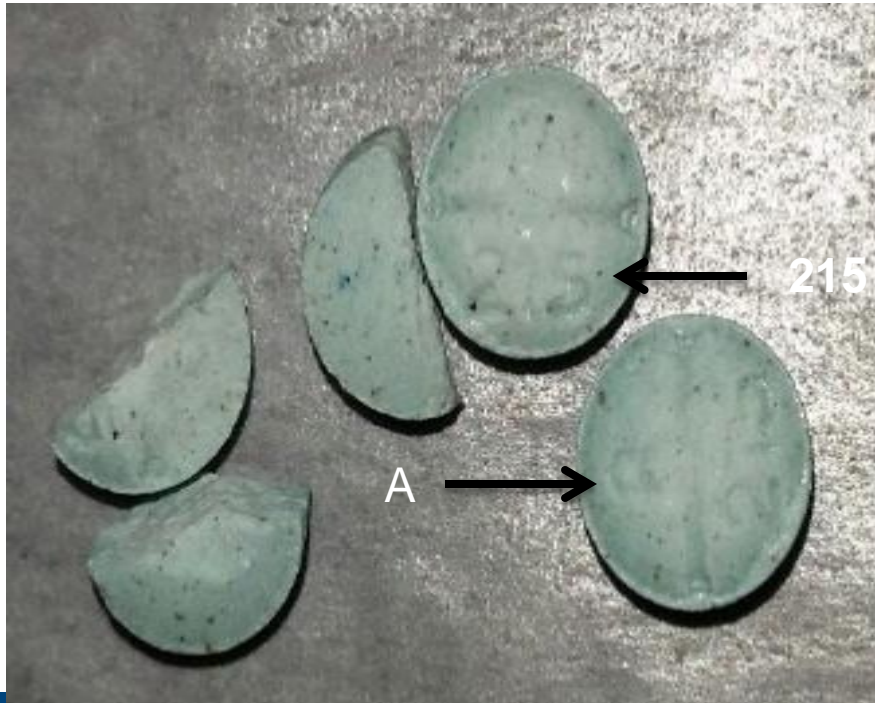


Non-medical Prescription Opioid Users Who Try Heroin

- Prescription opioid use is a risk factor for heroin use. Approximately 4 out of 5 recent heroin initiates ages 12-49 used prescription opioids non-medically before heroin initiation.¹
- Transition from prescription opioid abuse to heroin use is relatively rare; approximately 4 percent of prescription opioid abuse initiates begin using heroin within five years of their initiation of prescription opioid abuse.²
- Injection-drug users report that tolerance motivates them to try heroin.³
- New research shows that heroin's effects, price, availability, and ease of use motivate heroin users who formerly used prescription opioids.⁴



1. Muhuri, P.K. Gfroerer, J., Davies, C. (2013). Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. SAMHSA CBHSQ Data Review (August).
2. Ibid
3. Lankenau SE, et al. (2012). Initiation into prescription opioid misuse amongst young injection drug users. Int J Drug Policy. 2012 Jan;23(1):37-44. Epub 2011 Jun 20.
4. Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The Changing Face of Heroin Use in the United States



