

# 22<sup>nd</sup> National Conference Pharmaceutical and Chemical Diversion



## *Pharmaceutical Drug Abuse & Trafficking Trends*

**September 30, 2014**

**Ruth A. Carter, Chief  
Liaison and Policy Section  
Office of Diversion Control  
Ruth.A.Carter@usdoj.gov**



# 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
- Discuss law enforcement role in preventing abuse and trafficking



# Prescription Drug Abuse & Trafficking Trends

OR

Responding to America's Prescription Drug  
Abuse Crisis

*"When Two Addictions Collide"*



DRAWINGBOARD / SIGNE

# DRUG-FREE AMERICA





# Mayo Clinic Study on Prescription Drugs

atlanta.cbslocal.com/2013/06/19/study-70-percent-of-americans-on-prescription-drugs-one-fift

**CBS Atlanta** CW69 CABLE 10 THE GAME 92-9 News & Talk 1380 WAOK

Home News Sports Health Best Of Events Heard On Traffic Weather PI

Latest News CBS Top Headlines Politics CBS MoneyWatch CNET Tech Business Ente

**\$3 OFF** AmeriGas ALL GRILLS ARE NOT CREATED

## NEWS

### Study: 70 Percent Of Americans On Prescription Drugs

June 19, 2013 12:59 PM

Like 17k Share 1.8K View Comments



**Rochester, Minn. (CBS ATLANTA) –** Researchers find that nearly 70 percent of Americans are on at least one prescription drug, and more than half receive at least two prescriptions.

Mayo Clinic [researchers report](#) that antibiotics, antidepressants and painkiller opioids are the most common prescriptions given to Americans. Twenty percent of U.S. patients were also found to be on five or more prescription medications.

Research finds that nearly 70 percent of Americans are on at least one prescription drug, and more than half receive at least two prescriptions. (Getty Images)

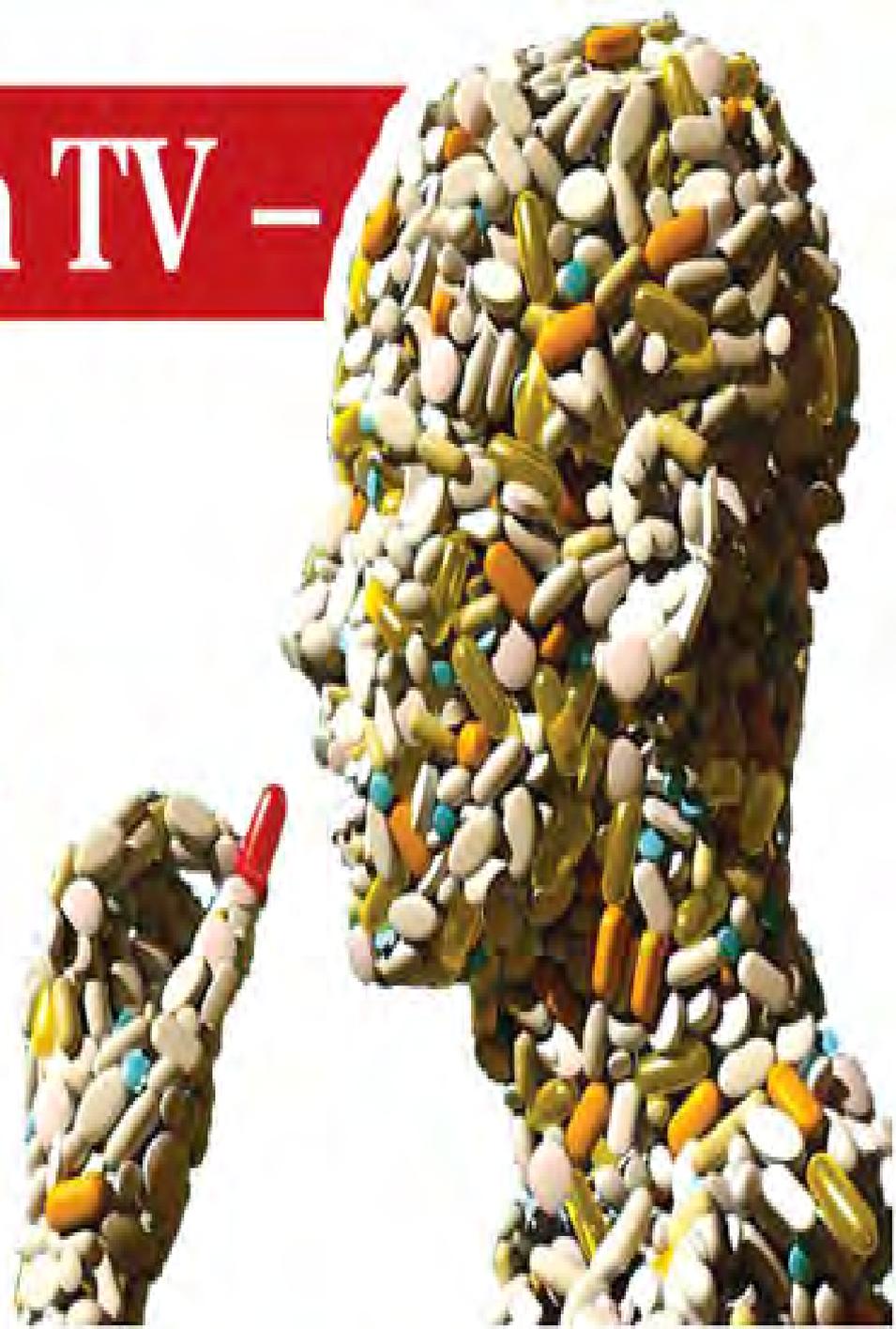
The [study](#) is uncovering valuable information

- The three most common types of prescriptions are antibiotics, antidepressants, and painkiller opioids
- 70% of Americans are taking at least one prescription drug
- More than 50% are on at least two prescriptions

# Rx Drug Ads on TV –

## Educational or Influential ?

Overweight? Suffering from anxiety or erectile dysfunction? Well, relief is just a prescription pill away according to the endless television ads promoting prescription drugs.





# 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.



# 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>

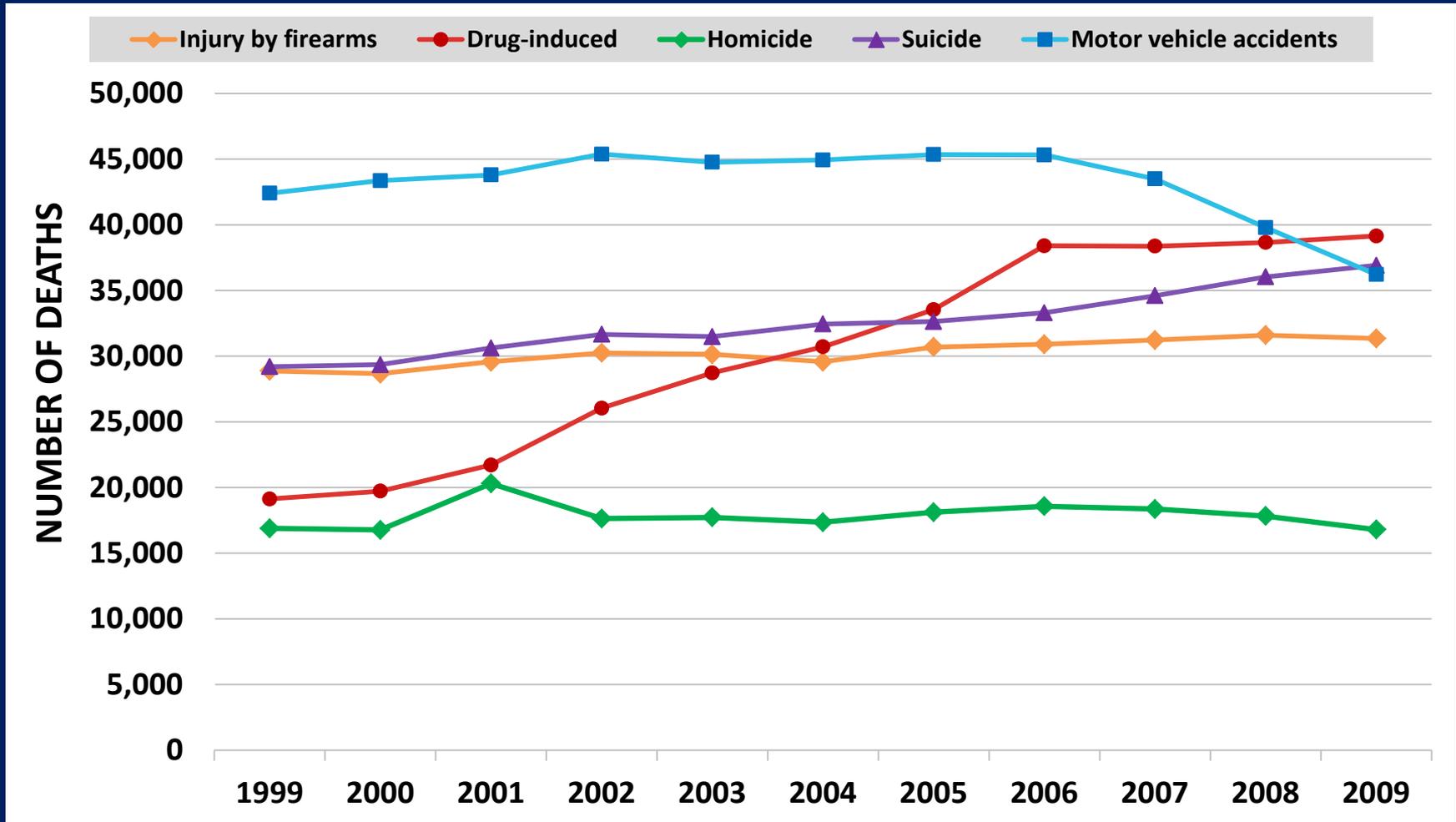
Of this number, 22,810 deaths were attributed to Prescription Drugs (16,917 attributed to opioid overdoses/ (74.165%).

