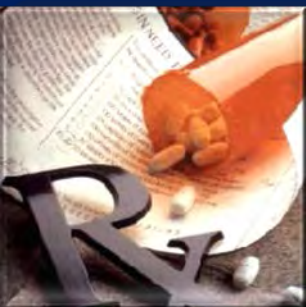




The United States Department of Justice

**Drug Enforcement Administration**



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

Nevada Pharmacy Diversion Awareness Conference  
National Association of Boards of Pharmacy (NABP)  
Nevada Board of Pharmacy  
Drug Enforcement Administration

**South Point Casino and Resort  
Las Vegas, Nevada  
February 7/8, 2015**

Joseph Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control



# 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
- 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 law enforcement role in preventing abuse and trafficking
- Discuss disposal regulations



# Responding to America's Prescription Drug Abuse Crisis

*“When Two Addictions Collide”*

Pharmaceuticals

Money - Greed





*Primum non nocere*



Prescription Drug Abuse  
is driven by

Indiscriminate Prescribing  
Criminal Activity



# Nothing New : Bad Doctors, “Pill Mills”, & Rogue Pain Clinics Have Been Around a Long Time !





# **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 12<sup>th</sup> consecutive year)<sup>1</sup>

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.

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



# 2011 Current Users (Past Month) 2012

ANY ILLICIT DRUG:  
22.5 million

MARIJUANA: 18.1 million

PSYCHOTHERAPEUTIC  
DRUGS: 6.1 million

COCAINE: 1.4 million

Methamphetamine 439,000

Heroin: 281,000



ANY ILLICIT DRUG:  
23.9 million

MARIJUANA: 18.9 million

PSYCHOTHERAPEUTIC  
DRUGS: 6.8 million

COCAINE: 1.6 million

Methamphetamine 440,000

Heroin: 335,000

Source: 2011 & 2012 NSDUH



# Prescription Drug Abuse

More Americans abuse prescription drugs than the number of:

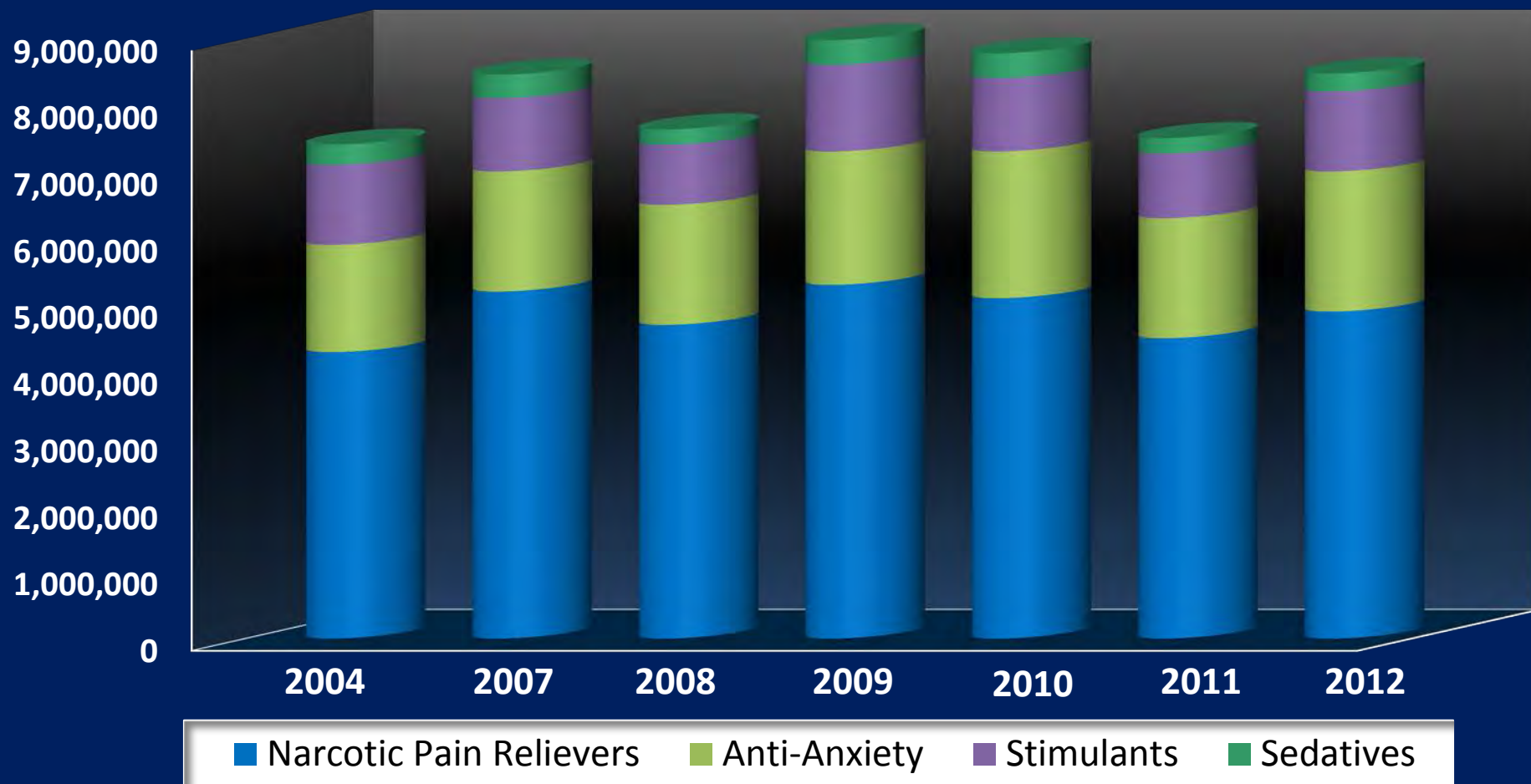
Cocaine, Hallucinogen, Heroin, and Inhalant abusers

**COMBINED!!!**





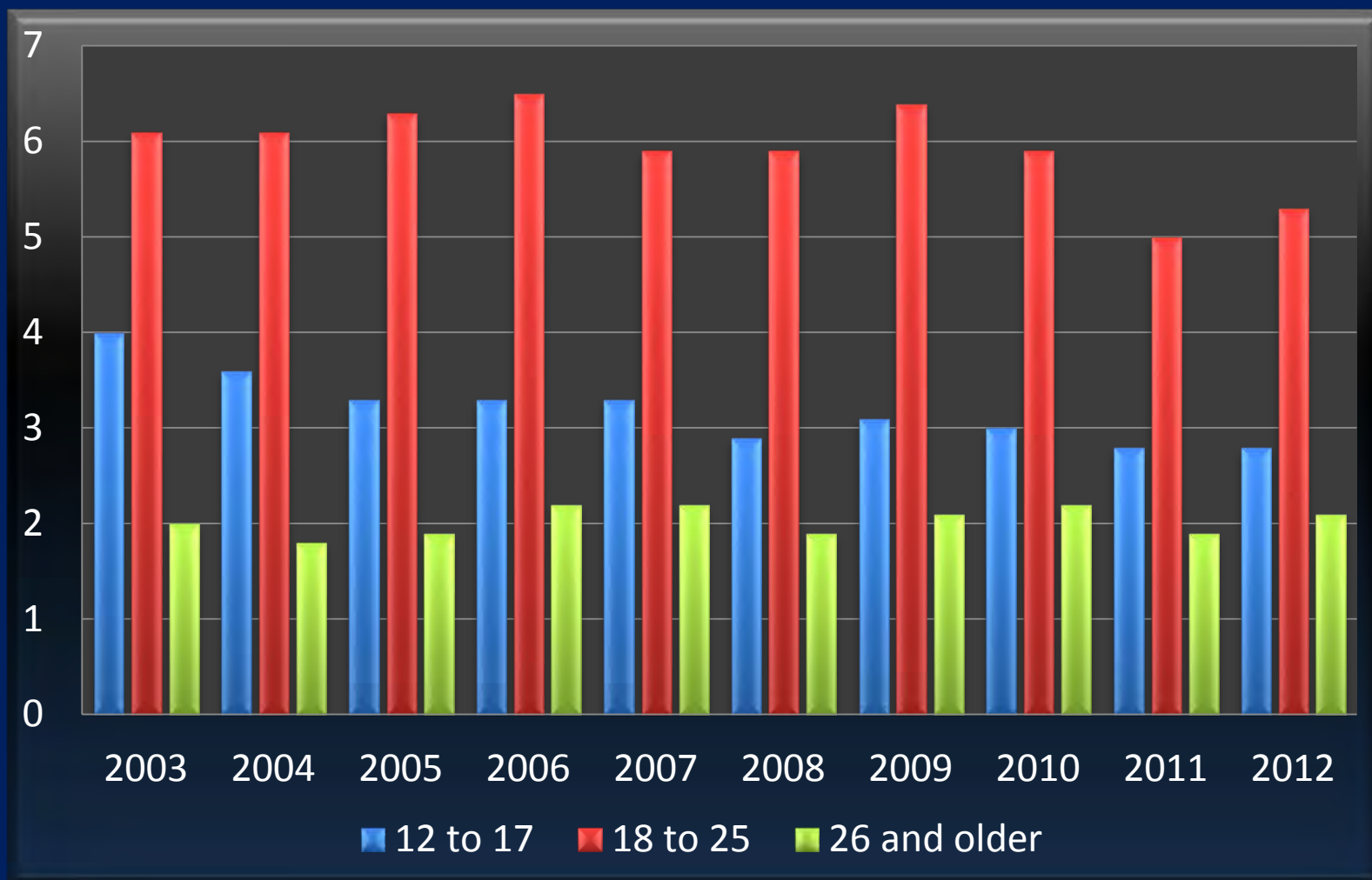
# Scope and Extent of Problem: Past Month Illicit Drug Use among Persons Aged 12 or Older







# Percentage of Past Month Nonmedical Use of Psychotherapeutics by Age, 2003-2012

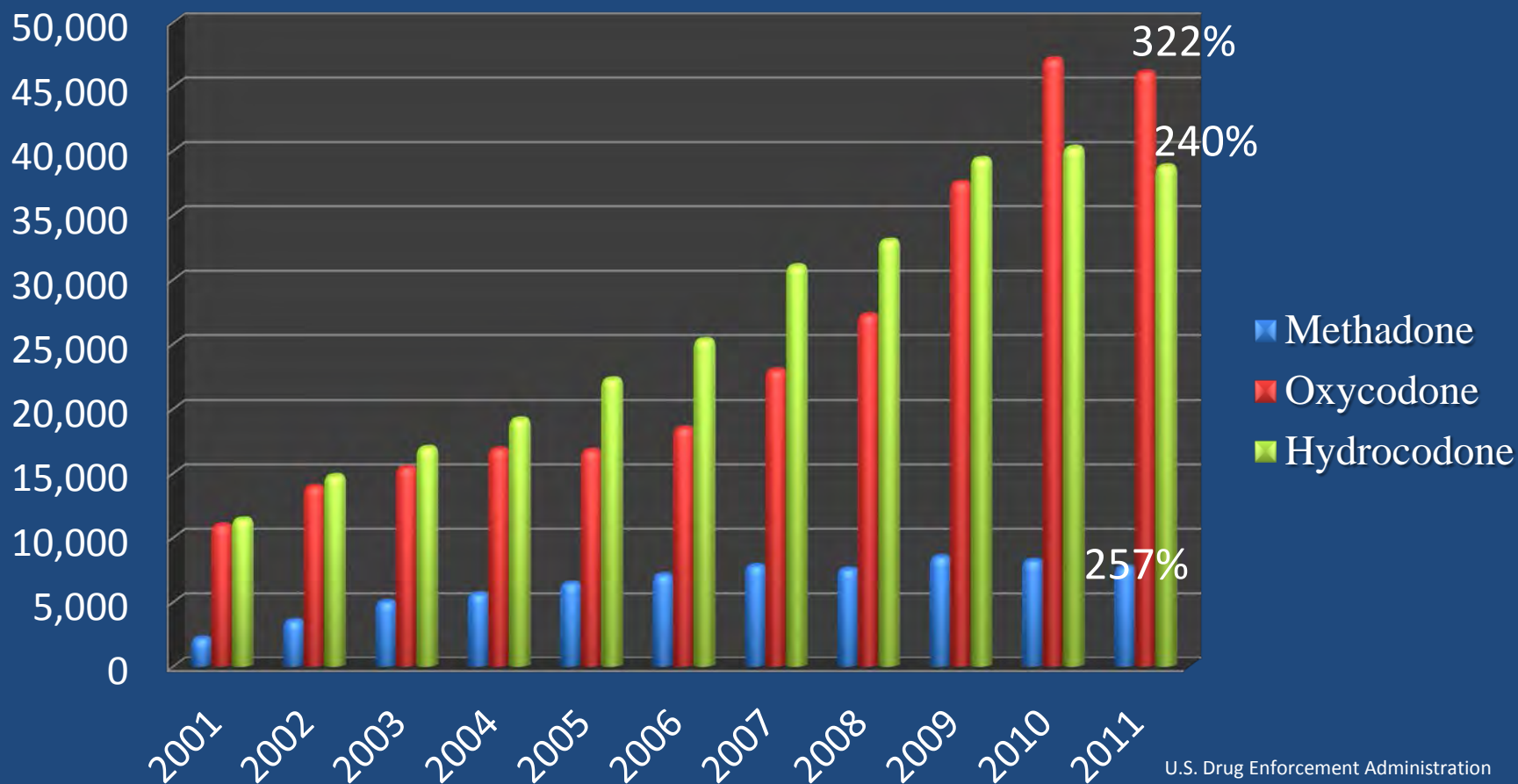




# Number of Forensic Cases 2001-2011

NFLIS

Estimated U.S. Law Enforcement Encounters





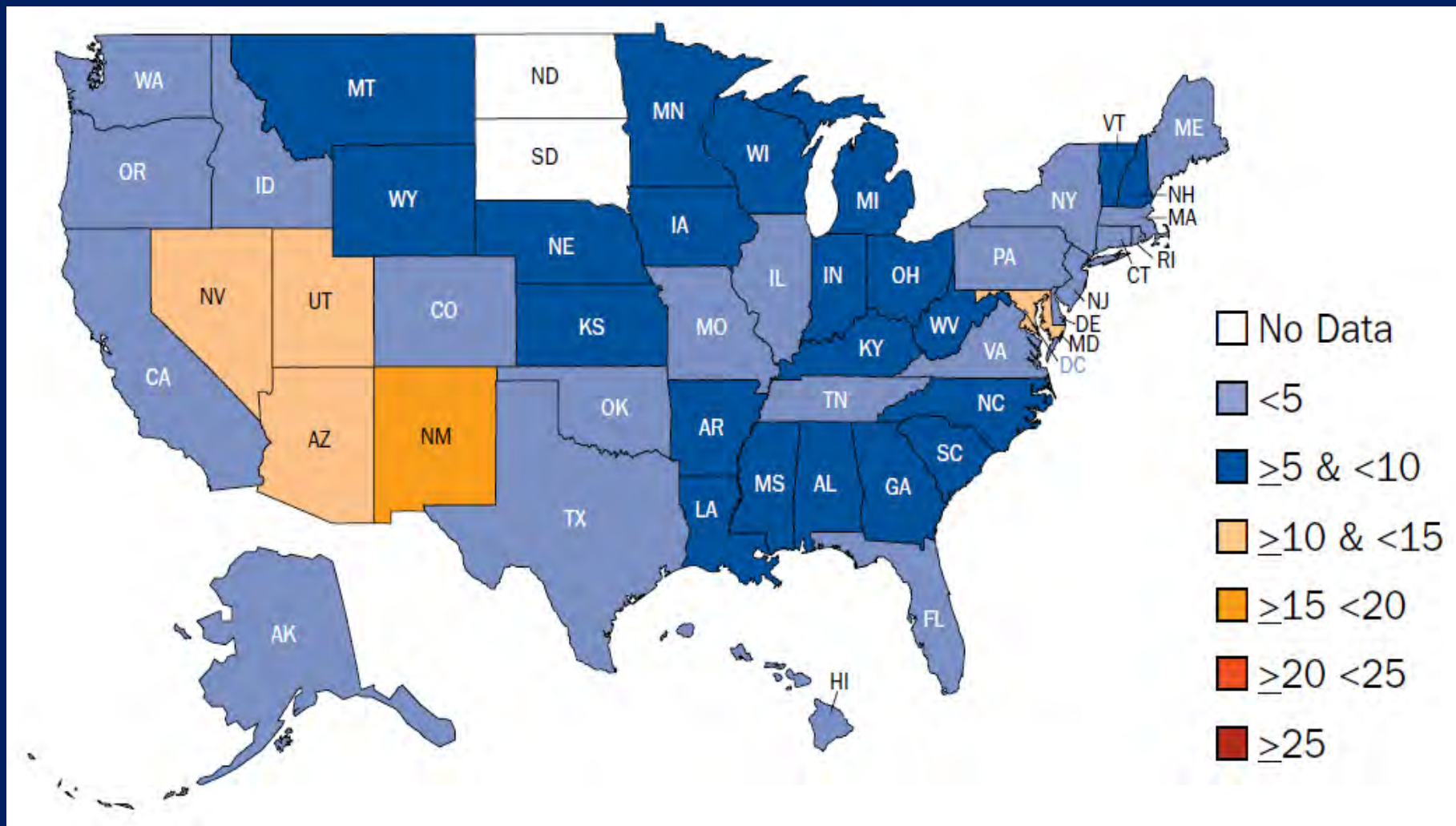
# Questions to Discuss

➤ According to the National Survey on Drug Use and Health (NSDUH), in 2012 there were 6.8 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

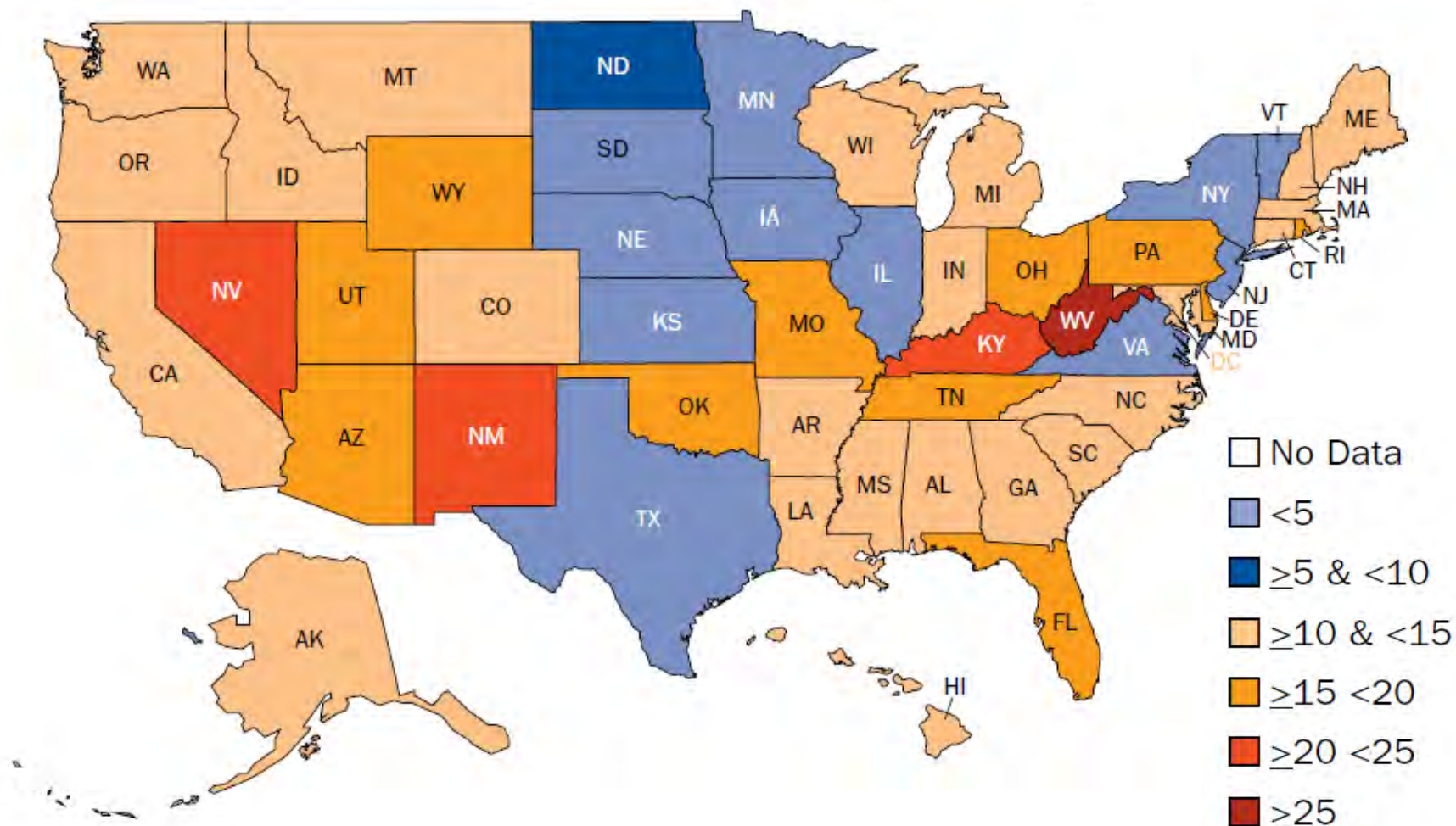


# Drug Overdose Mortality Rates per 100,000 People 1999





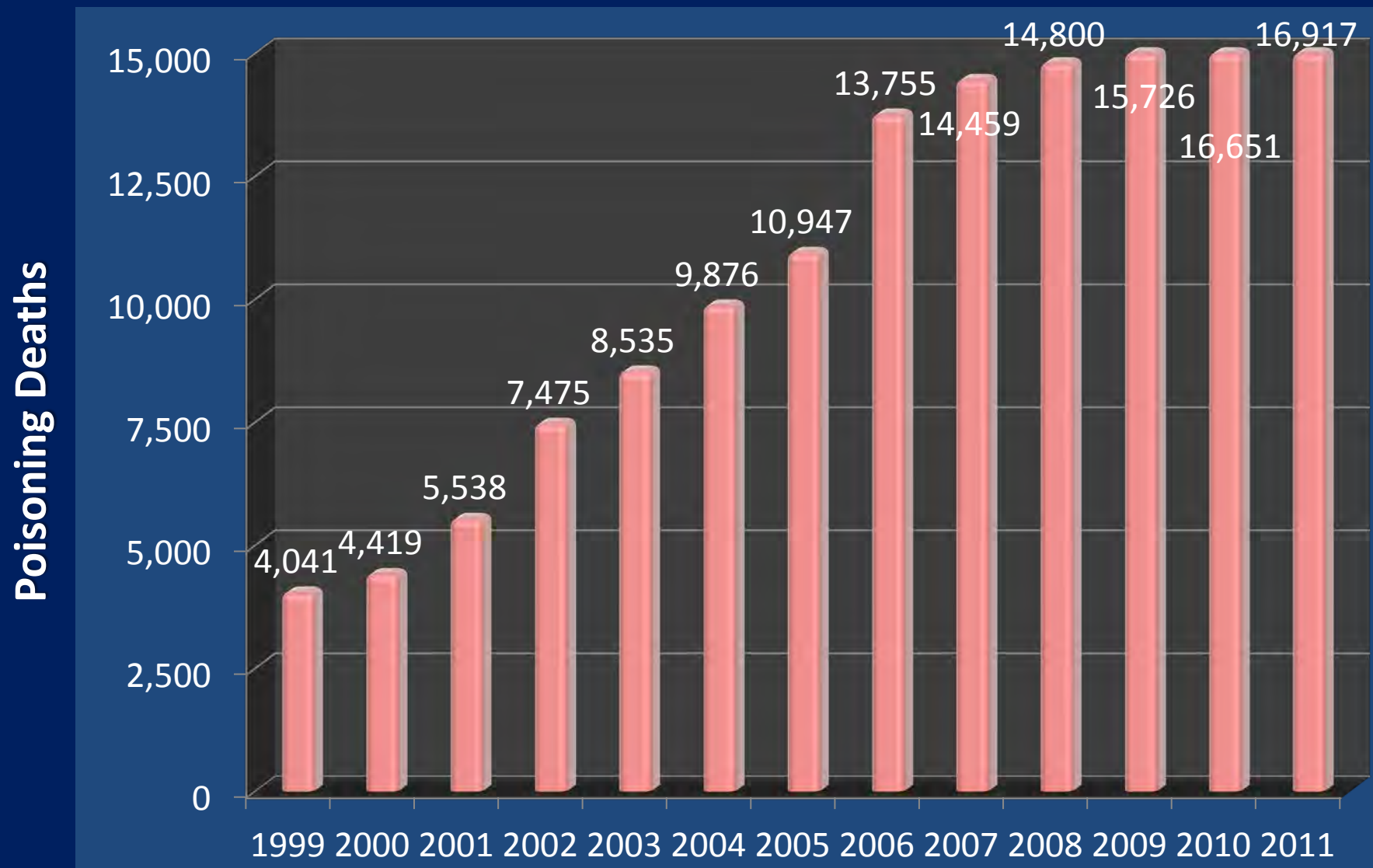
# Drug Overdose Mortality Rates per 100,000 People 2010