Heroin Seizure

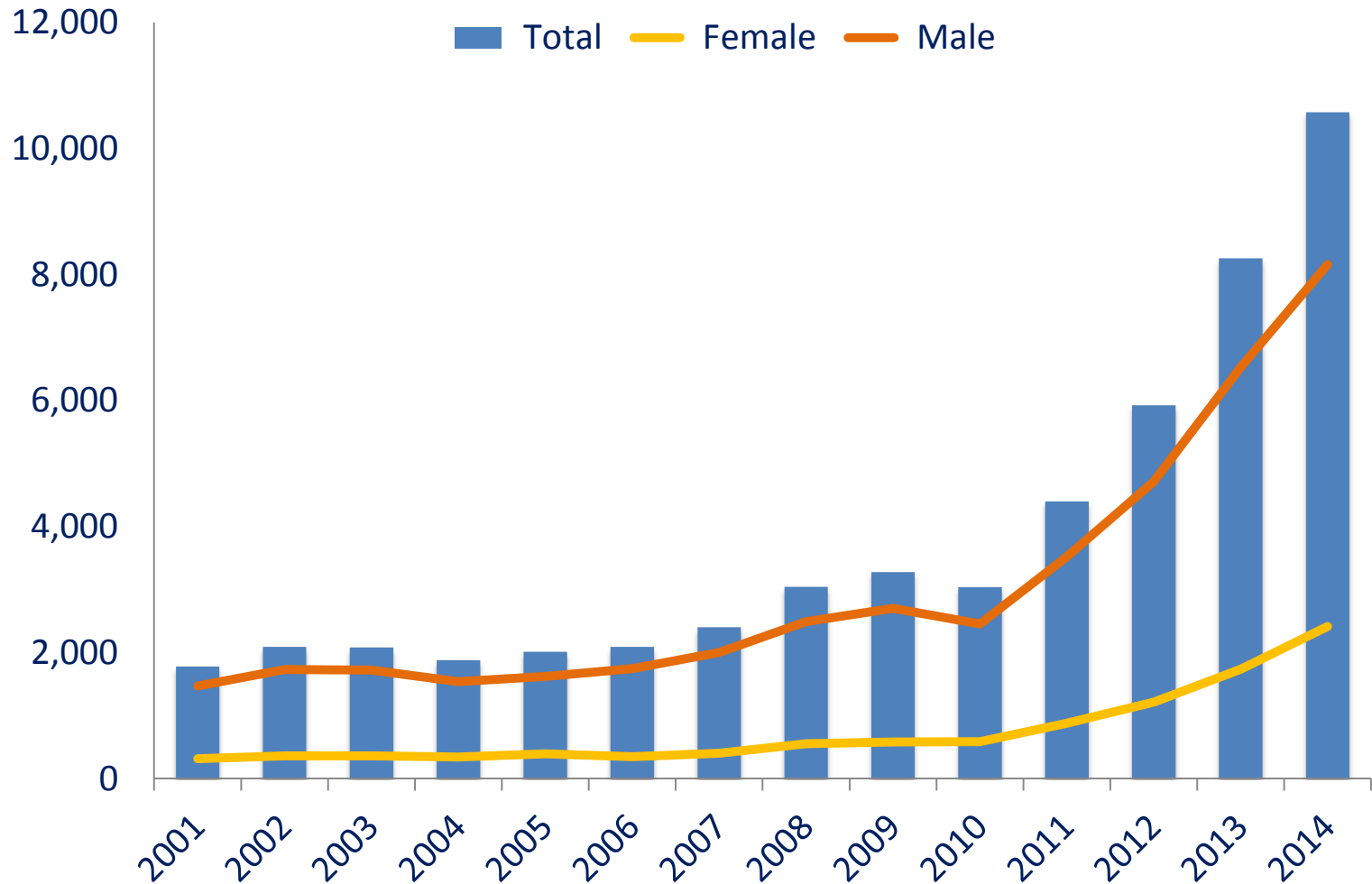


Pharmaceutical Oxycodone 30mg



National Overdose Deaths

Number of Deaths from Heroin



Source: National Center for Health Statistics, CDC Wonder

The Controlled Substances Act: Checks & Balances





Mission

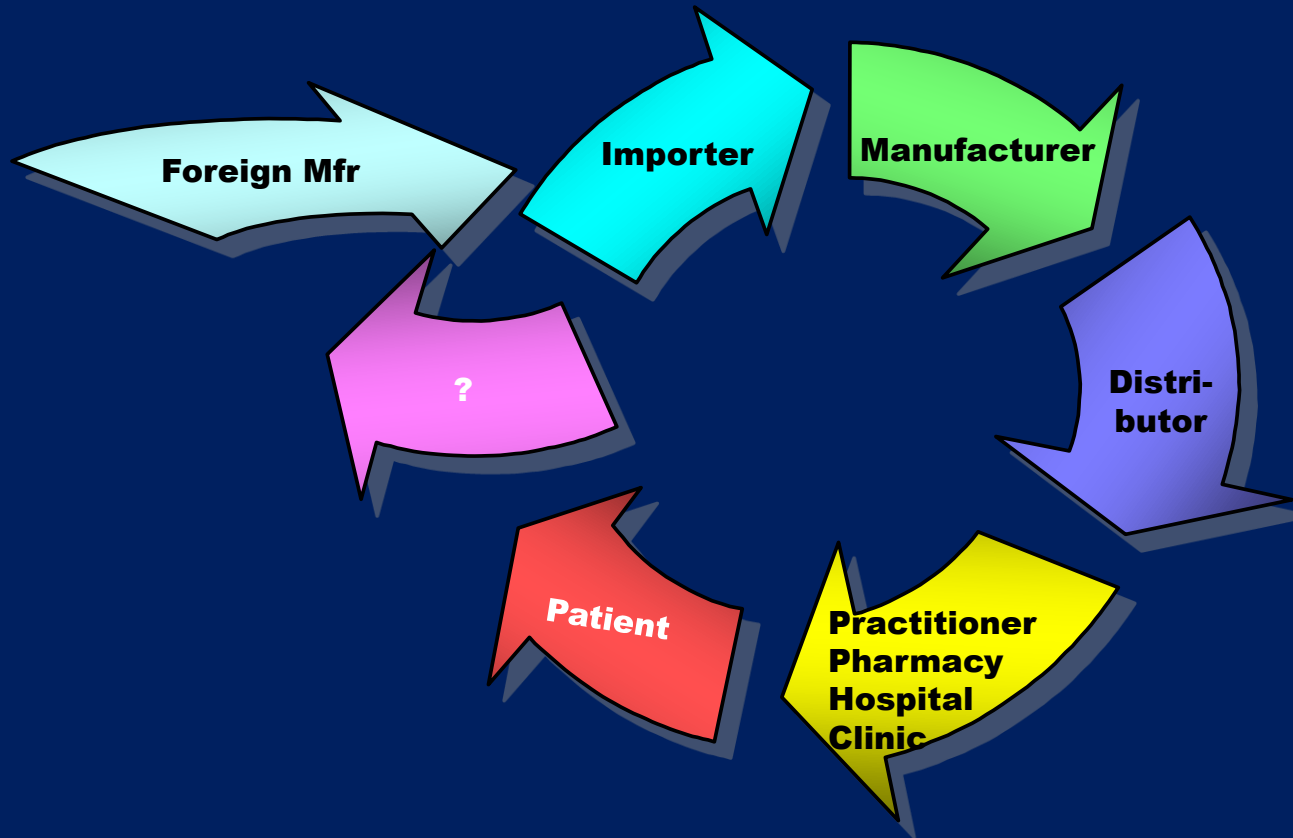
The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

while ...

ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs



Closed System of Distribution



1,604,158 (09/04/2015)

- Practitioners: 1,221,972
- Retail Pharmacies: 71,439
- Hospital/Clinics: 16,500



Closed System of Distribution

The DEA is responsible for:

- the oversight of the system
- the integrity of the system
- the protection of the public health and safety



Legal Obligations: DEA Registrant





Privilege NOT a Right

- The DEA registration may be denied if it would be inconsistent with the public interest. Factors considered are:
 - State Board recommendation
 - Applicant's conviction record
 - Compliance with State/Federal laws
 - Other conduct that threatens public health and safety.



Prescriptions

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

21 CFR § 1306.04(a)

*United States v Moore 423 US
122 (1975)*





Corresponding Responsibility

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

21 CFR § 1306.04(a)





Corresponding Responsibility

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate.
- When a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!



The Last Line of Defense



Drug Enforcement Administration/Operations
Division/Office of Diversion Control

The DEA Response







Diversion Partnership

- **Vigilant Enforcement and Regulation**
 - Identify the Threat
 - DEA Registrants Operating Outside the Law
 - Address the Threat
 - Tactical Diversion Squads (TDSs): 66 Nationally
 - Agents, Diversion Investigations, Intel Analysts
 - Diversion Investigators (DIs): 600+ Nationally
 - Mobile/Regional TDSs
 - Fluid Enforcement Capability
 - Agents/DIs/Analysts
 - Exploring Funding for AUSA / SAUSA Positions



Diversion Partnership

- Develop Data to Identify and Track Problems
 - Prescription Drug Monitoring Program (PDMP)
 - Connecting Registrants Nationwide
 - 49 Participant States / 30 States Interconnected
 - Working with NABP to get 40 states connected
 - Medical Examiners (ME's)
 - *Support funding/resources to have ME's do toxicology screens*
 - Work to Improve Technology and Improve Access to Data
 - *Support Proactive Alerts and Report Cards*



