



The United States Department of Justice

Drug Enforcement Administration



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

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

February 9, 2014
Hilton Downtown Hotel
Charlotte, North Carolina

Joseph Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

Disclosure Information

I have no financial relationships to disclose

and

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

OR

- **Responding to America's Prescription Drug Abuse Crisis**

- *“When Two Addictions Collide”*

Pharmaceuticals Money

Goals and Objectives

- Describe the scope of the prescription drug abuse problem
- Discuss legal obligations of the DEA registrant
- Identify methods of pharmaceutical diversion and discuss how the pharmacist can prevent diversion in the retail setting
- Review status of drug disposal legislation and regulations

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

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.

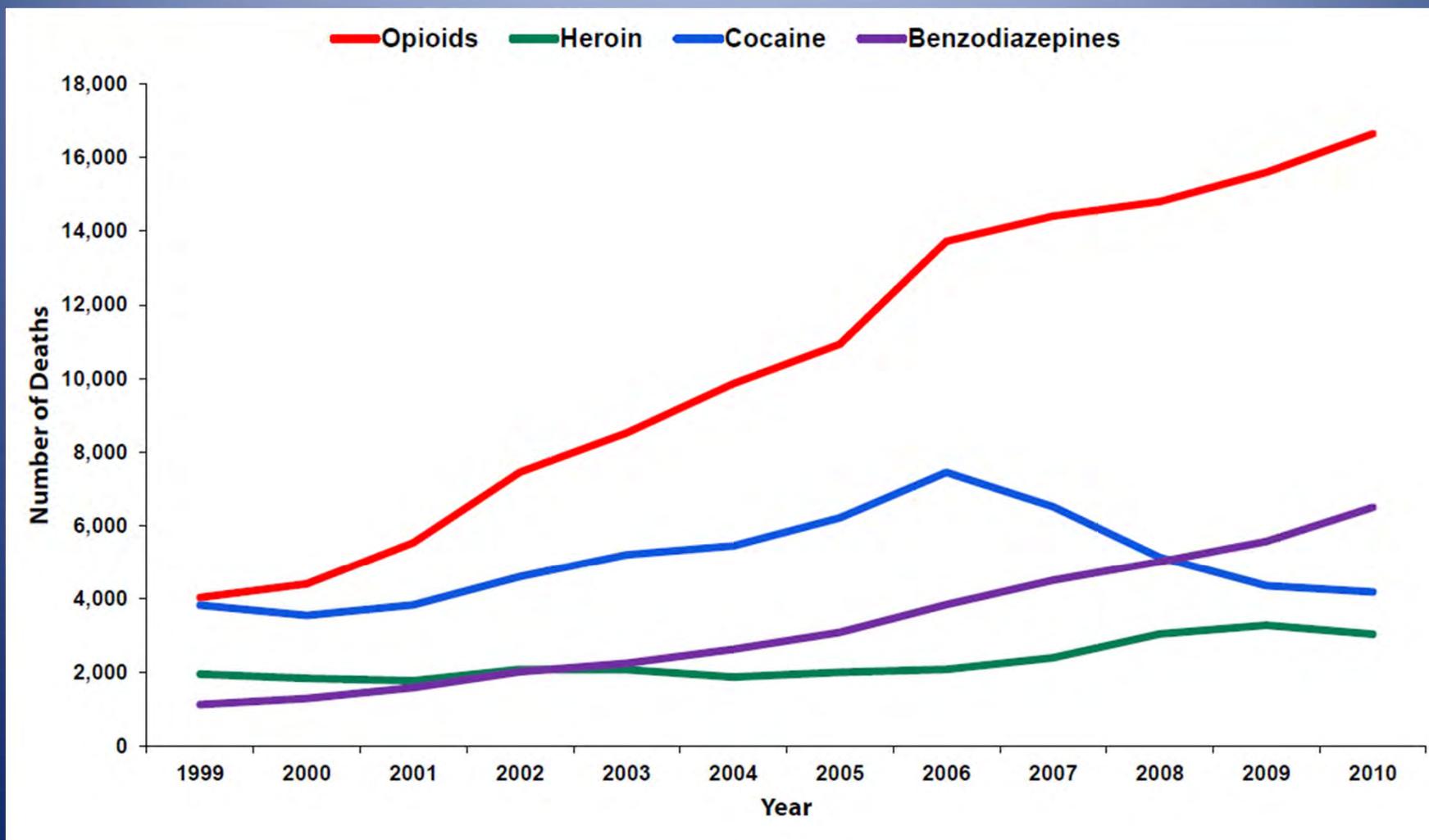
Vital Signs: Overdoses of Prescription Opioid Pain Relievers and Other Drugs Among Women — United States, 1999–2010

Although more men die from drug overdoses than woman, the percentage increase in deaths since 1999 is greater among woman. More woman have died each year from drug overdoses than from motor vehicle–related injuries since 2007. Deaths and ED visits related to OPR continue to increase among woman.

