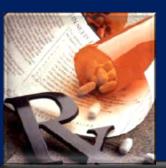


The Opioid Epidemic and the Practice of Medicine



Practitioner Diversion Awareness Conference Birmingham, Alabama December 16 & 17, 2019



The United States Department of Justice

Drug Enforcement Administration

Antonio R Guzman
Associate Section Chief
Liaison Section
Diversion Control Division

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Objectives

To Introduce the DEA registered Practitioner with:

- 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 Alabama placed on controlled substance prescriptions?
- 2. What are the top three most commonly prescribed controlled substances in the U.S.?

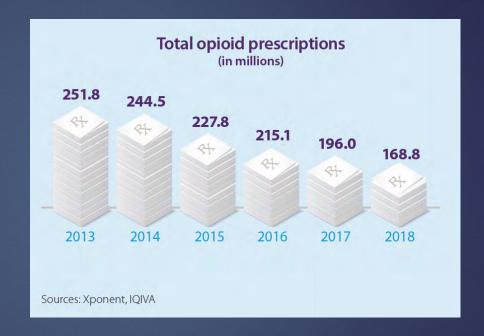


GREAT NEWS?

OPIOIDS PRESCRIPTIONS DECREASED 33% SINCE 2013

Between 2013 and 2018, the number of opioid prescriptions decreased by more than 80 million - a 33% percent decrease nationally. Every state has seen a decrease in opioid prescriptions over the last five years.¹

The nation saw a 12.4 percent decrease – more than 20 million fewer prescriptions – between 2017 and 2018 alone.





Pain Dependence Addiction Death



Public Health Epidemic

In 2014, there were 47,055 drug overdose deaths

In 2015, there were 52,404 drug overdose deaths

In 2016, there were 63,632 drug overdose deaths

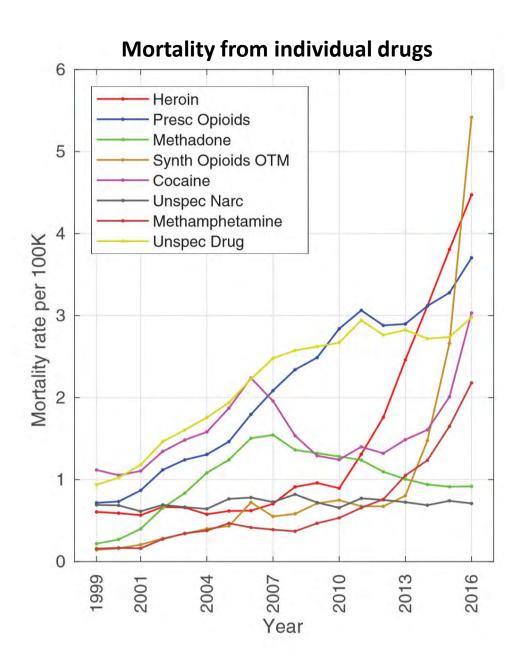
^{1.} Rudd R, et al. MMWR Morb Mortal Wkly Rep. 2016 Jan 1;64:1378-82.

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

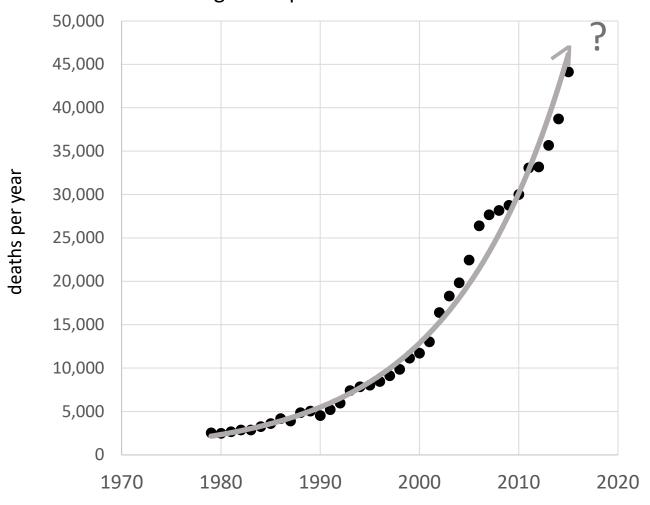


Public Health Epidemic

- In 2017, there were 70,237 drug overdose deaths,
 - ...one death every 7.5 minutes,
 - ...approximately 192 per day,
 - ...Opioids, many synthetic opioids (other than methadone) were involved in 47,600 overdose deaths..



Will the epidemic curve follow this remarkable exponential growth pattern into the future?





Conclusions

- The epidemic of overdose deaths in the USA has been growing, inexorably and exponentially, for four decades.
- Paradoxically, this overall long term smooth epidemic curve is a composite of multiple heterogeneous sub-epidemics which differ according location, age, drugs used, gender, race, and urbanicity. The mechanism(s) whereby these subepidemics seamlessly merge into a single smooth curve is unknown.
- Without effective new interventions, this overall pattern of predictable exponential growth is likely to continue into the future.