Diversion Partnership

- **Constructive Engagement with the Industry, Practitioners and Government Health Groups**

Office of National Drug Control Policy (ONDCP)

State and Local Health Authorities

National Association of Boards of Pharmacy (NABP)

Health and Human Service (HHS)

American Medical Association (AMA)

National Association of Chain Drug Stores (NACDS)

National Institute of Drug Abuse (NIDA)

Substance Abuse Mental Health Services Administration (SAMHSA)

Food and Drug Administration (FDA)

CDC Office of Noncommunicable Diseases, Injury & Environmental Health (ONDIEH)

CDC National Center for Injury, Prevention & Control (NCIPC)



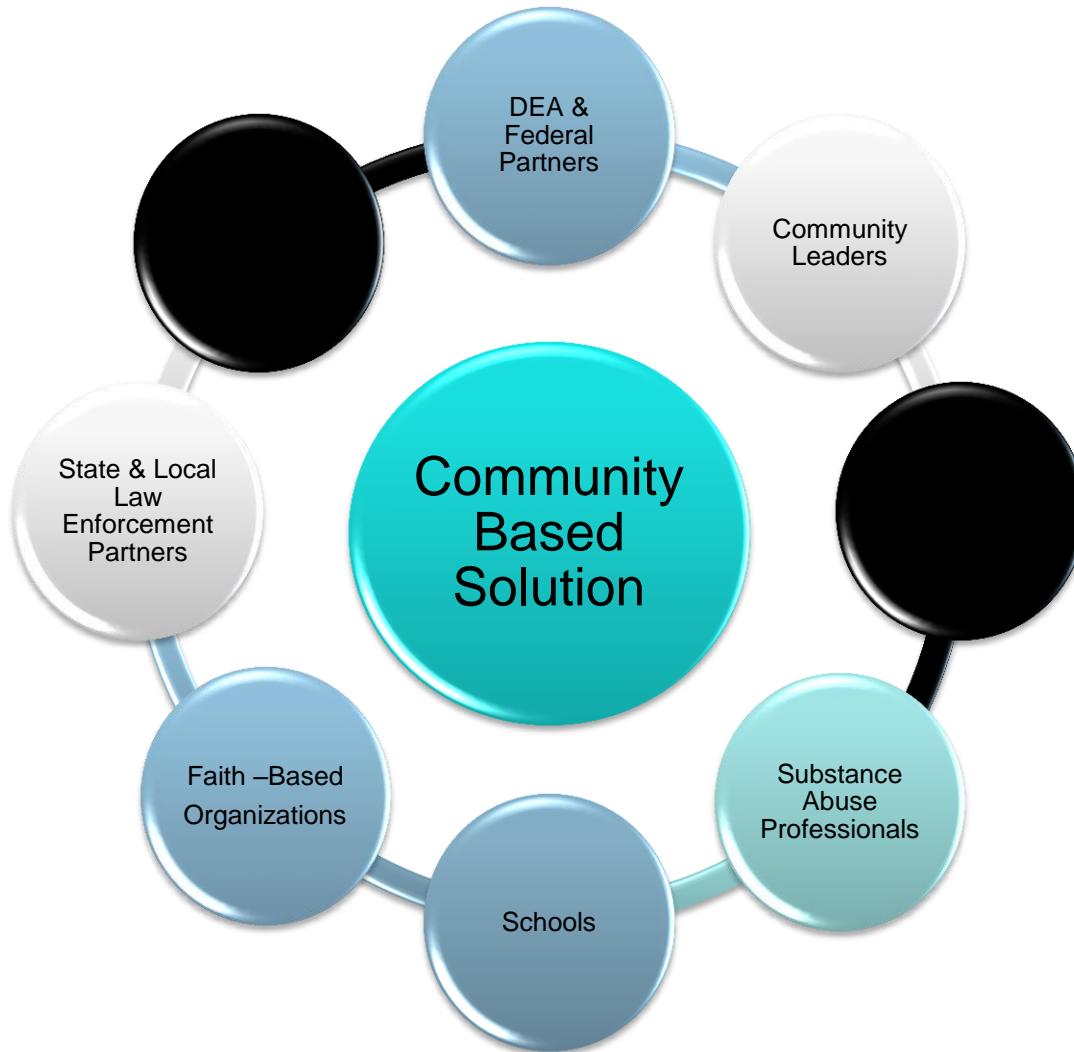
Diversion Partnership

■ Education and Outreach

- National Strategy - *Sustained & Consistent Messaging*
 - *Pharmacist Drug Awareness Conferences (PDAC)*
 - *Industry: Manufacturers, Distributors, Healthcare Executives*
 - *Law Enforcement, Medical Practitioners, Anti-Drug Organizations*