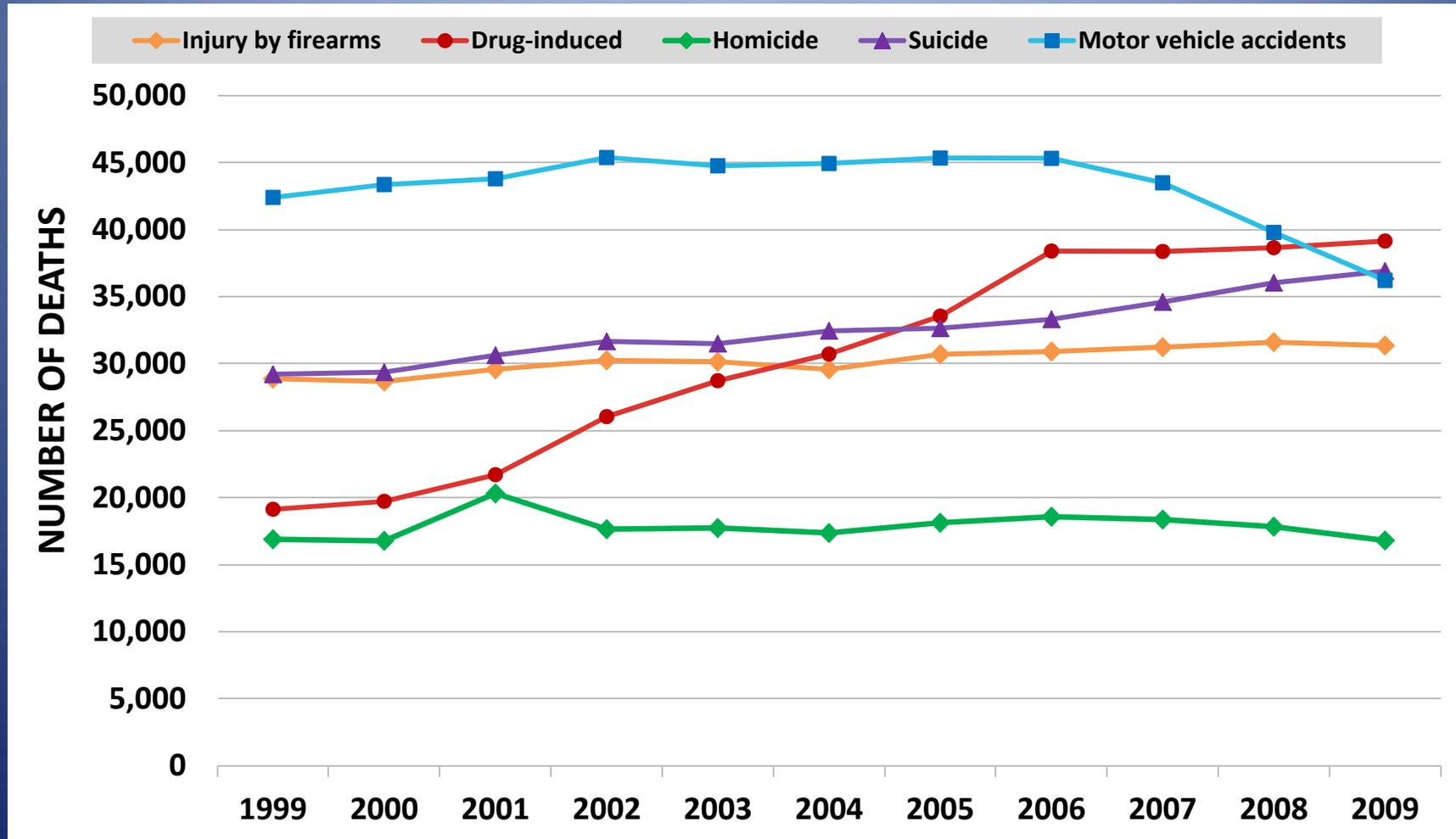
Conclusions: Although more men die from drug overdoses than women, the percentage increase in deaths since 1999 is greater among women. More women have died each year from drug overdoses than from motor vehicle–related injuries since 2007. Deaths and ED visits related to OPR continue to increase among women. The prominent involvement of psychotherapeutic drugs, such as benzodiazepines, among overdoses provides insight for prevention opportunities.

Implications for Public Health Practice: Health-care providers should follow guidelines for responsible prescribing,

U.S. Drug Overdose Deaths by Major Drug Type, 1999-2010



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.

Source: National Center for Health Statistics, Centers for Disease Control and Prevention. National Vital Statistics Reports *Deaths: Final Data* for the years 1999 to 2009 (January 2012).

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

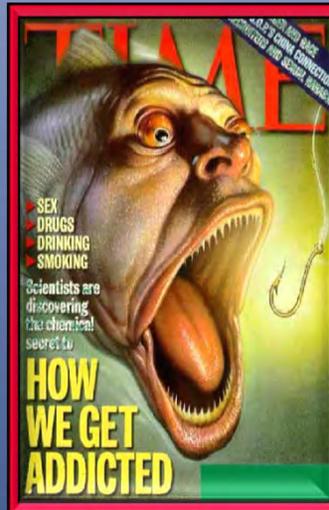
MARIJUANA: 18.9 million

PSYCHOTHERAPEUTIC
DRUGS: 6.8 million

COCAINE: 1.6 million

Methamphetamine 440,000

Heroin: 335,000



Source: 2011 & 2012 NSDUH

National Abuse Facts

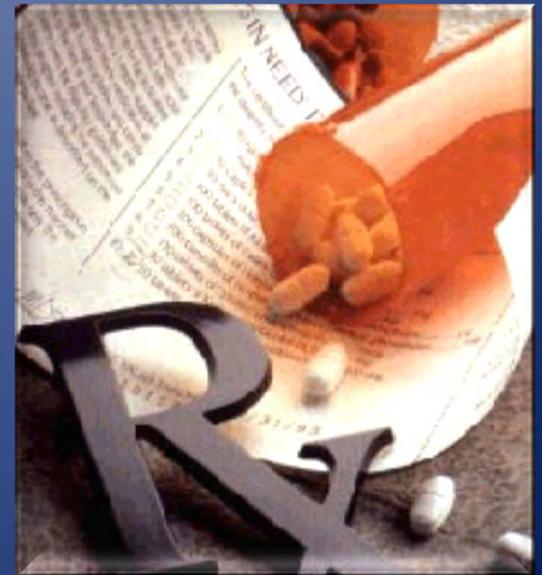
- In 2012, 23.9 million Americans aged 12 or older were current (past month) users of illicit drugs.
- 6.8 million used prescription-type psychotherapeutic drugs (any pain relievers, tranquilizers, stimulants or sedatives) for non-medical purposes in a one-month period.
- 2011: 6.1 million; 2010: 7.0 million.

Prescription Drug Abuse

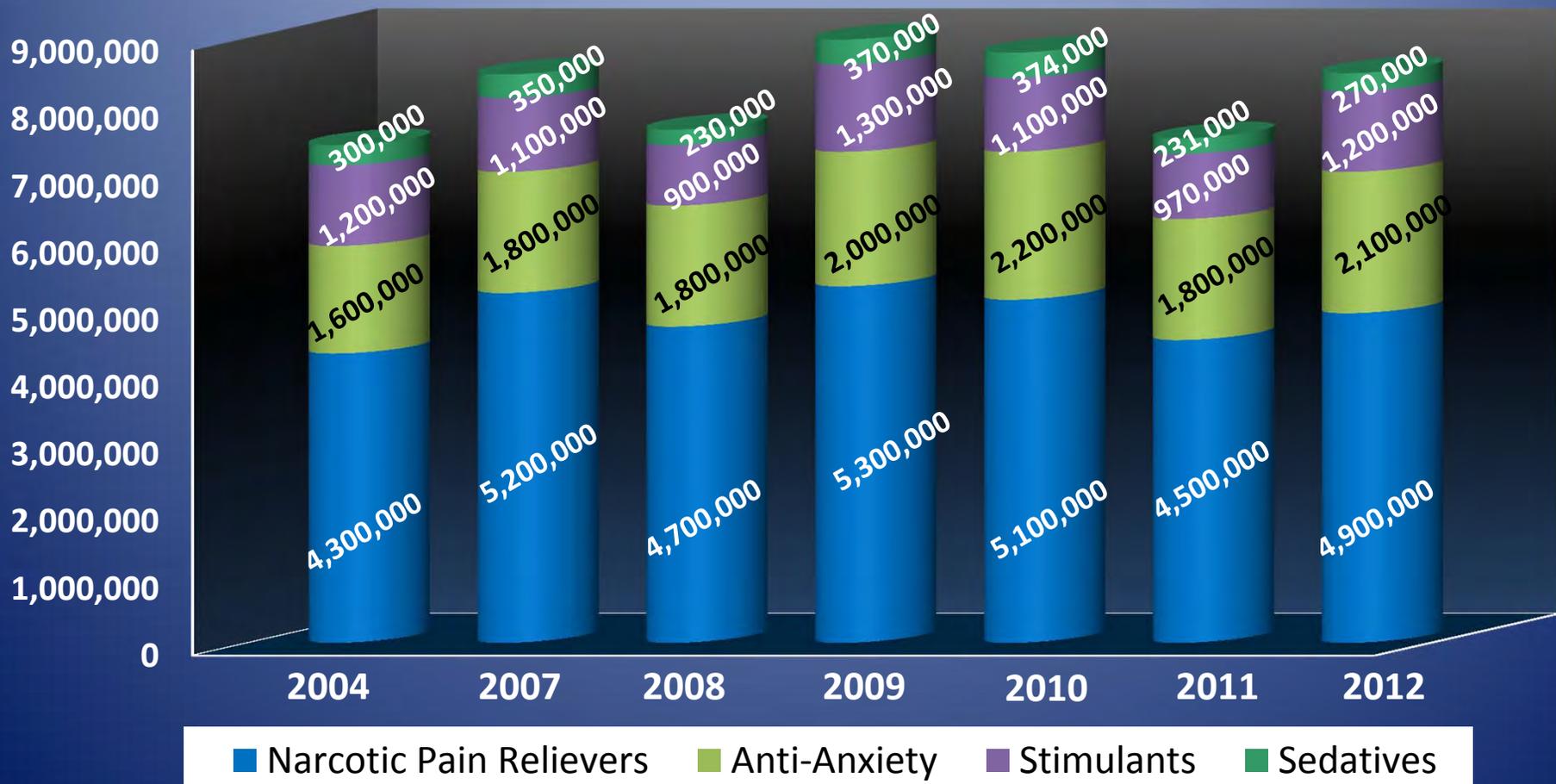
More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Heroin, and Inhalant abusers