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

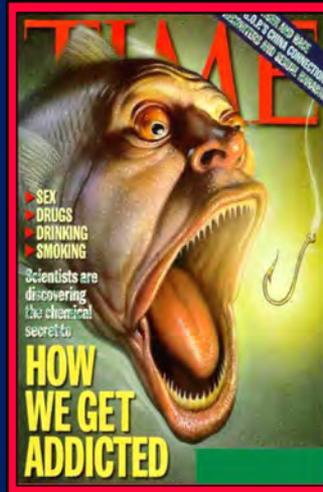
MARIJUANA: 18.9 million

PSYCHOTHERAPEUTIC  
DRUGS: 6.8 million

COCAINE: 1.6 million

Methamphetamine 440,000

Heroin: 335,000



Source: 2011 & 2012 NSDUH



# Prescription Drug Abuse

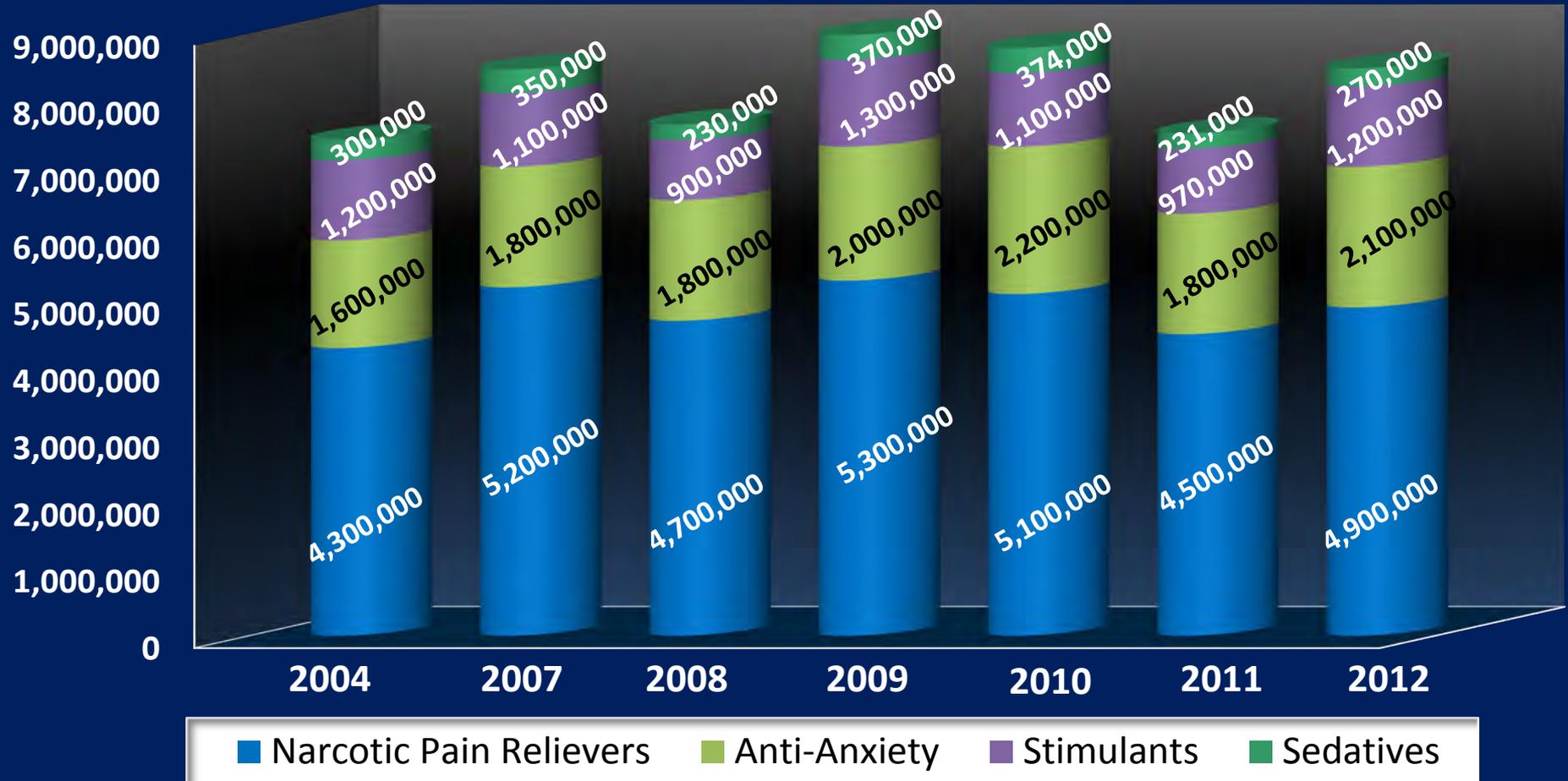
More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Heroin, and Inhalant abusers

**COMBINED!!!**

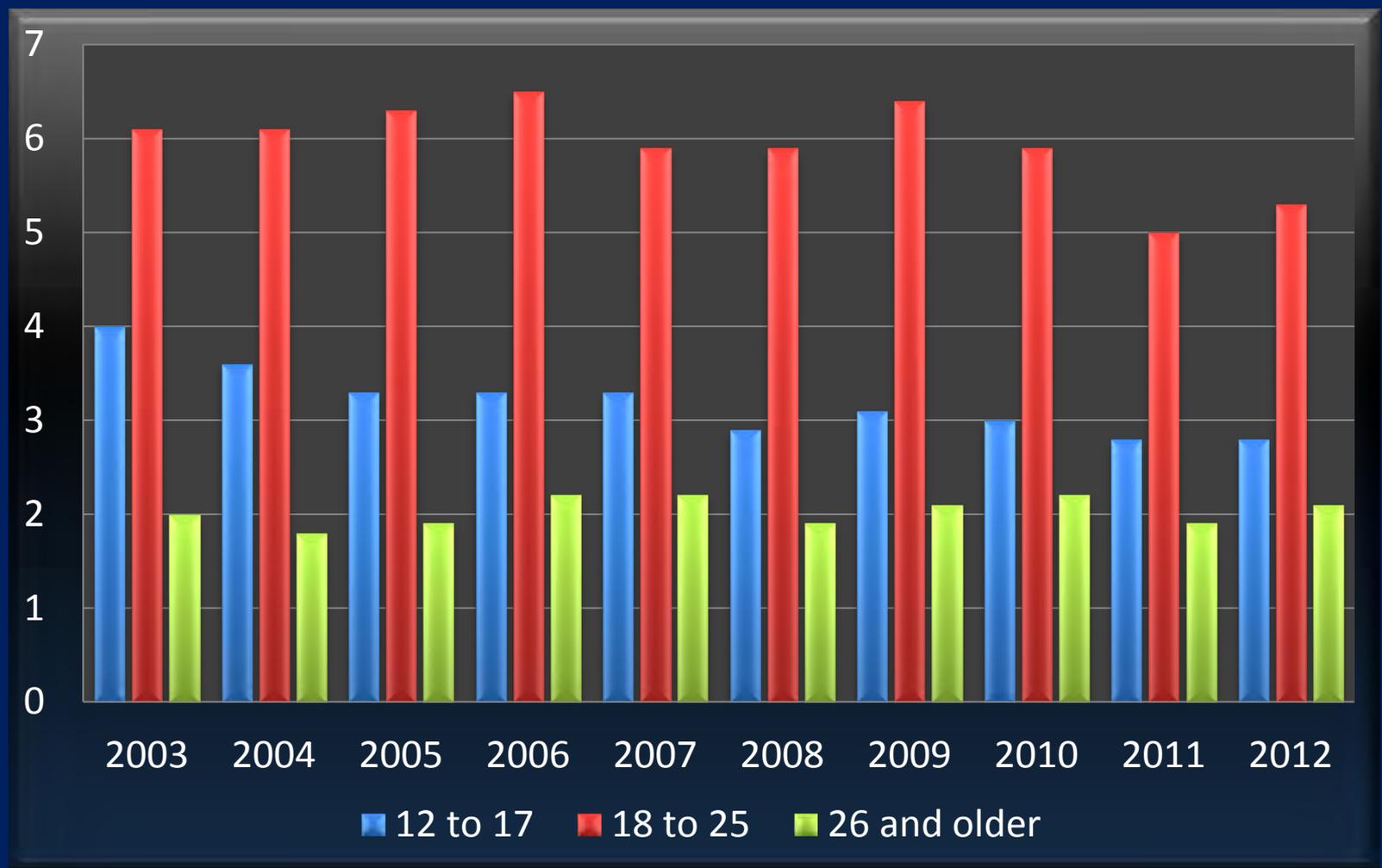


# Scope and Extent of Problem: Past Month Illicit Drug Use among Persons Aged 12 or Older





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





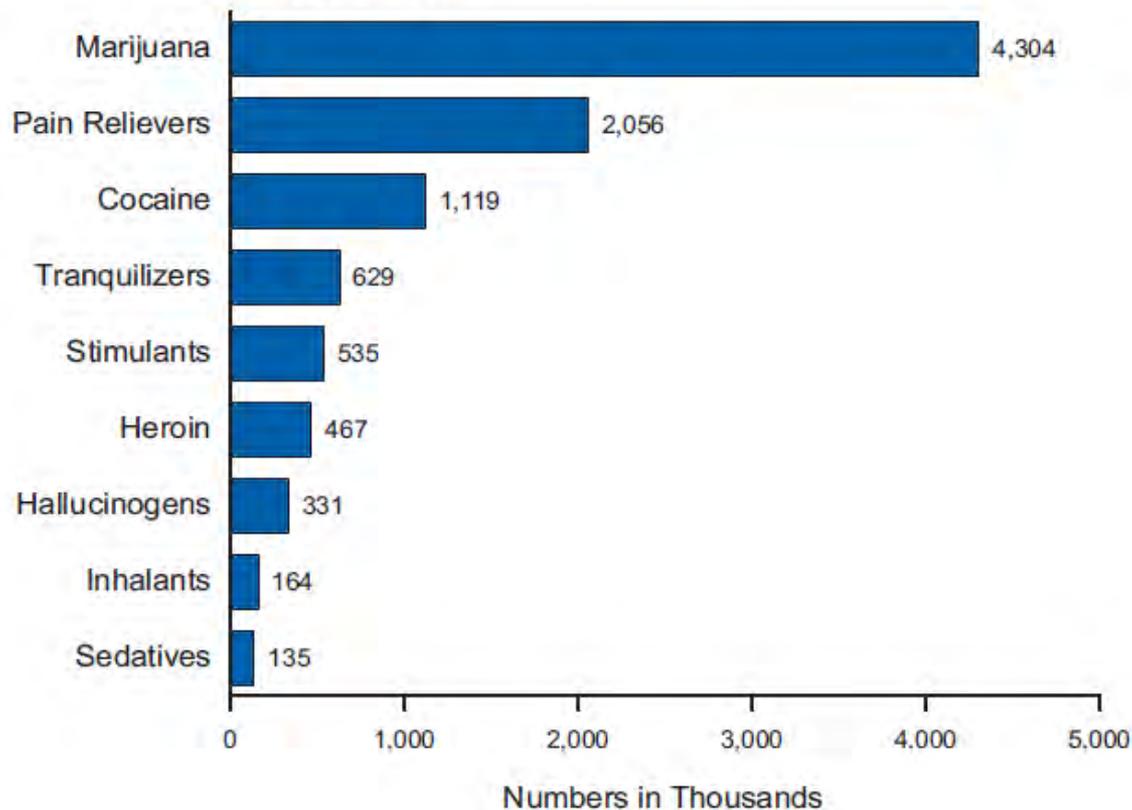
# Emergency Room Data 2004-2011

- 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**

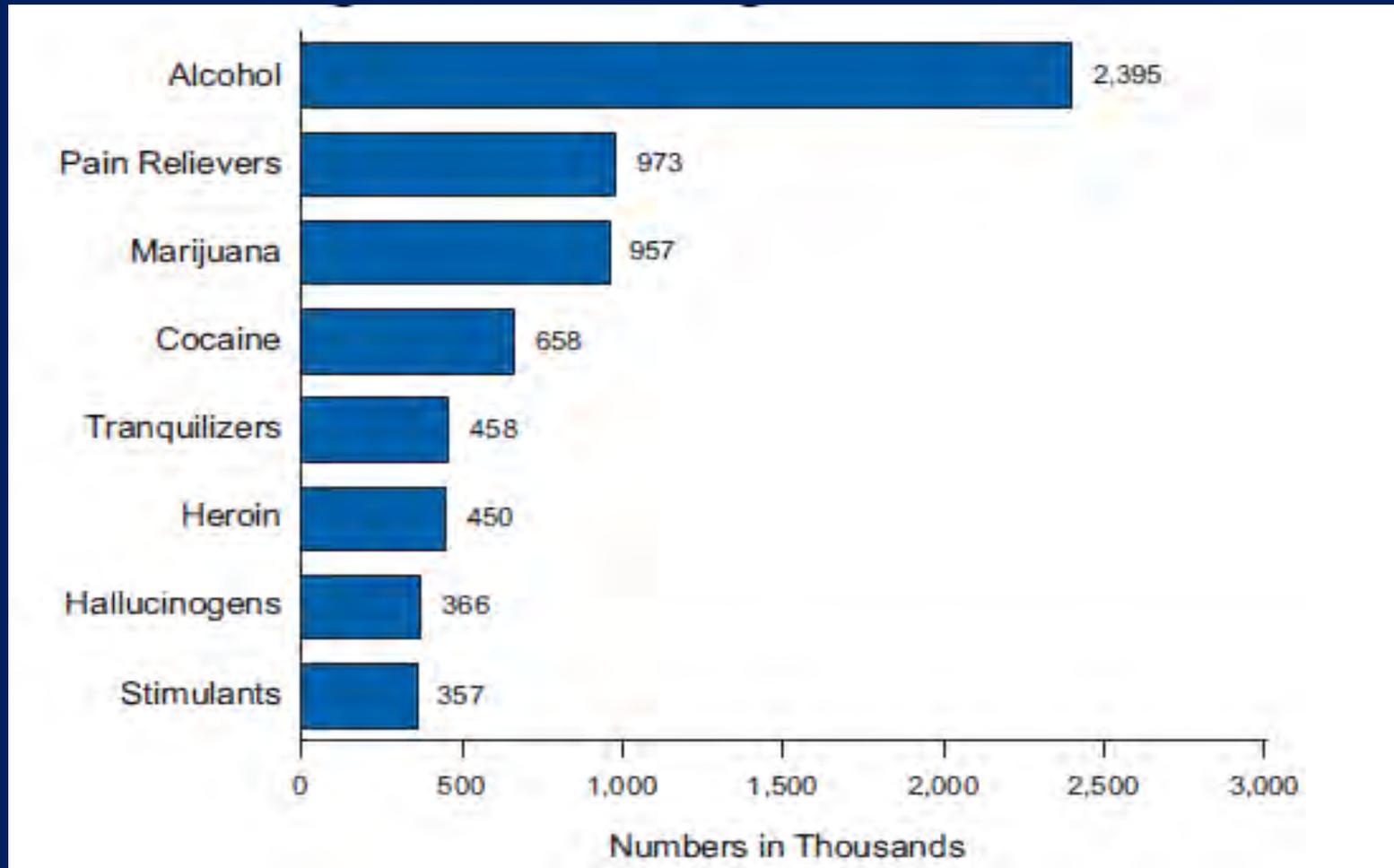


SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)