- Local Strategy in 360 Degree Target Areas
 - Heroin Enforcement Ops Create the “Time and Space”
 - Proactive and Robust Community Engagement
 - Local Practitioners/Community Groups
 - Local Field Divisions with HQ Support



Community Partnerships



- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education and prevention efforts.



We will not arrest our way out of this problem!!!!

- Enforcement is just as important as....
- Prevention/Education
- Treatment





Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use





Medicine Cabinets: Easy Access

- More than half of teens (**73%**) indicate that it's easy to get prescription drugs from their parent's medicine cabinet
- Half of parents (**55%**) say anyone can access their medicine cabinet
- Almost four in 10 teens (**38%**) who have misused or abused a prescription drug obtained it from their parent's medicine cabinet

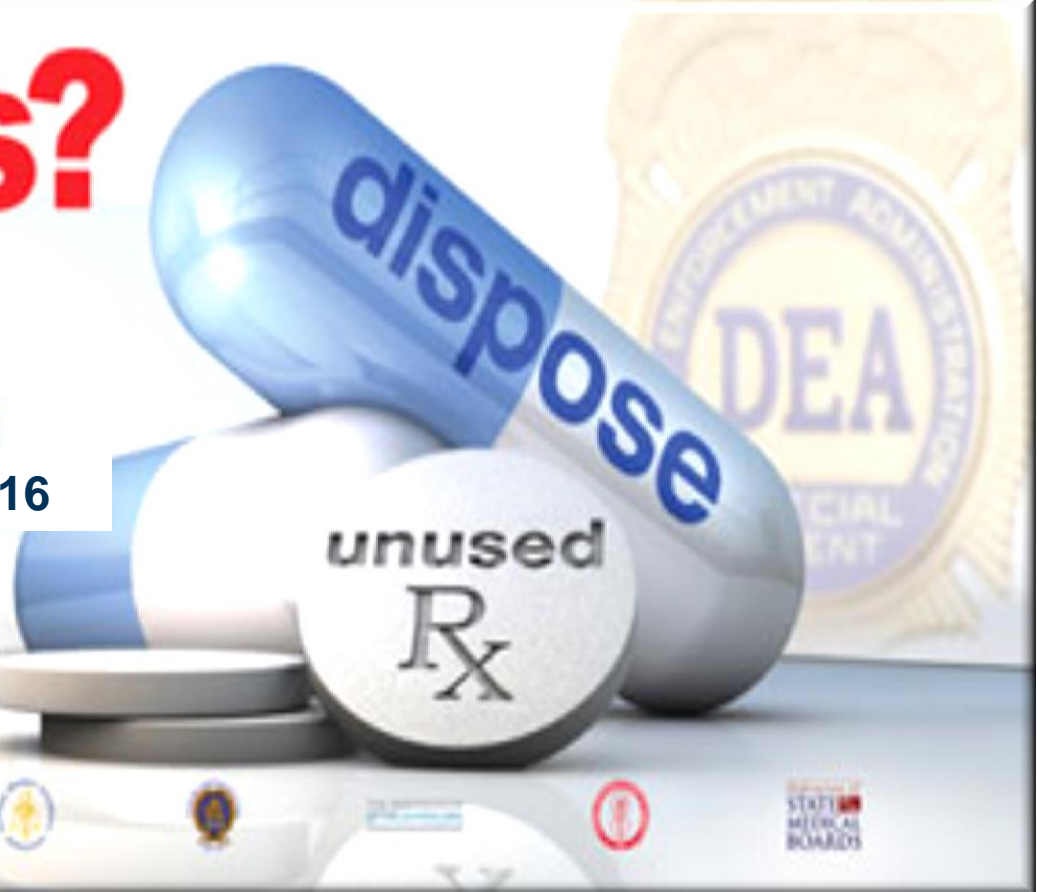
National Take Back Initiative

April 30, 2016

Got Drugs?

