The United States Department of Justice

Drug Enforcement Administration

Controlled Substance and Legend Drug Diversion; A Law Enforcement and Regulatory Perspective

Portland Pharmacy Diversion Awareness Conference
National Association of Boards of Pharmacy (NABP)
Maine Board of Pharmacy
New Hampshire Board of Pharmacy
Drug Enforcement Administration
Department of Health and Human Services – Office of Inspector General

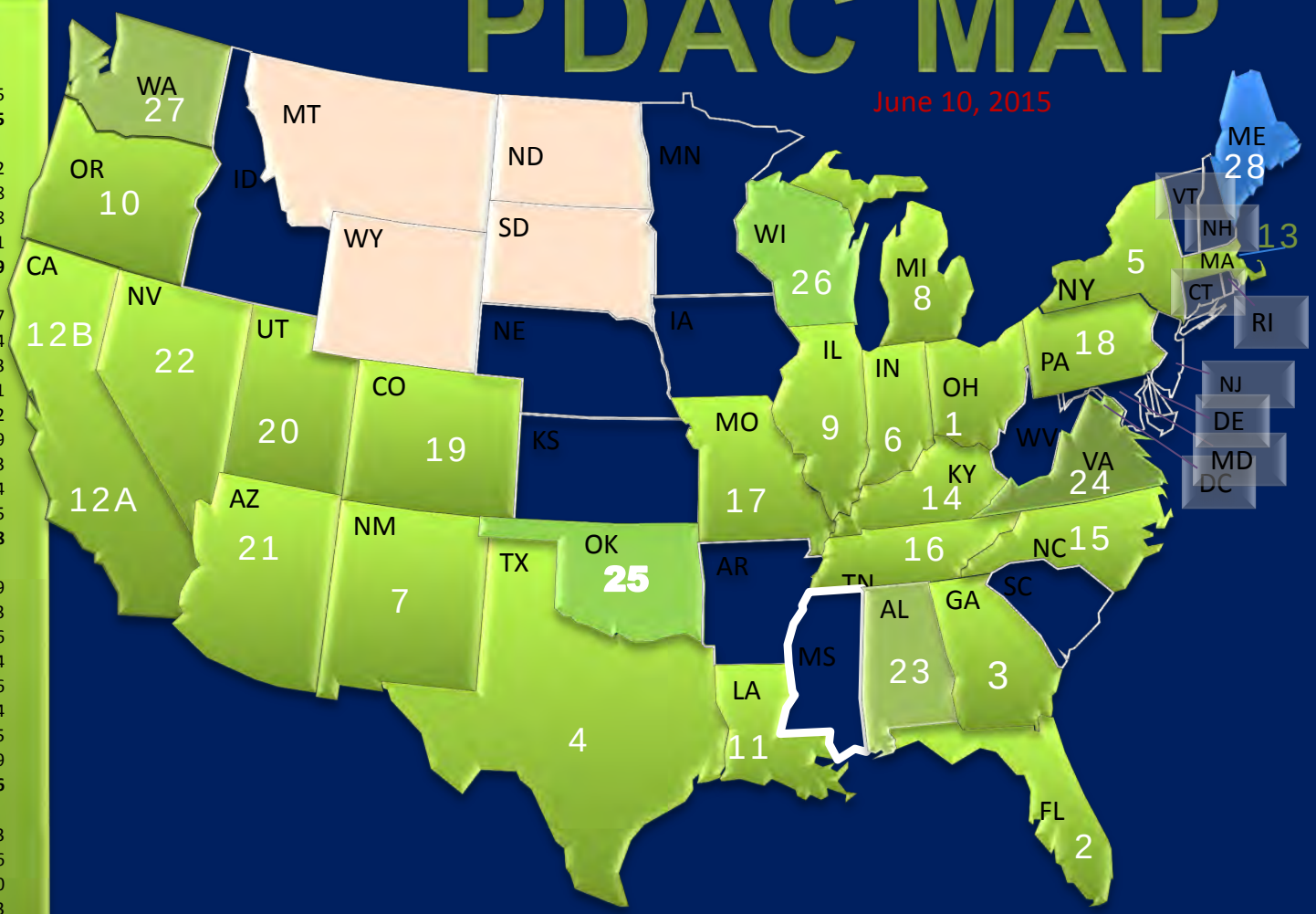
DoubleTree Hotel
Portland, Maine
September 12/13, 2015

Joseph Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

PDAC MAP

June 10, 2015

Completed PDACs	Attendance
FY-2011	
1-Cincinnati, OH 9/17-18/11	75
FY-2011 Total Attendance	**75**
FY-2012	
2-WPB, FL 3/17-18/12	1,192
3-Atlanta, GA 6/2-3/12	328
4-Houston, TX 9/8-9/12	518
5-Long Island, NY 9/15-16/12	391
FY-2012 Total Attendance	**2,429**
FY-2013	
6-Indianapolis, IN 12/8-9/12	137
7-Albuquerque, NM 3/2-3/13	284
8-Detroit, MI 5/4-5/13	643
9-Chicago, IL 6/22-23/13	321
10-Portland, OR 7/13-14/13	242
11-Baton Rouge, LA 8/3-4/13	259
12A-San Diego, CA 8/16-17/13	353
12B-San Jose, CA 8/18-19/13	434
13-Boston, MA 9/21-22/13	275
FY-2013 Total Attendance	**2,948**
FY-2014	
14-Louisville, KY 11/16-17/13	149
15-Charlotte, NC 2/8-9/14	513
16-Knoxville,TN 3/22-23/14	246
17-St. Louis, MO 4/5-6/14	224
18-Philadelphia,PA 7/12-13/14	276
19-Denver, CO 8/2-3/14	174
20-SLC, UT 8/23-24/14	355
21-Phoenix, AZ 9/13-14/14	259
FY-2014 Total Attendance	**2,196**
FY-2015	
22-Las Vegas, NV 2/7-8/15	193
23-Birmingham, AL 3/28-29/15	296
24-Norfolk, VA 5/30-31/15	410
25-Oklahoma City, Oklahoma 6/27-28	253
26-Milwaukee, WI 7/25-26/15	114
27-Seattle Washington	210
Total Attendance To Date	**9124**



Completed PDACs
Proposed PDACs
Postponed PDACs

Proposed FY-2015 PDACs
28-Portland, ME September 12-13, 2015

Postponed FY-2015 PDAC
Rapid City, SD

Disclosure Statement

I have no financial relationships to disclose

and

I will not discuss off-label use and/or investigational drug use in my presentation

Goals and Objectives

- Background of prescription drug and opioid use and abuse – scope of the problem and potential solutions
- Identify and discuss the pharmacology of commonly diverted and abused pharmaceuticals
- Identify methods of pharmaceutical diversion and discuss how the pharmacist can prevent diversion in the retail setting
- Discuss the pharmacist and corresponding responsibility

Questions to Discuss

- According to the National Survey on Drug Use and Health (NSDUH), in 2013 there were 6.5 million persons aged 12 and older who used prescription-type psychotherapeutic drugs non-medically in the last month. Which class of pharmaceutical had the highest level of non-medical use?

A) Stimulants
B) Sedatives
C) Pain relievers
D) Tranquilizers

Questions to Discuss

- According to the National Survey on Drug Use and Health (NSDUH), in 2013, participants identified the most frequent method of obtaining a prescription-type psychotherapeutic drug that they most recently non-medically used as:

A) Internet
B) From a friend or relative for free
C) Purchased from a friend or relative
D) Purchased from stranger/drug dealer

Questions to Discuss

- In determining whether a prescription is valid, a pharmacist is only required to 1) call the prescribing practitioner to verify that he/she authorized the prescription and 2) check to see if he/she has a valid and current DEA registration prior to dispensing the controlled substance;

- A) True
- B) False

Questions to Discuss

True or False…

For a controlled substance prescription to be effective, it must be, “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.”

- A) True
- B) False

Questions to Discuss

- What combination of drugs is referred to as the “trinity”?

A) Hydrocodone, alprazolam, and carisoprodol

B) Promethazine with codeine, methylphenidate and carisoprodol

C) Hydromorphone, carisoprodol and buprenorphine

D) Methadone, diazepam and tramadol

Responding to America's Prescription Drug Abuse Crisis

"When Two Addictions Collide"

Pharmaceuticals

Money - Greed

U.S. Drug Enforcement Administration
Office of Diversion Control

Primum non nocere

Prescription Drug Abuse is driven by

Indiscriminate Prescribing
Criminal Activity

What is the Societal Damage of Prescription Controlled Substance and Legend Drug Abuse?

Consequences

In 2011, approximately 41,340 unintentional drug overdose deaths occurred in the United States, one death every 12.45 minutes. (increased for 12th consecutive year)1

Of this number, 22,810 deaths were attributed to Prescription Drugs (16,917 attributed to opioid overdoses/ (74.165%).

Prescription drug abuse is the fastest growing drug problem in the United States.

[1]SOURCE: CDC National Center for Health Statistics/National Vital Statistics Report; June 2014
CDC Vital Signs: Opioid Painkiller Prescribing; July 2014

2012 Current Users (Past Month) 2013

2012	2013
ANY ILLICIT DRUG: 23.9 million	ANY ILLICIT DRUG: 24.6 million
MARIJUANA: 18.9 million	MARIJUANA: 19.8 million
PSYCHOTHERAPEUTIC DRUGS: 6.8 million	PSYCHOTHERAPEUTIC DRUGS: 6.5 million
COCAINE: 1.6 million	COCAINE: 1.5 million
Methamphetamine 440,000	Methamphetamine 595,000
Heroin: 335,000	Heroin: 289,000

Source: 2012 & 2013 NSDUH

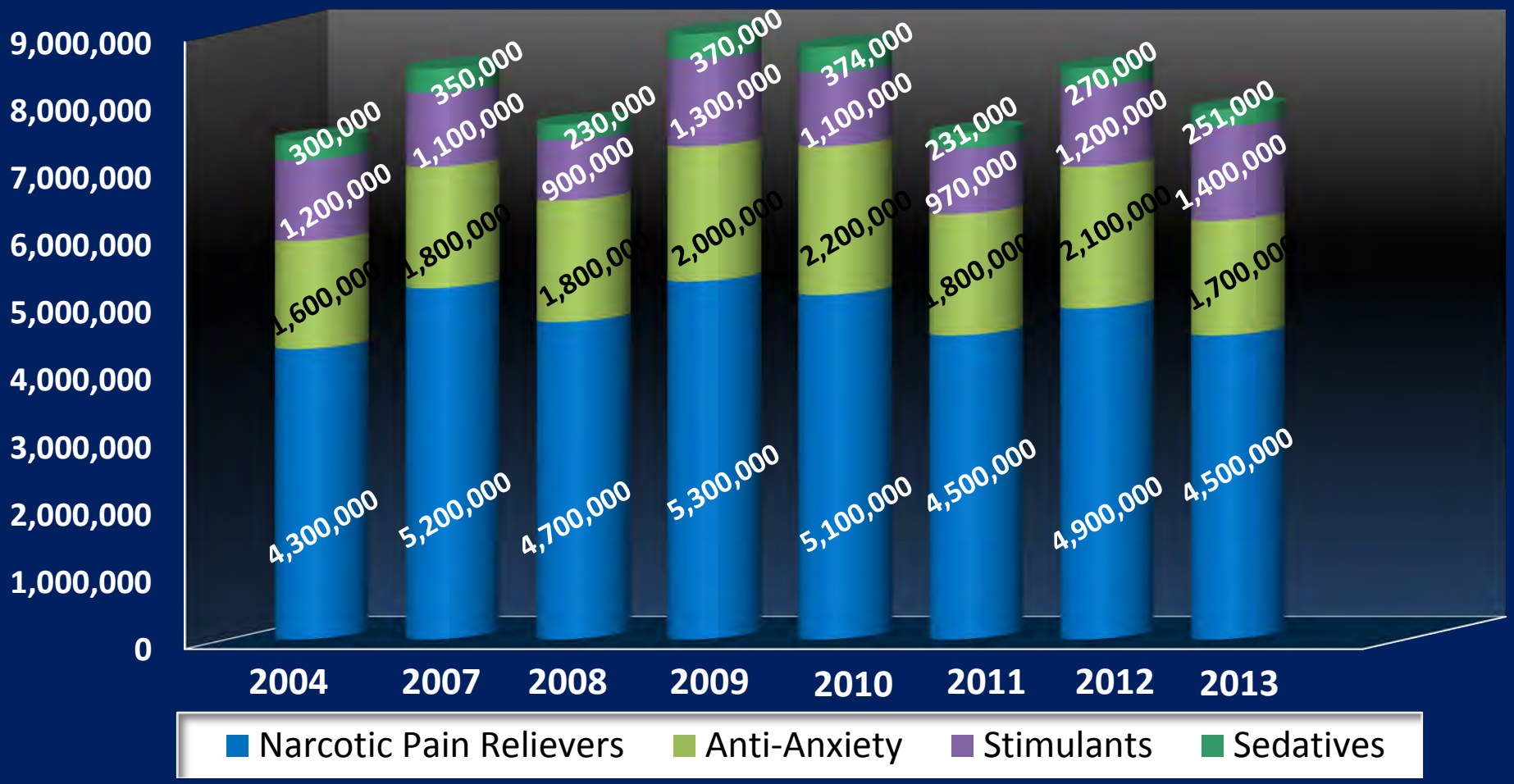
Prescription Drug Abuse

More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Heroin, and Inhalant abusers

COMBINED!!!

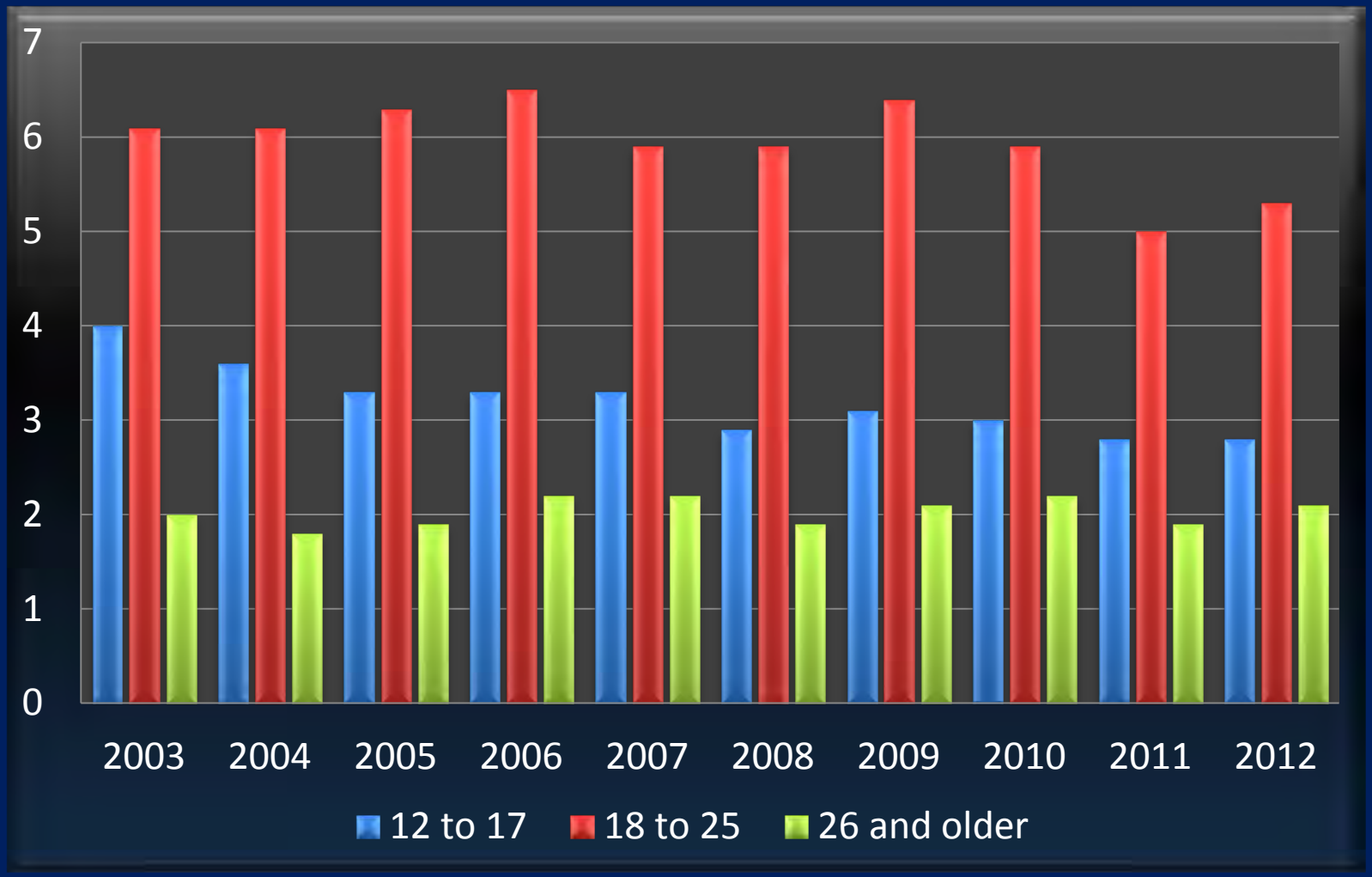
Scope and Extent of Problem: Past Month Illicit Drug Use among Persons Aged 12 or Older



Source: 2004, 2007, 2008, 2009, 2010, 2011, 2012 National Survey on Drug Use and Health

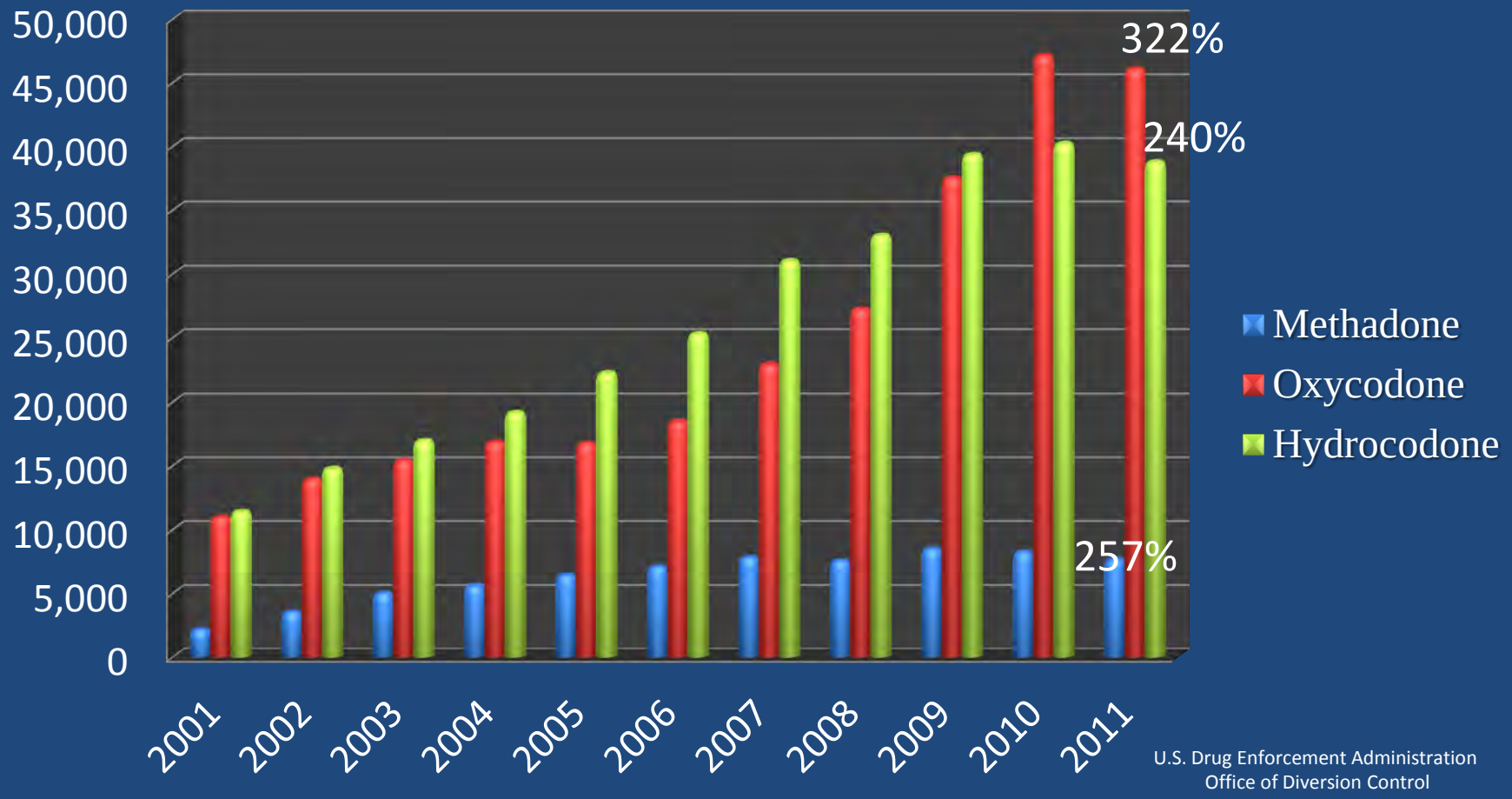
U.S. Drug Enforcement Administration
Office of Diversion Control

Percentage of Past Month Nonmedical Use of Psychotherapeutics by Age, 2003-2011

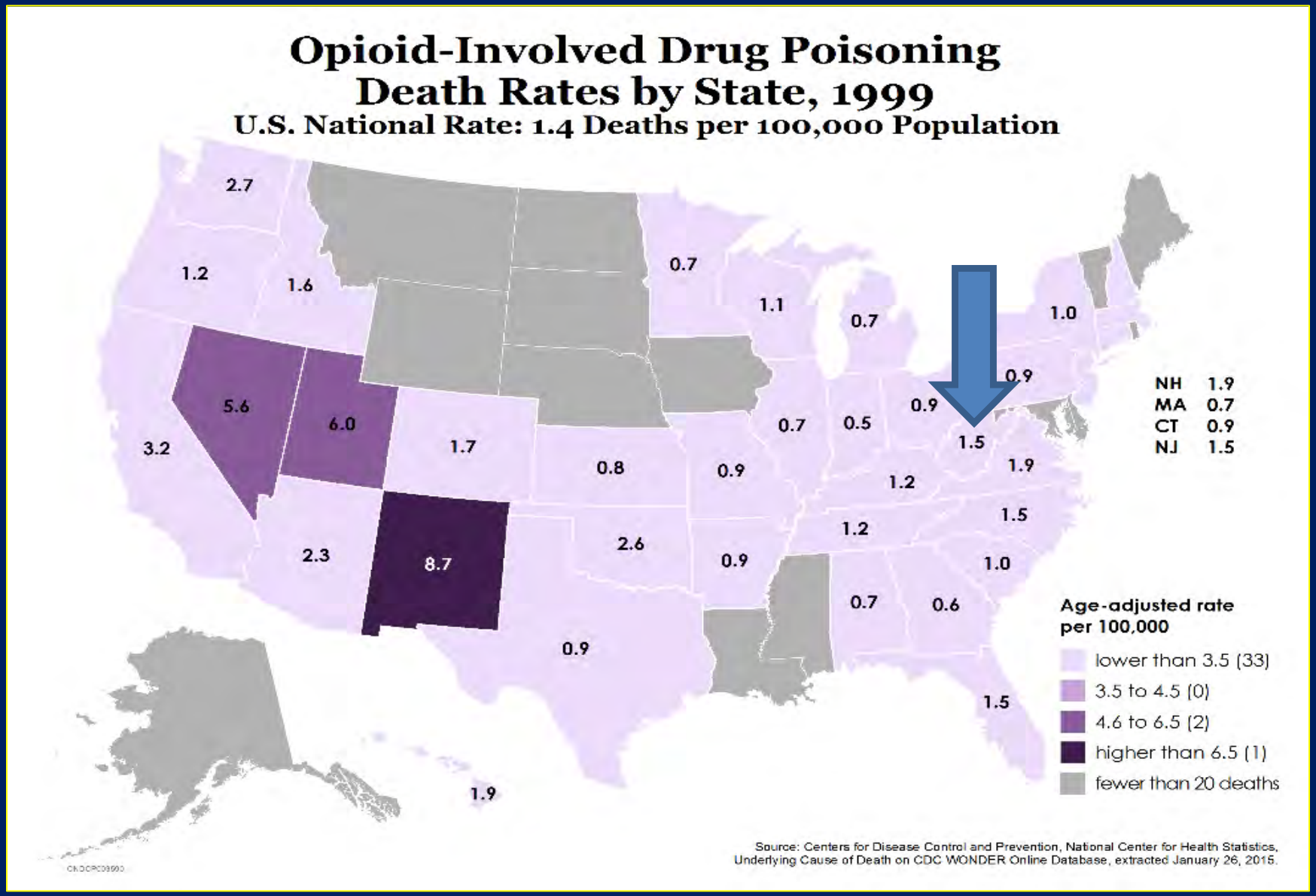


Source: 2011 National Survey on Drug Use and Health

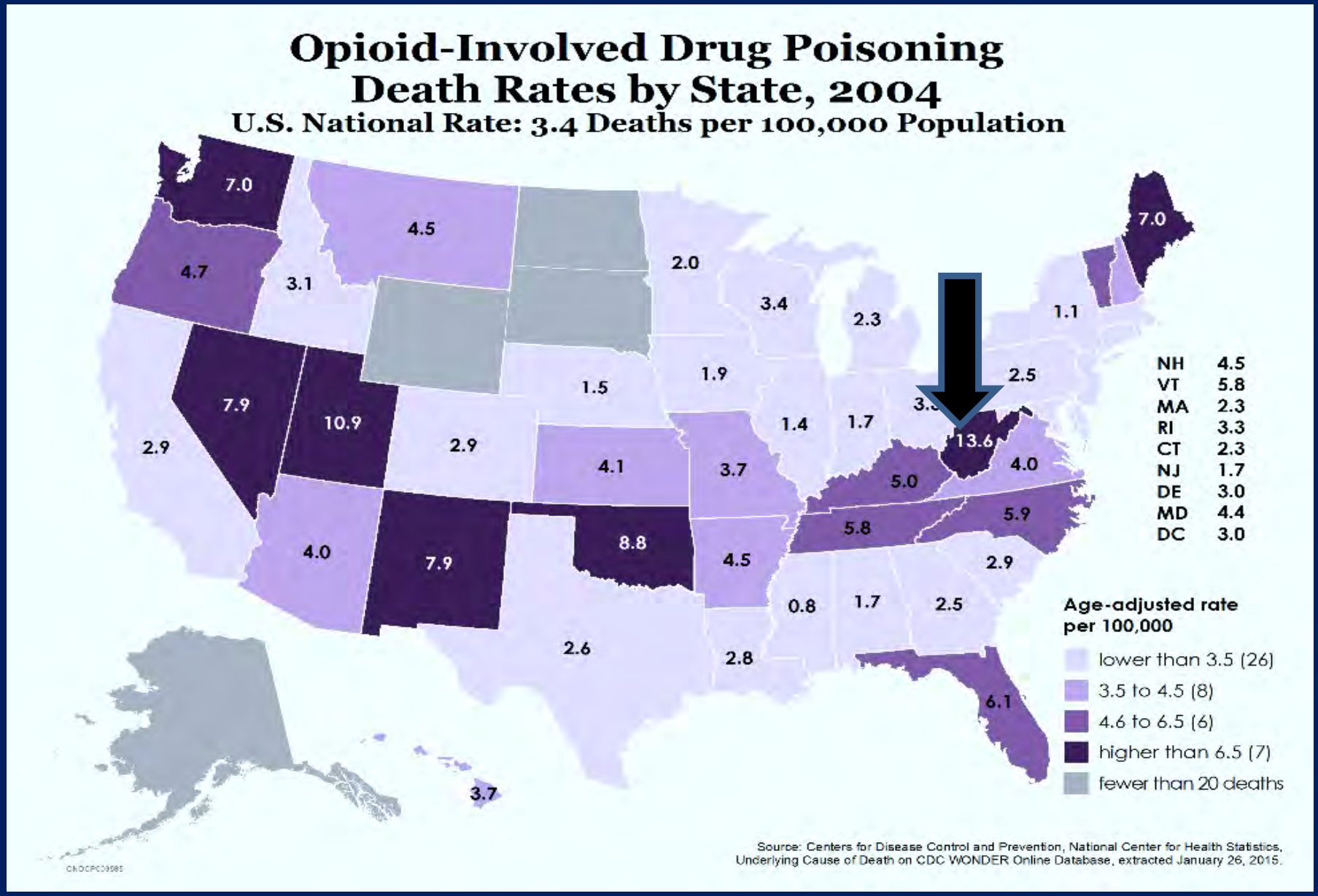
Number of Forensic Cases 2001-2011



Prescription Opioid Analgesics Poisoning Deaths



Prescription Opioid Analgesics Poisoning Deaths



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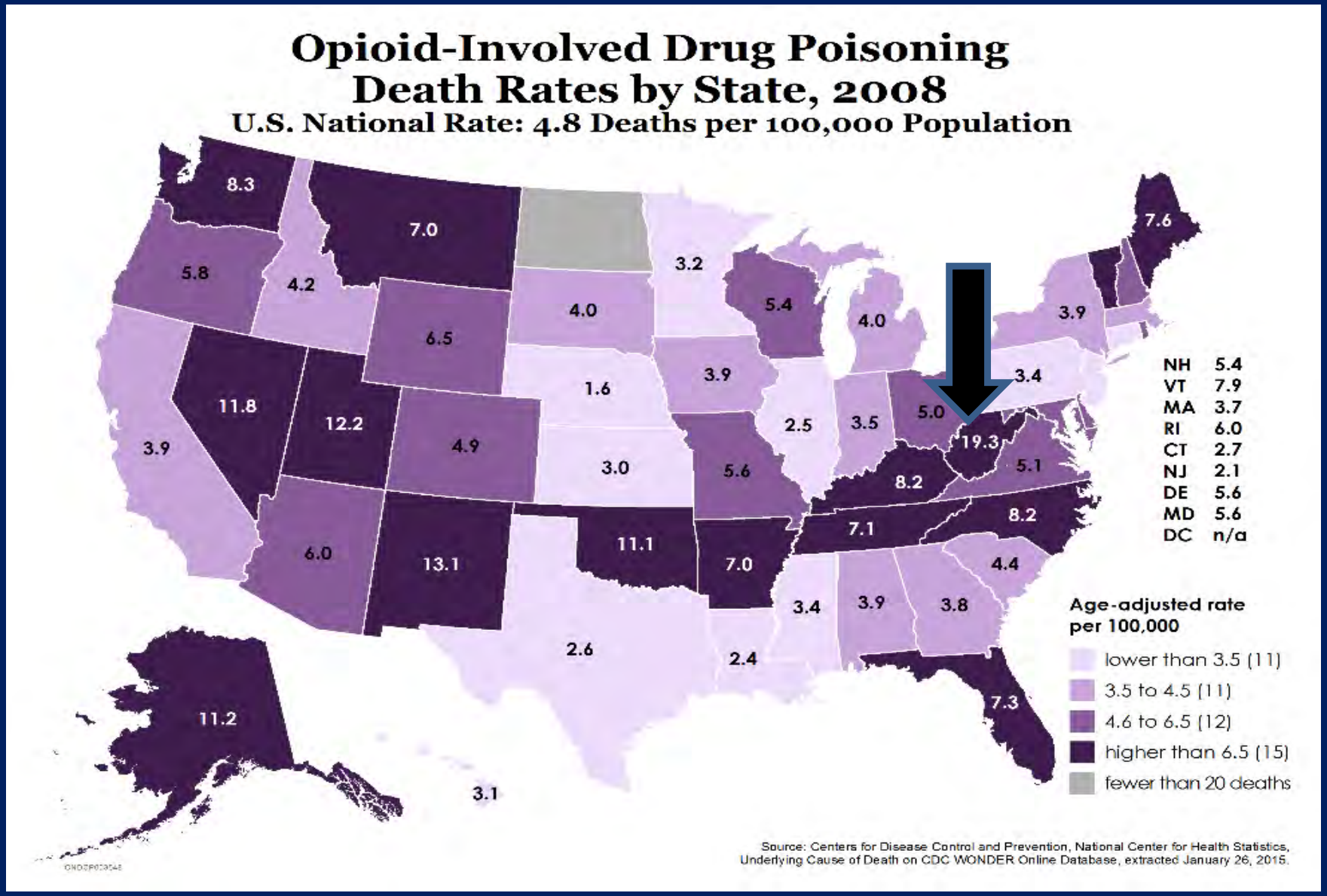
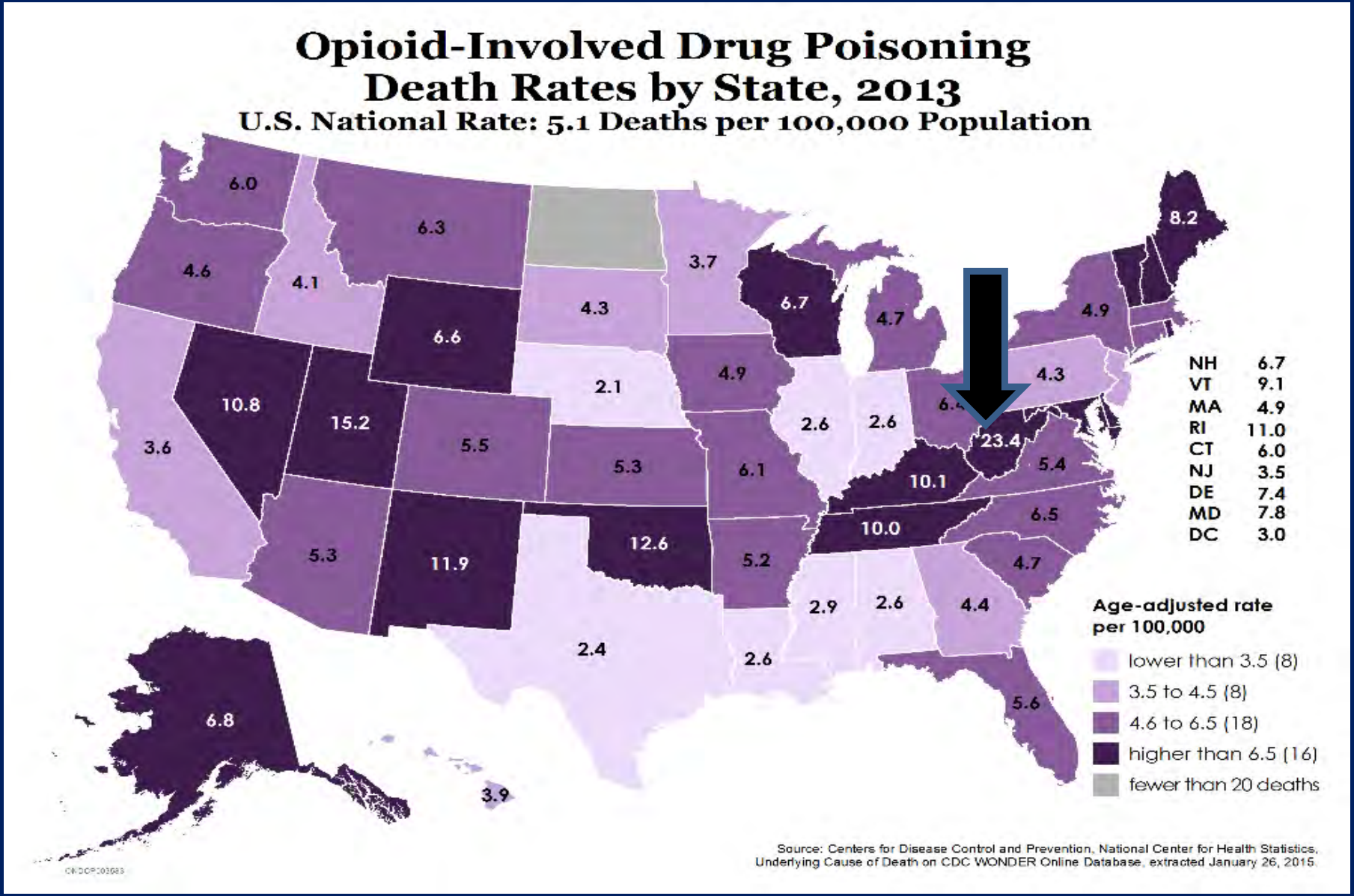
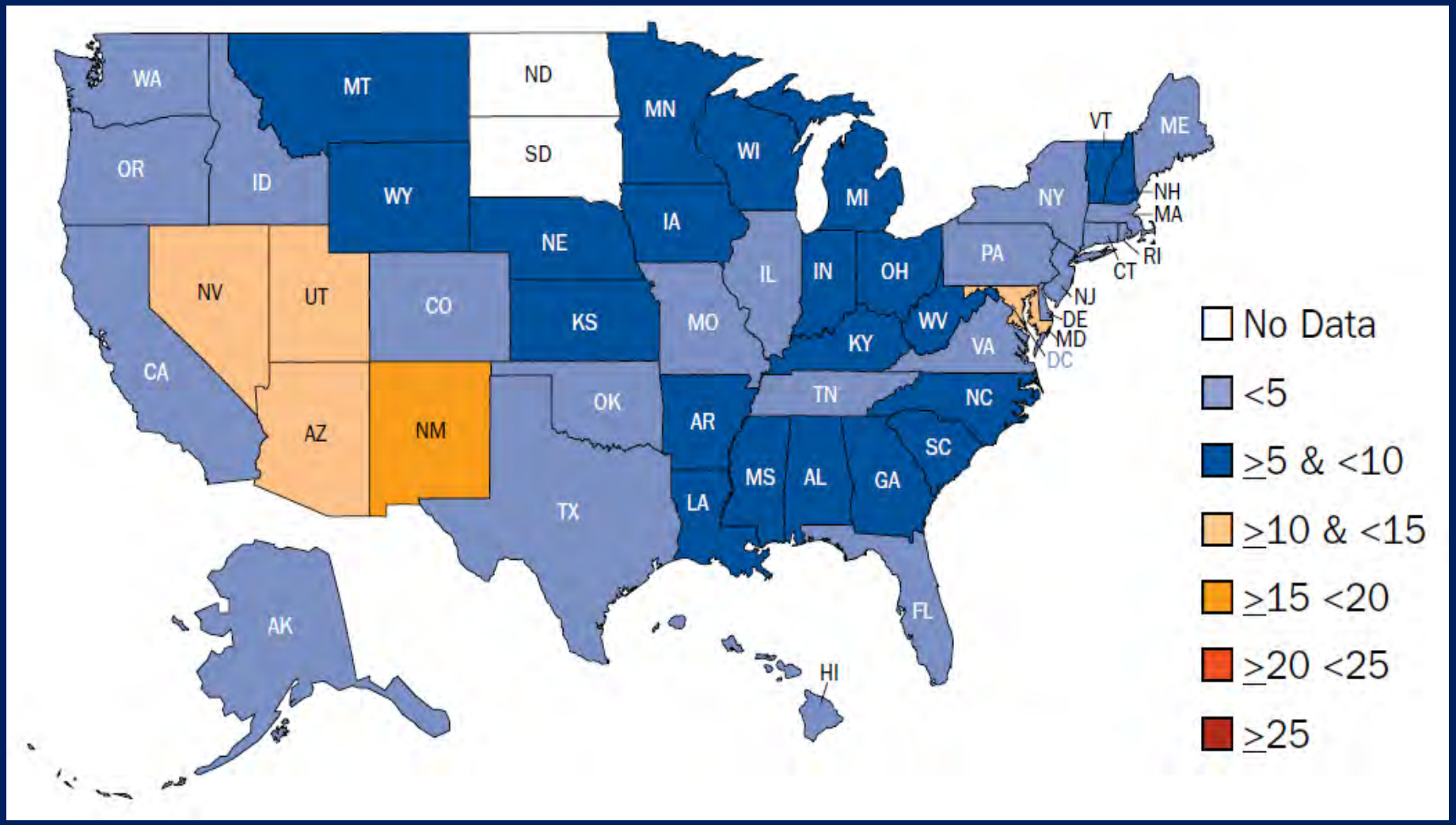
Prescription Opioid Analgesics Poisoning Deaths



