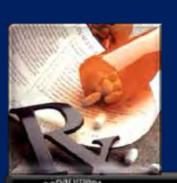


The Opioid Epidemic and the Practice of Legitimate Medicine



Practitioner Diversion Awareness Conference Orlando, Florida May 5 (6), 2018



James Arnold, Chief
Liaison and Policy
Diversion Control Division

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Objectives

To Introduce the DEA registered Practitioner with:

- Real Mission of the Diversion Control Division of the DEA
- Extent of the Opioid Epidemic in the U.S.
- History and Complexity of Drug Abuse in the U.S.
- Trends in Prescribing and Dispensing Patterns
- Nationwide Efforts to Combat the Problem

Questions To Discuss

At the completion of this block of instruction you will be able to answer the following questions:

- 1. What limits has Florida recently placed on Schedule 2 controlled substance prescriptions?
- 2. What are the top three most commonly prescribed controlled substances in the U.S.?

Questions To Discuss

- 3. According to the CDC approximately how many people died from drug overdoses in the year 2016?
- 4. Under Federal Law what is the primary responsibility of practitioners when it comes to issuing prescriptions for controlled substances?
- 5. According to IMS Data the total number of prescriptions being filled for oxycodone for the last three years has declined?



There Is Pain



There Is Legitimate Pain



There Is Dependence



There Is Addiction



Mission

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



Mission

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



21 C.F.R. § 1306.04 (a)

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.



In 2014, there were 47,055 drug overdose deaths,

- ...one death every 11.16 minutes,
- ...approximately 128 per day,
- ...19,000 were due to prescription opioid pain relievers

^{1.} Rudd R, et al. MMWR Morb Mortal Wkly Rep. 2016 Jan 1;64:1378-82.

^{2.} CDC. https://www.cdc.gov/drugoverdose/data/analysis.html. Feb 2017. Accessed May 2017.



Public Health Epidemic

In 2015, there were 52,404 drug overdose deaths,

- ...one death every 10.06 minutes,
- ...approximately 143 per day,
- ...22,598 were due to prescription opioid pain relievers



Public Health Epidemic

In 2016, there were 63,632 drug overdose deaths,

- ...one death every 8.28 minutes,
- ...approximately 174 per day,
- ...42,249 were due to opioids



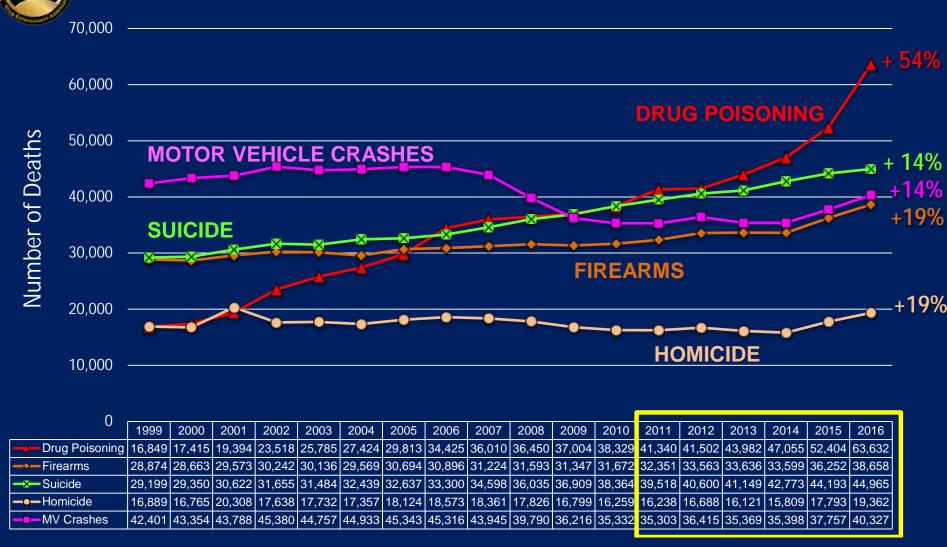


Drug Poisoning Deaths, 1999-2016



Source: Centers for Disease Control and Prevention, National Center for Health Statistics. *Underlying Cause of Death 1999-*2016 on CDC WONDER Online Database, released 2017. Data on drug poisoning deaths were extracted by ONDCP from http://wonder.cdc.gov/mcd-icd10.html on December 21, 2017.

Causes of Injury Death 1999-2016



NOTE: Suicide and homicide include deaths by drug poisoning or firearms

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. *Multiple Cause of Death 1999-2016* on CDC WONDER Online Database, released 2017. Data on drug poisoning deaths were extracted by ONDCP from http://wonder.cdc.gov/mcd-icd10.html on December 21, 2017.



Public Health Epidemic

Sharpest Increase in Drug Overdose Deaths

2016

Fentanyl and Fentanyl Analogues (Synthetic Opioids)

with over 20,000 Deaths

Ten Most Commonly Prescribed Controlled Substances in the U.S.