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Opioid Summaries by State

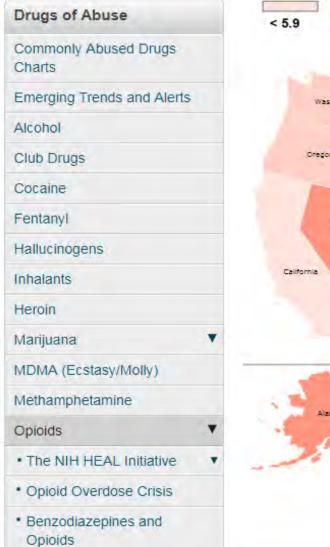


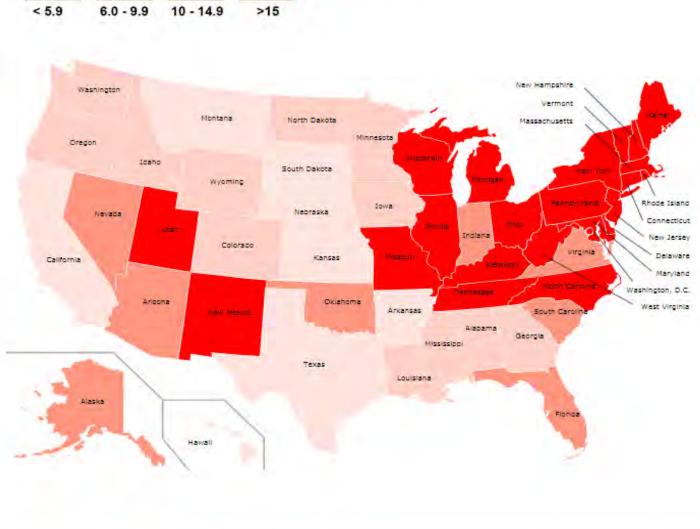




Revised February 2018

Opioid-Related Overdose Death Rates (per 100,000 people) 1





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Opioid Summaries by State

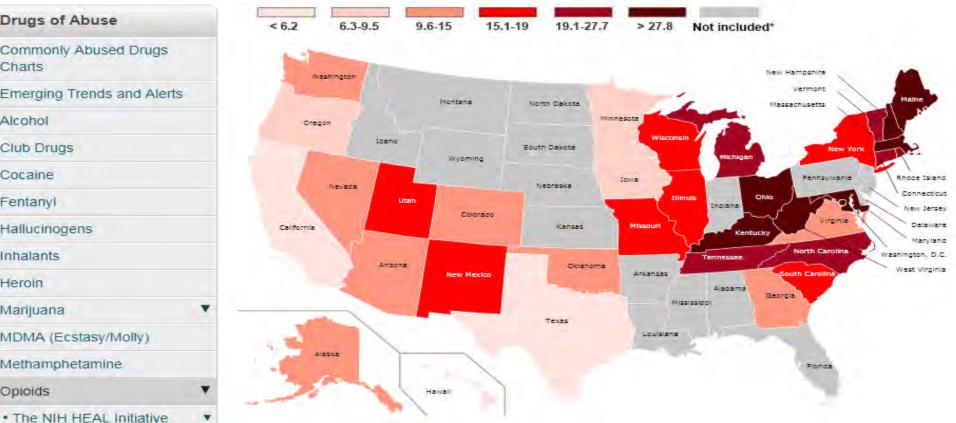






Revised May 2019

2017 Opioid-Involved Overdose Death Rates (per 100,000 people) 1



Drugs of Abuse Commonly Abused Drugs Charts **Emerging Trends and Alerts** Alcohol Club Drugs Cocaine Fentanyl Hallucinogens Inhalants Heroin. Marijuana MDMA (Ecstasy/Molly) Methamphetamine Opioids

Pills laced with deadly opioid infiltrating drug market, DEA says

The Guardian

By Susan Zalkind

The illegal drugs look like known prescription painkillers and contain high amounts of fentanyl as law enforcement says problem is expected to escalate. Hundreds of thousands of counterfeit prescription pills laced with a deadly synthetic opioid have infiltrated the US drug market, according to the (DEA)...

2018: Ten Most Commonly Filled Controlled Substances Prescriptions in the U.S.

- Hydrocodone
- Oxycodone
- Alprazolam
- Tramadol
- Dextroamphetamine

- Zolpidem
- Clonazepam
- Lorazepam
- Codeine
- Buprenorphine

The Most Common Drugs Involved in Prescription Opioid Overdose Deaths include:

Methadone

Oxycodone

Hydrocodone



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



Morphine is Distilled from Opium for the First Time



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"



Bayer Chemist Invents diacetylmorphine,

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.