Prescription Opioid Analgesics Poisoning Deaths

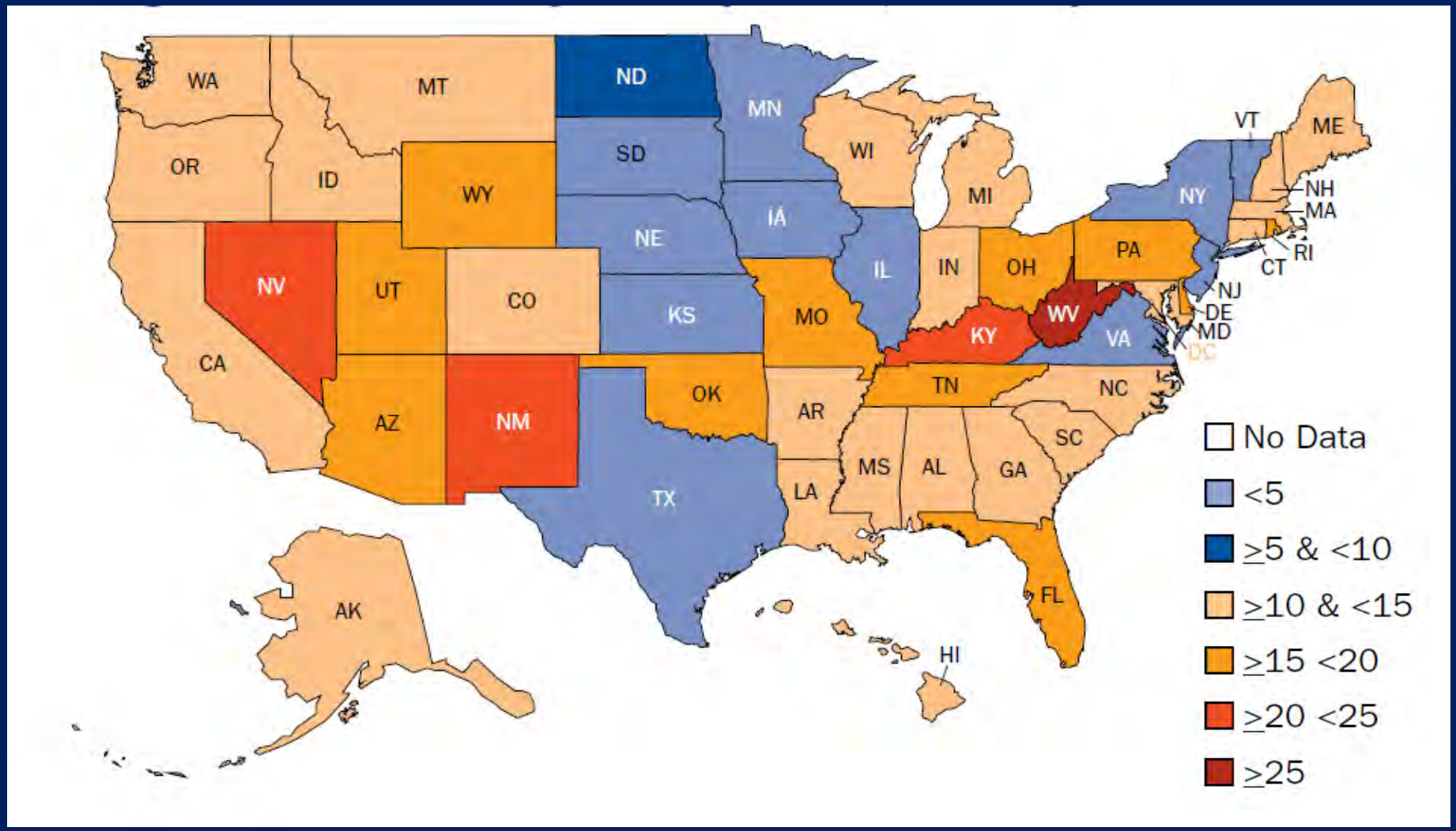


Drug Overdose Mortality Rates per 100,000 People 1999



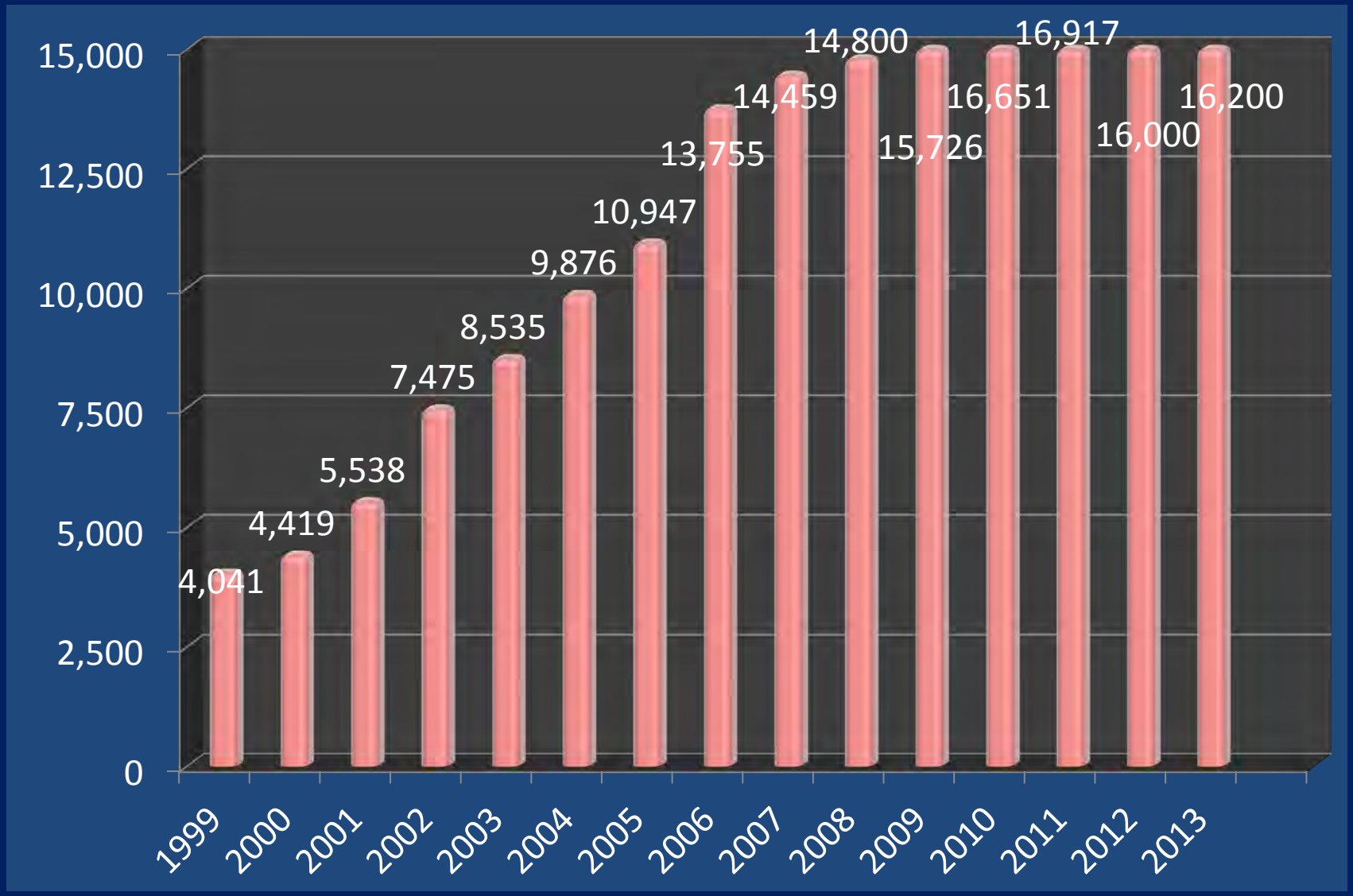
Source: Trust for America's Health, www.healthyamericans.org. "Prescription Drug Abuse: Strategies to Stop the Epidemic (2013)"

Drug Overdose Mortality Rates per 100,000 People 2010



Source: Trust for America's Health, www.healthyamericans.org. "Prescription Drug Abuse: Strategies to Stop the Epidemic (2013)"

Poisoning Deaths: Opioid Analgesics



Source: **CDC/NCHS**, National Vital Statistics System

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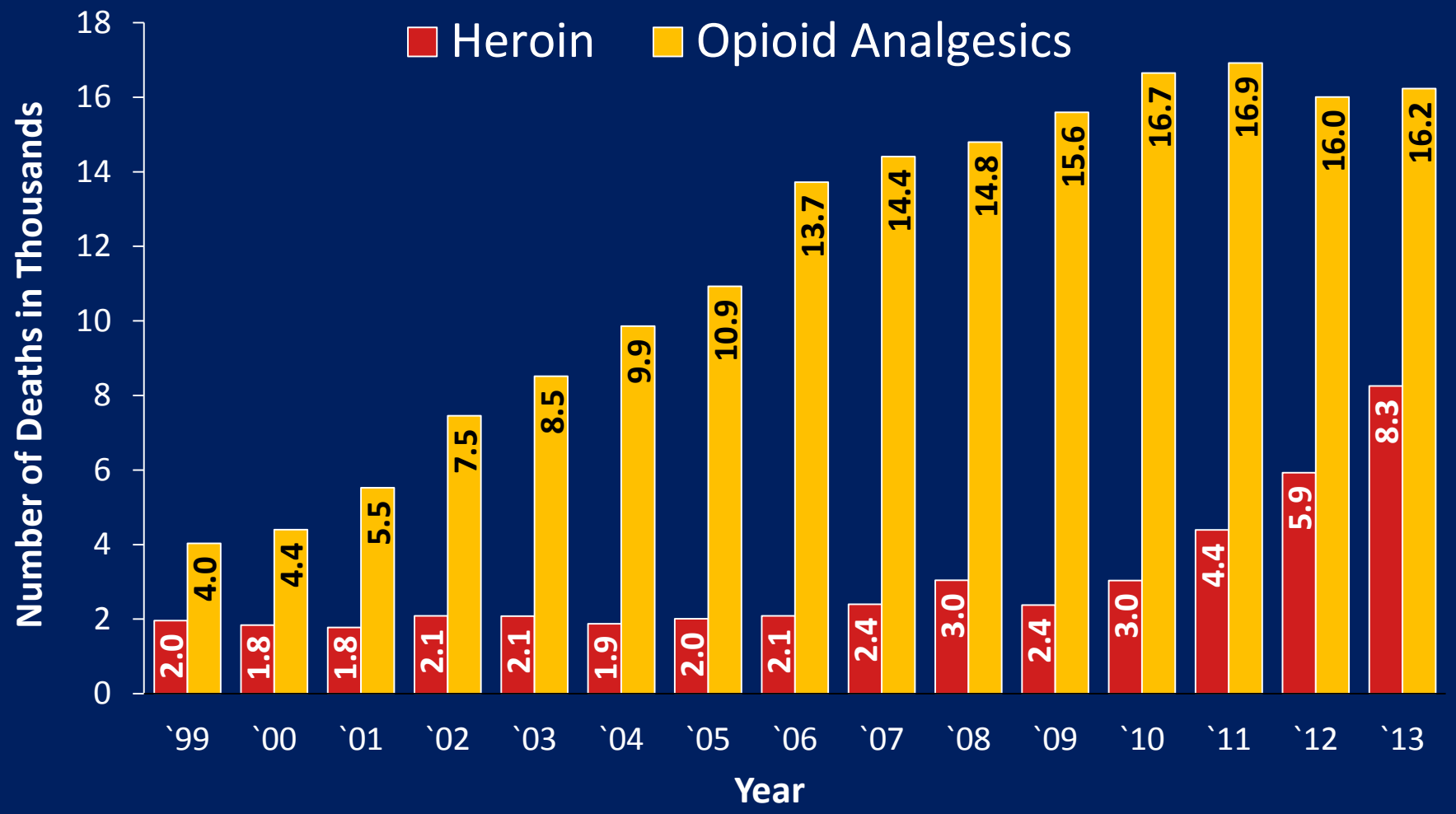
Drug-Poisoning Deaths Involving Opioid Analgesics or Heroin in the US, 1999-2013



Date Prepared/ Source: 01/28/15, CDC/NCHS, National Vital Statistics System, Mortality File

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Naloxone

Naloxone Hydrochloride - Narcan

NARCAN (naloxone) is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids, including propoxyphene, methadone and certain mixed agonist-antagonist analgesics: nalbuphine, pentazocine, butorphanol, and cyclazocine. NARCAN (naloxone) is also indicated for diagnosis of suspected or known acute opioid overdosage.

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Naloxone Hydrochloride - Narcan

NJ.com

Woodbridge police officer saves 2 overdose victims in 5 days using Narcan

An officer in Ocean County demonstrates a naloxone nasal-atomizer. (Ocean County Prosecutor's Office)

By Anthony G. Attrino | NJ Advance Media for NJ.com
on January 28, 2015 at 9:22 AM, updated January 28, 2015 at 11:08 AM

WOODBRIDGE – A township police officer who had just undergone training in the use of Narcan saved the lives of two overdose victims over five days, according to police. "The timing could not have been better," said Woodbridge police Capt. Roy Hoppock.

Narcan, also known as nasal naloxone, is an opioid-reversal drug recently approved for use by law enforcement to help save heroin and opioid users from death by overdose.

The first incident in Woodbridge occurred about 8:45 p.m. on Jan. 21 when police received a 911 call about a 25-year-old woman who had overdosed on narcotics in a home in the Colonia section.

"One officer immediately administered Nasal Naloxone (Narcan) to the victim," Hoppock said in a statement. "Almost immediately the victim showed signs of regaining consciousness."

Hoppock identified the officer as Patrolman Christopher McClay. Hoppock said McClay had received training in the use of Narcan just two hours before the 911 call.

At 2:43 a.m. on Jan. 25, police received a 911 call about an unconscious person in a business parking lot in the Iselin section. "As officers arrived, they observed the victim, a male age unknown breathing, but unconscious," Hoppock said.

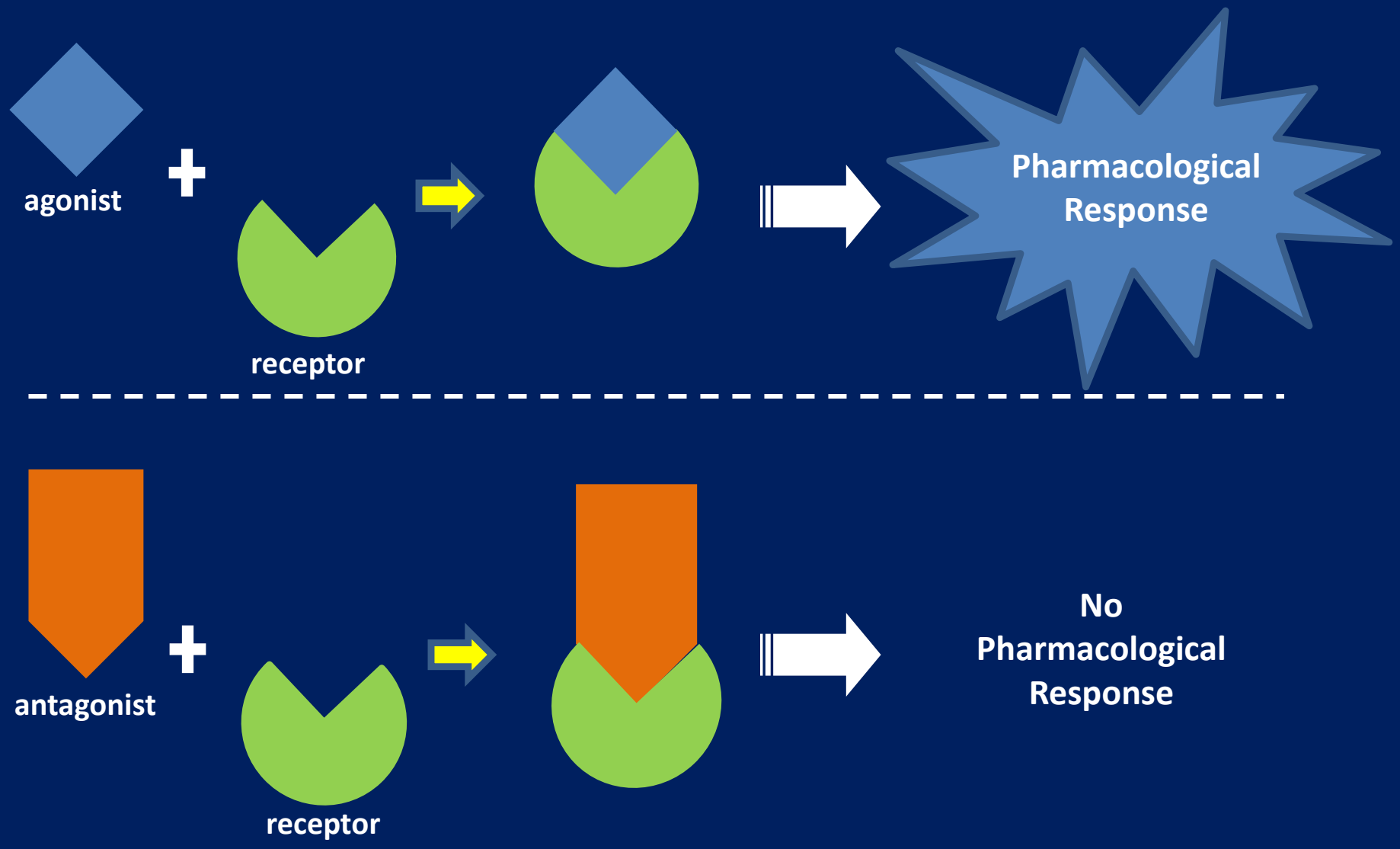
The same officer who participated in the Jan. 21 call, McClay, administered Narcan to the victim, Hoppock said. "The victim appeared to regain consciousness," Hoppock said. "At that point EMS arrived and the victim was transported to JFK Hospital. Hoppock said the Woodbridge Police Department is now in the process of training all patrol officers in the use of Narcan.

The drug has been used by paramedics and emergency room doctors for years. Only recently has it been given to police officers, who are often the first on the scene of drug overdoses.

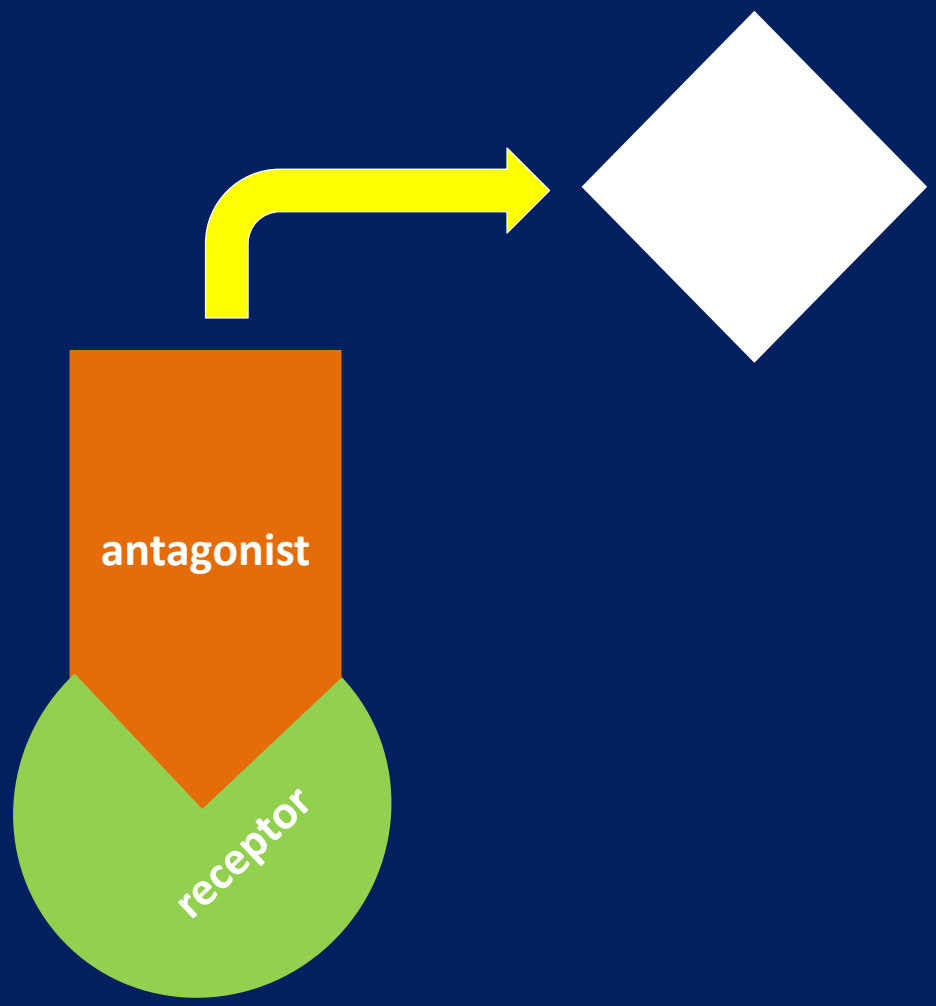
According to the state Attorney General's Office, there were 741 heroin-related deaths in New Jersey in 2013, a 160 percent increase since 2010.

U.S. Drug Enforcement Administration
Office of Diversion Control

Agonist vs. Antagonist



Opioid Displacement



- Naloxone displaces the opioid from the receptor
- Dependent on mode of administration onset can be apparent within a few minutes

Statistical Perspective

The U.S. Population Grows at a Rate of Less Than 1% Per Year!

Source: U.S. Census Bureau

Why are these statistics outpacing population growth?

We all want to feel good and prescription drug use/abuse is an accepted method of curing whatever ails you. There is a pill for everything and medication use is encouraged in society. Our children are following our lead.

Prescription drug epidemic?
How did we get to this point?

Laudanum is no more dangerous than many of the preparations sold as soothing syrups; it has the saving grace of the "poison" label. *(By courtesy of the Committee on Interstate and Foreign Commerce.)*

U.S. Drug Enforcement Administration
Office of Diversion Control

Heroin
Heroin

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PRODUCTS.
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the salicylates
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CREOSOTE CARB
PROTARGOL
QUINALGEN
PIPERAZINE
GUAIACOL CARB
EUROPHEN
HEROIN-HYDROCAL
HEROIN
The sedative for
coughs
LYCETOL
The uric acid solvent
FERRO-SOMATOSE
HEMICRANIN
SULFONAL
IODOTHYRINE
SOMATOSE
SYCOSE
PHENACETIN
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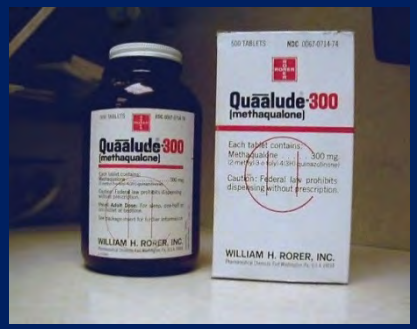
VIN TONIQUE MARIANI
COCA DU PEROU

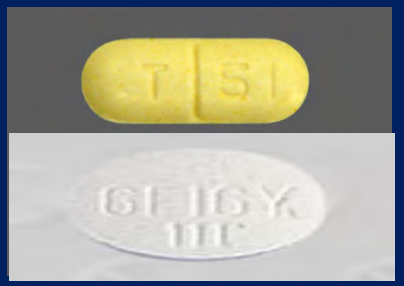
FARBENFABRIKEN
vorm.
FRIEDR. BAYER & Co
ELBERFELD.
Heroin
Name geschützt
Nom déposé

The 1960s/70s/80s

Uppers - Amphetamines



Quaalude

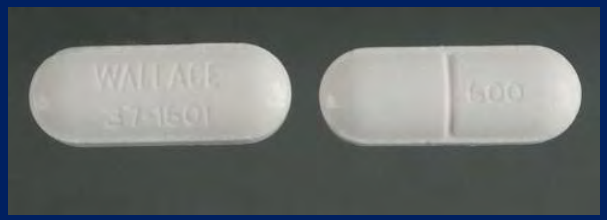


"Ts and Blues"

Downers - Barbiturates

Hydromorphone

"Fours and Doors"



Meprobamate

Oxycodone/APAP

OxyContin® Tablets
(oxycodone hydrochloride controlled-release)

The 1990s

Inadequate Pain Control

EDITORIAL PAGE OF THE **WASHINGTON TIMES** WASHINGTON JULY 1, 1919

The Washington Times — THE NATIONAL DAILY

"Have Another!"

Well-Known Greeting Still Useful in Boozeless World

By T. E. Powers

The District's Plight

Her Officials Could Be Heavily Punished For Violation of Law.

By BILL PRICE.

District Commissioners and their subordinate officials are all engaged today in violating a plain, clear provision of law of the United States—that which prohibits the creation of obligations until specific appropriations are made therefor.

To prevent the cessation of all municipal activities—which would mean serious disaster in many directions—the District government is running today without a dollar of authorized money. These officials are compelled to violate

The Curse of Drugs

You May Be Ignorant of a Danger That Threatens Your Children. Read About It and Size Thy

A further discovery, startling and alarming, was that among the better class of people, those outside the underworld, the habit of using narcotic drugs has its origin, to a great degree, in the prescribing by physicians of their use for the relief of pain.

July 1, 1919

to it, and likely soon to pass it, is heroin. This latter drug, which is taken in the form of snuff, seems to have a special appeal to boys and girls because they find little trouble in procuring it.

An investigation of a limited number of penal institutions showed that 626 inmates were morphine users and 558 heroin addicts, and that few of the latter were more than twenty years old.

A further discovery, startling and alarming, was that among the better class of people, those outside the underworld, the habit of using narcotic drugs has its origin, to a great degree, in the prescribing by physicians of their use for the relief of pain.

It was further found that the repeated taking of a narcotic drug over a period of thirty days, and in the case of susceptible patients over a period of ten days was sufficient to thoroughly establish the habit.

The drug habit in this country is an American habit. It is not indulged in to any extent by immigrants nor acquired by them after their arrival here.

Based on the most accurate figures obtainable, the per capita consumption of habit-forming drugs in the United States is TWELVE TIMES that recorded in any European country.

Naturally the addiction to these drugs is much more common in the cities than in the country and much more general in the large cities than in the small.

The issues evil has had enough bad features to work its own destruction, but beside the traffic in drugs the sale of liquor is a commendable occupation.

Particularly should there be the most careful investigation of the use of drugs by your boys and girls.

The teachers in the schools should be instructed to keep strict watch on any evidence of the habit.

A physician should prescribe a habit-forming drug only as a last resort in the case of great suffering. He should limit its use under any conditions to the lowest possible dose, bearing in mind always the greater suffering that will come to his patient if a habit is formed.

We are happily rid of the curse of whiskey. There cannot be too great provision made against the growth of an even greater evil in the spread of the sale of drugs.

P. S.—Beginning today there is likely to be offered a variety of drinks which will be described "just as good" as whiskey.

Ninety nine per cent of these concoctions will contain some narcotic drug. They will be extremely dangerous. Keep away from them.

Omission of Letter Gives Credit To Wrong Man

Beatrice Fairfax Writes of the Problems and Pitfalls of the War Workers

Especially for Washington Women

TODAY'S TOPIC
ANSWERS TO CORRESPONDENTS

HEARD AND SEEN

What's Doing; Where; When

Vol. 302 No. 2 CORRESPO

ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients[1] who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented

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.

Waltham, MA 02154 Boston University Medical Center

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

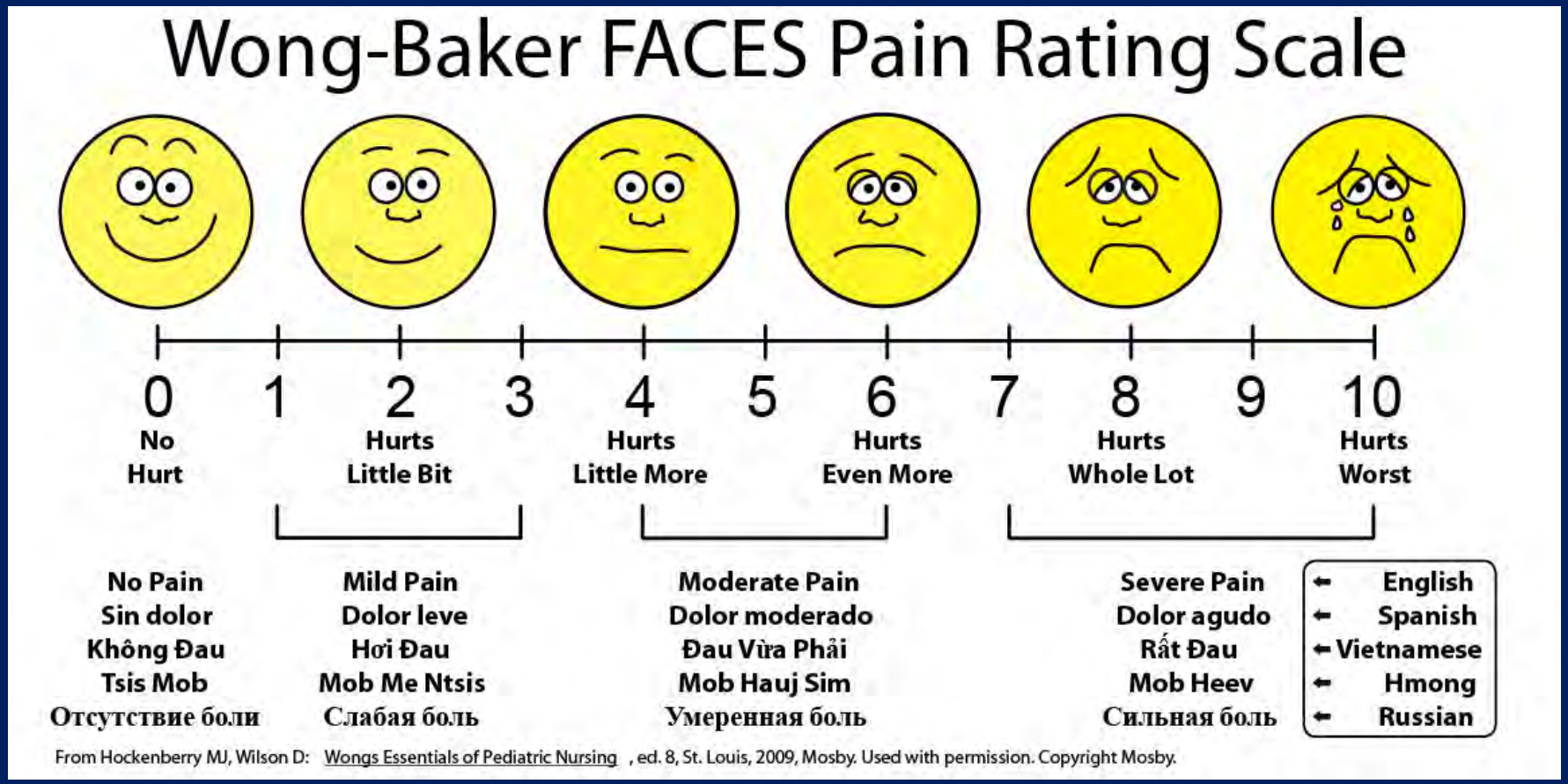
New England Journal of Medicine 1980;302:123

The Fifth Vital Sign?