- Hydrocodone Clonazepam
- Oxycodone
- Alprazolam
- Tramadol
- Zolpidem

- Lorazepam
- Dextroamphetamine
- Codeine
- Methylphenidate

The Most Common Drugs Involved in Prescription Opioid Overdose Deaths

Hydrocodone

Oxycodone

Methadone



Unfortunately, The United States has a Long History **Drug Use** and **Abuse**



1804

Morphine is Distilled from Opium for the First Time



1839

The First Opium War Breaks Out as Britain Forces China to Sell Its India Grown Opium



The Hypodermic Syringe is Invented

The Inventor's Wife is the First to Die of an Injected Drug Overdose

1861-1865 Morphine Addiction

The Civil War

The "Soldier's Disease"



1898 Bayer Chemist Invents diacetlymorphine,

Names It Heroin

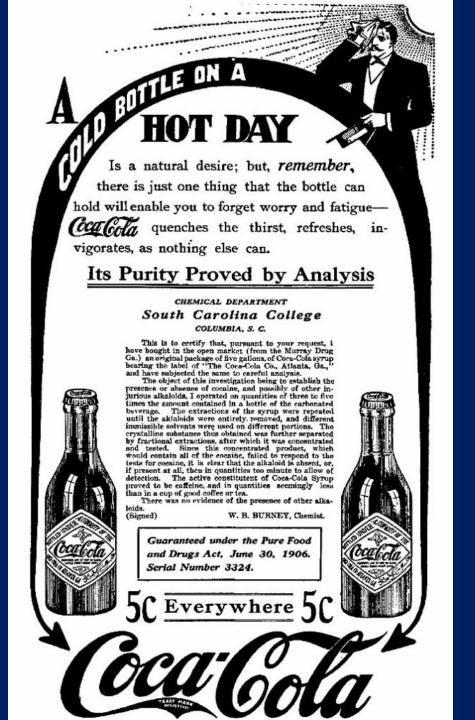
Advent of the 20th Century Abuse Of Opium And Morphine A Significant Problem In The US But There Was Widespread Distribution Of Medicinal Products **Containing The New** "Non-addictive" Alternative To Morphine -Heroin.















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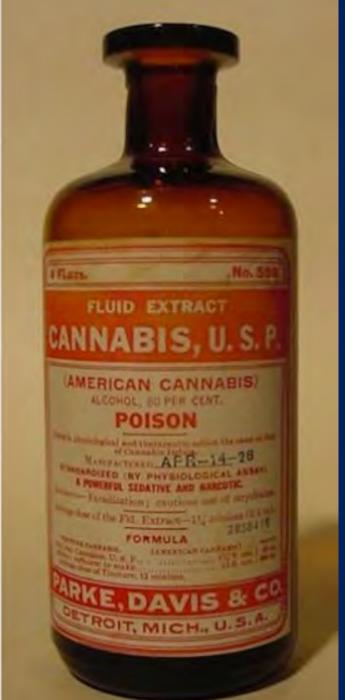
We will mail, gratis, 75 Portraits, Sketches, Biographical Notes and Autographs of Celebrities, testifying to excellence

of "Vin Mariani"

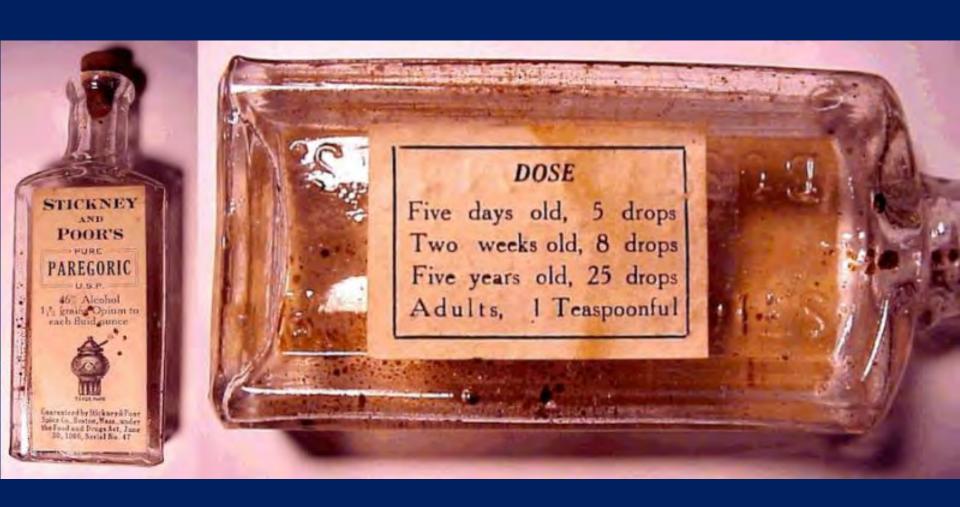
Paris: 41 Boulevard Haussmann London; 230 Oxford Street

Mariani & Co. 52 W. 15th St., New York













February 9, 1909 Congress Public Law 221

"An Act to Prohibit the Importation and Use of Opium for Other Than Medicinal Purposes"



U.S. Congress Passes Harrison Tax Act



Committee on the Problems of Drug Dependence is Formed

To Organize Research in Pursuit of the Holy Grail: A Non-addictive Painkiller



1951 Arthur Sackler Revolutionizes

Drug Advertising With Campaign for the Antibiotic Terramycin



Arthur Sackler's campaign for Valium makes it the industry's first \$100 million drug



The New England Journal of Medicine publishes a letter to the editor that becomes known as "Porter and Jick"



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

Jane Porter Hershel Jick, M.D. Boston Drug Surveillance Program **Boston University Medical Center** New England Journal of Medicine. January 1980 http://www.nejm.org/doi/pdf/10.1056/NEJ M1980011030020221



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

"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."