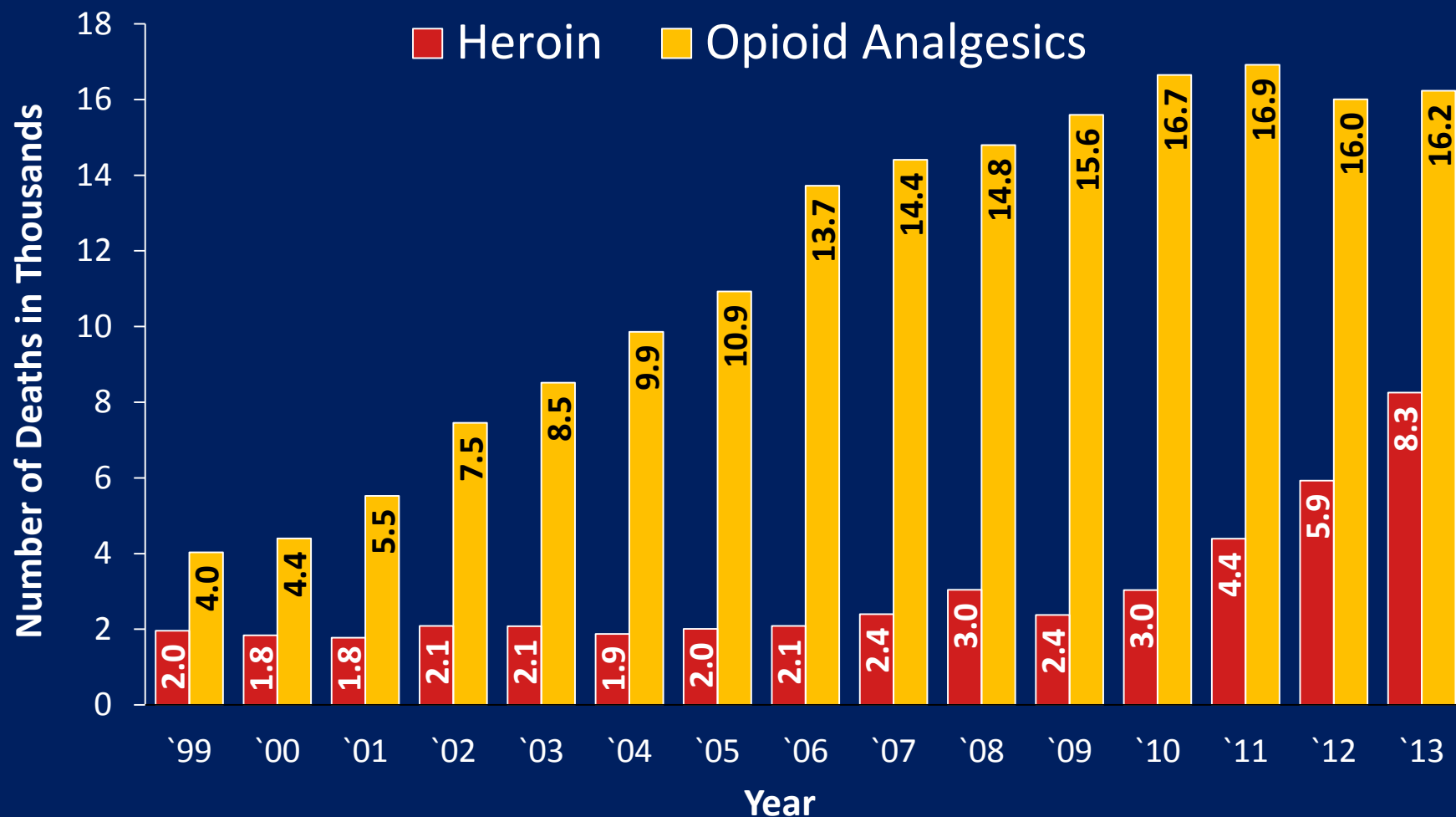


# Poisoning Deaths: Opioid Analgesics



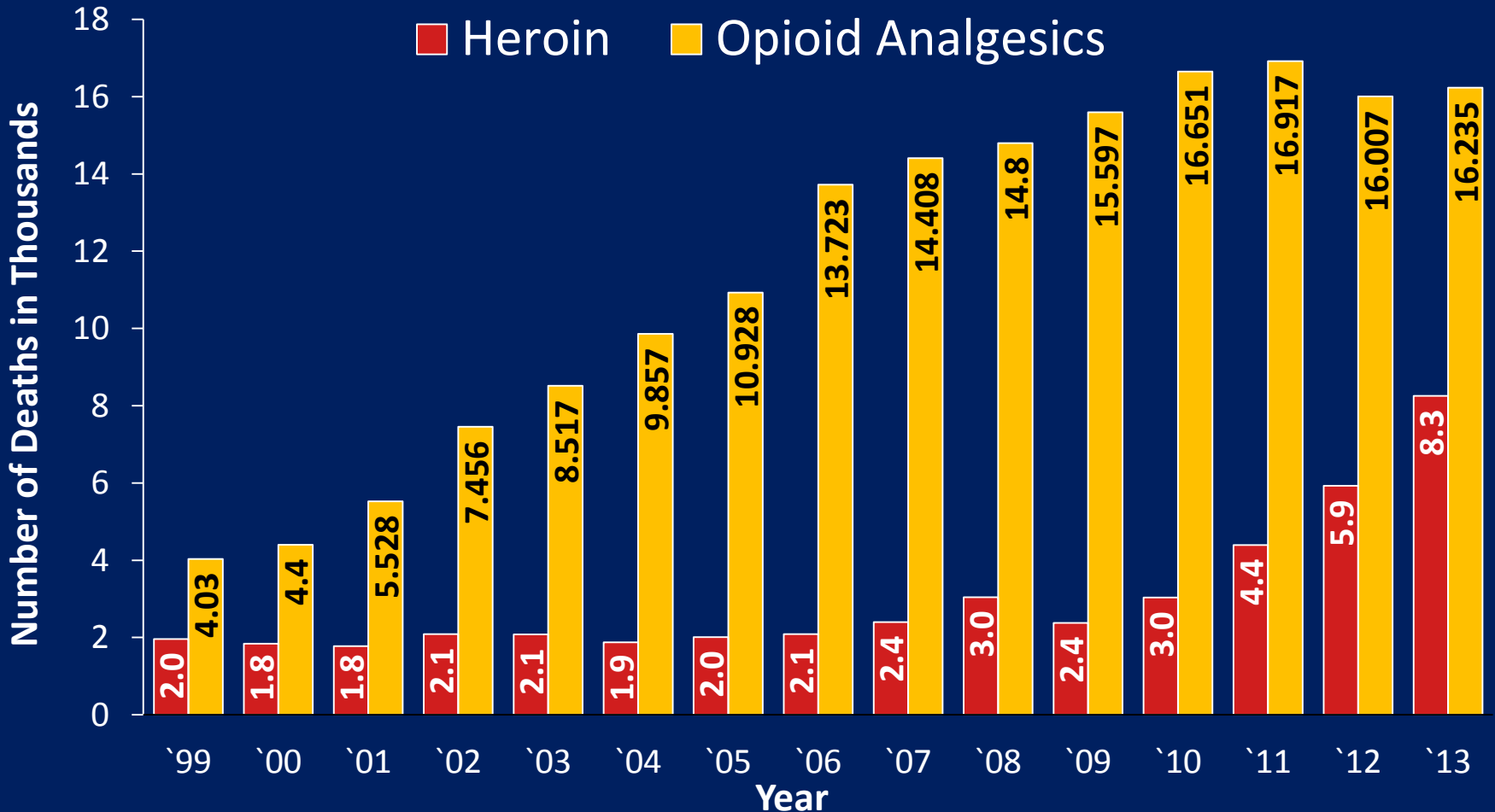


# Drug-Poisoning Deaths Involving Opioid Analgesics or Heroin in the US, 1999-2013





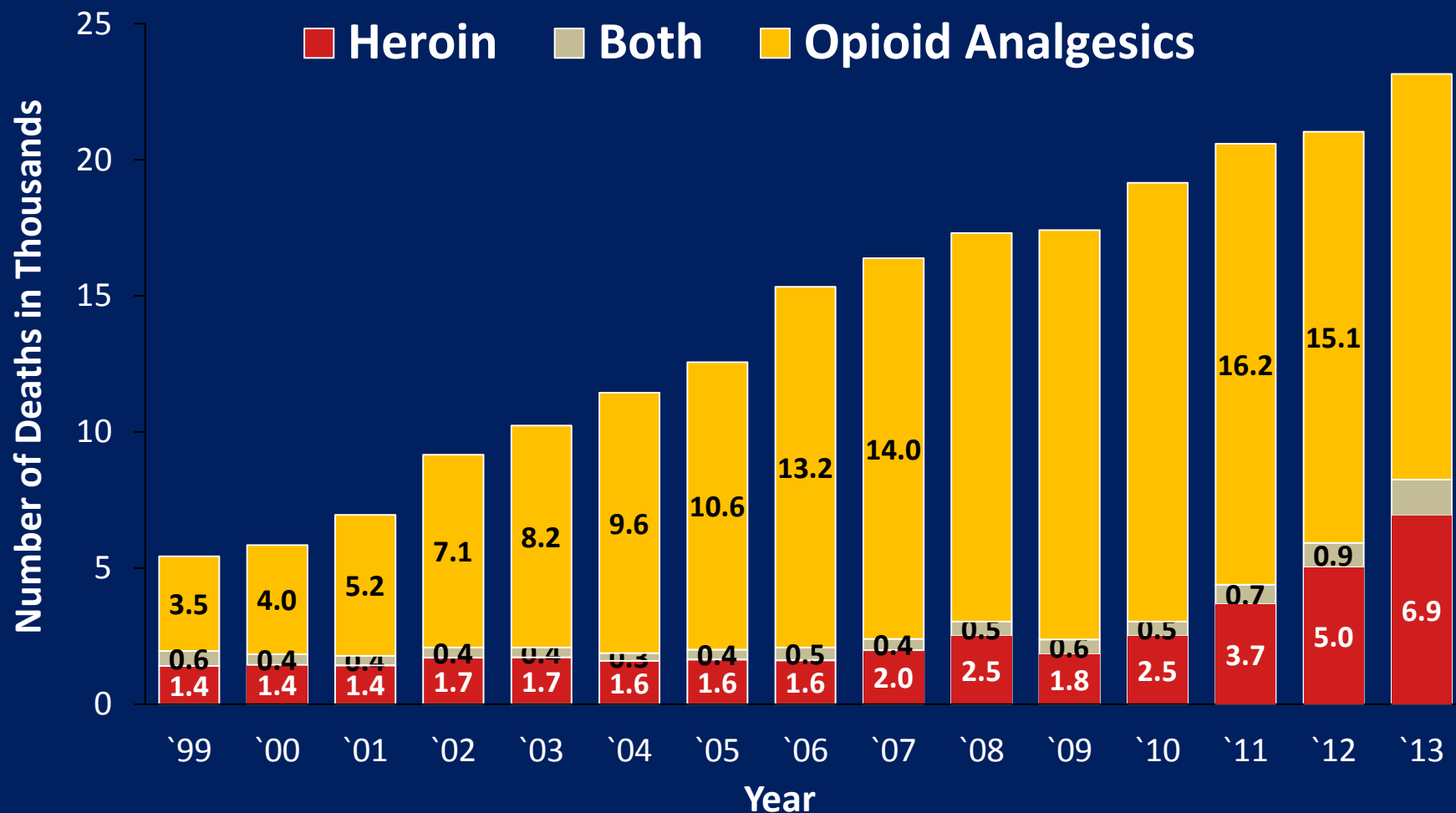
# Drug-Poisoning Deaths Involving Opioid Analgesics or Heroin in the US, 1999-2013





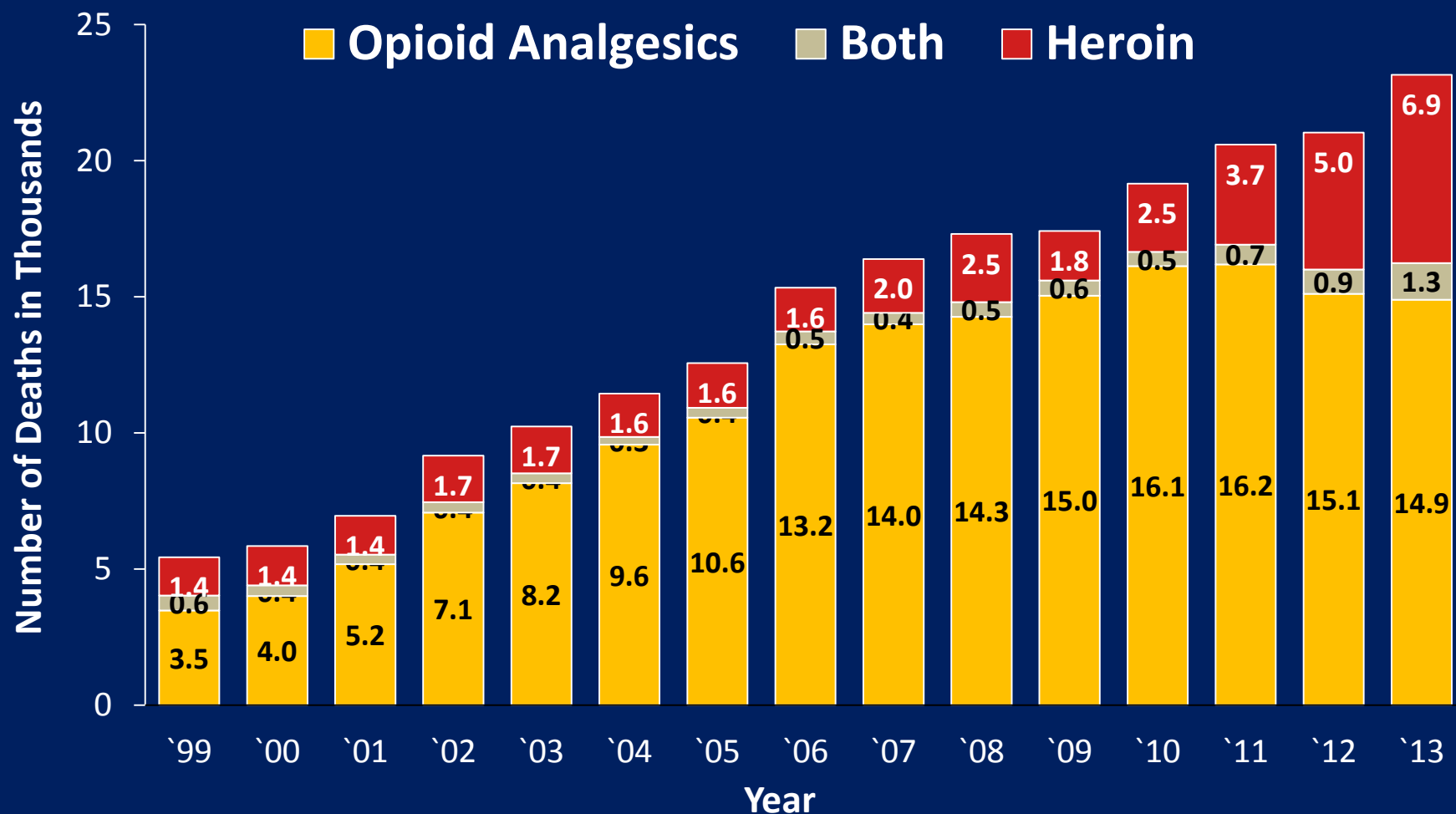


# Drug-Poisoning Deaths Involving Opioid Analgesics or Heroin in the US, 1999-2013





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





# 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 overdose.





# 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. Attino | NJ Advance Media for NJ.com  
on January 28, 2015 at 9:22 AM, updated January 28, 2015 at 11:08 AM

**WOODBIDGE** — 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.”

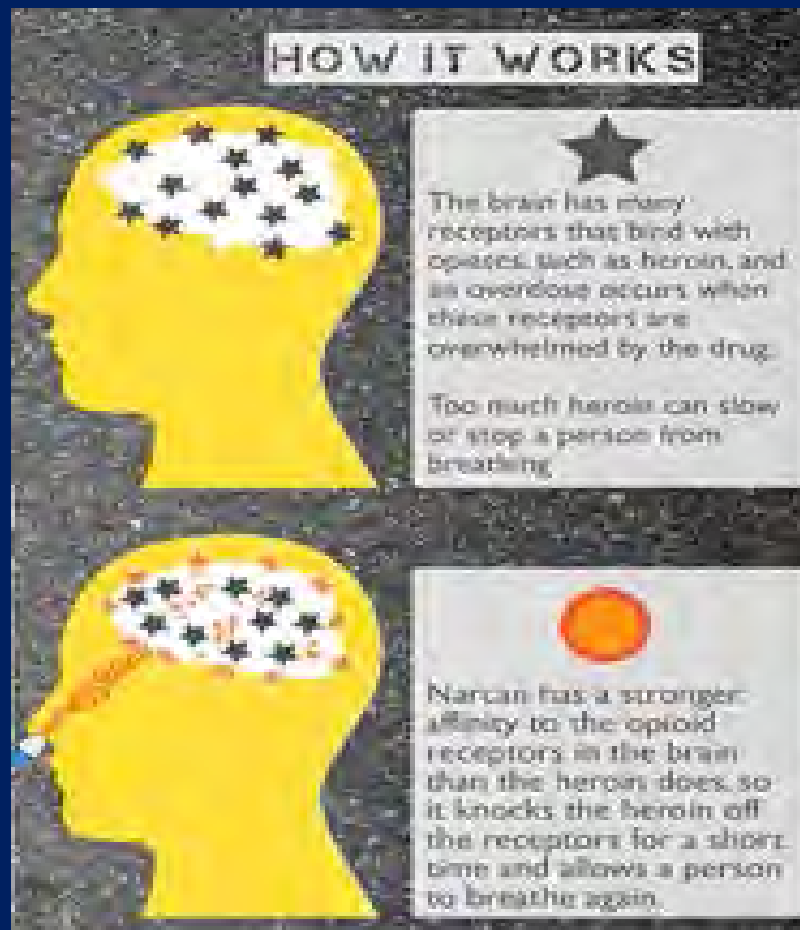
Hoppock identified the officer as Patrolman Christopher McClay. Hoppock said McClay had received training in the use of Narcan just two hours before the 911 call.

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.

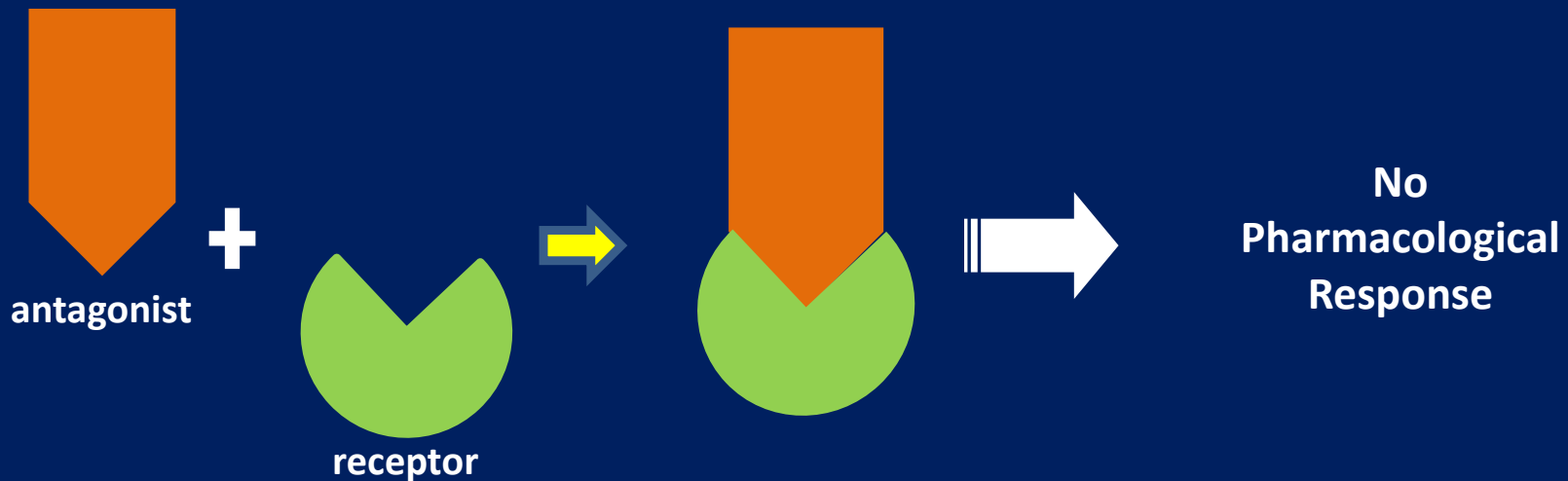
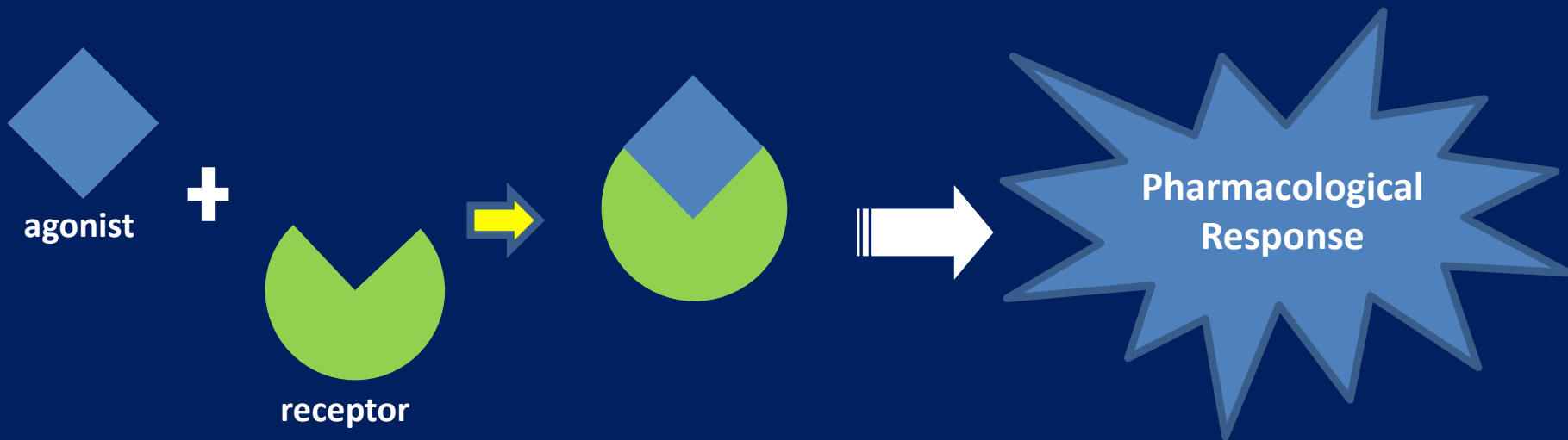
The same officer who participated in the Jan. 21 call, McClay, administered Narcan to the victim, Hoppock said. “The victim appeared to regain consciousness,” Hoppock said. “At that point EMS arrived and the victim was transported to JFK Hospital. Hoppock said the Woodbridge Police Department is now 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.