1. Temperature
2. Heart Rate
3. Blood Pressure
4. Respiration

5. Pain?

Pain Scale


Wong-Baker FACES Pain Rating Scale
0
1
2
3
4
5
6
7
8
9
10
No Hurt
Hurts Little Bit
Hurts Little More
Hurts Even More
Hurts Whole Lot
Hurts Worst
No Pain
Sin dolor
Không Đau
Tsis Mob
Отсутствие боли
Mild Pain
Dolor leve
Hơi Đau
Mob Me Ntsis
Слабая боль
Moderate Pain
Dolor moderado
Đau Vừa Phải
Mob Hauj Sim
Умеренная боль
Severe Pain
Dolor agudo
Rất Đau
Mob Heev
Сильная боль
English
Spanish
Vietnamese
Hmong
Russian
From Hockenberry MJ, Wilson D: Wongs Essentials of Pediatric Nursing , ed. 8, St. Louis, 2009, Mosby. Used with permission. Copyright Mosby.

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Back To EurekAle

Contact: Amy Jenkins
amy@jenkinspublicrelations.com
312-836-0613
American Academy of Pain Medicine

Experts call for balance in addressing under treated pain and drug abuse

Healthcare decisions must remain in the hands of healthcare professionals for the sake of patients

A balance must be struck between physicians' responsibility to treat chronic pain and the Drug Enforcement Administration's (DEA) duty to combat drug abuse, according to a series of seven commentaries by national thoughtleaders published today in th February issue of Pain Medicine.

The commentaries explore the current state of the use of pain medicine from a variety of perspectives, with an emphasis on the tension between physicians treating legitimate pain and the DEA. Pain Medicine is the journal of the American Academy of Pa Medicine (AAPM).

According to the American Pain Foundation, chronic pain affects more than 50 million Americans. People suffering from chronic pain may need pain medicine to lead normal lives, such as being able to work and to participate in family life. Many patients w chronic pain have lost access to appropriate medical care due to tension between regulatory/legislative bodies and the medical community.

The lead commentary describing current DEA policy on pain care with controlled substances was written by Howard A. Heit, MD, a pain and addiction medicine specialist who has collaborated with the DEA. AAPM President Scott M. Fishman, MD, presents collision of the war on drugs with efforts to improve pain care. Jennifer Bolen, JD, Former Assistant US Attorney with the United States Department of Justice, makes a compelling case that current DEA policies are founded on erroneous and inappropriate positions. Edward Covington, MD, Steven Passik, PhD, and Ben A. Rich, JD, PhD, add additional dimensions to the current perceived state of imbalance, while Will Rowe, Executive Director of the American Pain Foundation, a patient advocacy organization provides perspective on patient's rights.

Victories and Defeats in Pain Care
Dr. Heit and others worked with the DEA to develop the August 2004 Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel, which the DEA subsequently disavowed causing "confusion and consternation" among physicians who treat pain.

"It is now apparent to me that the spirit of cooperation that existed between the DEA and the pain community to achieve the goal of balance has broken down. The DEA seems to have ignored the input and needs of the healthcare professionals and pain patients who actually prescribe, dispense and use controlled substances," Dr. Heit states in his commentary.

"It is essential that we resume dialogue between the DEA and healthcare professions for the benefit of our patients and society," continues Dr. Heit. "The DEA and the healthcare professionals treating pain both have an important job to do in ensuring tho who need [controlled substances] for pain receive them while preventing misuse and diversion. Only through dialogue based on and mutual trust and respect can this balance be restored."

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As healthcare's regulatory authority shifts from health agencies to law enforcement agencies, the DEA and Federal prosecutors have used the courts to bypass state medical boards when scrutinizing physician practices. Dr. Fishman says that the recently passed national law, National All Schedules Prescription Electronic Reporting Act (NASPER), which institutes a national prescription monitoring program, may offer some steps forward, but it also carries the potential to impede optimal prescribing and coul even perpetuate aberrant prescribing that may facilitate abuse. While this new law is presented to the public as a clinical tool to improve patient care and safety, "...profound inadequacies suggest that this law may be intended less as a clinical tool than a physician mouse trap," Dr. Fishman states.

"Healthcare decisions, including those involving legitimate use of analgesics, must remain in the hands of healthcare professionals," comments Dr. Fishman. "The DEA should be required to work with health agencies and healthcare professionals in finding common ground and reaching the rational position of balance that is in the public's best interest...Healthcare oversight must remain within agencies whose primary responsibility is to improve public health continue to insist that drug abuse can be curbed without undermining patients in pain and striving for such policies is in the best interest of society. The least we can do is to make sure that the casualties legitimately deserve relief."

Freedom to Care for Pain Patients Critical
Reluctance to prescribe powerful pain medicine among the medical community for fear of retribution has led to the needless suffering of countless people in pain.

The Department of Justice must "stop the abuse and diversion of prescription medicines without harming access to these medicines for people affected by pain," states Will Rowe, Executive Director, Ame commentary points to a failure on the part of the DEA in not abiding by its commitment to the pain community to pursue a balance between the war on drugs and the rights of pain patients, and also cite assert the more comprehensive command."

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About the American Academy of Pain Medicine
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Founded in 1997, the American Pain Foundation is an independent nonprofit 501(c)3 organization serving people with pain through information, advocacy, and support. Our mission is to improve the qual awareness, providing practical information, promoting research, and advocating to remove barriers and increase access to effective pain management. For more information, visit www.painfoundation.org

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amy@jenkinspublicrelations.com
312-836-0613
American Academy of Pain Medicine

Experts call for balance in addressing under treated pain and drug abuse

Healthcare decisions must remain in the hands of healthcare professionals for the sake of patients

A balance must be struck between physicians' responsibility to treat chronic pain and the Drug Enforcement Administration's (DEA) duty to combat drug abuse, according to a series of seven commentaries by national thoughtleaders published today in February issue of Pain Medicine.

The commentaries explore the current state of the use of pain medicine from a variety of perspectives, with an emphasis on the tension between physicians treating legitimate pain and the DEA. Pain Medicine is the journal of the American Academy of Medicine (AAPM).

According to the American Pain Foundation, chronic pain affects more than 50 million Americans. People suffering from chronic pain may need pain medicine to lead normal lives, such as being able to work and to participate in family life. Many patients chronic pain have lost access to appropriate medical care due to tension between regulatory/legislative bodies and the medical community.

The lead commentary describing current DEA policy on pain care with controlled substances was written by Howard A. Heit, MD, a pain and addiction medicine specialist who has collaborated with the DEA. AAPM President Scott M. Fishman, MD, present collision of the war on drugs with efforts to improve pain care. Jennifer Bolen, JD, Former Assistant US Attorney with the United States Department of Justice, makes a compelling case that current DEA policies are founded on erroneous and inappropria positions. Edward Covington, MD, Steven Passik, PhD, and Ben A. Rich, JD, PhD, add additional dimensions to the current perceived state of imbalance, while Will Rowe, Executive Director of the American Pain Foundation, a patient advocacy organizati [illegible] on pa[illegible]nt's

THE CHILLING EFFECT

Victo[illegible]s and [illegible]ts in [illegible]in C[illegible]
Dr. H[illegible] and oth[illegible] worke[illegible]th t[illegible] DEA to develop t[illegible] August 2004 [illegible]quent[illegible]sked [illegible]esti[illegible] and Ans[illegible]s for Hea[illegible] Car[illegible]rofe[illegible] an[illegible]w E[illegible]ment Perso[illegible], which th[illegible] subse[illegible], disav[illegible]ed causin[illegible]onfusion and co[illegible]ernation amor[illegible]hysicia[illegible]who tre[illegible]ain.

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Dollars for Doctors
How Industry Money Reaches Physicians

American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics

This article is part of an ongoing investigation:

Dollars for Doctors: How Industry Money Reaches Physicians
ProPublica is tracking the financial ties between doctors and medical companies.

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The Story So Far

ProPublica is investigating the financial ties

For Immediate Release
May 08, 2012

Contact: Communications Office (Baucus), 202-224-4515
Jill Gerber (Grassley), 202-224-6522

Baucus, Grassley Seek Answers about Opioid Manufacturers' Ties to Medical Groups

Finance Leaders Investigate Whether Pharmaceutical Companies Encouraged Non-Profit Beneficiaries to Promote Misleading Information about Narcotic Painkillers

Washington, DC – Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior Committee member Chuck Grassley (R-Iowa) initiated an investigation today into the connections of drug manufacturers Purdue Pharma, Endo Pharmaceuticals, and Johnson & Johnson with medical groups and physicians who have advocated the increased use of narcotic painkillers, or opioids. The Senators also asked seven other medical groups to produce information about their financial ties and collaborations with opioid manufacturers. In letters sent to each yesterday, Baucus and Grassley requested documents and financial information from the companies and noted that deaths resulting from opioid overdoses have recently skyrocketed, growing nearly 400 percent between 1999 and 2008, the most recent year data was available. They also highlighted news reports suggesting the increase may be driven by misinformation and dubious marketing practices used by the pharmaceutical companies and the medical organizations they fund.

"Overdoses on narcotic painkillers have become an epidemic, and it's becoming clear that patients aren't getting a full and clear picture of the risks posed by their medications," Baucus said. **"When it comes to these highly-addictive painkillers, improper relationships between pharmaceutical**

Related Files

- Baucus Grassley Opioid Investigation Letter to Purdue Pharma [288.2 KB]
- Baucus Grassley Opioid Investigation Letter to Federation of State Medical Boards [276.9 KB]
- Baucus Grassley Opioid Investigation Letter to the Joint Commission [278.4 KB]
- Baucus Grassley Opioid Investigation Letter to Wisconsin Pain And Policy Studies Group [277.5 KB]
- Baucus Grassley Opioid Investigation Letter to American Academy of Pain Medicine [277.6 KB]
- Baucus Grassley Opioid Investigation Letter to American

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Watchdog Reports

U.S. Senate panel launches investigation of painkillers, drug companies

By *John Fauber* of the Journal Sentinel

May 9, 2012

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Meet the Watchdog team

"Recent investigative reporting from the Milwaukee Journal Sentinel/Medpage Today and ProPublica revealed extensive ties between companies that manufacture opioids and non-profit organizations such as the American Pain Foundation….and the Joint Commission."

State Medical Boards
- Letter to Johnson and Johnson
- Letter to Center for Practical Bioethics
- Letter to Endo Pharmaceuticals
- Letter to American Pain Foundation
- Letter to American Pain Society
- Letter to American Academy of Pain Medicine

"It is clear that the United States is suffering from an epidemic of accidental deaths and addiction resulting from increased use of powerful narcotic painkillers," said a joint statement from committee members U.S. Sens. Chuck Grassley (R-Iowa) and Max Baucus (D-Mont.).

The senators said there was growing evidence that drug companies have promoted misleading information about the safety and effectiveness of the drugs with help from nonprofits they have donated to.

"Recent investigative reporting from the Milwaukee Journal Sentinel/MedPage Today and ProPublica revealed extensive ties between companies that manufacture and market opioids and nonprofit organizations such as the American Pain Foundation, the American Pain Society, the American Academy of Pain Medicine, the Federation of State Medical Boards, the University of Wisconsin Pain and Policy Studies Group and the Joint Commission," Grassley and Baucus wrote.

In addition to the pain organizations, the committee also sought records from three leading drug companies: Purdue Pharma, Johnson & Johnson and Endo Pharmaceuticals. It also requested records from the Center for Practical Bioethics, a Kansas City, Mo., organization that has advocated for pain treatment.

The committee said it wants records dating back to 1997.

The letter notes that a February Journal Sentinel/MedPage Today story

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- Employment debate requires closer look
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Bioethics think tank's ties to pain pill industry studied

BY ALAN BAVLEY
The Kansas City Star

A U.S. Senate committee is examining a Kansas City-based bioethics think tank's financial ties to the pain-pill industry.

The inquiry is part of a sweeping investigation by the Senate Finance Committee of connections between pain drug manufacturers and organizations and physicians who have advocated for increased use of narcotic — also known as opioid — painkillers.

Abuse of these potentially addictive pain medications has become a national epidemic and accounts for more overdose deaths than heroin and cocaine combined. About 5 million people had used the drugs recently without a prescription, a federal survey found.

Breaking News
Homers by Francoeur and Butler lift Royals to 4 -2 victory over Orioles
La Crosse, Kan., is cleaning up after twister
No injuries but much damage in Columbia apartment fire
Franchitti wins 3rd Indy 500, gives nod to Wheldon
Former KC Chief charged with attempted murder
Man, 65, shoots motorcyclist in road rage incident

The Center for Practical Bioethics is one of seven organizations that received letters this week from the Senate committee asking them for information about their financial ties and collaborations with opioid manufacturers.

The other organizations are the American Pain Foundation, the American Academy of Pain Medicine, the American Pain Society, the Wisconsin Pain and Policy Study Group, the Joint Commission of Accreditation of Healthcare Organizations and the Federation of State Medical Boards.

Recent investigations by news organizations have found that some of these groups, such as the American Pain Foundation, a patient advocacy group, are funded largely by the drug industry.

The Senate committee is seeking to determine whether any of the groups promoted misleading information about the risks and benefits of opioids while receiving financial support from manufacturers of the drugs.

A Senate aide told The Kansas City Star that the investigation may bring into question guidelines for pain management, or the legitimacy of some of the organizations under scrutiny.

One of the organizations, the American Pain Foundation, disbanded last week, citing "irreparable economic circumstances."

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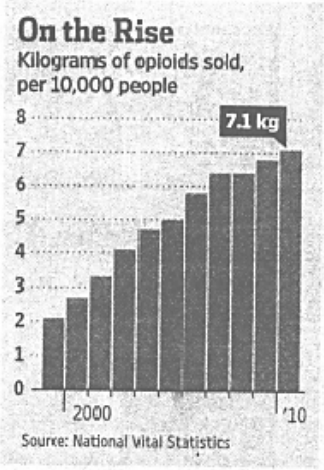
$5 for $10 of Food and Bevera

Now, Dr. Portenoy and other pain doctors who promoted the drugs say they erred by overstating the drugs' benefits and glossing over risks. "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did," Dr. Portenoy said in an interview with The Wall Street Journal. "We didn't know then what we know now."

A Pain-Drug Champion Has Second Thoughts



By Thomas Catan and Evan Perez

It has been his life's work. Now, Russell Portenoy appears to be having second thoughts.

Two decades ago, the prominent New York pain-care specialist drove a movement to help people with chronic pain. He campaigned to rehabilitate a group of painkillers derived from the opium poppy that were long shunned by physicians because of their addictiveness.

Dr. Portenoy's message was wildly successful. Today, drugs containing opioids like Vicodin, OxyContin and Percocet are among the most widely prescribed pharmaceuticals in America.

Opioids are also behind the country's deadliest drug epidemic. More than 16,500 people die of overdoses annually, more than all illegal drugs combined.

Now, Dr. Portenoy and other pain doctors who promoted the drugs say they erred by overstating the drugs' benefits and glossing over risks. "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did," Dr. Portenoy said in an interview with The Wall Street Journal. "We didn't know then what we know now."

Recent research suggests a significantly higher risk of addiction than previously thought, and questions whether opioids are effective against long-term chronic pain.

The change of heart among former champions of opioid use has happened quietly, largely beyond the notice of many doctors. New York psychiatrist Joseph Carmody said he was "shocked" after attending a recent lecture outlining the latest findings on opioid risk.

"It goes in the face of everything you've learned," he said. "You saw other doctors come around to it and saying, 'Oh my God, what are we doing?'"

Because doctors feared they were dangerous and addictive, opioids were long reserved mainly for cancer patients. But Dr. Portenoy argued that they could be also safely be taken for months or years by people suffering from chronic pain. Among the assertions he and his followers made in the 1990s: Less than 1% of opioid users became addicted, the drugs

Please turn to page A12

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

Enforcement is just as important as….

Prevention/Education

Treatment

Drug Education

or not

Teen Prescription Drug Misuse & Abuse

- **23%** report having abused RX medications at least once in their lifetime..
- **31%** believe "it's okay to use prescription drugs that were not prescribed to them to deal with an injury or pain, as long as they are not getting high."
- **22%** say their parents don't care as much if they are caught using RX drugs without a prescription, compared to getting caught with illegal drugs.

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14

Education

- Children/Teens
  - Information from the Internet or their peers
  - Following parents

GET INVOLVED

TEACH

DEA Web-based Resources

www.DEA.gov

Community Coalitions and Advocacy Groups

Community Anti-Drug Coalitions of America

WWW.cadca.org

Pharmaceuticals

Legend Drugs v. Controlled Substances

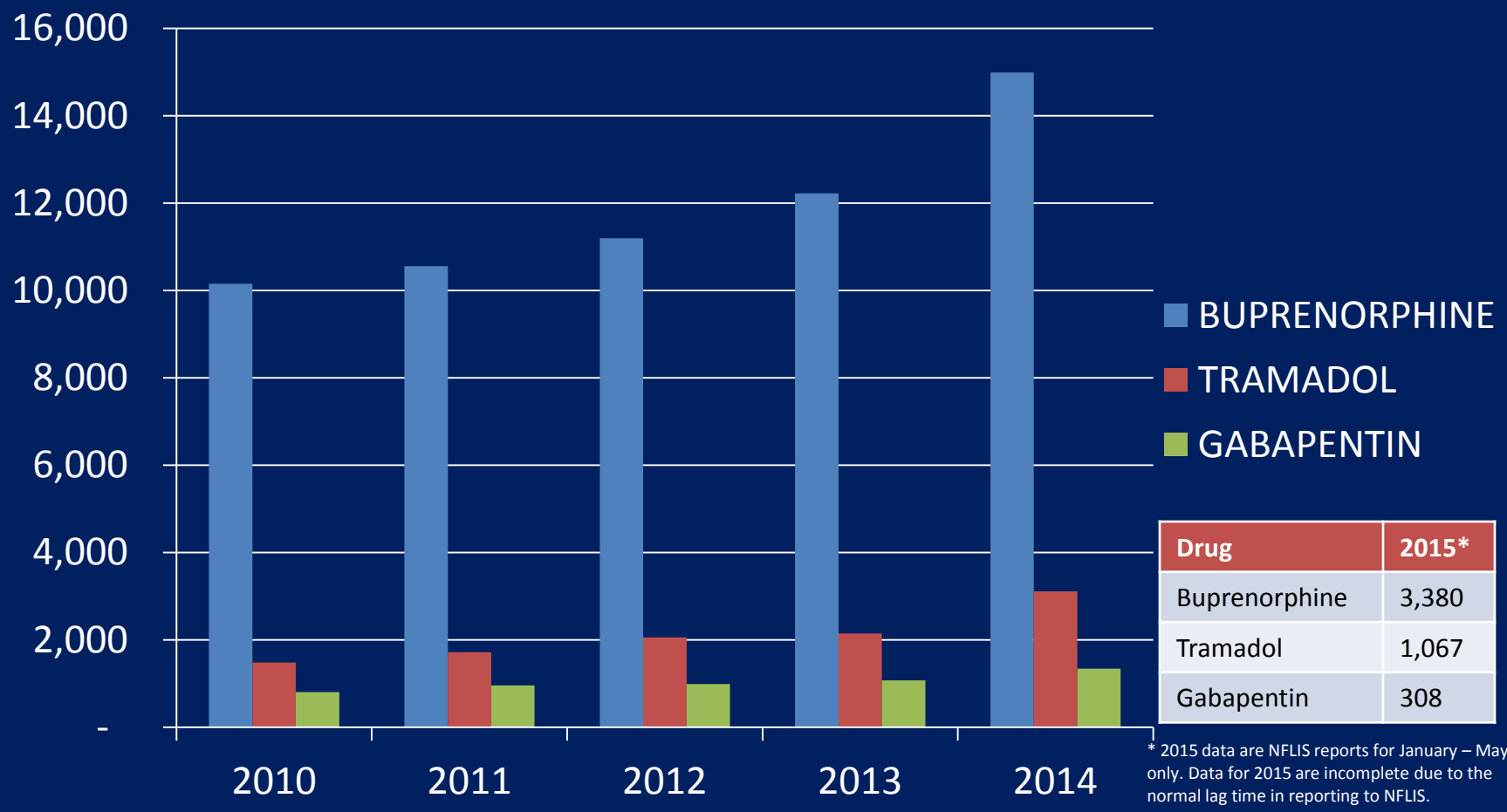
Legend Pharmaceuticals

Non-Controlled Substances

- Muscle Relaxant:
  - Cyclobenzaprine (Flexeril®)

NFLIS Selected Drug Reports, 2010 – 2015

Federal, State, and Local Labs



Drug	2015*
Buprenorphine	3,380
Tramadol	1,067
Gabapentin	308

* 2015 data are NFLIS reports for January – May, only. Data for 2015 are incomplete due to the normal lag time in reporting to NFLIS.

Gabapentin

- Structurally related to γ-amino-butyric acid (GABA), an inhibitor of neurotransmission
- Precise mechanism of action producing analgesic and anti-epiletic actions is unknown
- Approved for clinical and veterinary use as a prescription only medication
- Gabapentin is not named or defined under the CSA
- Anecdotal reports of misuse and abuse

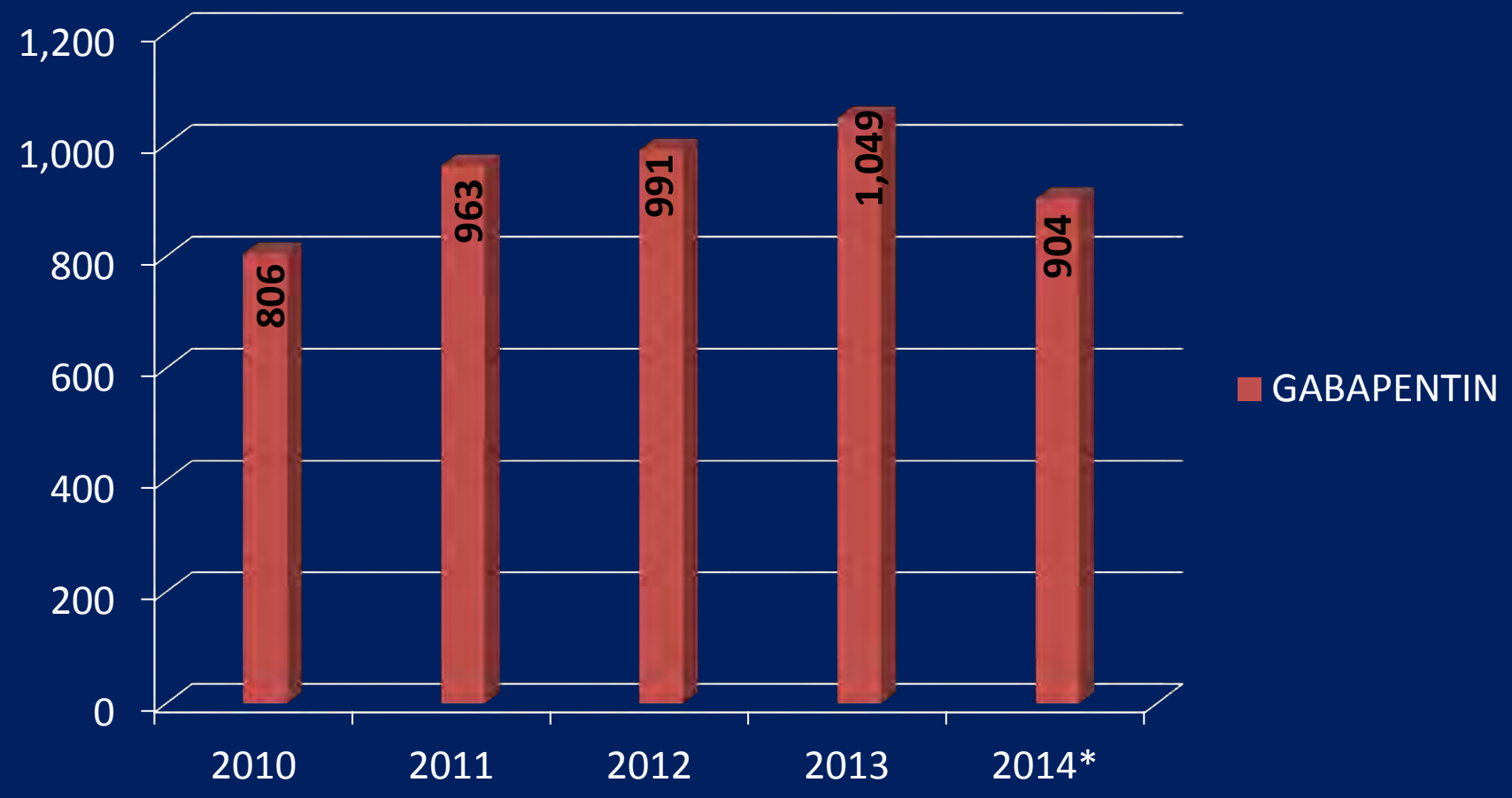
Gabapentin Therapeutic Use

- FDA-approved treatment with multiple off-label uses
  - Approved for the treatment of seizures and various pain states
  - Believed to have many advantages over other available medications and a first-line agent in the treatment of neuropathic pain
- Therapeutic category: anticonvulsant; analgesic
- Products: GABAPENTIN, GRALISE, HORIZANT, NEURONTIN
- Effective dose for the treatment of neuropathic pain varies but is similar to the doses effective for seizure treatment ranging from 300 mg/day to over 3600 mg/day

Gabapentin Abuse and Misuse

- Effects vary with user, dosage, past experience, psychiatric history, and expectations
- Abused alone or used as a cutting agent
- Range of experiences have been reported in relation to abuse: euphoria, sociability, marijuana-like high, zombie-like effects, sedation, and hallucinations
- Withdrawal symptoms reported:
  - Per Kruszewski et al.(2009), dependence and abuse involved toxic delirium, intense cravings, and prolonged post-withdrawal confusional state reminiscent of benzodiazepine withdrawal
- Two studies reporting concomitant abuse:
  - Used with cannabis, alcohol, SSRIs, LSD, amphetamine, and GHB (Psychother Psychosom, 2011)
  - Misuse to potentiate the 'high' obtain from methadone (Eur Addict Res, 2014)

NFLIS Drug Reports – Federal, State & Local Laboratories



*2014 data still being reported

Date Prepared/ Source: 01/28/15, NFLIS

U.S. Drug Enforcement Administration
Office of Diversion Control

Controlled Pharmaceuticals

Prescription Requirements

	Schedule II	Schedule III	Schedule IV	Schedule V
Written	Yes	Yes	Yes	Yes
Oral	Emergency Only*	Yes	Yes	Yes
Facsimile	Yes**	Yes	Yes	Yes
Refills	No	Yes#	Yes#	Yes#
Partial Fills	Yes***	Yes	Yes	Yes

* Must be reduced in writing, and followed by sign, hard copy of the prescription.
** A signed, hard copy of the prescription must be presented before the medication is dispensed.
*** 72 hour time limitation.
# With medical authorization, up to 5 in 6 months.

Marijuana

Question ?

Drug
or Not

Controlled
Substance
or Not

Harmful
or Not

"Medicinal"
or Not

Answer: It's a Drug, it's Controlled Federally, It's Harmful and the "Medicinal" value is not determined by science yet

Marijuana – Treatment ?

Alzheimer's Disease
Anorexia
AIDS
Arthritis
Cachexia
Cancer
Epilepsy
Glaucoma
HIV
Migraine
Multiple Sclerosis
Nausea
Pain

Wasting Syndrome
Neuropathic pain
Post-amputation pain
Neuropathy
Trigeminal neuralgia
rheumatoid arthritis
Nausea of cancer chemotherapy
AIDS wasting
Motion sickness
Menstrual cramps
Rheumatoid arthritis
Alzheimer's disease
Hypertension

Brain injury/stroke
Crohn's/colitis
Depression/mental illness
Eating disorders
Nail Patella Syndrome
Spinal cord injury
Tourette's syndrome
Pain
Fibromyalgia
Spasticity
Asthma

Regulatory Controls

- Marijuana is Federally controlled as a Schedule I controlled substance under the Controlled Substances Act (CSA).
- Marijuana has no approved use under the Food, Drug, and Cosmetic Act (FDCA).

1. Marijuana has a high potential for abuse and no accepted medical use in treatment in the United States
2. It lacks accepted safety for use under medical supervision
3. There is sound evidence that smoked marijuana is harmful

Research with Marijuana

Applicants submitting an application and protocol for legitimate research are approved by the Drug Enforcement Administration and the Food and Drug Administration

Substances are not approved for medical use through hysteria, rhetoric or public opinion

Substances are approved for medical use through sound science and analysis !