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





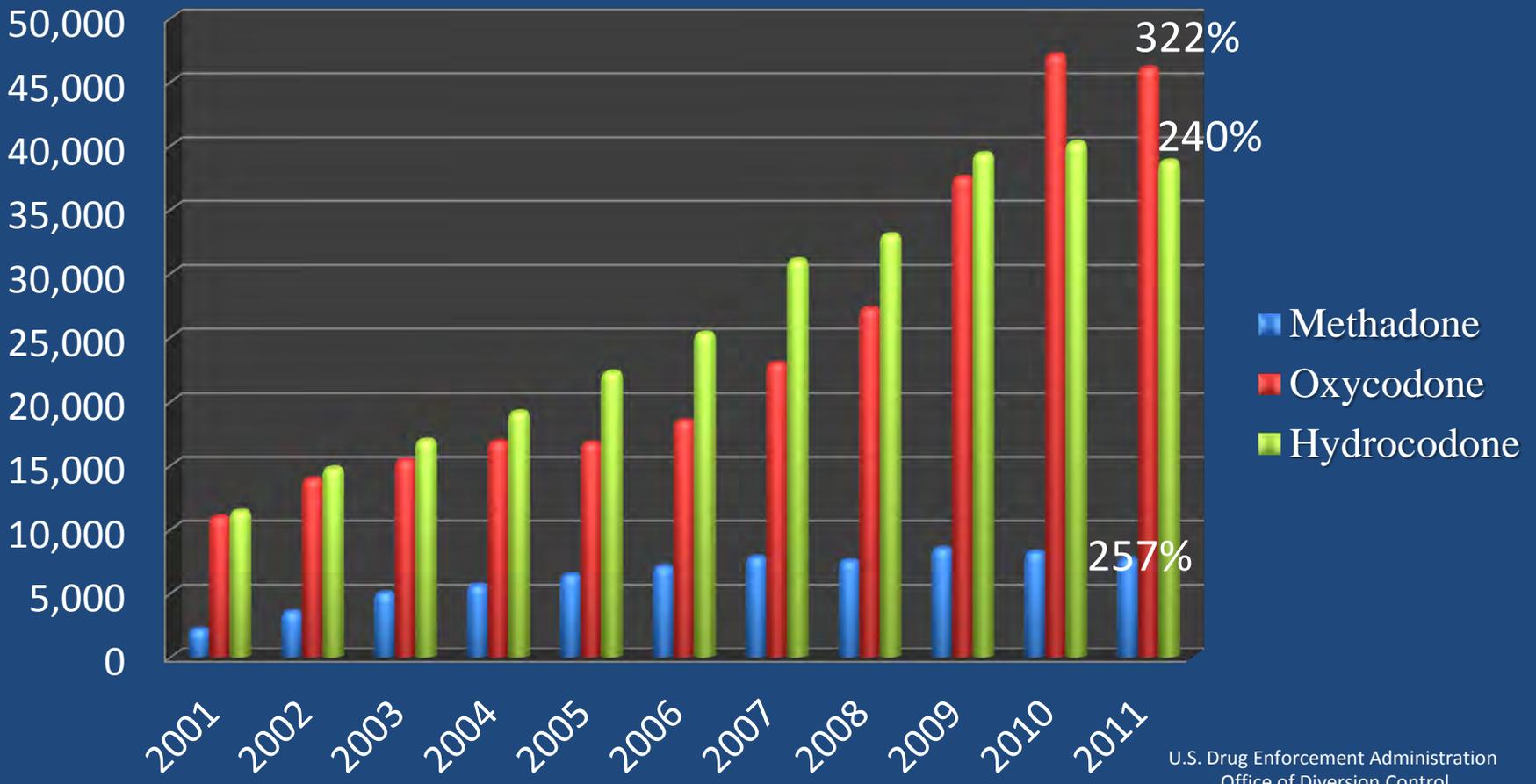
# Where Painkiller Prescriptions Are The Highest

- 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



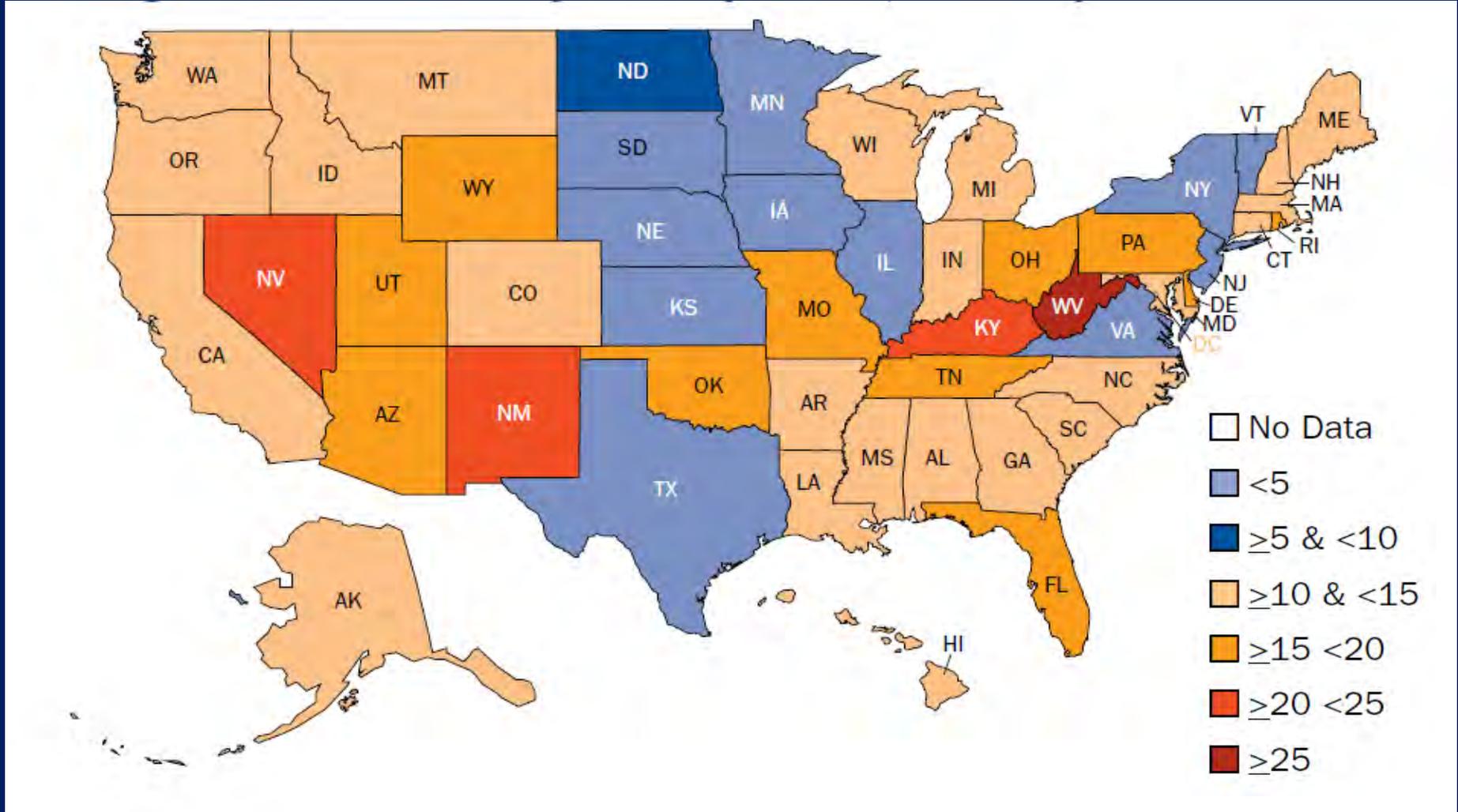
# Number of Forensic Cases 2001-2011

NFLIS  
Estimated U.S. Law Enforcement Encounters





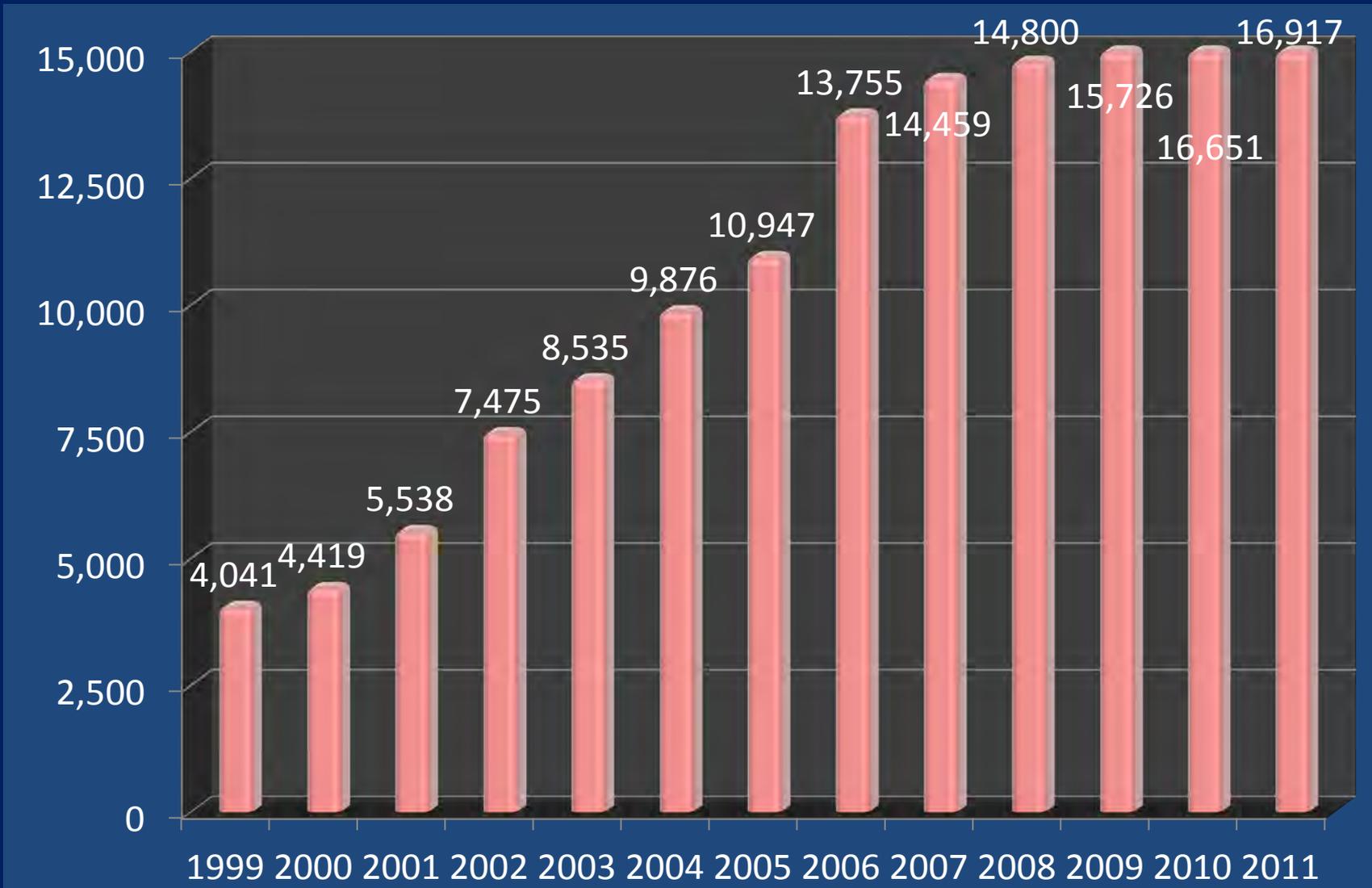
# Drug Overdose Mortality Rates per 100,000 People 2010