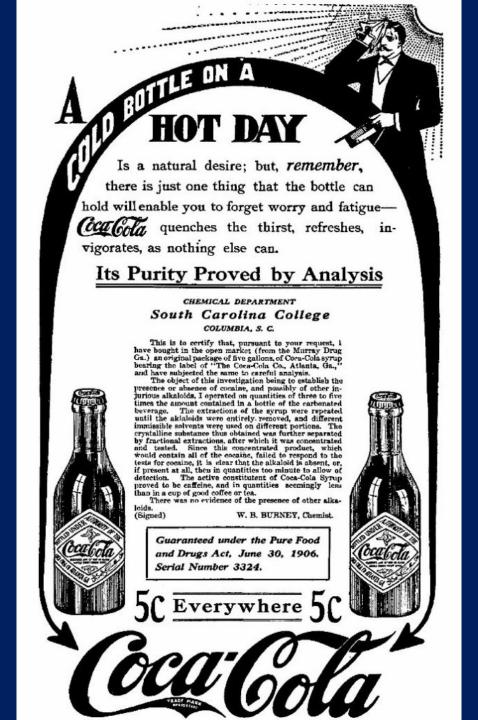
CATARRH, AND THROAT TROUBLES.

CURE NERVOUSNESS, HEADACHE, and SLEEPLESSNESS.

Price 50c. a box at Druggists or by mail. Send for Pamphlet. ALLEN COCAINE MFG. CO., 1254 Broadway, N. Y.









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



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/NEJM1980011030020221



ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

"We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is <u>rare</u> in medical patients with no history of addiction."

http://www.nejm.org/doi/pdf/10.1056/NEJM1980011030020221



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



Dr. Mitchell Max President American Pain Society

"therapeutic use of opiate analgesics rarely results in addiction..."

OxyContin

FDA approved labeling

"iatrogenic addiction was "very rare" and that the delayed absorption of OxyContin reduced the abuse liability of the drug"



"Iatrogenic"

"an illness that is caused by medical examination or treatment."

https://en.oxforddictonaries.com/definition/iatrogenic



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



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



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



October 2000

Department of Veterans Affairs

Pain: The Fifth Vital Sign Toolkit



October 31, 2000

106th U.S. Congress H.R. 3244

"Decade of Pain Control and Research."



Dr. Dennis O'Leary, President Joint Commission on Accreditation of Healthcare Organizations (The Joint Commission)

- standards for health care organizations to improve pain management.
- recommendation for systematic assessments and use of quantitative measures of pain



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



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 non-addictive painkiller



Intoxication: The Universal Drive for Mind Altering Substances

"Dr. Ron Siegel has suggested that throughout our entire history as a species, intoxication has functioned like the basic drives of hunger, thirst, or sex, sometimes overshadowing all other activities in life. Siegel further suggested "intoxication is the fourth drive".

"Individual and group survival depends on the ability to understand and control this basic motivation to seek out and use intoxicants."

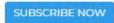


The **Problem** Affects Everyone



No one Is Un-Affected

















NEWS

CRIME ELECTIONS 20

TEXAS LEGISLATURE

POLITICS

EDUCATION

INVESTIGATION





https://www.dallasnews.com/news/investigations/2018/12/02/two-nurses-died-overdoses-inside-dallas-hospital-went-wrong

Health & Fitness

Northridge Nurse Arrested In Massive Prescription Drug Sting

Federal authorities arrested Southland doctors and clinic workers accused of black market opioid sales linked to at least one death.

By California News Wire Services, News Partner | Feb 22, 2019 1:14 am ET



Share







An opioid crackdown in the Los Angeles area has led to the arrest of four doctors and other medical professionals. ((AP Photo/Jae C. Hong))

Firefighters, cop, pizzeria owner among 7 arrested in Jersey Shore drug fraud ring with ties to James Kauffman

by Amy S. Rosenberg, Updated: March 15, 2019



COLT SHAW / THE PRESS OF ATLANTIC CITY VIA AP

Seven people, including three firefighters, a police officer, and an owner of Tony's Baltimore Grill in Atlantic City, were arrested Friday and charged in a \$50 million prescription-drug health-benefits scheme that has already snagged dozens of public employees and pharmaceutical representatives at the New Jersey Shore.

The arrests followed the unsealing of a 50-count federal indictment charging William Hickman, 42, of Northfield; his wife, Sara, 42; Ventnor Police Officer Thomas Schallus, 42; brothers and Margate Firefighters John, 37, and Thomas Sher, 46; Camden Firefighter Christopher Broccoli, 47, of West Deptford; and Brian Pugh, 41, of Absecon, identified in the indictment as a businessman.

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Nearly 60 Doctors, Other Medical Workers Charged In Federal Opioid Sting

April 17, 2019 CARRIE JOHNSON

Federal prosecutors are charging 60 doctors, pharmacists, medical professionals and others in connection with alleged opioid pushing and health care fraud, the Justice Department said Wednesday.

The cases involve more than 350,000 prescriptions for controlled substances and more than 32 million pills — the equivalent of a dose of opioids for "every man, woman and child," across Ohio, Kentucky, Tennessee, Alabama and West Virginia, said Assistant Attorney General Brian Benczkowski.