Turn in your
unused or expired
medication for safe disposal
Saturday, October 22nd, 2016

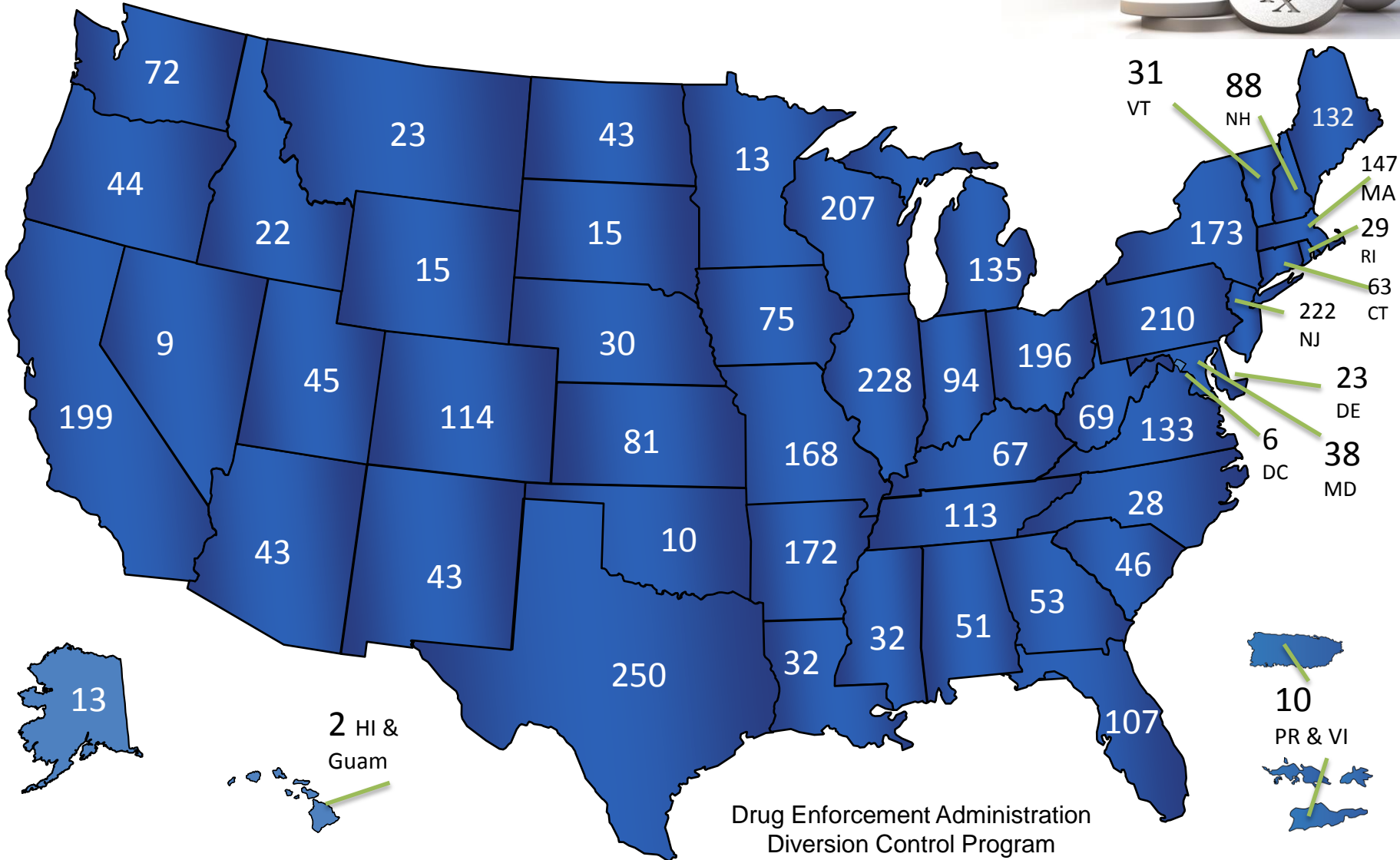
Click here
for a collection
site near you.