Currently there are over 265 researchers registered with DEA conducting scientific studies with marijuana, THC or its cannabinoids

Throughout the drug discovery process, pharmaceutical companies, academic institutions, research institutions, and other organizations publish their studies in scientific journals, books, and patents

According to established case law, marijuana has no ‘‘currently accepted medical use’’ because: The drug’s chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available

Schedule I Researchers

399 Total Schedule I Researcher Registrations

- **265 registered to perform bona fide research with marijuana, marijuana extracts, and THC**
- **194 of 265 registered for research with marijuana extracts and derivatives including CBD**
- **Clinical studies:**
  - **17 Researchers are conducting research with smoked marijuana**
  - **41 Researchers are conducting research with CBD**

Data from June 4, 2015

8-Factor Analysis

1. Actual or relative potential for abuse
2. Scientific evidence of pharmacological effects
3. State of the current scientific knowledge
4. History and current pattern of abuse
5. Scope duration and significance of abuse
6. What, if any, risk to public health
7. Psychic or physiological dependence liability
8. Whether an immediate precursor of a substance already controlled

HEMP

New Controlled Substances (Recently Scheduled)

- Analgesic:
  - Tramadol (Ultram®, Ultracet®)
  - Schedule IV in CSA as of August 18, 2014

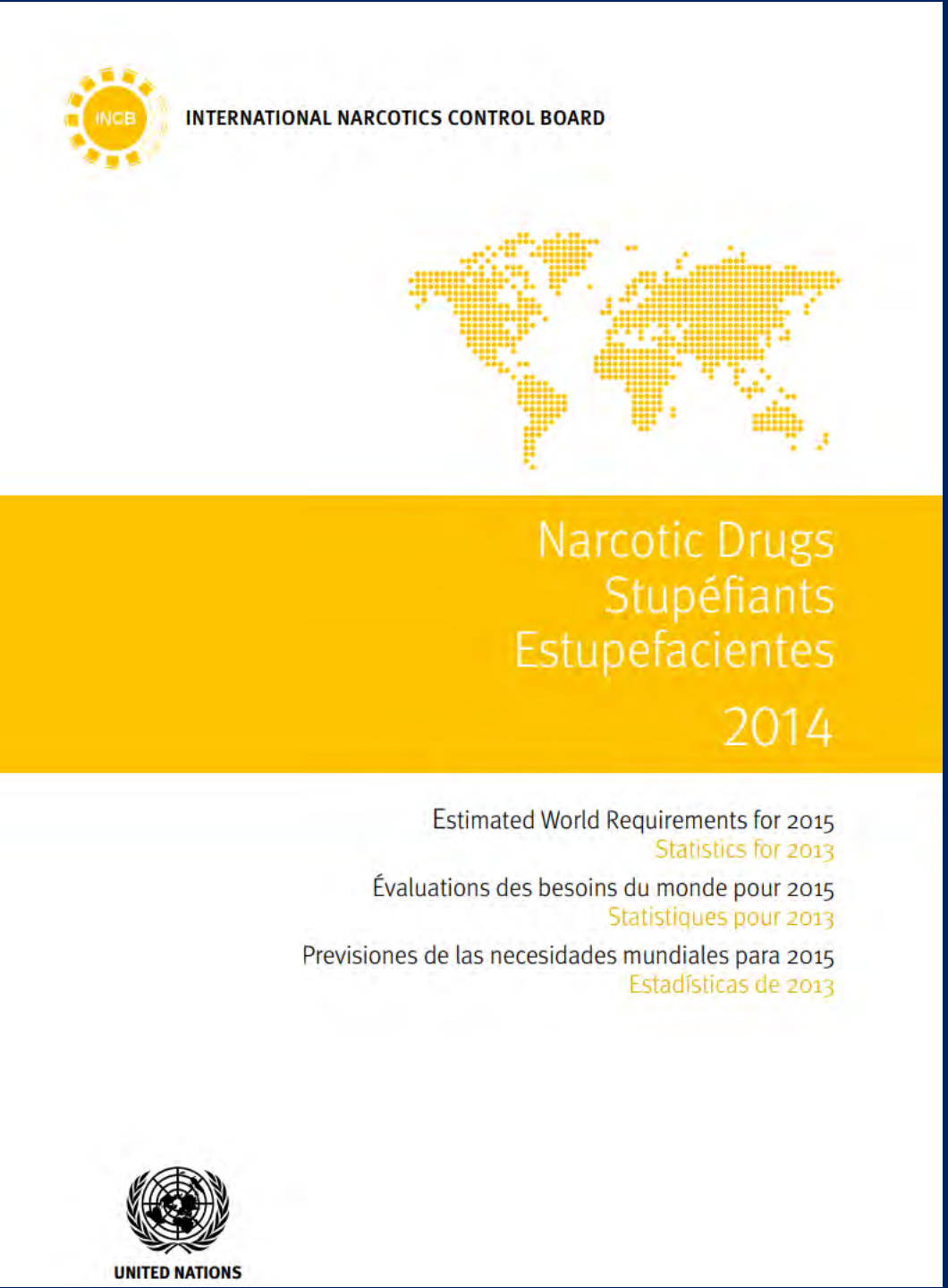
Opiates/Opioids

Papaver Somniferum

- Codeine
  - Hydrocodone

- Morphine
  - Hydromorphone

- Thebaine
  - Oxycodone
  - Hydrocodone



- INCB Annual Report Narcotic Drugs
- Estimated World Requirements for 2015
- Statistics for 2013

International Narcotics Control Board: Comments on Reported Statistics on Narcotic Drugs

The United States was the country with the highest consumption of the following drugs:

2013	DRUG	2012
99%	Hydrocodone	99%
78%	Oxycodone	82%
57%	Morphine	57%
51%	Hydromorphone	42%
51%	Methadone	49%
31.5%	Fentanyl	37%

Date Prepared/ Source: Prepared 7/16/15, INCB data

Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen

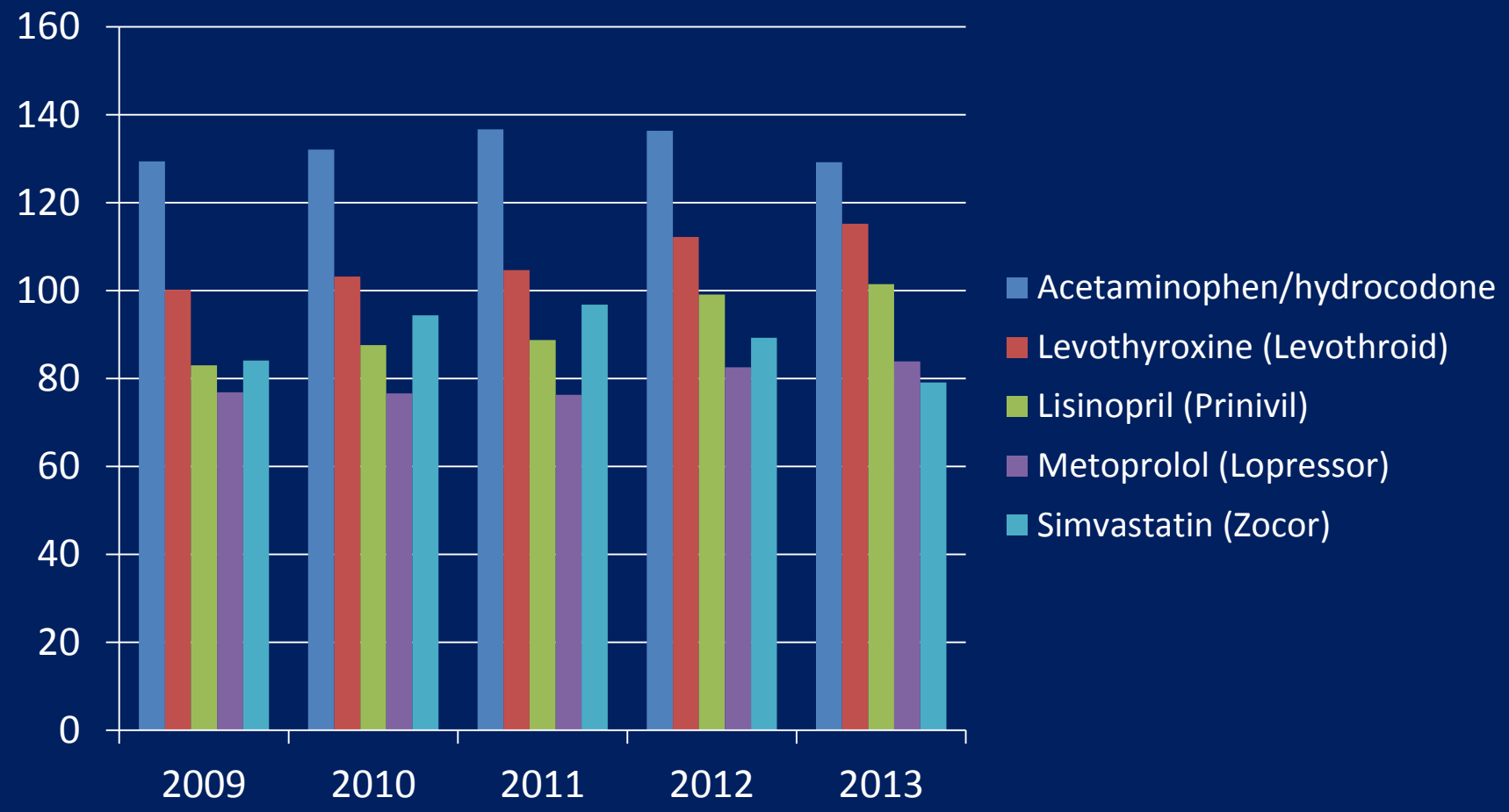
Estimated World Requirements of Narcotic Drugs 2015

Hydrocodone Top 10 List

➢ 10 Guatemala	10 kilograms
➢ 09 Mexico	10 kilograms
➢ 08 Vietnam	20 kilograms
➢ 07 China	20 kilograms
➢ 06 Denmark	25 kilograms
➢ 05 Columbia	50 kilograms
➢ 04 Syrian Republic	50 kilograms
➢ 03 Germany	60 kilograms
➢ 02 Canada	100 kilograms
➢ 01 United States	79,700 kilograms 99.5%

SOURCE: UN International Narcotics Control Board website. Estimated World Requirements of Narcotic Drugs in grams for 2015 http://www.incb.org . Accessed July 15, 2015

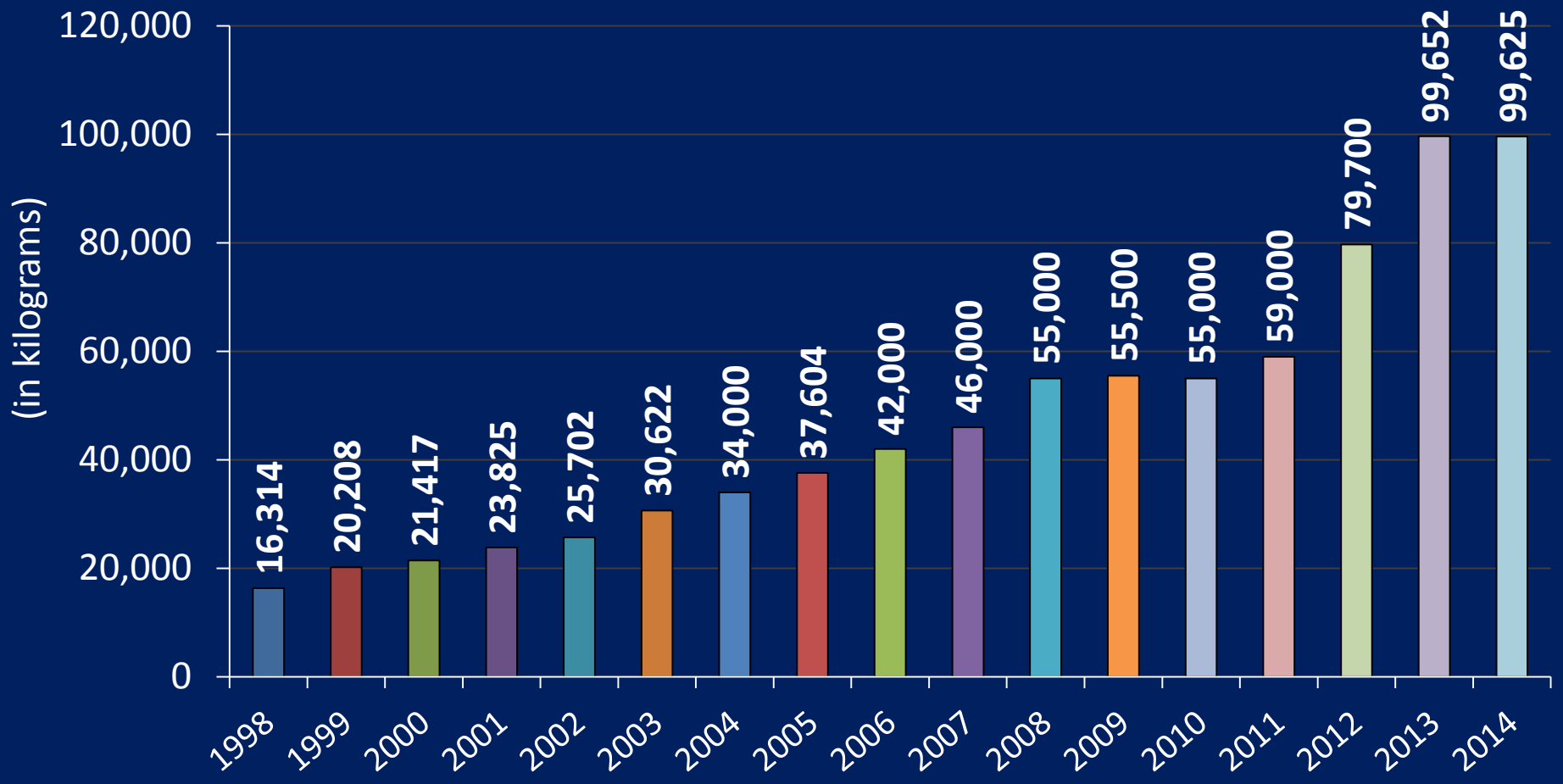
Top Five Dispensed Prescriptions CY2009 - 2013
IMS National Prescription Audit
(In Millions of Prescriptions)



Date Prepared/ Source: 07/07/2015, IMS

U.S. Drug Enforcement Administration
Office of Diversion Control

Hydrocodone
Aggregate Production Quota History



Date Prepared/ Source: 04/14/2014, ODQ
Revised APQ

U.S. Drug Enforcement Administration
Office of Diversion Control

State Ranking* - Hydrocodone

January – December 2013

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	982,753,220	12	NC	220,543,770	23	AR	125,187,020	34	NJ	54,941,330	45	NH	14,409,370
2	TX	812,141,952	13	NY	217,125,500	24	MS	123,188,700	35	ID	52,435,880	46	WY	13,179,270
3	TN	418,088,514	14	MO	207,872,984	25	OR	113,906,944	36	MD	49,448,687	47	AK	11,796,700
4	MI	412,915,381	15	KY	206,344,080	26	WI	110,312,770	37	NM	41,193,590	48	ND	10,835,260
5	FL	360,582,430	16	OK	188,704,600	27	KS	95,057,760	38	NE	38,116,235	49	DE	8,551,270
6	IL	316,993,320	17	LA	169,317,429	28	WV	84,004,800	39	CT	32,965,210	50	VT	7,360,560
7	IN	278,352,426	18	SC	158,208,080	29	CO	[illegible]	40	ME	27,390,940	51	DC	2,335,710
8	OH	277,099,286	19	WA	146,735,785	30	IA	70,917,830	41	MT	26,673,510	52	PR	1,896,180
9	GA	256,397,200	20	VA	143,641,503	31	MN	68,784,400	42	HI	19,188,150	53	VI	435,730
10	AL	251,071,776	21	AZ	142,370,620	32	UT	61,701,660	43	RI	18,408,190	54	GU	227,600
11	PA	236,295,746	22	NV	132,819,940	33	MA	56,870,370	44	SD	16,805,590	55	AS	0

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control,
Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

State Ranking* - Hydrocodone

January – December 2014

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	930,157,136	12	MO	205,753,360	23	MS	111,484,970	34	ID	51,020,610	45	NH	13,170,780
2	TX	725,293,840	13	NC	205,244,440	24	OR	107,449,314	35	NJ	48,919,330	46	WY	12,684,950
3	MI	404,191,120	14	KY	196,486,491	25	NV	105,594,720	36	MD	44,768,602	47	AK	11,326,380
4	TN	361,189,101	15	NY	187,989,690	26	WI	105,235,970	37	NM	38,505,610	48	ND	10,796,298
5	FL	347,504,235	16	OK	171,904,210	27	KS	88,513,490	38	NE	37,346,710	49	DE	7,833,910
6	IL	305,340,210	17	LA	155,956,326	28	WV	77,999,160	39	CT	29,460,870	50	VT	6,631,160
7	OH	259,345,043	18	SC	147,235,020	29	CO	[illegible]	40	ME	25,495,320	51	DC	1,962,610
8	GA	240,012,599	19	WA	142,840,470	30	IA	69,600,890	41	MT	24,770,970	52	PR	856,970
9	IN	236,137,270	20	AZ	135,697,040	31	MN	64,931,320	42	HI	17,986,700	53	VI	342,480
10	AL	229,162,364	21	VA	131,161,939	32	UT	58,709,040	43	SD	16,701,470	54	GU	167,300
11	PA	215,899,798	22	AR	122,272,100	33	MA	51,052,090	44	RI	15,801,520	55	AS	0

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

Hydrocodone Combinations

Currently, the CSA defines hydrocodone substance as Schedule II, while its combination products as Schedule III.

On October 6, 2014, all hydrocodone products were placed in schedule II.

(see 79FR49661 dated August 22, 2014)

Schedule II

- The drug or other substance has a high potential for abuse
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions
- Abuse of the drug or other substance may lead to severe psychological or physical dependence

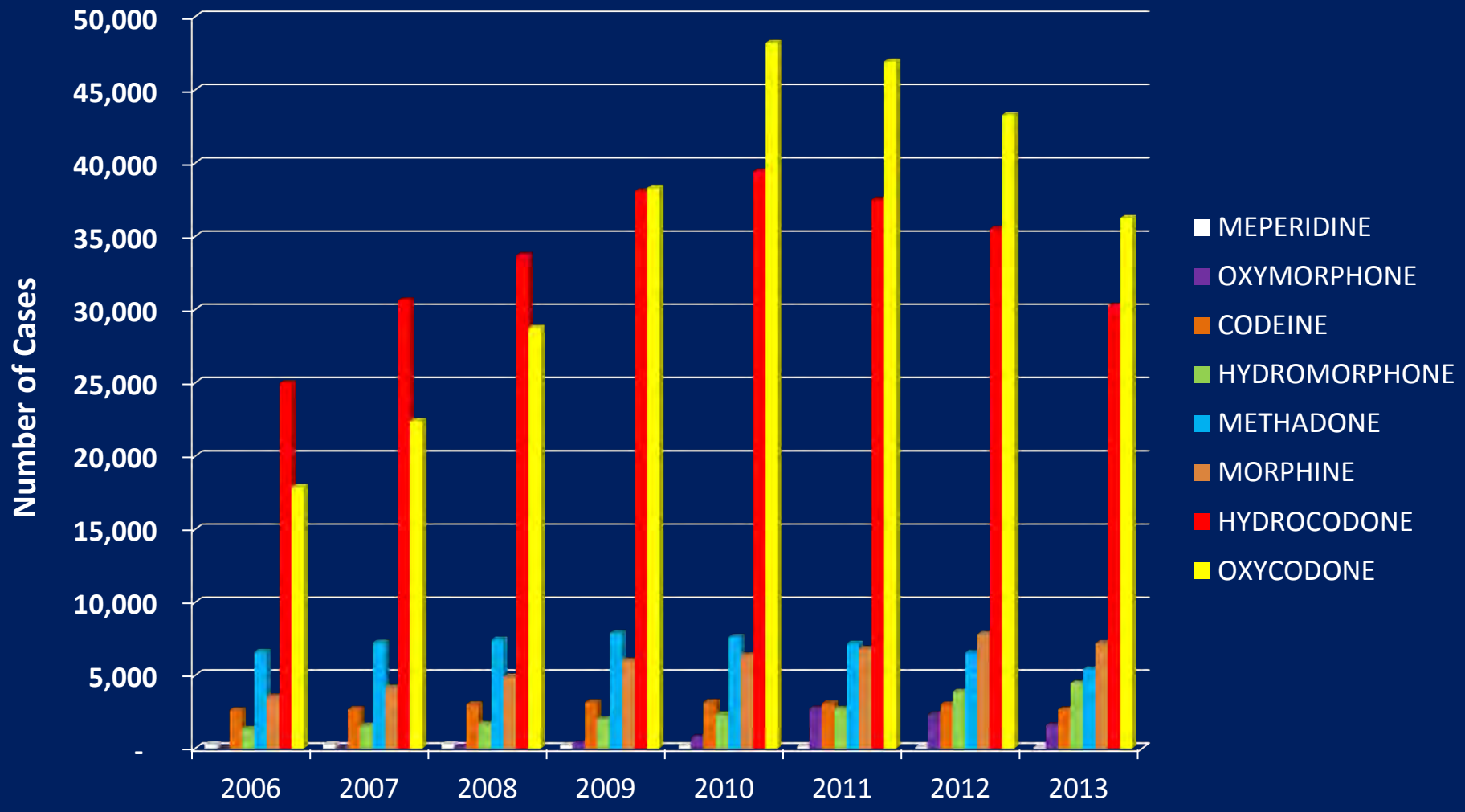
Schedule III

- The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I or II
- The drug or other substance has a currently accepted medical use in treatment in the United States
- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence

21 USC 812(b)(2),(3)

NFLIS Cases

(Federal, State, and Local)



Approval of Single Entity Extended Release Hydrocodone

OXYCODONE

U.S. Drug Enforcement Administration
Office of Diversion Control

State Ranking* - Oxycodone
January – December 2013

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	PA	297,341,980	12	MD	128,027,280	23	CT	72,412,470	34	KS	38,925,890	45	MT	15,404,320
2	FL	291,383,620	13	VA	124,771,088	24	MN	72,203,730	35	NM	36,568,830	46	PR	11,507,780
3	CA	281,630,294	14	GA	122,888,860	25	AL	66,004,480	36	MS	30,021,050	47	AK	10,382,220
4	NY	268,408,239	15	MO	102,988,470	26	TX	[illegible]	37	ME	29,744,160	48	VT	10,160,680
5	OH	254,919,240	16	WI	97,740,170	27	OK	60,056,840	38	NH	29,056,310	49	WY	9,042,220
6	NC	222,945,670	17	OR	95,608,810	28	NV	58,577,300	39	DE	26,926,890	50	DC	6,897,540
7	NJ	177,267,830	18	IN	92,666,390	29	LA	54,777,500	40	IA	24,029,580	51	ND	6,645,960
8	AZ	163,531,150	19	CO	89,415,210	30	UT	52,478,120	41	ID	18,623,640	52	SD	6,596,300
9	TN	155,131,080	20	MI	86,251,570	31	WV	44,705,160	42	RI	17,868,720	53	GU	411,600
10	MA	137,178,760	21	SC	79,444,900	32	IL	44,362,470	43	HI	16,361,480	54	VI	291,000
11	WA	129,721,790	22	KY	74,443,010	33	AR	39,813,350	44	NE	15,564,300	55	AS	0

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

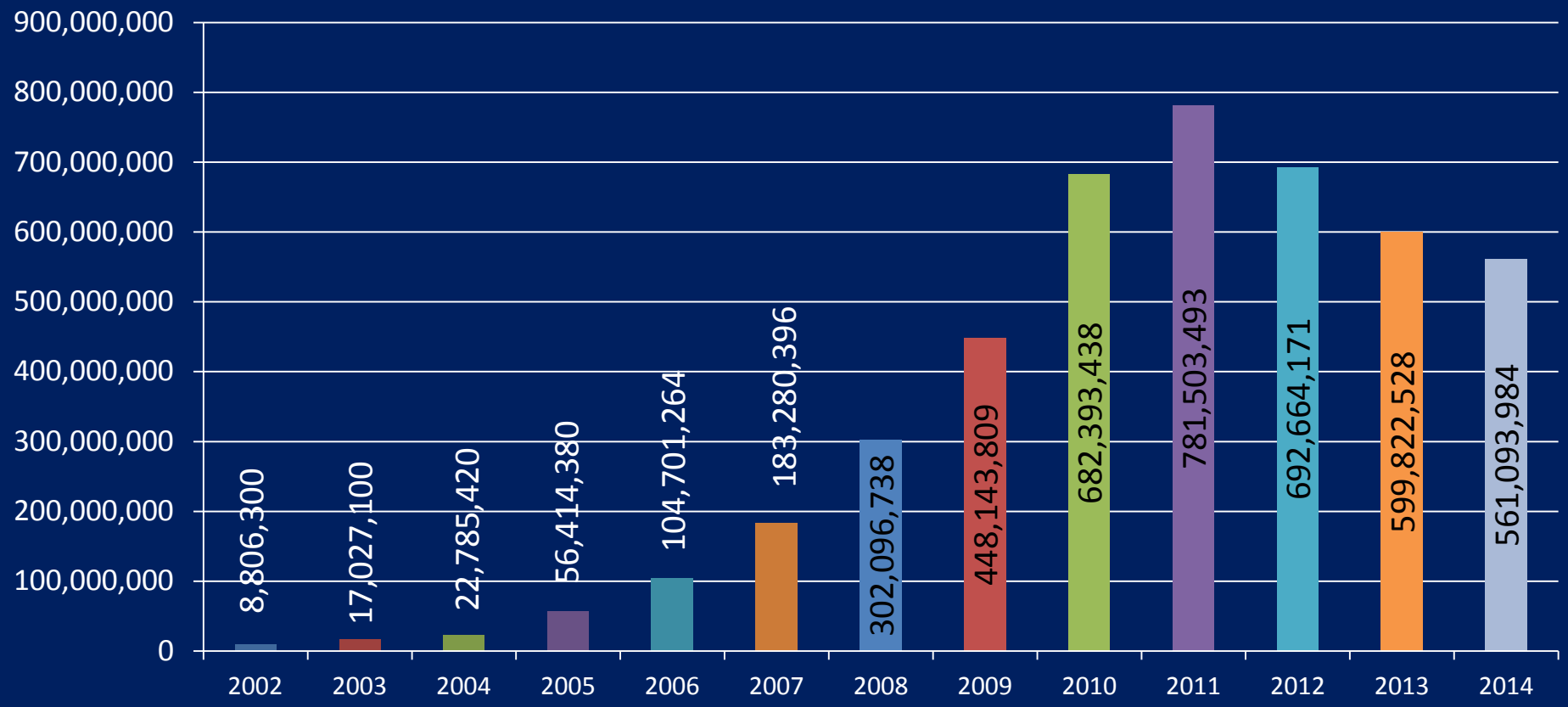
State Ranking* - Oxycodone
January – December 2014

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	PA	301,403,510	12	GA	130,041,000	23	MN	75,966,505	34	KS	41,458,610	45	MT	15,198,940
2	FL	293,166,306	13	MD	128,463,560	24	AL	74,049,020	35	NM	38,229,260	46	PR	11,109,960
3	CA	282,864,930	14	VA	128,447,960	25	CT	71,673,620	36	MS	33,211,550	47	AK	10,621,620
4	NY	273,616,600	15	MO	107,340,260	26	TX	66,958,410	37	NH	29,770,120	48	VT	10,029,200
5	OH	251,677,020	16	WI	99,920,140	27	O		38	ME	29,308,800	49	WY	9,575,680
6	NC	229,661,280	17	OR	96,325,445	28	LA	60,019,620	39	DE	25,961,260	50	SD	7,997,860
7	NJ	179,602,220	18	MI	92,417,910	29	NV	56,213,900	40	IA	24,590,530	51	DC	6,874,460
8	AZ	169,872,130	19	CO	89,303,420	30	UT	55,299,360	41	ID	20,023,140	52	ND	6,866,180
9	TN	162,087,440	20	IN	88,906,690	31	IL	47,259,460	42	RI	17,140,320	53	GU	386,660
10	WA	134,769,529	21	SC	84,522,920	32	WV	45,073,820	43	NE	16,331,980	54	VI	261,400
11	MA	132,636,690	22	KY	77,443,880	33	AR	43,238,500	44	HI	15,678,800	55	AS	0

**** Business Activity – Retail Pharmacies***

Source: Drug Enforcement Administration, Office of Diversion Control,
Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

Oxycodone 30mg Sales to Pharmacies and Practitioners
January 1, 2002 through December 31, 2014



Date Prepared/ Source: ARCOS, 3/26/2015

U.S. Drug Enforcement Administration
Office of Diversion Control

State Ranking* - Oxymorphone January – December 2013

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	NC	8,621,821	12	MI	2,020,472	23	NV	1,335,360	34	NM	435,669	45	MN	159,783
2	TN	8,145,510	13	AL	1,987,229	24	WA	1,333,688	35	AR	428,906	46	WY	129,511
3	CA	6,511,552	14	AZ	1,951,458	25	KY	1,219,666	36	DE	385,550	47	MT	116,721
4	PA	5,856,971	15	MD	1,921,612	26	[illegible]	[illegible]	37	ME	372,129	48	VT	97,620
5	FL	5,637,595	16	SC	1,843,598	27	OR	1,025,032	38	ID	363,429	49	AK	85,302
6	NY	5,476,047	17	IL	1,757,351	28	WV	973,615	39	NH	305,802	50	DC	43,873
7	OH	4,131,582	18	OK	1,745,516	29	WI	971,452	40	IA	296,276	51	ND	43,632
8	TX	3,837,483	19	GA	1,735,588	30	MA	900,033	41	NE	288,980	52	PR	4,520
9	VA	2,852,122	20	MO	1,695,523	31	MS	871,950	42	HI	254,500	53	VI	1,766
10	IN	2,412,242	21	LA	1,629,911	32	KS	861,194	43	SD	192,465	54	AS	0
11	NJ	2,102,229	22	CO	1,627,981	33	UT	810,857	44	RI	170,867	55	GU	0

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

State Ranking* - Oxymorphone January – December 2014

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	TN	9,403,120	12	NJ	2,212,360	23	CO	1,437,060	34	AR	537,120	45	MT	143,460
2	NC	9,377,580	13	MD	2,194,100	24	WA	1,343,120	35	IA	533,920	46	RI	141,060
3	PA	6,516,520	14	IN	2,192,000	25	KY	[illegible]	36	ME	471,100	47	WY	128,700
4	CA	6,272,060	15	AZ	2,146,640	26	CT	1,144,060	37	DE	455,560	48	VT	106,260
5	FL	6,202,740	16	SC	2,081,360	27	WI	1,054,580	38	NM	434,900	49	AK	75,860
6	NY	5,610,520	17	GA	1,951,320	28	MS	1,028,300	39	ID	395,700	50	DC	54,460
7	TX	3,899,540	18	OK	1,930,960	29	UT	971,600	40	NH	362,040	51	ND	53,800
8	OH	3,656,240	19	LA	1,914,300	30	WV	970,860	41	NE	320,660	52	PR	1,880
9	VA	3,012,540	20	MO	1,743,580	31	OR	891,280	42	HI	225,200	53	VI	1,680
10	MI	2,933,320	21	IL	1,721,860	32	KS	865,340	43	SD	207,140	54	AS	0
11	AL	2,256,380	22	NV	1,494,460	33	MA	750,480	44	MN	163,000	55	GU	0

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

State Ranking* - Hydromorphone January – December 2013

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	FL	42,112,076	12	OH	8,734,282	23	IN	4,818,262	34	NH	2,131,164	45	ND	807,848
2	CA	41,943,654	13	MA	8,436,554	24	SC	4,689,324	35	DE	2,033,006	46	RI	804,084
3	NY	18,541,210	14	IL	8,364,938	25	OK	3,253,084	36	UT	1,965,778	47	AK	741,012
4	TX	16,018,946	15	CO	7,010,882	26	IA	3,170,384	37	MT	1,810,554	48	HI	664,172
5	VA	12,347,728	16	CT	6,592,026	27	AL	3,131,472	38	ID	1,642,828	49	WY	631,400
6	PA	11,666,044	17	GA	6,464,995	28	WI	3,104,648	39	VT	1,629,024	50	DC	523,100
7	WA	10,542,090	18	AZ	6,359,788	29	N[illegible]	[illegible]	40	ME	1,537,142	51	SD	476,232
8	MI	9,266,400	19	MO	6,340,348	30	AR	2,804,078	41	MS	1,482,408	52	PR	40,600
9	NJ	9,146,008	20	OR	6,339,056	31	KS	2,797,794	42	NM	1,396,384	53	GU	35,200
10	MD	9,003,516	21	MN	5,264,954	32	LA	2,733,498	43	WV	1,377,282	54	VI	13,000
11	NC	8,823,974	22	TN	4,870,220	33	KY	2,235,398	44	NE	984,210	55	AS	0

**** Business Activity – Retail Pharmacies***

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

State Ranking* - Hydromorphone January – December 2014

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	40,190,940	12	IL	8,265,754	23	TN	4,836,992	34	NH	2,246,692	45	AK	824,320
2	FL	36,610,156	13	MA	8,134,144	24	IN	4,592,854	35	DE	2,216,706	46	ND	806,478
3	NY	17,879,384	14	OH	7,960,980	25	NV	3,277,698	36	KY	2,210,446	47	RI	733,942
4	TX	16,240,636	15	CT	6,730,204	26	OK	3,223,840	37	ID	1,778,514	48	HI	662,930
5	VA	12,212,874	16	CO	6,654,312	27	W		38	ME	1,721,238	49	WY	645,300
6	PA	11,826,576	17	GA	6,612,626	28	AL	3,167,630	39	MT	1,713,900	50	SD	577,170
7	WA	11,511,540	18	AZ	6,607,600	29	IA	3,142,920	40	NM	1,598,212	51	DC	529,374
8	NJ	9,586,168	19	OR	6,344,510	30	KS	2,917,036	41	VT	1,591,478	52	PR	39,800
9	MI	9,370,862	20	MO	6,153,892	31	AR	2,890,220	42	MS	1,535,238	53	GU	32,300
10	NC	9,225,228	21	MN	5,715,300	32	LA	2,690,700	43	WV	1,316,438	54	VI	24,000
11	MD	9,081,758	22	SC	4,862,110	33	UT	2,327,924	44	NE	1,074,994	55	AS	0

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

State Ranking* - Fentanyl
January – December 2013

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	7,411,696	12	TN	2,025,598	23	OR	1,204,275	34	AR	692,994	45	ND	237,800
2	PA	4,684,660	13	IN	1,882,515	24	CO	1,199,774	35	WV	513,661	46	RI	190,247
3	TX	4,633,573	14	MO	1,786,168	25	SC	1,090,611	36	NV	503,268	47	VT	174,455
4	FL	4,343,445	15	VA	1,754,237	26	KY	1,038,904	37	NE	473,690	48	WY	157,505
5	NY	[illegible]	16	WI	1,634,730	27	CT	1,030,739	38	ID	473,598	49	HI	152,267
6	OH	3,131,684	17	MD	1,464,746	28	MN	1,027,364	39	ME	434,349	50	AK	147,598
7	MI	2,915,032	18	WA	1,455,991	29	KS	920,642	40	NH	404,846	51	PR	101,905
8	NC	2,810,522	19	AZ	1,439,921	30	LA	892,114	41	NM	393,105	52	DC	51,510
9	IL	2,732,791	20	OK	1,406,890	31	IA	820,604	42	SD	365,578	53	GU	5,305
10	NJ	2,574,164	21	AL	1,393,861	32	MS	798,192	43	DE	332,557	54	VI	4,560
11	GA	2,115,961	22	MA	1,340,244	33	UT	724,782	44	MT	312,705	55	AS	0

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control,
Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 01/29/2015

State Ranking* - Fentanyl
January – September 2014

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	5,310,925	12	TN	1,521,276	23	OR	896,383	34	AR	531,300	45	ND	173,665
2	TX	3,391,973	13	MO	1,361,980	24	CO	860,682	35	WV	381,420	46	VT	131,215
3	PA	3,327,884	14	IN	1,321,624	25	SC	786,790	36	NV	369,922	47	RI	127,539
4	FL	3,311,284	15	VA	1,263,105	26	MN	745,276	37	ID	356,800	48	AK	113,473
5	NY	[illegible]	16	WI	1,225,992	27	CT	727,313	38	NE	338,903	49	HI	113,296
6	MI	2,149,694	17	WA	1,092,690	28	KY	727,000	39	ME	310,478	50	WY	107,095
7	OH	2,074,278	18	AZ	1,089,777	29	KS	698,294	40	NH	299,755	51	PR	79,865
8	NC	2,027,521	19	OK	1,070,616	30	LA	679,963	41	NM	297,248	52	DC	36,315
9	IL	1,975,241	20	AL	1,054,468	31	IA	602,667	42	SD	270,754	53	VI	3,750
10	NJ	1,782,413	21	MD	1,050,911	32	MS	597,258	43	DE	248,973	54	GU	3,560
11	GA	1,556,478	22	MA	931,742	33	UT	552,939	44	MT	223,200	55	AS	0

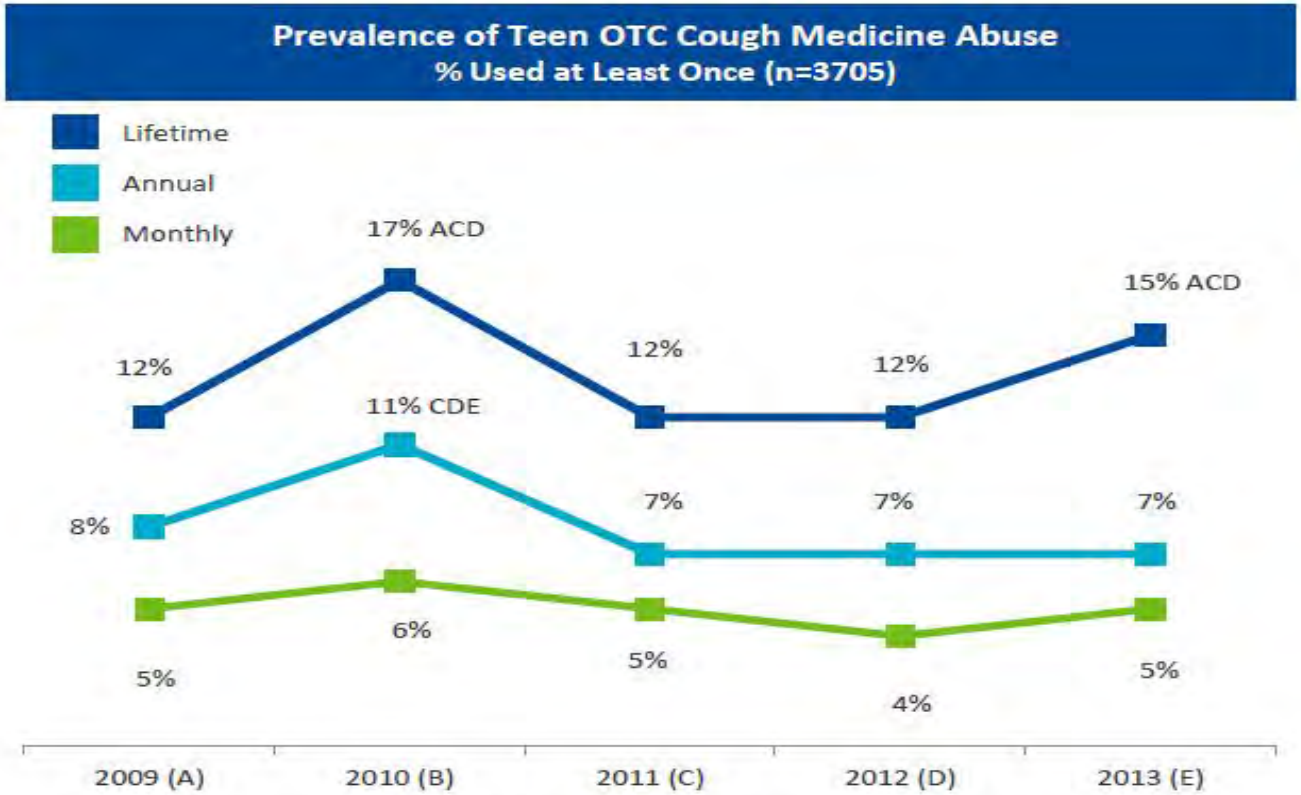
**** Business Activity – Retail Pharmacies***

Source: Drug Enforcement Administration, Office of Diversion Control,
Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 01/29/2015

Dextromethorphan (DXM)

- Cough suppressant in over 125 OTC medications (e.g. Robitussin and Coricidin)
- Bulk form on the Internet
- At high doses, has Ketamine - and PCP-like effects
- Produces physical and psychological dependence
- Deaths associated with DXM abuse

Teen OTC Cough Medicine Misuse and Abuse



"(In your lifetime/in the past 12 months/in the past 30 days), how many times have you taken a non-prescription cough or cold medicine to get high?"
A-E indicates a significant difference at the 95% confidence level.