What's Trending?

Some Good News?



CDC Preliminary Data 2018

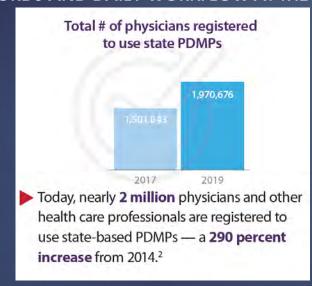
4.6 % drop in opioid deaths

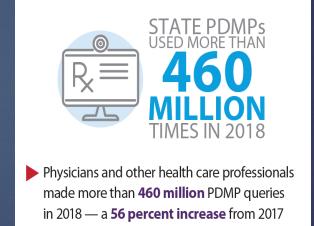
7% decline in prescription opioid deaths

11 % increase in deaths from illicit fentanyl

AMERICA'S PHYSICANS ARE USING STATE PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPs) MORE THAN EVER.

WE URGE STATES TO TAKE ACTION TO IMPROVE INTEGRATION WITH ELECTRONIC HEALTH RECORDS AND DAILY WORKFLOW AT THE POINT OF CARE.





and a 651 percent increase from 2014.3

 $2\,\&\,3$. Based on an AMA survey and responses from 49 state PDMP administrators. Figures will be adjusted as anew information becomes available.



U.S. Health Chief Says Overdose Deaths Are Starting to 'Plateau' But 'We Are So Far From the End'

- TIME Health
- (WASHINGTON) The number of U.S. drug overdose deaths has begun to level off after years of relentless increases driven by the opioid epidemic, (HHS) health secretary Alex Azar said Tuesday, cautioning it's too soon to declare victory.
- "We are so far from the end of the epidemic, but we are perhaps, at the end of the beginning," Azar said in prepared remarks for a health care event sponsored by the Milken Institute think tank.

Overdose Deaths Likely to Fall for First Time Since 1990

Health officials and scientists warn U.S. is far from defeating drug epidemic
Wall Street Journal
June 26, 2019

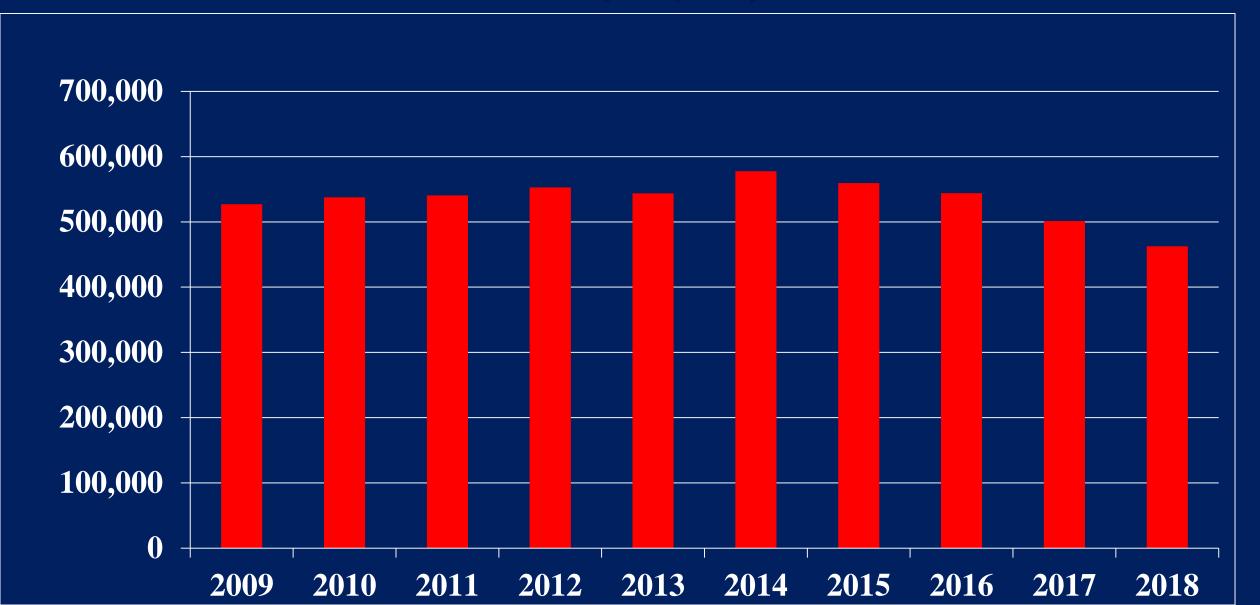
For the first time in decades, drug-overdose deaths in the U.S. are on the precipice of declining. Authorities are still counting fatalities around the U.S. from 2018, but provisional data from the Centers for Disease Control and Prevention are pointing lower. Those data predict there were nearly 69,100 drug deaths in the 12-month period ending last November, down from almost 72,300 predicted deaths for 12 months ending November 2017.