COMBINED!!!



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



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

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

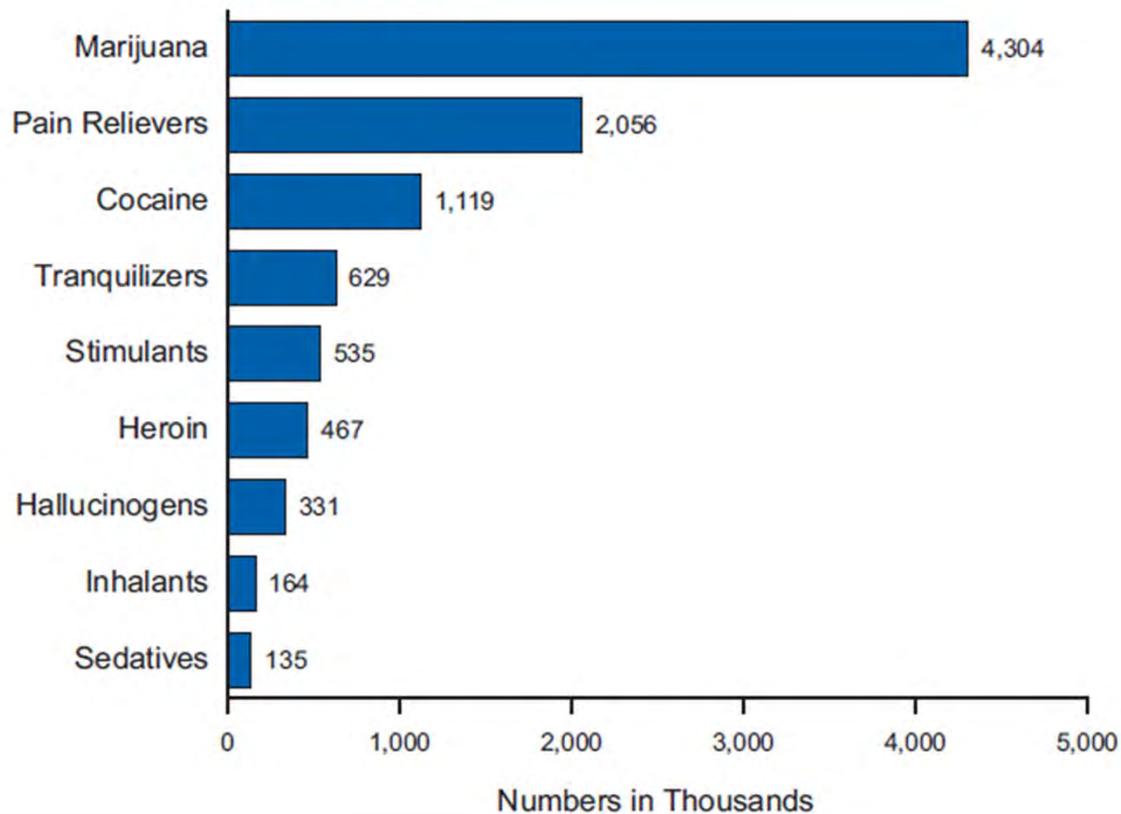


Source: 2011 National Survey on Drug Use and Health



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

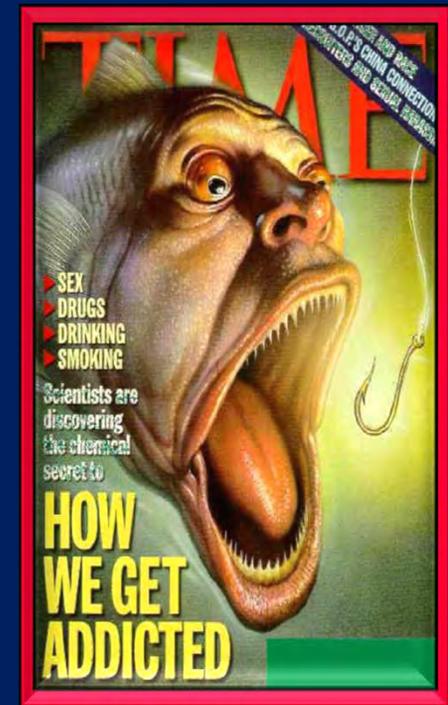


SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)



National Abuse Facts

- In 2012, there were 2.4 million persons aged 12 or older who used psychotherapeutics non-medically for the first time within the past year, approximately **6,700** new initiates per day.*
- One in four teens (**24%**) reports having misused a prescription drug at least once in their lifetime (up from 18% in 2008 to 24% in 2012), which translates to about 5 million teens. That is a **33% increase** over a five-year period.



