

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

Salt Lake City Pharmacy Diversion Awareness Conference  
National Association of Boards of Pharmacy (NABP)  
Utah Division of Occupational and Professional Licensing  
Drug Enforcement Administration

**Marriott Downtown at City Creek  
Salt Lake City, Utah**

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



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



# Consequences

In 2010, approximately 38,329 unintentional drug overdose deaths occurred in the United States, one death every 14 minutes.

Of this number, 22,134 of these deaths were attributed to Prescription Drugs (16,651 attributed to opioid overdoses/ 75.2 %).

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

Source: CDC Drug Overdose Deaths in the United States, 2010 (October 2012)



# 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>

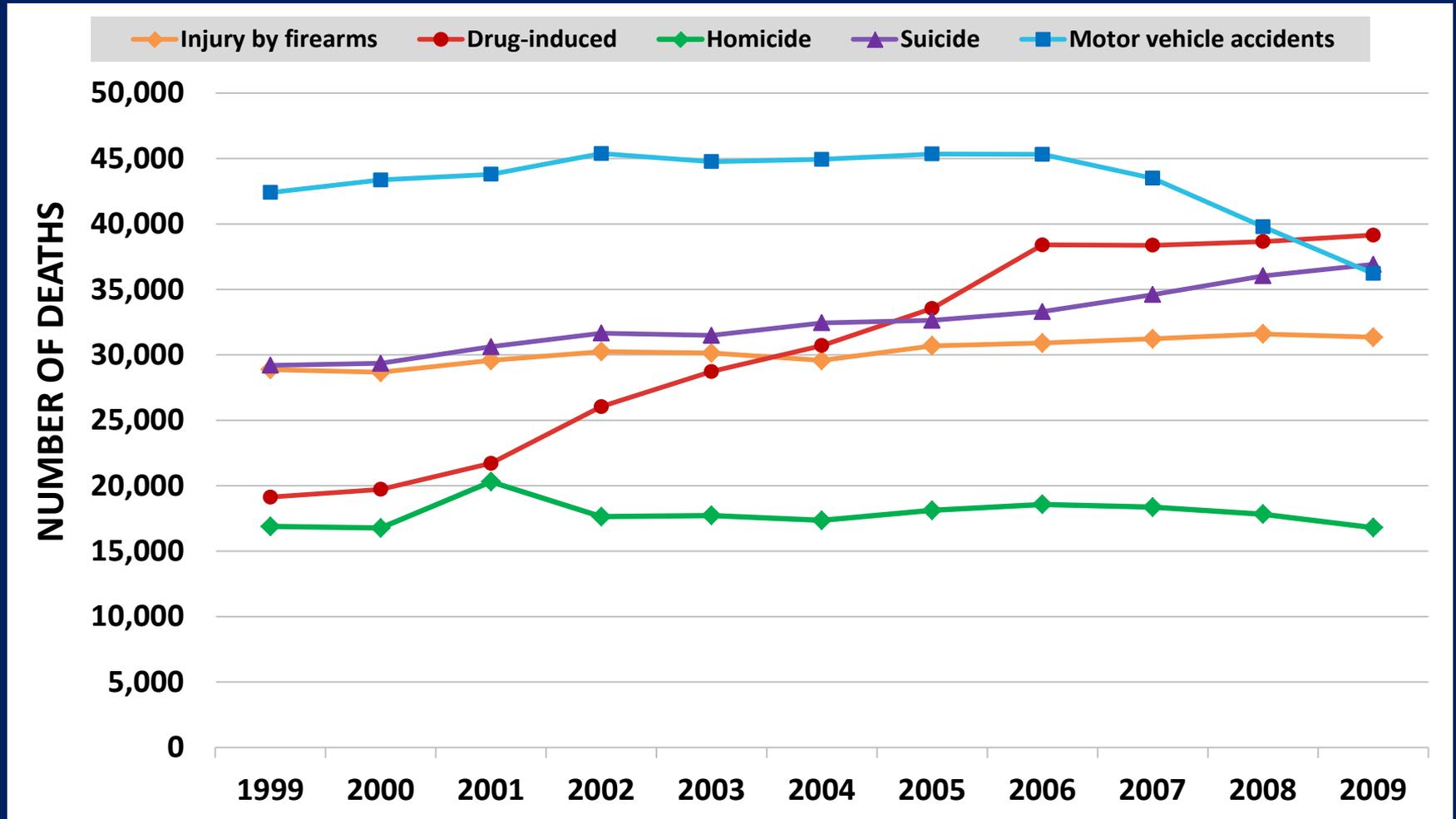
Of this number, 22,810 deaths were attributed to Prescription Drugs  
(16,917 attributed to opioid overdoses/ (74.165%).

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



# Drug-Induced Deaths vs. Other Injury Deaths (1999–2009)



Causes of death attributable to drugs include accidental or intentional poisonings by drugs and deaths from medical conditions resulting from chronic drug use. Drug-induced causes exclude accidents, homicides, and other causes indirectly related to drug use. Not all injury cause categories are mutually exclusive.



# 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

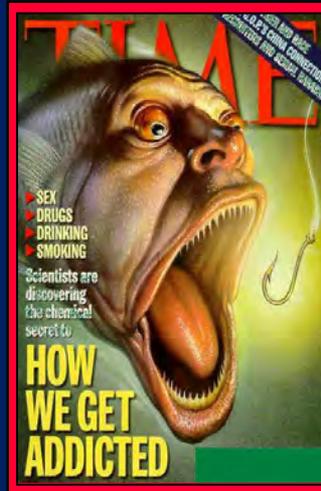
MARIJUANA: 18.9 million

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!!!**

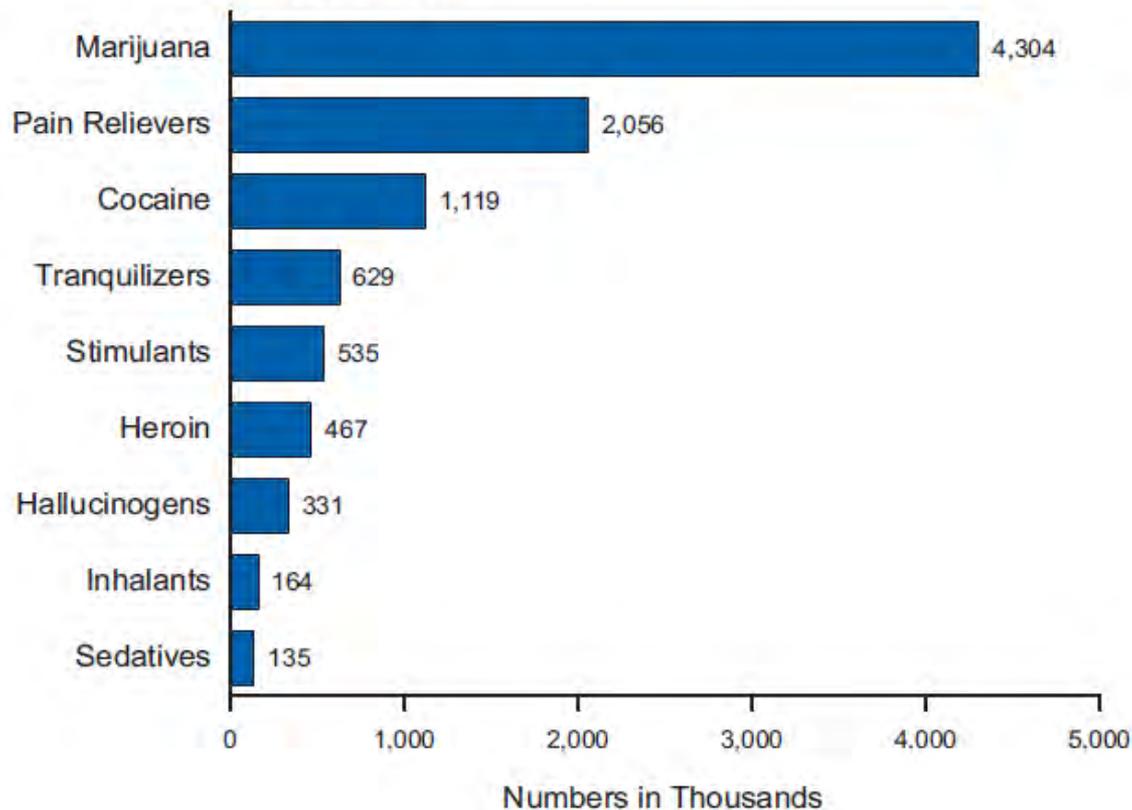


# Emergency Room Data 2004-2011

- Increase of 148%: ER visits attributable to pharmaceutical(s) alone (*i.e.*, with no other type of illicit drug or alcohol) (336,753 to 835,275)
  - No Statistically Significant Change: ER visits attributable to cocaine, heroin, or methamphetamine;
  - 62% increase in marijuana (281,619 to 455,668)
  
- Increase of 128%: ER visits attributable to pharmaceuticals alone, plus pharmaceutical(s) in combination with illicit drug(s) and/or alcohol (628,474 to 1,430,156)
  
- Rx Drugs most frequently implicated: Opiates/Opioids pain relievers (+183%)
  - Oxycodone products 262% increase
  - Hydrocodone products 107% increase
  
- Emergency room data 2004 – 2011
  - Fentanyl products 104% increase
  - Zolpidem 136% increase
  - Alprazolam 166% increase
  - Clonazepam 117% increase
  - Carisoprodol no statistically significant change
  
- For patients aged 20 and younger misuse/abuse of pharmaceuticals increased 45.4%
- For patients aged 20 and older the increase was 111%

# Past Year Initiates 2012 – Ages 12 and Older

**Figure 7.2 Specific Illicit Drug Dependence or Abuse in the Past Year among Persons Aged 12 or Older: 2012**

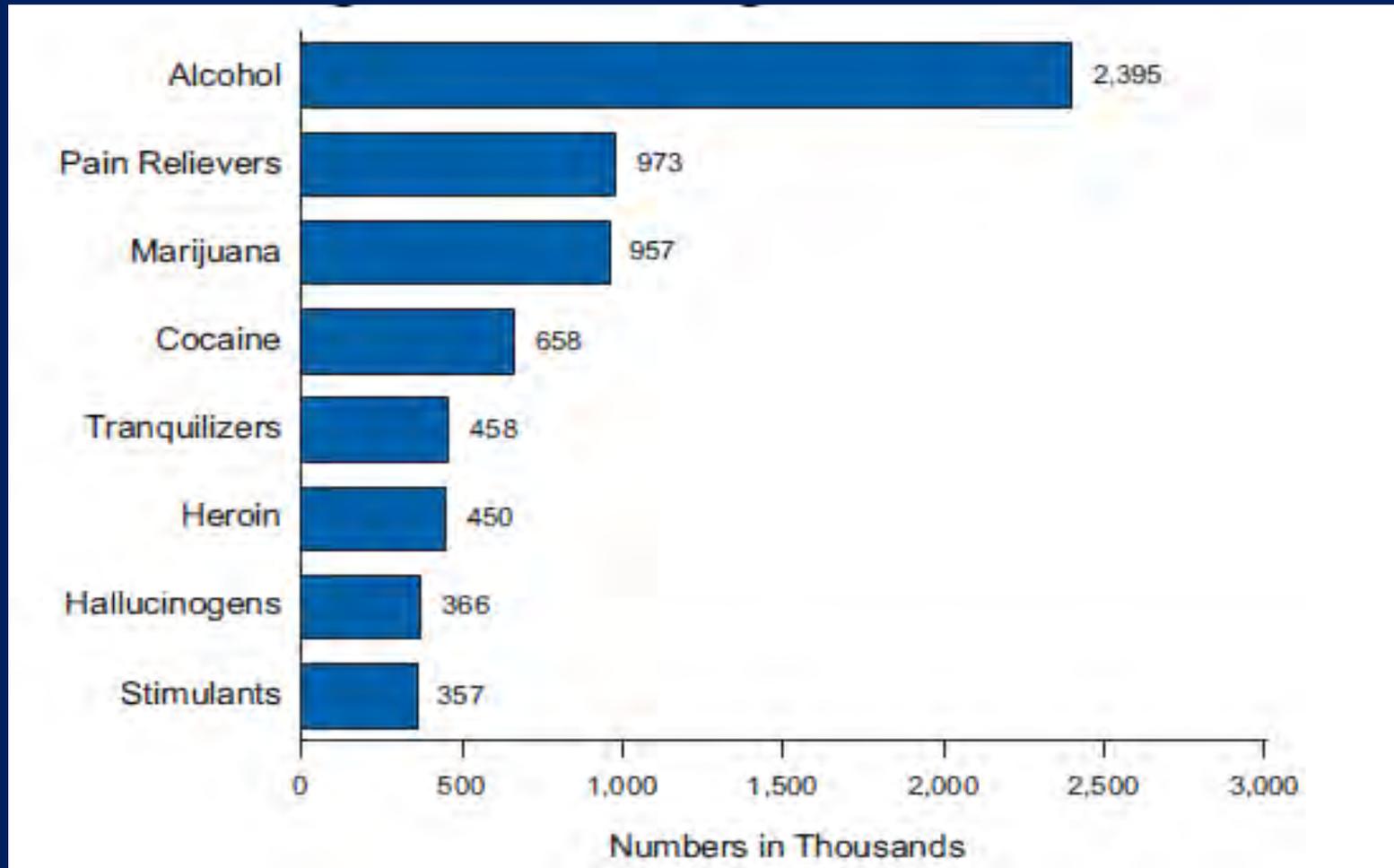


SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)