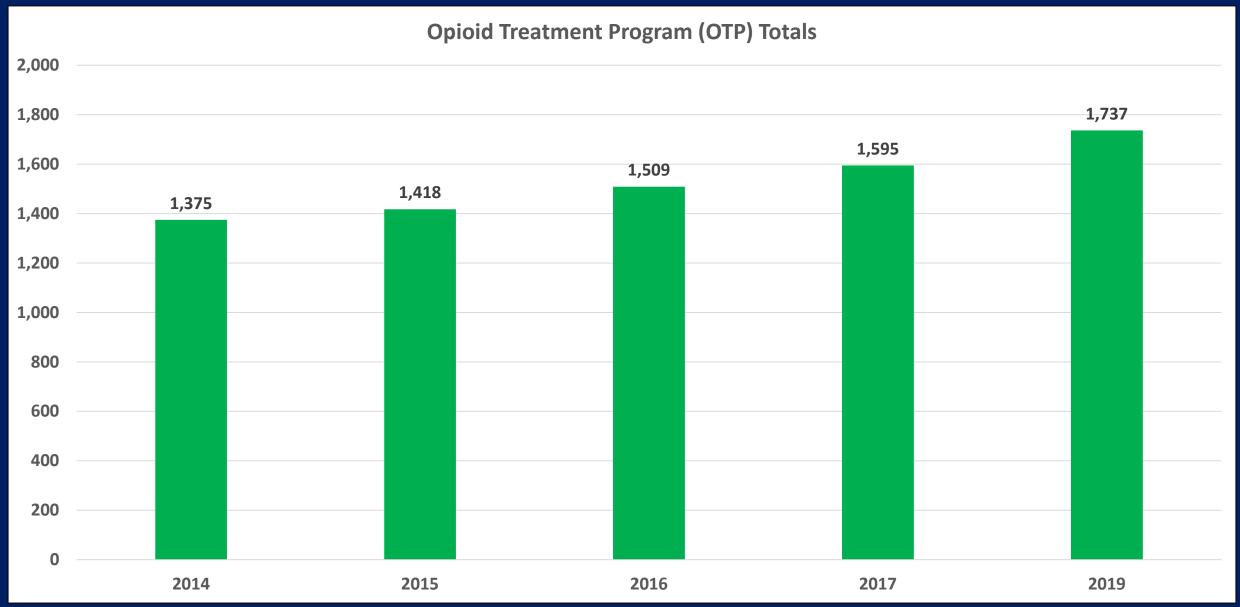
Total Controlled Substance RX's Filled 2009-2018



Data On File

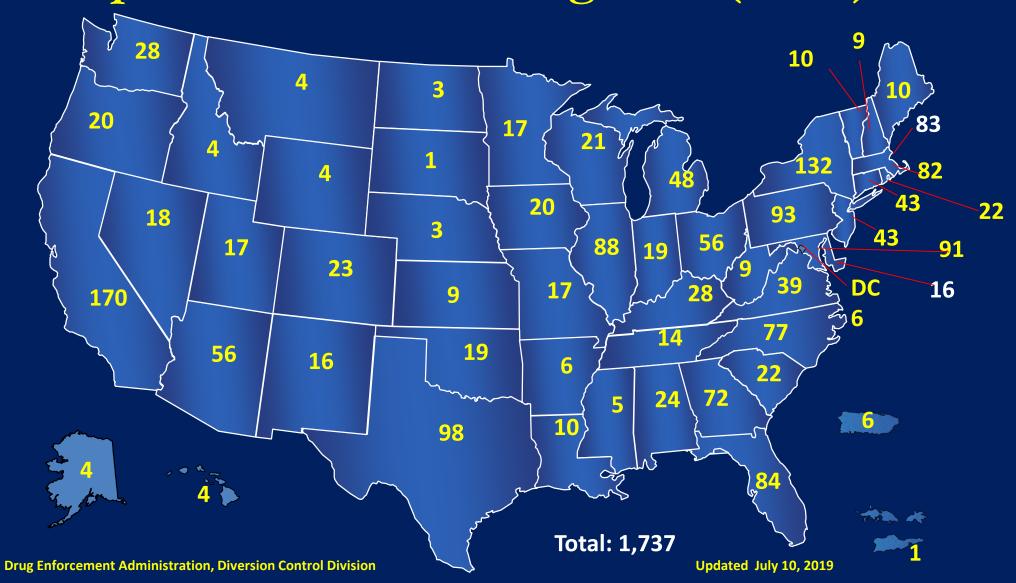


Opioid Treatment Programs (OTPs)