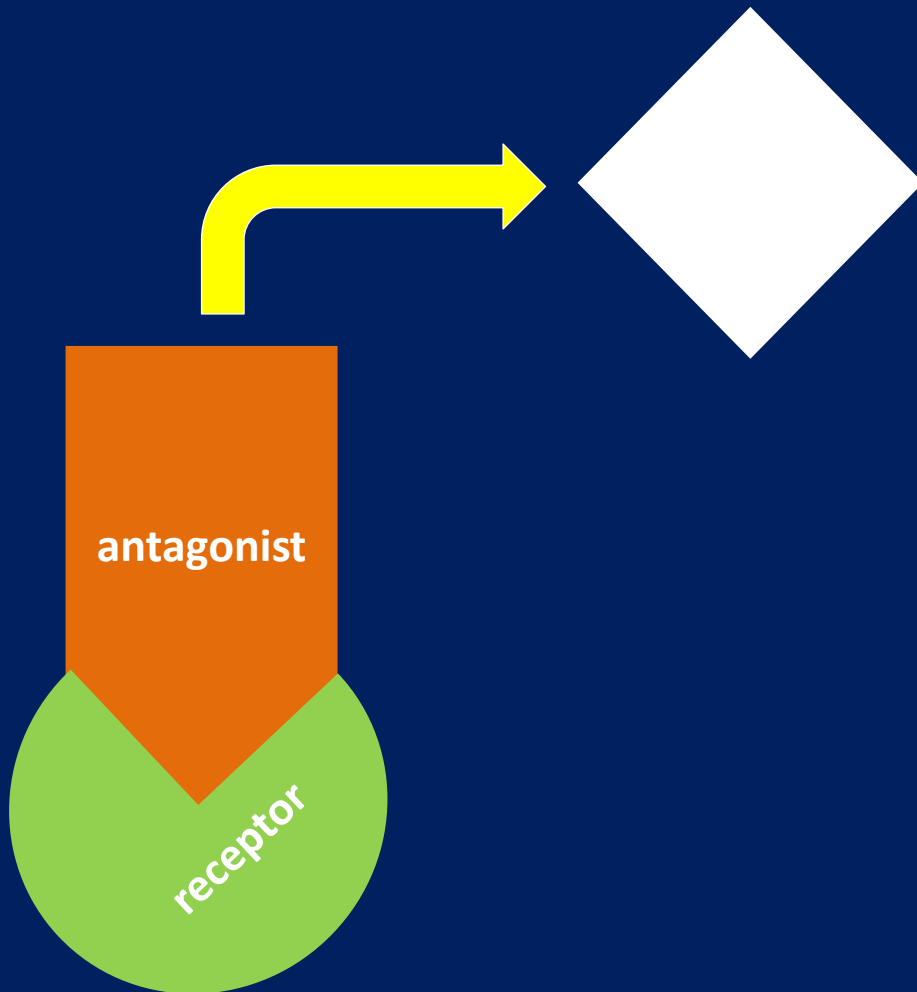
According to the state Attorney General’s Office, there were 741 heroin-related deaths in New Jersey in 2013, a 160 percent increase since 2010.



# 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!





# 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.

# Wrestler Benoit's doctor gets 10 years in prison

Updated 5/12/2009 2:34 PM | [Comment](#) | [Recommend](#)

[E-mail](#) | [Print](#) |



[Enlarge](#)

WWE via AP

NEWNAN, Ga. (AP) — The personal doctor to a professional wrestler who killed himself, his wife and their 7-year-old son was sentenced to 10 years in prison Tuesday for illegally distributing prescription drugs to patients.

Dr. Phil Astin, 54, had pleaded guilty Jan. 29 to a 175-count federal indictment.

Prosecutors said Astin prescribed painkillers and other drugs to known addicts for years. They said at least two of Astin's patients died because of his lax oversight of what medicines they were taking. However, the indictment was unclear about whether Chris Benoit, a wrestler for Stamford, Conn.-based World Wrestling Entertainment, was one of the two.

"I take full responsibility," Astin told the judge Tuesday. "I am sorry I hurt so many lives. I was thinking that I was looking after my patients."

U.S. District Judge Jack Camp said there was no doubt Astin tried to help hundreds of patients at his western Georgia clinic. But the judge said he could not overlook Astin's misconduct.

"The fact that two people did die outweighs other conditions

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U.S. District Judge Jack Camp said he could not overlook the misconduct





## Rush Limbaugh Arrested On Drug Charges

Rush Limbaugh and prosecutors in the long-running prescription fraud case against him have reached a deal, with the conservative commentator to be dropped without a guilty plea if he continues treatment, his attorney said Friday.

Limbaugh turned himself in to authorities on a warrant filed Friday charging him with fraud to conceal informant Barbara, a spokeswoman for the Palm Beach County Jail. He and his attorney Roy Black left about an hour and fingerprinted and he posted \$3,000 bail, Barbara said.

Prosecutors' three-year investigation of Limbaugh began after he publicly acknowledged being addicted to painkillers and entering a rehabilitation program. They accused Limbaugh of "doctor shopping," or illegally deceiving multiple doctors to obtain painkillers, learning that he received about 2,000 painkillers, prescribed by four doctors in six months, at a pharmacy near his home.

Limbaugh, who pleaded not guilty Friday, has steadfastly denied doctor shopping. Black said the charge will comply with court guidelines.

## Coheed and Cambria Bassist Arrested Before Gig

Originally posted Jul 10th 2011 5:18 PM PDT by TMZ Staff

**Michael Todd**, the bassist for the band **Coheed and Cambria**, was arrested for armed robbery after he allegedly held up a Walgreens by claiming he had a bomb ... and this all went down right before they played a show!

## Rangers' Boogaard died of alcohol, oxycodone mix

Updated 5/20/2011 11:09 PM |

MINNEAPOLIS (AP) — The death of New York Rangers enforcer **Derek Boogaard** was an accident, due to a toxic mix of alcohol and the powerful painkiller oxycodone.

The Hennepin County Medical Examiner announced Boogaard's cause of death Friday, saying it was unclear exactly when the 28-year-old died. Boogaard was found

his passion for the game, his teammates, and his community work was unstoppable."

Experts say mixing alcohol and medicines can cause dangerous reactions. Drinking alcohol while taking strong painkillers like oxycodone can result in breathing problems and increase the risk of an overdose, according to the National Institute on Alcohol Abuse and Alcoholism.

The family thanked the Rangers, Minnesota Wild, the NHL and the NHLPA for "supporting Derek's continued efforts in his battle."

"Regardless of the cause, Derek's passing is a tragedy," NHL spokesman Frank Brown said in an email. The Rangers and Wild had no comment.

# Jack Camp, Senior Federal Judge, Arrested On Drug, Gun Charges

ATLANTA — A veteran federal judge faces drug and firearms charges after an exotic dancer at an Atlanta strip club told authorities he used cocaine, marijuana and other illegal drugs with her.

Senior U.S. District Judge Jack T. Camp was arrested Friday minutes after he handed an undercover law enforcement agent \$160 for cocaine and Roxycodone, a narcotic pain medication, that he intended to use with the exotic dancer, authorities said in a court document released Monday. They said they also found two firearms in the front seat of his vehicle.

Camp, 67, who has presided over some high-profile cases, was released Monday on a \$50,000 bond. His attorney, William Morrison, said after a brief hearing that the judge intends to plead not guilty. Morrison said Camp would probably take a leave of absence and would not preside over any more cases until the charges are resolved.

William Morrison, said after a brief hearing that the judge intends to plead not guilty. Morrison said Camp would probably take a leave of absence and would not preside over any more cases until the charges are resolved.

U.S. Drug Enforcement Administration  
Office of Diversion Control



## Teachers Calm Students With 'Prescription' Mints

By SANDYMAPLE | February 10th, 2010 at 1:48 pm

The drug bottles were made more realistic with labels that read in part: “Watson’s Whiz Kid Pharmacy. Take 1 tablet by mouth EVERY 5 MINUTES to cure FCAT jitters. Repeated use may cause craft to spontaneously ooze from pores. No refills. Ms. Falcon’s authorization required.”

The teachers' unusual calming tactic was discovered by Sandy Young, who was greeted with the sight of a pill bottle on each student's desk when she visited her grandson's classroom. The teacher assured her that the pills were fake and just a lighthearted attempt at reducing the stress of the test-taking students.

**In Florida  
two  
Westchase  
teachers  
learn a  
lesson:  
Say 'no' to  
mints in pill  
bottles**



# Violence



# Armed Robbery

- Keep calm – Do as directed
- Do not challenge the bad actor – give him what he wants
- Let him leave the store without any intervention.
- As soon as he clears the store lock the door, call 911 and check on your customers/patients
- Write down any observations (clothing, height, weight, distinguishing features) while it is fresh in your mind
- Armed Robbery is an act of desperation. No amount of drug loss is worth your life or the life of your patients

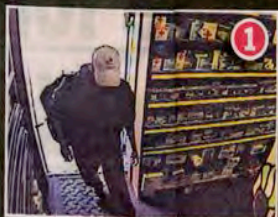




# Violence Related to Controlled Substance Pharmaceuticals



## ASSASSIN



Ready for mayhem, the lunatic strolls through the door.



Gun in his right hand, he walks coolly through an aisle.



He pulls his cap over his face as he leaves the store.



Now a mass murderer, he walks out into the sunlight.

## Chilling anatomy of drugstore massacre

He never gave them a chance. The coldblooded killer who massacred four people in a Long Island pharmacy methodically shot each victim, shocking, step-by-step surveillance footage of the slaughter revealed yesterday.

PAGES 4-5



## DRUGSTORE MASSACRE

Husband and wife busted in Rx-slay horror



## PAIN KILLER

David Laffer is the man caught on video wearing a fake beard (top) who slaughtered four people in a pharmacy to feed his wife Melinda's addiction, cops said yesterday.

PAGES 4-5



33

comments

# Slain Lansing Rite Aid pharmacist, father of toddler may not have known attacker



Michael Nana Baffour Addo was a well-liked pharmacist at Rite Aid in the Frandor Shopping Center in Lansing. (Courtesy photo)



By [Melissa Anders](#) | [manders@mlive.com](mailto:manders@mlive.com)

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on May 13, 2014 at 4:14 PM, updated May 14, 2014 at 5:38 PM

[Print](#)

Do you know a WWII vet?



Michigan has 39,000 living WWII veterans -- help us find them

[... Read more about the project](#)

Source:

[http://www.mlive.com/lansing-news/index.ssf/2014/05/michael\\_addo\\_rite\\_aid\\_frandor.html](http://www.mlive.com/lansing-news/index.ssf/2014/05/michael_addo_rite_aid_frandor.html)

LANSING — Michael Addo, known as a friendly Rite Aid pharmacist with a "million dollar smile," had a toddler and wife in Ghana, where he hoped

## RITE AID AND EAST LANSING SHOOTING CASE

[Tweet](#)

2.7k

Like



[HOME](#) » [NEWS](#)

## Pharmacist slain in Beach robbery was much beloved

[Share](#)
829
 [f](#)
777
 [t](#)
34
 [in](#)
18
 [p](#)
0
 [g+](#)
2



**1 OF 10 PHOTOS:** Shannon Rogers lays flowers near the store on Monday, April 14, 2014. Rogers said she just met the store's owner, David Kilgore, this weekend. Rogers, who called Kilgore "awesome," said he let her park her car at the store so she could spend a day at the beach. Police said Kilgore died after an attempted robbery in his drugstore Monday morning. (Brian J. Clark | The Virginian-Pilot)

[View all 10 photos](#) | [Buy Pilot photos](#)

By [Stacy Parker](#)  
The Virginian-Pilot  
© April 15, 2014

### VIRGINIA BEACH

When pharmacist David Kilgore left Rite Aid three-plus years ago, customers transferred their prescriptions to his new, small independent business.

They admired the way he connected with them on a personal level.

Monday, they placed flowers at his pharmacy's doorstep after learning the 46-year-old was shot during a morning robbery and later died.

"It was always, 'Hey Pete, how you doing?' " said Peter Carlson, who dropped off a colorful bouquet at Beach Pharmacy on Monday evening.

**Related:** [Suspect identified, charged with murder](#)

The pharmacist was working at Rite Aid on Laskin Road near the Oceanfront when development



The Kroger Co.  
Family of Stores

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**DAILY DEAL**

**50% DISCOUNT**

**BUY NOW FOR \$10**

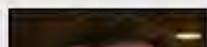
**A \$20 VALUE**

And Get \$20 Worth of Tasty Food at Ocean House Waterfront Dining!

[Daily Deal](#) | [Promote your business](#)

Source:

<http://hamptonroads.com/2014/04/pharmacist-slain-beach-robbery-was-much-beloved>



David Kilgore



# Burden on the health care delivery system



# 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.)

## LAUDANUM. -- Poison

EACH FLUID OUNCE CONTAINS  
45 1/2 GRAINS OPIUM and 65% ALCOHOL

DOSE:	
3 mo. old, 1 drop	10 yrs. old, 10 drops
1 yr. old, 3 drops	20 yrs. old, 20 drops
4 yrs. old, 5 drops	Adult, 25 drops

C. W. Malcolm, *Qualified Chemist*  
Memphis, TENN.







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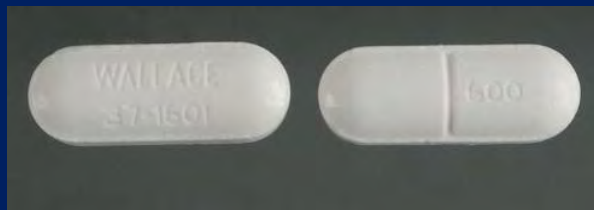
# The 1960s/70s/80s



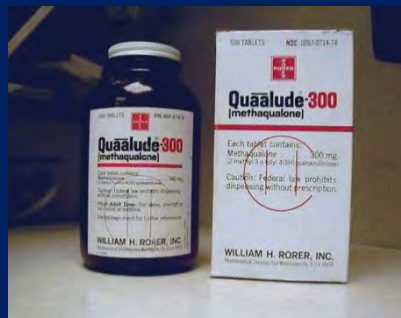
Uppers - Amphetamines



Downers - Barbiturates



Meprobamate



Quaalude



Hydromorphone



Oxycodone/APAP



"Ts and Blues"



"Fours and Doors"



10 mg



20 mg



40 mg



80 mg



160 mg



**OxyContin® Tablets**  
(oxycodone hydrochloride controlled-release)

# The 1990s



# Inadequate Pain Control





Vol. 302 No. 2

CORRESPONDENCE

## 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<sup>1</sup> 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, Mietinen 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.

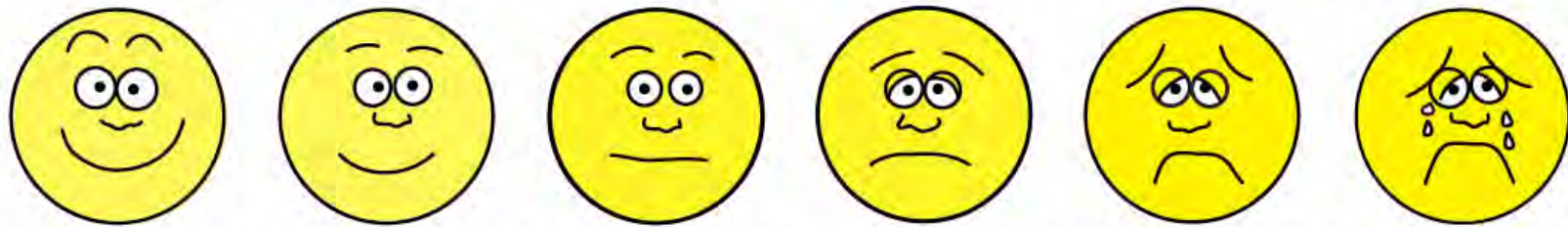


# The Fifth Vital Sign?

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.

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 the 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 Pain 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 with 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 a 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 that those 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."

Other government initiatives have challenged the line between health policy and law enforcement. This includes Congress's empowerment of the DEA allowing the agency authority in reviewing new drugs, a role previously held only by the Food and Drug Administration, according to Dr. Fishman. On Nov. 4, 2005, Congress reversed itself and rescinded the DEA's new authority.

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 could 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 as 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, American Pain Foundation. The 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 cites the more comprehensive command."

###

### **About the American Academy of Pain Medicine**

Founded in 1983 as the American Academy of Algology, the American Academy of Pain Medicine (AAPM) has evolved as the primary organization for physicians practicing the specialty of Pain Medicine in the United States. As the specialty of pain medicine has grown, a defined body of knowledge and scope of practice have emerged, and today, Pain Medicine is recognized as a discrete specialty by the American Medical Association (AMA). AAPM is the only national organization of pain medicine specialists. The journal Pain Medicine is published six times a year by Blackwell Science, Inc. For more information, visit [www.painmed.org](http://www.painmed.org).

### **About the American Pain Foundation**

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 quality of life for people with pain, providing practical information, promoting research, and advocating to remove barriers and increase access to effective pain management. For more information, visit [www.painfoundation.org](http://www.painfoundation.org).



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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 the 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 with 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, presented the 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, speaks on patients' behalf.

**Victims and Perpetrators in Chronic Pain**  
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 concern 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 that those 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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"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. The DEA's role in 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 of drug abuse legitimately deserve relief."

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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

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Baucus Grassley Opioid  
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Academy of Pain Medicine  
[277.6 KB]



Baucus Grassley Opioid  
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### U.S. Senate panel launches investigation of painkillers, drug companies

By John Fauber of the Journal Sentinel

May 9, 2012

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“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

#### Side Effects



"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

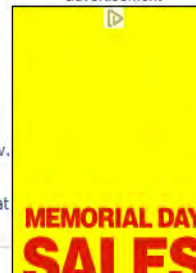


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## Bioethics think tank's ties to pain pill industry studied

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.

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."

### Breaking News

Homers by Francoeur and Butler lift Royals to 4-2 victory over Orioles

La Crosse, Kan., is cleaning up after twister

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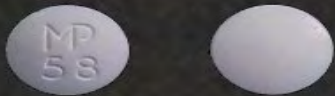
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# Commonly Abused Controlled Pharmaceuticals

Carisoprodol



C-IV as of 1/11/2012

**CYCLOBENZAPRINE  
(FLEXERIL)**



OxyContin 80mg  
Oxycodone HCL ER



Oxymorphone

**Hydrocodone**



**Oxycodone 30 mg**



**Alprazolam**



# The Holy Trinity



Oxycodone

Opiate



Carisoprodol

C-IV as of 1/11/2012

Muscle Relaxant



Alprazolam

Benzodiazepine



# Direct to Consumer Advertising



# 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



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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.



# Education

## ➤ Children/Teens

Information from the Internet  
or their peers

Following parents



# Where do kids get their information from?

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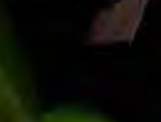


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U.S. Drug Enforcement Administration  
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#### THE FRONT PAGE

### Bluelight Remembers Ryan Haight, Launch of the Recovery forums

by [Sebastians\\_ghost](#) Published on 12-02-2013 06:41



Dear Bluelighters,

As some of you may remember, February 12th is the twelfth anniversary of the passing of one of our own. To most it will be remembered as the first day "Bluelight went black." To those of us who knew Ryan Haight (a.k.a Quicksilver) it is also the day we lost a friend.

The impact of Ryan's life and untimely death have echoed forward in the passage of the Ryan Haight Internet Pharmacy Consumer Protection Act of 2008, signed into law by President G.W. Bush in October of the same year. In honor of Ryan, Bluelight is proud to announce the launch of a new collection of forums designed to support sober living, and provide help to those struggling with drug

jaystyle

Bluelighter



Join Date: May 2010

Location: San Francisco, CA

Posts: 258

10-09-2010 13:46



Ok--- so here is my current experiment status' so far.

- 1.) Milling / Grinding OP 80 - I have found the best way to crush OP80 with the use of a foot file / nail file. Hoseclamp did not work good. Using the file, I was able to get it to a powder around 20% thicker than the old OC.
- 2.) Experiment 1: Fail - My first experiment was to mill the OP80 and I left it overnight in a mixture of apple cider vinegar and lemon juice. 8-9 hours later, I drank it and received minimal if any effects except a horrible case of acid stomach. I suspect all the acid may have killed the alkaloids or something, or just failed to extract it completely.
- 3.) Experiment 2: Fail - Grinding up and parachuting - despite milling these OPs down, they still retain substantial time release. I found this to be a failure and it released the oxy slowly over the course of many hours.
- 4.) M.L.K - I read that if you put M.L.K drops (a popular, common solvent) in a spoon to saturate some milled OP 80, then let it evaporate, it dissolves the plastic and leaves a snortable powder that does not Gel. Many people report success with this, but I did not. Perhaps I did not use enough M.L.K or let it dissolve for long enough.

I posted this in the other thread, but I find this information useful and suggest you all read it here in case u missed it:

From the Purdue website, here is a summary of the info I found:

<http://www.fda.gov/ohrms/dockets/ac/...-05-Purdue.pdf>

Besides the obvious Simple, Medium, and Complex solvent thing that has everyone confused--- here is some information you guys should consider in ur investigations:

- 1.) At room temperature, using commonly found solvents, the best they could do was extracting 50% of the oxycodone for SHORT DURATION Shakign Extractions at room temperature.
- 2.) At room temperature with some less readily available solvents, extraction was as high as 70% during a "SHORT DURATION" shaking extraction at room temp.
- 3.) When we are dealing with EXTENDED extraction times at ROOM temperature--- some SIMPLE HOUSEHOLD solvents extracted up to 78% of the oxycodone! That might mean if we leave oxycodone soaked in acetone, M.E.K, or Ether for some time we can get almost 80% of the OC out. How long is an extended duration, I wonder? 1 hour, 2, hour, 4 hours-- shaking and stirring it. In the end, I woudl assume we would filter out the gunk, evaporate the solvent, and be left with pure oxycodone residue. The 22% or so that wasnt extracted would remain in the gunk we filter and we could eat them or something. There was one simple solvent they listed, however, that only got 2-9% out--- in otherwords destroying the alkaloid entirely. Not sure which one that is but maybe we can research solvents known to destroy oxycodone molecules. The Medium and Complex solvents all removed most of the oxycodone when leaving them at room temperature for extended periods of time.



## 5 mg alprazolam has done nothing

#1

looneytoon7

Greenlighter



Join Date: Jan 2014

Posts: 5

04-04-2014 14:14

Months ago, maybe even a year ago now, a friend introduced me to Xanax because we had been on a meth bender and sleeping had become impossible for me and I needed sleep bad. I took quarter of a 2 mg brick and it knocked me out and I loved it, the refreshing sleep. I've taken it around 10 times since then, every now and then when I really need to get to sleep and never more than 1-2 mg. So I definitely don't have a high tolerance to the stuff or anything.

I haven't had them for months now though. I had been smoking meth today and wanted to sleep. So well over 5 hours ago now, I took quarter of a 2 mg brick. 45 minutes later it hadn't done a thing, so I took another quarter. So I'd had 1 mg. Half an hour later, still nothing. Waited a bit then swallowed the other half of the brick, 2 mg still would do anything at all other than make me feel slightly relaxed. Swallowed another half a brick or 1 mg, waited 40 minutes, still nothing. Swallowed another whole brick, bringing the total dose up to 5 mg about half an hour ago and still I am wide awake.

They aren't fake Xanax. So wtf is up with this? 😞 a few days before this I was taking a couple 25mg seroquels per night for about a week if that make a difference, haven't had any for a few days though.

Does anybody know wtf is up with this?

REPLY

QUOTE



#2

deerman

Greenlighter



Join Date: Apr 2014

Location: Dagoon Mountains

Posts: 18

04-04-2014 22:39

Xanax doesn't do anything of value for me, except make me pass out if I take too much.

Ativan on the other hand does wonders. Lorazepam is a highly effective benzo for putting one to sleep, in fact I have never heard of a doctor prescribing xanax for sleep, however it is common with lorazepam. Actually Xanax is downright destructive for sleep, do some research.

Perhaps your Xanax is old? Otherwise, join the club. Xanax fucking sucks for me. Ativan is the wonder benzo, not that I have a need for benzos anymore.

Maybe one should lay off the meth if they feel a need to take meds to go to sleep? How about a big hot meal with lots of vegetables and some chelated magnesium and lots of water? Get your body back in balance, meth will wreck your CNS if you aren't being a careful user.

If you insist on using a prescription medication to help come down off meth and get to sleep, I would use lorazepam or ambien. But you're just wreaking more havoc to your body by taking all those drugs...

## Is there any way to get high off of just 5mg of hydrocodone?



#1

Hydromethomine

Bluelighter



Join Date: Mar 2014

Location: Ohio

Posts: 78

07-04-2014 22:40



I have only been up to 25mg, and it has worked plenty fine for me. 10 gives me a slightly euphoric feeling. Could I use a certain **potentiator**, or maybe use a certain method? I only have this one 5/500 pill left. Thanks.

REPLY

QUOTE



#2

danolaa420

Greenlighter

Join Date: Mar 2014

Posts: 12

Yesterday 00:38



Crush it into fine powder and grab a pinch at a time and put it in ur rear end or put the powder in a capsle and stick it up should dissolve

REPLY

QUOTE



#3

Hydromethomine

Bluelighter



Join Date: Mar 2014

Location: Ohio

Posts: 78

Yesterday 00:45



Would snorting help at all? I know some people have different reactions to snorting it. I know the acetaminophen isn't nice on the nose, but still.