# Poisoning Deaths: Opioid Analgesics

Poisoning Deaths





# 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.



**Rush Limbaugh**



**Steven Tyler**

# ***ABUSERS***



**Eminem**



**Brett Farve**

# Wrestler Benoit's doctor gets 10 years in prison

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

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



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

Share

Add to Mixx

Facebook

Twitter

More

Subscribe

myYahoo

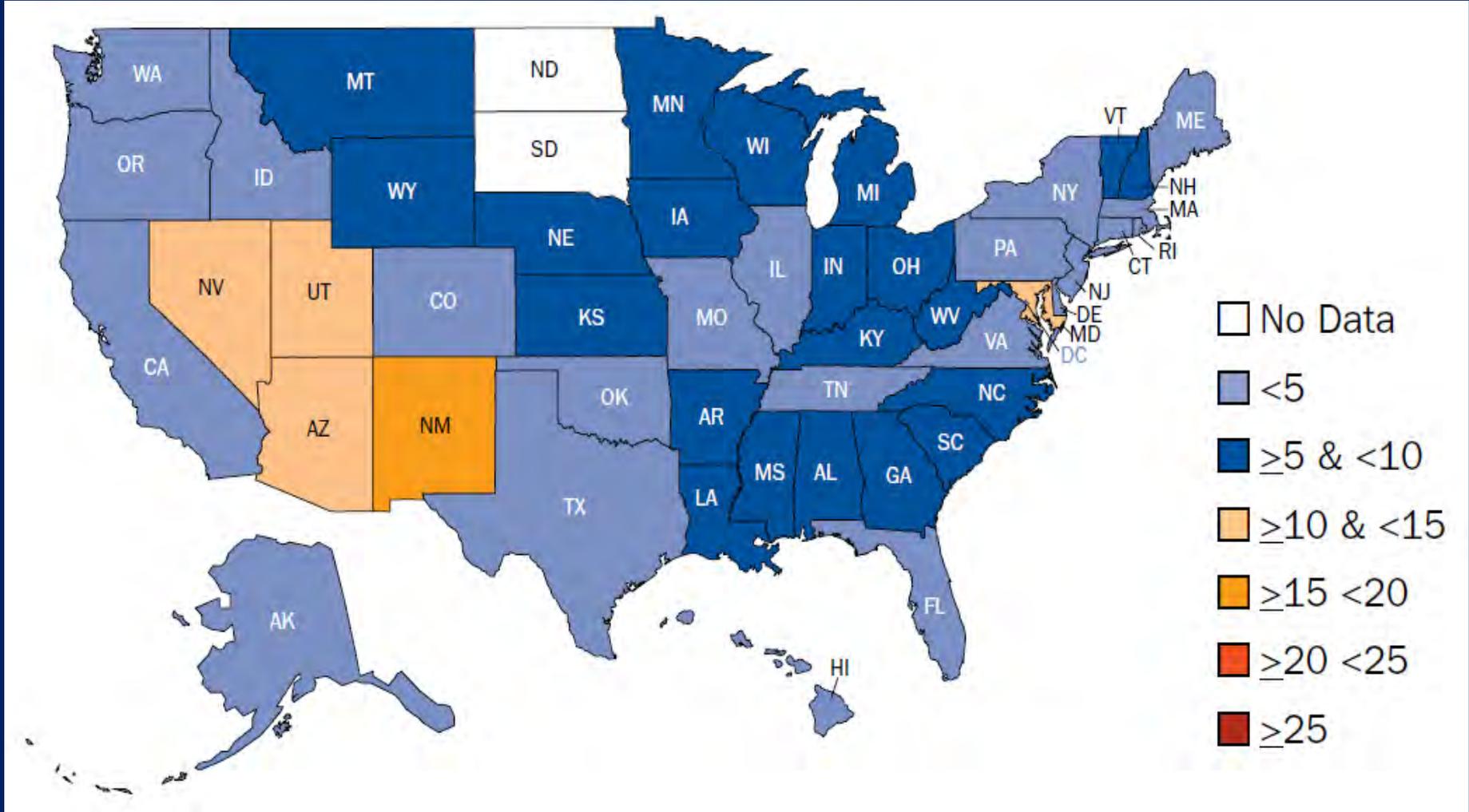
iGoogle

More

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



# 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)"



# 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.



# BAYER PHARMACEUTICAL PRODUCTS.

Send for samples  
and Literature to



FARBENFABRIKEN OF  
ELBERFELD CO.

40 STONE STREET,  
NEW YORK.

## COCAINE TOOTHACHE DROPS

Instantaneous Cure!  
PRICE 15 CENTS.  
Prepared by the  
**LLOYD MANUFACTURING CO.**  
218 HUDSON AVE., ALBANY, N. Y.  
For sale by all Druggists.  
(Registered March 1885.)

4

ADVERTISEMENTS.

### For Body and Brain

Since 30 Years all Eminent Physicians recommend

## VIN MARIANI

Over 7,000 written endorsements from prominent Physicians in Europe and America

Nourishes  
Fortifies  
Refreshes  
Strengthens the Entire System

The most Agreeable, Effective and Lasting Tonic

Most popularly used Tonic-Stimulant in Hospitals, Public & Religious Institutions Everywhere

EVERY Test, strictly on its Own Merits, proves its Exceptional Reputation

To avoid disappointments accept no substitutions

### Free Offer!

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

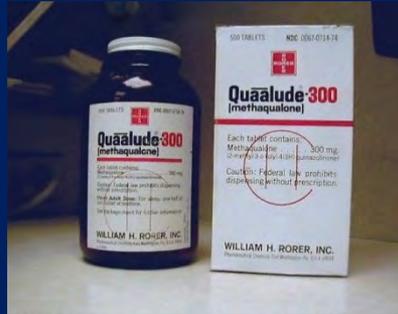
Paris: 41 Boulevard Haussmann  
London: 239 Oxford Street

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





# The 1960s/70s/80s



"Ts and Blues"

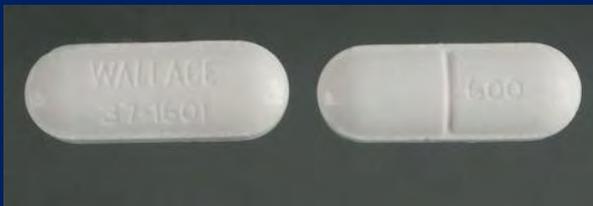
Uppers - Amphetamines

Quaalude



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)



# Inadequate Pain Control

### 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

Surveillance Program  
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.





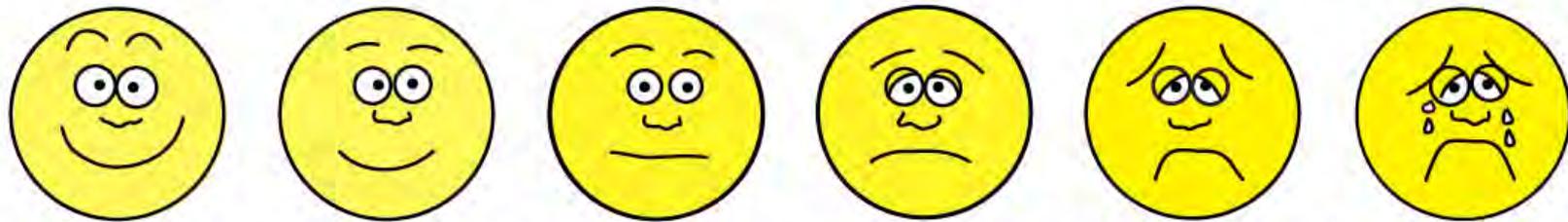
# The Fifth Vital Sign?

1. Temperature
2. Heart Rate
3. Blood Pressure
4. Respiration
5. Pain?



# Pain Scale

## Wong-Baker FACES Pain Rating Scale



0 No Hurt  
1  
2 Hurts Little Bit  
3  
4 Hurts Little More  
5  
6 Hurts Even More  
7  
8 Hurts Whole Lot  
9  
10 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



# Pharmaceutical Controlled Substances



# Opiates



**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



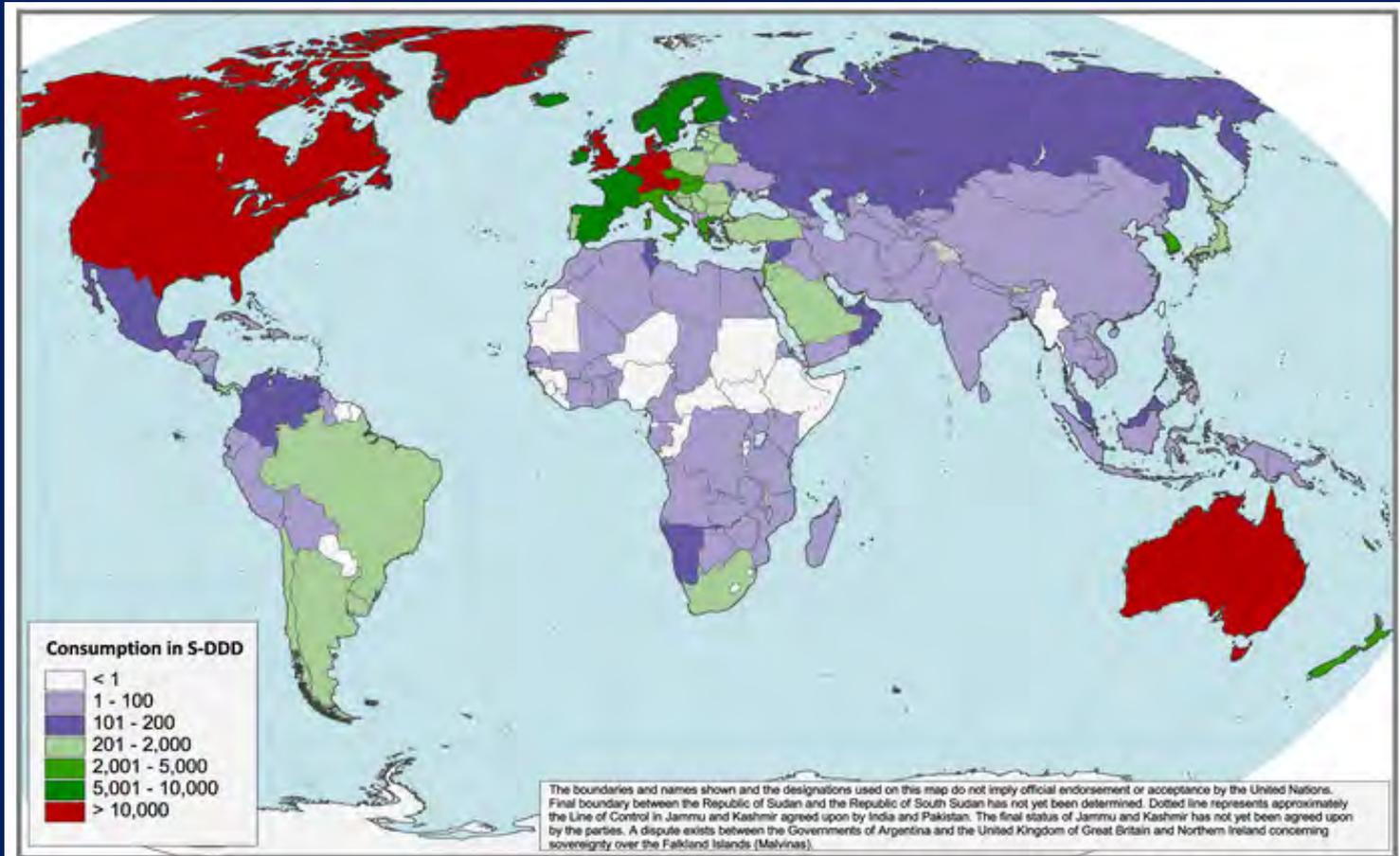
# Top 10 List

- 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)