Drs. Kathleen Foley and Russell Portenoy publish paper in the journal Pain, opening a debate about use of opiate painkillers for wider variety of pain



Purdue releases OxyContin, timed-released oxycodone, marketed largely for chronic-pain patients



Dr. David Procter's clinic in South Shore, Kentucky, is presumed the nation's first pill mill



1996 President of American Pain Society urges doctors to treat pain as a vital sign



Dr. David Procter pleads guilty to drug trafficking and conspiracy and serves eleven years in federal prison



Purdue and three executives plead guilty to misdemeanor charges of false branding of OxyContin; fined \$634 million



Drug overdoses, mostly from opiates, surpass auto fatalities as leading cause of accidental death in the United States



2011 Ohio passes House Bill 93, regulating pain clinics



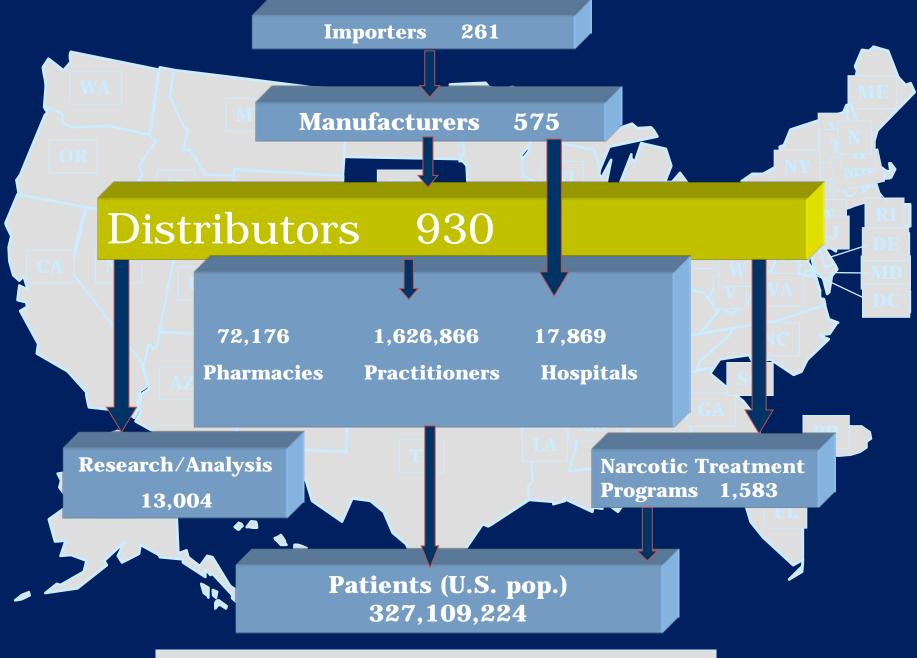
The College on the Problems of Drug Dependence turns seventy-five without finding the Holy Grail of a nonaddictive painkiller



The **Problem** Affects Everyone



No one Is Un-Affected





Livonia doctor, 7 others charged in \$18M prescription drug scheme

January 9, 2018

http://www.fox2detroit.com/news/local-news/livonia-doctor-7-others-charged-in-18m-prescription-drug-scheme



N.J. Doctor Allegedly Had Radio Host Wife Murdered — to Protect Drug Ring He Ran With Biker Gang

January 10, 2018

CHRIS HARRIS, People Magazine,, http://people.com/crime/nj-doctor-radio-host-wife-alleged-murder-hire-biker-group/

"Unlicensed pharmacist arrested for allegedly giving out meds in Cobb"

January 10, 2018

Ben Brasch, The Atlanta Journal-Constitution, http://www.ajc.com/news/local/unlicensed-pharmacist-arrested-for-allegedly-giving-out-meds-cobb/jsx4rFHyaaFzJKroZere7O/

"Great Falls pharmacy manager charged with stealing drugs"

January 12, 2018

Seaborn Larson, Great Falls Tribune, https://www.greatfallstribune.com/story/news/crime/2018/01/12/great-falls-pharmacy-manager-charged-stealing-drugs/1029290001/

"Police: Maryland officer arrested after he stole opioids from a bedridden citizen"

February 2, 2018

Brad Bell, WJLA News, http://wjla.com/news/local/md-police-officer-arrested-sources-say-he-was-allegedly-stealing-opioids-from-citizens

"Ex-dentist pleads guilty to illegally prescribing drugs"

February 5, 2018

Fox 61, http://fox61.com/2018/02/05/ex-dentist-pleads-guilty-to-illegally-prescribing-drugs/

"More than a dozen people arrested in Bloomington drug investigation"

February 6, 2018

Fox59 News, http://fox59.com/2018/02/06/more-than-a-dozen-people-arrested-in-bloomington-drug-investigation/

"Doctor prescribed needless pills and bilked Medicare, feds say"

February 12, 2018

Paula McMahon, Sun Sentinel, http://www.sun-sentinel.com/local/broward/fl-reg-doctor-arrested-fraud-pain-pills-20180212-story.html

"Las Vegas doctor charged with unlawful distribution of opioid, health care fraud"

February 14, 2018

Brenda Yahm, Fox 5 Vegas, http://www.fox5vegas.com/story/37505788/las-vegas-doctor-charged-with-unlawful-distribution-of-opioid-health-care-fraud

"Nurse arrested for forging opioid prescriptions"

February 18, 2018

Jesse Leavenworth, EMS1, https://www.ems1.com/opioids/articles/375512048-Nurse-arrested-for-forging-opioid-prescriptions/

"Federal agents raid doctor's office and suspected 'pill mill'"

February 27, 2018

Lee Zurik, Megan Luther, and Andy Miller, WTXL News, http://www.wtxl.com/news/federal-agents-raid-doctor-s-office-and-suspected-pill-mill/article_0e8a0064-1bf3-11e8-b409-cb776b750102.html

"Doctor accused of trading prescription drugs for sex; 44 arrested in massive bust"

March 1, 2018

Mark Winne, WSBTV, http://www.wsbtv.com/news/local/doctor-accused-of-trading-prescription-drugs-for-sex-44-arrested-in-massive-bust/709268909