# GET INVOLVED TEACH



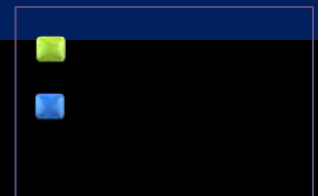
# DEA Web-based Resources

www.DEA.gov

The screenshot shows the DEA website homepage. At the top, the URL is <http://www.justice.gov/dea/index.shtml>. The main header features the large 'DEA' logo in gold, followed by 'UNITED STATES Drug Enforcement Administration' and the tagline 'TOUGH WORK, VITAL MISSION'. A navigation bar includes links for HOME, ABOUT, CAREERS, OPERATIONS, DRUG INFO, PREVENTION, and PRESS ROOM. The main content area has a large blue graphic with the text 'Tough Work, Vital Mission The Facts About DEA' and a smaller DEA seal. To the right, there are three boxes: 'Drug Facts for Today's Teens' (JustThinkTwice.com), 'A DEA Resource for Parents' (GetSmartAboutDrugs.com), and 'Wall of Honor' (DEA Remembers). Below these are three columns: 'TOP STORY' with a headline 'Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy' dated 'JAN 29 (BROWNSVILLE, TEXAS)'; 'TOPICS OF INTEREST' with links to 'DEA Fact Sheet', 'Drugs of Abuse: A DEA Resource Guide', 'Extension of Temporary Placement of Five Synthetic Cannabinoids', and 'The DEA Position on Marijuana'; and 'RESOURCE CENTER' with links to 'Controlled Substances Act', 'DEA Museum and Visitors Center', 'Doing Business with DEA', 'Drug Disposal', and 'Employee Assistance Program'.



# Community Coalitions and Advocacy Groups





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

## Friends and Family...For Free!!





# The Medicine Cabinet and the Problem of Pharmaceutical Controlled Substance Disposal



# Medicine Cabinets: Easy Access

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



# So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules



# National Take Back Initiative

## September 27, 2014

# Got Drugs?

Turn in your  
unused or expired  
medication for safe disposal

Saturday **September 27, 2014**

Click here  
for a collection  
site near you.



10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration  
Office of Diversion Control



# Nationwide Take-back Initiative

Over 3.4 million pounds (1,733 tons) collected

➤ On September 30, 2010, approximately 122 tons

➤ On April 30, 2011, approximately 188 tons

➤ On October 29, 2011, approximately 189 tons

➤ On April 28, 2012, approximately 276 tons

➤ On September 29, 2012, approximately 244 tons

➤ On April 27, 2013, approximately 376 tons

➤ On October 26 , 2013, approximately 324 tons

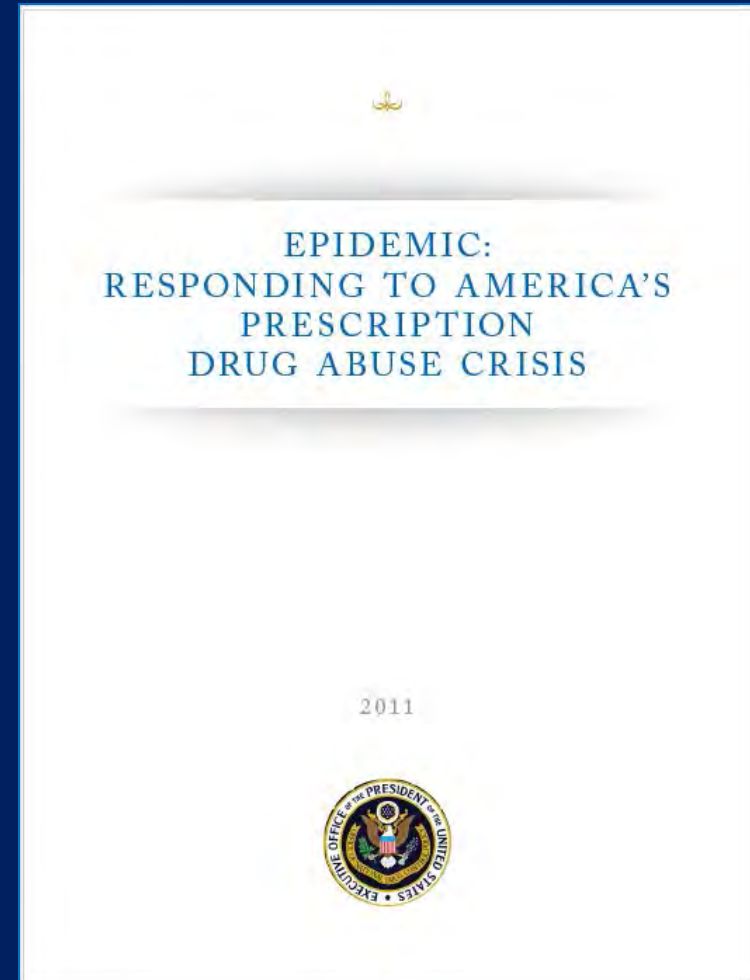
➤ On April 26, 2014, approximately 390 tons

➤ On September 27, 2014, approximately 309 tons



# Prescription Drug Abuse Prevention Plan

- Coordinated effort across the Federal Government
- Four focus areas:
  - 1) Education
  - 2) Prescription Drug Monitoring Programs
  - 3) **Proper Disposal of Medication**
  - 4) Enforcement



# Secure and Responsible Drug Disposal Act of 2010

- Legislation that provides ultimate users and long-term care facilities (LTCFs) with additional methods to dispose of unused, unwanted, or expired controlled pharmaceuticals in a secure, safe, and responsible manner.
- Authorized DEA to promulgate regulations that allow ultimate users to transfer pharmaceutical controlled substances to authorized entities for disposal.
  - Specific language in the regulation continues to allow Federal, State, tribal, and local law enforcement to maintain collection receptacles at the law enforcement's physical location; and either independently or in partnership with private entities or community groups, to voluntarily hold take-back events and administer mail-back programs.
- Created an exception for LTCFs to transfer pharmaceutical controlled substances for disposal on behalf of patients who reside or have resided at that facility

# ‘Ultimate User’

An *ultimate user* is defined as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”<sup>1</sup>

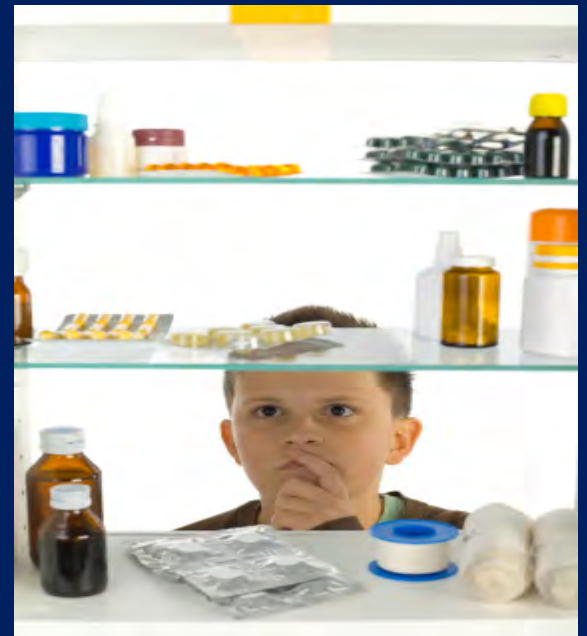
<sup>1</sup> Federal Register /Vol. 79, No. 174 /Tuesday, September 9, 2014 /Rules and Regulations, 21 CFR Parts 1300, 1301, 1304, et al. Disposal of Controlled Substances; Final Rule 21 USC § 802(27)

# Secure and Responsible Drug Disposal Act of 2010

- Regulations do not limit the ways ultimate users may dispose of pharmaceutical controlled substances – **they expand them.**
- Any method of pharmaceutical disposal that was valid prior to these regulations continues to be valid.
- Participation is voluntary.
- DEA may not require any person to establish or operate a disposal program.

# Disposal of Controlled Substances, Final Rule

- ✓ Ultimate users will now have more locations where they can securely, safely, responsibly, and conveniently dispose of their unwanted pharmaceutical controlled substances.
- ✓ Expected benefit to the public by:
  - Decreasing the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
  - Protecting the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users.





# Law Enforcement

- Law enforcement continues to have **autonomy with respect to how they collect controlled substances** from ultimate users, including:
  - maintaining collection receptacles
  - conducting mail-back programs
  - conducting take-back events

# Take Back Events

- Take-back events are intended to be limited-duration events that may take place at an unregistered location that is easily accessible to the public, such as a community center or town center.
- Law Enforcement may continue to conduct take-back events.
- Any person may partner with Law Enforcement.
- Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- Authorized collection receptacles and inner liners “should” be used.

*21 CFR §§ 1317.35 and 1317.65*



# Tips for Take Back Events

- No prohibition against holding such events with events such as hazardous waste or non-controlled pharmaceutical disposal events.
- The comingling of controlled and non-controlled substances is permitted, but not required. Co-sponsors of events may specify that only controlled substances will be accepted and/or provide a separate receptacle for non-controlled substances at the take-back event.
- No requirement for drugs to be in their original packaging.
- With low physical security at such locations, the DEA believes that it is imperative to ensure active law enforcement participation for the safety of the event participants and the community, as well as to help deter theft and diversion of pharmaceutical controlled substances.
- Others may assist law enforcement officers who conduct take-back events.

# Collection

*Collection* means to receive a controlled substance for the purpose of destruction from an:

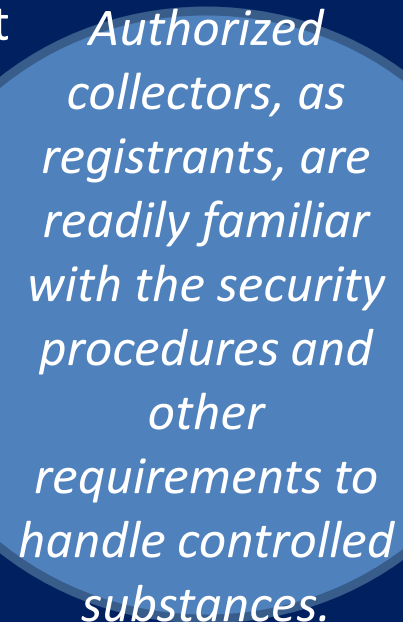
- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

# Authorized to Collect

- The following persons are authorized to collect from ultimate user and other non-registrants for destruction:
  - Any DEA registrant authorized pursuant to § 1317.40
  - Federal, State, tribal, or local law enforcement when in the course of official duties and pursuant to § 1317.35

## Registrants authorized to collect:

- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs
- Hospitals/clinics with an on-site pharmacy
- Retail Pharmacies



*Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.*



# How does a registrant become a collector?

- Authorized registrant must be registered to handle schedule II controlled substances
- Request a modification in writing to the DEA or on-line at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov)
- Request must contain:
  - Registrant's name, address, and DEA number
  - The method(s) of collection:
    - Collection receptacle and/or mail-back program
  - Authorized signature per § 1301.13(j)
- No fee is required for this modification request

# **New Authorized Methods of Collection**

- Collection receptacles
- Mail-back programs

# Collection Receptacles

- Only ultimate users *shall* put the controlled substances directly into the collection receptacle.
- Controlled and non-controlled substances may be comingled.
- Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Registrants shall not dispose of stock/inventory in collection receptacles.

# Design of Collection Receptacle

- Securely fastened to a permanent structure.
- Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have small opening that allows for contents to be added but does not allow for removal of contents.



# Collection Receptacle Location

- Must be securely placed and maintained:
  - Inside collector's registered location
  - Inside law enforcement's physical location, or
  - Inside an authorized LTCF





# Collection Receptacle Location

- **Registered location** – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
- **LTCF** – located in secure area regularly monitored by LTCF employees.
- **Hospital/clinic** – located in an area regularly monitored by employees, **not** in proximity of where emergency or urgent care is provided.
- **NTP** – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

# Collection Receptacle Inner Liner

- Waterproof, tamper-evident, and tear-resistant.
- Removable and sealable upon removal without emptying or touching contents.
- Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon).
- Outside of liner shall have permanent, unique ID number.

# Access & Handling Sealed Inner Liners

- Only employees of the collector may access the inner liners.
- The inner liner shall be sealed by **two employees** immediately upon removal from the permanent outer container.
- Sealed inner liner **shall not** be opened, x-rayed, analyzed, or otherwise penetrated.
- Practitioners **cannot** transport collected controlled substances.

# Mail-Back Program

## Requirements of mail-back program

- Only lawfully possessed schedules II-V controlled substances may be collected
- Controlled and non-controlled substances may be collected together

# **Mail-back Program: Who is Authorized to Operate?**

Any authorized collector that has and utilizes at its registered location (on-site) a method of destruction consistent with § 1317.90



# Mail-Back Packaging Specifications

- Packages may be made available for sale or free of charge;
- Any person may partner with a collector or law enforcement to make packages available to the public;
- Nondescript and no markings that indicate it contains controlled substances;
- Water- and spill-proof, tamper-evident, tear-resistant, and sealable;
- Pre-addressed with the collector's registered address;
- Pre-paid postage;
- Unique ID number so package can be tracked; and
- Instructions for mailing.

# Destruction of Controlled Substances

- All controlled substances destroyed by a registrant or caused to be destroyed by a registrant shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered **non-retrievable**.

# Registrant Disposal

## Destruction of Mail-Back Packages

**Mail-Back Packages** (upon receipt of a sealed mail-back package):

- Promptly destroy the package using an on-site method of destruction; or
- Securely store the package at the collector's registered location until prompt on-site destruction.

# Registrant Disposal

## Destruction of Sealed Inner Liners

- Practitioners and Non-Practitioners shall **dispose of sealed inner liners** by:
  - Prompt on-site destruction
  - Prompt delivery to reverse distributor by common or contract carrier or reverse distributor pick-up
  - Deliver sealed inner liners to a **distributor's** registered location by common or contract carrier or distributor pick-up
- **Practitioner** may **also** request assistance from the Special Agent in Charge (SAC)
- **Non-Practitioner** may **also** transport to reverse distributor or unregistered destruction location (e.g. incinerator).
- Freight forwarding facilities may NOT be used

# Termination of Authorization to Collect

- Registrant shall notify the DEA in writing or online.
- In addition, an authorized mail-back program shall:
  - Make a reasonable effort to notify the public prior to the discontinuance of collection activity;
  - Obtain a written agreement with another collector that has and utilizes at its registered location a method of destruction (on-site) consistent with § 1317.90 to receive all remaining mail-back packages; and
  - Provide the DEA with the name, address, and DEA number of the collector that will receive the remaining packages.

*21 CFR §§ 1301.52(f) and 1317.70 (e)(3)*





# Community Efforts

**Educate the Community:** DEA encourages voluntary, educational outreach to the public on the abuse potential and proper disposal of pharmaceutical controlled substances, whether it be through law enforcement, community groups, or professional organizations.

**Conduct Take-Back Events:** Entities may choose to establish disposal programs for various reasons, including for profit, to build goodwill in the community, to attract customers, to advertise businesses, and to preserve the environment.



# PROZAC® (fluoxetine HCl) FISH (?)





# Medicines Recommended for Disposal by Flushing Listed by Medicine and Active Ingredient

This list from FDA tells you what expired, unwanted, or unused medicines you should flush down the sink or toilet to help prevent danger to **people and pets in the home**.

Medicine	Active Ingredient
Abstral, tablets (sublingual)	Fentanyl
Actiq, oral transmucosal lozenge *	Fentanyl Citrate
Avinza, capsules (extended release)	Morphine Sulfate
Buprenorphine Hydrochloride, tablets (sublingual) *	Buprenorphine Hydrochloride
Buprenorphine Hydrochloride; Naloxone Hydrochloride, tablets (sublingual) *	Buprenorphine Hydrochloride; Naloxone Hydrochloride
Butrans, transdermal patch system	Buprenorphine
Daytrana, transdermal patch system	Methylphenidate
Demerol, tablets *	Meperidine Hydrochloride
Demerol, oral solution *	Meperidine Hydrochloride
Diastat/Diastat AcuDial, rectal gel	Diazepam
Dilaudid, tablets *	Hydromorphone Hydrochloride
Dilaudid, oral liquid	Hydromorphone Hydrochloride
Dolophine Hydrochloride, tablets *	Methadone Hydrochloride
Duragesic, patch (extended-release) *	Fentanyl
Embeda, capsules (extended release)	Morphine Sulfate; Naltrexone Hydrochloride
Exalgo, tablets (extended release)	Hydromorphone Hydrochloride
Fentora, tablets (buccal)	Fentanyl Citrate
Kadian, capsules (extended release)	Morphine Sulfate
Methadone Hydrochloride, oral solution *	Methadone Hydrochloride
Methadose, tablets *	Methadone Hydrochloride
Morphine Sulfate, tablets (immediate release) *	Morphine Sulfate
Morphine Sulfate, oral solution *	Morphine Sulfate
MS Contin, tablets (extended release) *	Morphine Sulfate
Nucynta ER, tablets (extended release)	Tapentadol
Onsolis, soluble film (buccal)	Fentanyl Citrate
Opana, tablets (immediate release)	Oxycodone Hydrochloride
Opana ER, tablets (extended release)	Oxycodone Hydrochloride
Oxecta, tablets (immediate release)	Oxycodone Hydrochloride
Oxycodone Hydrochloride, capsules	Oxycodone Hydrochloride
Oxycodone Hydrochloride, oral solution	Oxycodone Hydrochloride
Oxycontin, tablets (extended release) *	Oxycodone Hydrochloride
Percocet, tablets *	Acetaminophen; Oxycodone Hydrochloride
Percodan, tablets *	Aspirin; Oxycodone Hydrochloride
Suboxone, film (sublingual)	Buprenorphine Hydrochloride; Naloxone Hydrochloride
Xyrem, oral solution	Sodium Oxybate
Zubsolv, tablets (sublingual)	Buprenorphine Hydrochloride; Naloxone Hydrochloride

November 2013

Active Ingredient	Medicine
Acetaminophen; Oxycodone Hydrochloride	Percocet, tablets *
Aspirin; Oxycodone Hydrochloride	Percodan, tablets *
Buprenorphine	Butrans, transdermal patch (extended release)
Buprenorphine Hydrochloride	Buprenorphine Hydrochloride, tablets (sublingual) *
Buprenorphine Hydrochloride; Naloxone Hydrochloride	Buprenorphine Hydrochloride; Naloxone Hydrochloride, tablets (sublingual)
	Suboxone, film (sublingual)
	Zubsolv, tablets (sublingual)
Diazepam	Diastat/Diastat AcuDial, rectal gel
Fentanyl	Abstral, tablets (sublingual)
	Duragesic, patch (extended-release) *
Fentanyl Citrate	Actiq, oral transmucosal lozenge *
	Fentora, tablets (buccal)
	Onsolis, soluble film (buccal)
Hydromorphone Hydrochloride	Dilaudid, tablets *
	Dilaudid, oral liquid
	Exalgo, tablets (extended release)
Meperidine Hydrochloride	Demerol, tablets *
	Demerol, oral solution *
Methadone Hydrochloride	Dolophine Hydrochloride, tablets *
	Methadone Hydrochloride, oral solution *
	Methadose, tablets *
Methylphenidate	Daytrana, transdermal patch system
Morphine Sulfate	Avinza, capsules (extended release)
	Kadian, capsules (extended release)
	Morphine Sulfate, tablets (immediate release) *
	Morphine Sulfate, oral solution
	MS Contin, tablets (extended release)
Morphine Sulfate; Naltrexone Hydrochloride	Embeda, capsules (extended release)
Oxycodone Hydrochloride	Oxecta, tablets (immediate release)
	Oxycodone Hydrochloride, capsules
	Oxycodone Hydrochloride, oral solution
	Oxycontin, tablets (extended release) *
Oxycodone Hydrochloride	Opana, tablets (immediate release)
	Opana ER, tablets (extended release)
Sodium Oxybate	Xyrem, oral solution
Tapentadol	Nucynta ER, tablets (extended release)

November 2013



# Questions to Discuss

- According to the National Survey on Drug Use and Health (NSDUH), in 2012, 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



# Pharmaceuticals





# Legend Drugs v. Controlled Substances



# Legend Pharmaceuticals



# Non-Controlled Substances

## ➤ Analgesic:

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

## ➤ Muscle Relaxant:

- Cyclobenzaprine (Flexeril®)



# 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.





# Opiates



*Papaver*



*Somniferum*

Codeine

Morphine

Thebaine

Hydrocodone

Hydromorphone

Oxycodone  
Hydrocodone



INTERNATIONAL NARCOTICS CONTROL BOARD



# Narcotic Drugs Stupéfiants Estupefacientes 2013

Estimated World Requirements for 2014

Statistics for 2012

Évaluations des besoins du monde pour 2014

Statistiques pour 2012

Previsiones de las necesidades mundiales para 2014

Estadísticas de 2012



UNITED NATIONS



# International Narcotics Control Board

## Comments on the Reported Statistics on Narcotic Drugs - 2012

- U.S. was the country with the highest consumption of Hydrocodone (approximately 45.5 tons or 99% of global consumption)
- U.S. was the country with the highest consumption of Oxycodone (approximately 77.8 tons or 82% of global consumption)
- U.S. was the country with the highest consumption of Morphine (approximately 24.9 tons or 57% of global consumption)
- U.S. was the country with the highest consumption of Methadone (approximately 15.2 tons or 49% of global consumption)
- U.S. was the country with the highest consumption of hydromorphone (approximately 1.42 tons or 42% of global consumption)
- U.S. was the country with the highest consumption of fentanyl (approximately .48 tons or 37% of global consumption)



Most commonly prescribed prescription  
medicine?