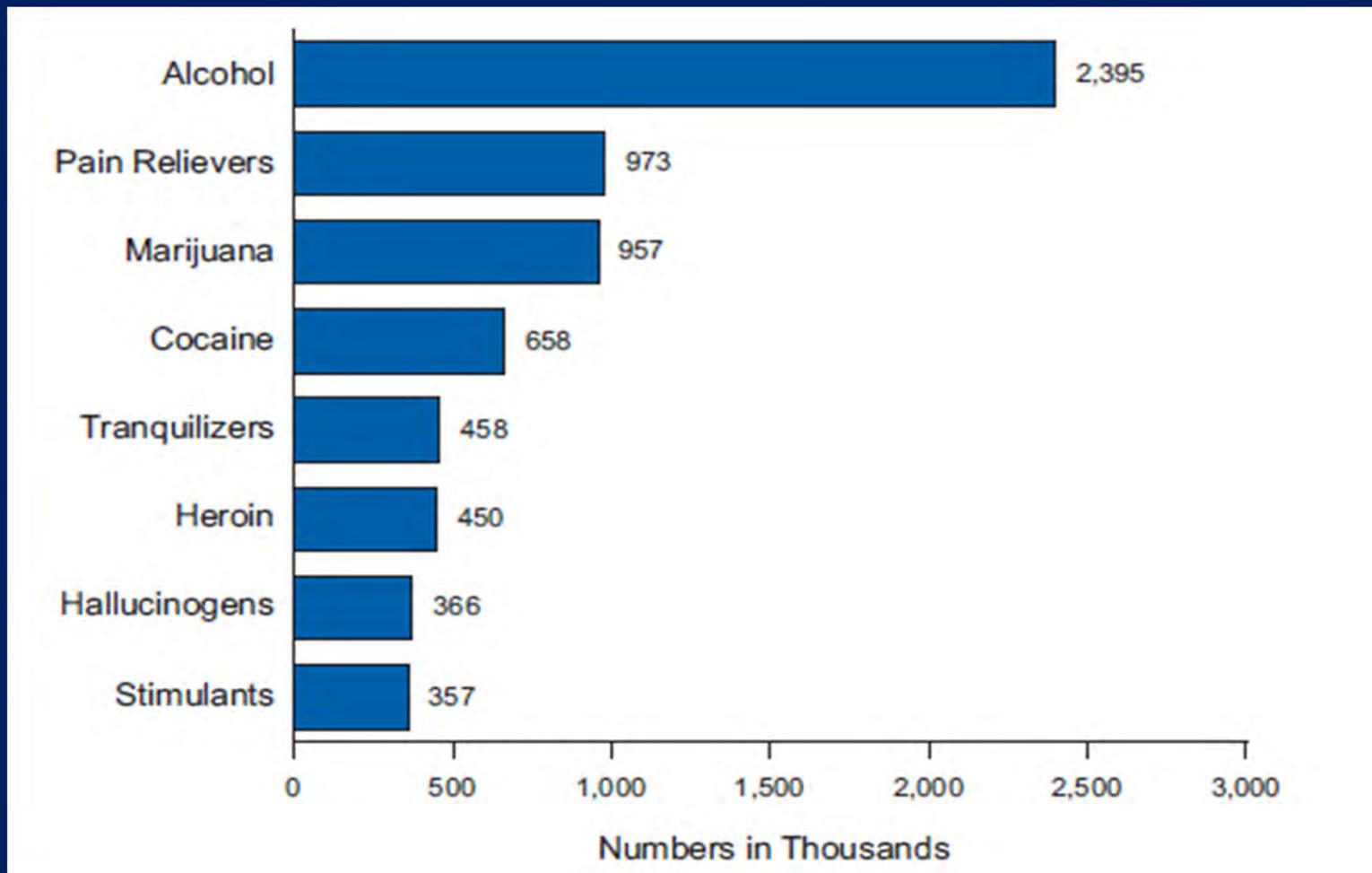
SOURCE: * 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)

** The Partnership at Drugfree.org / MetLife Foundation Partnership Attitude Tracking Studies 2012 , published April 2013

Emergency Room Data 2004-2010

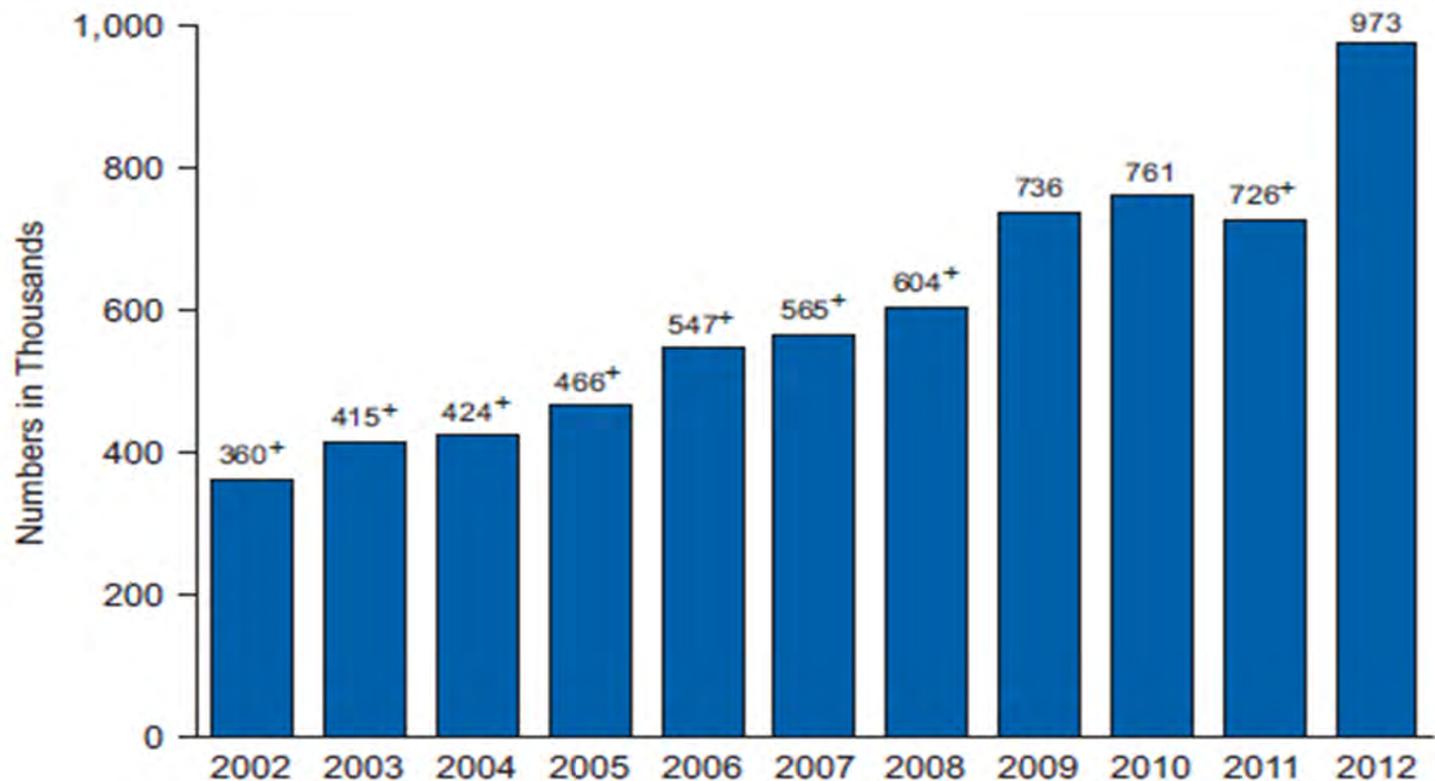
SOURCE: The DAWN Report, *Highlights of the 2009 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits*, December 28, 2010