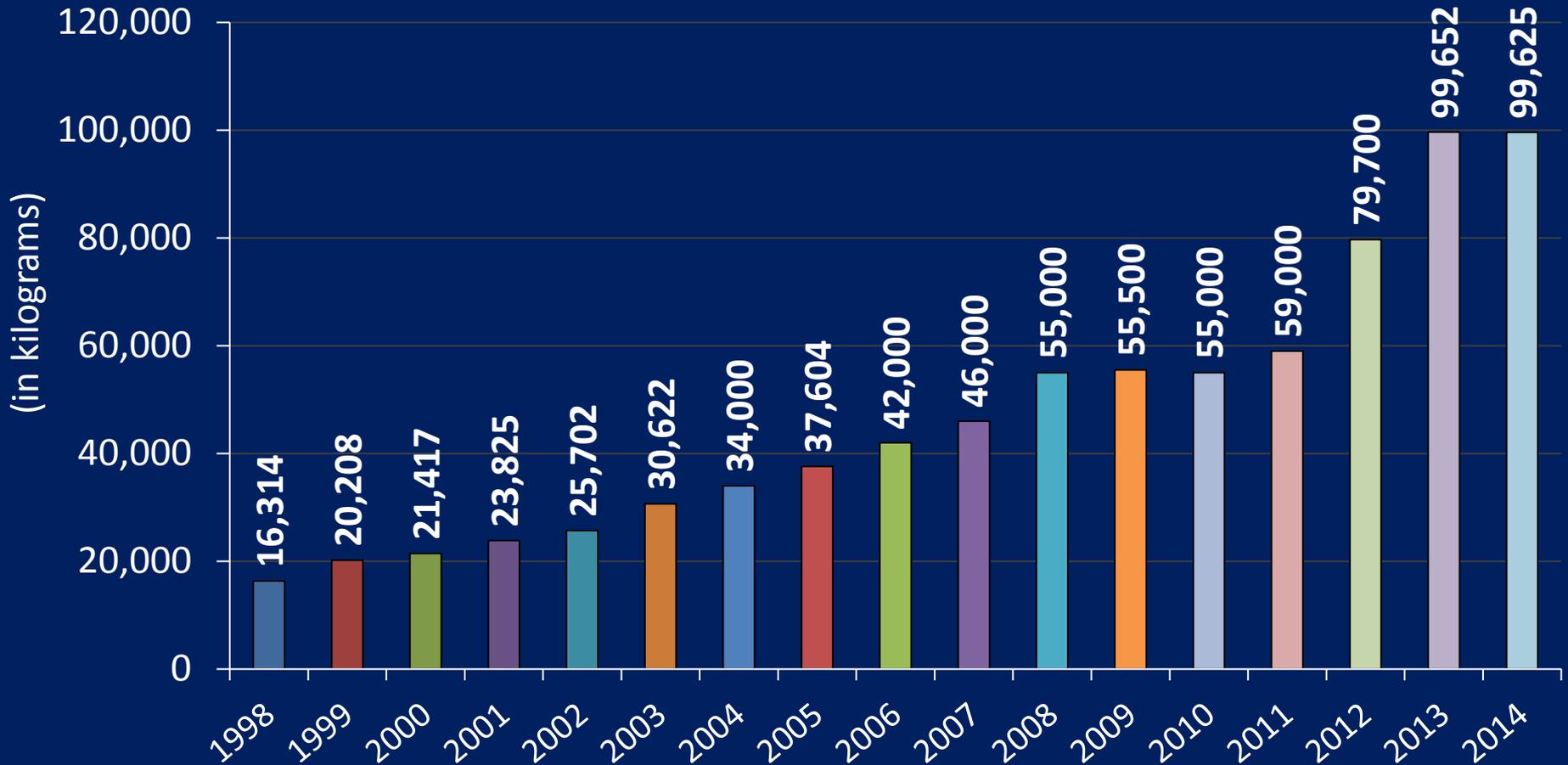
(Consumption in defined daily doses for statistical purposes (S-DDD) per million inhabitants per day)



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

# Hydrocodone

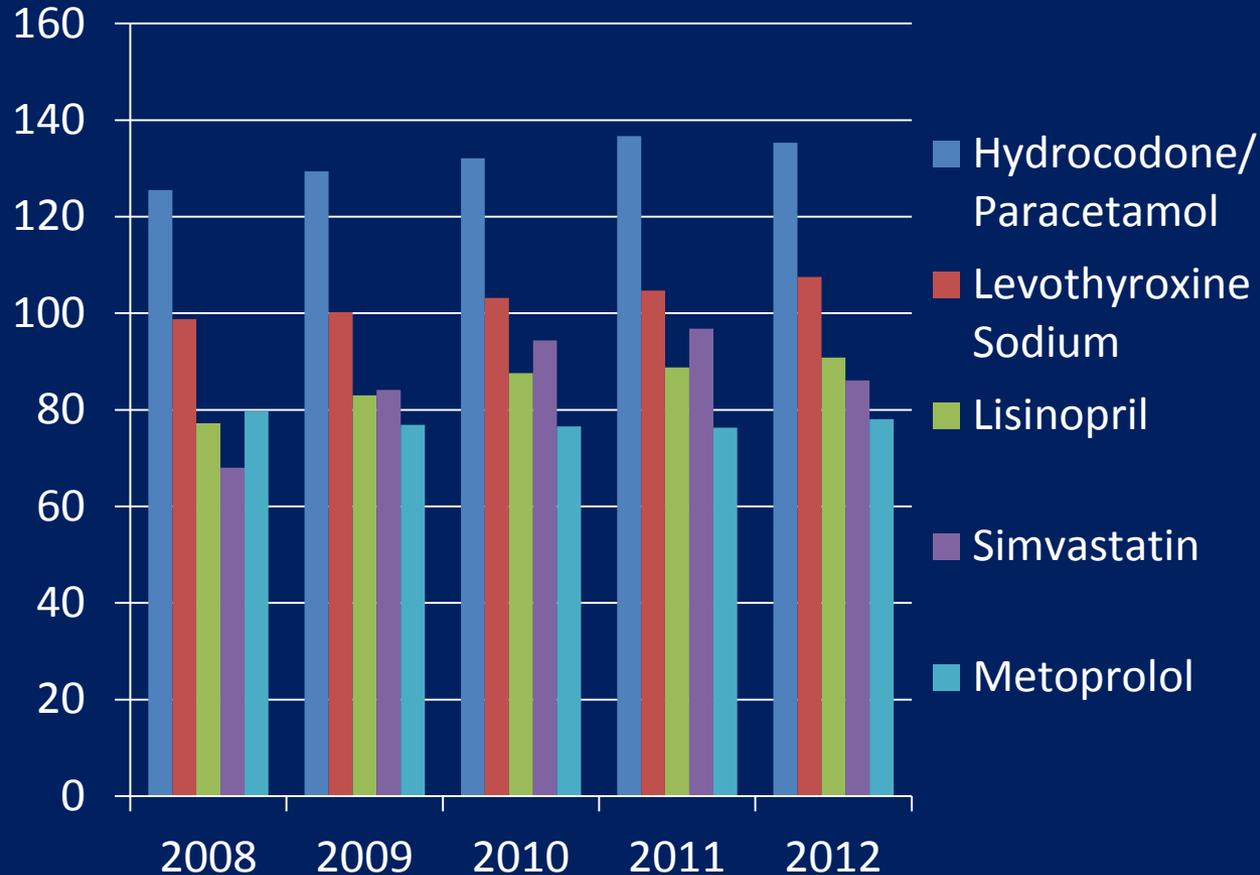
## Aggregate Production Quota History





# 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, APAP C-III

- Hydrocodone / Acetaminophen (toxicity)
- Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin<sup>®</sup>, Lortab<sup>®</sup>, Lorcet<sup>®</sup>
- “Cocktail” or “Holy Trinity”
  - Hydrocodone
  - Soma <sup>®</sup> / carisoprodol
  - Alprazolam / Xanax<sup>®</sup>
- Street prices: \$2 to \$10+ per tablet depending on strength & region





# Hydrocodone Combination Products

October 6, 2014

Hydrocodone combination products  
placed into schedule II of the CSA

**79FR49661 dated August 22, 2014**



# State Ranking\* - Oxycodone

## January – December 2013

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	PA	297,341,980	12	MD	128,027,280	23	CT	72,412,470	34	KS	38,925,890	45	MT	15,404,320
2	FL	291,383,620	13	VA	124,771,088	24	MN	72,203,730	35	NM	36,568,830	46	PR	11,507,780
3	CA	281,630,294	14	GA	122,888,860	25	AL	66,004,480	36	MS	30,021,050	47	AK	10,382,220
4	NY	268,408,239	15	MO	102,988,470	26	TX	61,493,810	37	ME	29,744,160	48	VT	10,160,680
5	OH	254,919,240	16	WI	97,740,170	27	OK	60,056,840	38	NH	29,056,310	49	WY	9,042,220
6	NC	222,945,670	17	OR	95,608,810	28	NV	58,577,300	39	DE	26,926,890	50	DC	6,897,540
7	NJ	177,267,830	18	IN	92,666,390	29	LA	54,777,500	40	IA	24,029,580	51	ND	6,645,960
8	AZ	163,531,150	19	CO	89,415,210	30	UT	52,478,120	41	ID	18,623,640	52	SD	6,596,300
9	TN	155,131,080	20	MI	86,251,570	31	WV	44,705,160	42	RI	17,868,720	53	GU	411,600
10	MA	137,178,760	21	SC	79,444,900	32	IL	44,362,470	43	HI	16,361,480	54	VI	291,000
11	WA	129,721,790	22	KY	74,443,010	33	AR	39,813,350	44	NE	15,564,300	55	AS	0

**\* Business Activity – Retail Pharmacies**

Source: Drug Enforcement Administration, Office of Diversion Control,  
Pharmaceutical Investigations Section, Targeting and Analysis Unit  
Most current ARCOS information as of March 18, 2014

U.S. Drug Enforcement Administration  
Office of Diversion Control

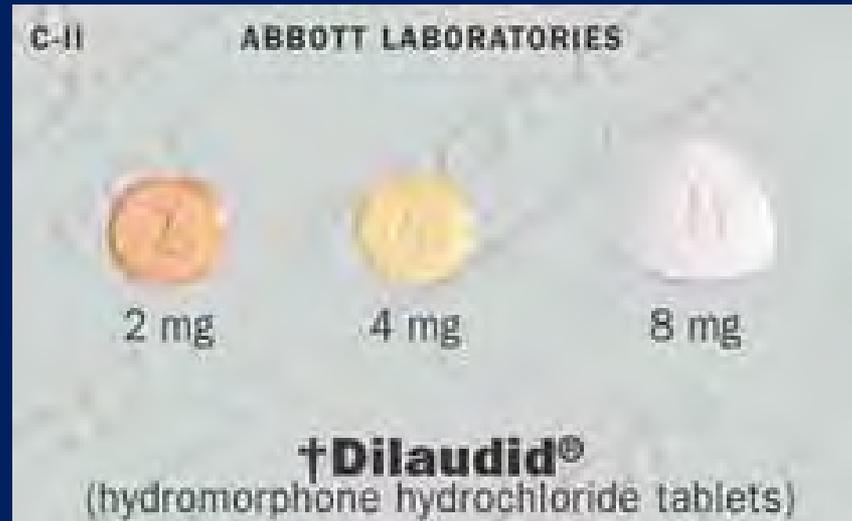


# Oxycodone HCL CR (OxyContin®) Reformulation





# 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 0854-0264-25 100 Tablets

**HYDROMORPHONE HYDROCHLORIDE**   
Tablets, USP

**4 mg**

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

 **Roxane Laboratories**

00540 26425

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° (68° to 77°F) [See USP Controlled Room Temperature].  
Rx Only

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

0327-1355-01



# 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



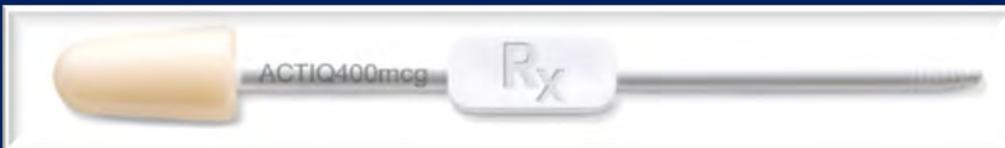
**Trade Name: Dilaudid**  
Controlled Ingredient:  
hydromorphone hydrochloride, 4 mg