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14

U.S. Drug Enforcement Administration
Office of Diversion Control

Cough Syrup Cocktails

- "Syrup and Soda"
- "Seven and Syrup"
- "Purple Drank"

Opioids v. Heroin

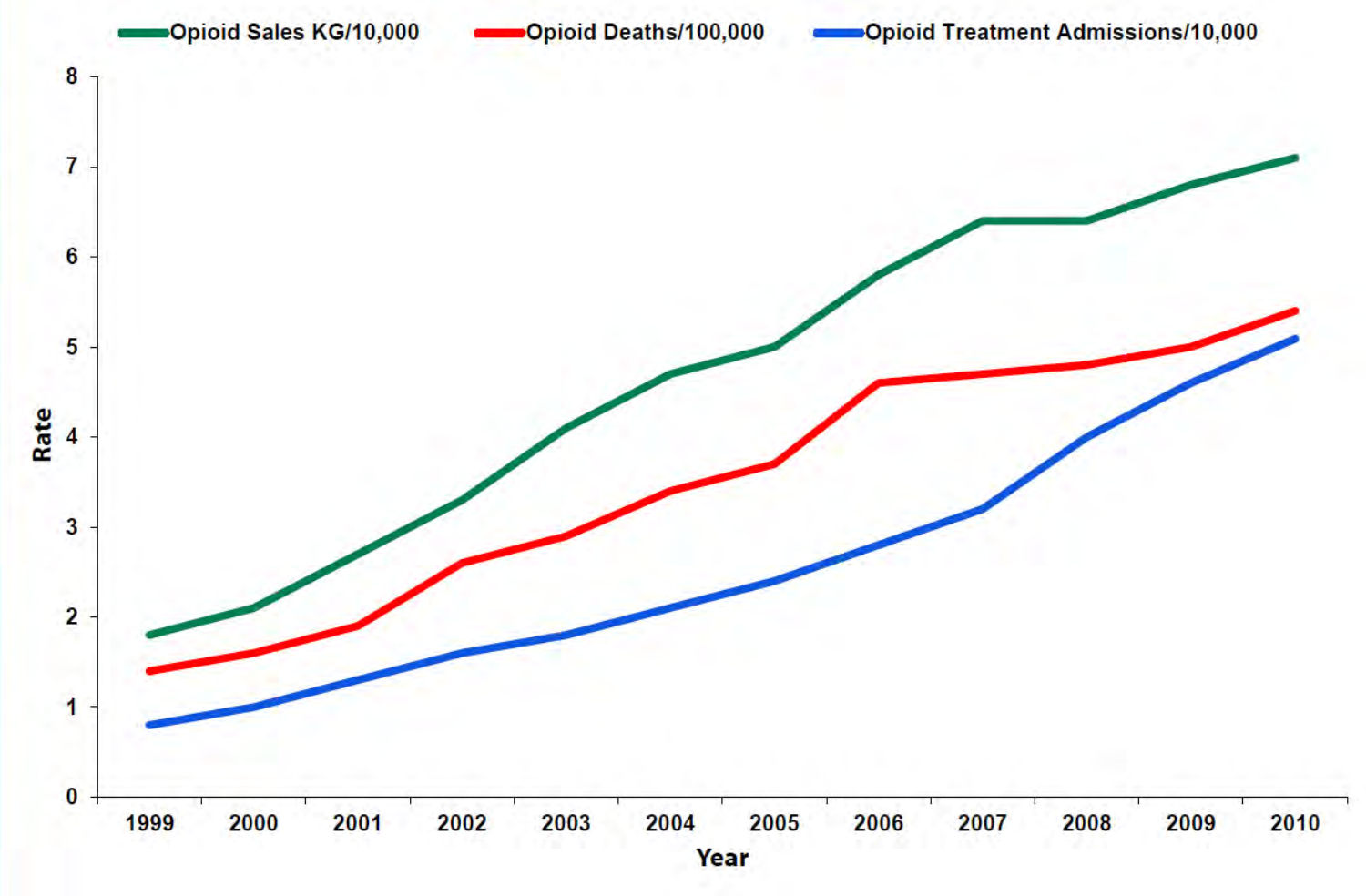
Papaver Somniferum

Codeine

Morphine

Thebaine

U.S. Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, 1999-2010



Source: National Vital Statistics System (NVSS), DEA's Automation of Reports and Consolidated Orders System, SAMHSA's Treatment Episode Data Set

Circle of Addiction & the Next Generation

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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

Community Impact?

Heroin trafficking organizations relocating to areas where prescription drug abuse is on the rise

Heroin traffickers pave the way for increasing crime and violence

Law enforcement and prosecutors eventually fighting the problem on two fronts (prescription opiate diversion and heroin distribution) further depleting resources

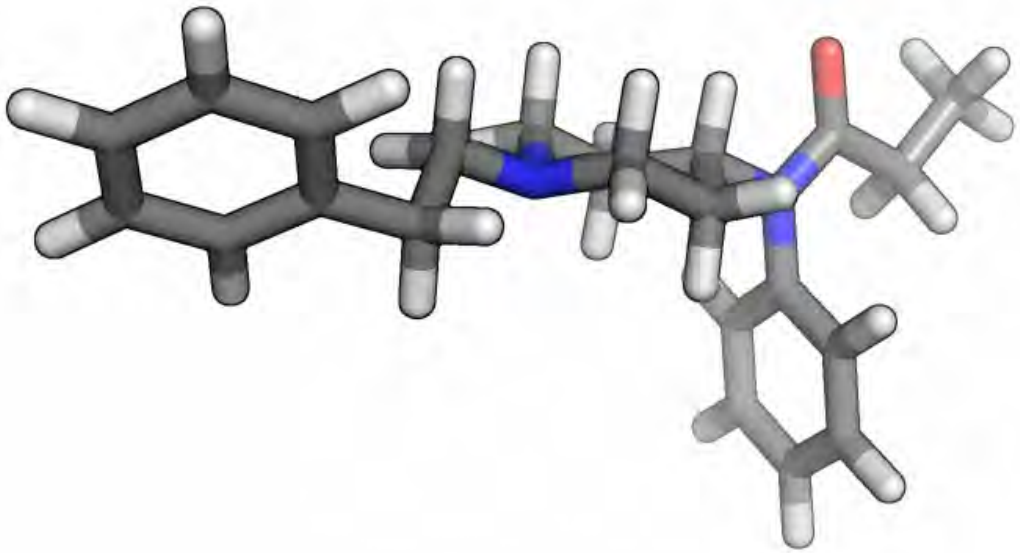
Communities suffer

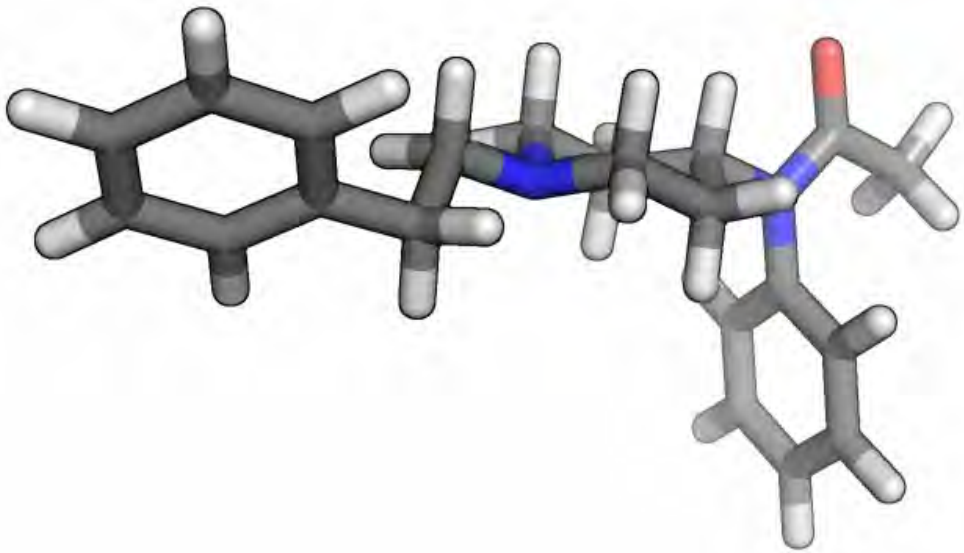
HEROIN CASES and EXHIBITS
National Forensic Laboratory Information System

Year	# Exhibits	# Cases
2004	69,467	60,851
2005	73,569	64,471
2006	83,945	72,351
2007	82,408	69,850
2008	94,229	79,366
2009	107,272	87,249
2010	104,676	84,170
2011	109,049	86,513
2012	127,568	101,512
2013	142,433	114,1485

Clandestinely Produced Synthetic Opioids

What is a synthetic designer drug and why is law enforcement struggling to keep up with these compounds?



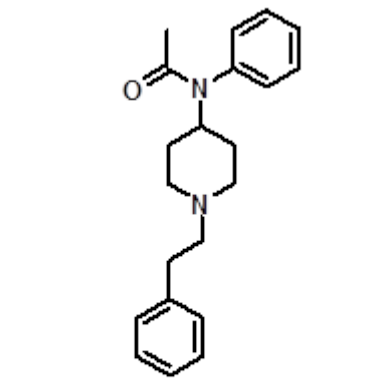


Acetylfentanyl

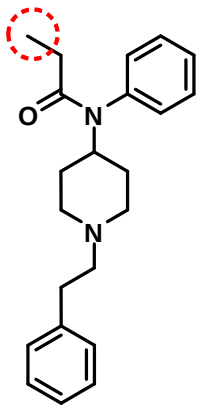
- Chemically-modified derivative of the powerful prescription painkiller Fentanyl
- is reportedly “50 times more potent than heroin and 100 times stronger than morphine
- May 2013 - 10,000 pills of “Desmethyl Fentanyl” intercepted in Montreal— hidden inside a microwave oven and a toaster destined for Colorado
  - Additional 1,500 kilograms of various raw materials; enough to make an additional 3 million pills seized

Acetylfentanyl

- RI Medical Examiner's Office regarding twelve **(12)** overdose deaths in March/April 2013
- Preliminary Lab/Toxicology reports attribute OD deaths to Acetylfentanyl
  - 5 of 12 overdose deaths occurred in Woonsocket, RI
  - May 16, 2013 two individuals arrested in Woonsocket, RI in possession of 28 grams of suspected Acetyl fentanyl
    - Attempts will be made to confirm link to OD deaths



Acetyl fentanyl
potential controlled substance analogue of fentanyl



Fentanyl
Schedule II

Drug Enforcement Administration
Office of Diversion Control
Drug & Chemical Evaluation Section

Acetylfentanyl
(*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide)

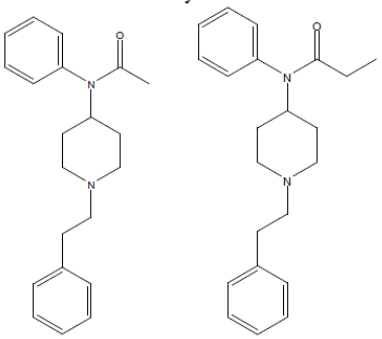
December 2013
DEA/OD/ODE

Introduction:

Acetylfentanyl, similar to the Schedule II opioid fentanyl, is a potent opioid analgesic. Recently, it has been linked to a number of overdose deaths in the northeastern part of the U.S. Acetylfentanyl is not a part of most illicit drug screens and remained undetected in many of these cases. Upon being identified in one death, secondary analyses were performed to confirm the presence of acetylfentanyl in numerous jurisdictions.

Chemistry:

The chemical structure of acetylfentanyl and the Schedule II substance fentanyl are shown below.



Acetylfentanyl Fentanyl

Acetylfentanyl and fentanyl are both synthetic opioids and have similar structures. With one less methyl group attached to the amide group, acetylfentanyl is the N-acetyl version of fentanyl.

Pharmacology:

Acetylfentanyl (EC_{50} = 676 nM), similar to morphine (EC_{50} = 23.6 nM), has been shown to bind to μ-opioid receptors in rat cerebrum membrane preparations. Acetylfentanyl, similar to morphine, has been shown to inhibit the twitch response in electrically stimulated vas deferens preparation. A pharmacology study using acetic acid writhing test showed that acetylfentanyl produces analgesic response in mice 15.7-fold more potent than that of morphine. Potency of acetylfentanyl was about 3-fold less than that of fentanyl in this assay. The ED_{50} (the dose at which 50% of test animals had met the criterion for analgesic response) dose for acetylfentanyl, fentanyl and morphine were 0.021, 0.0061, and 0.33 mg/kg, respectively. Similarly, in another study using tail flick and phenylquinone writhing tests, acetylfentanyl produced analgesic response in mice. Acetylfentanyl has been shown to completely suppress the signs of withdrawal in morphine-dependent monkeys.

Besides analgesia, fentanyl-like substances, similar to other opioid analgesics, produce a variety of pharmacological effects including alteration in mood, euphoria, drowsiness, respiratory depression, suppression of cough reflex, constriction of pupils (miosis), and impaired gastrointestinal motility. Clinical studies evaluating pharmacological effects of acetylfentanyl in humans have not been reported in the scientific literature.

In acute toxicity studies in mice, the LD_{50} (the dose causing death of 50% of test animals) of acetylfentanyl and fentanyl are 9.3 mg/kg and 62 mg/kg, respectively. Significant bleeding in the small intestines of mice was observed in acetylfentanyl-administered mice.

Licit Uses:

There are no published studies as to the safety of acetylfentanyl for human use. There are no commercial or medical uses for this substance.

Illicit Uses:

As a μ-opioid receptor agonist, acetylfentanyl may serve as a direct substitute for heroin or other μ-opioid receptor agonist substances in opioid dependent individuals.

Recently, the Centers for Disease Control and Prevention (CDC) issued a health alert to report that between March 2013 and May 2013, 14 overdose deaths related to injected acetylfentanyl had occurred among intravenous drug users (ages between 19 and 57 years) in Rhode Island.

After confirming five overdoses in one county, including a fatality, Pennsylvania asked coroners and medical examiners across the state to screen for acetylfentanyl. This request led to 50 confirmed fatalities and five non-fatal overdoses statewide in 2013.

Control Status

Acetylfentanyl is not currently scheduled under the Controlled Substance Act (CSA). However, if intended for human consumption, acetylfentanyl may be treated as a "controlled substance analogue" under the CSA pursuant to 21 U.S.C §§802(32)(A) and 813.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 202-353-1263, telephone 202-307-7183, or E-mail ODE@usdoj.gov.

Acetyl Fentanyl Deaths

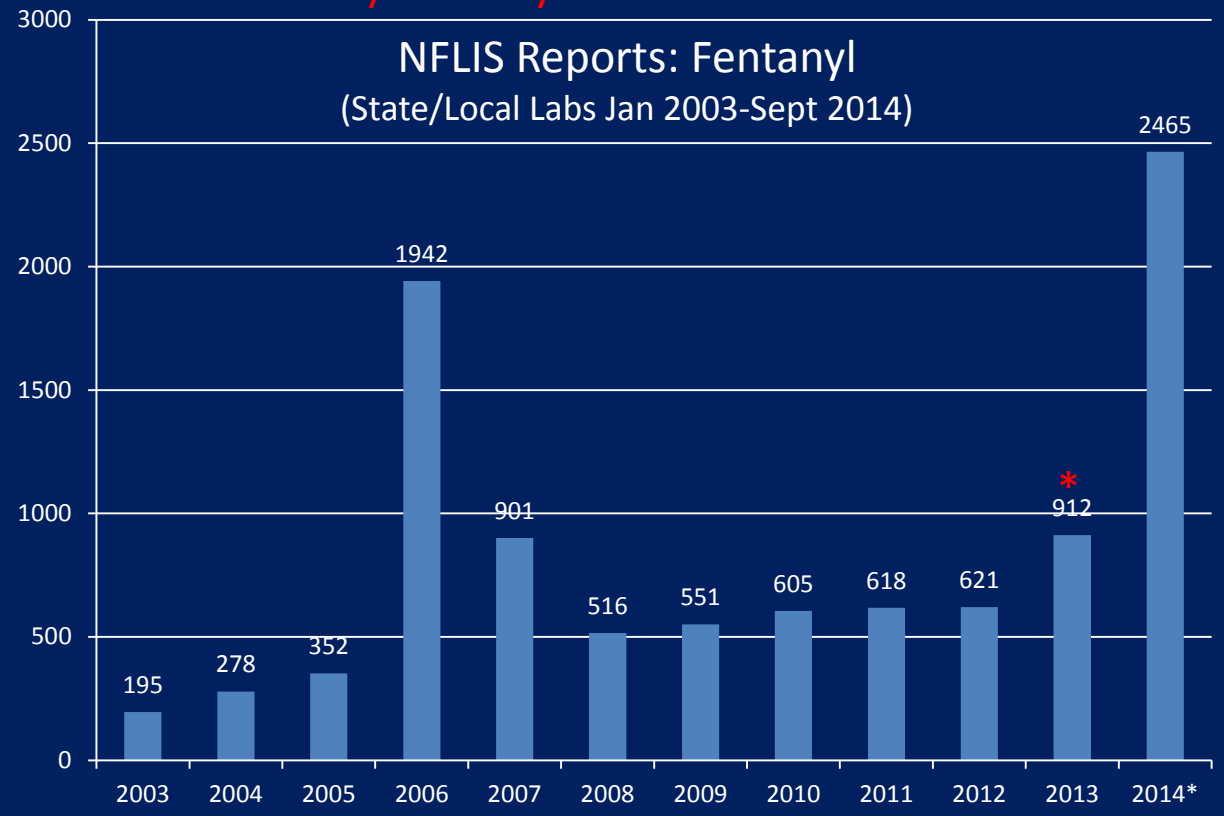
- Most recent: September 2014, Bend, OR, confirmed by M.E. toxicology
- **14** overdose deaths in RI; March-May 2013, reported by CDC
- Approximately **50** overdose deaths in PA; 2013, (caused by fentanyl *or* acetyl fentanyl) reported by PA Dept. of Drug and Alcohol Programs
- **3** overdose deaths in NC; February 2014, Reported by NC Dept. of Health and Human Services
- **5** overdose deaths in LA; October 2013, reported by the media
- Likely that the prevalence of acetyl fentanyl in opioid-related emergency room admissions and deaths are under-reported. Since standard radioimmunoassays (e.g. ELISA) detect presence of fentanyl and its analogues. ***Confirmatory GC/MS is necessary.***
- DEA monitoring Acetyl fentanyl deaths for possible scheduling
- Total number of fentanyl and acetyl fentanyl deaths unknown without old DAWN system.

Other Fentanyl-Related Compounds Include:

	TEMPORARY SCHEDULING under 21 USC 811(h)			EXTENSION OF TEMPORARY SCHEDULING			PERMANENT SCHEDULING				RESCHEDULING from CI to CII			
SUBSTANCE	PUB DATE	FEDERAL REGISTER CITATION	CSA SCHEDULE	PUB DATE	FEDERAL REGISTER CITATION	CSA SCHEDULE	PROPOSAL PUB DATE	PUB DATE	FEDERAL REGISTER CITATION	CSA SCHEDULE	PROPOSAL PUB DATE	PUB DATE	FEDERAL REGISTER CITATION	CSA SCHEDULE
Sufentanyl								09-30-80	45 FR 64571		03-20-84	05-25-84	49 FR 22074	I -> II
Alpha-Methylfentanyl							08-05-81	09-22-81	46 FR 46799	I Narcotic				
Alfentanyl								06-25-84	49 FR 25849	I Narcotic	04-17-86	01-23-87	52 FR 2516	I -> II Narcotic
3-Methylfentanyl	03-25-85	50 FR 11690	I	04-24-86	51 FR 15474	I	04-24-86	09-22-86	51 FR 33592	I Narcotic				
Beta-Hydroxyfentanyl	10-29-85	50 FR 43698	I	11-26-86	51 FR 42834	I	11-28-86	05-29-87	52 FR 20070	I Narcotic				
Benzylfentanyl	10-29-85	50 FR 43698	I Expired 11/29/1986											
Beta-Hydroxy-3-Methylfentanyl	10-29-85	50 FR 43698	I	11-26-86	51 FR 42834	I Expired 5/29/1987	11-28-86	01-08-88	53 FR 500	I Narcotic				
Acetyl-Alpha-Methylfentanyl	10-29-85	50 FR 43698	I	11-26-86	51 FR 42834	I	11-28-86	05-29-87	52 FR 20070	I Narcotic				
Thiofentanyl	10-29-85	50 FR 43698	I	11-26-86	51 FR 42834	I	11-28-86	05-29-87	52 FR 20070	I Narcotic				
Thenylfentanyl	10-29-85	50 FR 43698	I Expired 11/29/1986											
3-Methylthiofentanyl	10-29-85	50 FR 43698	I	11-26-86	51 FR 42834	I	11-28-86	05-29-87	52 FR 20070	I Narcotic				
Alpha-Methylthiofentanyl	10-29-85	50 FR 43698	I	11-26-86	51 FR 42834	I	11-28-86	05-29-87	52 FR 20070	I Narcotic				
Para-Fluorofentanyl	02-07-86	51 FR 4722	I	03-10-87	52 FR 7270	I	03-10-87	05-29-87	52 FR 20070	I Narcotic				
Carfentanil							01-12-88	10-28-88	53 FR 43684	II Narcotic				
Remifentanil							09-16-96	11-05-96	61 FR 56893	II Narcotic				

DEA History Fentanyl-Related Events

- April 2005 - March 2007: Spike in fentanyl seizures and over ***1013 documented non-pharmaceutical overdose deaths***
  - Synthetic route identified as ***Siegfried method***
  - DEA Controlled Precursor *N*-phenethyl-4-piperdidone ***(NPP) in 2007 as List 1*** Chemical and 4-anilino-*N*-phenethyl-4-piperidine ***(ANPP) as a Schedule II immediate precursor in 2010.***
- Recent Spike in Fentanyl seizures 2013-14
  - Identification of acetyl fentanyl



** Through Sept 2014

Synthetic Opioid AH-7921

- Synthetic Opioid
- Mimics heroin
- 21 overdose deaths associated in Europe
- Relatively new in US market Seized in Reno, NV
- Dealer attempting to get a substance that is “not an analogue”
- This is marketed as “badger repellant”

W-15 (Synthetic Opioid)

#1
04-08-2013, 09:07 PM

xool
Peasant

Join Date: Jan 2009
Thanks: 28
Thanked 11 Times in 7 Posts

W-15 (New RC opioid)

Noticed a few vendors stocking W-15 recently. Seriously little info available on it, but I thought there might be a few people here interested. Apparently it's about 5x more potent than morphine. That's all I've really found out, so here's some pics!

Looks like this:

Hopefully a few knowledgeable people will have some insight.

UPDATE: Found an experience report whilst searching. It's on reddit:http://www.reddit.com/r/opiates/comm...ort_rc_opiate/

According to that, doesn't look very promising :/

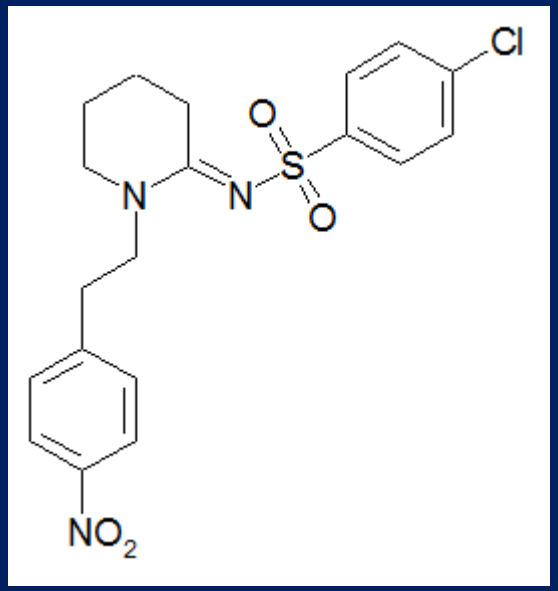
Last edited by xool; 04-08-2013 at 09:15 PM.

Quote

W-18 (Synthetic Opioid)

- **-(4-Nitrophenylethyl)piperidylidene-2-(4-chlorophenyl)sulfonamide** (**W-18**) is a potent μ-opioid agonist with a distinctive chemical structure which is not closely related to other established families of opioid drugs.
- This compound was found to be around 10,000x more potent than morphine in animal studies, however due to its structural differences from other opioid drugs it would be difficult to represent as being "substantially similar in chemical structure" to any controlled drugs. This makes it likely that it would not be illegalized under drug analog laws.

- **Nitrophenylethyl)piperidylidene-2-(4-chlorophenyl)sulfonamide**



METHADONE

State Ranking* - Methadone

January – December 2013

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	76,770,300	12	GA	17,349,100	23	NV	8,426,800	34	ID	4,893,800	45	NM	2,064,900
2	FL	43,294,600	13	IN	16,977,500	24	IL	8,152,000	35	CT	4,523,200	46	NE	1,940,000
3	MI	27,065,900	14	VA	13,664,800	25	LA	7,477,600	36	NH	3,986,000	47	RI	1,193,700
4	WA	24,649,700	15	MA	12,565,800	26	AR	6,996,100	37	WV	3,745,000	48	SD	763,900
5	TX	23,886,000	16	TN	11,459,400	27	CO	6,622,900	38	MS	3,150,800	49	WY	735,800
6	NY	23,757,900	17	MD	11,249,100	28	UT	6,427,100	39	IA	3,137,600	50	ND	727,100
7	PA	22,528,100	18	AZ	10,765,700	29	OK	6,415,000	40	HI	2,569,900	51	DC	294,400
8	NC		19	WI	9,665,400	30	SC	6,375,200	41	DE	2,519,000	52	PR	40,700
9	OH	19,959,900	20	KY	9,457,500	31	MN	5,889,700	42	AK	2,354,800	53	GU	34,600
10	OR	18,541,800	21	NJ	8,924,100	32	KS	5,275,500	43	VT	2,352,000	54	VI	15,600
11	AL	18,324,700	22	MO	8,584,900	33	ME	5,076,000	44	MT	2,187,700	55	AS	0

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control,
Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/10/2014

State Ranking* - Methadone
January – September 2014

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	52,222,700	12	GA	11,862,900	23	NV	5,822,700	34	ID	3,451,800	45	NM	1,406,500
2	FL	28,096,000	13	IN	10,743,400	24	IL	5,816,300	35	CT	3,094,700	46	MT	1,373,800
3	MI	19,425,100	14	VA	9,589,000	25	AR	5,013,600	36	NH	3,000,700	47	RI	783,800
4	TX	17,186,800	15	MA	8,634,000	26	LA	4,823,900	37	WV	2,629,800	48	SD	644,300
5	NY	17,009,400	16	MD	8,025,600	27	SC	4,672,400	38	MS	2,370,800	49	WY	529,500
6	WA	16,685,300	17	AZ	7,616,600	28	UT	4,638,200	39	IA	2,173,100	50	ND	524,000
7	PA	16,082,600	18	TN	7,231,400	29	OK	4,637,800	40	DE	1,926,900	51	DC	190,000
8	NC	14,442,200	19	NJ	6,782,300	30	CO	4,605,900	41	AK	1,762,900	52	PR	27,100
9	OH	[illegible]	20	WI	6,774,200	31	MN	4,340,200	42	HI	1,720,300	53	GU	16,200
10	AL	12,402,900	21	KY	6,381,800	32	ME	3,938,400	43	VT	1,701,400	54	VI	9,200
11	OR	12,176,400	22	MO	6,333,600	33	KS	3,732,600	44	NE	1,420,000	55	AS	0

**** Business Activity – Retail Pharmacies***

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 01/29/2015

Methadone- 5mg &10mg

Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg

Treatment of Narcotic Addiction

WHY IS IT ALSO USED AS AN ANALGESIC?

Cheapest narcotic pain reliever – synthetic

Insurance companies

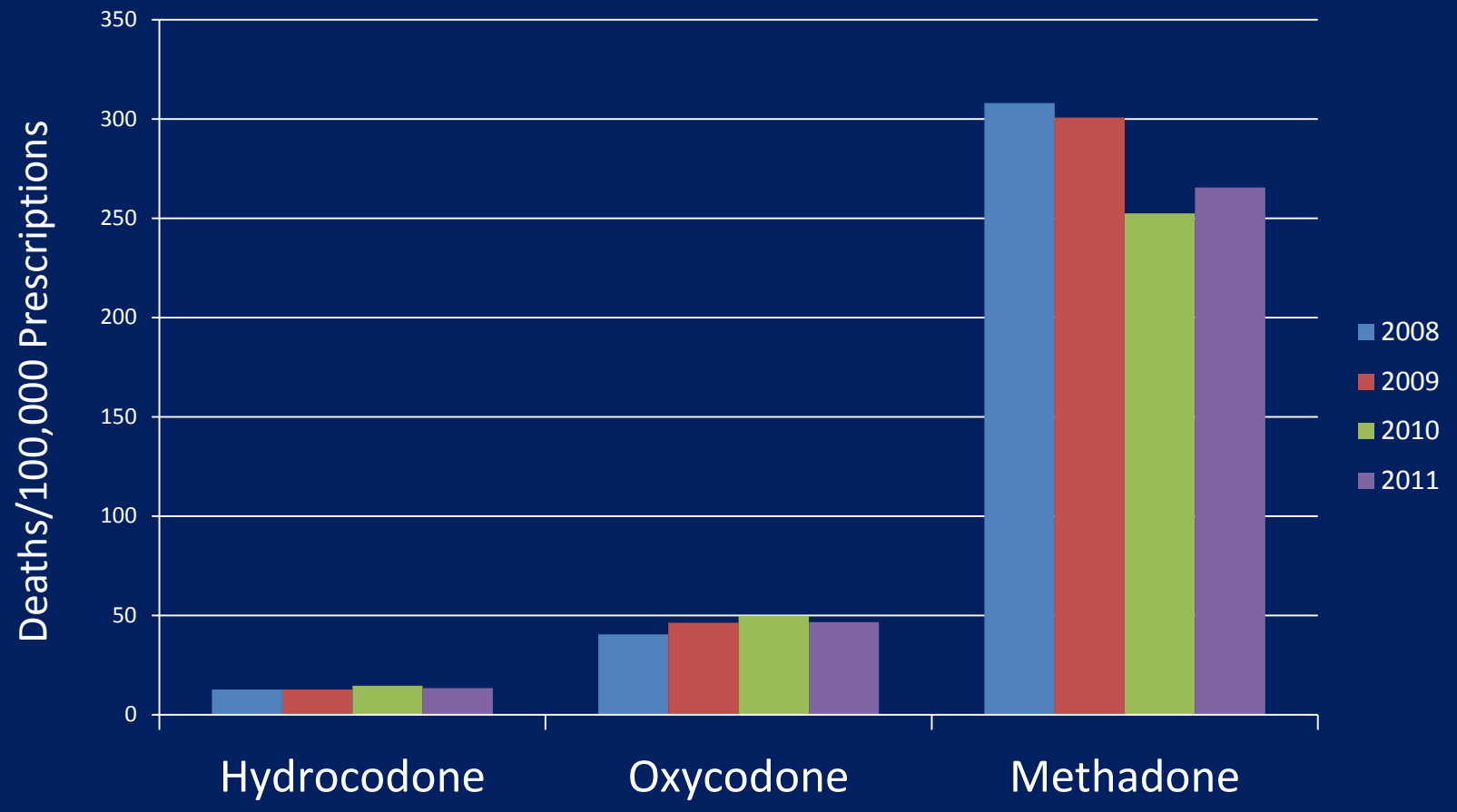
What's the problem?

Overdose...Why?

- Patients not taking the drug as directed
- Physicians not properly prescribing the drug
- Non medical users ingesting with other substances
- Opiate naive

Florida Deaths Per 100,000 Prescriptions

2008-2011



- Sources:
- Death Data : Florida Department of Law Enforcement, "Drugs Identified in Deceased Persons by Florida Medical Examiners"
- Prescription Data: IMS Exponent, State Level: Florida Retail Prescription Data

U.S. Drug Enforcement Administration
Office of Diversion Control

One Pill can Kill

CE Article: (ACCME, CMI, ACFEI) 1 CE credit for this article

By Jonathan J. Lipman, PhD

THE METHADONE POISONING "Epidemic"

Increasing use of Methadone as a pain killer may be fueling a disturbing increase in deaths related to this potent drug.

Name _____

Address _____ Date _____

Rx

Death and morbidity associated with methadone treatment has increased dramatically in recent years, largely in the population prescribed this drug for pain control rather than addiction maintenance. Inadvertent overdose is becoming increasingly common, likely in part because the drug's acute pain-relieving effect lasts only 4 to 6 hours, yet it has a very long and variable plasma half-life of 24 to 36 (in some studies 15 to 55) hours, is stored in body tissues, and toxic accumulation occurs with too-frequent consumption. Adverse effects are most common in patients treated with methadone in combination with other drugs. Both cardiac and respiratory systems are vulnerable targets for the drug's toxic actions, and other co-administered drugs can interactively increase the risk of death through a variety of mechanisms including direct central nervous system depression of respiration, idiosyncratic respiratory vulnerabilities, and lethal cardiac arrhythmias. Idiosyncratic factors also play a part in methadone's cardiac toxicity, and risk factors are well characterized, though perhaps not sufficiently widely known and understood by key stakeholders. The recent change in FDA labeling requirements for the drug—and the November 2006 posting of a government warning regarding its use in pain treatment—has not yet reduced morbidity and mortality associated with methadone as reported in the MedWatch database for the first quarter of 2007.