U.S. Drug Enforcement Administration  
Office of Diversion Control



# Substances for Which Most Recent Treatment Was Received in the Past Year among Persons Aged 12 or Older: 2012





# Where Painkiller Prescriptions Are The Highest

- In 2012, Southern states had the most per person.
- The top three states were Alabama, Tennessee, and West Virginia;
  - Alabama: 143 per 100 people
  - Tennessee: 143 per 100 people
  - West Virginia: 138 per 100 people
- Lowest-Hawaii: 52 per 100 people

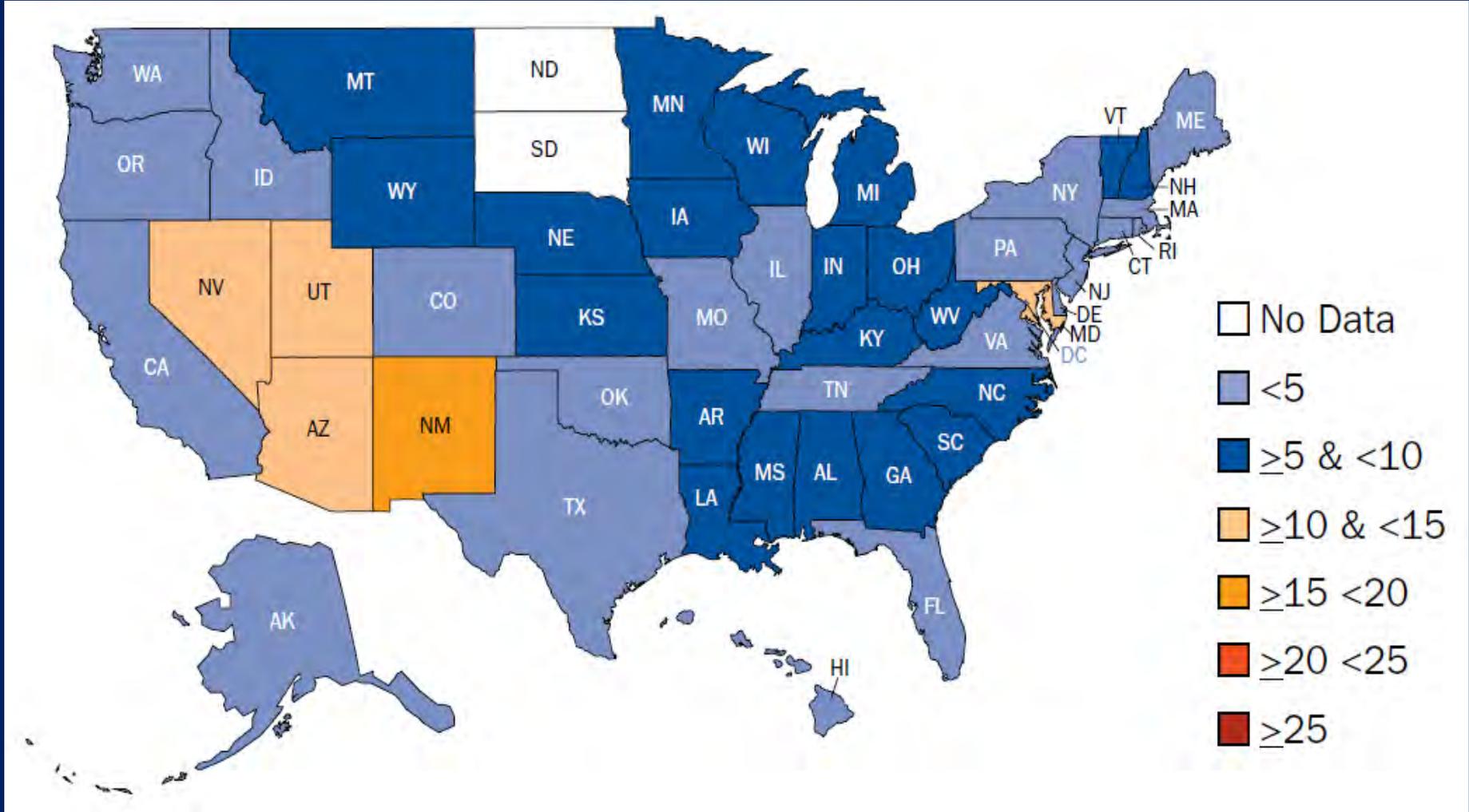


# Questions to Discuss

- 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



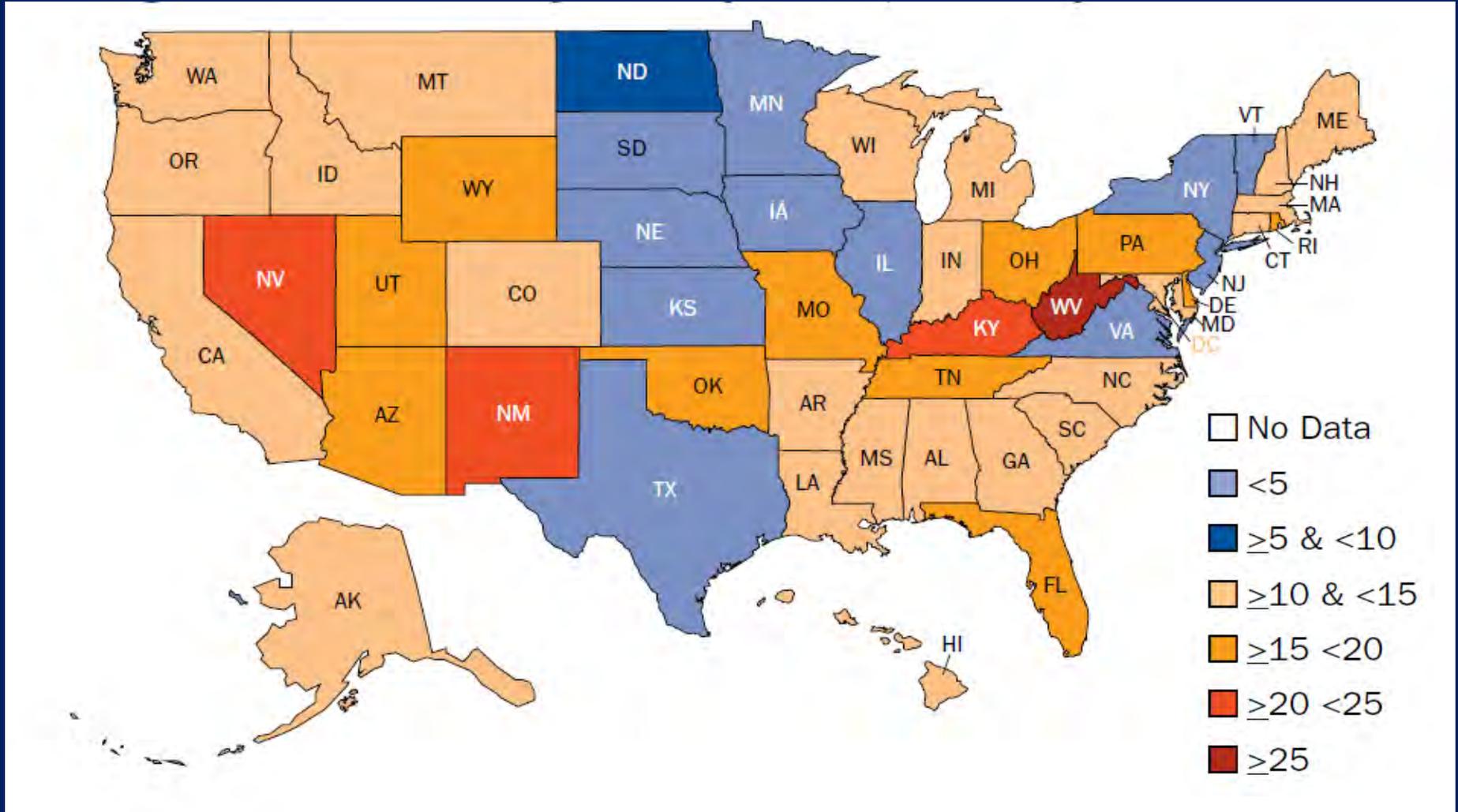
# Drug Overdose Mortality Rates per 100,000 People 1999



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



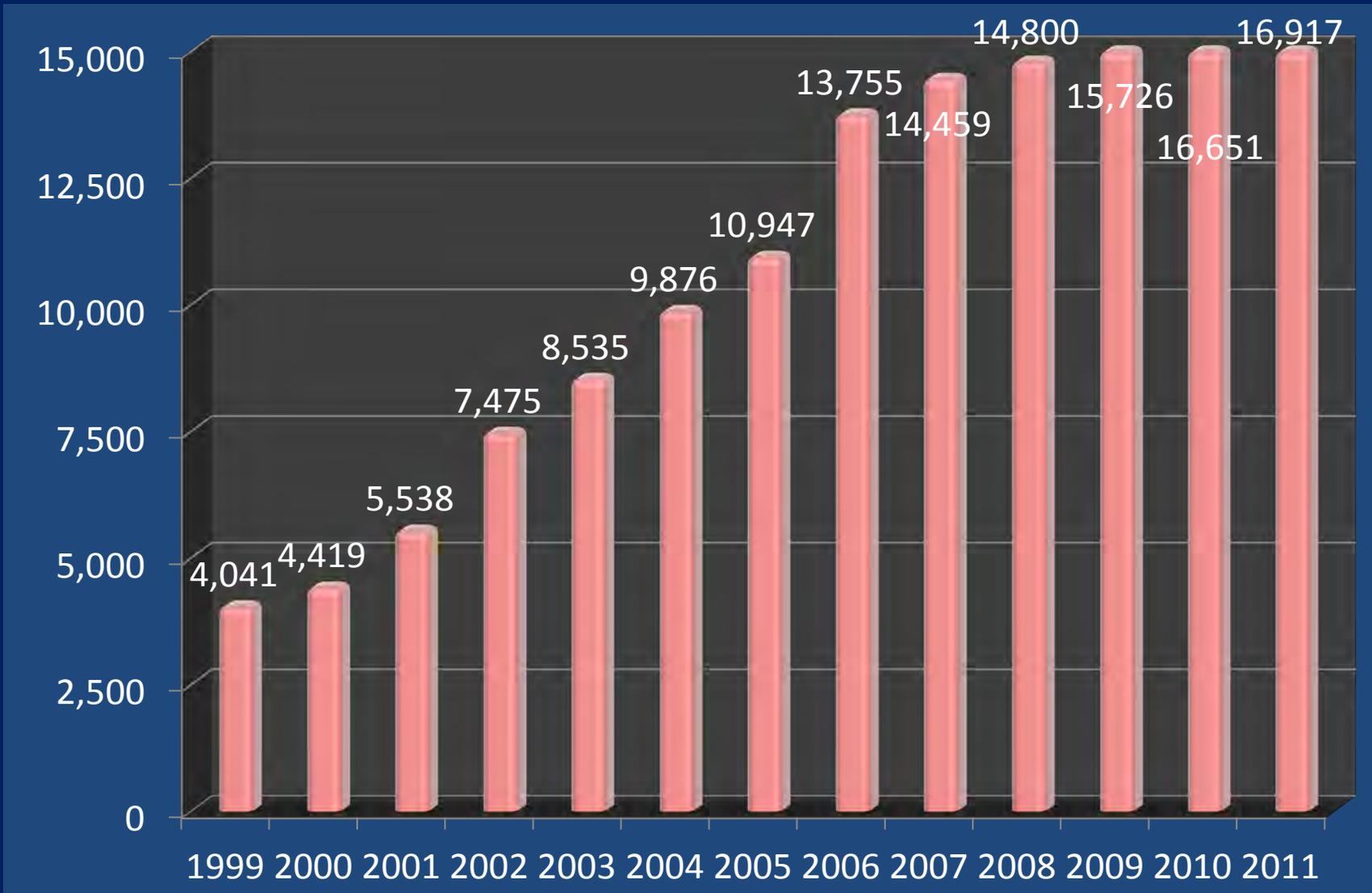
# Drug Overdose Mortality Rates per 100,000 People 2010





# Poisoning Deaths: Opioid Analgesics

Poisoning Deaths





# Naloxone



# 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.



# 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

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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

Do you know a WWII vet?