# Fentanyl



**Fentora®**

- 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



**Actiq®**



# Opiates v. Heroin



*Papaver*



*Somniferum*

Codeine

Morphine

Thebaine

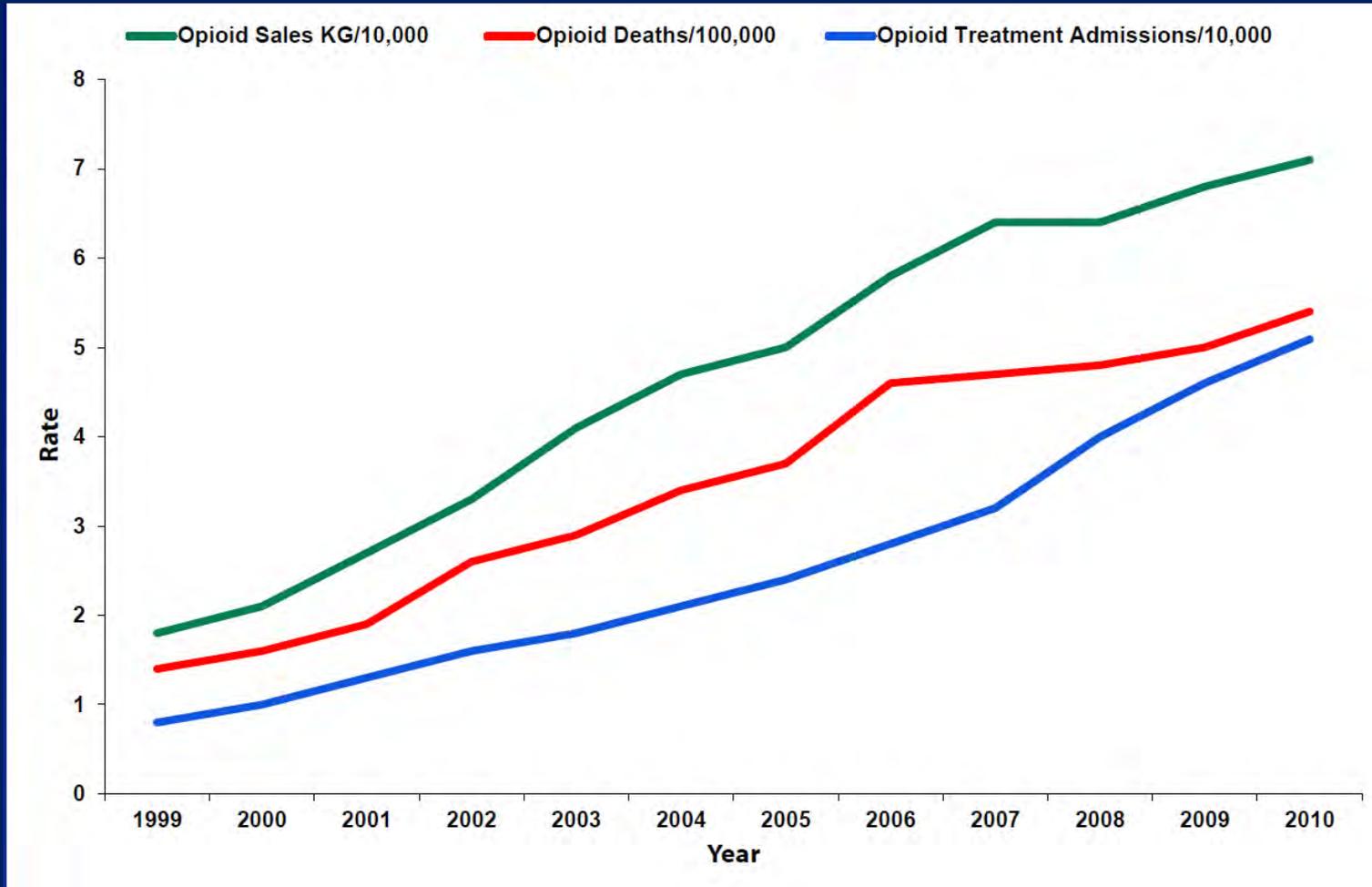
Hydrocodone

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®

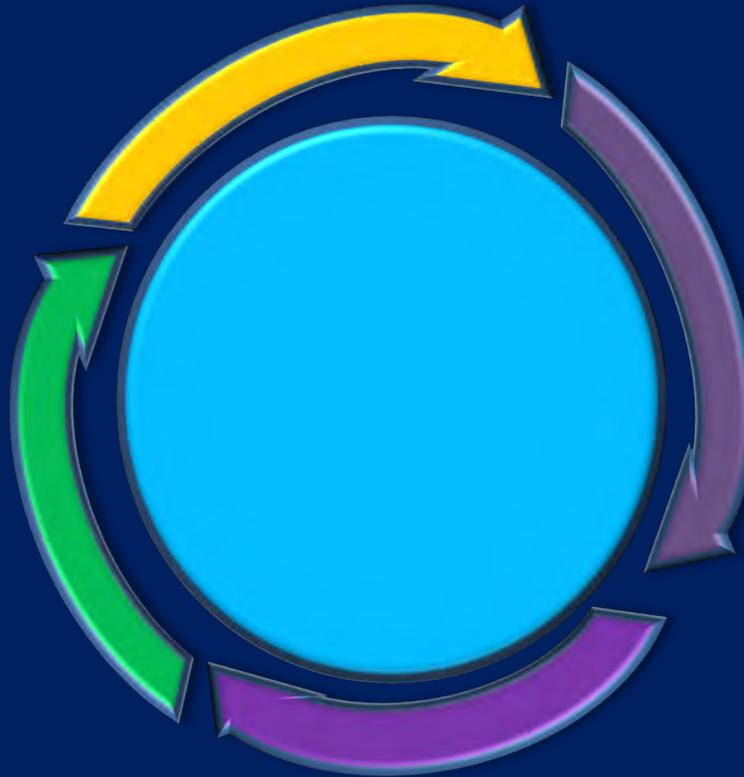
Oxycodone IR

15mg, 30mg

\$30-\$40/tab

Heroin

\$10/bag



NOW OPEN



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

12511 Prosperity Drive • Silver Spring, MD 20904

**1-888-589-3065**

[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

# 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



# Overdose... Why?

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



# One Pill can Kill



CE Article: JACCME, 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.

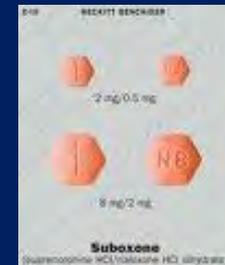
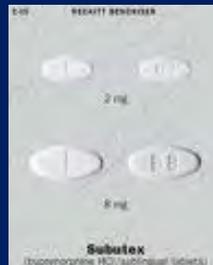


# Other FDA Approved Drugs for Narcotic Addiction Treatment

## ➤ Schedule III

– Buprenorphine – Drug Code 9064

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



# Benzodiazepines

Alprazolam



Clonazepam



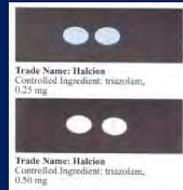
Diazepam



Lorazepam



Triazolam



Temazepam



Flunitrazepam



Midazolam





# Stimulants

## Amphetamine Salts C-II

➤ Adderall® C-II



## Methylphenidate C-II

➤ Ritalin®

➤ Concerta®

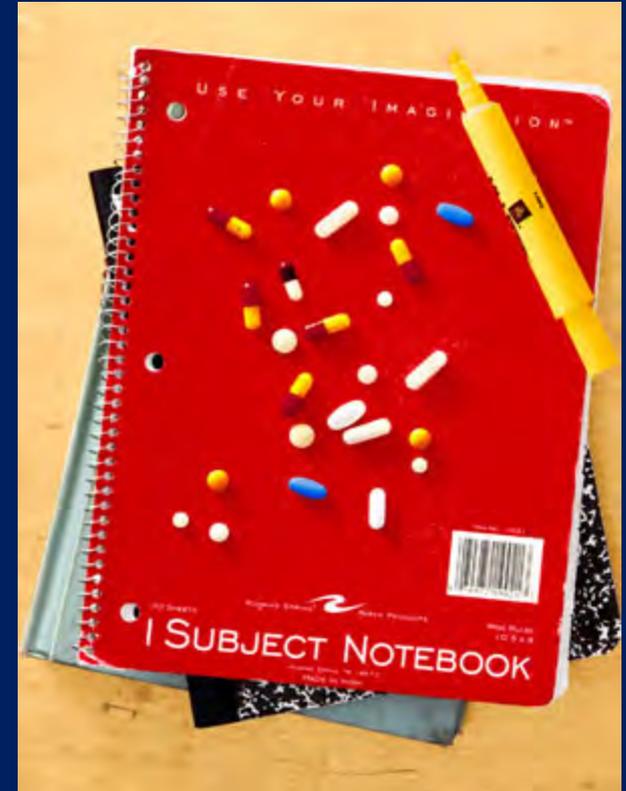


# Ritalin® / Concerta® / Adderall®

- 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

# ADHD Medication

- ✓ **1** in **8** teens (2.7 million) misuse or abuse
- ✓ **29%** parents believe can improve academic or testing performance, even if teen is does not have ADHD
- ✓ **1** in **4** teens believes these drugs can be used as a study aid