The Methadone Poisoning by Jonathan J. Lipman, Ph.D.

Prescription Opioid Trafficking Trends DATA-2000 Physicians

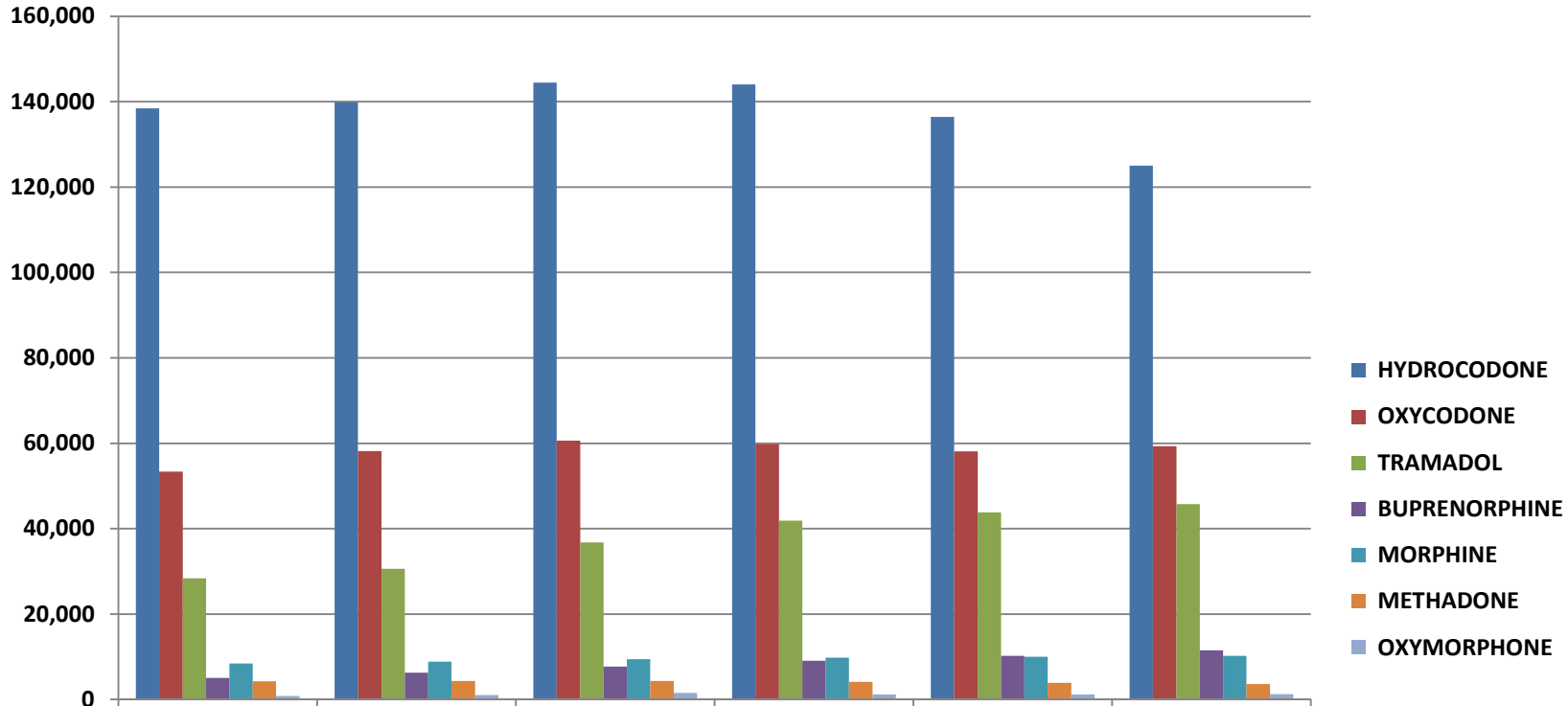
Joseph Rannazzisi
Deputy Assistant Administrator
DEA Office of Diversion Control

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control

Other FDA Approved Drugs for Narcotic Addiction Treatment

- Schedule III
  - Buprenorphine – Drug Code 9064
    - Subutex (sublingual, single entity tablet)
    - Suboxone (sublingual, buprenorphine/naloxone tablet)

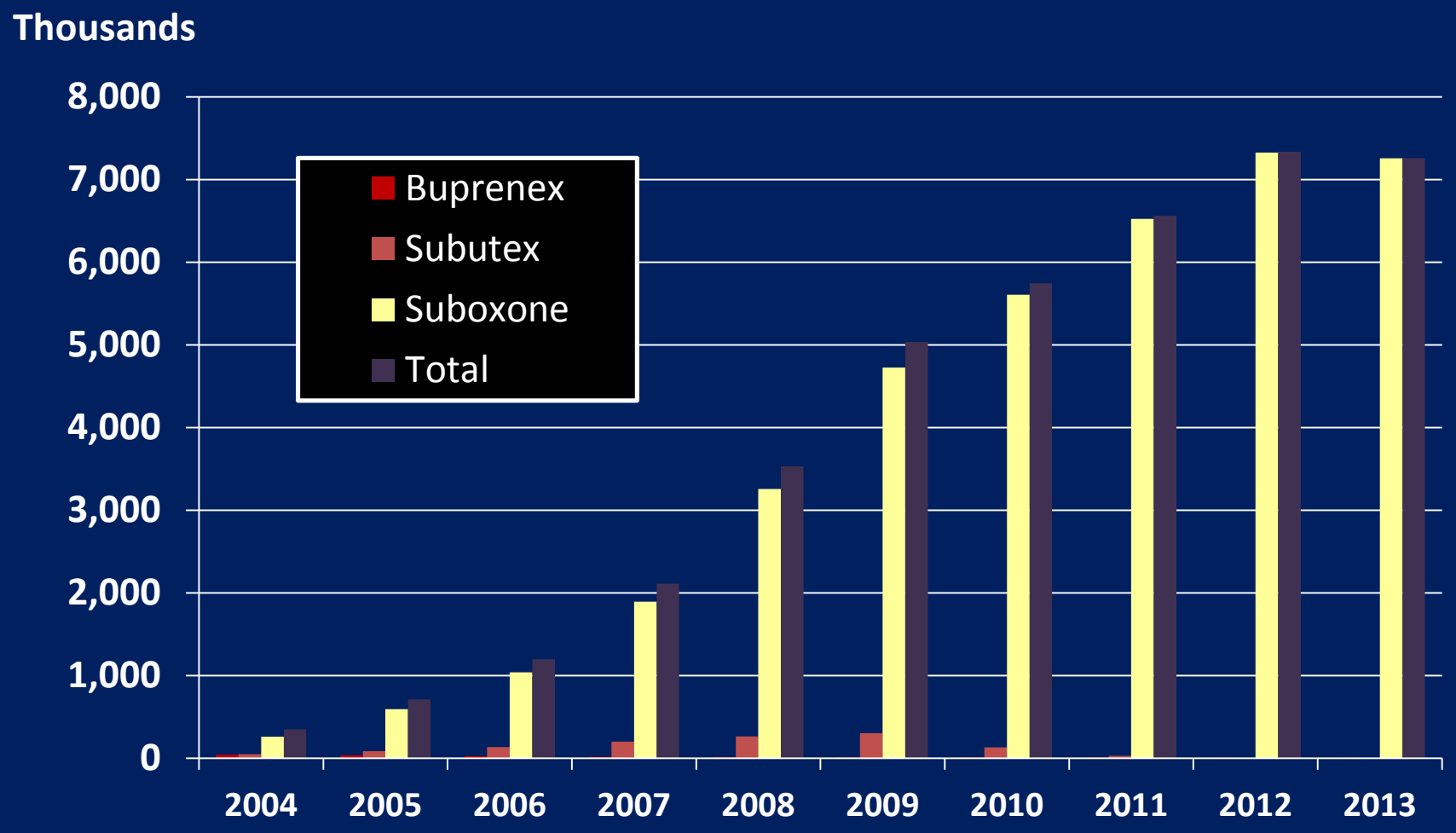
Dispensed Total U.S. Prescriptions 2009-2014
(In thousands of Prescriptions)



	2009	2010	2011	2012	2013	2014
HYDROCODONE	138,450	139,837	144,455	144,049	136,432	124,973
OXYCODONE	53,347	58,199	60,635	59,806	58,098	59,307
TRAMADOL	28,366	30,586	36,808	41,882	43,785	45,718
BUPRENORPHINE	5,080	6,254	7,689	9,052	10,243	11,533
MORPHINE	8,389	8,871	9,427	9,759	10,002	10,183
METHADONE	4,292	4,350	4,350	4,116	3,886	3,630
OXYMORPHONE	782	1,011	1,498	1,155	1,143	1,236

Source: IMS Health National Prescription Audit

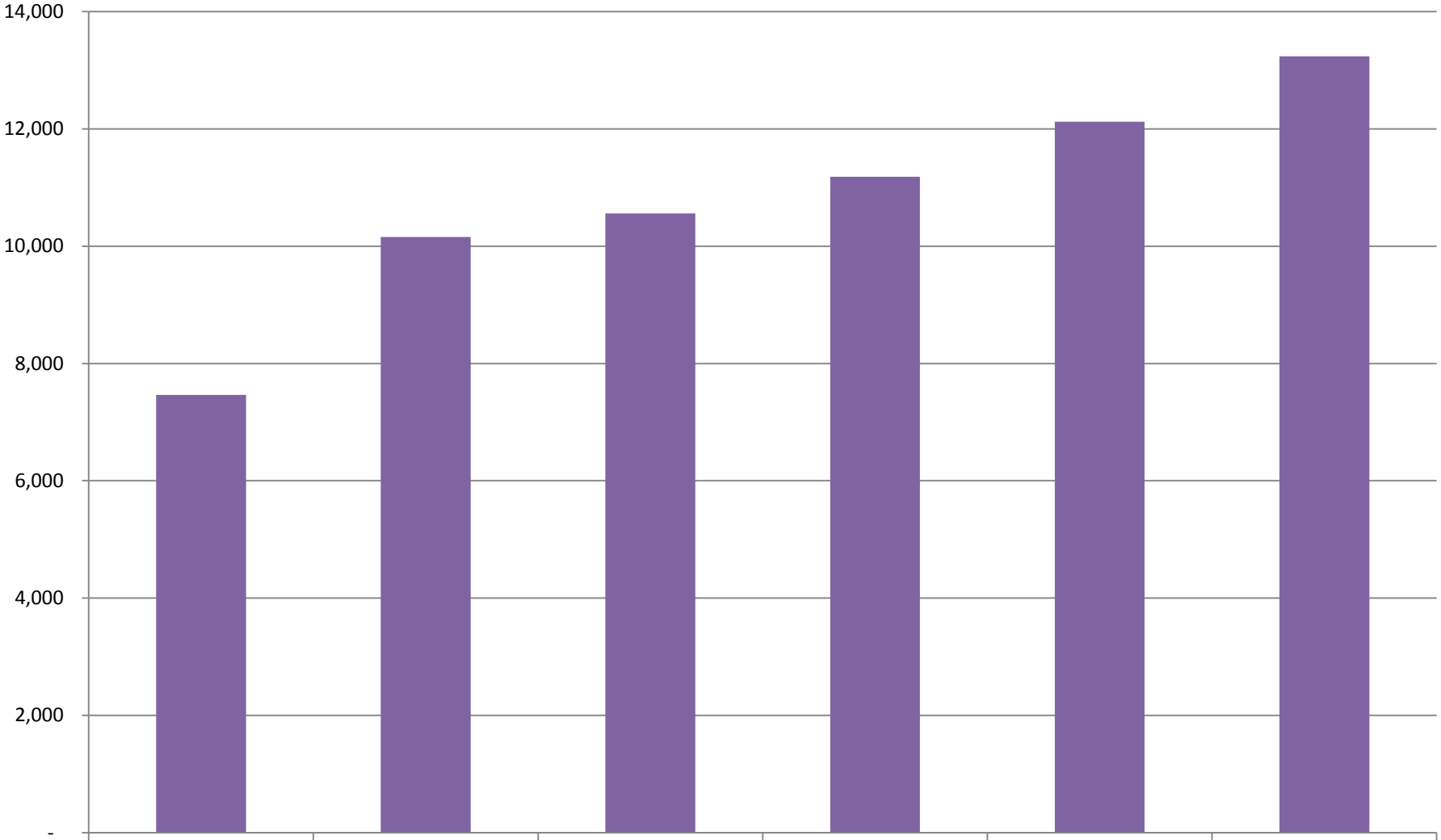
Buprenorphine Rx
Calendar Years 2004 – 2013



Source: IMS, National Prescription Audit, retrieved 08-22-2014

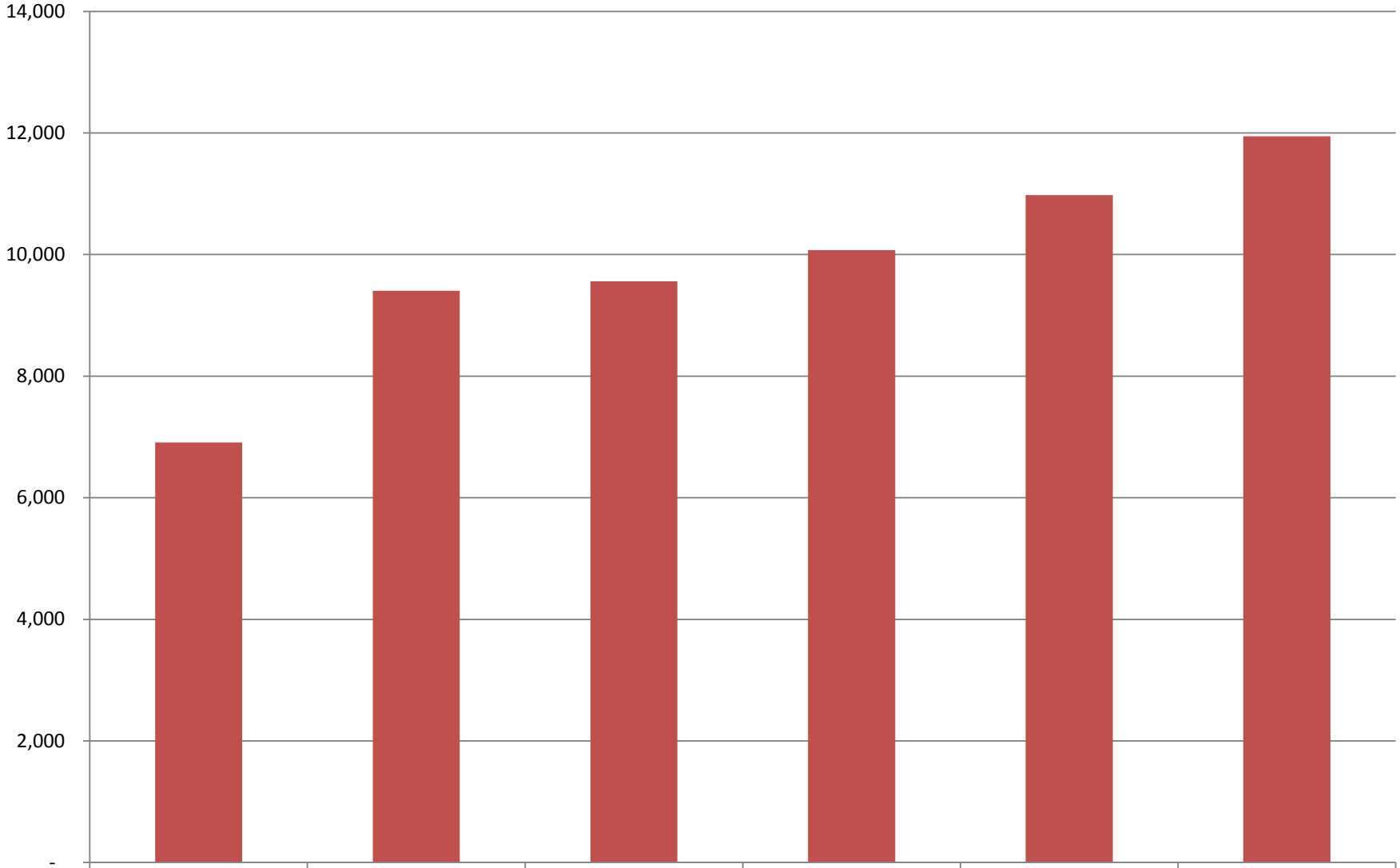
Number of NFLIS Buprenorphine Reports, 2009 - 2014

Federal, State, and Local Labs



	2009	2010	2011	2012	2013	2014
Reports	7,464	10,157	10,558	11,182	12,122	13,236

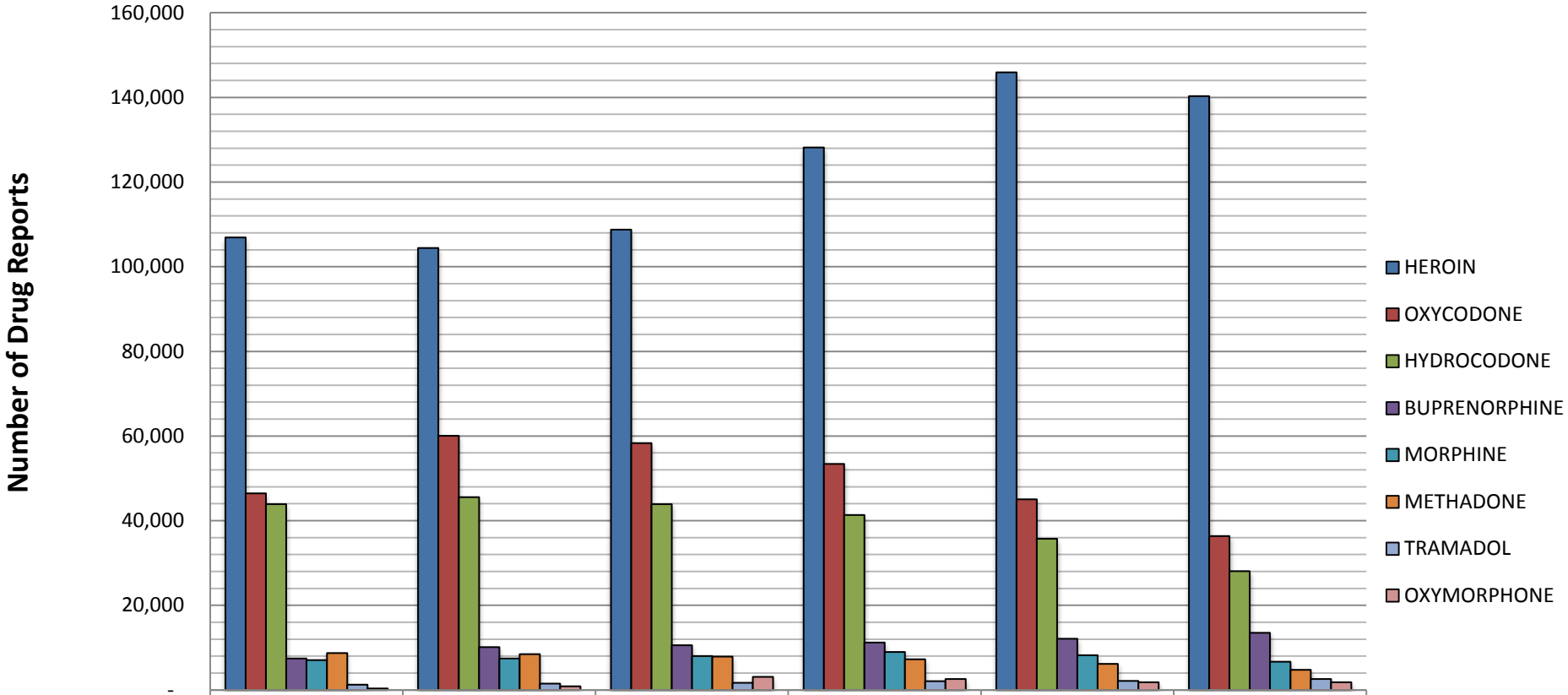
Number of NFLIS Buprenorphine Cases, 2009 - 2014
Federal, State, and Local Labs



	2009	2010	2011	2012	2013	2014
Cases	6,909	9,403	9,560	10,074	10,976	11,947

Number of NFLIS Drug Reports, 2009 - 2014

Federal, State, and Local Labs



	2009	2010	2011	2012	2013	2014
HEROIN	106,924	104,446	108,789	128,155	145,886	140,330
OXYCODONE	46,453	60,054	58,327	53,443	45,019	36,365
HYDROCODONE	43,912	45,591	43,902	41,362	35,738	28,046
BUPRENORPHINE	7,464	10,157	10,558	11,182	12,129	13,491
MORPHINE	7,079	7,431	8,032	8,950	8,219	6,654
METHADONE	8,748	8,472	7,871	7,238	6,147	4,797
TRAMADOL	1,284	1,482	1,720	2,062	2,132	2,613
OXYMORPHONE	387	869	3,090	2,618	1,804	1,823

Benzodiazepines

Alprazolam (Schedule IV)

- Brand name formulation of ***Xanax®***
- Anti-anxiety agent used primarily for short-term relief of mild to moderate anxiety
- Part of the class of drugs called benzodiazepines, more commonly referred to as 'benzos'
- Extremely addictive
  - Once dependence has occurred, Xanax makes it markedly more difficult for individuals to successfully self-detox than other benzodiazepines $2.00-$2.50 for 2mg dosage unit.

Alprazolam Xanax® (Z-bars)

- Drug abusers often prefer alprazolam due to its rapid onset and longer duration of action
- Alprazolam was ranked third in the number of prescriptions for controlled substances in 2003, 2004, 2005 and 2006*
- For all sales of generic pharmaceuticals, alprazolam was ranked 7th**

* Source IMS Health
** Source Verispan VONA

Stimulants

Amphetamine Salts C-II

- Adderall ® C-II

Methylphenidate C-II

- Ritalin®
- Concerta®

Ritalin® / Concerta® / Adderall

Used legitimately to treat ADHD

Used non-medically to get high and as an academic "performance-enhancer" to improve memory and improve concentration – gain the edge

- Higher GPA
- Higher SAT / ACT score
- Get that scholarship

Parents' Relaxed Attitudes and Permissiveness

- Approximately 29% of parents surveyed say they believe ADHD medication can improve a child's academic or testing performance, even if the teen does not have ADHD

Source: 2012 Partnership Attitude Tracking Study, published 4/23/13

Teen Attitudes

- ✓ **31%** believe prescription drugs (Ritalin or Adderall) can be used as study aids.

- ✓ **29%** believe taking a larger dose than prescribed to them is okay as long as they are not getting high.

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14

U.S. Drug Enforcement Administration
Office of Diversion Control

ADHD Drugs

- Used legitimately to treat ADHD
- Abuse prevalent among college students; can be snorted, injected or smoked; nicknamed "College Crack"
- $5.00 to $10.00 per pill on illicit market
- Adderall® Abusers are 5 times more likely to also abuse prescription pain relievers, 8 times more likely to abuse Benzodiazepines

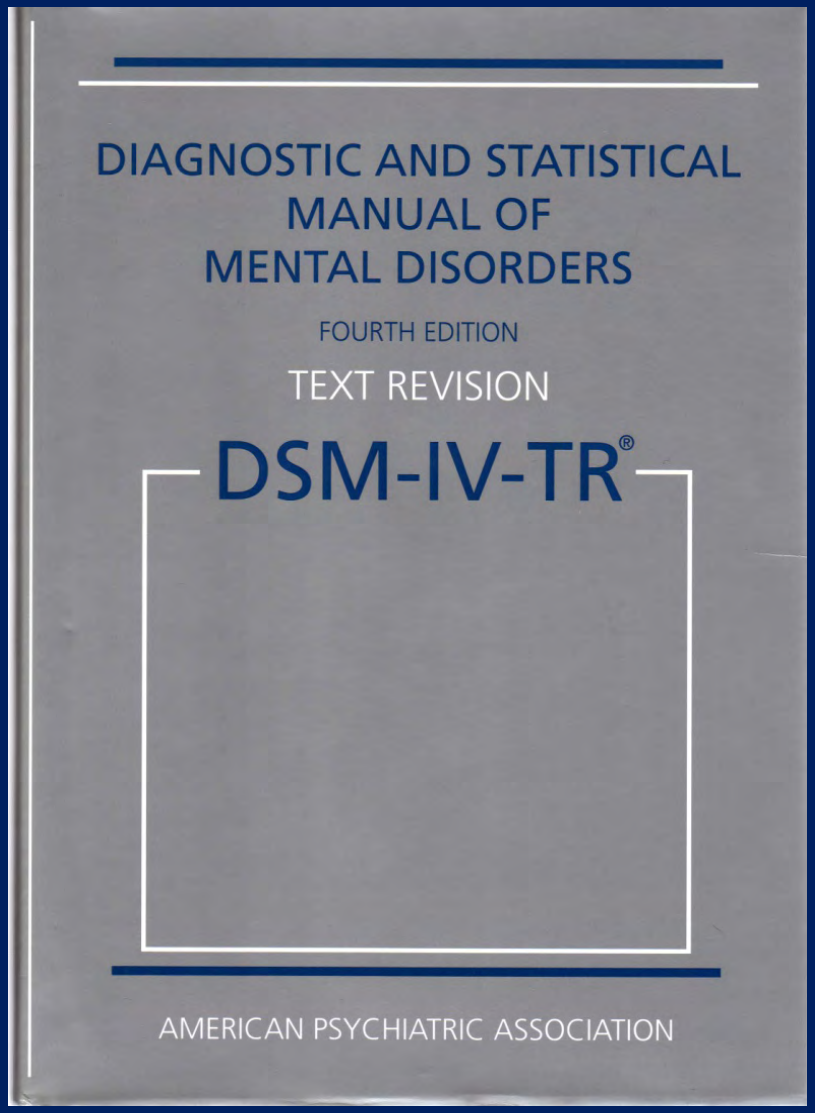
Source: NSDUH Report; Non-Medical Use of Adderall Among Full-Time College Students, published April 2009

Trends in Abuse of Ritalin/Adderall

- One in eight teens (about 2.7 million) now reports having misused or abused these prescription stimulants at least once in their **lifetime**
- 9% of teens (about 1.9 million) report having misused or abused these prescription stimulants in the **past year** (up from 6% in 2008)
- 6% of teens (about 1.3 million) report abuse of these prescription stimulants in the past month (up from 4% in 2008)
- One in four teens (26%) believes that prescription drugs can be used as a study aid
- More than one in five teens (22%) says there is little or no risk in using Ritalin/Adderall without a prescription

Source: 2012 Partnership Attitude Tracking Study, published 4/23/13

REQUIRED READING



Attention-Deficit and Disruptive Behavior Disorders

Attention-Deficit/Hyperactivity Disorder

Some hyperactive-impulsive or inattentive symptoms that cause impairment must have been present before age 7 years, although many individuals are diagnosed after the symptoms have been present for a number of years, especially in the case of individuals with the Predominantly Inattentive Type (Criterion B)

culty sustaining attention in tasks or play activities and often find it hard to persist with tasks until completion (Criterion A1b). They often appear as if their mind is elsewhere or as if they are not listening or did not hear what has just been said (Criterion A1c). There may be frequent shifts from one uncompleted activity to another. Individuals diagnosed with this disorder may begin a task, move on to another, then turn to yet something else, prior to completing any one task. They often do not follow through on requests or instructions and fail to complete schoolwork, chores, or other duties (Criterion A1d). Failure to complete tasks should be considered in making this diagnosis only if it is due to inattention as opposed to other possible reasons (e.g., failure to understand instructions, defiance). These individuals often have difficulties organizing tasks and activities (Criterion A1e). Tasks that require sustained mental effort are experienced as unpleasant and markedly aversive. As a result, these individuals typically avoid or have a strong dislike for activities that demand sustained self-application and mental effort or that require organizational demands or close concentration (e.g., homework or paperwork) (Criterion A1f). This avoidance must be due to the person's difficulties with attention and not due to a primary oppositional attitude, although secondary oppositionalism may also occur. Work habits are often disorganized and the materials necessary for doing the task are often scattered, lost, or carelessly handled and damaged (Criterion A1g). Individuals with this disor-

- Fails to give close attention to details…makes careless mistakes in schoolwork, work
- Difficulty sustaining attention in tasks
- Does not seem to listen when spoken to
- Does not follow through on instructions
- Difficulty organizing tasks
- Often loses things necessary for tasks
- Easily distracted
- Forgetful

(g) often loses things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools)
(h) is often easily distracted by extraneous stimuli
(i) is often forgetful in daily activities

(2) *six (or more)* of the following symptoms of **hyperactivity-impulsivity** have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:

- Fidgets
- Can't remain seated
- Restlessness
- Difficulty awaiting turn
- Often interrupts or intrudes

(g) often blurts out answers before questions have been completed
(h) often has difficulty awaiting turn
(i) often interrupts or intrudes on others (e.g., butts into conversations or games)

B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.

C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).

that requests be met, mood lability, demoralization, dysphoria, rejection by peers, and poor self-esteem. Academic achievement is often markedly impaired and deval-

There are no laboratory tests, neurological assessments, or attentional assessments that have been established as diagnostic in the clinical assessment of Attention-Deficit/Hyperactivity Disorder

Conduct Disorder. The rates of co-occurrence of Attention-Deficit/Hyperactivity Disorder with these other Disruptive Behavior Disorders are higher than with other mental disorders, and this co-occurrence is most likely in the two subtypes marked by hyperactivity-impulsivity (Hyperactive-Impulsive and Combined Types). Other associated disorders include Mood Disorders, Anxiety Disorders, Learning Disorders, and Communication Disorders in children with Attention-Deficit/Hyperactivity Disorder. Although Attention-Deficit/Hyperactivity Disorder appears in at least 50% of clinic-referred individuals with Tourette's Disorder, most individuals with Attention-Deficit/Hyperactivity Disorder do not have accompanying Tourette's Disorder. When the two disorders coexist, the onset of the Attention-Deficit/Hyperactivity Disorder often precedes the onset of the Tourette's Disorder.

There may be a history of child abuse or neglect, multiple foster placements, neurotoxin exposure (e.g., lead poisoning), infections (e.g., encephalitis), drug exposure in utero, or Mental Retardation. Although low birth weight may sometimes be associated with Attention-Deficit/Hyperactivity Disorder, most children with low birth weight do not develop Attention-Deficit/Hyperactivity Disorder, and most children with Attention-Deficit/Hyperactivity Disorder do not have a history of low birth weight.

Associated laboratory findings. There are no laboratory tests, neurological assessments, or attentional assessments that have been established as diagnostic in the clin-

experience few demands for sustained attention. However, even the attention of toddlers can be held in a variety of situations (e.g., the average 2- or 3-year-old child can typically sit with an adult looking through picture books). Young children with Attention-Deficit/Hyperactivity Disorder move excessively and typically are difficult to contain. Inquiring about a wide variety of behaviors in a young child may be helpful in ensuring that a full clinical picture has been obtained. Substantial impairment has been demonstrated in preschool-age children with Attention-Deficit/Hyperactivity Disorder. In school-age children, symptoms of inattention affect classroom work and academic performance. Impulsive symptoms may also lead to the breaking of familial, interpersonal, and educational rules. Symptoms of Attention-Deficit/Hyperactivity Disorder are typically at their most prominent during the elementary grades. As children mature, symptoms usually become less conspicuous. By late childhood and early adolescence, signs of excessive gross motor activity (e.g., excessive running and climbing, not remaining seated) are less common, and hyperactivity symptoms may be confined to fidgetiness or an inner feeling of jitteriness or restlessness. In adulthood, restlessness may lead to difficulty in participating in sedentary activities and to avoiding pastimes or occupations that provide limited opportunity for spontaneous movement (e.g., desk jobs). Social dysfunction in adults appears to be especially likely in those who had additional concurrent diagnoses in childhood. Caution should be exercised in making the diagnosis of Attention-Deficit/Hyperactivity Disorder in adults solely on the basis of the adult's recall of being inattentive or hyperactive as a child, because the validity of such retrospective data is

Methods of Diversion

- Practitioners / Pharmacists
  - Illegal distribution
  - Self abuse
  - Trading drugs for sex
- Employee pilferage
  - Hospitals
  - Practitioners' offices
  - Nursing homes
  - Retail pharmacies
  - Manufacturing / distribution facilities
- Pharmacy / Other Theft
  - Armed robbery
  - Burglary (Night Break-ins)
  - In Transit Loss (Hijacking)
  - Smurfing
- Patients / Drug Seekers
  - Drug rings
  - Doctor-shopping
  - Forged / fraudulent / altered prescriptions
- The medicine cabinet / obituaries
- The Internet
- Pain Clinics

Where are the Pharmaceuticals Coming From?