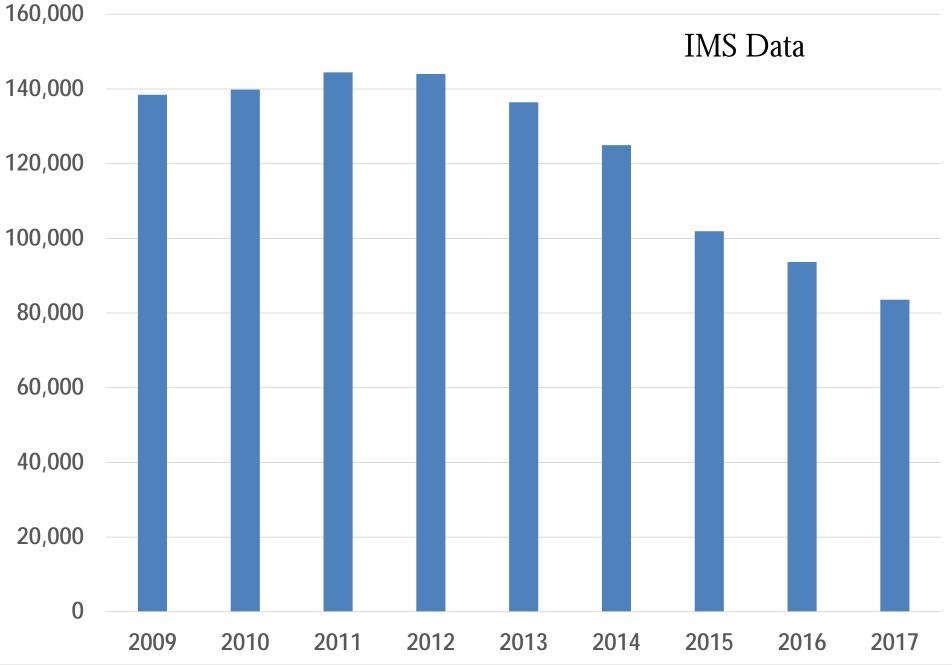
"2 UPMC doctors from Allegheny County arrested, charged with conspiracy"

March 2, 2018

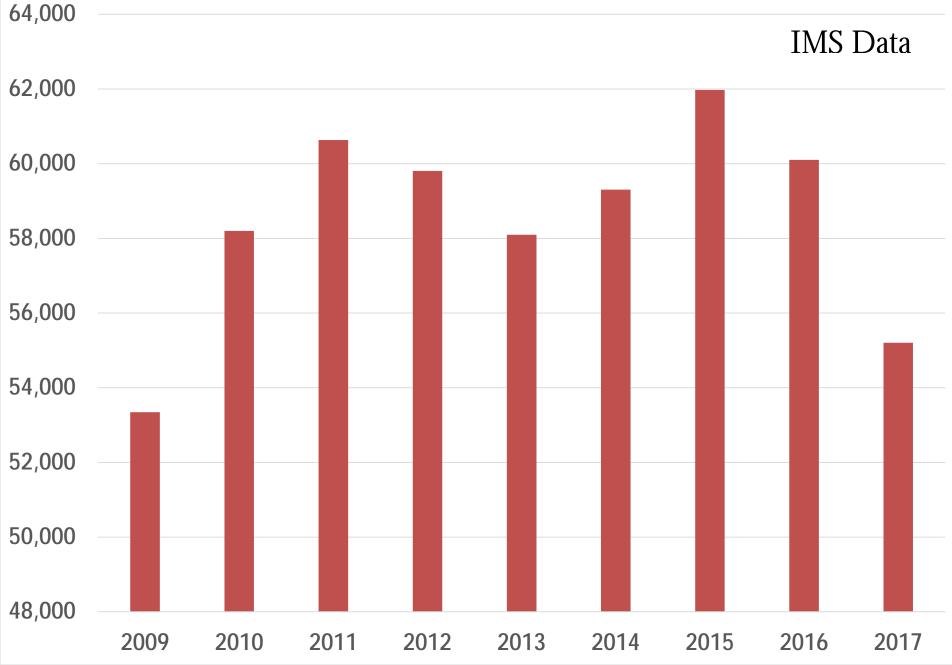
Natasha Lindstrom, The Tribune-Review, http://triblive.com/local/allegheny/13373830-74/2-allegheny-county-doctors-arrested-charged-with-conspiracy

What's Trending

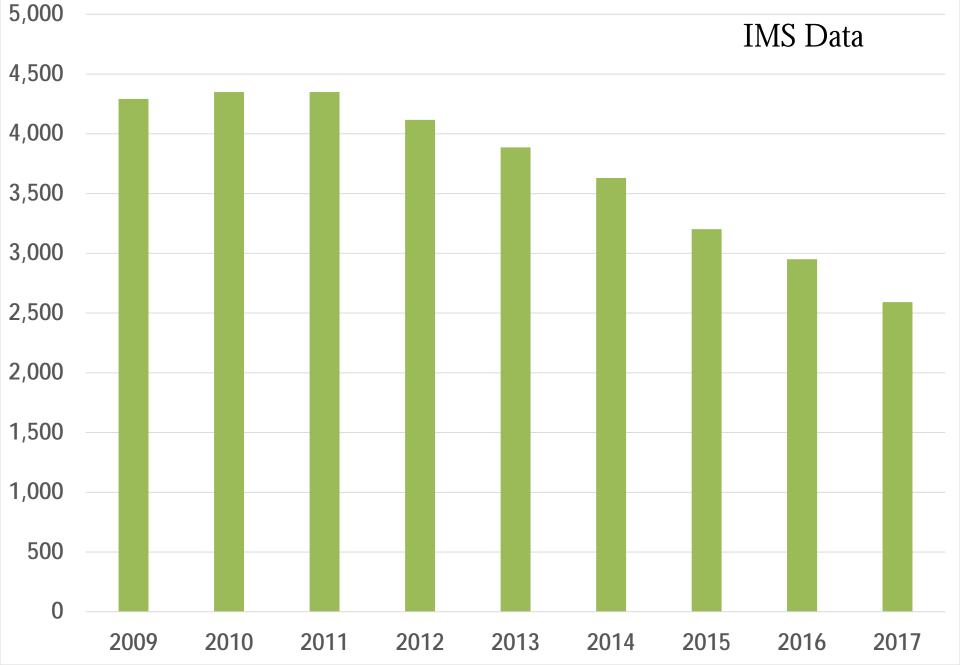
Total Prescriptions Filled : Hydrocodone 2009-2017