Hydrocodone/acetaminophen





# Worldwide Hydrocodone Use

- 67 Countries reported an estimated need requirement for hydrocodone to the International Narcotics Control Board
- 20 countries reported an estimated need of 1 kilogram or greater.
- 4 countries reported an estimated need between 500 grams and 999 grams
- 10 countries reported an estimated need between 100 grams and 499 grams
- 6 countries reported a need between 25 grams and 99 grams
- 27 countries reported a need of less than 25 grams



# Worldwide Hydrocodone Use

- **Of the 20 Countries** that reported an estimated needs requirement for hydrocodone at one kilogram or more
- **8 countries** reported an estimated need of 1 kilogram to 5 kilograms
- **4 countries** reported an estimated need over 5 kilograms to 10 kilograms
- **8 countries** reported an estimated need over 10 kilograms



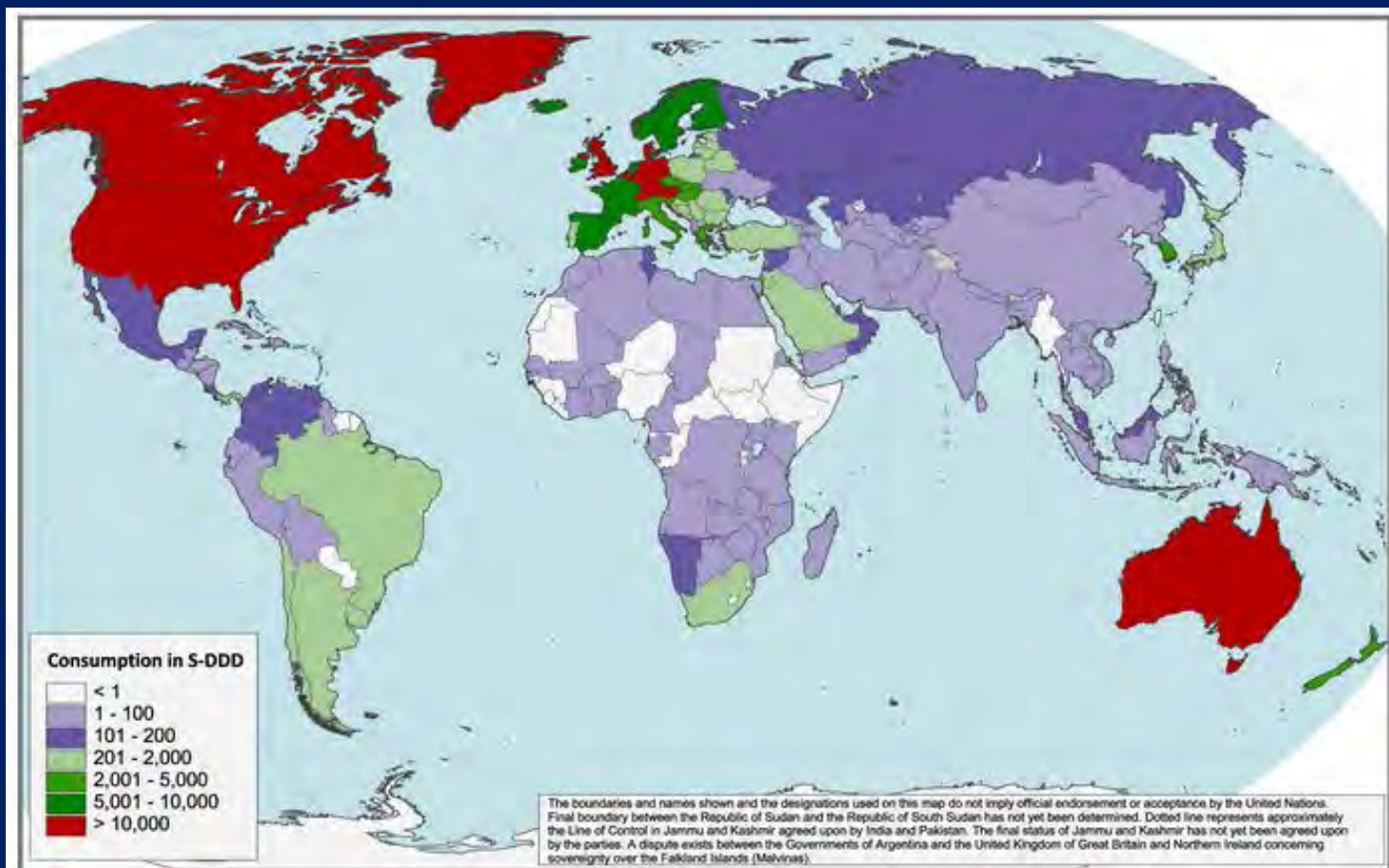
# Top 10 List

- 10 Guatemala 10 kilograms
- 09 India 10 kilograms
- 08 Vietnam 20 kilograms
- 07 China 20 kilograms
- 06 Denmark 25.5 kilograms
- 05 Columbia 30 kilograms
- 04 Syrian Republic 50 kilograms
- 03 Canada 115.5 kilograms
- 02 United Kingdom 200 kilograms
- 01 United States 79,700 kilograms 99.3%



# INCB: Availability of opioids\* for pain management (2010-2012 average)

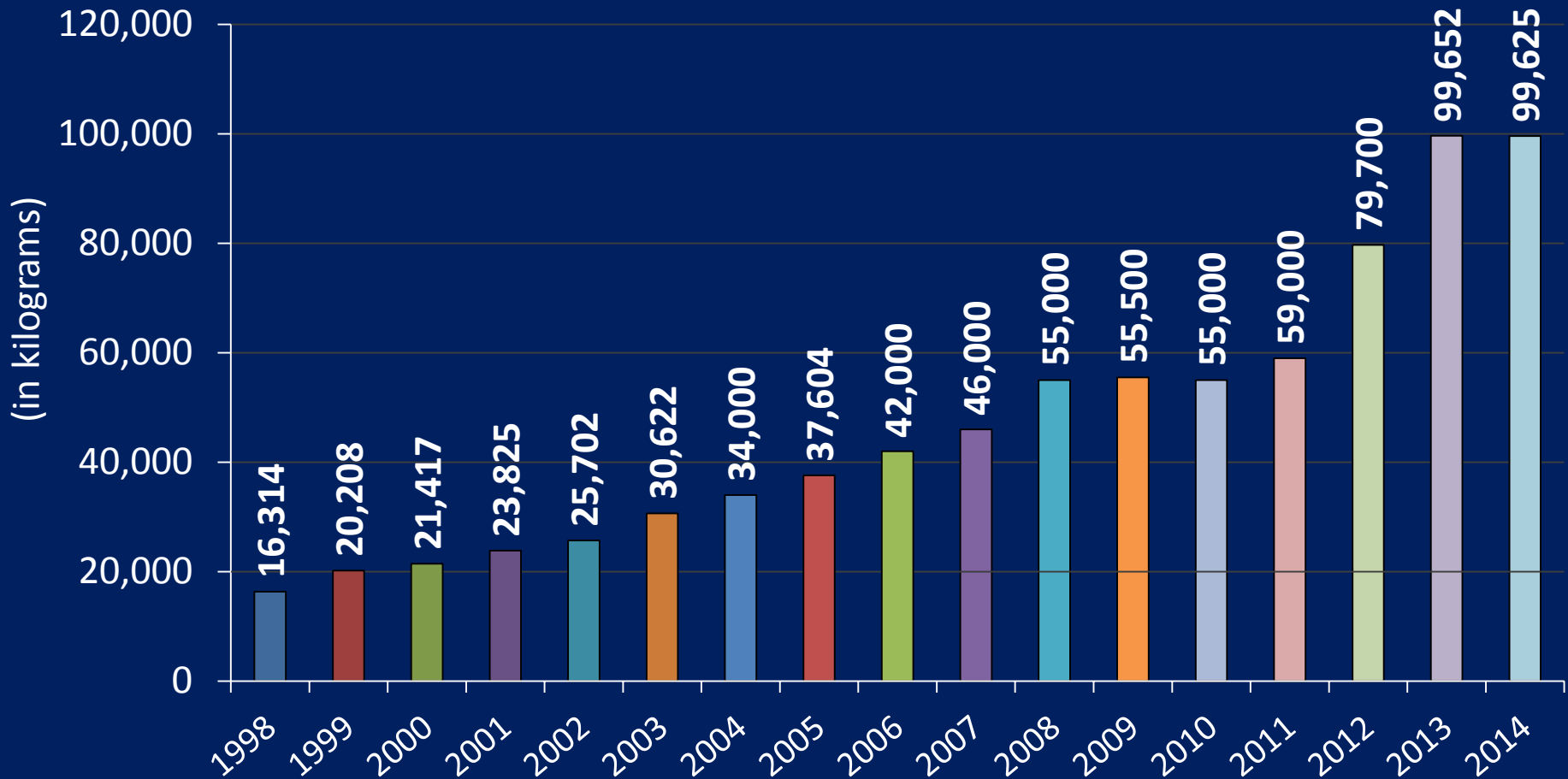
(Consumption in defined daily doses for statistical purposes (S-DDD)  
per million inhabitants per day)



\*Codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimeperidine.

# Hydrocodone

## Aggregate Production Quota History





# 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 will be 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

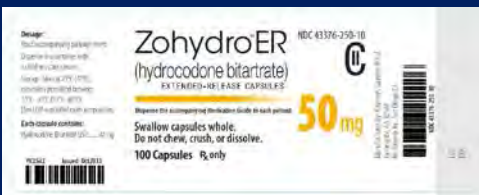
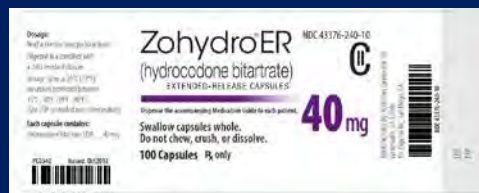
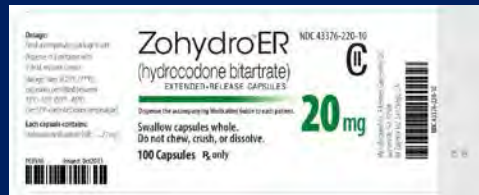
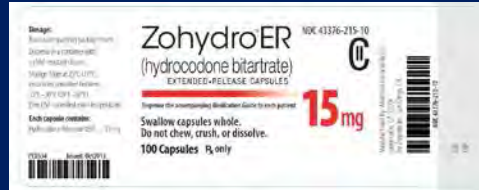
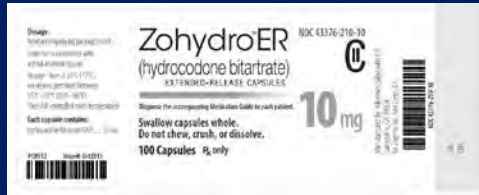


# Dosing Data for Clinically Employed Opioid Analgesics

DRUG	APPROXIMATE EQUI-ANALGESIC ORAL DOSE	APPROXIMATE EQUI-ANALGESIC PARENTERAL DOSE	RECOMMENDED STARTING DOSE (adults >50 kg)		RECOMMENDED STARTING DOSE (children and adults <50 kg) <sup>a</sup>	
			ORAL	PARENTERAL	ORAL	PARENTERAL
<b>Opioid Agonists</b>						
Morphine <sup>b</sup>	30 mg q3–4h (around-the-clock dosing) 60 mg q3–4h (single dose or intermittent dosing)	10 mg q3–4h	15 mg q3–4h	5 mg q3–4h	0.3 mg/kg q3–4h	0.1 mg/kg q3–4h
Codeine <sup>c</sup>	130 mg q3–4h	75 mg q3–4h	30 mg q3–4h	30 mg q2h (IM/SC)	1 mg/kg q3–4h <sup>d</sup>	Not recommended
Hydromorphone <sup>b</sup> (DILAUDID)	7.5 mg q3–4h	1.5 mg q3–4h	4 mg q3–4h	1 mg q3–4h	0.06 mg/kg q3–4h	0.015 mg/kg q3–4h
Hydrocodone (in LORCET, LORTAB, VICODIN, others, typically with acetaminophen)	30 mg q3–4h	Not available	5 mg q3–4h	Not available	0.2 mg/kg q3–4h <sup>d</sup>	Not available
Levorphanol	4 mg q6–8h	2 mg q6–8h	2 mg q6–8h	1 mg q6–8h	0.04 mg/kg q6–8h	0.02 mg/kg q6–8h
Meperidine (DEMEROL)	300 mg q2–3h	100 mg q3h	Not recommended	50 mg q3h	Not recommended	0.75 mg/kg q2–3h
Methadone (DOLOPHINE, others)	20 mg q6–8h	10 mg q6–8h	2.5 mg q12h	2.5 mg q12h	0.2 mg/kg q12h	0.1 mg/kg q6–8h
Oxycodone (REXICODONE, OXYCONTIN, also in PERCOCET, PERCODAN, TYLOX, others) <sup>g</sup>	30 mg q3–4h	Not available	5 mg q3–4h	Not available	0.2 mg/kg q3–4h <sup>d</sup>	Not available
Oxymorphone <sup>b</sup> (NUMORPHAN)	Not available	1 mg q3–4h	Not available	1 mg q3–4h	Not recommended	Not recommended
Propoxyphene (DARVON)	130 mg <sup>e</sup>	Not available	65 mg q4–6h <sup>e</sup>	Not available	Not recommended	Not recommended
Tramadol <sup>f</sup> (ULTRAM)	100 mg <sup>e</sup>	100 mg	50–100 mg q6h <sup>e</sup>	50–100 mg q6h <sup>e</sup>	Not recommended	Not recommended
<b>Opioid Agonist–Antagonists or Partial Agonists</b>						
Buprenorphine (BUPRENEX)	Not available	0.3–0.4 mg q6–8h	Not available	0.4 mg q6–8h	Not available	0.004 mg/kg q6–8h
Butorphanol (STADOL)	Not available	2 mg q3–4h	Not available	2 mg q3–4h	Not available	Not recommended
Nalbuphine (NUBAIN)	Not available	10 mg q3–4h	Not available	10 mg q3–4h	Not available	0.1 mg/kg q3–4h



# Approval of Single Entity Extended Release Hydrocodone



# Zohydro<sup>TM</sup>ER

(hydrocodone bitartrate) 

EXTENDED-RELEASE CAPSULES

10 mg • 15 mg • 20 mg • 30 mg • 40 mg • 50 mg

Manufactured by Alkermes Gainesville  
LLC for Zogenix, Inc. (San Diego, CA)

FDA Approval October 2013

Anticipated Launch March 2014

CURRENT RESEARCH (click one to see how you can help): Support Bluelight by taking the 2013 Inflexion survey!

## Thread: Zohydro's Here: Our New Problem Child? (HOLY LORD IN HEAVEN)

POST REPLY

Results 1 to 25 of 63 Page 1 of 3 1 2 3 Last

View First Unread Thread Tools Search Thread Display

### Zohydro's Here: Our New Problem Child? (HOLY LORD IN HEAVEN)



bigzip44

Greenlighter



Join Date: Aug 2009

Location: Seattle

Posts: 36



18-02-2014 01:19



**Zohydro** ER (hydrocodone bitartrate), created by Zogenix, which also makes needle-free sumatriptan injections, is to be released next month (March). They will be releasing this drug in 10, 15, 20, 30, 40, and 50 milligram CAPSULES, which I assume will be filled with a pure hydrocodone powder, despite the 11-2 panel of experts the FDA created to vote on the approval of the drug. This drug is now in production, obviously.

I was badly addicted to OxyContin for many years and I remain on buprenorphine to this day. This "new" drug, made from the same compound that first triggered my addiction to opioids (which I found in vicodin, of course) is to be released in EXACTLY the same way careless way that OXYCONTIN was released by Purdue Pharma except in a presumably even more abusable form, a powder within a capsule. Zogenix and **Zohydro**'s proponents have even gone so far as to reject claims that the new Tylenol-free formulation should be required to have a similar abuse preventative formulation that Purdue Pharma was finally forced into creating so as to continue selling their pure-formulation OxyCodone which is now, of course, the new, very unsexy OP.

Ah, now down to business. This drug is making my scrotum stir with anticipation; I cannot see a future where **Zohydro** exists where I also do not get high on it. What the fuck do you guys think about this new thing? Could this be the gnarliest opiate "epidemic" since, well, morphine? I want thoughts, information, experience, opinion, conjecture or speculation any of you professionals have on this new drug.

In my opinion, this is going to change history.

(FYI, this thread was moved from Other Drugs)

REPLY

QUOTE



miscbrahh

18-02-2014 03:06



shimazu

Ex-Bluelighter

Join Date: Mar 2012

Posts: 18,698

22-02-2014 16:02



I like hydrocodone but it always took too long for me to really enjoy vicodin. Not really a huge fan of the capsule approach either but people also produce fake Oxycodone pills so it always comes down to where you're getting them from.

Im just interested to see how hard these are pushed onto current pain patients vs how many people just stick with their regular hydro pills. Still though, any drug in an ER version that isn't abuse proof is cool in my book

REPLY

QUOTE



#32

StealYourFace

Bluelighter

Join Date: Oct 2011

Posts: 66

25-02-2014 00:29



The good news (for us) is that it uses Spheroidal Oral Drug Absorption System. Similar to Adderall XR, you can mash up the little beads and release the goodness 😊

REPLY

QUOTE



#33

Felonious Monk

Moderator

Drug Culture

Join Date: Nov 2013

Location: Interzone

Posts: 710

25-02-2014 00:44



Originally Posted by shimazu

*are more people using opiates now on average or are there just more people period and more ways to get in trouble for it?*

*rhetorical question really, but I tend to think a lot of famous "eccentric" people back in the day were really just huge drug addicts*

I think the consensus is that more people are using opioids nowadays, especially in the last 5 years, which is why it's starting to be recognized as a problem again. Everything I've read says that all markers of opioid use are up, and anecdotally people are seeing a lot more problems than they used to as well.

- treatment centers/prisons are seeing more upper-middle-class white males using heroin and strong opiates than they ever have before (and more of that population on MMT or bupe as well)

- opiate OD has become a major COD for middle-aged women

- heroin is stronger (in 😊 than it's ever been since the passage of the CSA (and cheaper)



Location: Boston

Posts: 825

REPLY

QUOTE



StealYourFace

Bluelighter

Join Date: Oct 2011

Posts: 66

18-02-2014 16:40



Looking at the product sheet on the mfg website, it looks as if the time release system is similar to Adderall XR/ Dex Spansules with the little time release balls inside. If this is true, these would be awesome. I've never sniffed hydrocodone before for obvious reasons, but this would make it very easy.

\*Crosses fingers\*

REPLY

QUOTE



Whosajiggawaaa

Bluelighter



Join Date: Jul 2011

Location: Here. I grew up in a crackhouse.

Posts: 3,152

18-02-2014 18:09



I have never tried hydrocodone only oxy and almost every other opiod. Sort of amped.

REPLY

QUOTE



#11



jackie jones

Bluelight Crew



Join Date: Jul 2008

Location: A spoonful of sugar  
helps the medicine go down.

Posts: 5,589

20-02-2014 15:32

#19



**ZohydroER**  
(hydrocodone bitartrate)  
EXTENDED-RELEASE CAPSULES

1<sup>st</sup>

Oral, Extended Release  
Hydrocodone without  
Acetaminophen for Treating  
Chronic Pain

PDUFA Date March 1, 2013



REPLY

QUOTE



Bigfanofthemdrugs

Moderator

Drug Culture  
Cannabis Discussion



Join Date: Mar 2012

Location: The Limbic System

20-02-2014 20:20

#20



Idk what you guys are tripping about, I'm stoked to get in on some of that, hydrocodone is one of my favorite opioids. It's just as euphoric as oxy IMO.



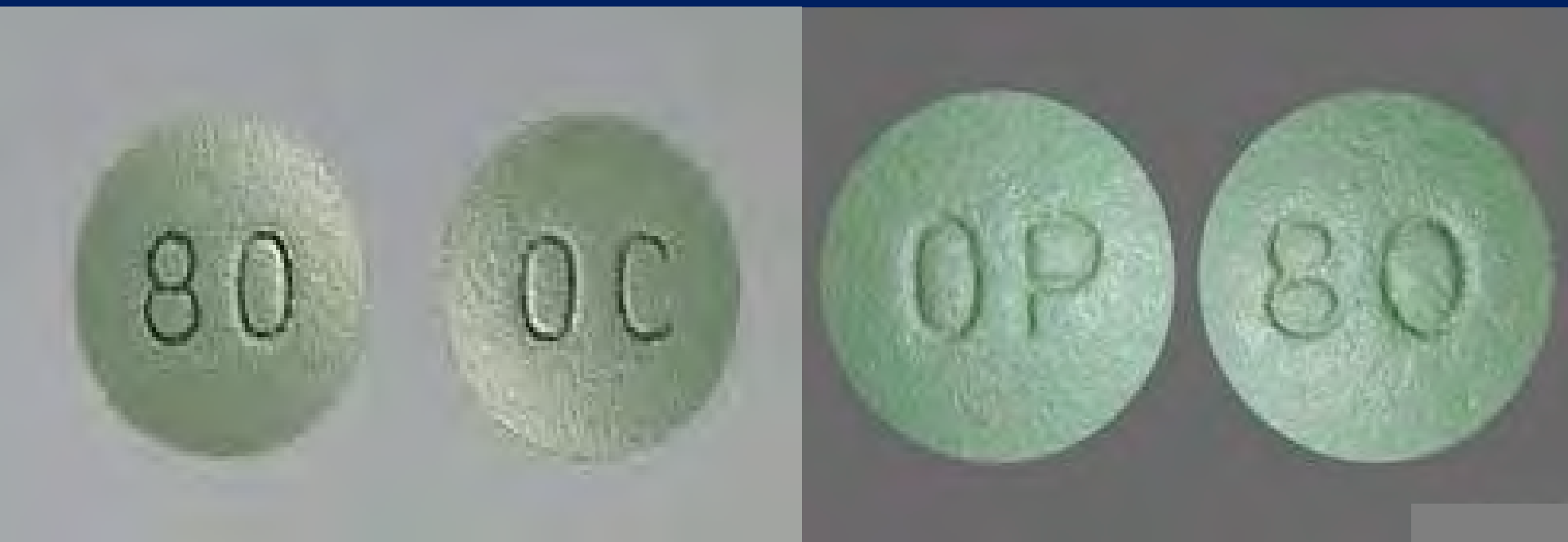


# OXYCODONE





# Oxycodone HCL CR (OxyContin®) Reformulation







# New OxyContin<sup>®</sup> OP



08-27-2010, 01:11 AM

[mz.mary420](#)  
Member



Join Date: May 2010  
Location: down south  
Posts: 6

#17

well just got ours and they suck! when snorted the pill balls up in your nose and gets stuck, so i tried sucking on one and it did ok, but tastes nasty. No way you can shoot them as metioned in a previous post. havent tried smoking it yet, kinda in a hole money wise, it cost me over \$700.00 to get my 80s filled and i probably wont even get half my money back 😞

\* if anyone has tried to smoke this new formulated shit, please post! thanks

Quote

08-27-2010, 06:09 AM

[mephist00](#)  
Member



Join Date: Apr 2008  
Location: NY  
Age: 25  
Posts: 628

#18

ya my friend has tried to smoke the new ones... said its very harsh on the lungs and throat..

so far the only way ive been able to beat the time release, is use a hose clamp to grind it very fine, and snort it.. it doesnt gel up like you would think (doesnt gel up like the football shaped generic 40's do anyways) it just kinda turns snotty.. but if you can get it down fast it seems to work ok

Quote:

Originally Posted by **stalk**  
*I've come to the conclusion it's because these psychedelic visions are simply vibrating on a higher, or different, spectrum of frequencies that normally the monkey does not perceive.*



# Oxycodone 15mg/30mg Immediate Release







# Other Oxycodone Products

Percodan

Tylox

Percocet



**Trade Name:** Percodan-Demi  
Controlled Ingredient: oxycodone hydrochloride 2.25 mg and  
oxycodone terephthalate 0.19 mg  
Other Ingredients: aspirin, 325 mg



**Trade Name:** Percodan  
Controlled Ingredient: oxycodone hydrochloride 4.5 mg and  
oxycodone terephthalate 0.38 mg  
Other Ingredients: aspirin, 325 mg

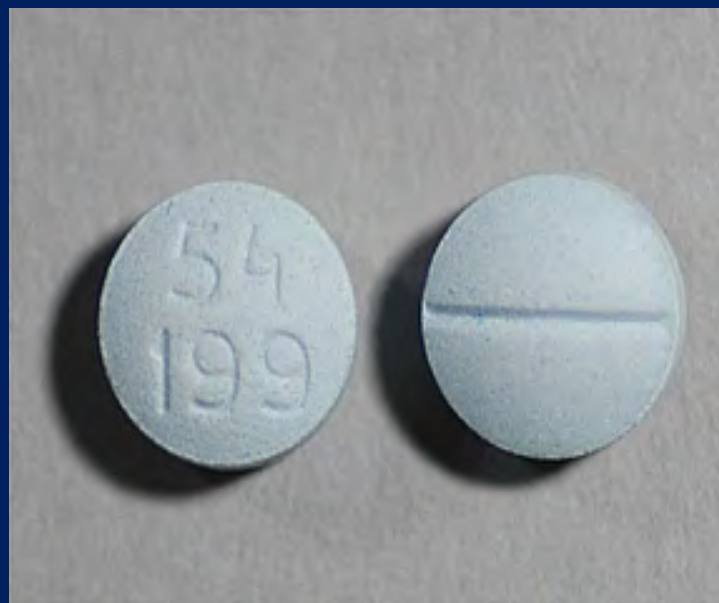


**Trade Name:** Tylox  
Controlled Ingredient: oxycodone hydrochloride 4.5 mg and  
oxycodone terephthalate 38 mg  
Other Ingredients: Acetaminophen, 500 mg



**Trade Name:** Percocet  
Controlled Ingredient: oxycodone hydrochloride, 5 mg  
Other Ingredients: Acetaminophen, 325 mg

## Roxicodone



# FDA Approves Abuse-Deterrent Oxycodone/Naloxone Combo

Susan Jeffrey

July 23, 2014

The US Food and Drug Administration (FDA) has approved an abuse-deterrent extended-release formulation of oxycodone (*Targiniq ER*, Purdue Pharma LP), a combination of oxycodone hydrochloride and naloxone hydrochloride, the agency announced today.

The new formulation is approved to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment, for which alternative treatment options are inadequate.

It is the second extended-release/long acting (ER/LA) opioid with FDA-approved labeling describing its abuse-deterrent properties "consistent with the FDA's 2013 draft guidance for industry, [Abuse-Deterrent Opioids – Evaluation and Labeling](#)," a statement from the FDA notes.

"The FDA is committed to combating the misuse and abuse of all opioids, and the development of opioids that are harder to abuse is needed in order to help address the public health crisis of prescription drug abuse in the US," said Sharon Hertz, MD, deputy director of the Division of Anesthesia, Analgesia, and Addiction Products in the FDA's Center for Drug Evaluation and Research. "Encouraging the development of opioids with abuse-deterrent properties is just one component of a broader approach to reducing abuse and misuse, and will better enable the FDA to balance addressing this problem with meeting the needs of the millions of people in this country suffering from pain."