# 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

- 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

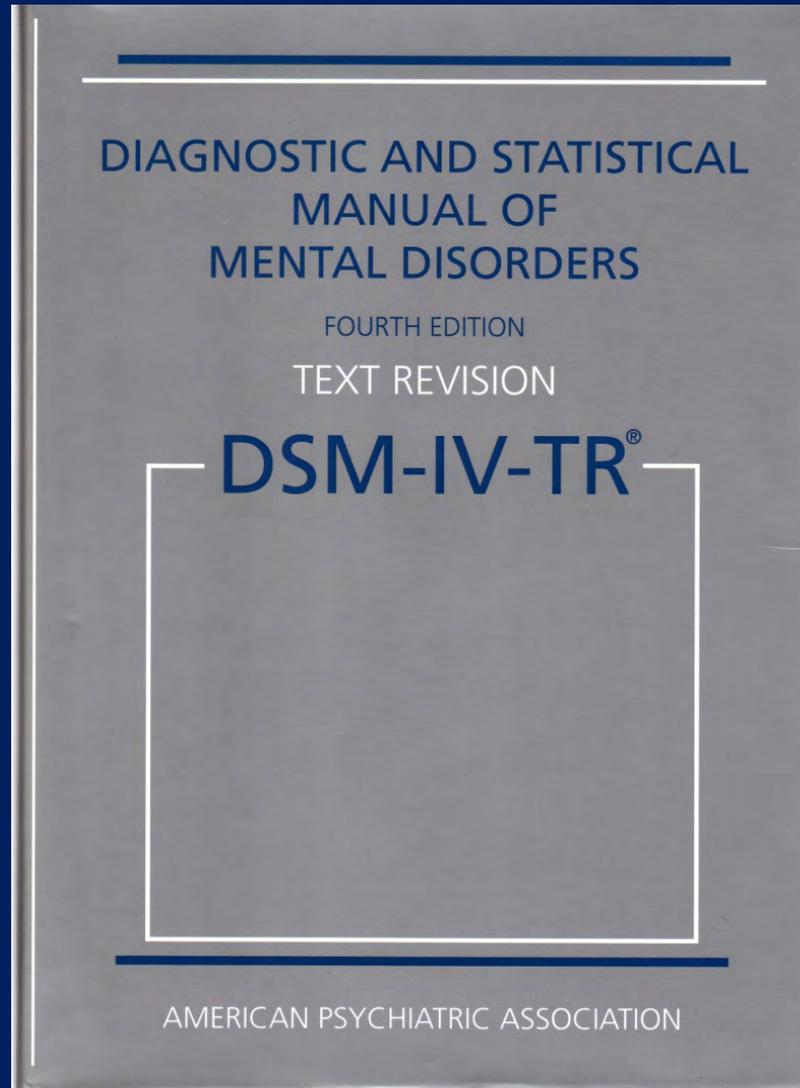


# Trends in Abuse of Ritalin/Adderall

- 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



# REQUIRED READING

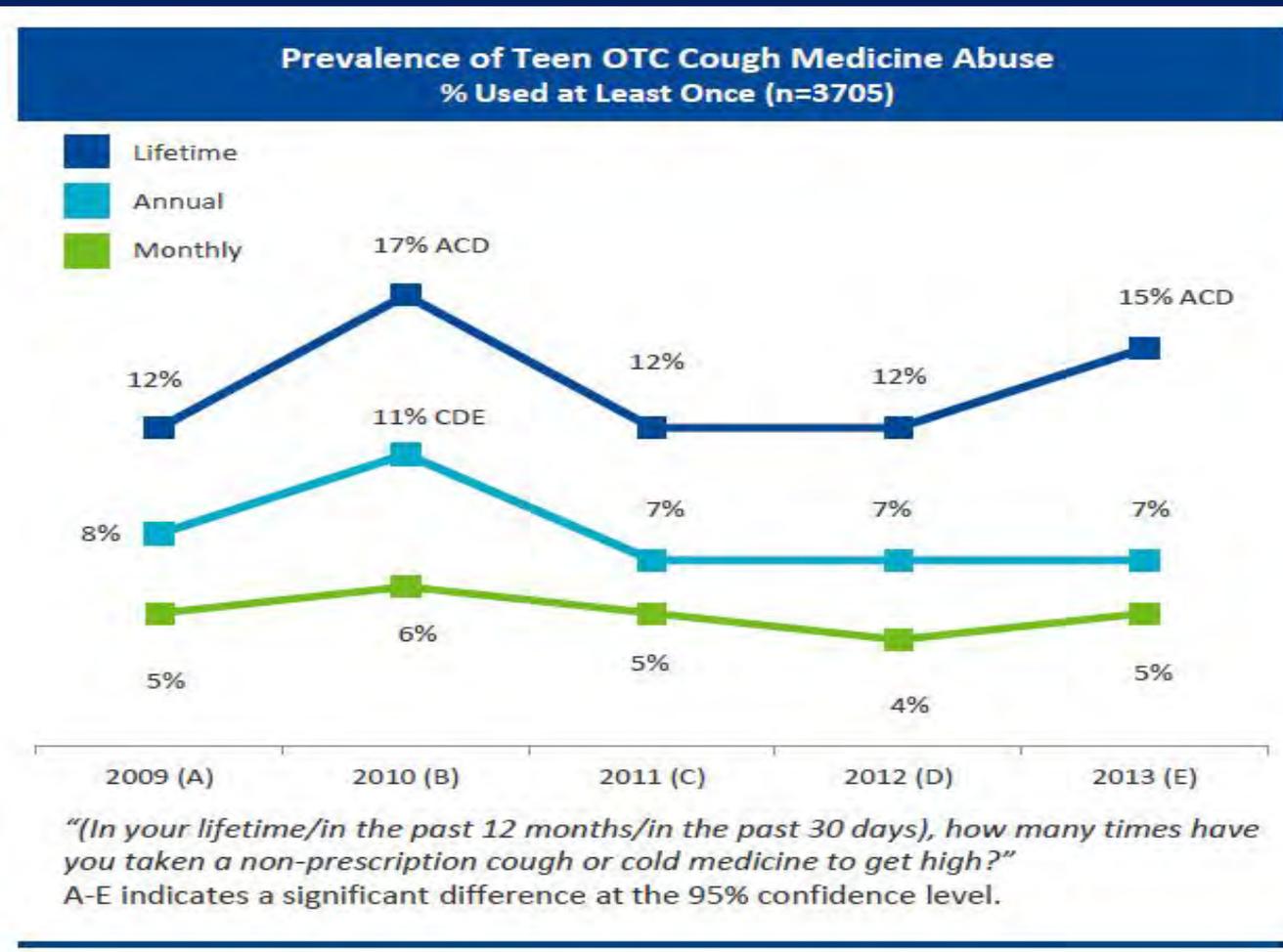


# Dextromethorphan (DXM)

- 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





# 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”



**PURPLE DRANK**  
ima grip and sip



# Non-Controlled Substances

- Analgesic:
  - Tramadol (Ultram®), Ultracet®)
  - Notice of Proposed Rulemaking to place Tramadol into Schedule IV issued November 4, 2013.
  - Effective August 18, 2014, Schedule IV controlled substance
- Muscle Relaxant:
  - Cyclobenzaprine (Flexeril®)

# Tramadol Prescriptions



Source: IMS Health National Prescription Audit Plus

# Cyclobenzaprine

## (Amrix® , Flexeril® , Fexmid®)

---

---

- A skeletal muscle relaxant prescribed for acute temporary muscle spasms caused by local trauma or strain.
- Marketed in the United States since 1977 (by Merck Com.).
- Currently non-controlled under the CSA.
- Chemical structure related to tricyclic antidepressant drugs (e.g., amitriptyline)
- Cyclobenzaprine, similar to other skeletal muscle relaxants, is being diverted and abused



# Pharmaceutical Diversion



# 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



# Doctor Shopping





# Commonly Abused Controlled Pharmaceuticals

Carisoprodol



C-IV as of 1/11/2012

**CYCLOBENZAPRINE  
(FLEXERIL)**



OxyContin 80mg  
Oxycodone HCL ER



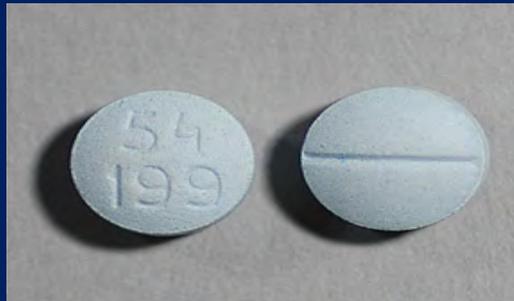
Oxymorphone



**Hydrocodone**



**Oxycodone 30 mg**



Xanax (Alprazolam)

Photo from the Physicians Desk Reference

**Alprazolam**



# The Holy Trinity



Oxycodone

Opiate



Carisoprodol

C-IV as of 1/11/2012

Muscle Relaxant



Alprazolam

Benzodiazepine





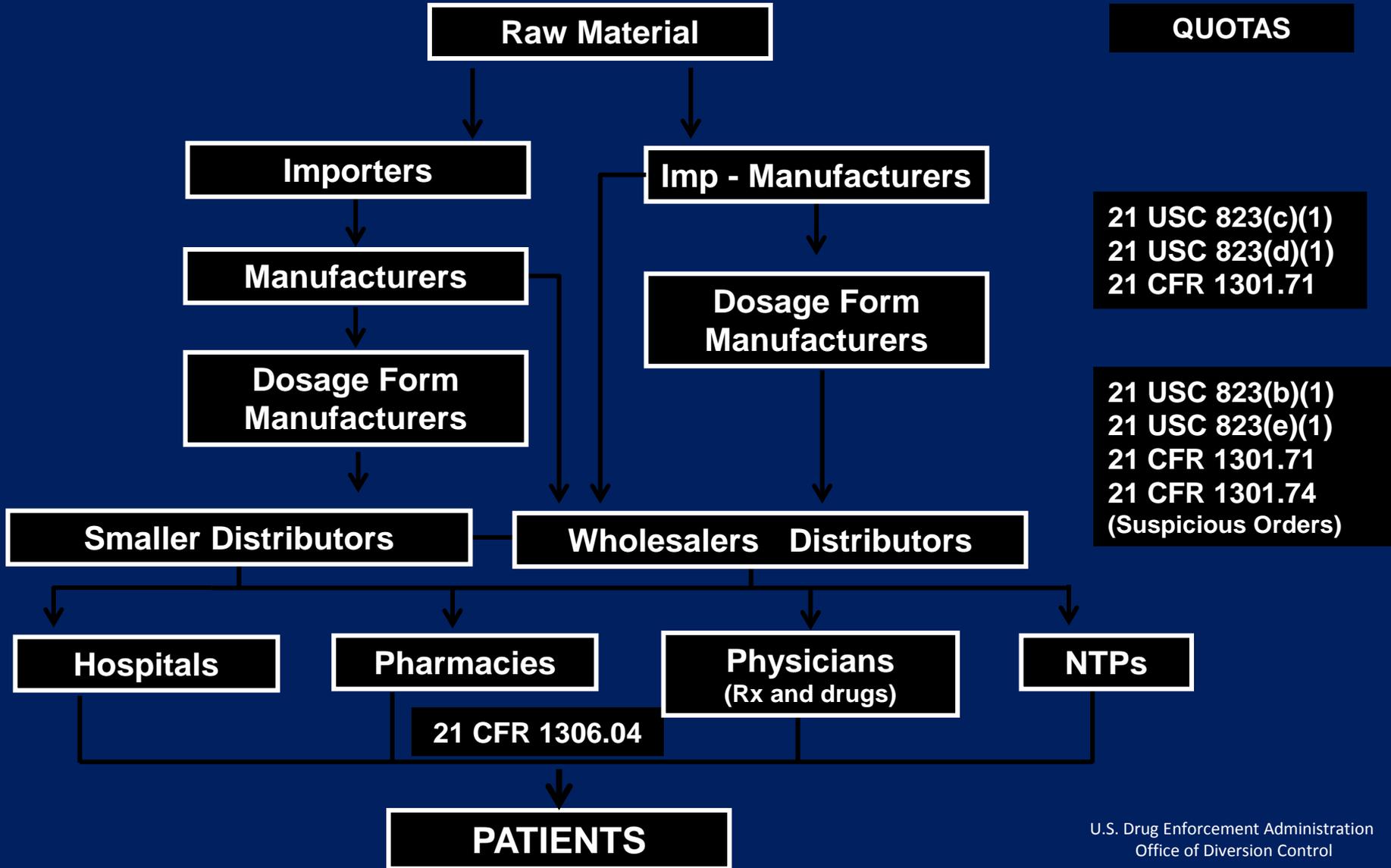
# The Controlled Substances Act

## Checks and Balances



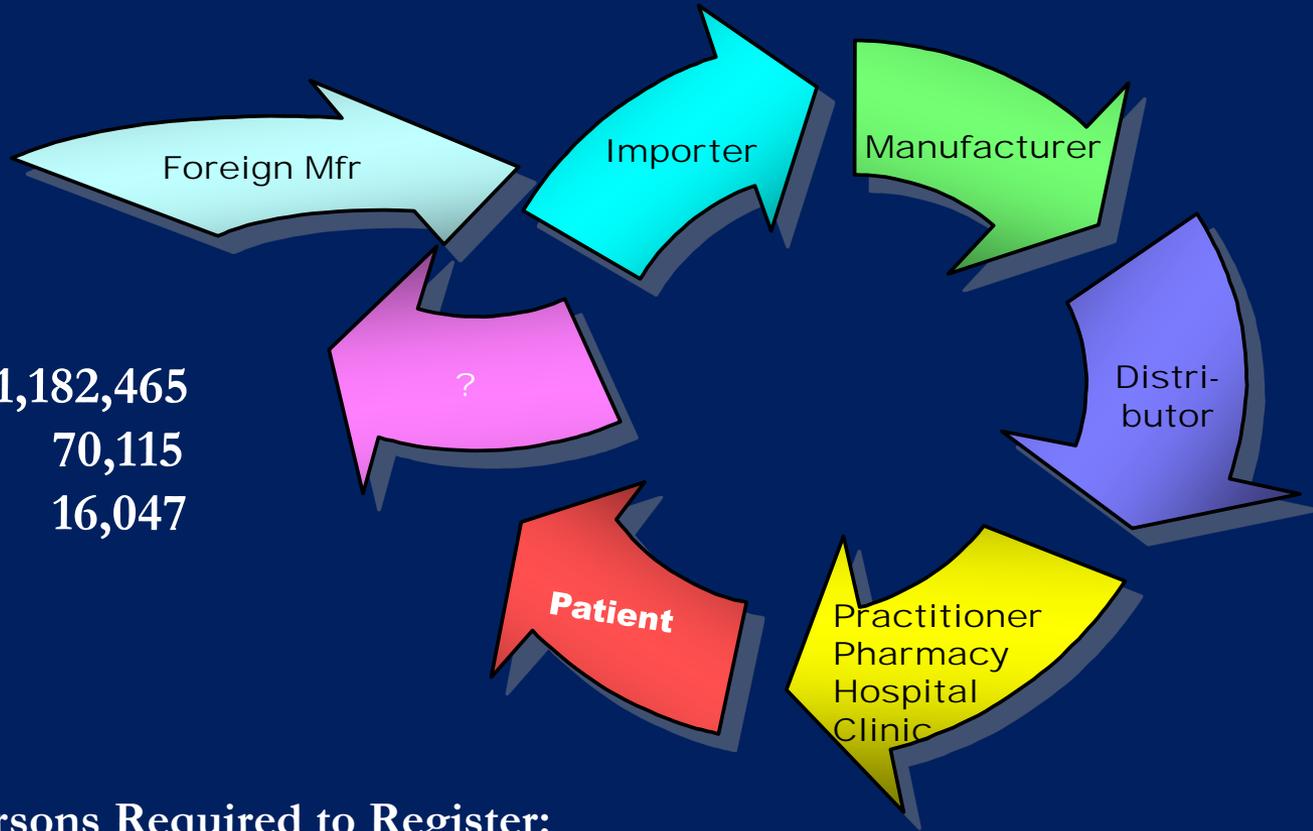


# The Flow of Pharmaceuticals





# Closed System of Distribution



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

<b>Practitioners:</b>	1,182,465
<b>Retail Pharmacies:</b>	70,115
<b>Hospital/Clinics:</b>	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





# 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)*



# 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



# US v. Moore 423 US 122 (1975)

Perfunctory initial physical exam...return visits no exam

Physical exam included needle mark checks...some were simulated

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

Unsupervised urinalysis – results did not matter

Accurate records not kept – quantity dispensed not recorded

Practitioner not authorized to conduct methadone maintenance;

Patient directed prescribing;