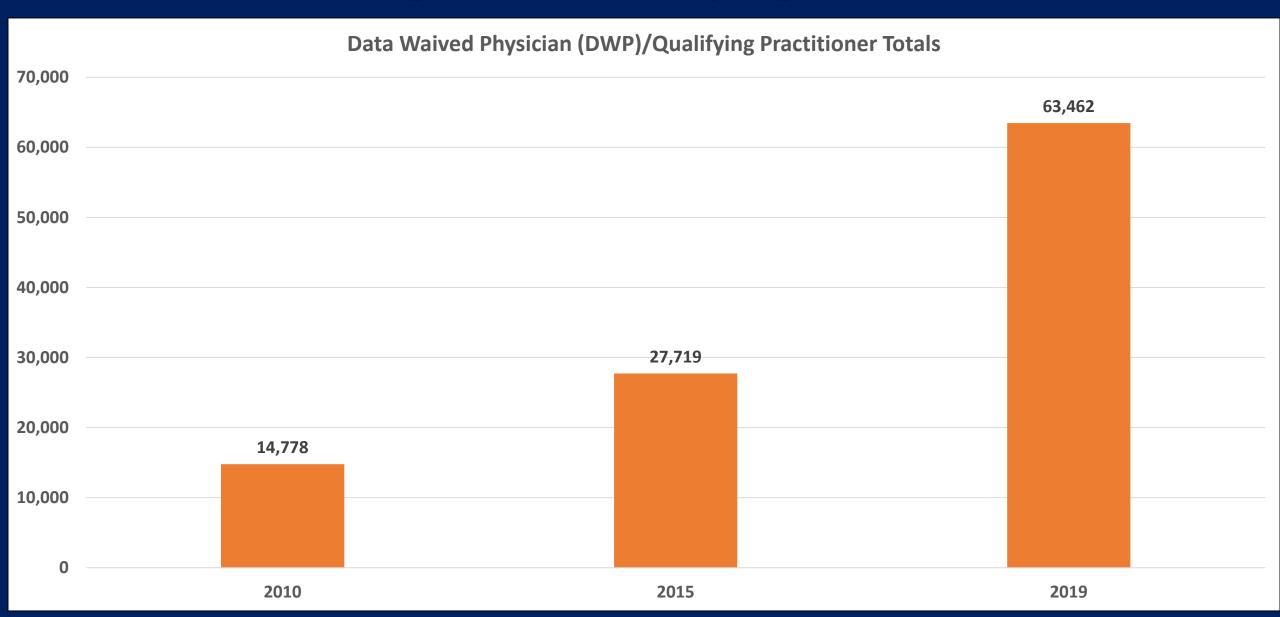


*As of July 10, 2019: DEA Registration Data

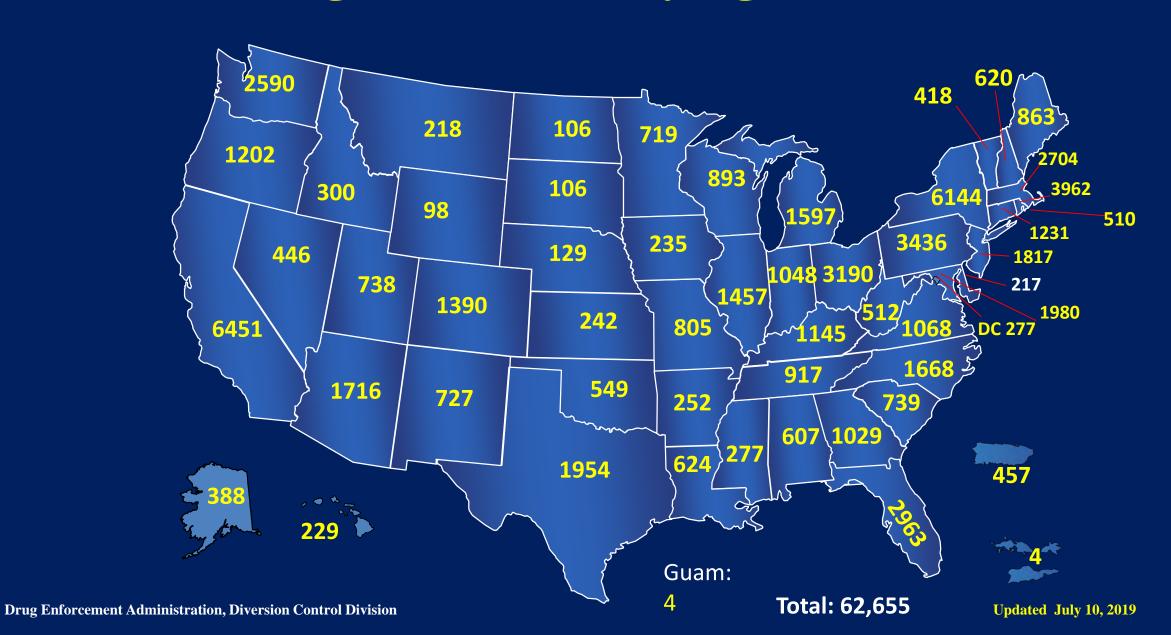
DEA Registered Opioid Treatment Programs (OTP)



DEA Registered Qualifying Practitioners



DEA Registered Qualifying Practitioners





Qualifying Practitioners (US)

Practitioner DW-30	36,046
• Practitioner DW-100	9,045
• Practitioner DW-275	4,505
• Nurse Practitioner DW-30	9,166
• Physician Assistant DW-30	2,449
• Nurse Practitioner DW-100	1,793
• Physician Assistant DW-100	471