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

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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)

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## Pharmacist slain in Beach robbery was much beloved

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**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



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Source:

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



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**

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|  |                     |                       |
|--|---------------------|-----------------------|
|  | -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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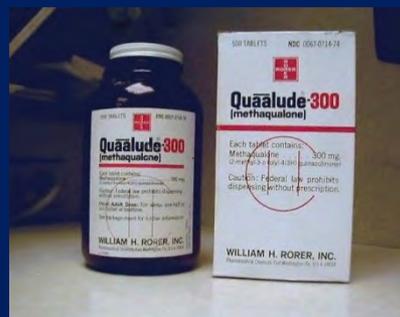




# The 1960s/70s/80s



Uppers - Amphetamines



Quaalude



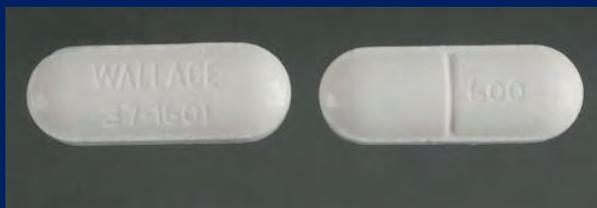
"Ts and Blues"



Downers - Barbiturates



Hydromorphone



Meprobamate



Oxycodone/APAP



"Fours and Doors"



10 mg



20 mg



40 mg



80 mg



160 mg



# The 1990s

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



**Dollars for Doctors**  
How Industry Money Reaches Physicians

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



This article is part of an ongoing investigation.

**Dollars for Doctors: How Industry Money Reaches Physicians**

ProPublica is tracking the financial ties between doctors and medical companies.



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**The Story So Far**

ProPublica is investigating the financial ties



[For Immediate Release](#)

May 08, 2012

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

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

*[Finance Leaders Investigate Whether Pharmaceutical Companies Encouraged Non-Profit Beneficiaries to Promote Misleading Information about Narcotic Painkillers](#)*

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

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

### Related Files



[Baucus Grassley Opioid Investigation Letter to Purdue Pharma](#)  
[288.2 KB]



[Baucus Grassley Opioid Investigation Letter to Federation of State Medical Boards](#)  
[276.9 KB]



[Baucus Grassley Opioid Investigation Letter to the Joint Commission](#)  
[278.4 KB]



[Baucus Grassley Opioid Investigation Letter to Wisconsin Pain And Policy Studies Group](#)  
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[Baucus Grassley Opioid Investigation Letter to American Academy of Pain Medicine](#)  
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[Baucus Grassley Opioid Investigation Letter to American](#)

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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

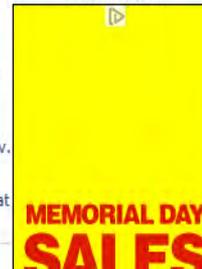


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## Bioethics think tank's ties to pain pill industry studied

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

No injuries but much damage in Columbia apartment fire

Franchitti wins 3rd Indy 500, gives nod to Wheldon

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KansasCity.com

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# Commonly Abused Controlled Pharmaceuticals

Carisoprodol



C-IV as of 1/11/2012

**CYCLOBENZAPRINE  
(FLEXERIL)**



OxyContin 80mg  
Oxycodone HCL ER

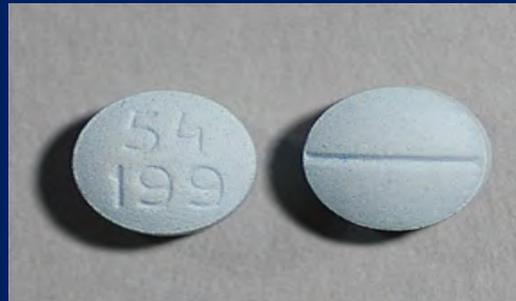


Oxymorphone

**Hydrocodone**



**Oxycodone 30 mg**



**Alprazolam**



# 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



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

Enforcement is just as important as...

Prevention/Education

Treatment



# Drug Education

# or not

# Teen Prescription Drug Misuse & Abuse

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



# Education

## ➤ Children/Teens

Information from the Internet  
or their peers

Following parents



# What are kids listening to... Eminem?

- Rap star Eminem has a Vicodin® (Hydrocodone) tattoo on his arm and a picture of a Vicodin® tablet on one of his CDs



'Vike'





GET INVOLVED

TEACH



# DEA Web-based Resources

www.DEA.gov

The screenshot shows the DEA website homepage with the following elements:

- Header:** "DEA" in large gold letters, "UNITED STATES Drug Enforcement Administration" in white, and the slogan "TOUGH WORK, VITAL MISSION".
- Navigation Menu:** HOME, ABOUT, CAREERS, OPERATIONS, DRUG INFO, PREVENTION, PRESS ROOM.
- Main Content Area:**
  - Left: "Tough Work, Vital Mission The Facts About DEA" with a blue graphic of a hand holding a scale.
  - Center: A large gold DEA Special Agent badge.
  - Right: Three resource boxes:
    - "Drug Facts for Today's Teens" from JustThinkTwice.com.
    - "A DEA Resource for Parents" from GetSmartAboutDrugs.com.
    - "Wall of Honor" - DEA Remembers.
- Bottom Section:** Three columns of content:
  - TOP STORY:** "Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy" dated JAN 29 (BROWNSVILLE, TEXAS). Below the headline is a small image of a woman and a man.
  - TOPICS OF INTEREST:** DEA Fact Sheet, Drugs of Abuse: A DEA Resource Guide, Extension of Temporary Placement of Five Synthetic Cannabinoids, The DEA Position on Marijuana.
  - RESOURCE CENTER:** Controlled Substances Act, DEA Museum and Visitors Center, Doing Business with DEA, Drug Disposal, Employee Assistance Program.



# Community Coalitions and Advocacy Groups



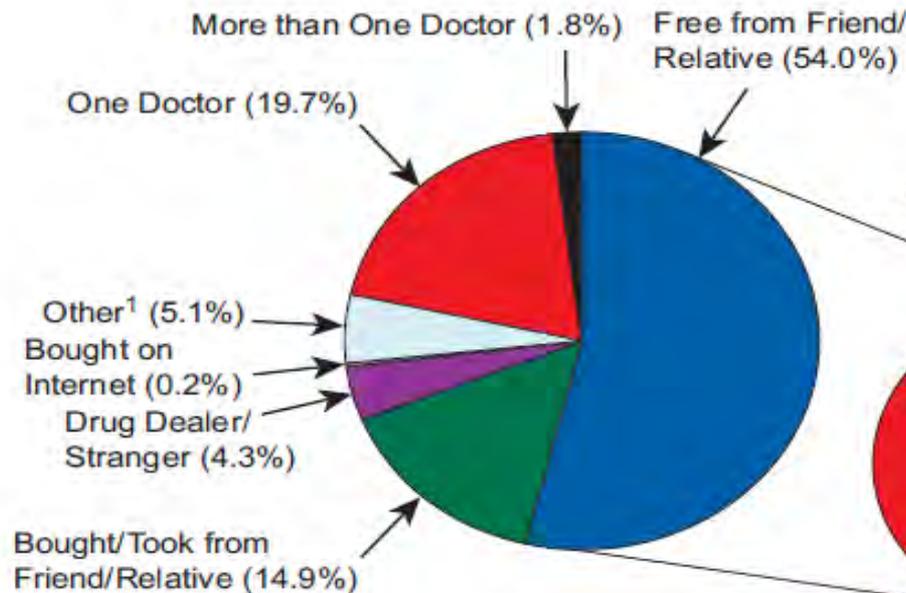
# Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non-Medical Use

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

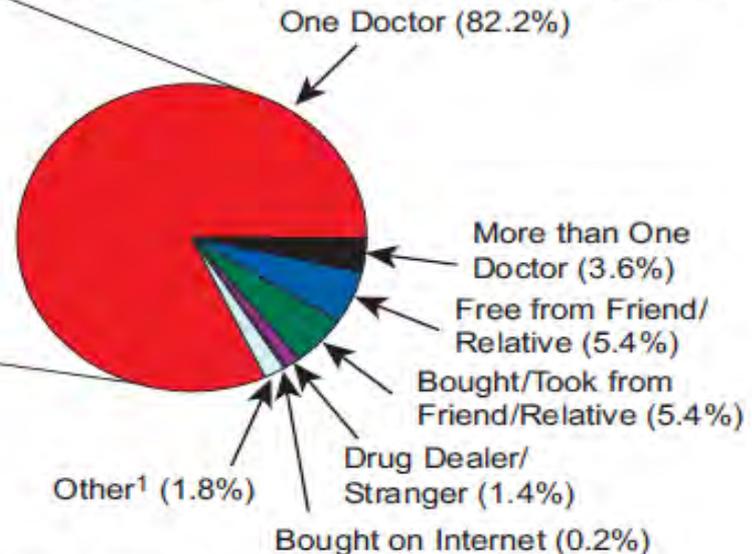


# Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use Among Past Year Users Aged 12 or Older: 2011-2012

Source Where User Obtained



Source Where Friend/Relative Obtained



<sup>1</sup> The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."



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



# The Problem – Easy Access





# Medicine Cabinets: Easy Access

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



# National Take Back Initiative

## April 26, 2014

# Got Drugs?

Turn in your  
unused or expired  
medication for safe disposal  
Saturday **April 26, 2014**

Click here  
for a collection  
site near you.