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



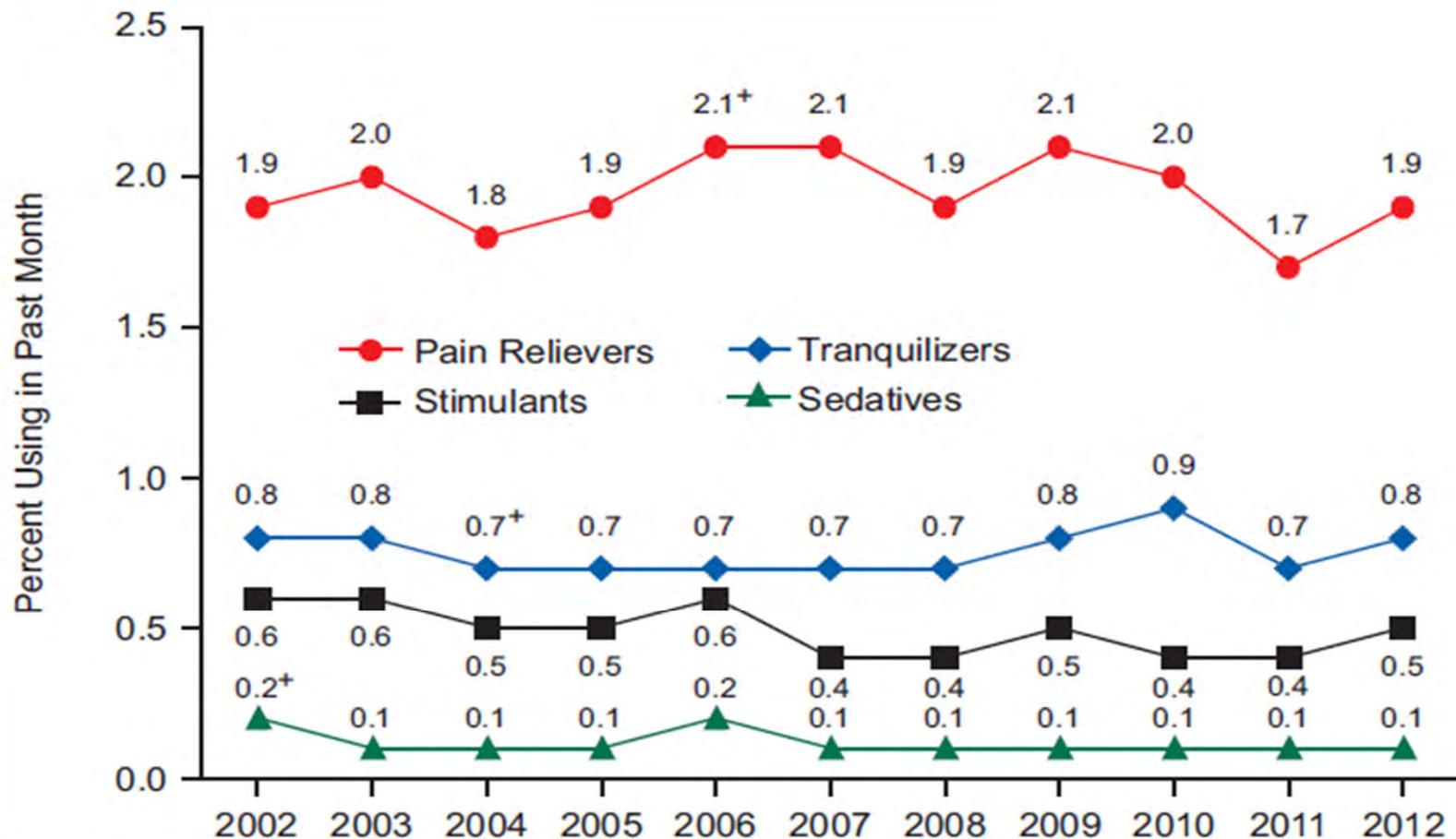
SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)

Received Most Recent Treatment in the Past Year for the Use of Pain Relievers among Persons Aged 12 or Older: 2002 - 2012



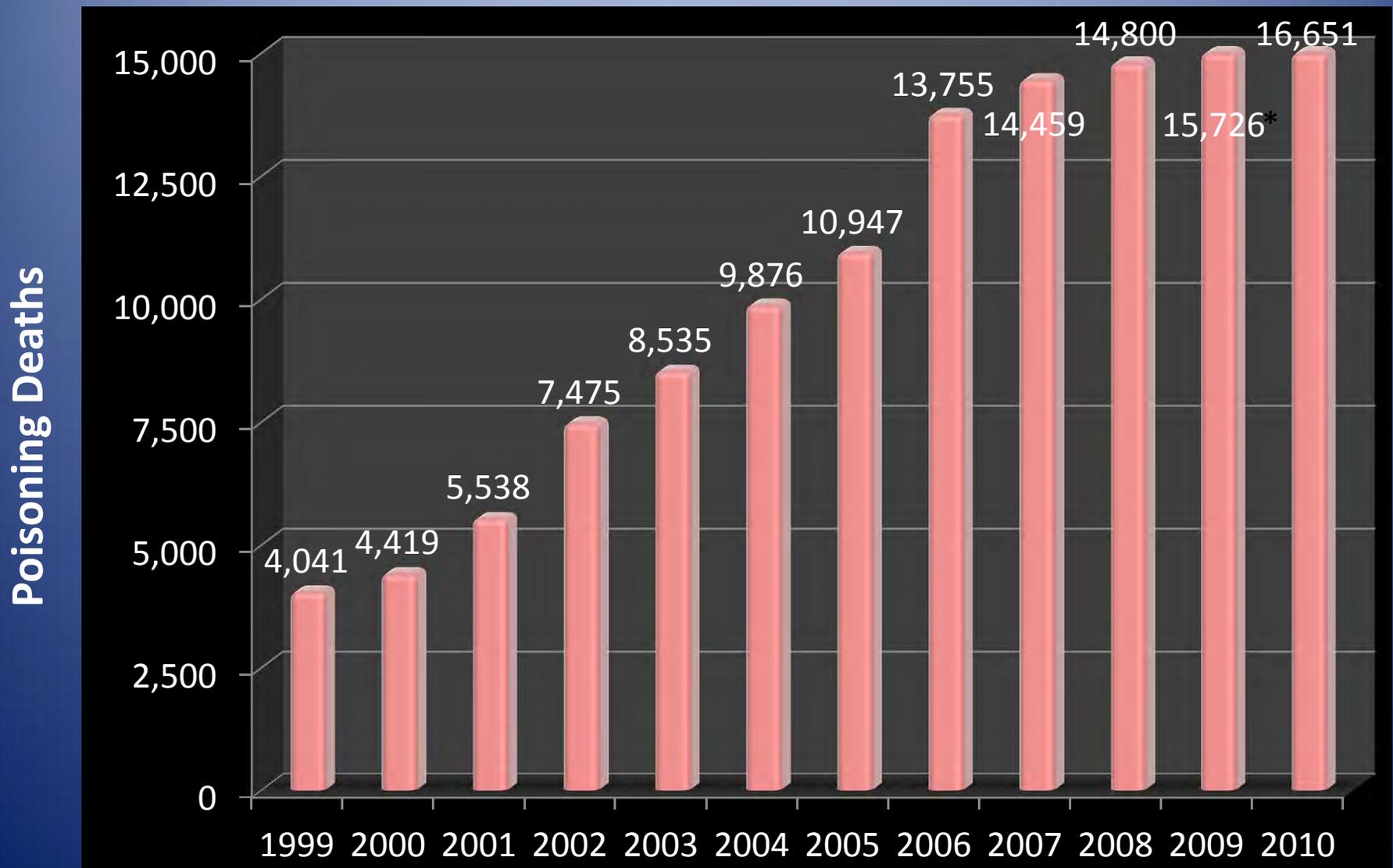
⁺ Difference between this estimate and the 2012 estimate is statistically significant at the .05 level.