Qualifying Practitioners (IN)

• Practitioner DW-30	431
• Practitioner DW-100	161
• Practitioner DW-275	120
• Nurse Practitioner DW-30	226
• Physician Assistant DW-30	22
• Nurse Practitioner DW-100	80
• Physician Assistant DW-100	11

Nationwide Efforts to Combat the Problem



States

Practitioners

Hospitals

Treatment Providers

Medical Schools

Pharmacies



State Limits: Opioid Prescribing

- In March 2016, Massachusetts became the 1st state to enact legislation to limit the supply of opioid painkillers prescribed by practitioners.
- 35 States Have Enacted Legislation with Some Type of Limit, Guidance, or Requirement Related to Opioid Prescribing
- Seven Day Supply in the Most Common
- Most States Exempt Treatment for Cancer, Palliative Care, Medication Assisted Treatment
- Exceptions for the Professional Judgement of the Provider/Documented

Utah and Washington Become Latest States to Require Conversations between Prescribers and Patients

12 States Now Require Patient Notification of Opioid Risks

With the recent adoptions by Utah and Washington, 12 states have now passed versions of the Patient Notification Law, requiring a conversation between prescribers and patients and parents, when a minor is being treated, before an opioid-painkiller is prescribed to warn about risks of dependence and when appropriate to discuss the use of a non-opioid pain relief alternative.

info@preventopioidabuse.org

Utah and Washington Become Latest States to Require Conversations between Prescribers and Patients (continued)

Versions of this life-saving legislation have also passed in California, Connecticut, Maryland, Michigan, New Jersey, Nevada, Oklahoma, Ohio and Rhode Island and West Virginia Efforts to adopt this life-saving legislation are currently underway in Alaska, Kansas, Missouri, Maine, Pennsylvania and Texas.

In the states where this legislation is being implemented, it is driving down the number of opioid pain reliever prescriptions written. In New Jersey, for example, opioid prescriptions have declined by 25% in a little over a year.



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

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.

Knowing the Risks of Opioid Prescription Pain Medications (Rite Aid)

Opioid prescription pain medications are a type of medicine used to relieve pain. Some of the common names include oxycodone and acetaminophen (Percocet®); oxycodone, (OxyContin®); and hydrocodone and acetaminophen (Vicodin®).

These medications...

- Cause your brain to block the feeling of pain; they **do not** treat the underlying cause of pain.
- Are very addictive, especially if they are not used correctly.
- *Increase your chances of accidental overdose, coma, and death* if taken with prescription medications, including anti-anxiety and sedating medications, and alcohol.

Effective non-opioid options are available for relieving short-term pain, including ibuprofen (Advil®, Motrin®), acetaminophen (Tylenol®), physical therapy, chiropractic, acupuncture, and cognitive behavioral therapy. Talk with your pharmacist or healthcare provider to learn more.

Protect yourself - and your loved ones - with Naloxone (Rite Aid)

What is Naloxone?

• Naloxone is a lifesaving, rescue medication that can be used in an emergency to reverse the effects of an accidental opioid overdose.

Why should I get Naloxone?

- Any prescription opioid medication has the potential risk for unintended consequences such as slowed breathing and accidental overdose.
- Guidelines recommend naloxone if you take high doses of opioids, certain interacting medications or have medical condition(s) that increase your risk.
- Having naloxone at home can not only protect yourself, but loved ones that may ingest the opioid by accident an emergency can occur after just one dose.
- Similar to a fire extinguisher in your home, **naloxone** is important to have "just in case" of an emergency or accident *it is always better to take appropriate precautions and be safe!*

"Tylenol, Motrin just as effective in treating pain in ER patients as opioids"

November 7, 2017

Lindsey Tanner, November 7, 2017, The Denver Post, https://www.denverpost.com/2017/11/07/tylenol-motrin-effective-treating-pain-er-patients-as-opioids/

Reducing opioids not associated with lower patient satisfaction scores, study finds Science Daily

A Kaiser Permanente study of nearly 2,500 patients who used high doses of opioids for at least six months showed that reducing their opioid use did not lower their satisfaction with care. The study, "Satisfaction With Care After Reducing Opioids for Chronic Pain," was published today in The American Journal of Managed Care.

"Physicians are often concerned they will receive lower satisfaction scores if they reduce opioids for patients who are accustomed to high opioid doses to manage chronic pain," said the study's lead author, Adam L. Sharp, MD, MS, of Kaiser Permanente Southern California Department of Research & Evaluation. "This study showed that following current recommendations and reducing opioids for chronic pain did not result in lower satisfaction scores."

Most doctors are ill-equipped to deal with the opioid epidemic. Few medical schools teach addiction. Jan Hoffman, The New York Times

Comprehensive addiction training is rare in American medical education. A report by the National Center on Addiction and Substance Abuse at Columbia University called out "the failure of the medical profession at every level — in medical school, residency training, continuing education and in practice" to adequately address addiction.