10:00 AM – 2:00 PM



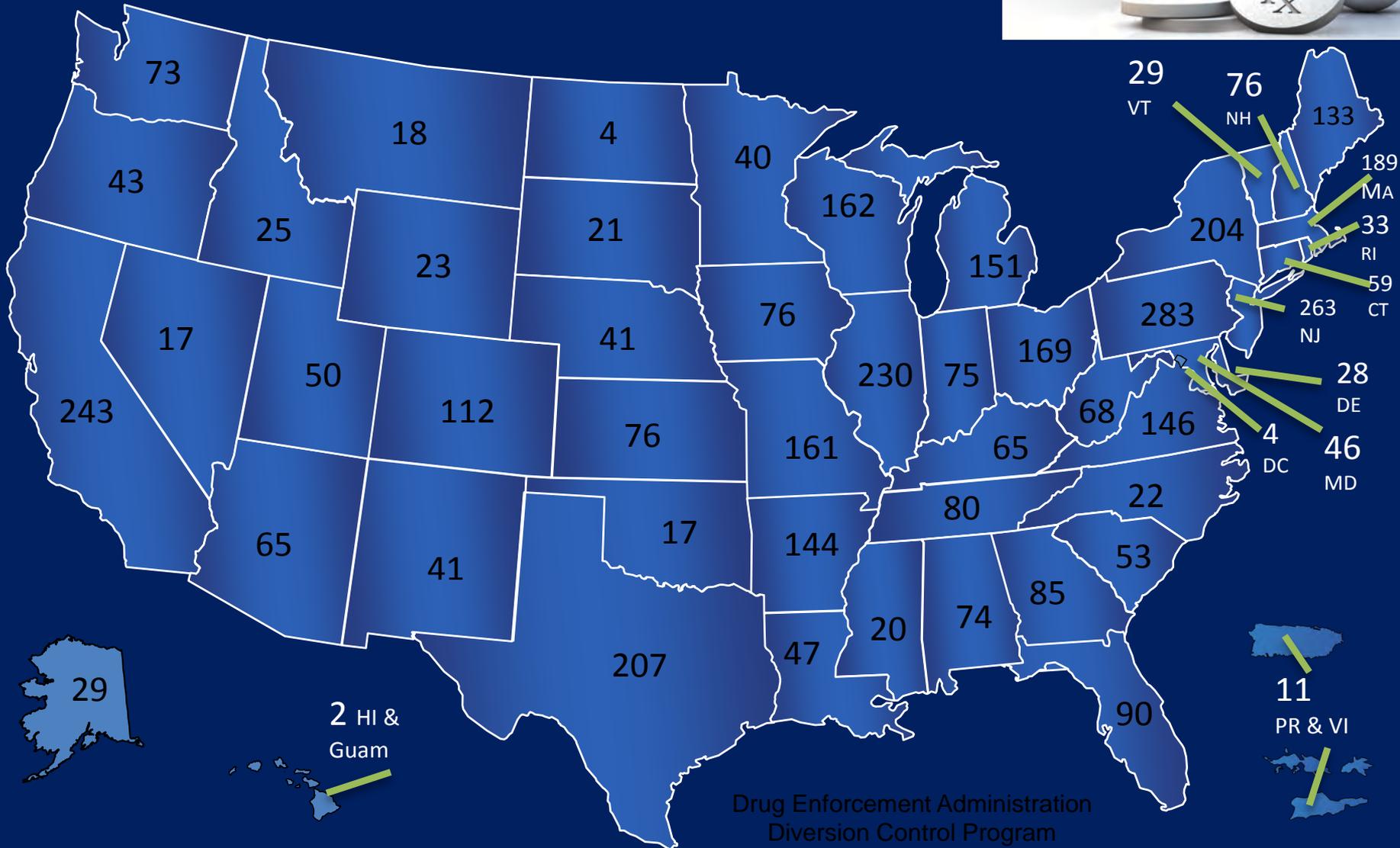
# Nationwide Take-back Initiative

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

# National Take Back Day: April 26, 2014

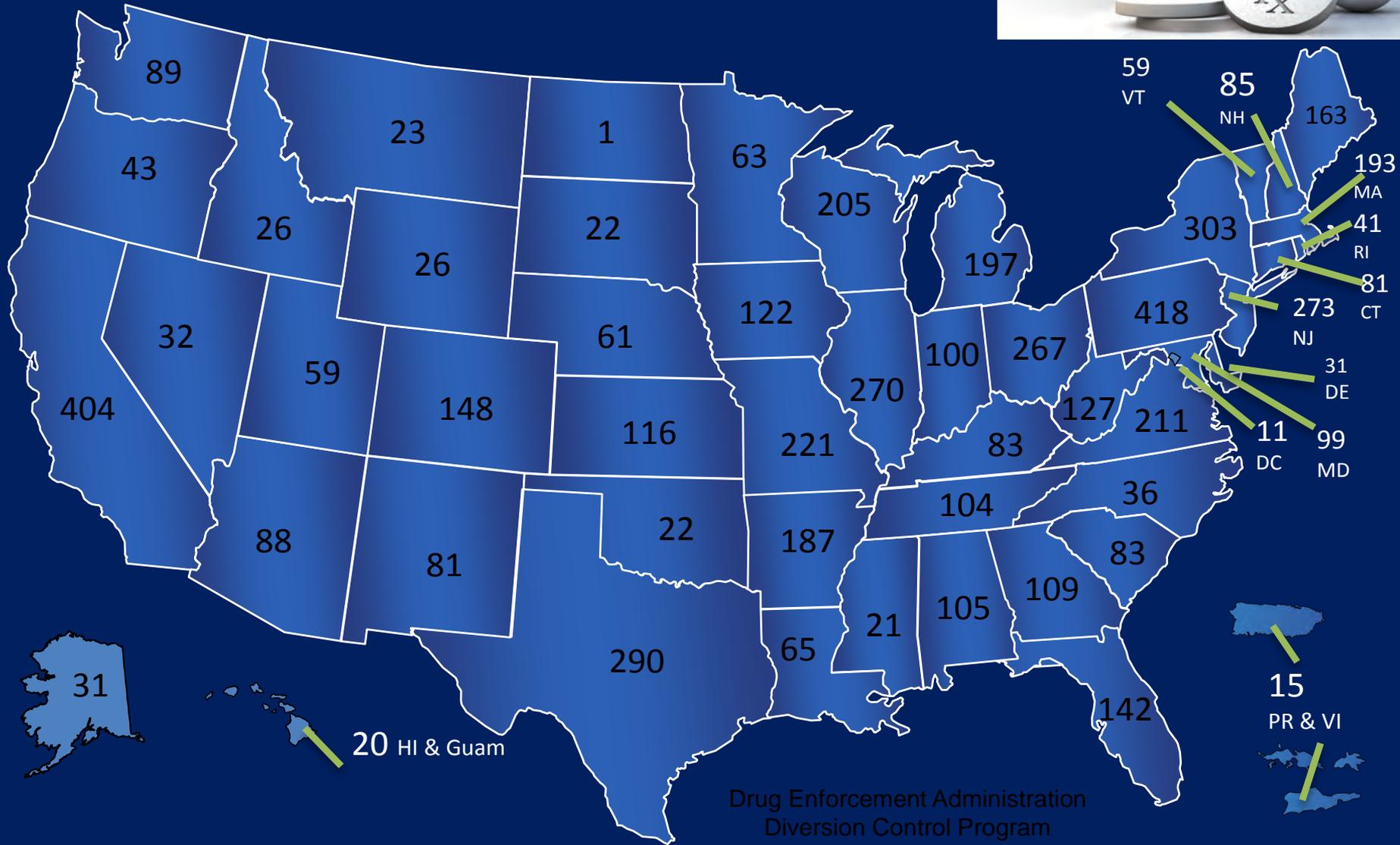
Total Law Enforcement Participation: 4,423



Drug Enforcement Administration  
Diversion Control Program

# National Take Back Day: **April 26, 2014**

Total Collection Sites: 6,072



Drug Enforcement Administration  
Diversion Control Program





# Notice of Proposed Rulemaking



# 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:

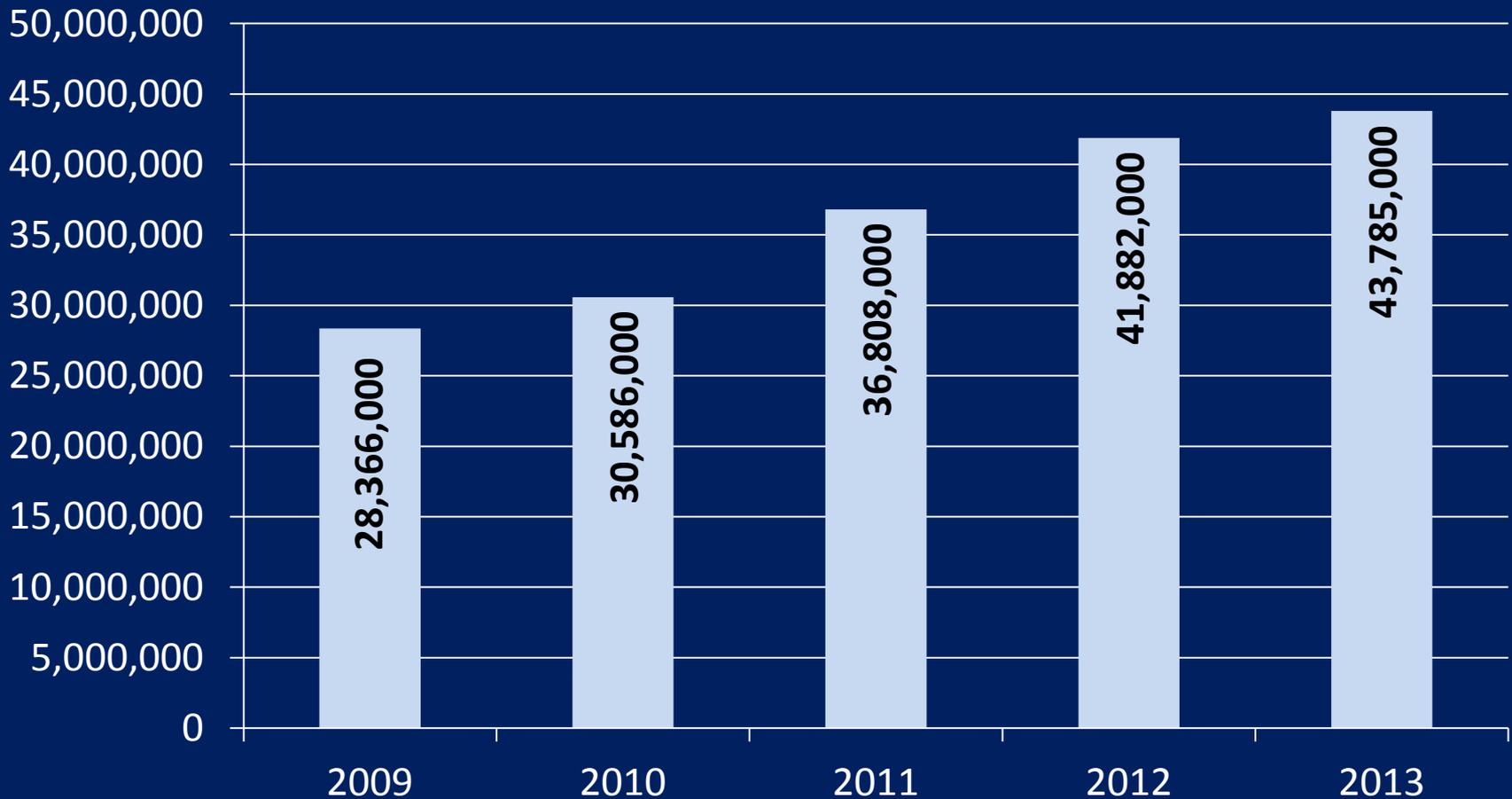
- Tramadol (Ultram®), Ultracet®)
- Schedule IV in CSA as of August 18, 2014

## ➤ Muscle Relaxant:

- Cyclobenzaprine (Flexeril®)