Substances for Which Most Recent Treatment Was Received in the Past Year among Persons Aged 12 or Older: 2002-2012



Difference between this estimate and the 2012 estimate is statistically significant at the .05 level.

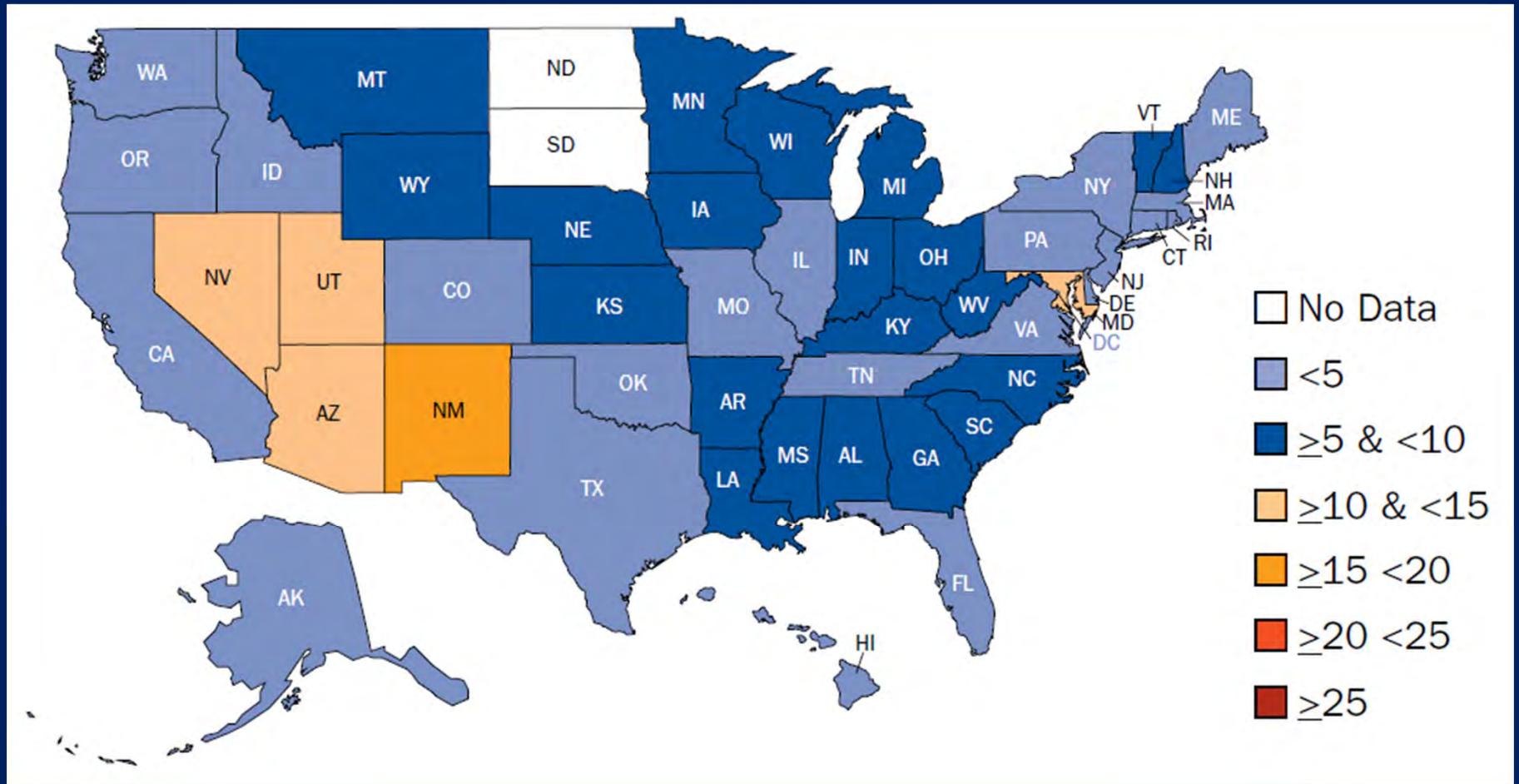
Poisoning Deaths: Opioid Analgesics



Source: CDC/NCHS, National Vital Statistics System

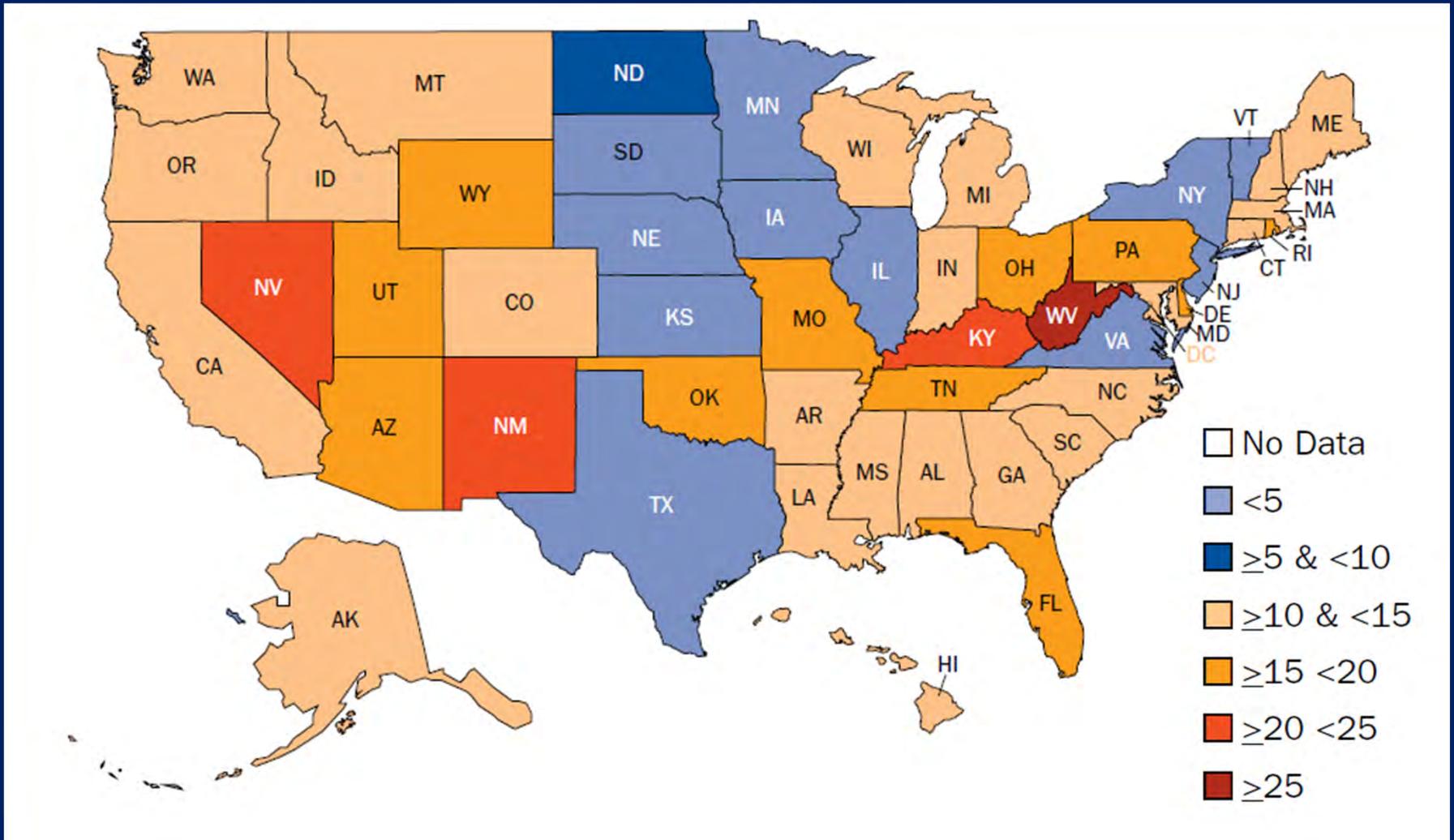
*2009 data approximated

Drug Overdose Mortality Rates per 100,000 People 1999



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

Drug Overdose Mortality Rates per 100,000 People 2010



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

Where Prescription Painkiller Overdose Deaths Are The Highest

- Most severe in Southwest and Appalachian
- In 2010, the top three states were West Virginia, New Mexico, and Kentucky;
 - West Virginia: 28.9 deaths per 100,000
 - New Mexico: 23.8 deaths per 100,000
 - Kentucky: 23.6 deaths per 100,000
- Lowest-North Dakota: 3.4 deaths per 100,000
- **Minnesota ranked 47th 7.3 deaths per 100,000**



Statistical Perspective

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



*Why is the problem outpacing
population growth?*

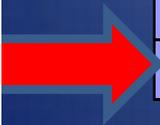
We all want to feel good and
prescription drug abuse is an
accepted method of curing
whatever ails you. After all, it is a
medicine.

Violence

Pharmacy Armed Robberies Rankings by State

January 1 thru December 31, 2011 (693)

RANK	STATE	TOTAL												
1	IN	53	12	MD	22	23	AL	12	34	LA	4	ID	1	0
2	AZ	50	13	WA	21	24	TX	11	35	DE	3	IA	1	0
3	FL	49	14	OK	19	25	MS	8	36	WV	2	AK	0	0
4	TN	43	15	NV	17	26	IL	8	37	MT	2	HI	0	0
5	CA	39	16	ME	17	27	NH	7	38	CT	2	ND	0	0
6	CO	38	17	OH	16	28	MO	7	39	WY	1	VT	0	0
7	PA	36	18	SC	15	29	MN	7	40	SD	1			
8	NY	29	19	OR	15	30	WI	6	41	RI	1			
9	KY	27	20	NJ	14	31	GA	5	42	NM	1			
10	MI	24	21	VA	13	32	AR	5	43	NE	1			
11	NC	23	22	MA	12	33	UT	4	44	KS	1			



Pharmacy Armed Robberies