September 27, 2018

Guidelines for the Chronic Use of Opioid Analgesics

Federation of State Medical Boards

April 2017

CDC

• New project to estimate best practice opioid prescribing in the United States.

• Using large health insurance claims data, CDC will estimate current opioid prescribing rates in the US for various conditions and procedures. Using clinical guidelines and related research, CDC will estimate what the prescribing rates would be for these conditions and procedures if best practices were followed.

Study: Dental painkillers may put young people at risk of opioid addiction

The Washington Post
By Ronnie Cohen

Dentists who prescribe opioid painkillers to teenagers and young adults after pulling their wisdom teeth may be putting their patients at risk of addiction, a new study finds.

The study, published in JAMA Internal Medicine Monday, shines a light on the largely overlooked role dental prescriptions play in an epidemic of addiction that has swept the United States, leading to a record 70,237 drug overdose deaths in 2017.

"Given the gravity of the opioid epidemic, the degree of persistent use and abuse we observed in adolescents and young adults, especially females, is alarming," said researcher Alan Schroeder, a pediatrician and professor at Stanford University School of Medicine. "Our findings should trigger heightened scrutiny over the frequency of prescribing dental opioids."

Adolescents and young adults often are introduced to highly addictive opioid painkillers when they have their third molars pulled. Millions of Americans undergo the procedure every year, and dentists routinely prescribe opioids to the vast majority. Only recently have dentists — the most frequent prescribers of opioids for youths between the ages of 10 and 19 in 2009 — started to reconsider the use of narcotics in managing post-surgical pain.

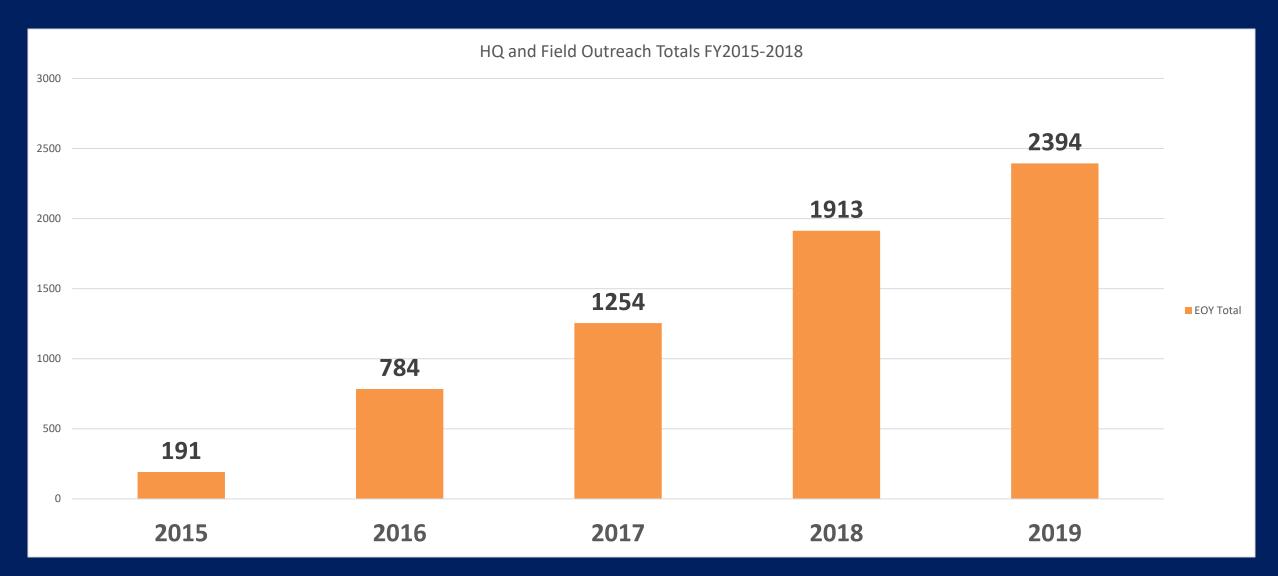
87



DEA Initiatives



Diversion Control Division: Outreach Activities FY 2015 - FY 2019(3rd Quarter)





A Final Note



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 <u>legitimate</u> medical purpose by an individual practitioner acting in the usual course of his professional practice.



Solutions to the Problem

Prevention/Detection

Education

Treatment

Enforcement

- 1. What are some basic limits Alabama has placed on Schedule 2 opioid controlled substance prescriptions?
 - A. 5 Day Supply for Minors
 - B. 15 Days (ER and Urgent Care)
 - C. No Special Restriction
 - D. 7 Day Supply for Initial Prescription

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

- A. Hydrocodone
- B. Oxycodone
- C. Alprazolam
- D. Methadone
- E. A,B, & C

3. According to the CDC approximately how many people died from drug overdoses in the year 2017?

A. 47, 055

B. 52,404

C. 63,632

D. 70,237

- 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