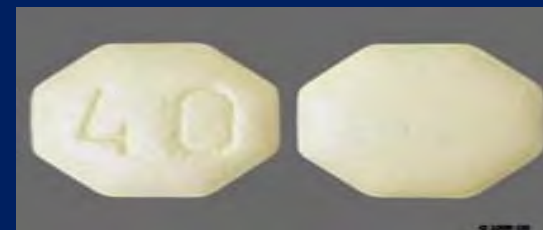
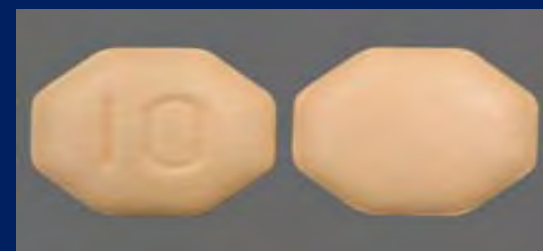
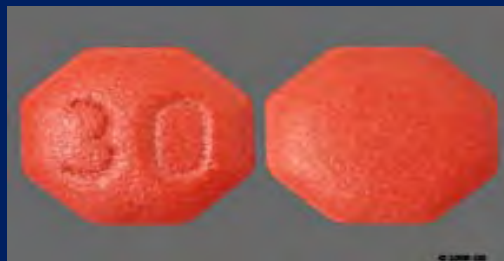
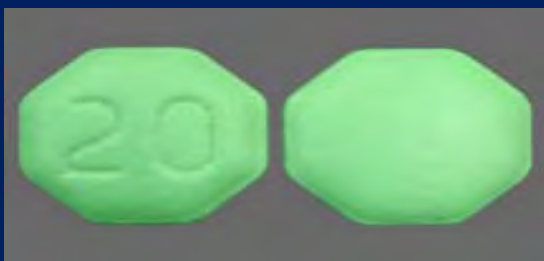


# Oxymorphone Extended Release

## Opana ER® (Schedule II)

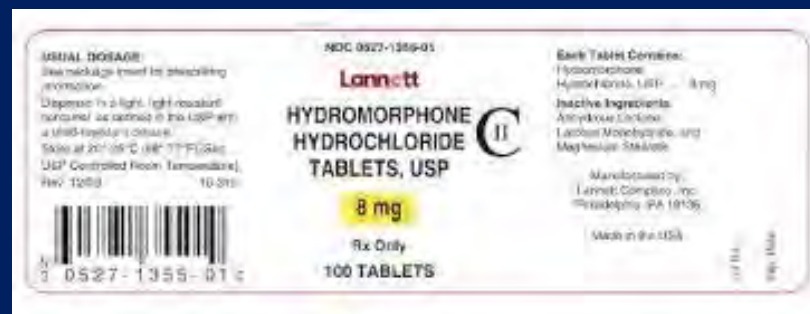
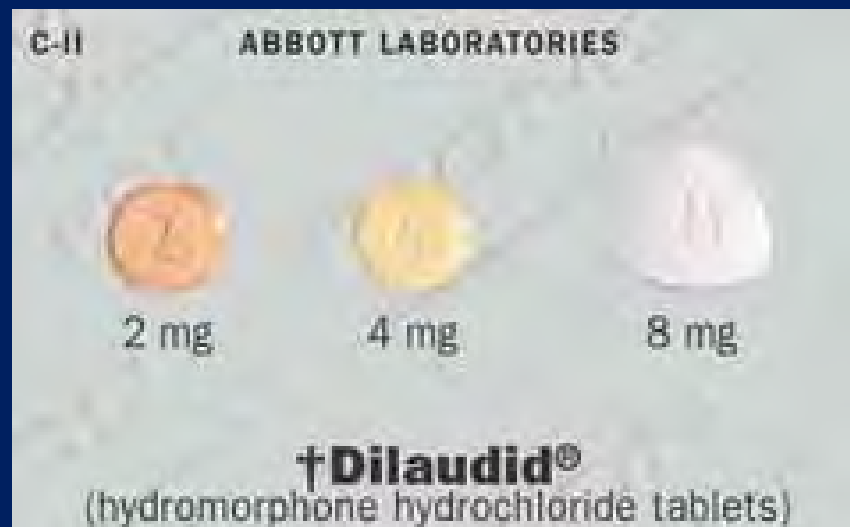
### ➤ Opana ER® - (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming popular and is abused in similar fashion to oxycodone ; August 2010 (Los Angeles FD TDS)
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: \$10.00 – \$80.00





# Hydromorphone





# Other Opiates of Interest



**Trade Name: MS Contin**  
Controlled Ingredient: morphine sulfate, 100 mg



**Trade Name: MS Contin**  
Controlled Ingredient: morphine sulfate, 15 mg



**Trade Name: MS Contin**  
Controlled Ingredient: morphine sulfate, 30 mg



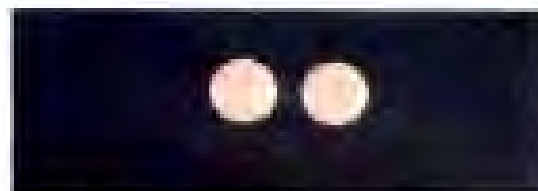
**Trade Name: Oramorph SR**  
Controlled Ingredient: morphine sulfate, 30 mg



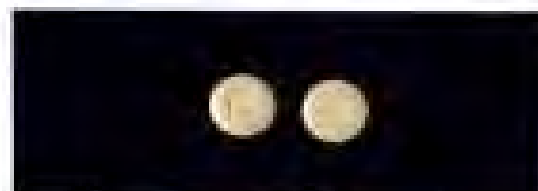
**Trade Name: Oramorph SR**  
Controlled Ingredient: morphine sulfate, 100 mg



**Trade Name: Oramorph SR**  
Controlled Ingredient: morphine sulfate, 60 mg



**Trade Name: Dilaudid**  
Controlled Ingredient:  
hydromorphone hydrochloride, 2 mg



**Trade Name: Dilaudid**  
Controlled Ingredient:  
hydromorphone hydrochloride, 4 mg



# Fentanyl



**Fentora®**



**Actiq®**

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

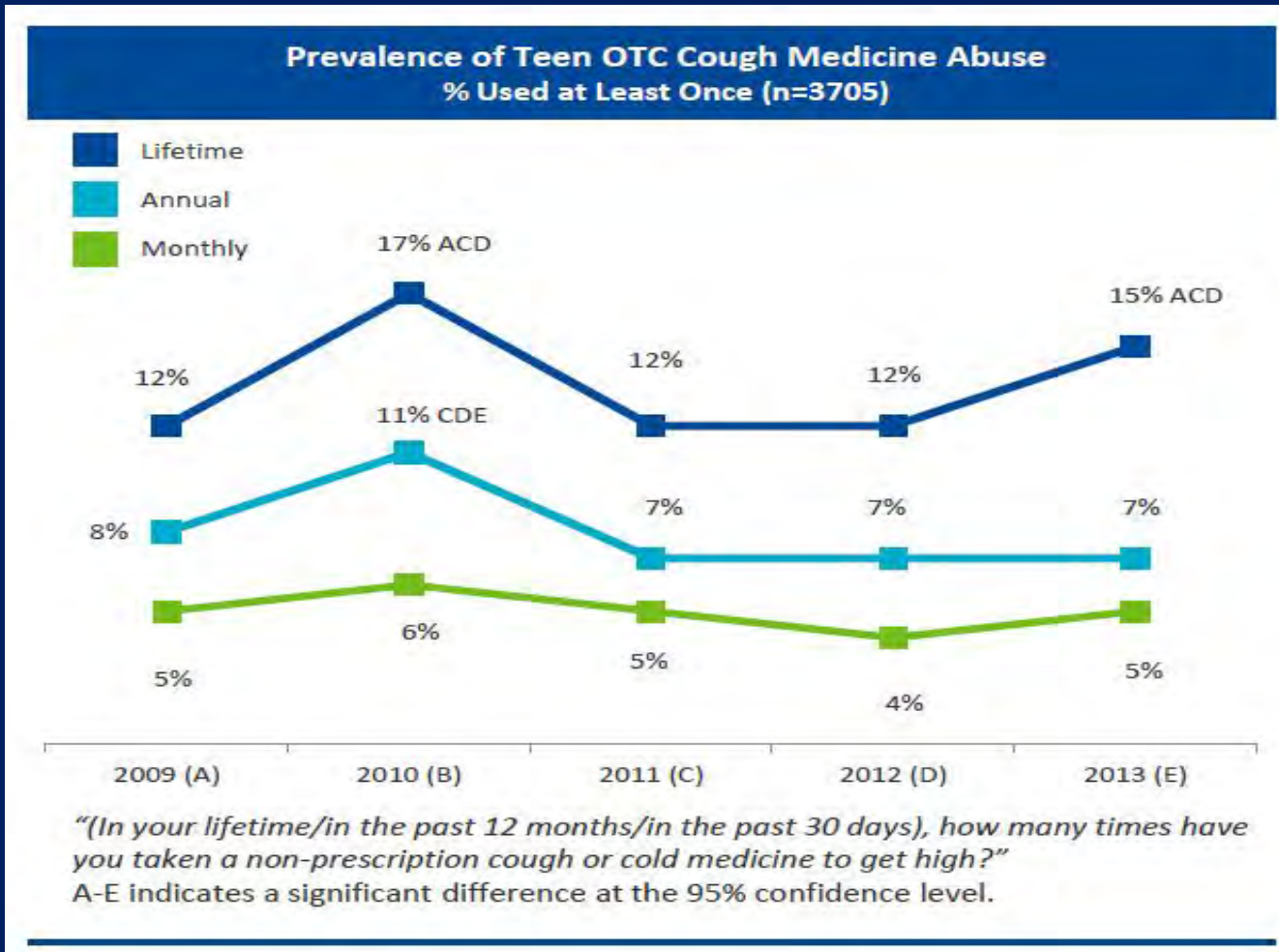


# Dextromethorphan (DXM)

- 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







# Cough Syrup Cocktails

- “Syrup and Soda”
- “Seven and Syrup”
- “Purple Drank”



**PURPLE DRANK**  
ima grip and sip





# Opioids v. Heroin



*Papaver*



*Somniferum*

Codeine

Morphine

Thebaine

Hydrocodone

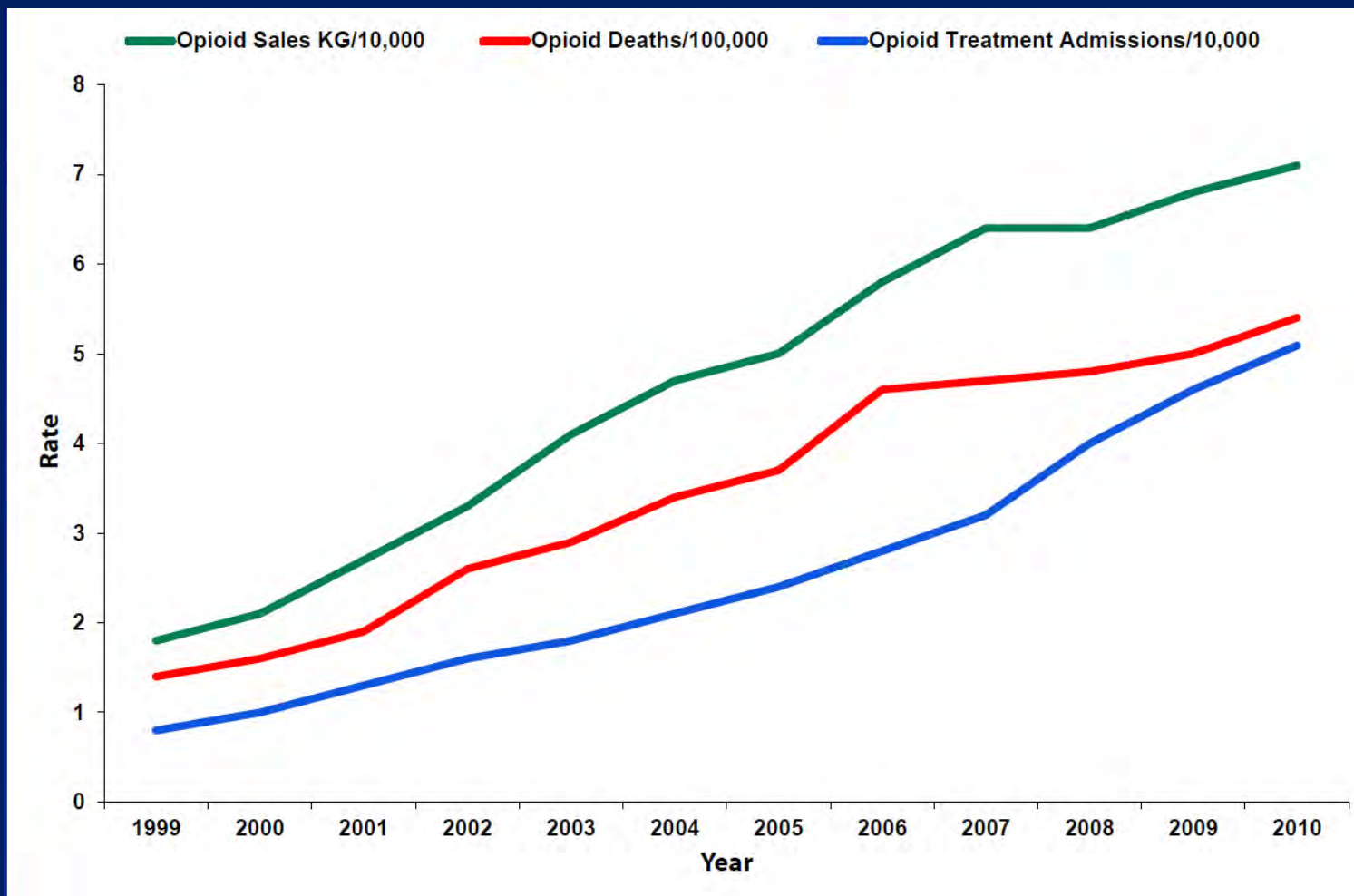
Hydromorphone

Oxycodone  
Hydrocodone





# 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

U.S. Drug Enforcement Administration  
Office of Diversion Control



# Circle of Addiction & the Next Generation

Oxycodone  
Combinations

Percocet®

\$7-\$10/tab

Hydrocodone

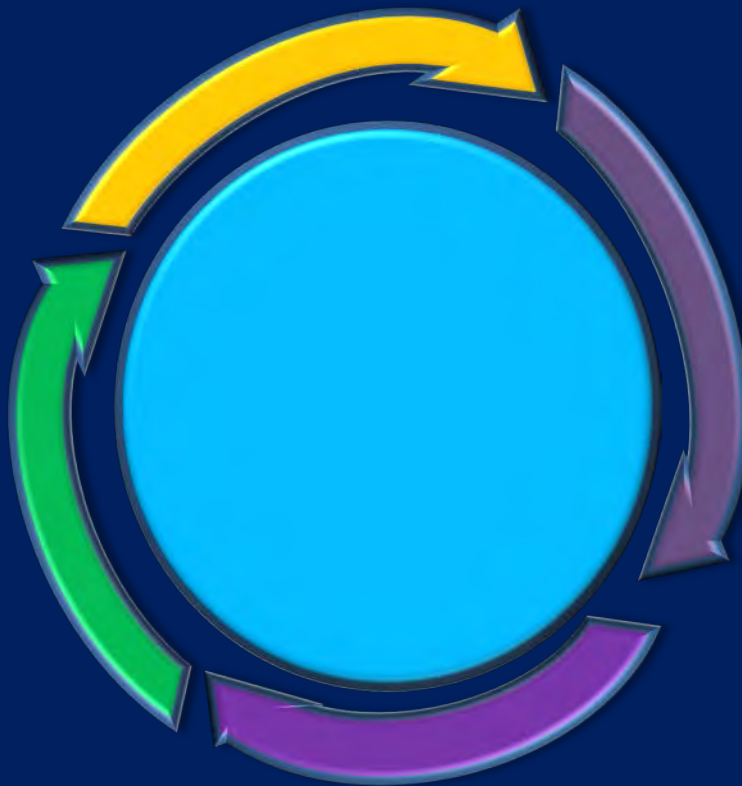
Lorcet®

\$5-\$7/tab

OxyContin®  
\$80/tab

Roxicodone®  
Oxycodone IR  
15mg, 30mg  
\$30-\$40/tab

Heroin  
\$10/bag





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# The Examiner

## WASHINGTON

WEDNESDAY, DECEMBER 5, 2012

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### 'Liaisons Dangereuses'

New approach to classic P. 19



### Playoff possibilities

Schedule favors Skins P. 35

### Cooling down



**60° 34°**

DETAILS P. 4

#### POLITICS

### Stalemate on 'cliff'

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

#### LOCAL

### FBI analyst busted

# Heroin use spikes in area suburbs

## Pill addicts risk deadly drug

Post Nation

# More people died from heroin overdoses in New York City last year than any year since 2003



By **Mark Berman** August 28  [Follow @themarkberman](#)

The number of people who died from unintentional heroin overdoses in New York City last year was the highest toll the city has seen in a decade, according to [data released Thursday](#) by the city's Department of Health and Mental Hygiene.

In New York, where the overall rate of drug overdose deaths has dramatically risen since 2010, there is a national problem playing out across the city's streets. The number of overdoses involving heroin in the city has significantly increased since 2010, accounting for more than half of New York City's overdoses last year. And more than three-quarters of the overdoses in the city involved an opioid of some kind.

This information comes amid a pair of national epidemics operating in tandem: A [surge in heroin usage](#) nationwide has been accompanied by a [much larger opioid epidemic](#), with drugs such as oxycodone and

Advertisement

Source: The Washington Post, August 28, 2014  
<http://www.washingtonpost.com/news/post-nation/wp/2014/08/28/more-people-died-from-heroin-overdoses-in-new-york-city-last-year-than-any-year-since-2003/>

## Most Read National

**1** 4chan: The 'shock post' site that hosted the private Jennifer Lawre...



**2** Leaks of nude celebrity photos raise concerns about security of the cl...







# 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

# Acetylfentanyl

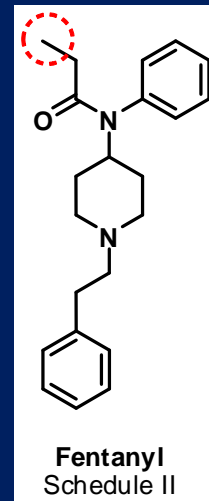
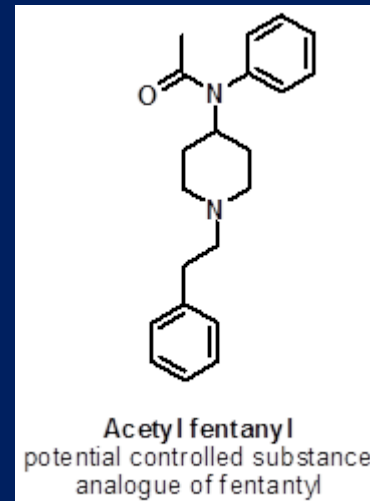
- Chemically-modified derivative of the powerful prescription painkiller Fentanyl
- is reportedly “50 times more potent than heroin and 100 times stronger than morphine
- May 2013 - 10,000 pills of “Desmethy Fentanyl” intercepted in Montreal— hidden inside a microwave oven and a toaster destined for 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



# 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”

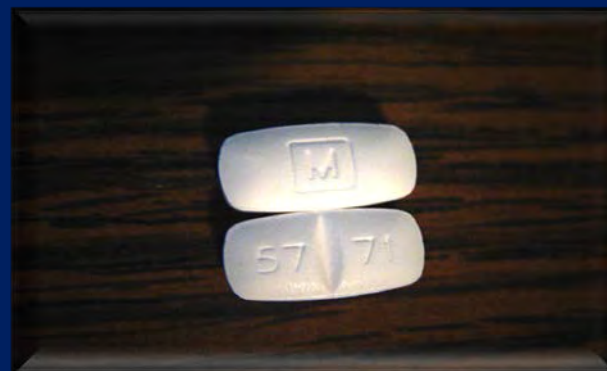




# METHADONE



# Methadone- 5mg & 10mg



Mallinckrodt Pharmaceuticals 5 mg & 10mg

# Methadone 40 mg



NDC 0406-0540-34

100 TABLETS

**METHADOSE™**  
Dispersible Tablets **C II**  
(Methadone Hydrochloride  
Tablets for Oral Suspension USP)

**40 mg**

Each tablet contains:  
Methadone Hydrochloride USP..... 40 mg  
**Rx only**

**Mallinckrodt**

**COVIDIEN™**

**Usual Dosage:**  
See accompanying literature for dosage.

Keep tightly closed.

Dispense in a tight container (USP) with a child-resistant closure.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.,  
Hazelwood, MO 63042 USA.

3 0406-0540-34 7

100M10 Rev 01/09/99

# Treatment of Narcotic Addiction





# WHY IS IT ALSO USED AS AN ANALGESIC?

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?



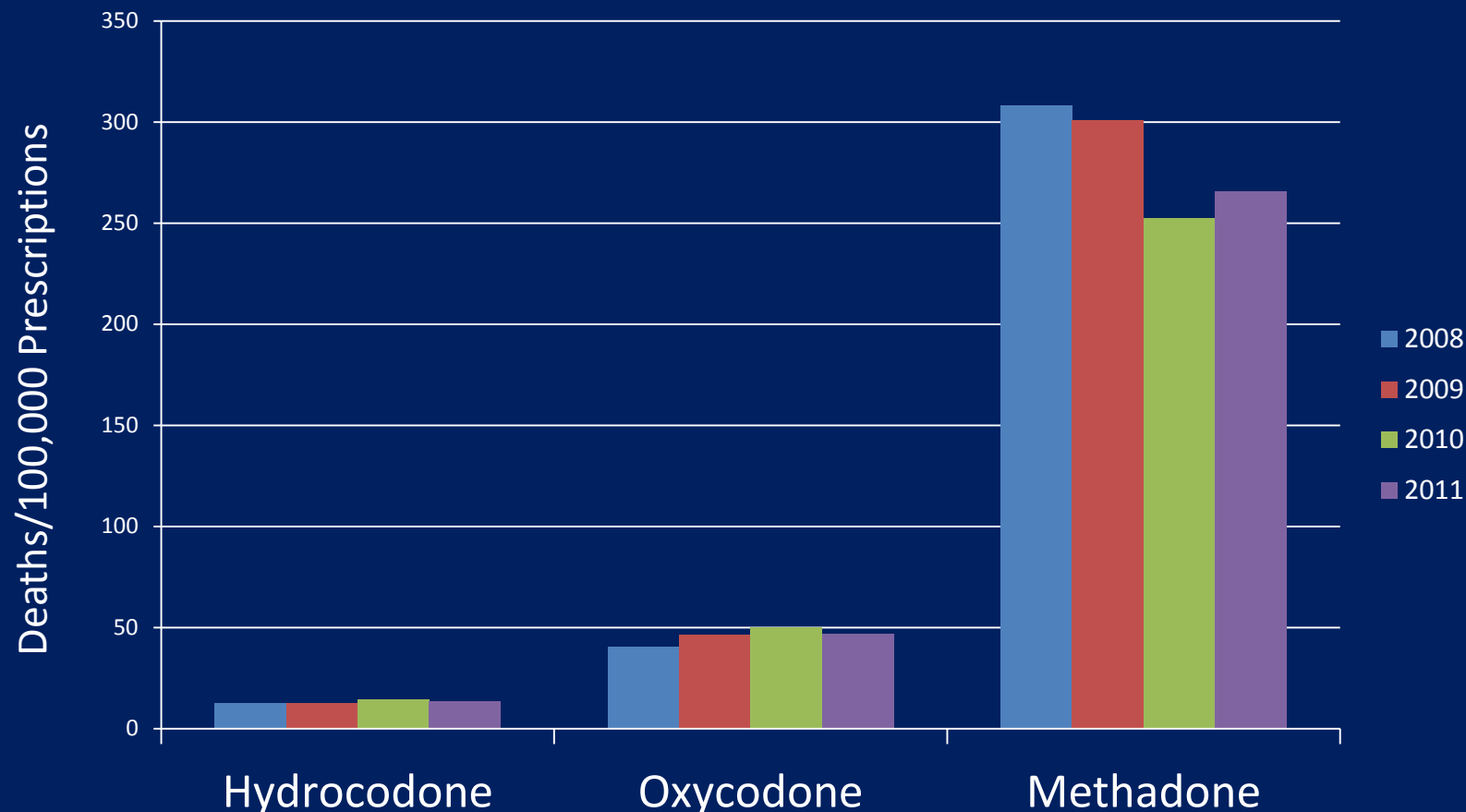
# Overdose...Why?