# Tramadol Total U.S. Dispensed Prescriptions



Source: IMS Health National Prescription Audit Plus downloaded 7/1/2014



# 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



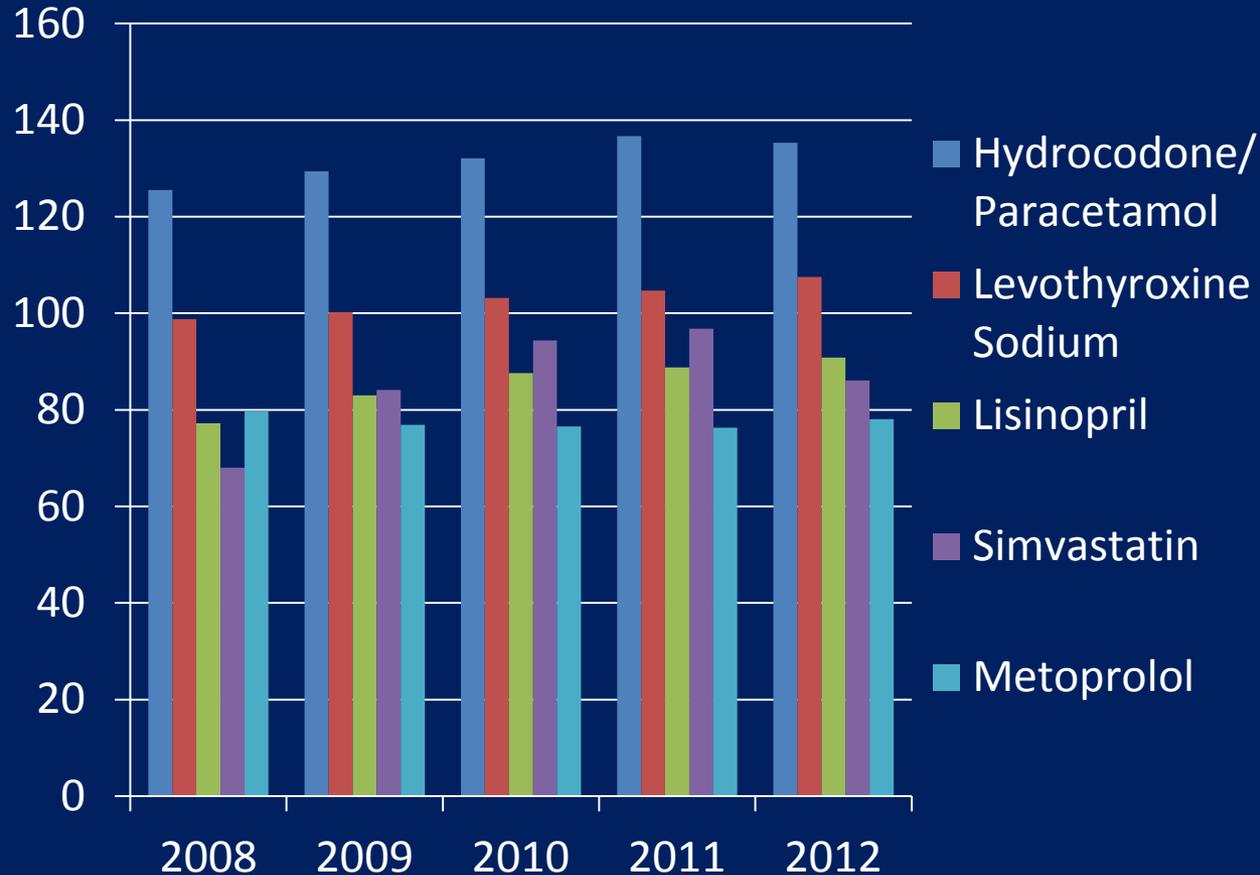
Most commonly prescribed prescription  
medicine?

Hydrocodone/acetaminophen



# Top Five Prescription Drugs Sold in the U.S. (2008-2011)

Millions of  
Prescriptions



Source: IMS Health

Source: IMS Health, National Prescription Audit, Updated 02/24/14

U.S. Drug Enforcement Administration  
Office of Diversion Control



# Hydrocodone Combinations

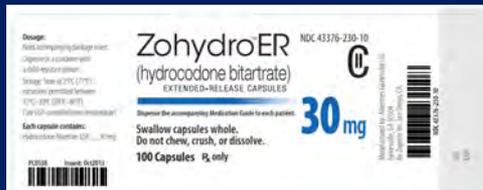
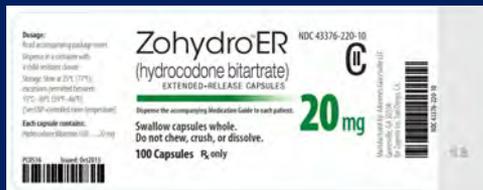
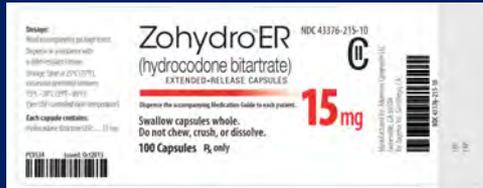
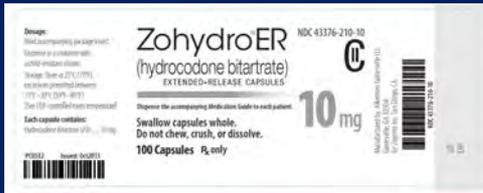
Currently, the CSA defines hydrocodone substance as Schedule II, while its combination products as Schedule III.

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

(see 79FR49661 dated August 22, 2014)



# Approval of Single Entity Extended Release Hydrocodone



**Zohydro™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**



# OXYCODONE





# Oxycodone HCL CR (OxyContin®) Reformulation





# New OxyContin<sup>®</sup> OP



08-27-2010, 01:11 AM

#17

[mz.mary420](#)

Member



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

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 mentioned 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



08-27-2010, 06:09 AM

#18

[mephist00](#)

Member



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

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



**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

Tylox

Percocet

## 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.

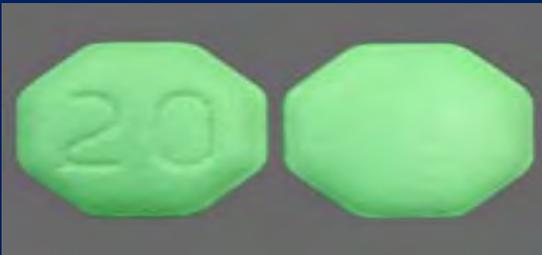
"The FDA is committed to combating the misuse and abuse of all opioids, and the development of opioids that are harder to abuse is needed in order to help address the public health crisis of prescription drug abuse in the US," said Sharon Hertz, MD, deputy director of the Division of Anesthesia, Analgesia, 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)

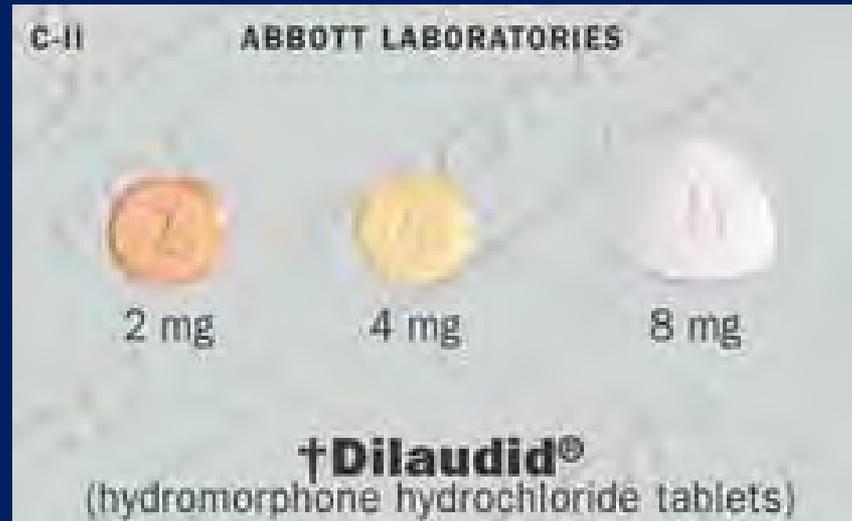
## ➤ Opana ER® - (Schedule II)

- 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



Usual Dose: See package insert

Storage: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Dispense in a light, light resistant container as defined in the USP.

Roxane Laboratories, Inc.  
Columbus, Ohio 43216

NDC 0854-0264-2S 100 Tablets

**HYDROMORPHONE HYDROCHLORIDE**   
Tablets, USP

**4 mg**

Each tablet contains 4 mg hydromorphone hydrochloride USP, Rx only.

 **Roxane Laboratories**

100540 26425 3

10005693402 © RLI, 2009

EXP. LOT

USUAL DOSAGE:  
See package insert for prescribing information.  
Dispense in a light, light resistant container as defined in the USP with a child-resistant closure.  
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].  
Nw 1209 10-210

NDC 0327-1355-01

**Lannett**

**HYDROMORPHONE HYDROCHLORIDE**   
TABLETS, USP

**8 mg**

Rx Only  
100 TABLETS

Each Tablet Contains:  
Hydromorphone Hydrochloride, USP ... 8 mg

Inert Ingredients:  
Allylbutyl Lactone,  
Lactose Monohydrate, and  
Magnesium Stearate