Drug Enforcement Administration/Operations
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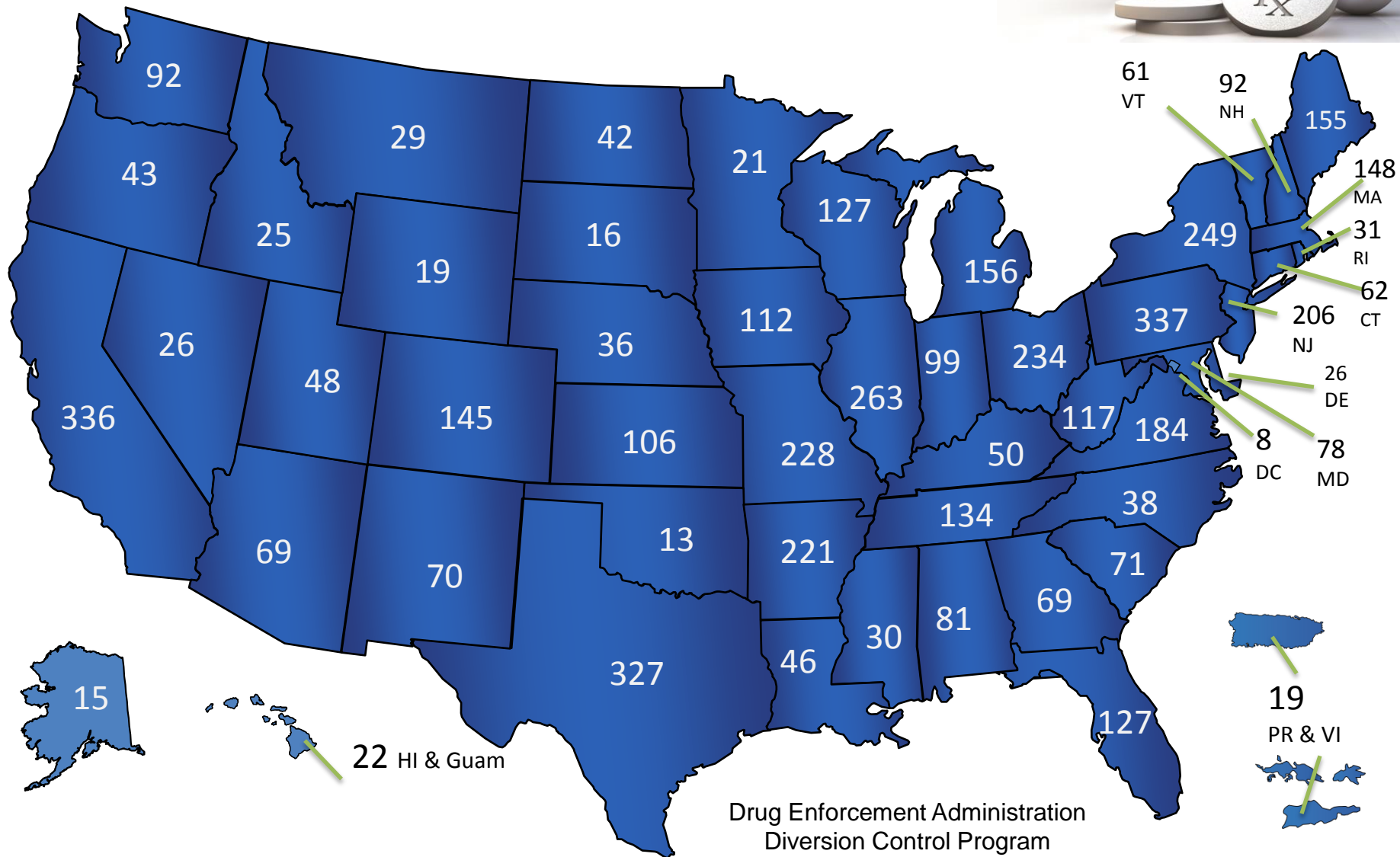
11th National Take Back Day: April 30, 2016