January 1 thru December 31, 2011

- U.S. (Nationwide) – 693
- State of North Carolina – 23

NORTH CAROLINA COUNTIES	Number of Pharmacy Thefts
BRUNSWICK	2
BUNCOMBE	3
COLUMBUS	1
CUMBERLAND	3
DARE	1
GASTON	1
IREDELL	1
JOHNSTON	1
MECKLENBURG	2
NEW HANOVER	2
ONSLow	3
PITT	1
POLK	1
WAKE	1
No Reported Armed Robberies in remaining counties	

Pharmacy Armed Robberies Rankings by State

January 1 thru December 31, 2012 (780)

RANK	STATE	TOTAL												
1	IN	104	12	NY	22	23	WA	13	34	NV	5	45	DE	1
2	AZ	66	13	WI	20	24	AL	11	35	RI	5	46	WY	1
3	OH	49	14	CO	19	25	MN	10	36	NE	4	47	AK	0
4	PA	43	15	OK	19	26	AR	7	37	IA	3	48	AS	0
5	TN	41	16	SC	18	27	NH	7	38	MS	3	49	DC	0
6	CA	37	17	FL	17	28	GA	6	39	KS	2	50	GU	0
7	ME	36	18	VA	17	29	MO	6	40	MT	2	51	HI	0
8	TX	28	19	KY	16	30	NM	6	41	PR	2	52	ID	0
9	MD	26	20	MI	14	31	OR	6	42	UT	2	53	ND	0
10	MA	23	21	NJ	14	32	CT	5	43	VT	2	54	SD	0
11	NC	22	22	IL	13	33	LA	5	44	WV	2	55	VI	0



Source: DEA Drug Theft & Loss Database as of February 7, 2014

Pharmacy Armed Robberies

January 1 thru December 31, 2012

- U.S. (Nationwide) – 780
- State of North Carolina – 22

NORTH CAROLINA COUNTIES	Number of Pharmacy Thefts
GUILFORD	2
HARNETT	2
ROBESON	2
CARTERET	1
CATAWBA	1
CLEVELAND	1
CUMBERLAND	1
GASTON	1
LEE	1
MECKLENBURG	1
NEW HANOVER	1
PASQUOTANK	1
PERSON	1
STANLY	1
STOKES	1
UNION	1
VANCE	1
WATAUGA	1
YADKIN	1
No Reported Armed Robberies in remaining counties	

Pharmacy Armed Robberies Rankings by State

January 1 thru December 31, 2013 (638)

RANK	STATE	TOTAL												
1	AZ	73	12	MD	18	23	NM	8	34	ID	3	45	MS	1
2	IN	59	13	NJ	18	24	AL	7	35	MN	3	46	MT	1
3	CA	45	14	NY	16	25	IA	7	36	NE	3	47	AK	0
4	PA	40	15	CT	15	26	OR	7	37	NH	3	48	AS	0
5	TN	33	16	VA	14	27	GA	5	38	RI	3	49	DC	0
6	MA	30	17	WA	14	28	ME	5	39	WY	3	50	GU	0
7	NC	30	18	FL	12	29	MI	5	40	DE	2	51	ND	0
8	OH	27	19	CO	11	30	AR	4	41	IL	2	52	PR	0
9	TX	24	20	OK	10	31	KS	4	42	LA	2	53	SD	0
10	SC	22	21	KY	9	32	VT	4	43	NV	2	54	UT	0
11	WI	20	22	MO	9	33	WV	4	44	HI	1	55	VI	0