Manufactured by:  
Lannett Company, Inc.  
Pittsburgh, PA 15206

Made in the USA

1 0527-1355-01 c



# 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

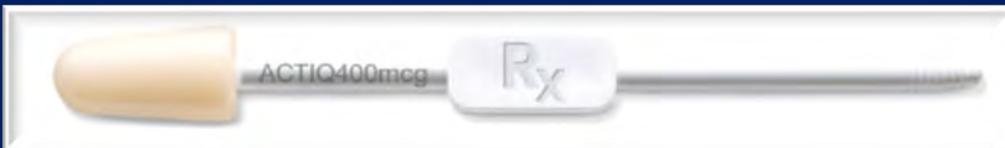


**Trade Name: Dilaudid**  
Controlled Ingredient:  
hydromorphone hydrochloride, 4 mg

# 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





# Cough Syrup Cocktails

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

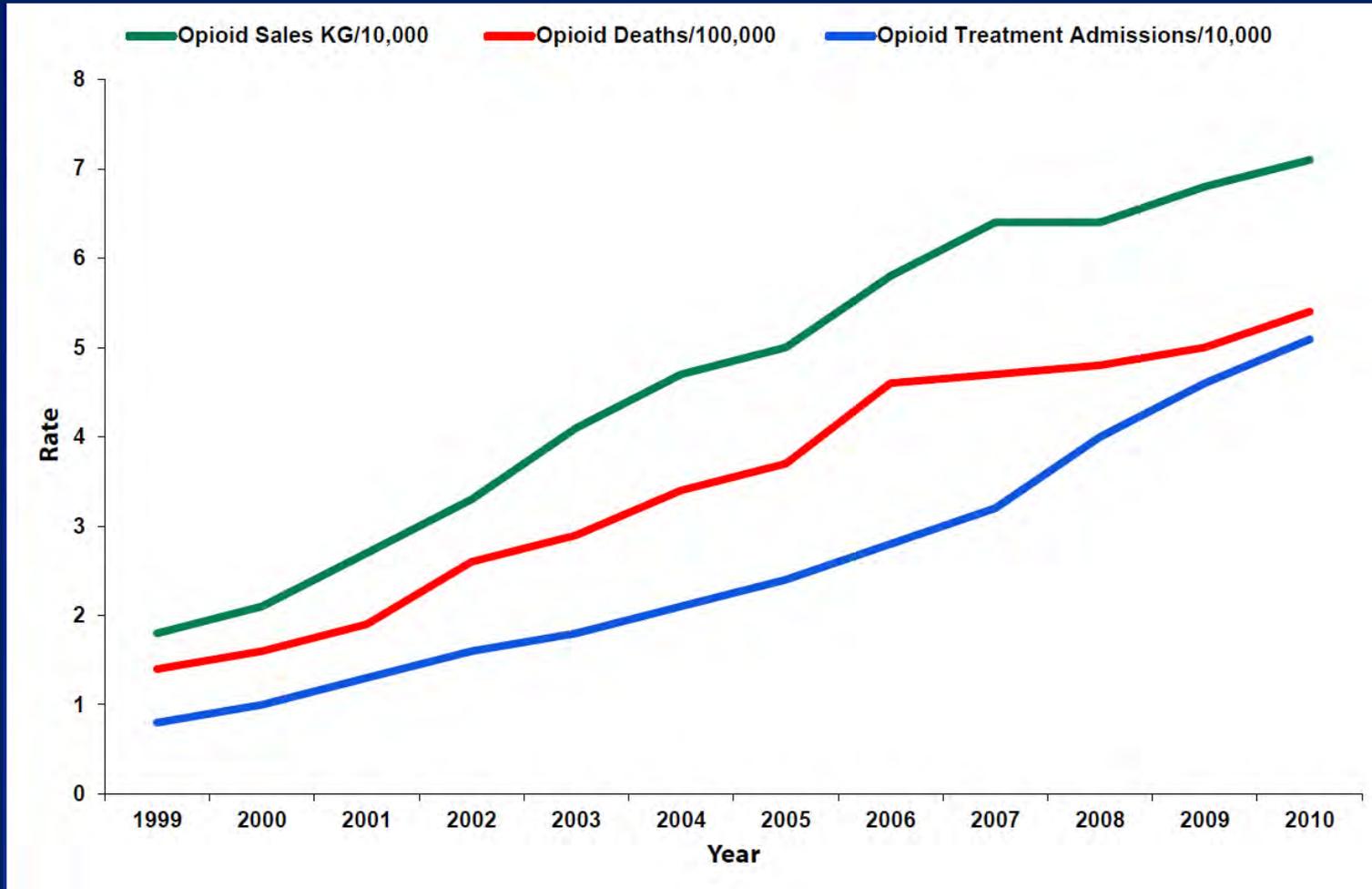




# Opiates v. Heroin



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



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



# Circle of Addiction & the Next Generation

Oxycodone  
Combinations

Percocet®

\$7-\$10/tab

Hydrocodone

Lorcet®

\$5-\$7/tab

OxyContin®

\$80/tab

Roxicodone®

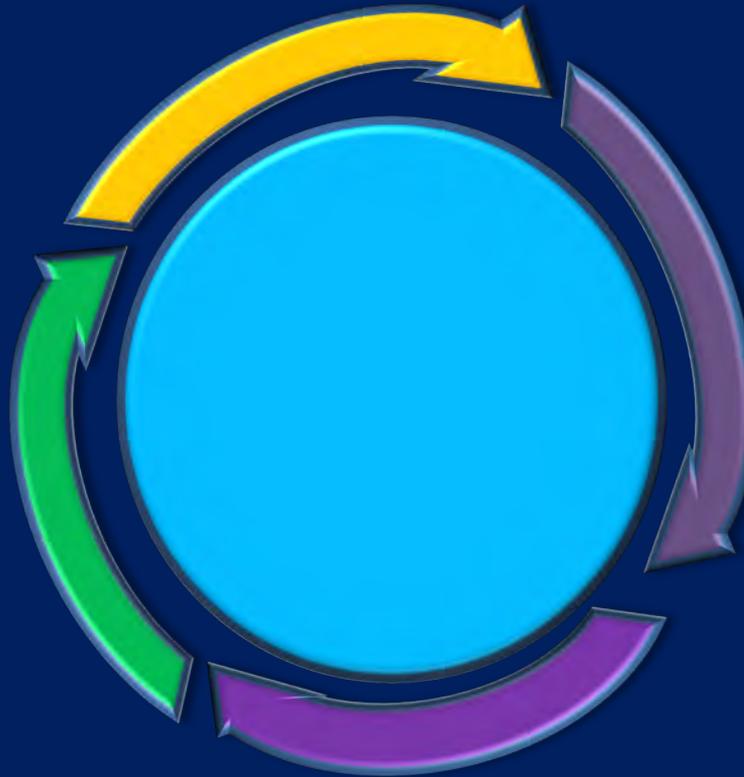
Oxycodone IR

15mg, 30mg

\$30-\$40/tab

Heroin

\$10/bag



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See what it's like to love car buying  
**OF SILVER SPRING**  
Sales & Service

12511 Prosperity Drive • Silver Spring, MD 20904

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[www.DARCARSvolkswagen.com](http://www.DARCARSvolkswagen.com)

Call / Email Alex Pedram, General Sales Manager  
APedram@darcars.com

[washingtonexaminer.com](http://washingtonexaminer.com)



# The Examiner

WASHINGTON

WEDNESDAY, DECEMBER 5, 2012

**Ship's Hatch**

Army, Navy,  
USAF, USMC & USCG

Promotion/Retirement  
Gifts, Flag Cases,  
Presentation Clocks

**703.413.6289**

[www.shipshatch.com](http://www.shipshatch.com)

Located in the Shops at Crystal City



## '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



# 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

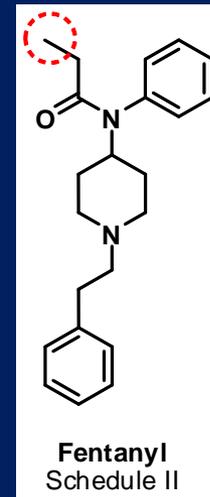
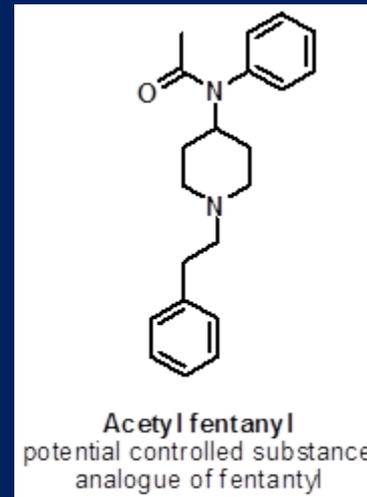
# Acetylfentanyl

- 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 “Desmethyl Fentanyl” intercepted in Montreal— hidden inside a microwave oven and a toaster destined for Colorado
  - Additional 1,500 kilograms of various raw materials; enough to make an additional 3 million pills seized



# Acetylfentanyl

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



# 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 repellent”



# W-15 (Synthetic Opioid)

#1

04-08-2013, 09:07 PM

XOOL   
Peasant

Join Date: Jan 2009

Thanks: 28

Thanked 11 Times in 7 Posts

## W-15 (New RC opioid)

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

Looks like this:



Hopefully a few knowledgeable people will have some insight. 😊

UPDATE: Found an experience report whilst searching. It's on [reddit: http://www.reddit.com/r/opiates/comment/ort\\_rc\\_opiate/](http://www.reddit.com/r/opiates/comment/ort_rc_opiate/)

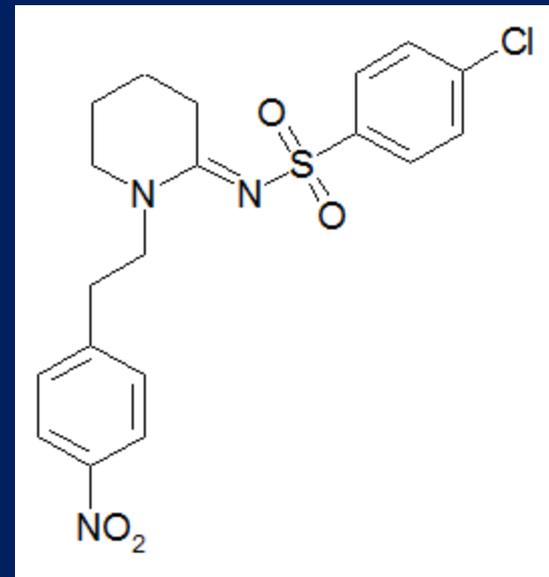
According to that, doesn't look very promising :/

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



# W-18 (Synthetic Opioid)

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





# METHADONE



# Treatment of Narcotic Addiction



# Methadone- 5mg & 10mg



Mallinckrodt Pharmaceuticals 5 mg & 10mg

# Methadone 40 mg



NDC 0406-0540-34 **100 TABLETS**

**METHADOSE™**  
 Dispersible Tablets **Ⓒ**  
 (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  
 L00M10 Rev:01/09/09



# WHY IS IT ALSO USED AS AN ANALGESIC?

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?



# One Pill can Kill



CE Article: (AOCME, CMI, ACEFI) 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.



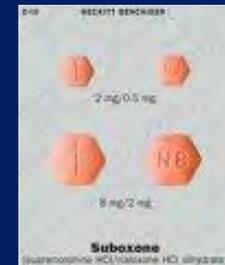
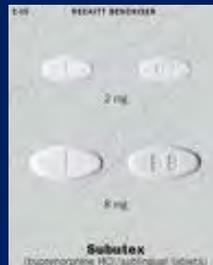


# Other FDA Approved Drugs for Narcotic Addiction Treatment

## ➤ Schedule III

– Buprenorphine – Drug Code 9064

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





# 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®





# Ritalin® / Concerta® / Adderall

Used legitimately to treat ADHD

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

Higher GPA

Higher SAT / ACT score

Get that scholarship



# Parents' Lax Attitudes and Permissiveness

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

# Teen Attitudes

- ✓ **31%** believe prescription drugs (Ritalin or Adderall) can be used as study aids.
- ✓ **29%** believe taking a larger dose than prescribed to them is okay as long as they are not getting high.