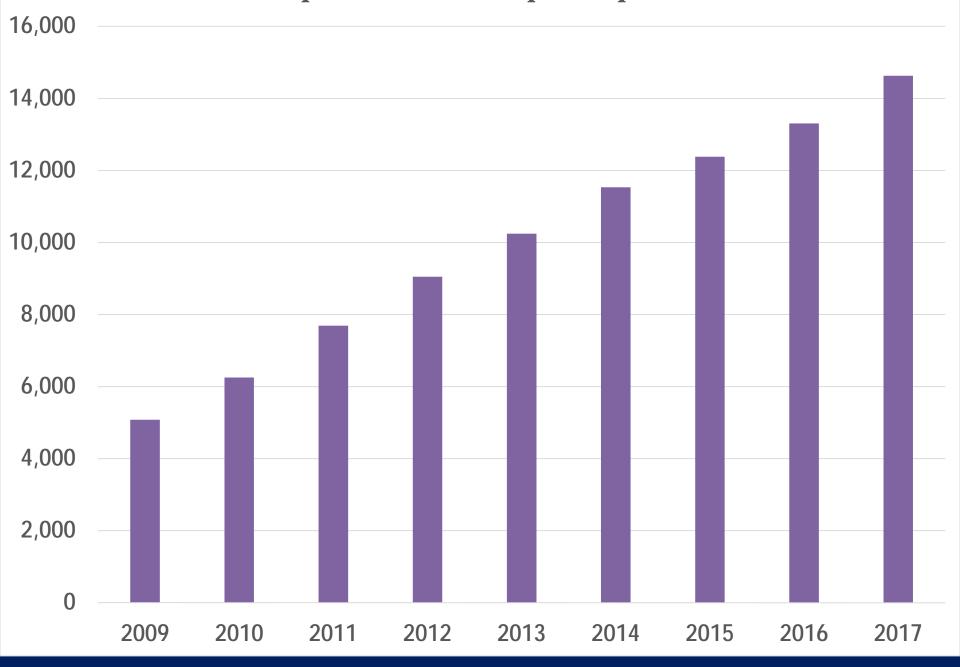
Total Prescriptions Filled: Oxycodone 2009-2017



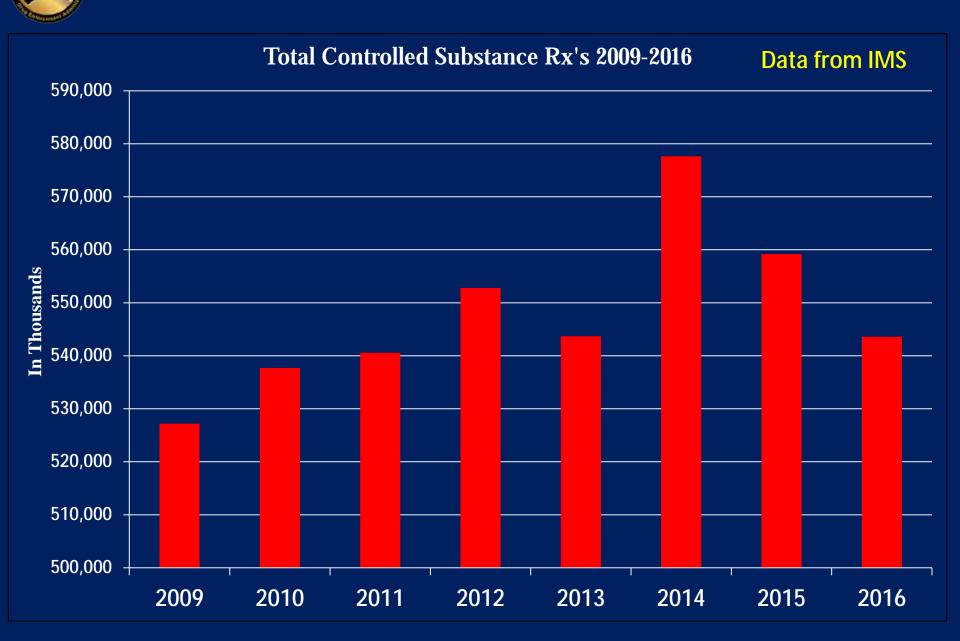
Total Prescriptions Filled: Methadone 2009-2017



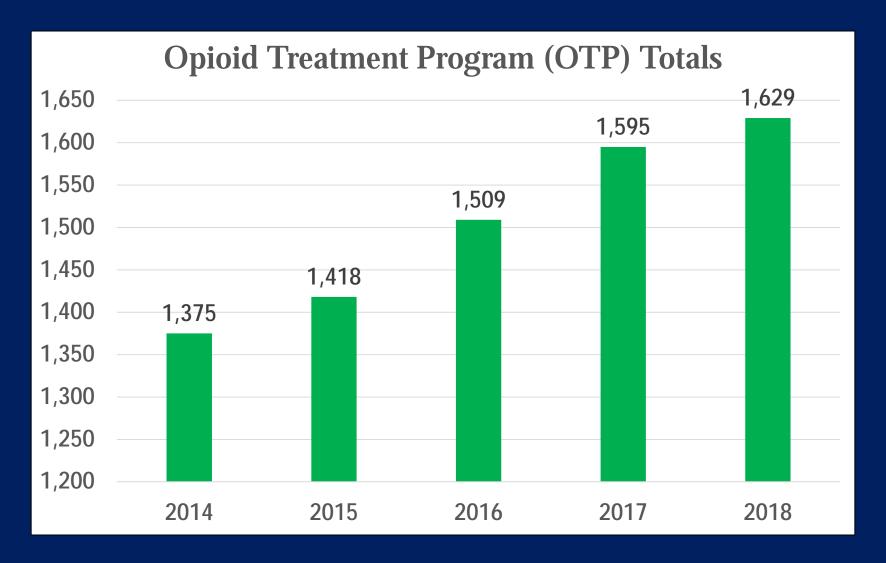
Total Prescriptions Filled: Buprenorphine 2009-2017