Total Law Enforcement Participation: 4,264



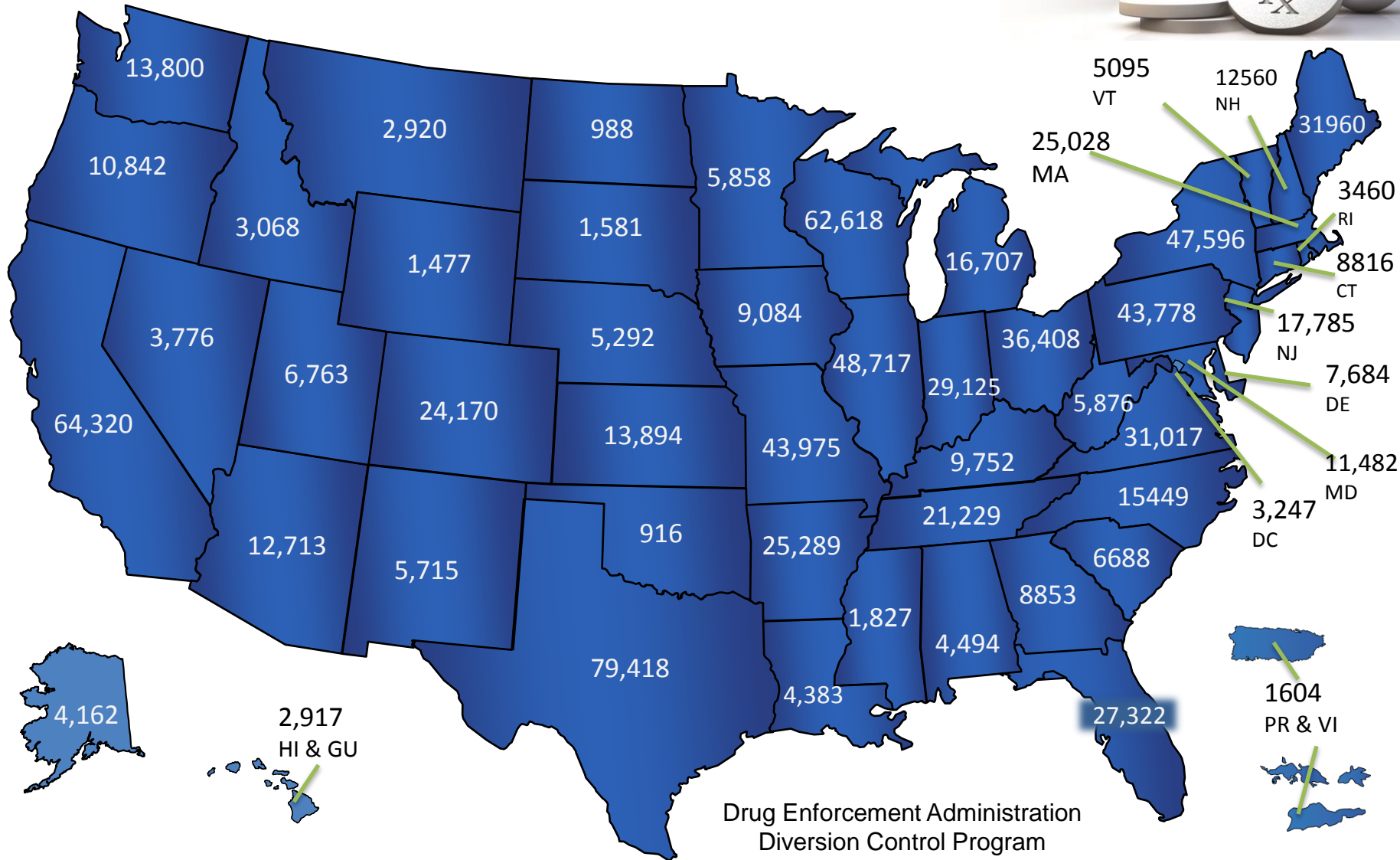
11th National Take Back Day: **April 30, 2016**

Total Collection Sites: 5,359



11th National Take Back Day: **April 30, 2016**

Total Weight Collected (pounds): 893,498 (447 Tons)





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214-366-6936