# ADHD Drugs

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



# Trends in Abuse of Ritalin/Adderall

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



# 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



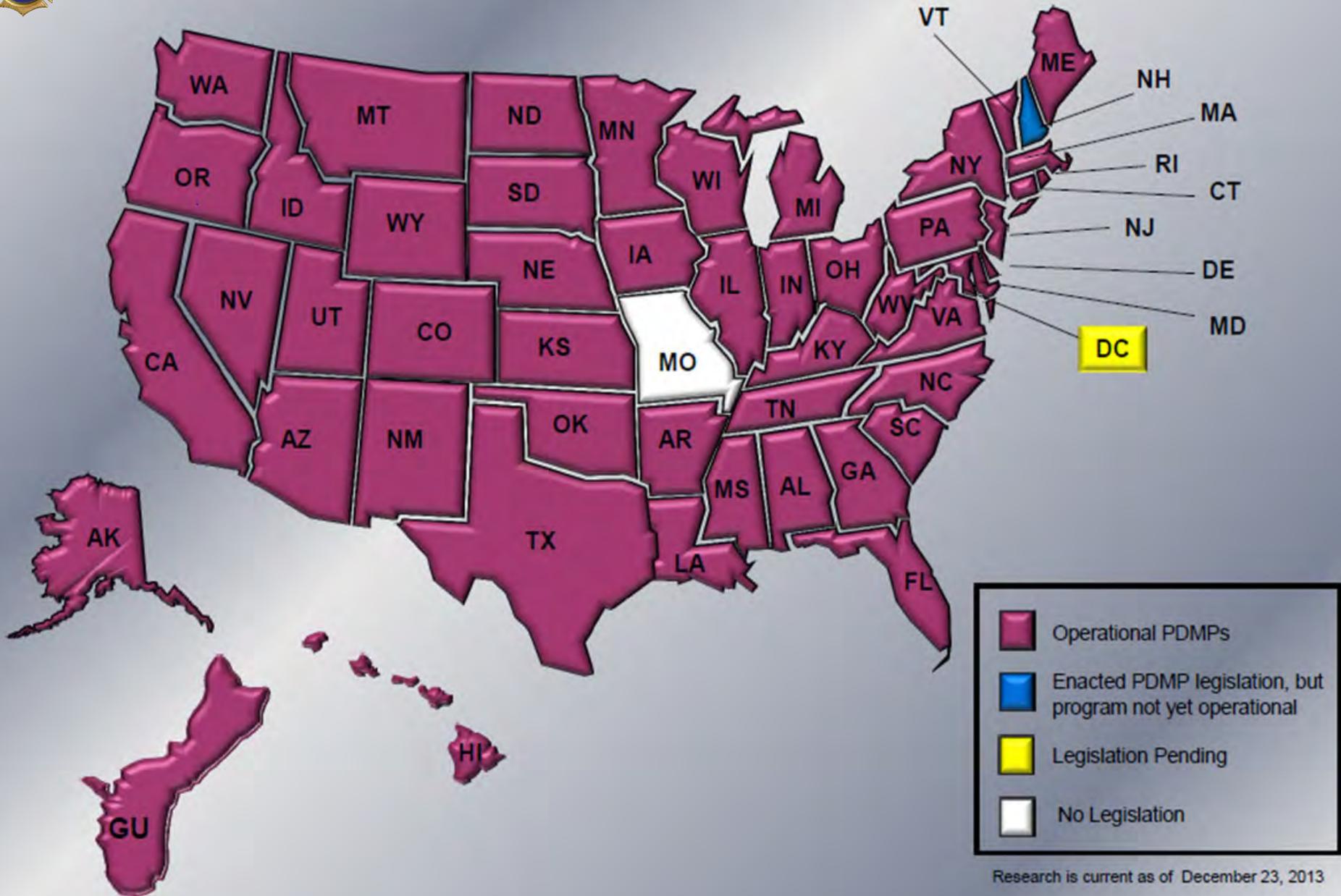


# Prescription Drug Monitoring Programs



# 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

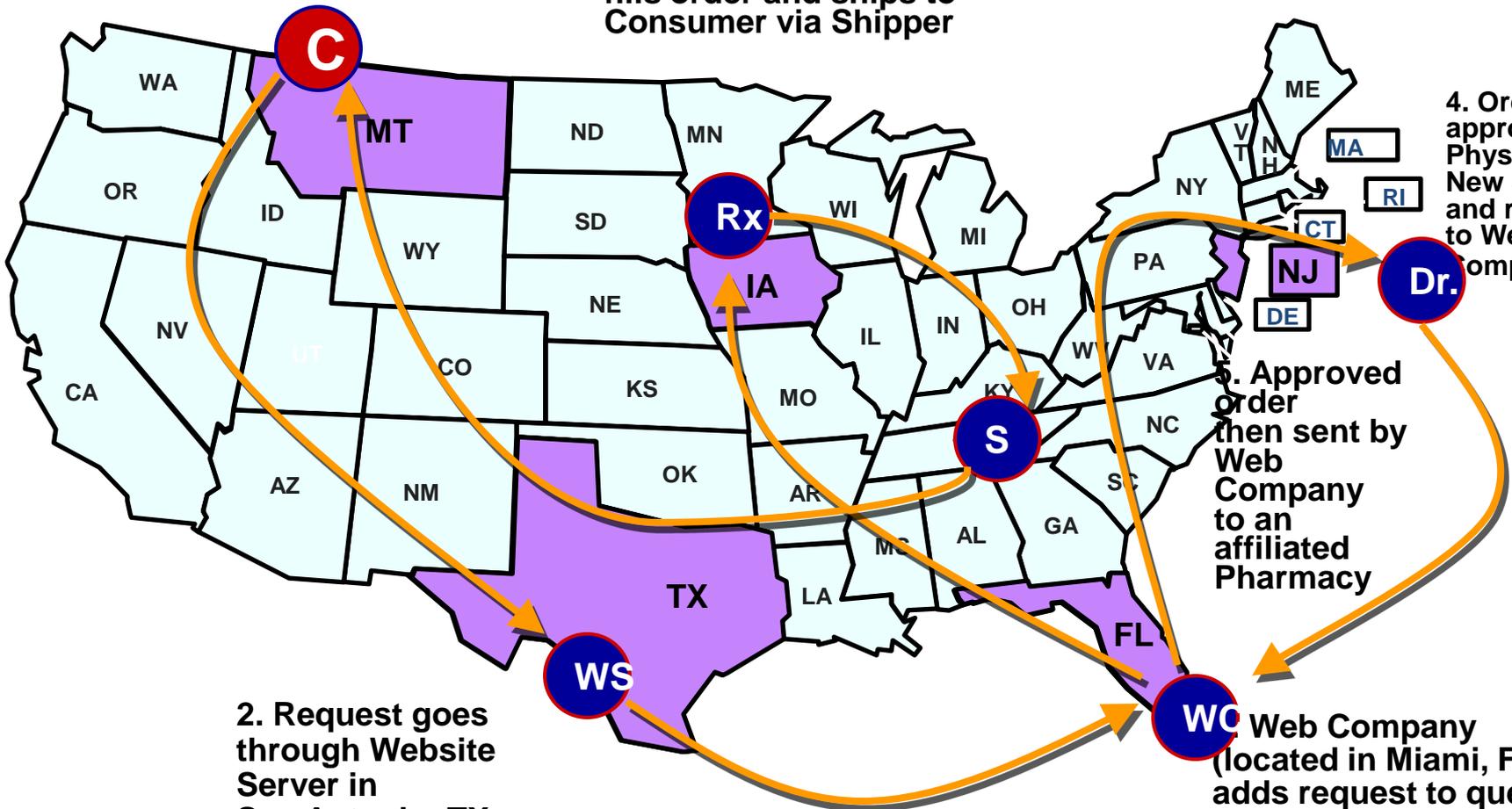
1. Consumer in Montana orders hydrocodone on the Internet

6. Pharmacy in Iowa fills order and ships to Consumer via Shipper

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

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

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





# 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



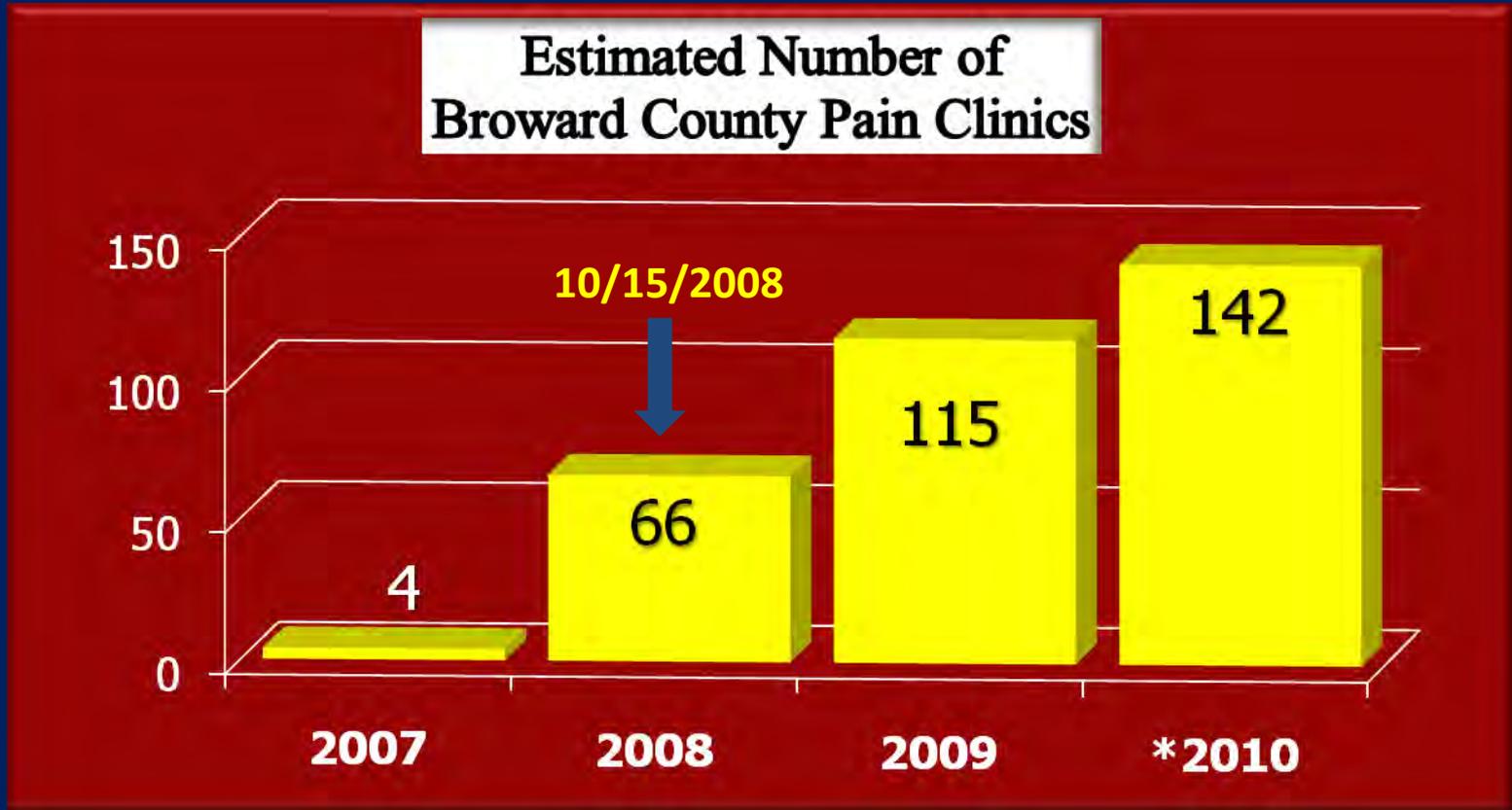
# What took the place of Internet Medical Care and Internet CS pharmaceutical Distribution?



# 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



# State of Florida Legislative Actions

## ➤ **Effective October 1, 2010**

- **Pain clinics are banned from advertising that they sell narcotics**
- **They can only dispense 72-hour supply of narcotics**
- **Prohibits the registration of pain clinics unless they are owned by physicians or licensed by non-physicians as a health care clinic**

## ➤ **Effective July 1, 2011**

- **Clinics must turn over their supply of C-II and C-III controlled substances**
- **Clinics are no longer able to dispense these drugs**
- **Clinics cannot have ANY affiliation with a doctor that has lost a DEA number**