Total Controlled Substance Rx's Filled

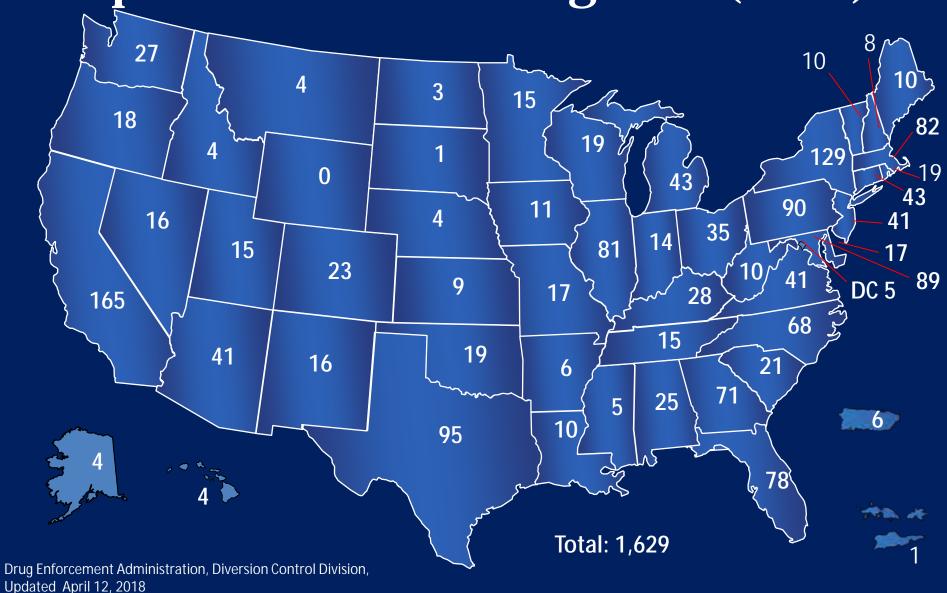


Opioid Treatment Programs (OTPs)

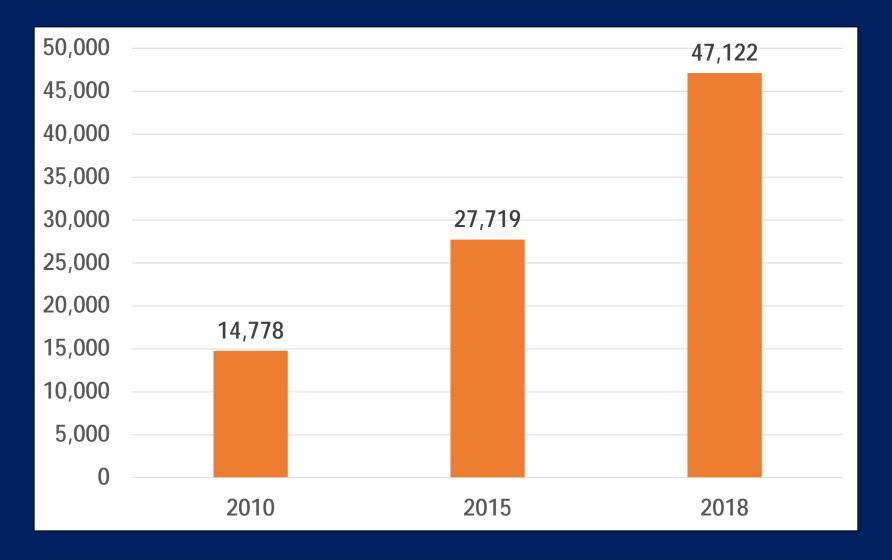


*As of April 12, 2018: DEA Data

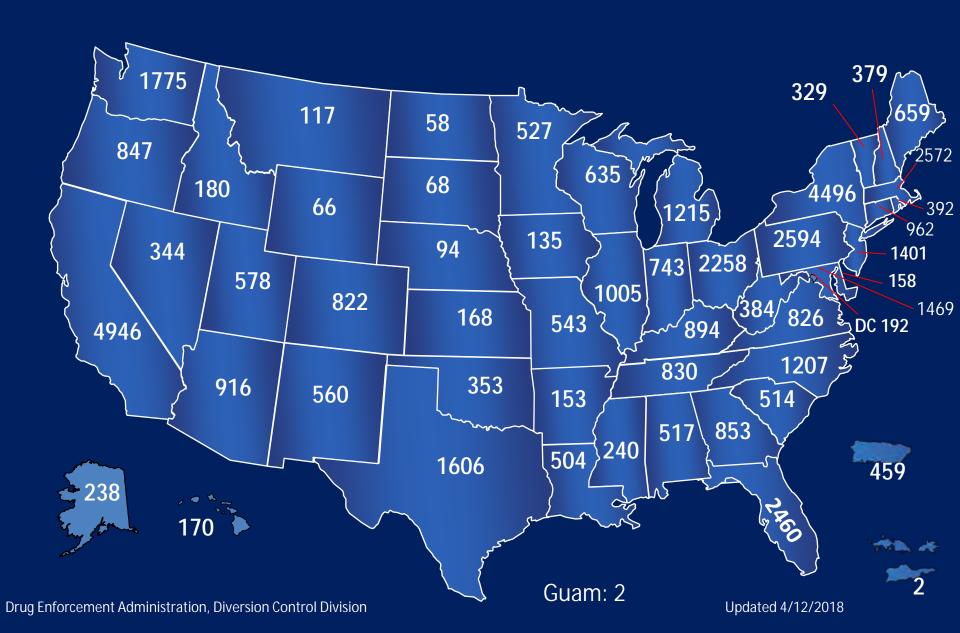
DEA Registered Opioid Treatment Programs (OTP)