- Friends and Family for Free
- Medicine Cabinet
- Doctor Shopping
- Internet
- Pain Clinics

Prescription Fraud

- **Fake prescriptions**
  - Highly organized
  - Use real physician name and DEA Registrant Number
    - Contact Information false or “fake office”
      - (change locations often to avoid detection)
  - Prescription printing services utilized
    - Not required to ask questions or verify information printed
- **Stolen prescriptions**
  - Forged
  - “Smurfed” to a large number of different pharmacies

Criminal Activity

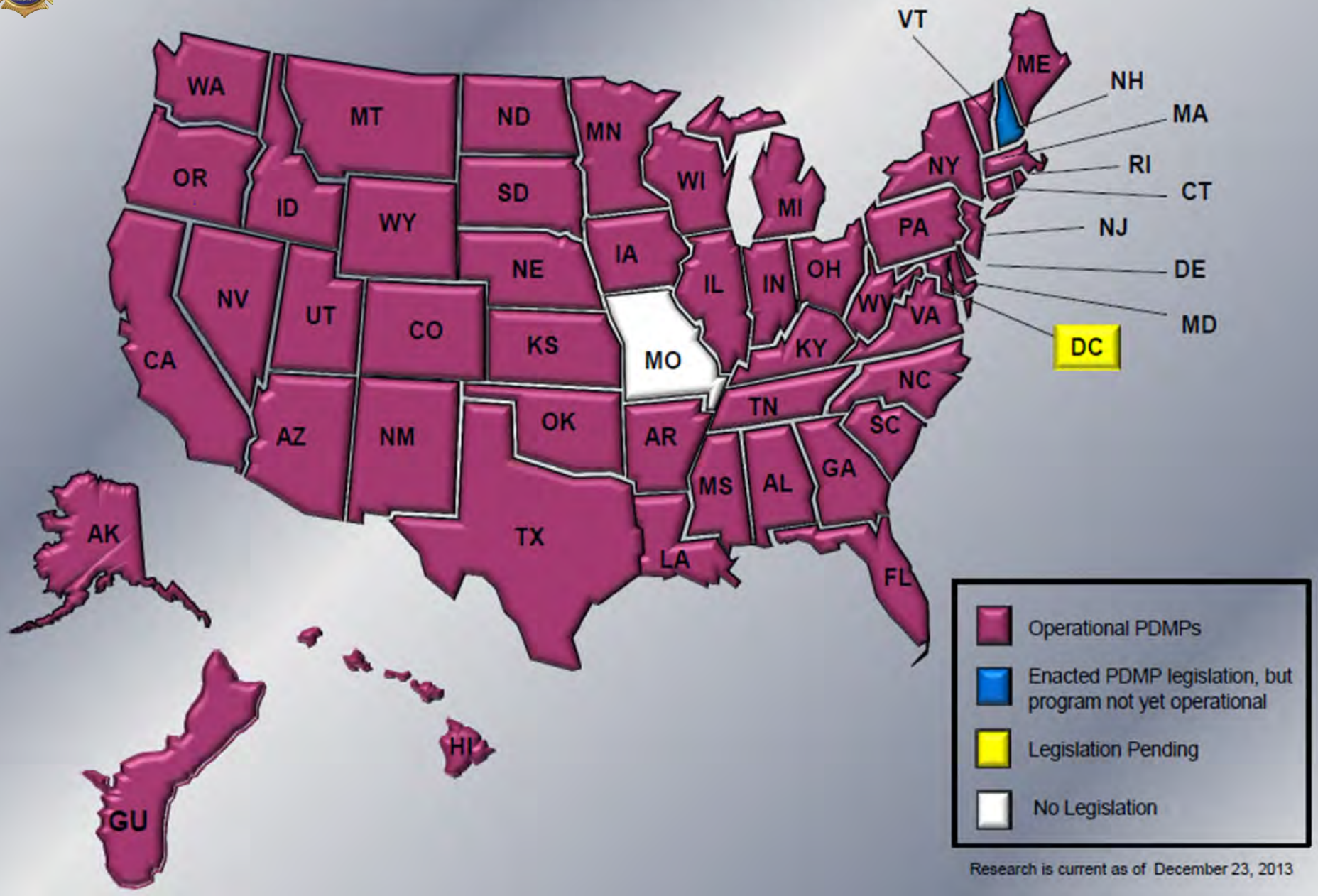
Egregious Activity
(Not on the fringes)

Doctor Shopping

Prescription Drug Monitoring Programs

Status of Prescription Drug Monitoring Programs (PDMPs)

** To view PDMP Contact information, hover the mouse pointer over the state abbreviation*



Research is current as of December 23, 2013

Mandatory PDMP review before prescribing CS?

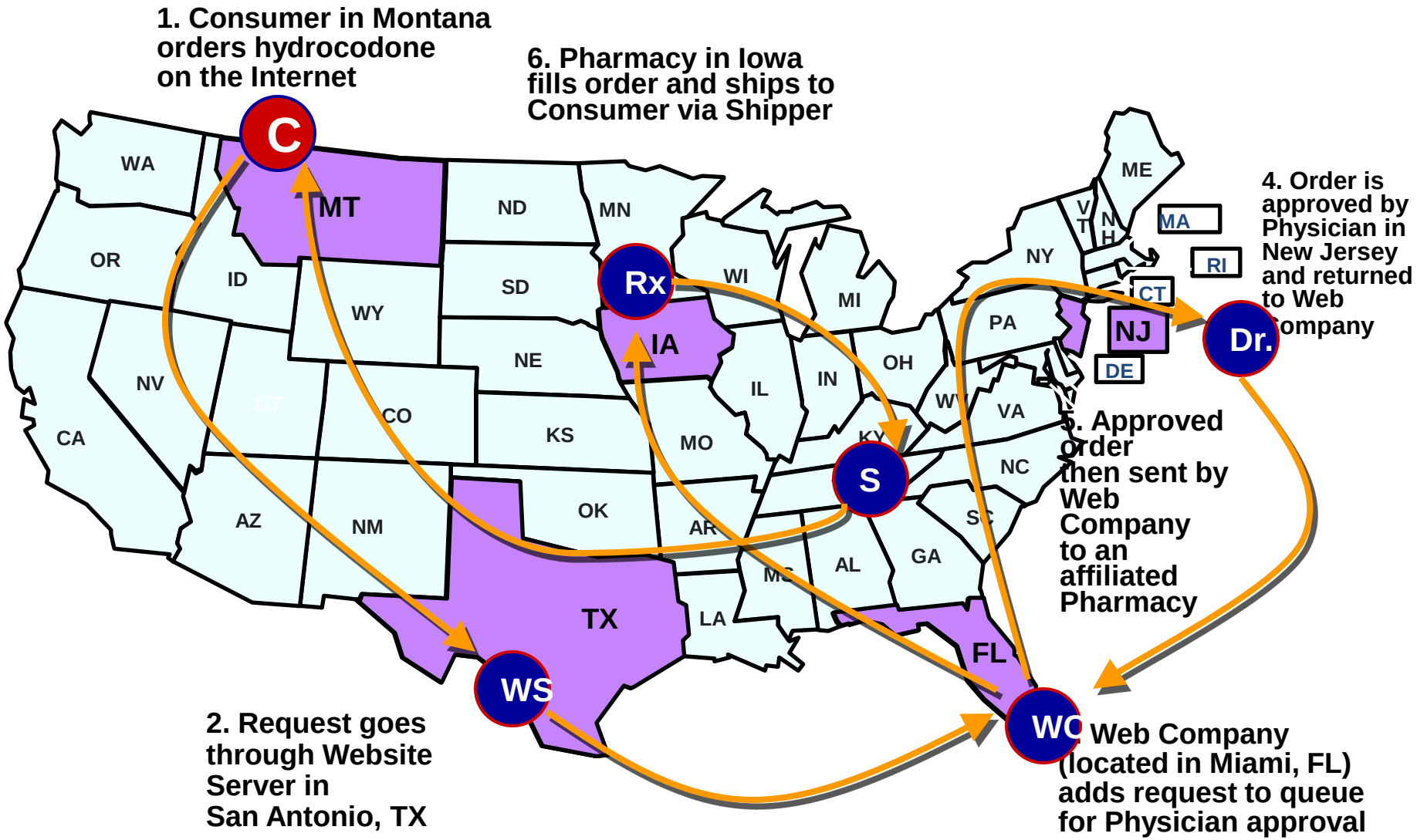
Pharmacist access to PDMP

Standard of Care

National Association of Boards of Pharmacy

Diversion via the Internet

Domestic ‘R_X’ Flow



New Felony Offense Internet Trafficking - 10/15/2008

- 21 USC 841(h)(1): It shall be unlawful for any person to knowingly or intentionally:

  (A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this title; or

  (B) aid or abet any violation in (A)

What has been the reaction????

Per Se Violations

Automatic Violation of the CSA if any of the following occurs:

- No in-person medical evaluation by prescribing practitioner
- Online pharmacy not properly registered with *modified registration*.
- Website fails to display required information

Current CSA Registrant Population

Total Population	**1,582,633**
Practitioner	**1,207,876**
Mid-Level Practitioner	**272,586**
Pharmacy	**71,110**
Hospital-Clinic	**16,411**
Teaching Institution	**299**
Manufacturer	**538**
Distributor	**816**
Researcher	**7,748**
Analytical Labs	**1,512**
NTP	**1,413**
Importer/Exporter	**493**
ADS Machine	**1,636**
Chemicals	**989**

As of 06/25/15

SOOOO…How many have applied for registration for Internet Pharmacy Operations?????

53 applications filed

40 withdrawn

9 applications filed in error

4 pending

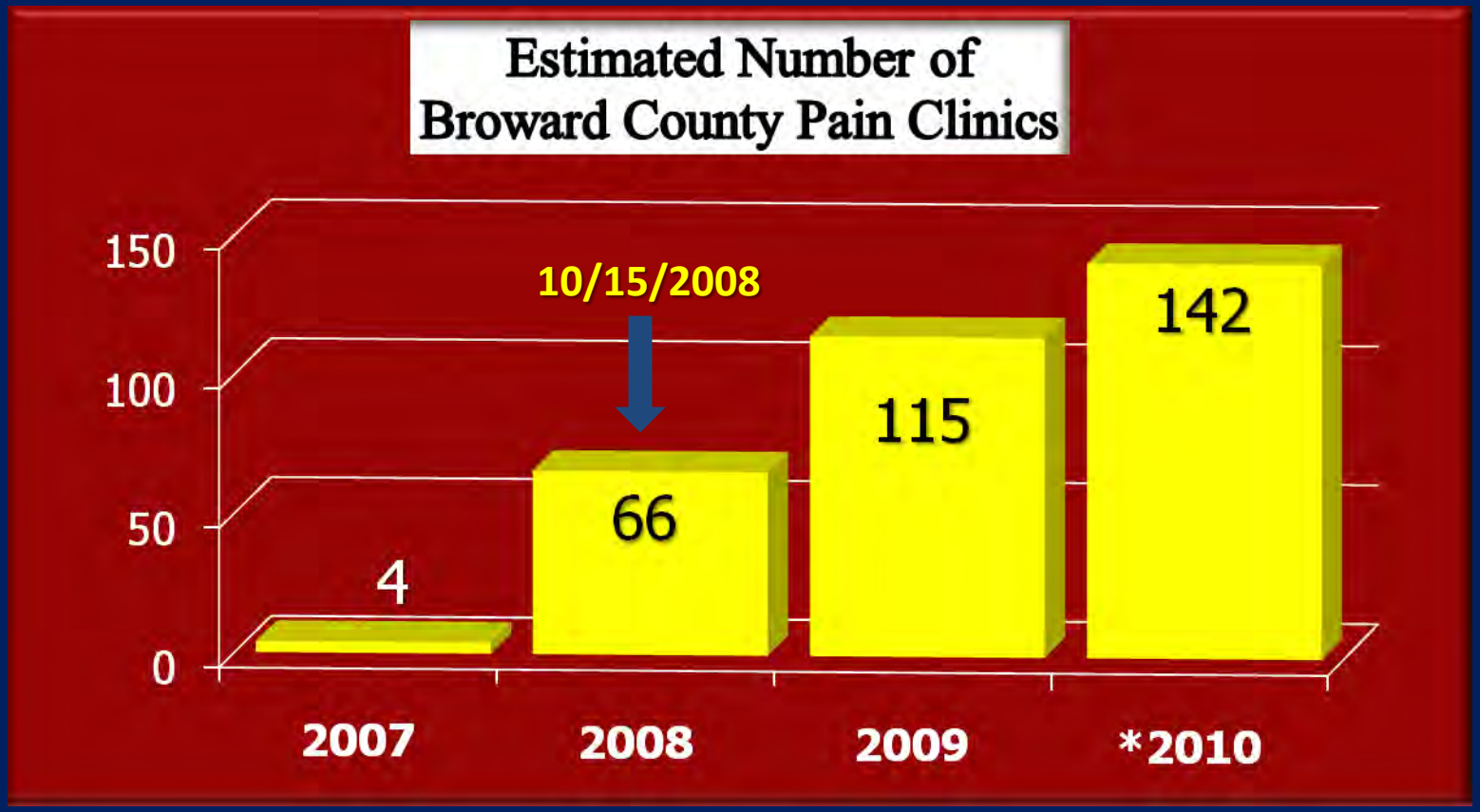
NONE APPROVED

As of June 11, 2015

What took the place of Internet Medical Care and Internet CS pharmaceutical Distribution?

Pain Clinics

Explosion of South Florida Pain Clinics



As of June 4, 2010, Florida has received 1,118 applications and has approved 1026
*As of May 14, 2010, Broward 142; Miami-Dade 79; Palm Beach 111

NFLIS – Federal, State, and local cases reported

	Hydrocodone	Oxycodone
2002	9,376	8,288
2003	12,130	9,715
2004	16,401	13,492
2005	21,190	14,643
2006	24,984	17,927
2007	30,637	22,425
Ryan-Haight → **2008**	33,731	28,756
2009	38,084	38,332
2010	39,444	48,210
2011	37,483	46,906
2012	35,140	42,869
2013*	26,844	31,897

NFLIS Query Date: 02/24/14

Medical Care ?

- Many of these clinics are prescription/dispensing mills
- Minimal practitioner/patient interaction

Increased Law Enforcement Pressure

- Clinics migrating north and west
- Funded by owners in Florida

MIGRATION OF PAIN CLINICS

U.S. Drug Enforcement Administration
Office of Diversion Control

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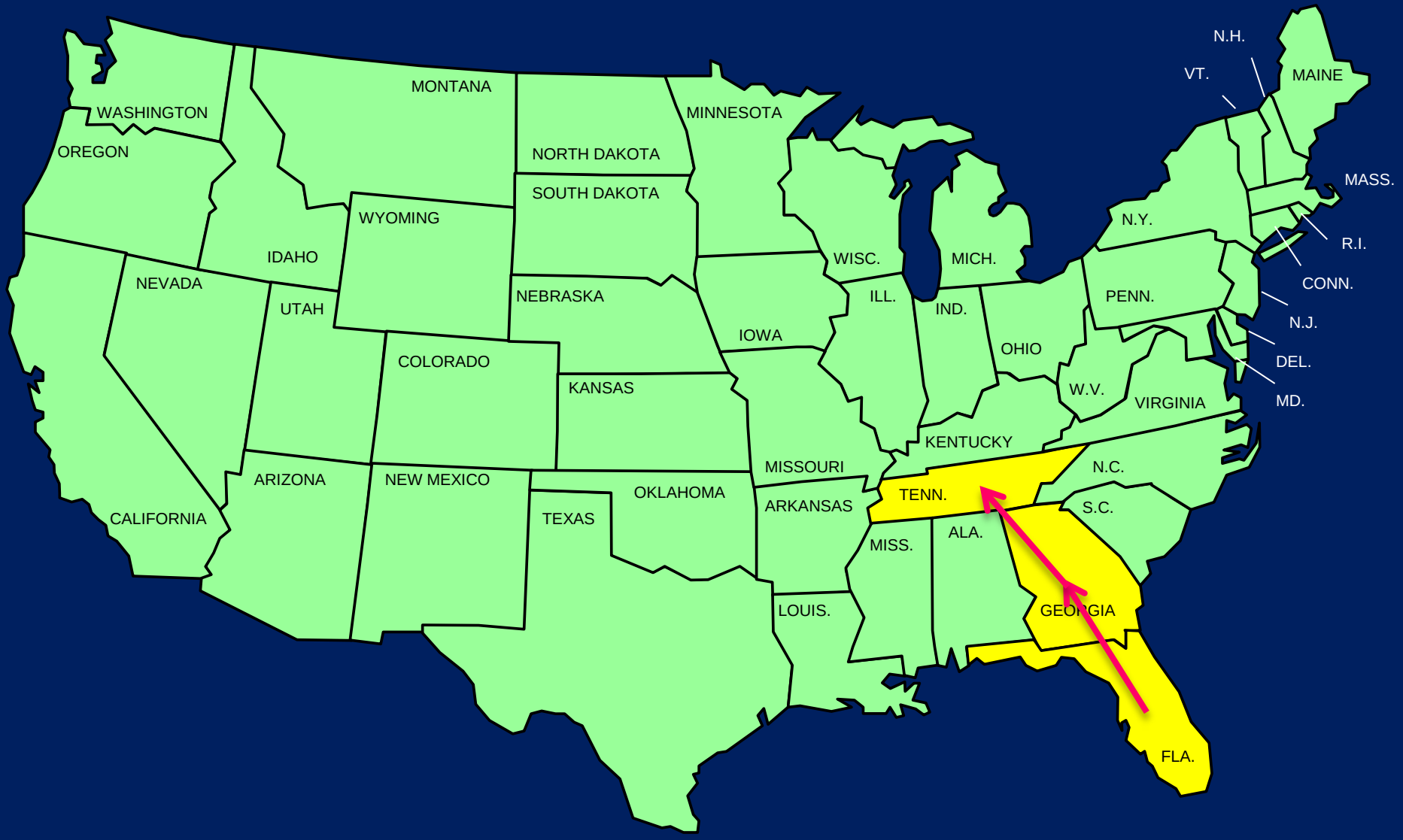
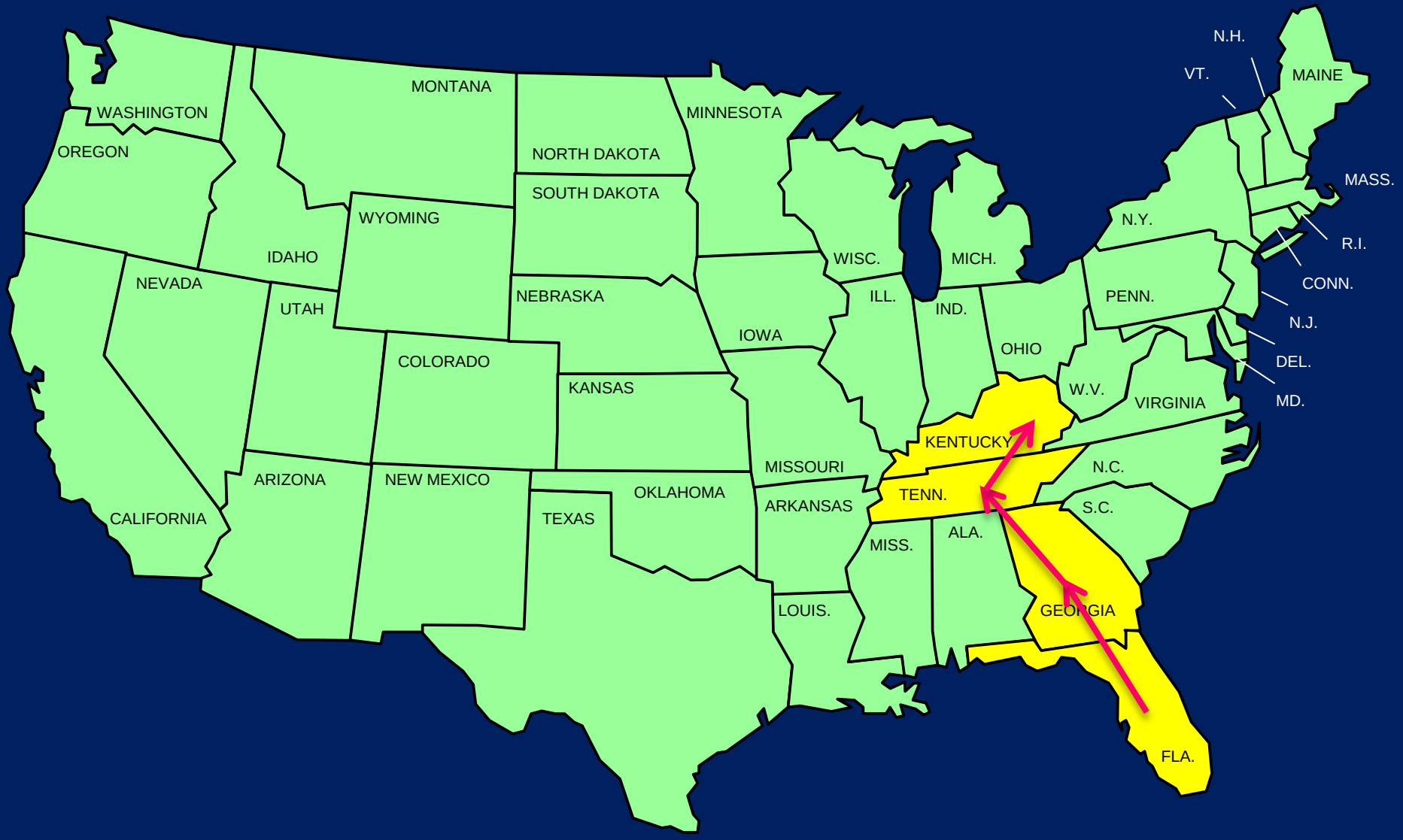
MIGRATION OF PAIN CLINICS



U.S. Drug Enforcement Administration
Office of Diversion Control

MIGRATION OF PAIN CLINICS



U.S. Drug Enforcement Administration
Office of Diversion Control

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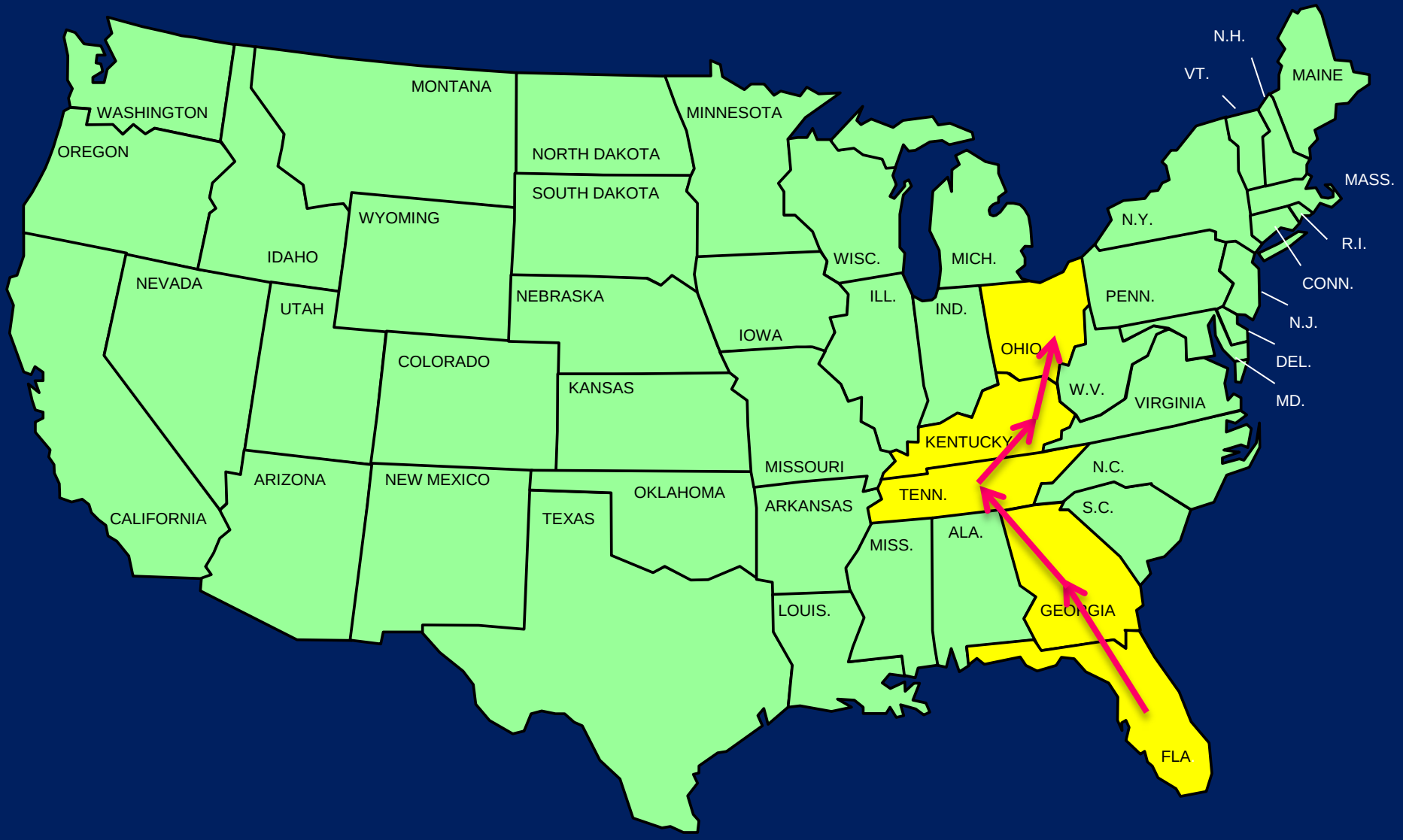

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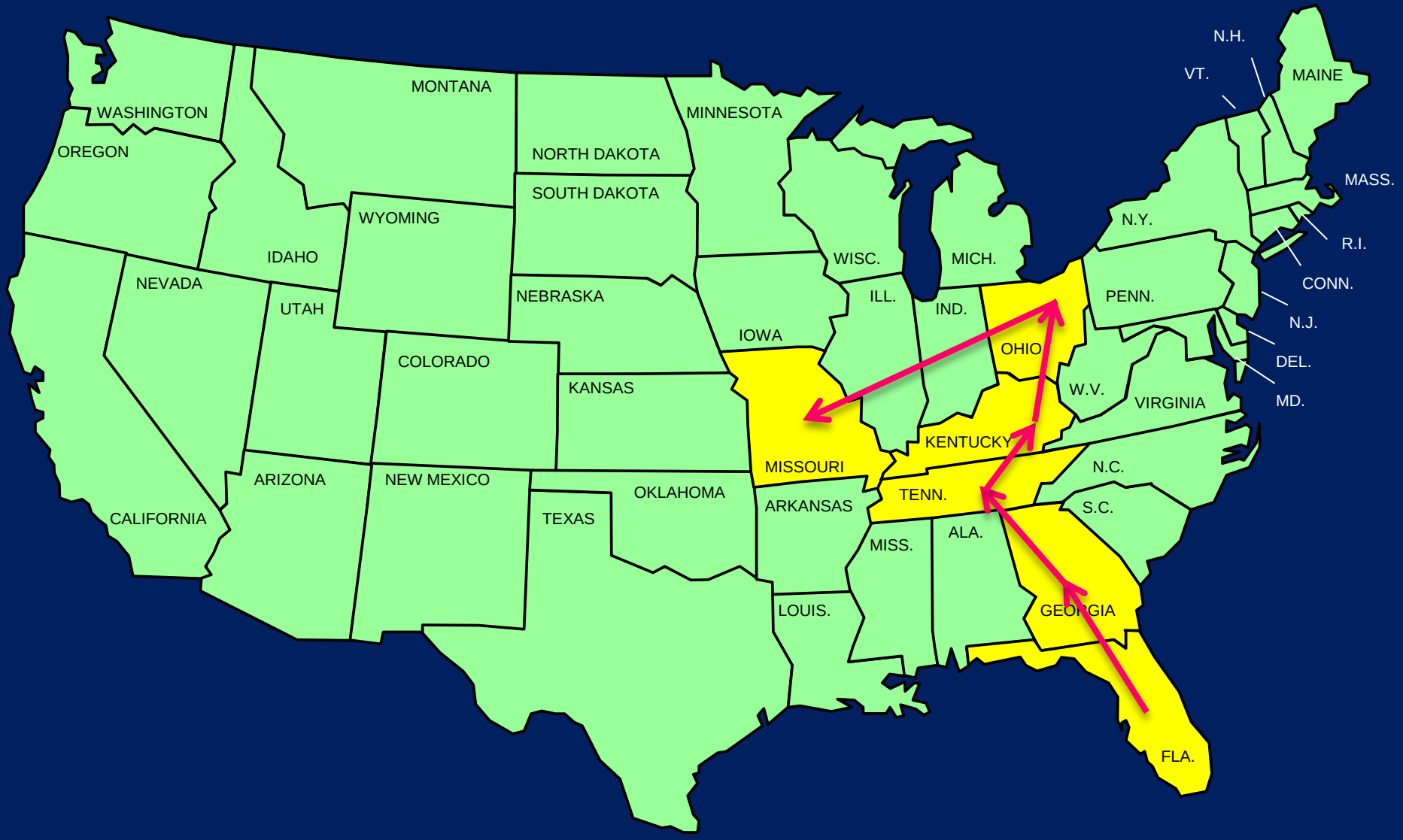


U.S. Drug Enforcement Administration
Office of Diversion Control

Drugs Prescribed

- A ‘cocktail’ of oxycodone and alprazolam (Xanax®)
- An average ‘patient’ receives prescriptions or medications in combination

Schedule II	Schedule III	Schedule IV
Oxycodone 15mg, 30mg	Vicodin (Hydrocodone)	Xanax (Alprazolam)
Roxicodone 15mg, 30mg	Lorcet	Valium (Diazepam)
Percocet	Lortab	
Percodan	Tylenol #3 (codeine)	
Demerol	Tylenol #4 (codeine)	
Methadone		

The Controlled Substances Act

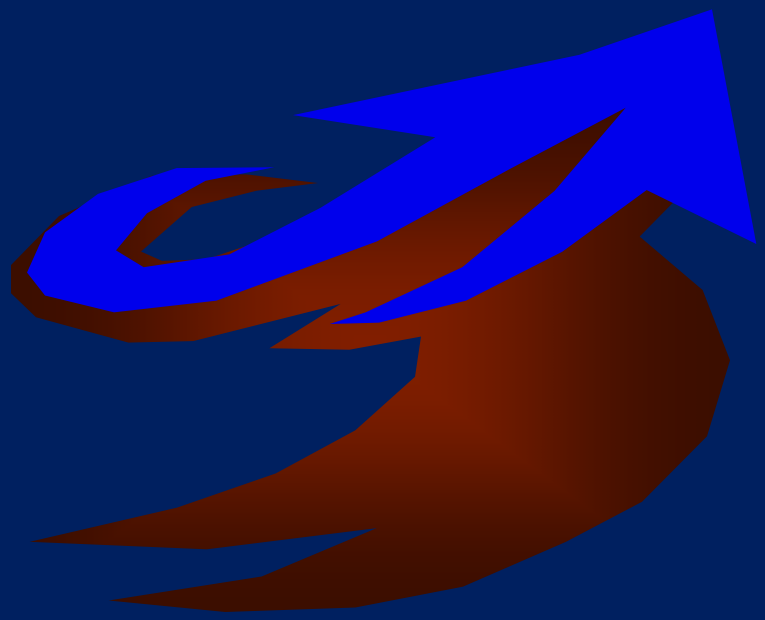
21 United States Code

CSA Registrant Population

Current Number of
DEA Registrants.....

1,582,633

June 12, 2015

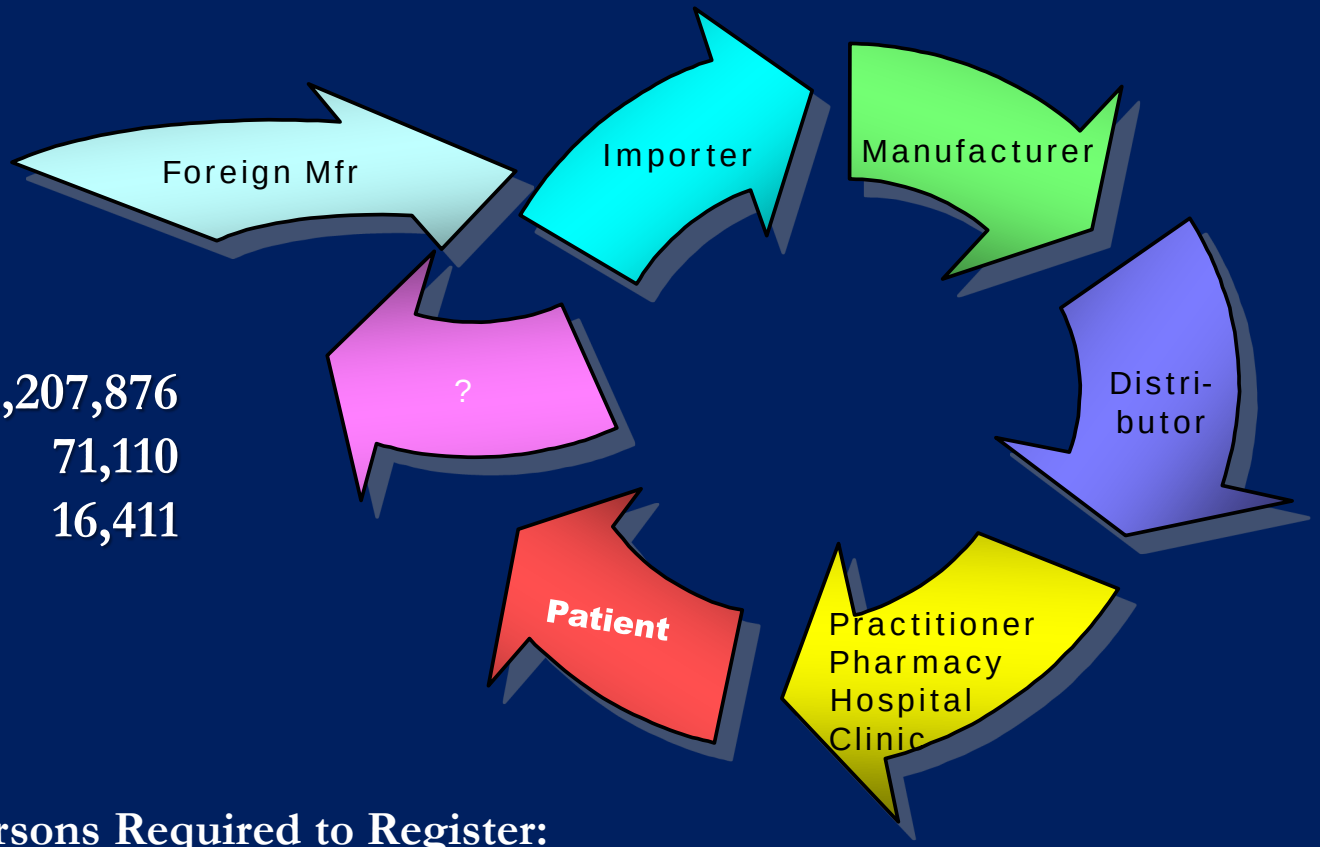


480,000

1973

Provisional registrations in effect at the time CSA was passed (relative to the Harrison Narcotics Act of 1914)

Closed System of Distribution



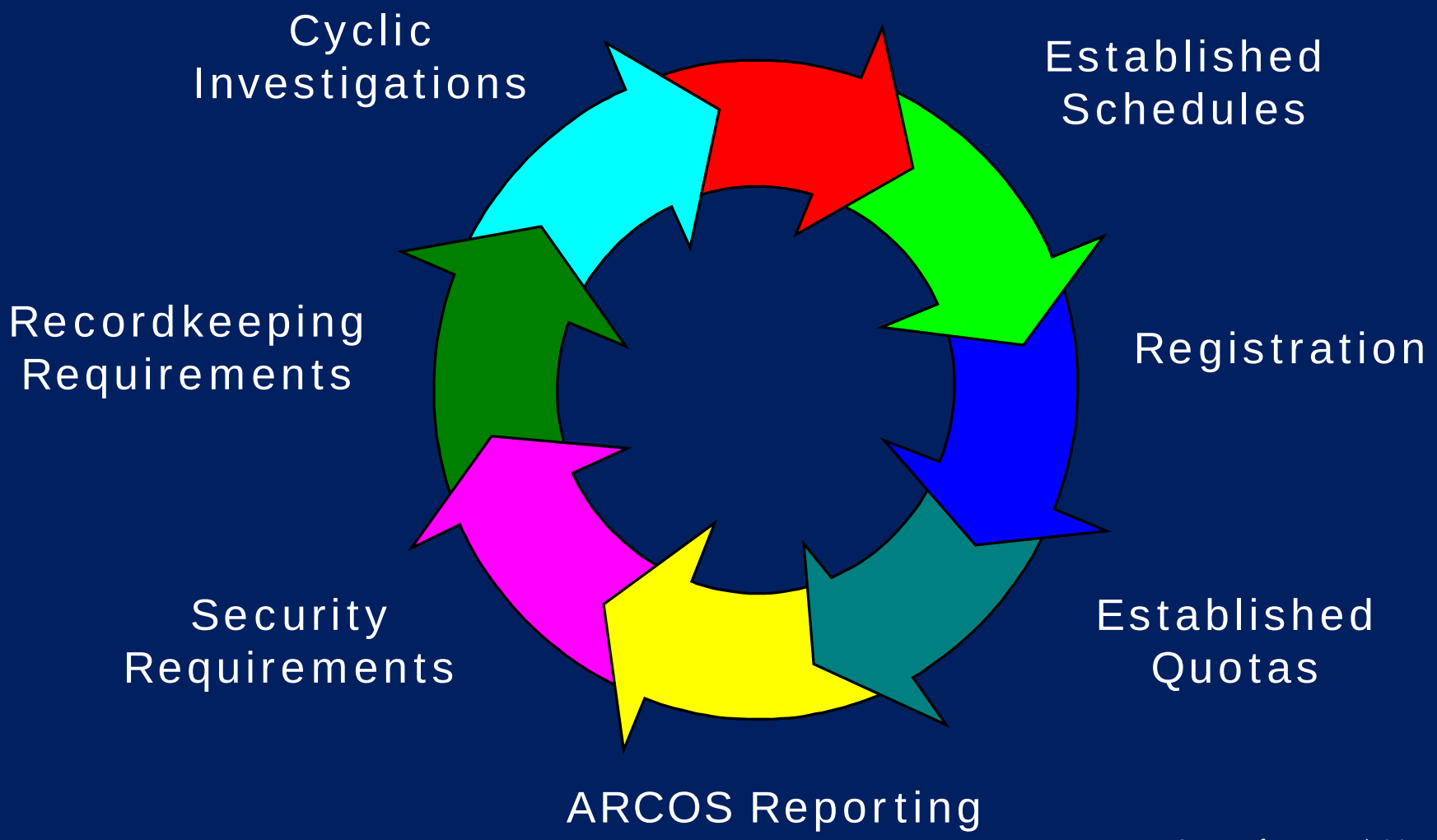
1,582,633 (06/12/15)

Practitioners:	**1,207,876**
Retail Pharmacies:	**71,110**
Hospital/Clinics:	**16,411**

Law: 21 USC 822 (a) (1) Persons Required to Register:
"Every person who manufactures or distributes any Controlled Substance or List I Chemical or who proposes to engage in .."