# 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

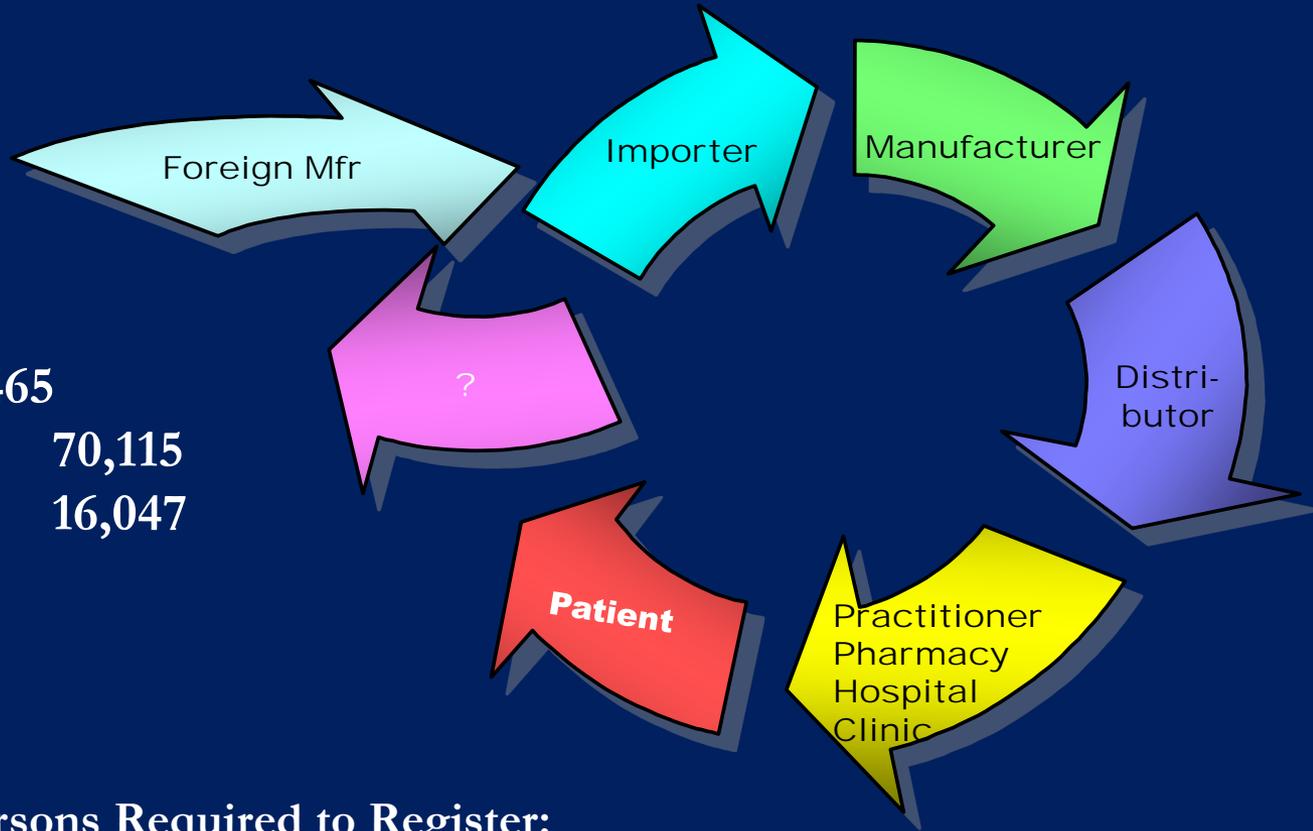
## Definitions

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



# 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





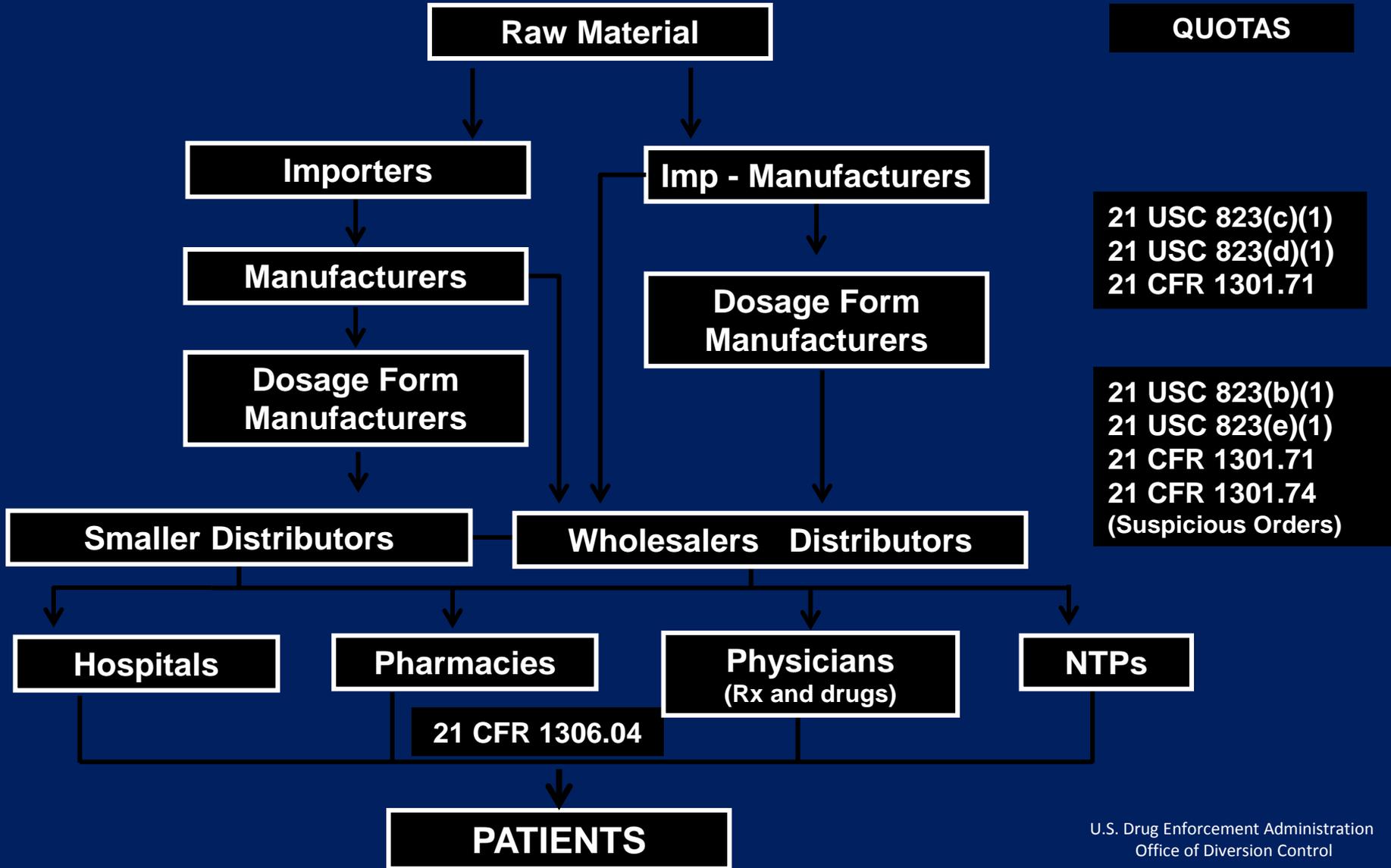
# The Controlled Substances Act

## Checks and Balances





# The Flow of Pharmaceuticals





# 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)*



# 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**



# 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 AACP 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)*

*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)*



# The Last Line of Defense



# Corresponding Responsibility

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

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



# Corresponding Responsibility Cases

## **East Main Street Pharmacy; Affirmance of Suspension Order**

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

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

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



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?

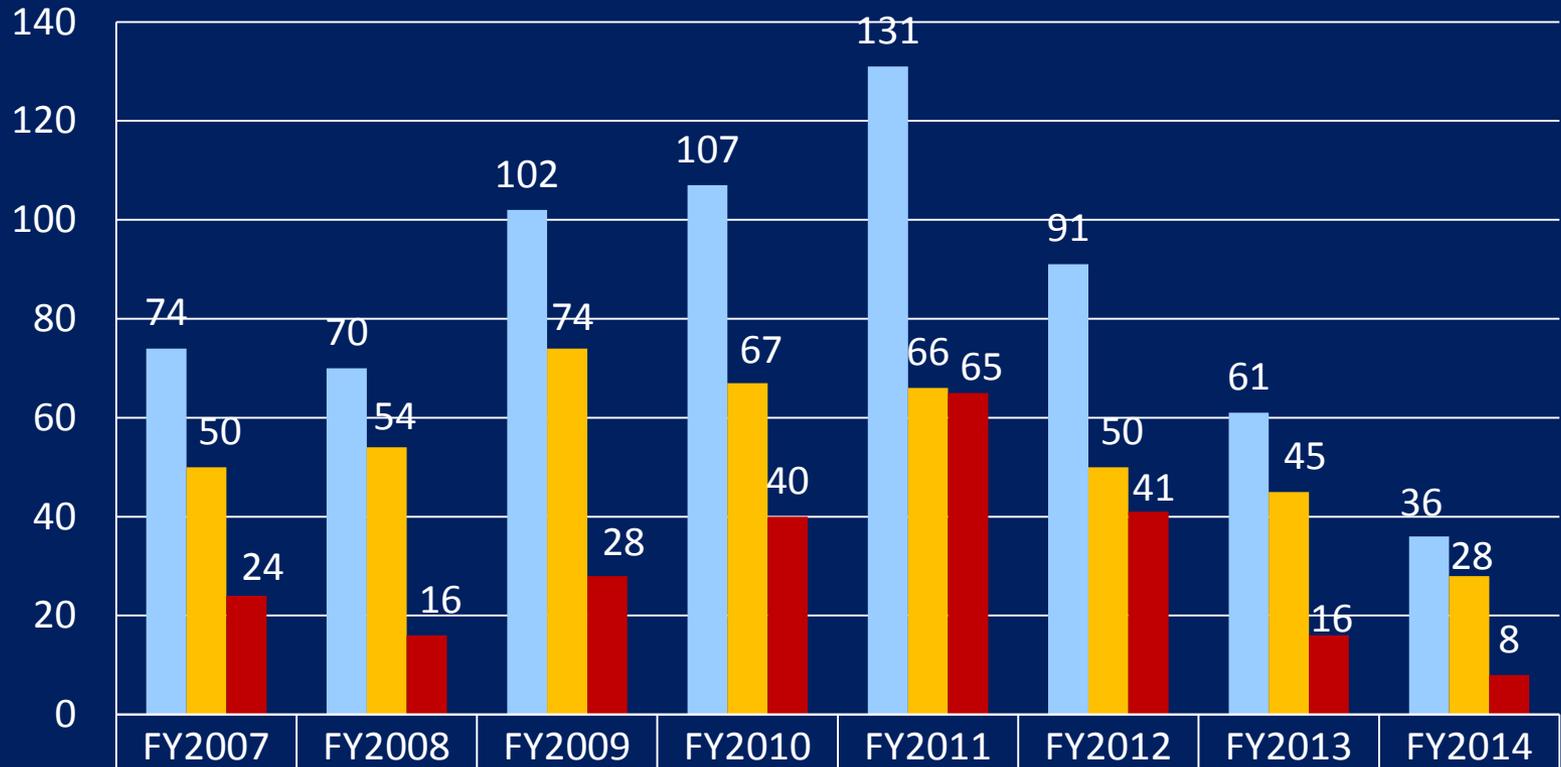
## The Order to Show Cause Process

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

# Administrative Actions Initiated by DEA

## FY2007 thru 2014\*



|                 |    |    |     |     |     |    |    |    |
|-----------------|----|----|-----|-----|-----|----|----|----|
| ■ Total Actions | 74 | 70 | 102 | 107 | 131 | 91 | 61 | 36 |
| ■ OTSCs         | 50 | 54 | 74  | 67  | 66  | 50 | 45 | 28 |
| ■ ISOs          | 24 | 16 | 28  | 40  | 65  | 41 | 16 | 8  |

\* FY2014 as of August 14, 2014



# 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



# 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



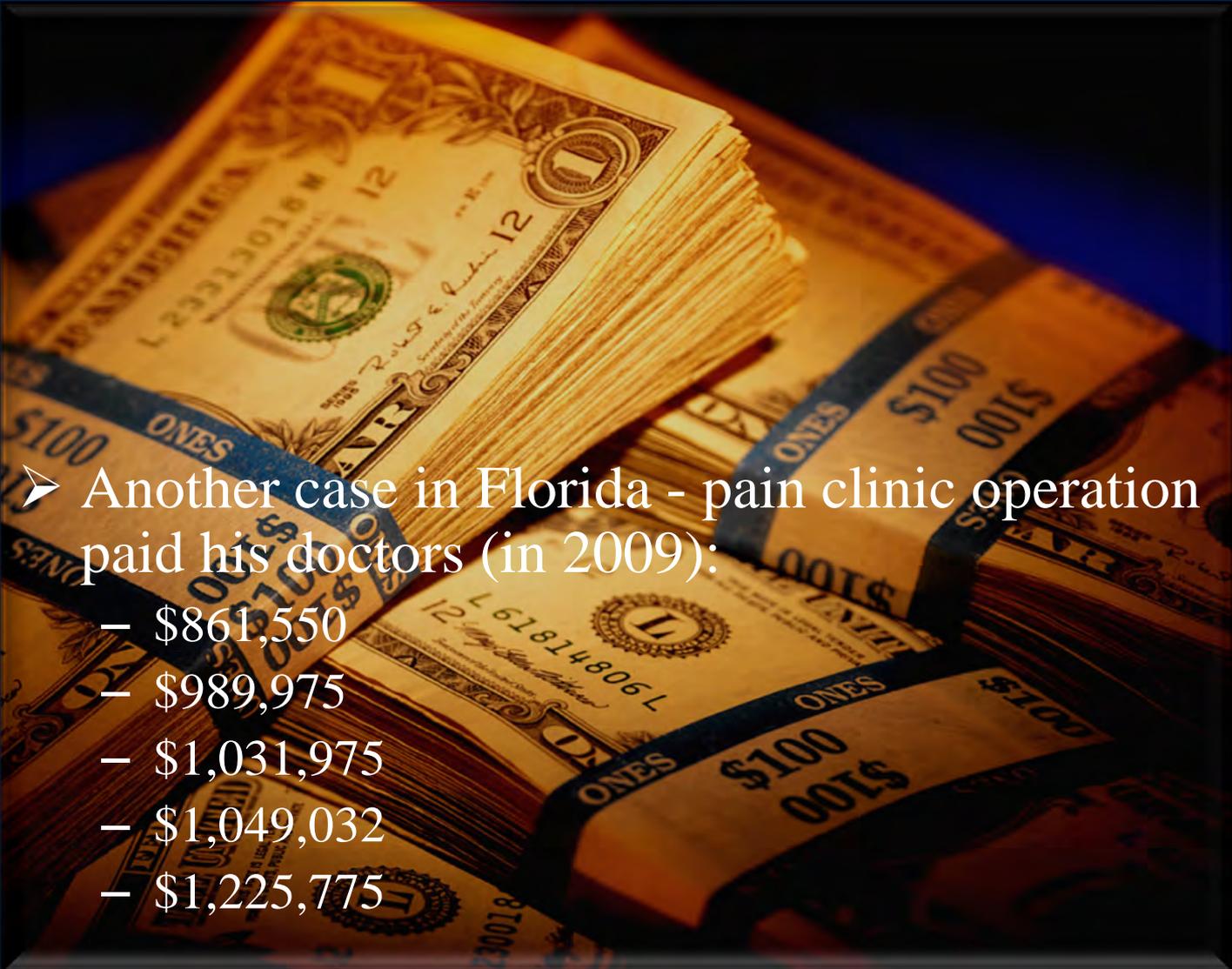
# What's the Profit?



- 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?

- 
- A photograph of several stacks of US one hundred dollar bills, tied with blue bands. The bills are fanned out, showing the front side with the portrait of Benjamin Franklin. The stacks are arranged in a way that creates a sense of depth and abundance of cash.
- 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



Questions



Thank You!