DEA Registered Qualifying Practitioners



DEA Registered Qualifying Practitioners



Nationwide Efforts to Combat the Problem



States

Practitioners

Hospitals

Treatment Providers

Medical Schools

Pharmacies



Alaska 7 Day Supply (initial prescription)

Arizona 7 Day Supply (initial prescription)

7 Day Supply (for minors)

Connecticut 7 Day Supply (initial prescription)

7 Day Supply (for minors)

Delaware Up to 100 dosage units or a

31 day supply, whatever is greater



District of Columbia 7 Day Supply

(emergency situation)

Florida
 3 Day Limit/Acute Pain

7 Day Supply/Medically Necessary

Hawaii
 30 Day Supply

• Illinois 30 Day Supply: CII

(Some exceptions under certain

conditions)

Indiana
 7 Day Supply (initial prescription)

7 Day Supply (for minors)

89



Kansas 30 Day Supply

(Substances to treat obesity)

Kentucky 3 Day Supply (acute pain with

exceptions)

Louisiana 10 Day Supply: CII-III

(Prescribers not licensed in Louisiana)

Maine 30 Day Supply (chronic pain)

7 Day Supply (acute pain)



Massachusetts 7 Day Supply (unless more in

indicated)

7 Day Supply (all opioids for minors)

Massachusetts 30 Day Supply: CII-III

60 Day Supply (Dextroamphetemine)

Missouri 30 Day Supply: CII

90 Day (If medical reason given)

New Hampshire 34 Day Supply: CII

60 Day Supply (ADD/ADHD)



New Jersey First prescription: 5 Day Supply

New York 30 Day Supply

7 Day Supply (initial prescription)

North Carolina 5 Day Supply (acute pain)

Ohio 7 Day Supply

5 Day Supply (for minors)

Oregon 7 Day Supply (initial prescription)

7 Day Supply (for minors)



Pennsylvania 7 Day Supply (for minors)

7 Day Supply

(emergency department

and urgent care centers)

Rhode Island 20 Doses for opioids (initial

prescription)

No more than 30 morphine

MME/day

South Carolina 31 Day Supply

(Except Transdermal patches)

90 Day Supply: CIII-V



Tennessee 30 Day Supply of Opioids and

Benzodiazepines

Texas 90 Day Supply (multiple

prescriptions)

Utah 30 Day Supply: CII

Vermont 90 Day Supply

72 MME (first prescription for

minors)

350 MME – 7 Day limit (acute pain,

first prescription)



Virginia Limitations on Number of Days

7 Day Supply (acute pain)

14 Day Supply (surgical procedures)

(Some exceptions)

Washington 7 Day Supply (initial prescription)

3 Day Supply (dentist)

West Virginia 72 Hour Supply

30 Day Supply: Hydrocodone

CVS Pharmacy Policy: 2/01/18

- Acute Pain (Opioid Naïve Patients: No Opioid Script within the Past Year)
- 7-Day Supply
- Opioid Prescriptions
- Requirement to Counsel Patients:
 - -Risks Of Addiction
 - -Secure Storage Of Medications In The Home
 - -Proper Disposal of Medications