Law: 21 USC 822 (a) (2) Persons Required to Register:
"Every person who dispenses, or who proposes to dispense any controlled substance ..."

Closed System of Distribution

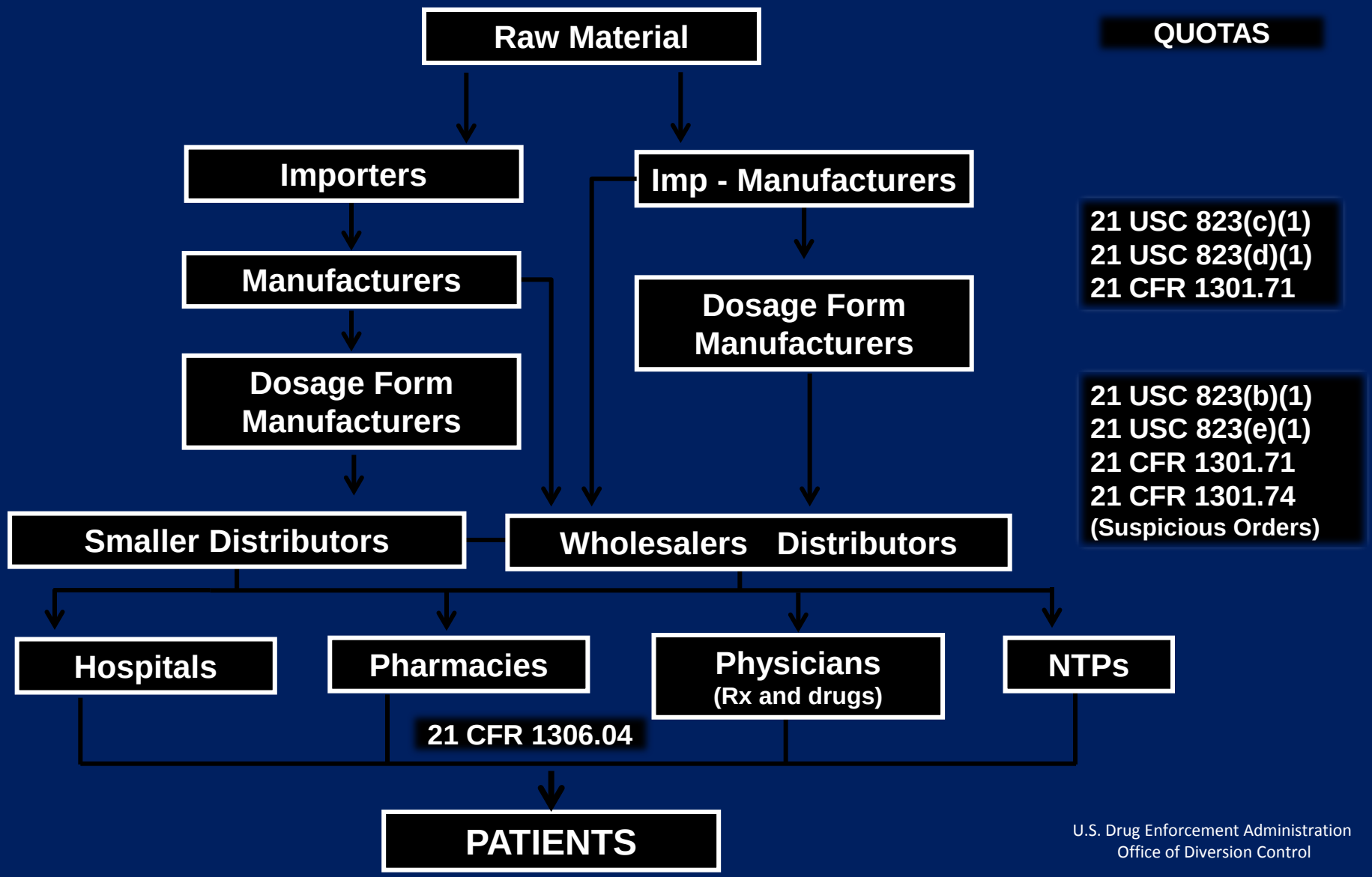


Cutting off the Source of Supply

The Controlled Substances Act

Checks and Balances

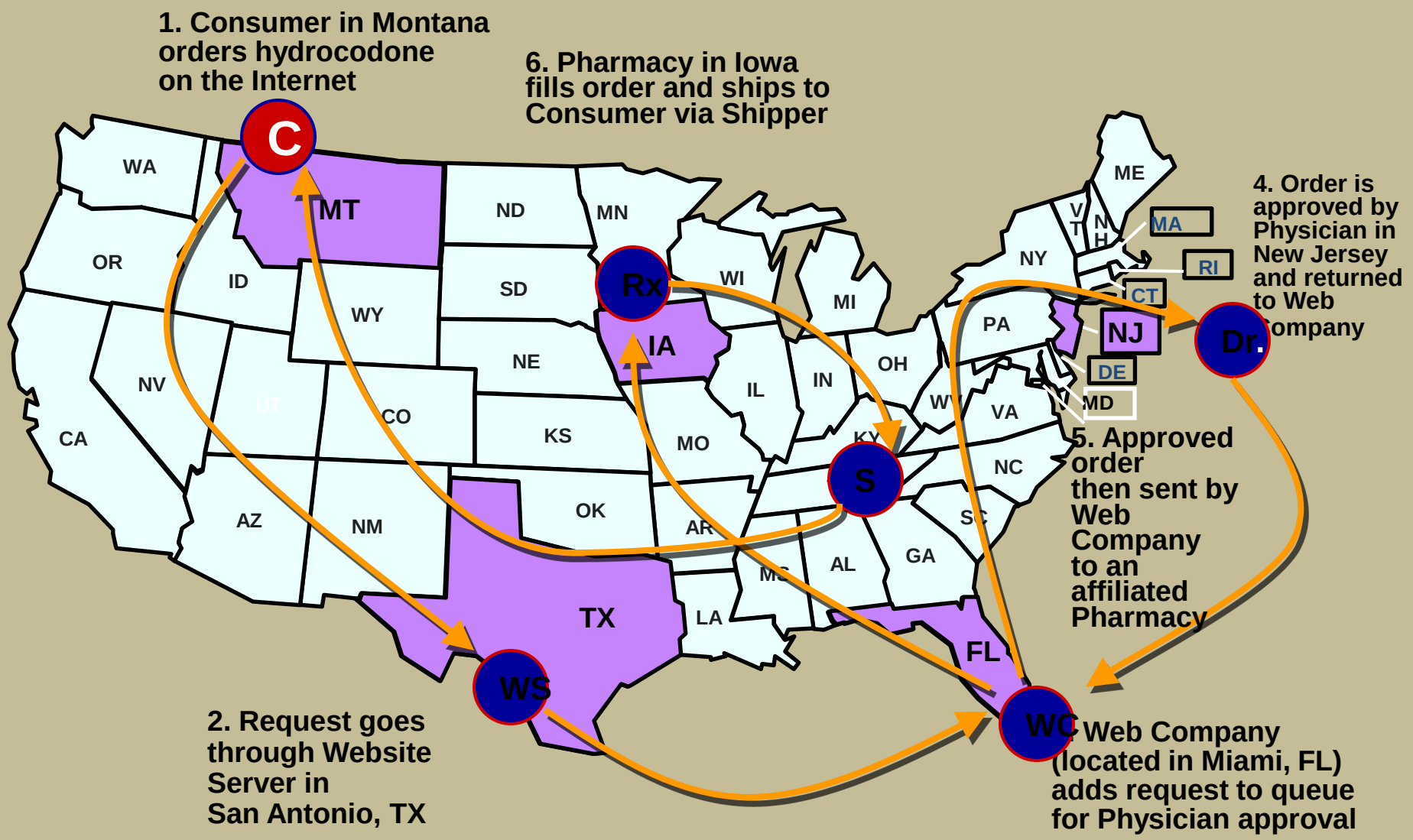
The Flow of Pharmaceuticals



U.S. Drug Enforcement Administration
Office of Diversion Control

Diversion via the Internet

Domestic ‘R_X’ Flow



Checks and Balances of the CSA and the Regulatory Scheme

- **<u>Distributors</u> of controlled substances**

"The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances…Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." **(21 CFR § 1301.74)**

Checks and Balances Under the CSA

- **Practitioners**

"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 professional practice." **(21 CFR § 1306.04(a))**

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

US v. Moore 423 US 122 (1975)

Perfunctory initial physical exam…return visits no exam

Physical exam included needle mark checks…some were simulated

Patient received quantity of drugs requested…were charged based on quantity

Unsupervised urinalysis – results did not matter

Accurate records not kept – quantity dispensed not recorded

Practitioner not authorized to conduct methadone maintenance;

Patient directed prescribing;

The Controlled Substances Act
Illegal Distribution

21 U.S.C. § 841 (a) Unlawful acts:

Except as authorized by this subchapter, it shall be unlawful for any person to knowingly or intentionally

(1) to manufacture, distribute or dispense, or possess with intent to manufacture, distribute or dispense, a controlled substance; or

Pharmacists have a responsibility to protect patients, as well as the public, from the abuse, misuse and diversion of prescription drugs.

2014 AACP Program Material

Checks and Balances Under the CSA

<u>Pharmacists</u> – The Last Line of Defense

"The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."
(21 CFR § 1306.04(a))

U.S v. Hayes 595 F. 2d 258 (5th Cir 1979)

U.S. v. Leal 75 F. 3d 219 (6th Cir 1996)

U.S. v. Birbragher 603 F. 3d 478 (8th Cir 2010)

East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)

Checks and Balances Under the CSA

<u>Pharmacists</u> – The Last Line of Defense

"An order purporting to be a prescription issued not in the course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the act (21 USC 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." **(21 CFR § 1306.04(a))**

U.S v. Hayes 595 F. 2d 258 (5th Cir 1979)

U.S. v. Leal 75 F. 3d 219 (6th Cir 1996)

U.S. v. Birbragher 603 F. 3d 478 (8th Cir 2010)

East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)

The Last Line of Defense

Corresponding Responsibility

When prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescriptions.

(Ralph J. Bertolino, 55 FR 4729, 4730 (1990)),

Corresponding Responsibility Cases

East Main Street Pharmacy; Affirmance of Suspension Order

[Federal Register (Volume 75, Number 207) October 27, 2010
pages 66149-66165] ; see also Paul H. Volkman 73 FR 30630, 30642 (2008)

Holiday CVS, L.L.C, d/b/a CVS/Pharmacy Nos. 219 and 5195; Decision and order

[Federal Register Volume 77, Number 198 (Friday October 12, 2012) pages 62315-62346]

Potential Red Flags

Many customers receiving the same combination of prescriptions; cocktail

Many customers receiving the same strength of controlled substances; no individualized dosing: multiple prescriptions for the strongest dose

Many customers paying cash for their prescriptions

Early refills

Many customers with the same diagnosis codes written on their prescriptions;

Individuals driving long distances to visit physicians and/or to fill prescriptions;

Potential Red Flags continued

Customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and

Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).

Overwhelming proportion of prescriptions filled by pharmacy are controlled substances

Pharmacist did not reach out to other pharmacists to determine why they were not filling a particular doctor's prescription

Verification of legitimacy not satisfied by a call to the doctors office

Red Flag?

What happens next?

You attempt to resolve…

Resolution is comprised of many factors

- Verification of a valid practitioner DEA number ! It is not, however, the end of the pharmacist's duty. Invalid DEA number = Invalid RX
- Resolution cannot be based solely on patient ID and prescriber verification.
- You must use your professional judgment, training and experience…we all make mistakes
- Knowledge and history with the patient
- Circumstances of prescription presentation
- Experience with the prescribing practitioner
- It does not require a call to the practitioner for every CS RX
- This is not an all-inclusive list…

Who do I call to report a practitioner?

- State Board of Pharmacy/Medicine/Nursing/Dental
- State/County/Local Police
- DEA local office and Tactical Diversion Squad
- Health department
- HHS OIG if Medicare/Medicaid fraud

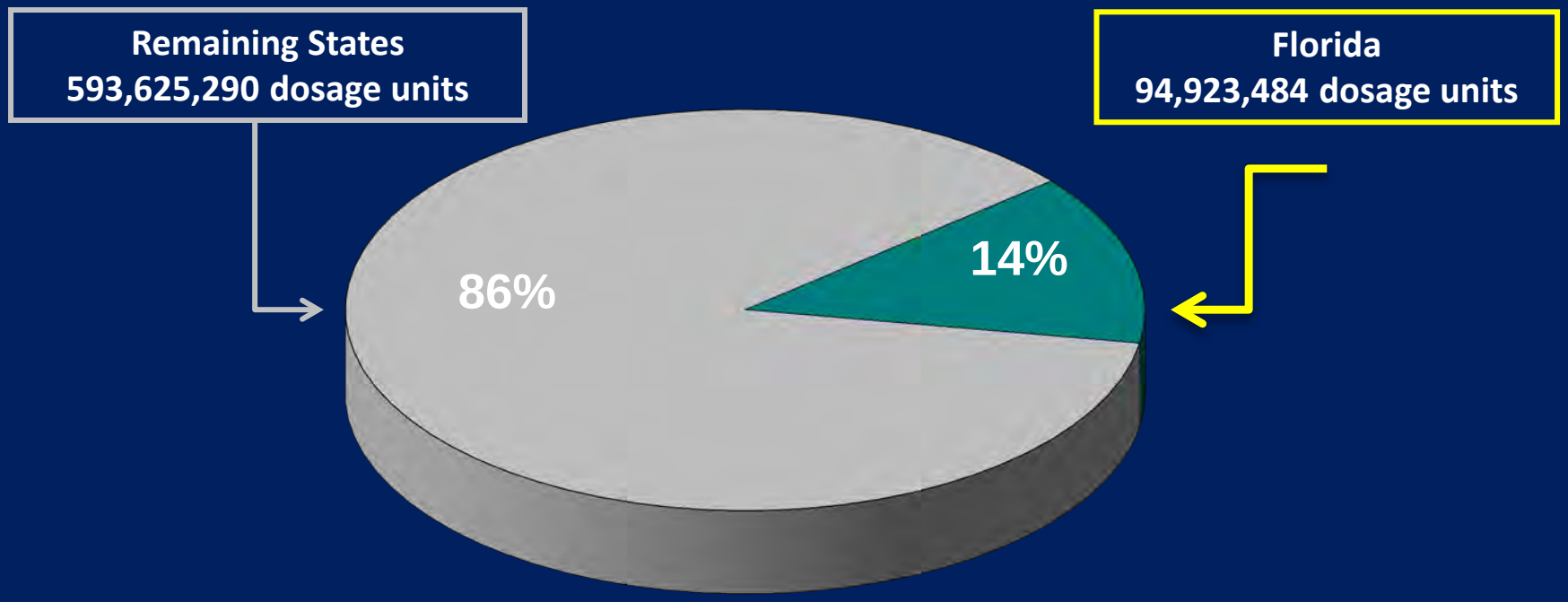
Practical Application of the Controlled Substances Act to the Current Rogue Pain Clinic Situation

What can happen when these checks and balances collapse and diversion occurs?

Purchases of Oxycodone 30mg

- In 2009, 44% of all oxycodone 30mg products were distributed to Florida
- In 2010, 43% of all oxycodone 30mg products were distributed to Florida

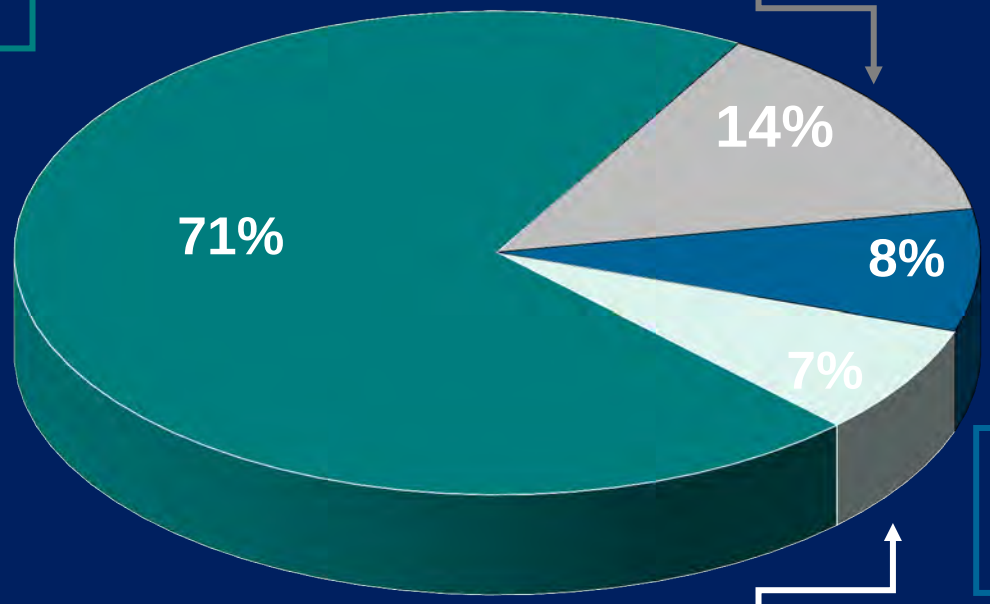
Nationwide Distribution of Oxycodone 30mg
January – December, 2012



Source: ARCOS
Date Prepared: 01/30/2014

U.S. Drug Enforcement Administration
Office of Diversion Control

Nationwide Distribution of Oxycodone 30mg
January – December, 2012



Source: ARCOS
Date Prepared: 01/30/2014

U.S. Drug Enforcement Administration
Office of Diversion Control

Drug Dealers Masquerading as Doctors

Paul Volkman, Chicago Doctor, Gets 4 Life Terms In Drug Overdose Case

ANDREW WELSH-HUGGINS 02/14/12 06:45 PM ET Associated Press

COLUMBUS, Ohio — A Chicago doctor who prosecutors say dispensed more of the powerful painkiller oxycodone from 2003 to 2005 than any other physician in the country was sentenced Tuesday to four life terms in the overdose deaths of four patients.

Dr. Paul Volkman made weekly trips from Chicago to three locations in Portsmouth in southern Ohio and one in Chillicothe in central Ohio before federal investigators shut down the operations in 2006, prosecutors said. He was sentenced in federal court in Cincinnati.

"This criminal conduct had devastating consequences to the community Volkman was supposed to serve," Assistant U.S. Attorneys Adam Wright and Tim Oakley said in a court filing ahead of Tuesday's hearing.

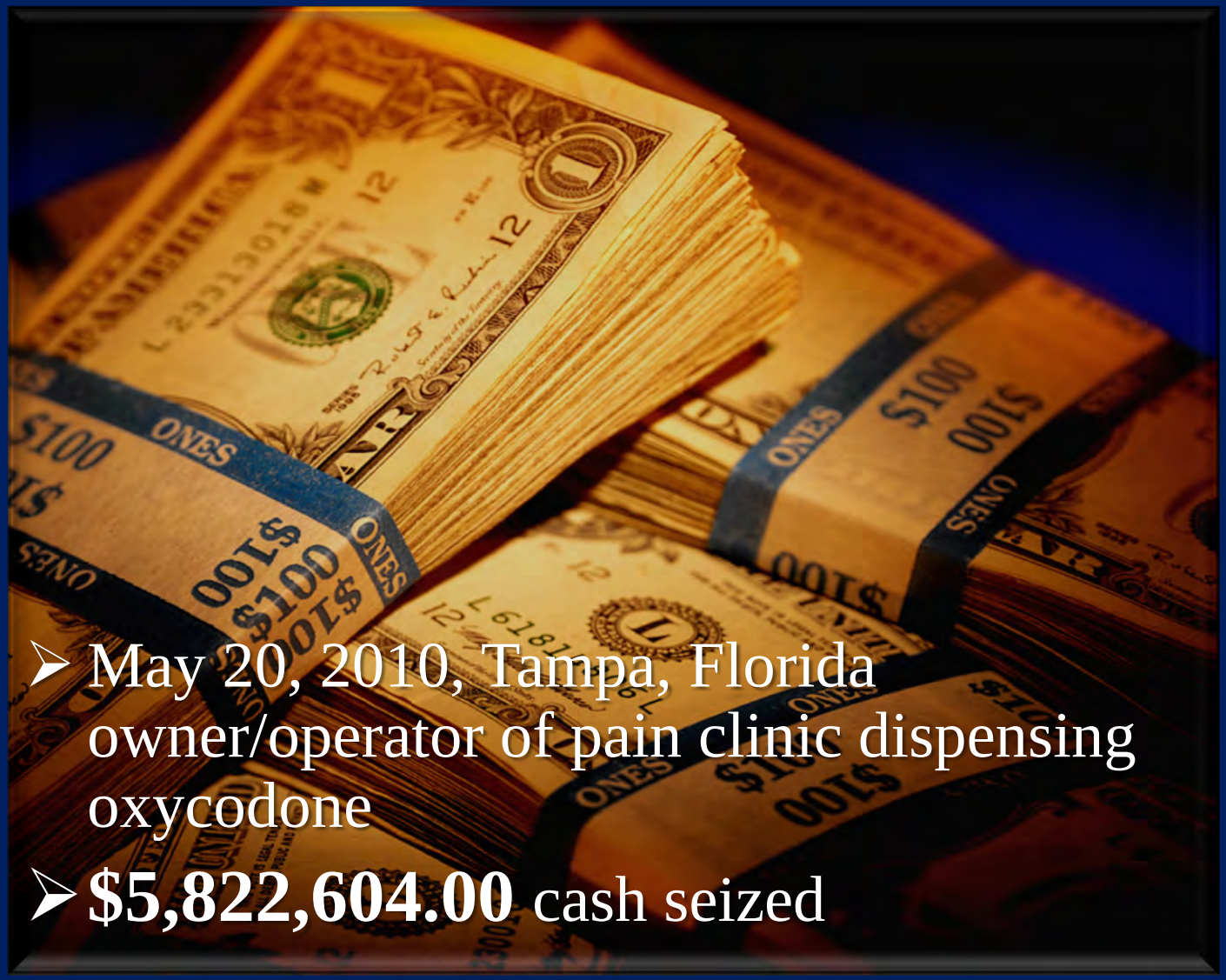
"Volkman's actions created and prolonged debilitating addictions; distributed countless drugs to be sold on the street; and took the lives of numerous individuals who died just days after visiting him," they said.

The 64-year-old Volkman fired his attorneys earlier this month and said he acted at all times as a doctor, not a drug dealer.

"The typical drug dealer does not care how much drugs a client buys, how often he buys, or what he does with his drugs," Volkman said in a 28-page handwritten court filing Monday, maintaining that he did all those things and more for his patients.

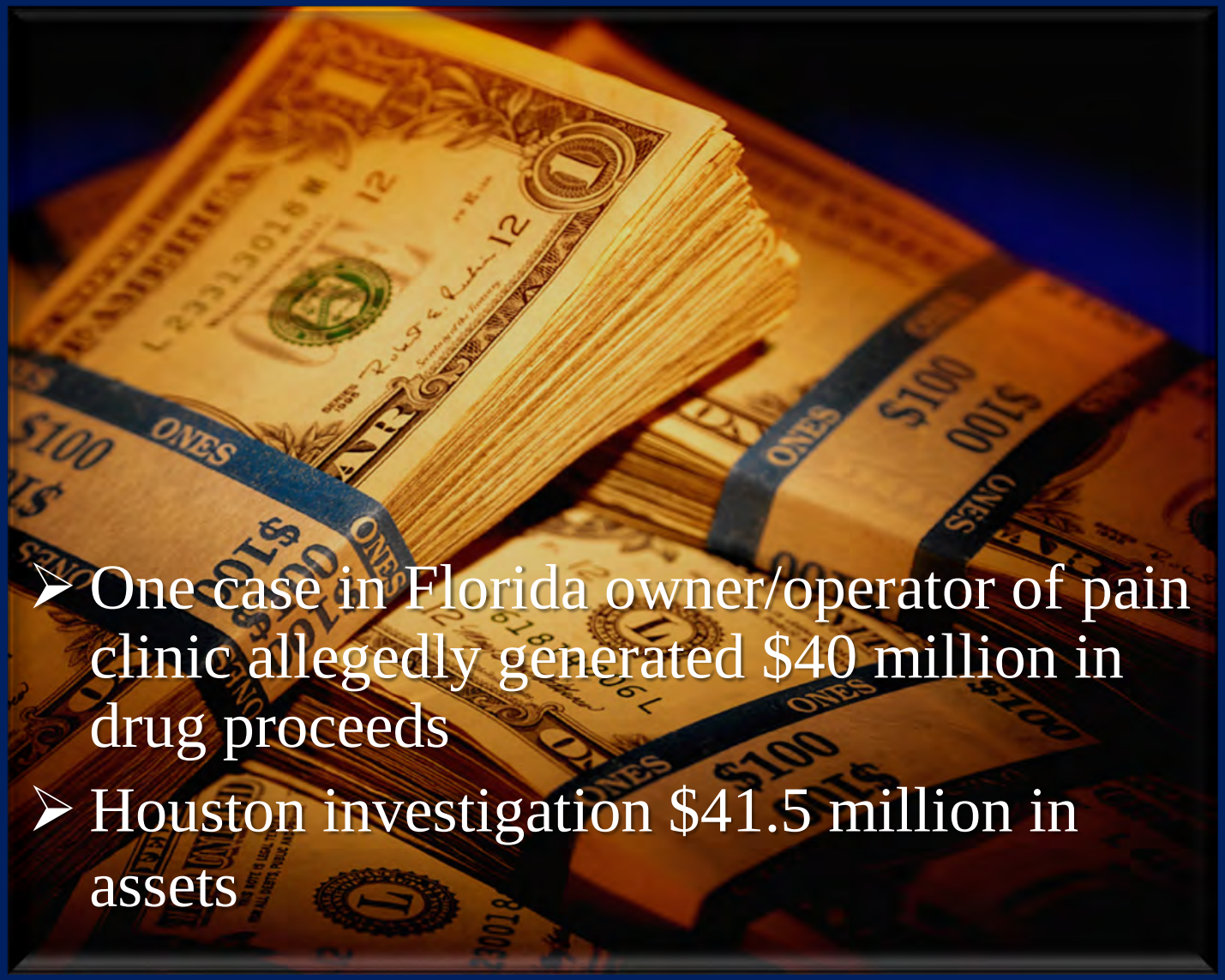
Why is this happening?

What's the Profit?



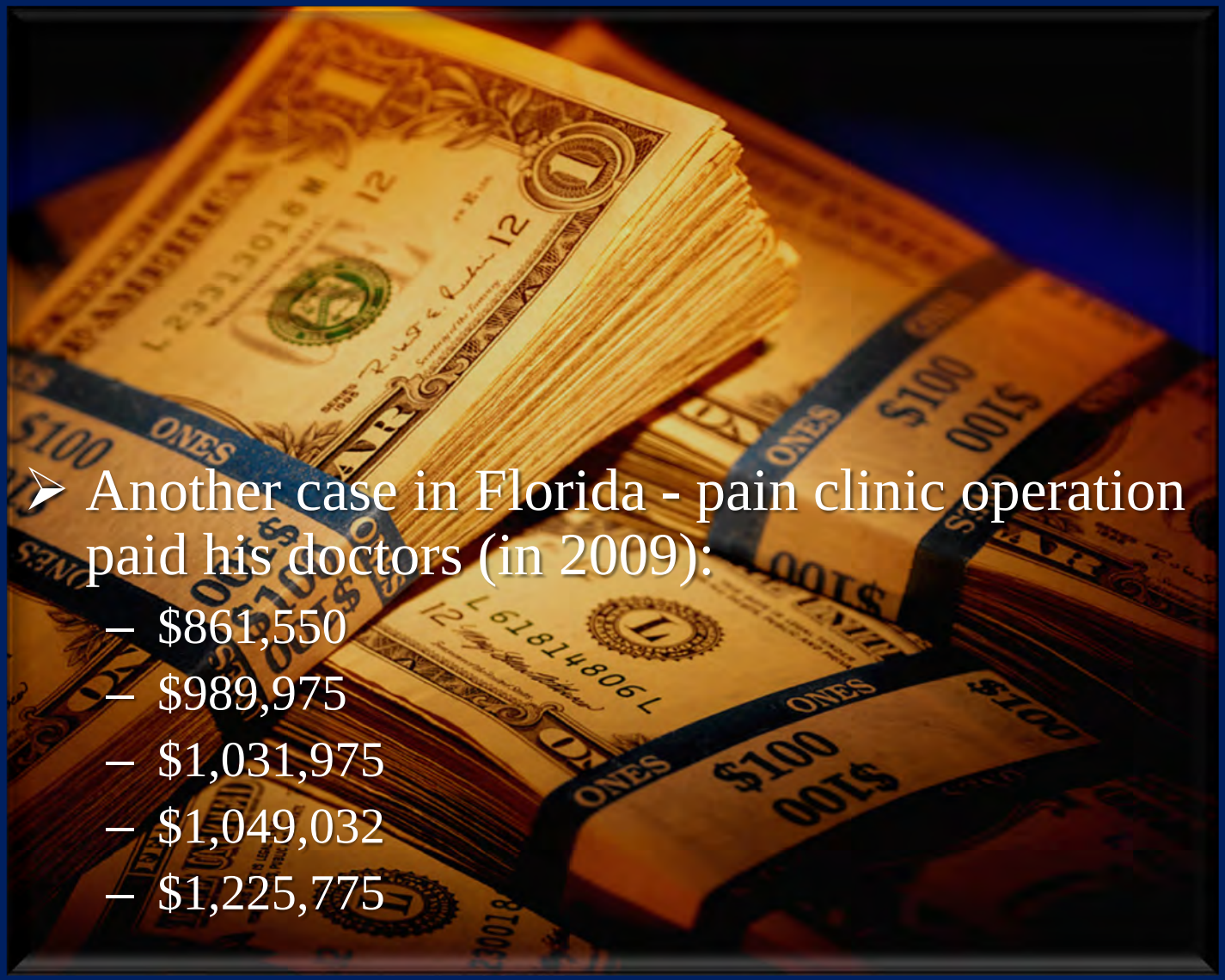
- May 20, 2010, Tampa, Florida owner/operator of pain clinic dispensing oxycodone
- **$5,822,604.00** cash seized

What's the Profit?



- One case in Florida owner/operator of pain clinic allegedly generated $40 million in drug proceeds
- Houston investigation $41.5 million in assets

What's the Profit?



- Another case in Florida - pain clinic operation paid his doctors (in 2009):
  - $861,550
  - $989,975
  - $1,031,975
  - $1,049,032
  - $1,225,775

Deaths Associated with Rx Drugs in Florida

Reports of Rx Drugs Detected in Deceased Persons and Cause of Death									
Drug	2005	2006	2007	2008	2009	2010	2011	2012	2013
Methadone	620	716	785	693	720	694	691	512	389
Oxycodone	340	496	705	941	1,185	1,516	1,247	735	534
Hydrocodone	221	236	264	270	265	315	307	244	291
Benzodiazepines	574	553	743	929	1,099	1,304	1,950	1,337*	1091
Morphine	247	229	255	300	302	262	345	415	568
TOTAL	2,002	2,230	2,752	3,133	3,571	4,091	6,551	5,255	

* Many of the deaths were found to have several drugs contributing to the cause of death, thus, the count of specific drugs is greater than the number of cases. In report years 2010 and earlier, drug categories as a whole had included the total number of deaths per category, as well as total deaths per each specific drug. For example, in 2010, benzodiazepenes were the cause of death in 1,304 cases. However, benzodiazepenes were present 1,726 times in those 1,304 deaths (i.e., a single death could have been caused by multiple benzodiazepenes). Report year 2011 does not provide a total per category (i.e., cause vs present).

SOURCE: Florida Medical Examiner's Commission

19 Manatees Rescued From Storm Drain in Satellite Beach, Florida

Crews Battle to Free Manatees From Drainage Pipe

NBC NEWS

A group of 19 manatees was freed after being trapped in a 36-inch storm drain, officials said early Tuesday.

www.nbcnews.com/news/us-news/19-manatees-rescued-storm-drain-satellite-beach-florida-n311506,

Questions

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DRUG ENFORCEMENT ADMINISTRATION
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Thank You!