- 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



# One Pill can Kill



CE Article: (AOCME, CMI, ACEH) 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 \_\_\_\_\_ Date \_\_\_\_\_  
Address \_\_\_\_\_

### Rx

**D**eath 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.

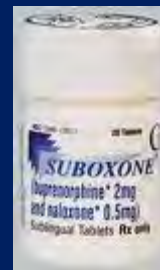
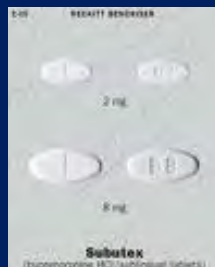


# Other FDA Approved Drugs for Narcotic Addiction Treatment

## ➤ Schedule III

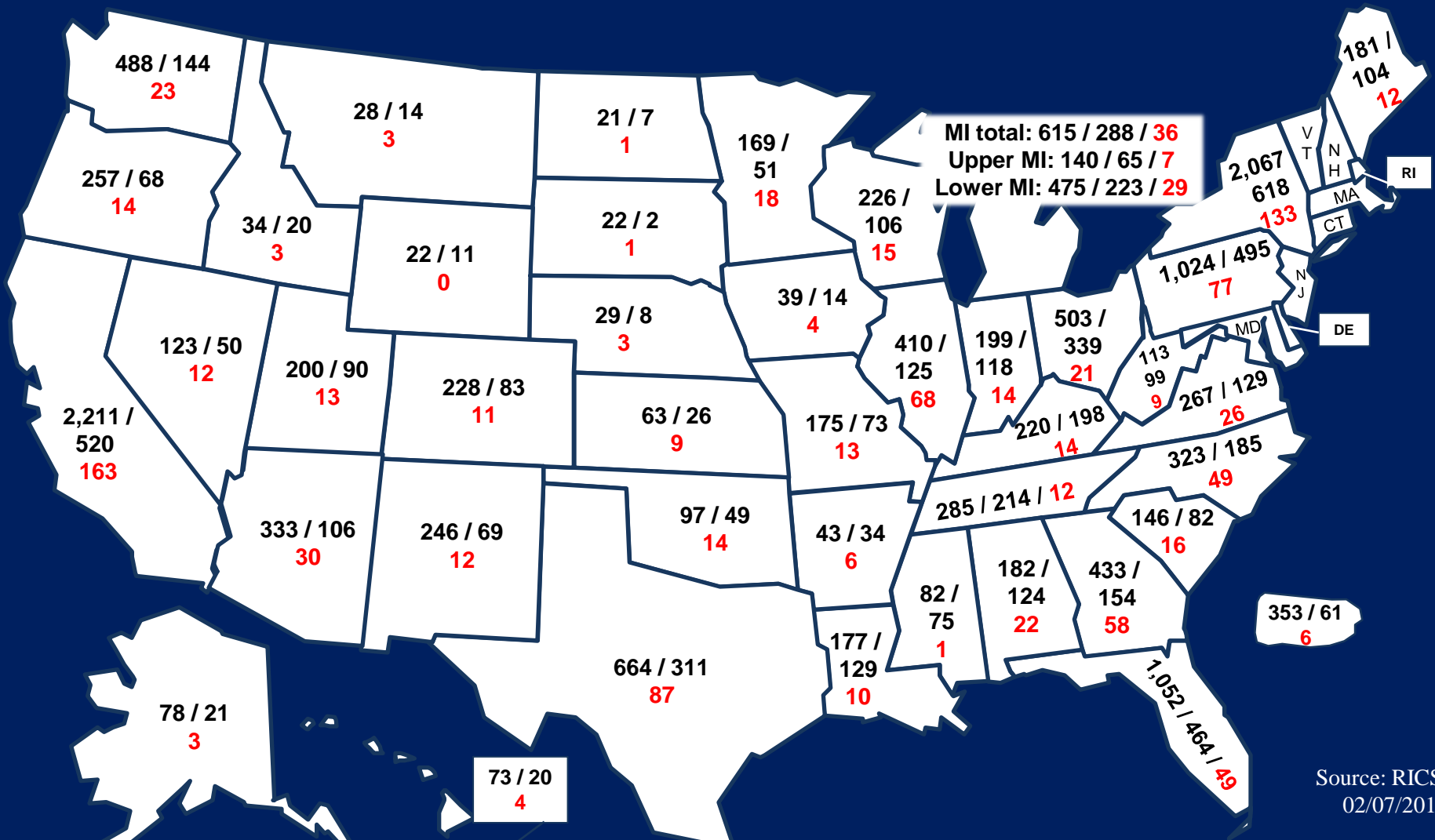
### – Buprenorphine – Drug Code 9064

- Subutex (sublingual, single entity tablet)
- Suboxone (sublingual, buprenorphine/naloxone tablet)





# Current DATA-Waived (DW) Practitioners and Narcotic Treatment Programs (NTP), by State



Source: RICS,  
02/07/2014

Key: 1<sup>st</sup> number = DW 30 (17,333)  
 2<sup>nd</sup> number = DW 100 (7,169)  
 3<sup>rd</sup> number = NTP (1,344)

State	DW30	DW100	NTPs
VT	133	43	10
NH	56	37	8
MA	845	395	61

State	DW30	DW100	NTPs
CT	333	153	38
RI	113	66	17
NJ	624	281	35

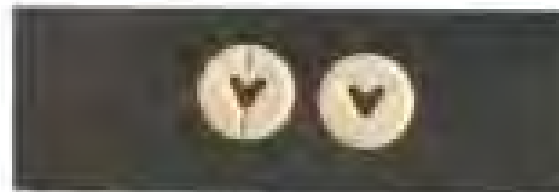
State	DW30	DW100	NTPs
DE	55	31	9
MD	587	247	65
DC	74	15	5



# Benzodiazepines



Trade Name: Valium  
Controlled Ingredient: diazepam,  
10 mg



Trade Name: Valium  
Controlled Ingredient: diazepam,  
5 mg



Trade Name: Valium  
Controlled Ingredient: diazepam,  
2 mg



# 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<sup>®</sup> (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 7<sup>th</sup>\*\*

\* Source IMS Health

\*\* Source Verispan VONA





# Stimulants

## Amphetamine Salts C-II

### ➤ Adderall ® C-II



## Methylphenidate C-II

### ➤ Ritalin®

### ➤ Concerta®







# 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



# Doctor Shopping





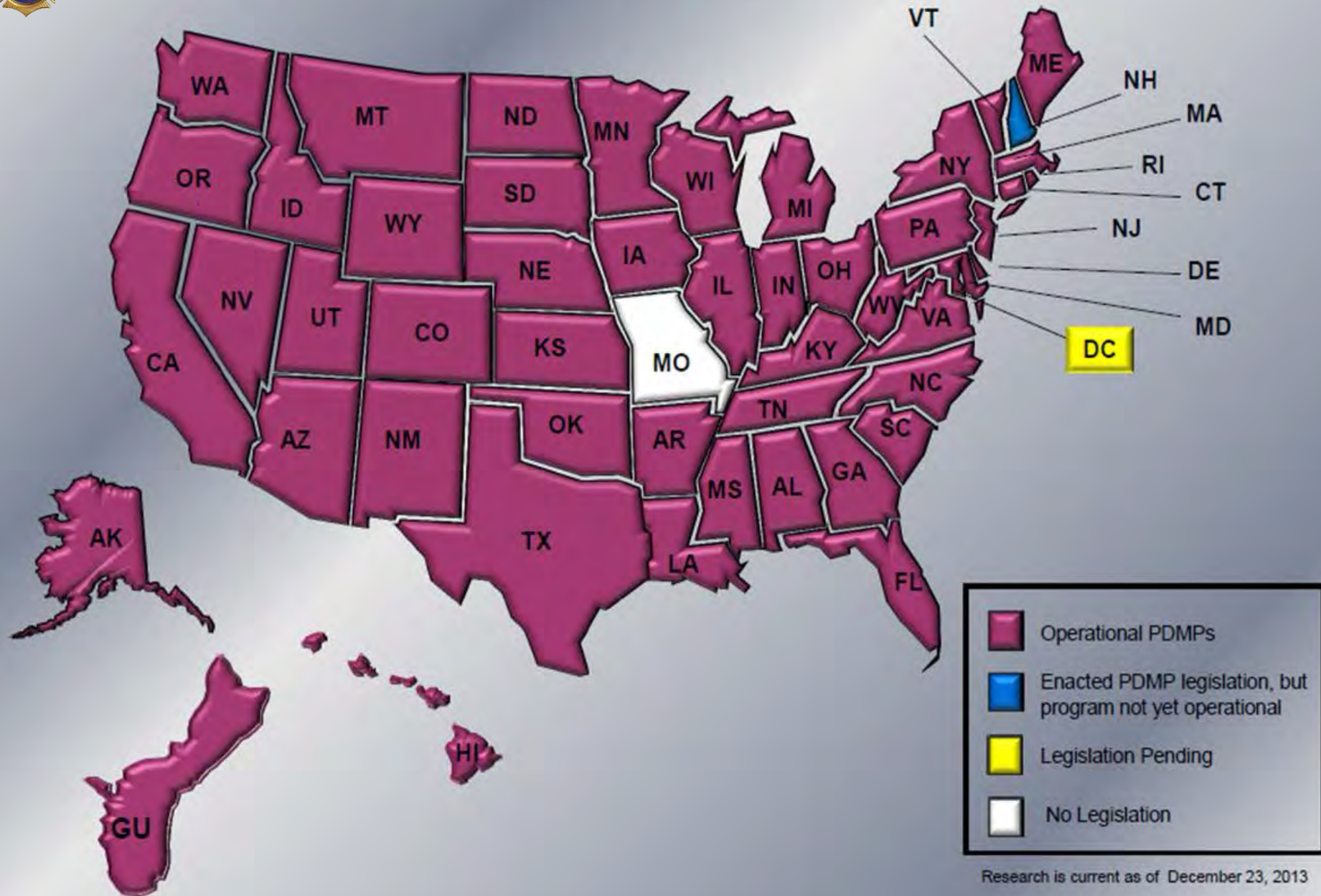
# Prescription Drug Monitoring Programs





# Status of Prescription Drug Monitoring Programs (PDMPs)

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





# Mandatory PDMP review before prescribing CS?



# Pharmacist access to PDMP



# Standard of Care



# National Association of Boards of Pharmacy



# Diversion via the Internet





# Domestic 'Rx' Flow

1. Consumer in Montana orders hydrocodone on the Internet

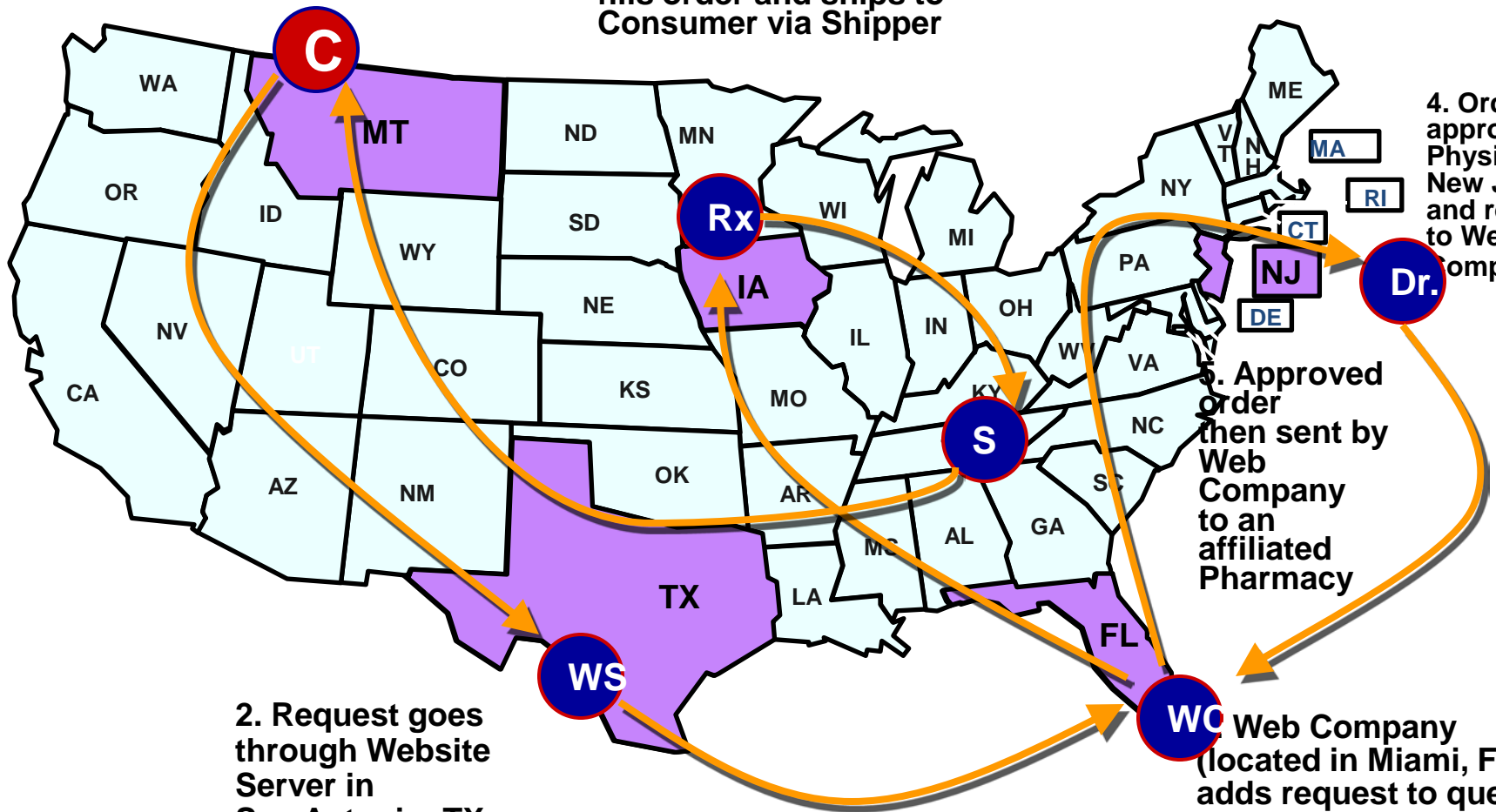
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4. Order is approved by Physician in New Jersey and returned to Web Company

2. Request goes through Website Server in San Antonio, TX

3. Approved order then sent by Web Company to an affiliated Pharmacy

5. Web Company (located in Miami, FL) adds request to queue for Physician approval





# 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: 1,522,913**

➤ Practitioner	-	1,177,306
➤ Mid-Level Practitioner	-	246,443
➤ Pharmacy	-	69,794
➤ Hospital/Clinic	-	16,045
➤ Teaching Institution	-	312
➤ Manufacturer	-	543
➤ Distributor	-	839
➤ Researcher	-	7,336
➤ Analytical Labs	-	1,524
➤ NTP	-	1,365
➤ Importer/Exporter	-	476
➤ ADS Machine	-	755
➤ Chemicals	-	1,005



# SOOOO...How many have applied for registration for Internet Pharmacy Operations????

43 applications filed

23 withdrawn

7 applications filed in error

12 pending

**NONE APPROVED**



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

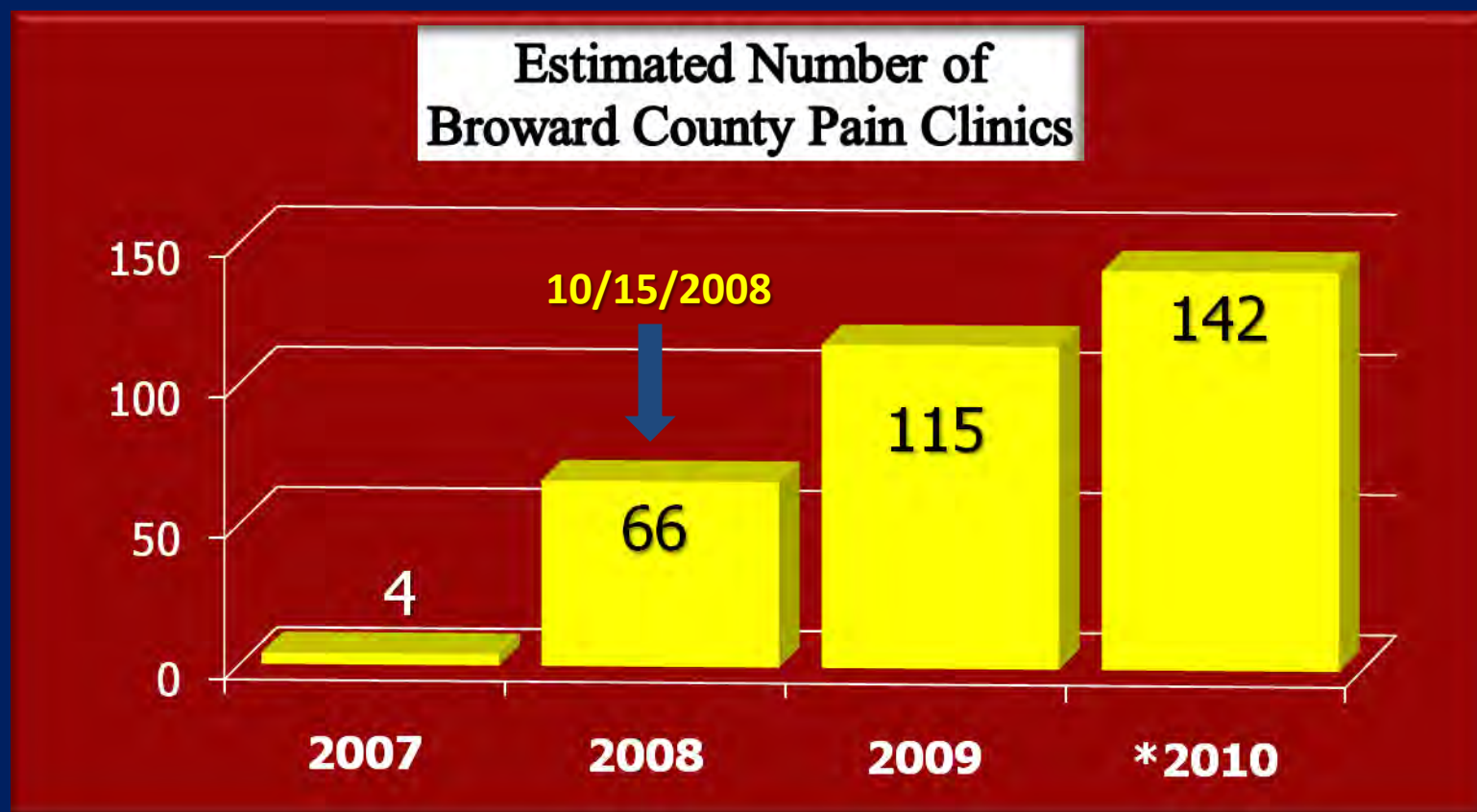




# Pain Clinics



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



# 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



# The Controlled Substances Act

# 21 United States Code



# 21 USC 801

## Congressional Findings and declarations: Controlled Substances

Many of the drugs included within subchapter have a useful and legitimate purpose and are necessary to maintain health and general welfare

The illegal importation, manufacture, distribution and possession and improper use of a CS has a substantial detrimental effect on the health and welfare of the American People

Major portion of the traffic in controlled substances flows through interstate and foreign commerce

Local distribution and possession of CSs contribute to the swelling of interstate trafficking of such substances

CSs manufactured and distributed Intrastate cannot be differentiated from those distributed interstate

Federal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic

U.S. is party to international conventions designed to establish effective controls over CS trafficking

# 21 USC 802

## Definitions

Probably the most important section of the Controlled Substances Act (“CSA”) and also the least read and understood

Provides definitions of words and terms used in the statutory construction of the CSA that will give the reader a better understanding of the true meaning of sections and provisions within of the CSA



# CSA Registrant Population

Current Number of  
DEA Registrants.....

**1,523,712**

March 20, 2014

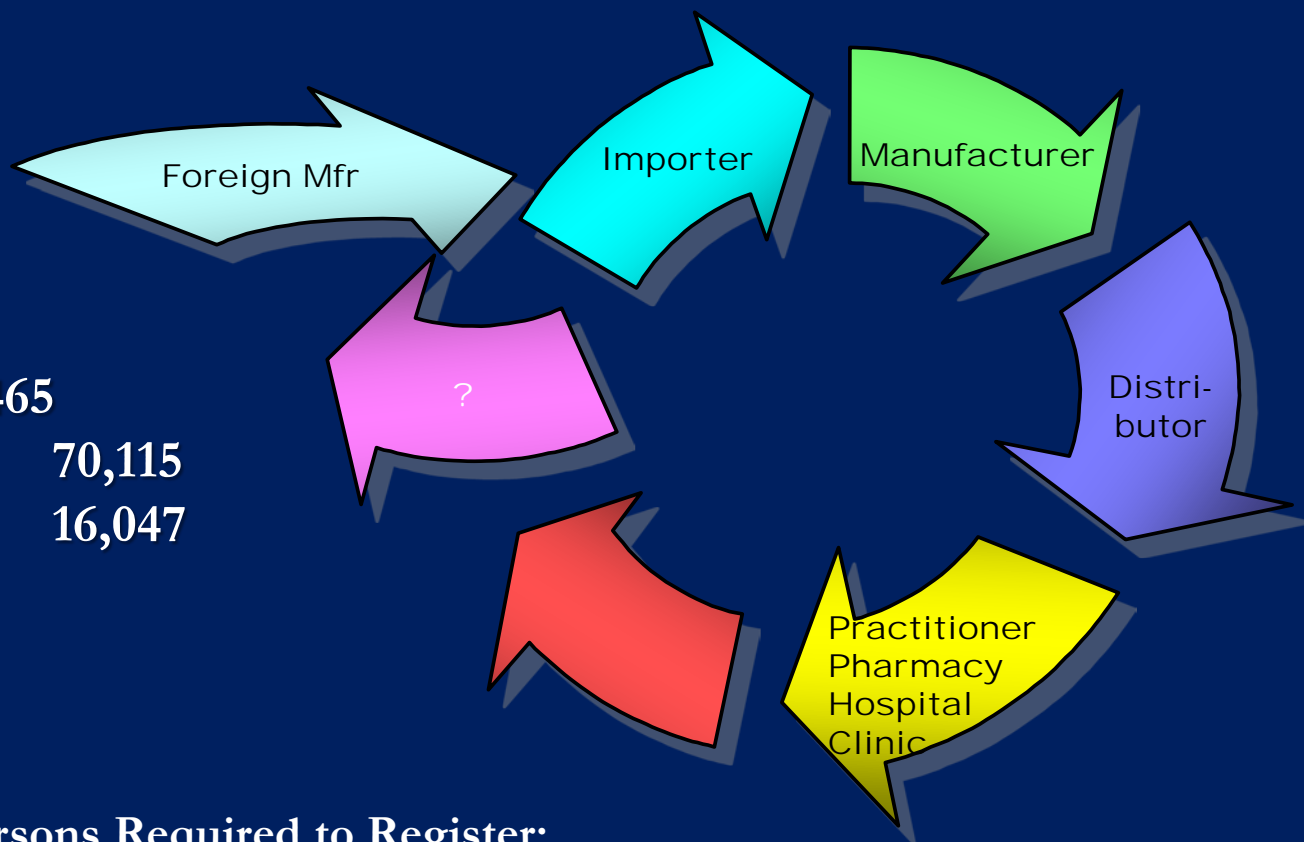
**480,000**

**1973**

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



# Closed System of Distribution



1,532,161 (06/04/2014)

Practitioners: 1,182,465

Retail Pharmacies: 70,115

Hospital/Clinics: 16,047

**Law: 21 USC 822 (a) (1) Persons Required to Register:**

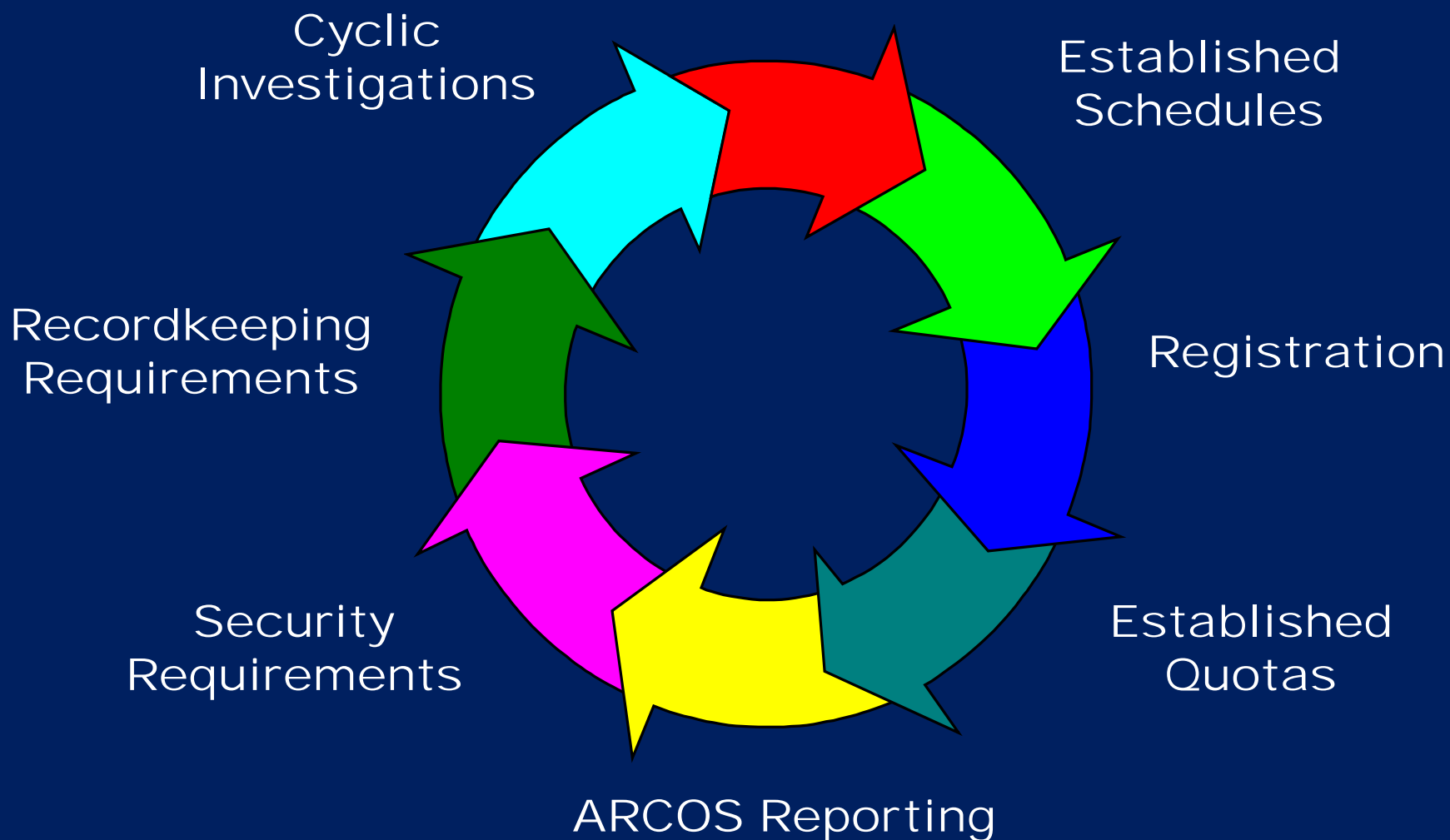
“Every person who manufactures or distributes any Controlled Substance or List I Chemical or who proposes to engage in ..”