Walmart giving away solution to dispose of unused prescription pills

January 26, 2018

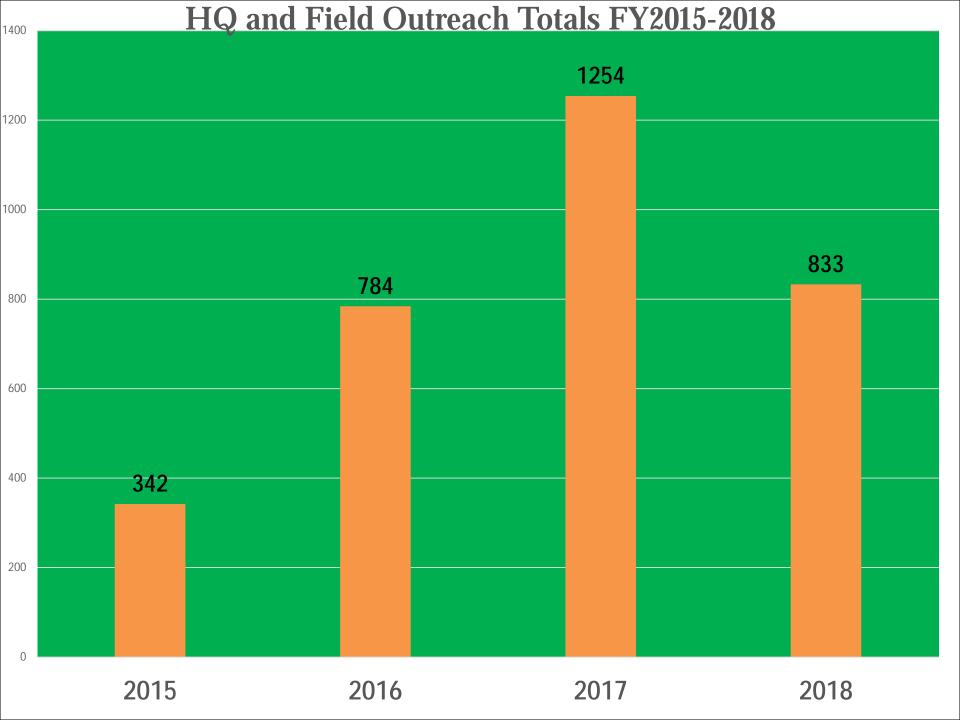


Narcan available at more than 8,000 Walgreens locations nationwide

- CBS News, By Peter Martinez: October 27, 2017
- Walgreens (WBA) is now stocking Narcan at all of its more than 8,000 locations nationwide, the company announced Thursday. The nasal spray, which is an FDA-approved form of naloxone, can reverse the effects of an opioid overdose.
- The drug store chain said the move was "part of its comprehensive national plan to combat drug abuse" and help the communities it serves.



DEA Initiatives



Dear DEA-Registered Practitioner - February 2018

CDC's Recommendations for the Prescribing of Opioid Pain Medications

Dear DEA-Registered Practitioner:

In March, 2016, the Centers for Disease Control and Prevention (CDC) published its "CDC Guideline for Prescribing Opioids for Chronic Pain" to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.

CDC's Guideline is part of a comprehensive approach to addressing the opioid overdose epidemic and is one step toward a more systematic approach to the prescribing of opioids, while ensuring that patients with chronic pain receive safer and effective pain management. According to the CDC, The Guideline's twelve recommendations, published in August 2017, are based on three key principles:

- 1. Non-opioid therapy is preferred for chronic pain outside of active cancer, palliative, and end-of-life care. Opioids should only be used when their benefits are expected to outweigh their substantial risks.
- 2. When opioids are used, the lowest possible effective dosage should be prescribed to reduce risks of opioid use disorder and overdose. Clinicians should start low and go slow.
- 3. Providers should always exercise caution when prescribing opioids and monitor all patients closely. Clinicians should minimize risk to patients—whether checking the state prescription drug monitoring program, or having an 'off-ramp' plan to taper.

You are receiving this email as part of DEA's effort to improve its communication with its more than 1.7 million registrants while simultaneously improving the dissemination of the CDC Guidelines to those authorized to prescribe opioids.

A copy of CDC's publication entitled, "Guideline for Prescribing Opioids for Chronic Pain: Recommendations" may be found at: https://www.cdc.gov/drugoverdose/pdf/Guidelines Factsheet-a.pdf.

Additionally, an Interactive Training Webinar for providers who prescribe opioids may be found at: https://www.cdc.gov/drugoverdose/training/index.html.



More than

11 million people
abused prescription
opioids in 2016.

Opioid Addiction Resources - March 16, 2018

Opioid Addiction Resources



Resources for DEA Registered Practitioners for Patients Who May Be Dependent and/or Addicted To Opioids

According to the U.S. Centers for Disease Control and Prevention (CDC) there were 63,632 drug overdose deaths in the United States in 2016; 174 deaths per day; one death every 8.28 minutes; 42,249 (66.4%) of those

deaths were due to opioids. More deaths than those as a result of firearms, homicide, suicide, and motor vehicle crashes.

Practitioners are in a unique position to help combat the current opioid epidemic in this country. Please take time to understand and recognize the signs of this disease in your patients. If you or anyone in your office suspects that a patient may have a problem with opioid dependence, please provide your patients with the below listed information so they, or someone in their family, can get the help that they may need.

Practitioners may also wish to talk with their patients who are currently taking opioids for a legitimate medical issue about the benefits of naloxone (e.g. Narcan®, Evzio®) in the case of an overdose situation which may involve themselves or anyone in their family. These types of products can rapidly reverse the effects of an opioid overdose and are the standard treatment for these types of situations. Information on naloxone products can be found at www.fda.gov.

The Substance Abuse and Mental Health Services Administration (SAMHSA) has a National Helpline, **1-800-662-HELP (4357)**, for those with a possible opioid use disorder. The Helpline is a confidential, free, 24-hour-a-day, 365-day-a-year, information service, in English and Spanish, for individuals and family members facing mental and/or substance use disorders. This service provides referrals to local treatment facilities, support groups, and community-based organizations. Callers can also order free publications and other information here.

To find an authorized Opioid Treatment Program dispensing methadone or buprenorphine to treat opioid dependency in your state visit:









EMPOWERING PROVIDERS

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN:

www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf.





NATIONALHELP (4357)

WWW.samhsa.gov/find-help

NATIONALHELP LANE

Do You or a Family Member Need Help with Drugs?

1-800-662-HELP (4357)









A Final Note



Solutions to the Problem

Prevention/Detection

Education

Treatment

Enforcement

- 1. What limits has Florida recently placed on Schedule 2 controlled substance prescriptions?
 - A. 3 Day Supply Acute Pain
 - B. 7 Day Supply/Medically Necessary
 - C. 14 Day Supply
 - **D.** A&B

2. What are the top three most commonly prescribed controlled substances in the U.S.?

A. Hydrocodone

B. Methadone

C. Oxycodone

D. Alprazolam

E. Tramadol

F. A,C, & D.

3. According to the CDC approximately how many people died from drug overdoses in the year 2016?

A. 52,404

B. 47,055

C. 63,632

- 4. Under Federal Law what is the primary responsibility of practitioners when it comes to issuing prescriptions for controlled substances?
 - A. A prescription must be issued for a legitimate medical need.
 - B. A prescription must issued in the usual course of professional practice.
 - C. A&B

5. According to IMS Data the total number of prescriptions being filled for oxycodone for the last three years has declined?

A. Yes

B. No



Thank You





Contact Information

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202-353-1414 (Office)