# **The Controlled Substances Act**

## **Illegal Distribution**

### **21 U.S.C. § 841 (a) Unlawful acts:**

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

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



# 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))



# System of Checks and Balances



The Last Line of Defense





# DEA Legal Recourse

## ➤ Administrative

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

## ➤ Civil

Fines

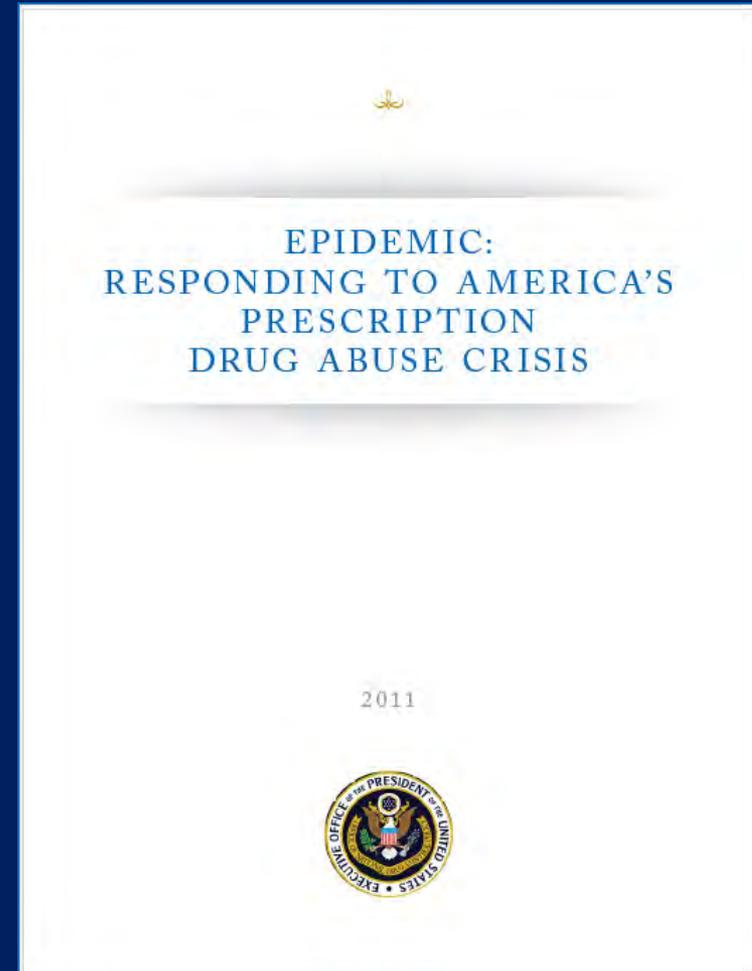
## ➤ Criminal

Tactical Diversion Squads



# Prescription Drug Abuse Prevention Plan

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





# ONDCP Strategy

“Epidemic: Responding To America’s Prescription Drug Abuse Crisis” (Released in April 2011)

## ➤ Education

- Healthcare Provider Education
- Parent, Youth, and Patient Education

## ➤ Tracking and Monitoring

- Work with states to establish effective PDMPs
- Support NASPER
- Explore reimbursements to prescribers who check PDMPs before writing a prescription

## ➤ Proper Medicine Disposal

## ➤ Enforcement

- Assist states address doctor shopping and pill mills
- Increase HIDTA intelligence-gathering and investigation of prescription drug trafficking
- Expand the use of PDMPs to identify criminal prescribers and clinics





# 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



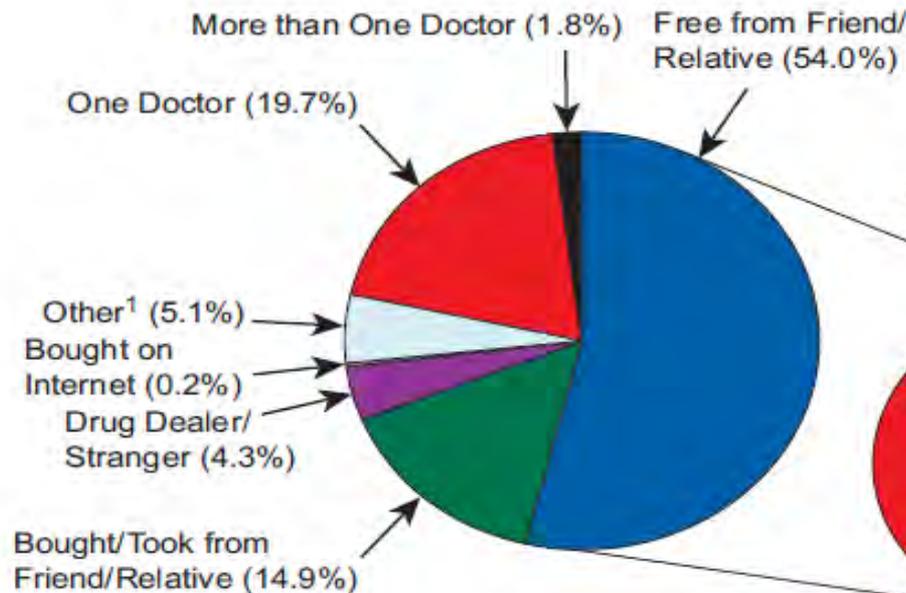
# **Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non- Medical Use**

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

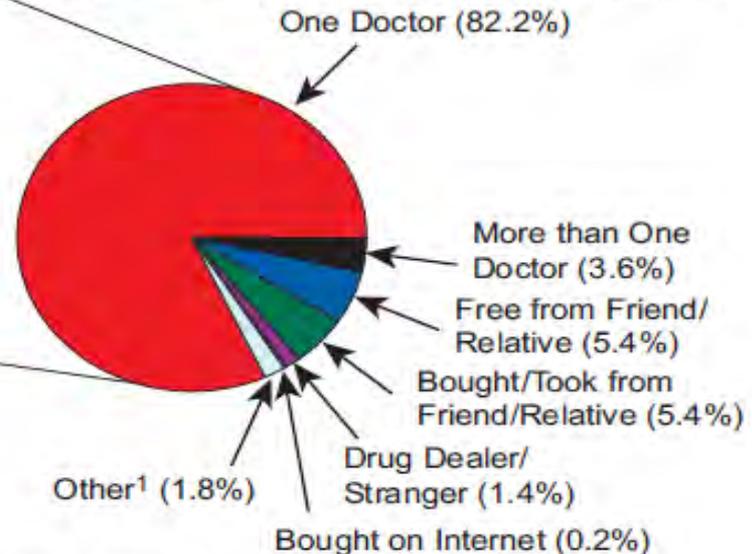


# Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use Among Past Year Users Aged 12 or Older: 2011-2012

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

## 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



# Nationwide Take-Back Initiative

Over 4.1 million pounds (2,123 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



# Secure and Responsible Drug Disposal Act of 2010

- Disposal rule eliminated existing 21 CFR 1307.12 and 1307.21
- New part 1317 contains the requirements on:
  - disposal procedures;
  - collection of pharmaceutical controlled substances from ultimate users;
  - return and recall; and
  - destruction of controlled substances



# Secure and Responsible Drug Disposal Act of 2010

- Regulations do not limit the ways that 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.





# DEA Web-based Resources

www.DEA.gov

The screenshot displays the homepage of the Drug Enforcement Administration website. At the top, the URL 'http://www.justice.gov/dea/index.shtml' is visible in the browser's address bar. 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 menu includes links for HOME, ABOUT, CAREERS, OPERATIONS, DRUG INFO, PREVENTION, and PRESS ROOM. The central banner area contains the text 'Tough Work, Vital Mission The Facts About DEA' and a large image of the DEA seal. To the right of the seal are three featured resource boxes: 'Drug Facts for Today's Teens' (JustThinkTwice.com), 'A DEA Resource for Parents' (GetSmartAboutDrugs.com), and 'Wall of Honor' (DEA Remembers). Below the banner are three columns of content: 'TOP STORY' with a headline about a couple's sentences for cocaine trafficking; 'TOPICS OF INTEREST' listing various guides and positions; and 'RESOURCE CENTER' listing legal and support resources.

**DEA** UNITED STATES Drug Enforcement Administration  
TOUGH WORK, VITAL MISSION

HOME ABOUT CAREERS OPERATIONS DRUG INFO PREVENTION PRESS ROOM

Tough Work, Vital Mission  
The Facts About DEA

Drug Facts for Today's Teens  
JustThinkTwice.com

A DEA Resource for Parents  
GetSmartAboutDrugs.com

Wall of Honor  
DEA Remembers

**TOP STORY**

**Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy**

JAN 29 (BROWNSVILLE, TEXAS)

*Norma Alicia Galleaga, 30, and her husband Jose Carlos...*

**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



# DEA Web-based Resources

www.JustThinkTwice.com

The screenshot shows the homepage of the Just Think Twice website. At the top, there is a navigation bar with the following links: HOME (return home), DRUG FACTS (learn the truth), FACTS & FICTION (know the difference), CONSEQUENCES (life changing events), TEENS TO TEENS (sharing our experience), and INSIDE DEA (find out more). A search bar is located on the right side of the navigation bar. The main content area features a large banner for "THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF" with a photo of a young woman. Below the banner, there are three buttons for "MARIJUANA", "COCAINE", and "METH". To the right of the banner, there are three smaller promotional boxes: "IT'S TIME TO SMATTER THE MYTHS ABOUT DRUGS AND DRUG ABUSE" with a "Learn More" link, "FACTS & FICTION Get the Facts", and "TEENS TO TEENS Advice from teens on the D.A.R.E. Youth Advisory Board" with a "READ MORE" link. The website is displayed in a browser window with the URL "http://www.justthinktwice.com" and the title "Just Think Twice".

**JUST THINK TWICE**  
YOU'VE HEARD THE FICTION. NOW LEARN THE FACTS.

Parents & Educators | Drug Glossary

SEARCH

HOME *return home* | DRUG FACTS *learn the truth* | FACTS & FICTION *know the difference* | CONSEQUENCES *life changing events* | TEENS TO TEENS *sharing our experience* | INSIDE DEA *find out more*

**THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF**

Maybe you've heard it's made of the same stuff as cold medicine. Well, that's not all. Some of the ingredients used to make meth include battery acid, gasoline, and drain cleaner.

[GET THE FACTS ABOUT METHAMPHETAMINE »](#)

MARIJUANA | COCAINE | METH

**IT'S TIME TO SMATTER THE MYTHS ABOUT DRUGS AND DRUG ABUSE**  
[Learn More](#)

**FACTS & FICTION**  
*Get the Facts*

**TEENS TO TEENS**  
Advice from teens on the D.A.R.E. Youth Advisory Board  
[READ MORE »](#)

**Did You Know?** Combine toxic chemicals with neglected hygiene, and you get a condition called "meth mouth"—rotten and decaying teeth.



# DEA Web-based Resources

www.GetSmartAboutDrugs.com

The screenshot shows the homepage of the GetSmartAboutDrugs.com website. At the top left is the DEA logo and the text "GetSmartAboutDrugs A DEA Resource for Parents". A navigation menu includes links for Home, Identify, Prevent, Help, Hot Topics, DEA in the Community, and Communities of Practice. A search bar is located on the right side of the menu. The main content area features a large article titled "COMMUNITIES of PRACTICE" with a sub-header "The new Communities of Practice section includes three PowerPoint presentations about drug abuse and awareness and an online Train the Trainer module that provides presenters with techniques to effectively deliver the presentations." Below this is a "Learn more" button with a right-pointing arrow. To the right of the article are two promotional boxes: "DEA Publications" with a "READ MORE" button and "Watch the Videos" with a "VIEW" button. At the bottom, there are three columns: "Latest News" with a link to "See All News Stories", "Voices" featuring "Irma Perez's Story", and "Inside DEA" with a paragraph about the agency's members.

Home Identify Prevent Help Hot Topics DEA in the Community Communities of Practice Search

The new Communities of Practice section includes three PowerPoint presentations about drug abuse and awareness and an online Train the Trainer module that provides presenters with techniques to effectively deliver the presentations

[Learn more](#)

BACK STOP NEXT

**COMMUNITIES of PRACTICE**

**DEA Publications**  
Download or request *Drugs of Abuse* and *Prescription for Disaster*.  
[READ MORE](#)

**Watch the Videos**  
View videos to learn how to keep your family safe, including ways to avoid prescription drug abuse.  
[VIEW](#)

**Latest News** [See All News Stories](#)

**Drug Court Offers Hope for the Future**  
Jan 22, 2013 The Columbia River Partnerships for Change, a nonprofit in Oregon, is seeing tremendous success with its three drug court programs: adult treatment, juvenile treatment, and families restored.

**ER Visits Tied to Energy Drinks Double Since 2007**  
Jan 16, 2013 Hospitals around the country have seen a gradual uptick in the number of emergency room visits involving energy drinks.

**Voices**

**Irma Perez's Story**

Irma was a 14 year old girl from Belmont, California who took an Ecstasy pill on April 23, 2004. She became sick immediately---vomiting and writhing in pain---yet her friends did not seek medical help for her. Instead, they gave

**Inside DEA**

The men and women of DEA aren't just drug enforcement agents---we're parents, grandparents, brothers and sisters. We've seen how drugs rob young people of their promise and dreams, and how entire families are affected by a child's drug abuse...



---

# Thank You / Questions

---



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