**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







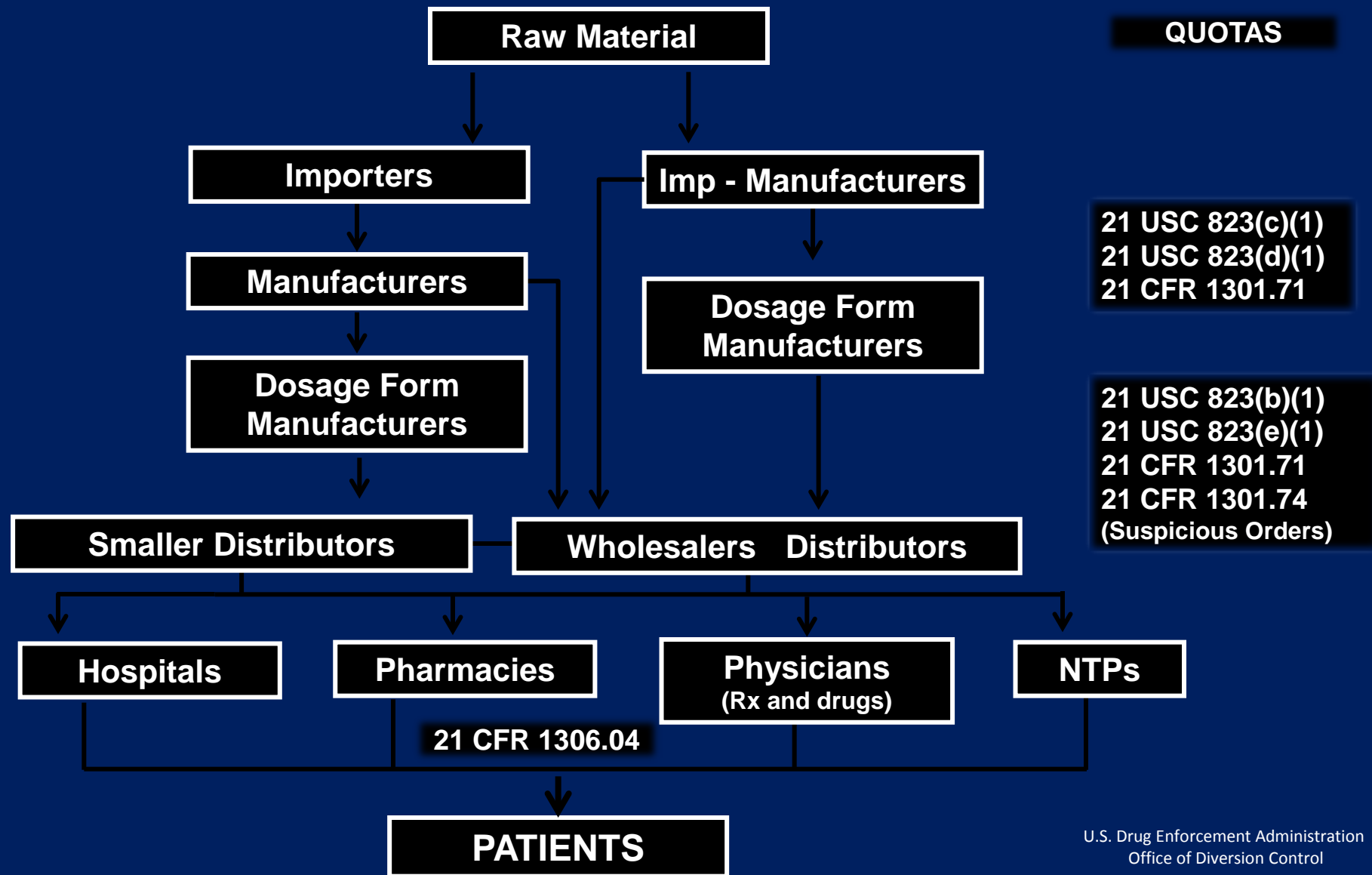
# The Controlled Substances Act

## Checks and Balances





# The Flow of Pharmaceuticals





# Diversion via the Internet



# Domestic 'Rx' Flow

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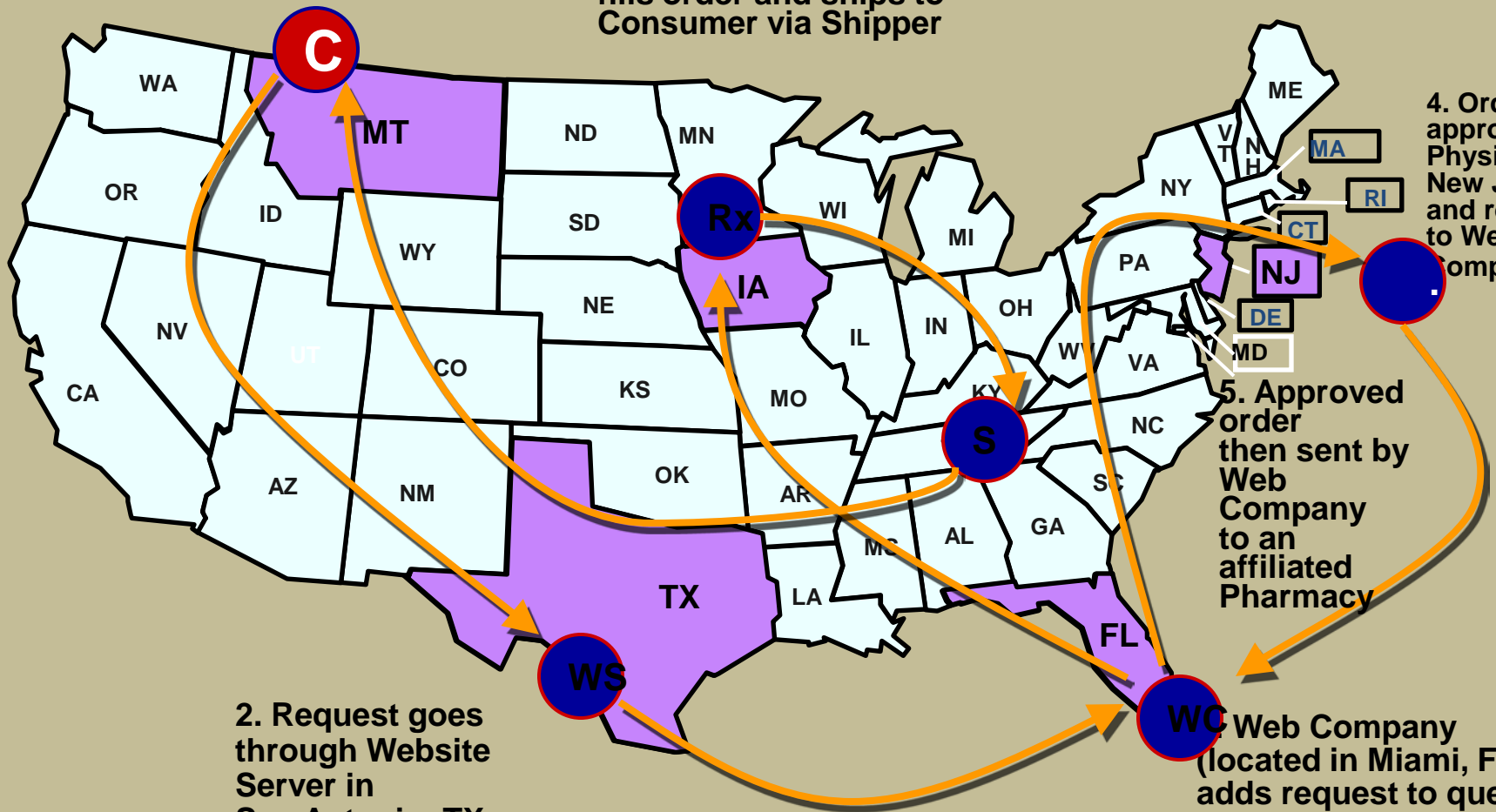
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# Purchases of hydrocodone by Known and Suspected Rogue Internet Pharmacies January 1, 2006 – December 31, 2006

1		Hillsborough	TAMPA	FLORIDA	33614	15,596,380
2		Pinellas	CLEARWATER	FLORIDA	33765	9,077,810
3		Hillsborough	TAMPA	FLORIDA	33614	8,760,876
4		Baltimore City	BALTIMORE	MARYLAND	21213	5,876,300
5		Hillsborough	TAMPA	FLORIDA	33619	5,718,200
6		Jefferson	RIVER RIDGE	LOUISIANA	70123	4,892,900
7		Hillsborough	TAMPA	FLORIDA	33634	4,733,290
8		Polk	LAKELAND	FLORIDA	33813	4,564,480
9		Hillsborough	TAMPA	FLORIDA	33612	4,220,840
10		Pinellas	CLEARWATER	FLORIDA	33759	3,819,320
11		Hillsborough	TAMPA	FLORIDA	33610	3,044,160
12				FLORIDA	33809	3,039,490
13					70123	2,750,000
14					34652	2,664,120
15					33613	1,902,900
16					33801	1,726,020
17		Hillsborough	TAMPA	FLORIDA	33612	1,619,765
18		Hillsborough	TAMPA	FLORIDA	33604	1,570,350
19		Pinellas	TARPON SPRINGS	FLORIDA	34689	1,464,900
20		Lincoln	DENVER	NORTH CAROLINA	28037	1,402,450
21		Hillsborough	TAMPA	FLORIDA	33617	1,282,800
22		Hillsborough	TAMPA	FLORIDA	33619	1,272,860
23		Polk	LAKELAND	FLORIDA	33813	1,039,400
24		Pasco	WESLEY CHAPEL	FLORIDA	33543	1,030,050
25		Iredell	MOORESVILLE	NORTH CAROLINA	28117	902,500
26		Polk	LAKELAND	FLORIDA	33815	867,800
27		Broward	HOLLYWOOD	FLORIDA	33021	865,700
28		Los Angeles	ENCINO	CALIFORNIA	91436	798,100
29		Hillsborough	TAMPA	FLORIDA	33604	793,350
30		Pasco	NEW PORT RICHEY	FLORIDA	34652	583,400
31		Ravalli	FLORENCE	MONTANA	59833	362,000
32		Hillsborough	TAMPA	FLORIDA	33619	162,000
33		Broward	DEERFIELD BEACH	FLORIDA	33441	112,600
34		Hillsborough	TAMPA	FLORIDA	33614	49,600
						2,899,021

98,566,711



# Checks and Balances of the CSA and the Regulatory Scheme

## ➤ Distributors 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)*



# DEA Distributor Initiative

- **Purpose and format:**
- **Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances**

- **August 2005 – Present:**

**Briefings to 83 firms with 276 locations**

**Examples of civil action against distributors:**

**Cardinal Health , \$34 million civil fine**

**McKesson, \$13.25 million civil fine**

**Harvard, \$6 million civil fine**

**Examples of suspension, surrender or revocation of DEA registration**

**Keysource, loss of DEA registration**

**Sunrise, loss of DEA registration**



# 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)*



# **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**



# 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;



# US v. Rosen 582 F.2d 1032 (5<sup>th</sup> Cir. 1978)

Rosen was a 68 yo physician who had a practice that was focused on obesity. He dispensed large quantities of stimulants to undercover officers outside the scope and not for a legitimate purpose.

The 5<sup>th</sup> circuit had to address whether the medication was dispensed “for a legitimate medical purpose and in the course of the doctors professional practice.” In its analysis, the court stated, “We are however, able to glean from reported cases, certain recurring concomitance of condemned behavior, examples of which include the following:

- An inordinately large quantity of controlled substances prescribed

- Large numbers of prescription were issued

- No physical exam given

- The physician warned the patient to fill prescriptions at different drug stores



# Rosen Factors (Red Flags)

- The physician issued prescriptions to a patient known to be delivering the drugs to others
- The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment
- The physician involved used street slang rather than medical terminology for the drugs prescribed
- There was no logical relationship between the drug prescribed and treatment of the condition allegedly existing
- The physician wrote more than one prescription on occasions in order to spread them out





# Other Factors (not all-inclusive)

Patients receiving the same combination of prescriptions; cocktail

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

Majority of patients paying cash for their prescriptions

Patient asking for drugs in street slang

Patient directed prescribing

Early refills

No specialized training in pain management;

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

No records/patient contracts/ urinalysis



# 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



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

*2014 AACCP Program Material*



# Checks and Balances Under the CSA

## Pharmacists – 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 (5<sup>th</sup> Cir 1979)

*U.S. v. Leal* 75 F. 3d 219 (6<sup>th</sup> Cir 1996)

*U.S. v. Birbragher* 603 F. 3d 478 (8<sup>th</sup> Cir 2010)

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



# Checks and Balances Under the CSA

## Pharmacists – 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 (5<sup>th</sup> Cir 1979)*

*U.S. v. Leal 75 F. 3d 219 (6<sup>th</sup> Cir 1996)*

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# The Last Line of Defense

## THE PHARMACIST



# 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 is required! 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



Are you involved in prescribing or dispensing in violation of the CSA?

What happens next?



# DEA Legal Recourse

## ➤ Administrative

Immediate Suspension Order (ISO)  
Memorandum of Agreement (MOA)  
Order to Show Cause (OTSC)

## ➤ Civil

Fines

## ➤ Criminal

Tactical Diversion Squads





# How Do You Lose Your Registration?

## The Order to Show Cause Process

21 USC § 824

- a) Grounds –
  - 1. Falsification of Application
  - 2. Felony Conviction
  - 3. State License or Registration suspended, revoked or denied – no longer authorized by State law
  - 4. Inconsistent with Public Interest
  - 5. Excluded from participation in Title 42 USC § 1320a-7(a) program
  
- b) AG discretion, may suspend any registration simultaneously with Order to Show Cause upon a finding of Imminent Danger to Public Health and Safety



# Questions to Discuss

- The Attorney General can immediately suspend a DEA registration based on the determination that the continued registration poses an imminent danger to public health or safety;
- A) True
- B) False





**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



# 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.



# The Last Line of Defense

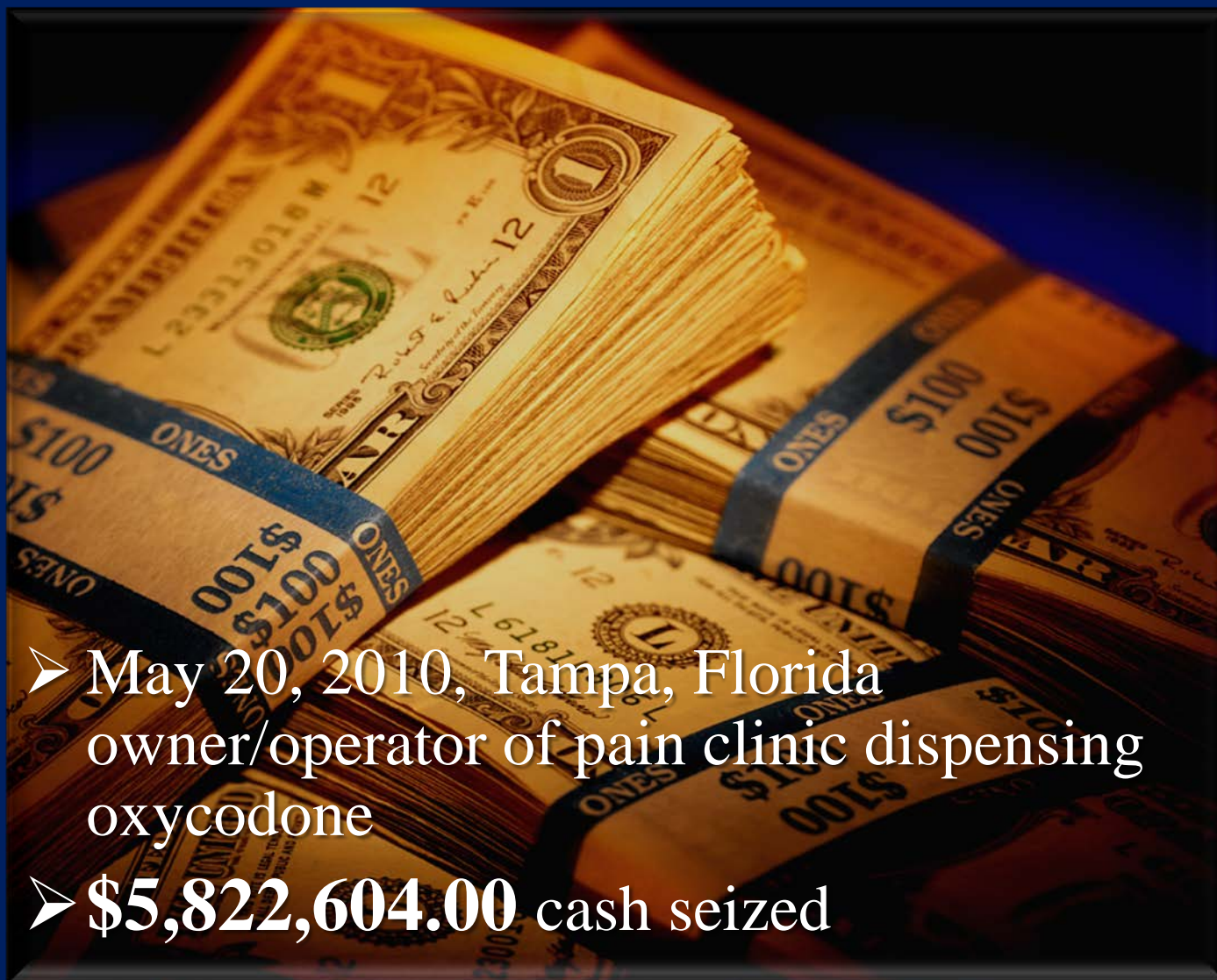




# Why is this happening?



# What's the Profit?

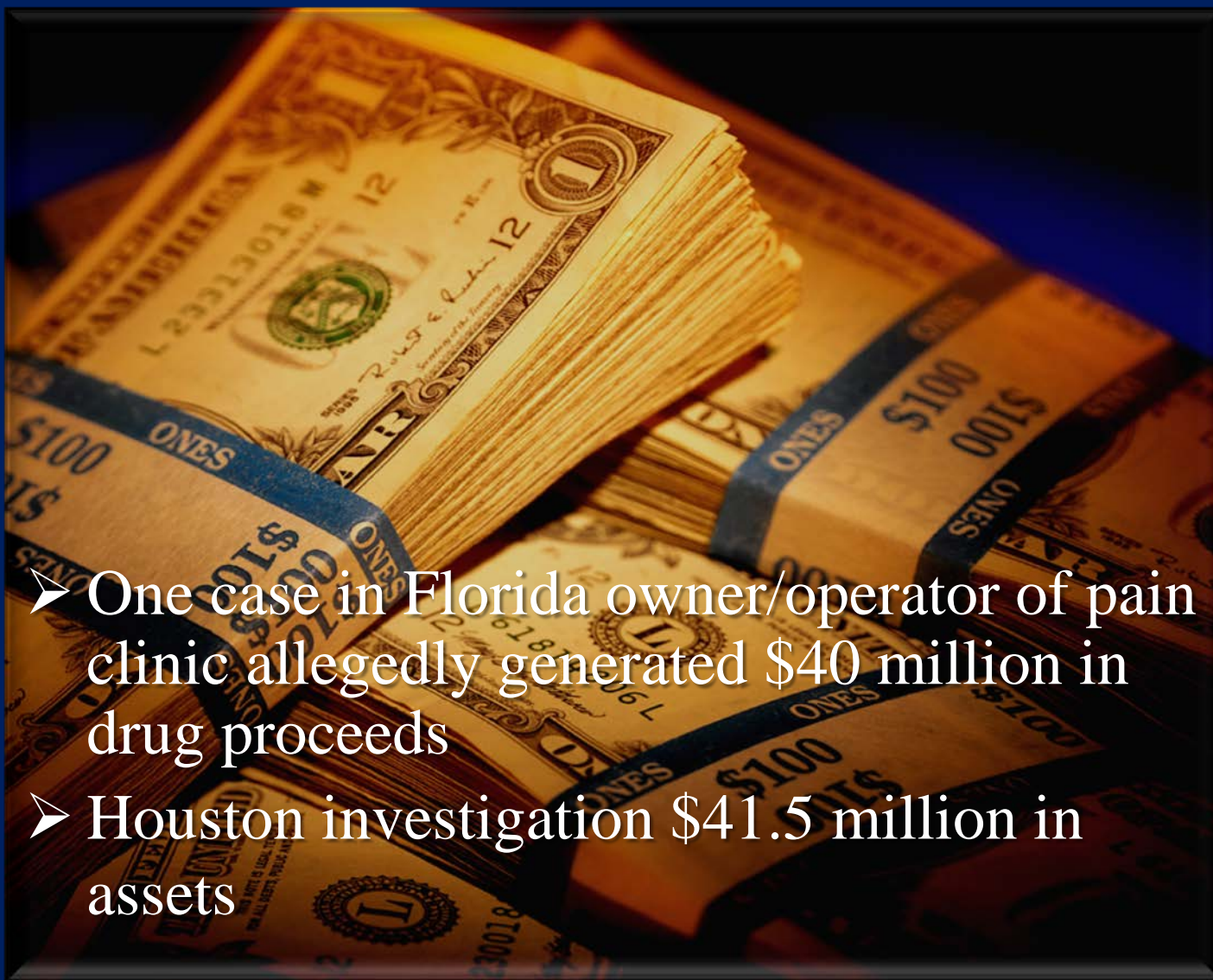


- May 20, 2010, Tampa, Florida owner/operator of pain clinic dispensing oxycodone
- **\$5,822,604.00** cash seized





# 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





# Florida Pain Clinic Raid



# Deaths Associated with Rx Drugs in Florida

Reports of Rx Drugs Detected in Deceased Persons and Cause of Death									% Increase 2005 - 2012
Drug	2005	2006	2007	2008	2009	2010	2011	2012	
Methadone	620	716	785	693	720	694	691	512	-17%
Oxycodone	340	496	705	941	1,185	1,516	1,247	735	↑ 116%
Hydrocodone	221	236	264	270	265	315	307	244	10%
Benzodiazepines	574	553	743	929	1,099	1,304	1,950*	1,337	↑ 133%
Morphine	247	229	255	300	302	262	345	415	68%
TOTAL	2,002	2,230	2,752	3,133	3,571	4,091	6,551	5,255	162%

\* 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





# Questions



# Thank You!