Pharmacy Armed Robberies

January 1 thru December 31, 2013

- U.S. (Nationwide) – 638
- State of North Carolina – 30

NORTH CAROLINA COUNTIES	Number of Pharmacy Thefts
CATAWBA	4
FORSYTH	4
CABARRUS	3
MECKLENBURG	3
ALEXANDER	2
GASTON	2
BUNCOMBE	1
BURKE	1
CHEROKEE	1
CUMBERLAND	1
DARE	1
DAVIE	1
DUPLIN	1
GUILFORD	1
LINCOLN	1
MCDOWELL	1
MITCHELL	1
WILKES	1
No Reported Armed Robberies in remaining counties	

Violence Related to Controlled Substance Pharmaceuticals

 **NEW YORK POST** Page Six
TUESDAY, JUNE 21, 2011 / T-storm, 85 / Weather: P. 26 METRO EDITION www.nypost.com \$1.00

ASSASSIN



1 Ready for mayhem, the lunatic strolls through the door.

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

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

4 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

 **NEW YORK POST** Page Six
THURSDAY, JUNE 23, 2011 / T-storm, 85 / Weather: P. 18 METRO EDITION www.nypost.com \$1.00

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



Nassau police respond to the scene of a

Nassau police respond to the scene of a shooting Saturday at Charlie's Family Pharmacy, 3931 Merrick Rd., in Seaford. (Dec. 31, 2011) Photo Credit: Kevin P. Coughlin



Long Island

Robbery suspect, federal agent killed in Seaford

A robbery suspect and a federal agent who had dropped by to pick up a prescription for his ailing father both died of gunshot wounds Dec. 31, 2011, after police struggled with the suspect in the doorway of a Seaford pharmacy.

Be the first to rate: ★★★★★ [Click to rate](#)

Related



Nassau
Cops: Fatal shooting at Seaford drugstore

Newsday



GO MOBILE!
Get

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.

The 1960/70s/80s



Uppers - Amphetamines



Bottle of Methaqualone tablets
Anonymous Photographer, © 2002 Erowid.org



"Ts and Blues"



Downers - Barbiturates



Hydromorphone



"Fours and Doors"



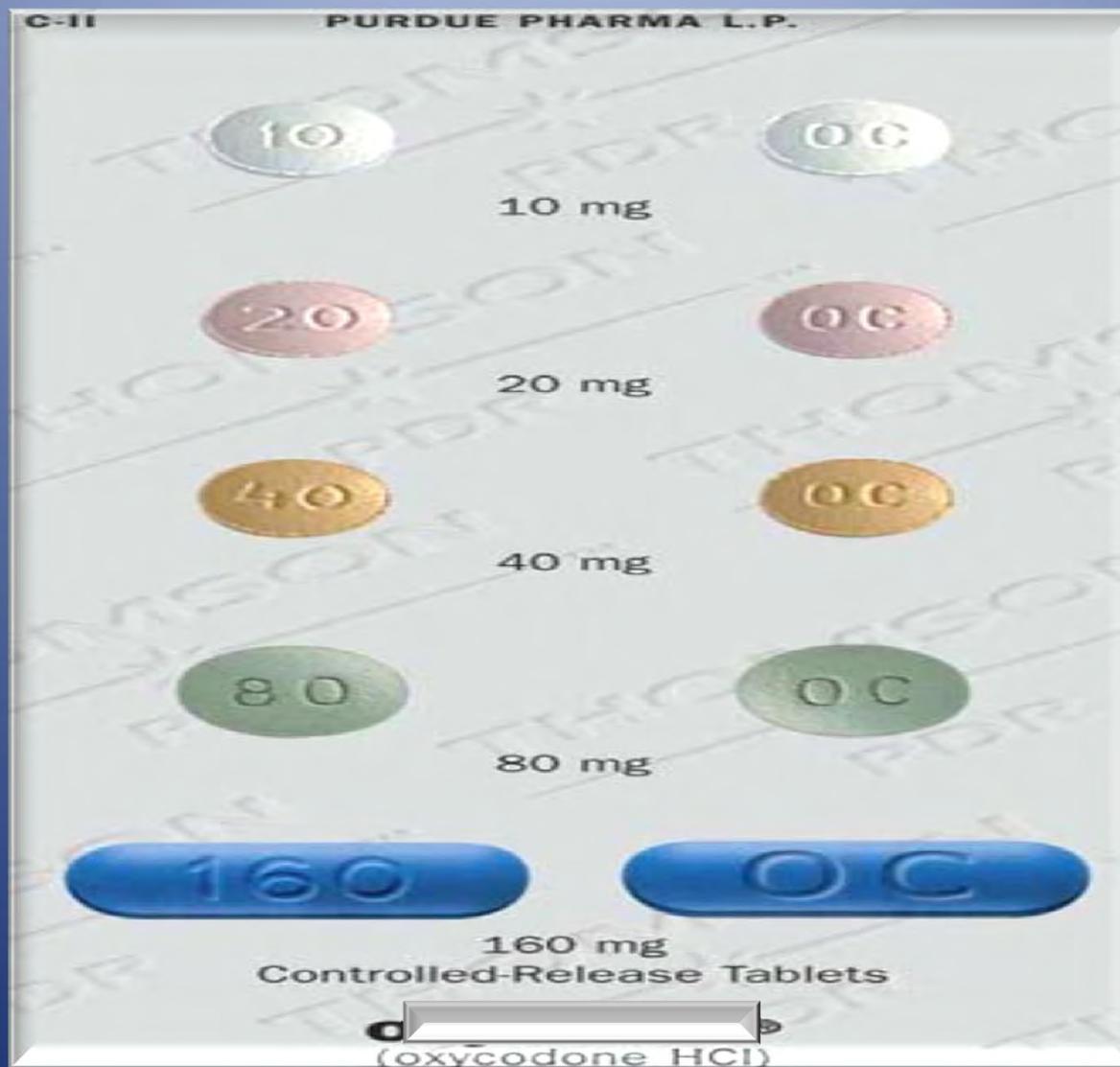
Meprobamate



Oxycodone/APAP

The 1990s

OxyContin



Commonly Abused Controlled

Pharmaceuticals



**CYCLOBENZAPRINE
(FLEXERIL)**

C-IV as of 1/11/2012



Hydrocodone



OxyContin 80mg



Oxymorphone



Oxycodone 30 mg



Alprazolam

The Trinity



Opiate



Muscle Relaxant



Benzodiazepine

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 patients¹ 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 addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs im-

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.

2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. *J Clin Pharmacol.* 1978; 18:180-8.

The Fifth Vital Sign?

Temperature

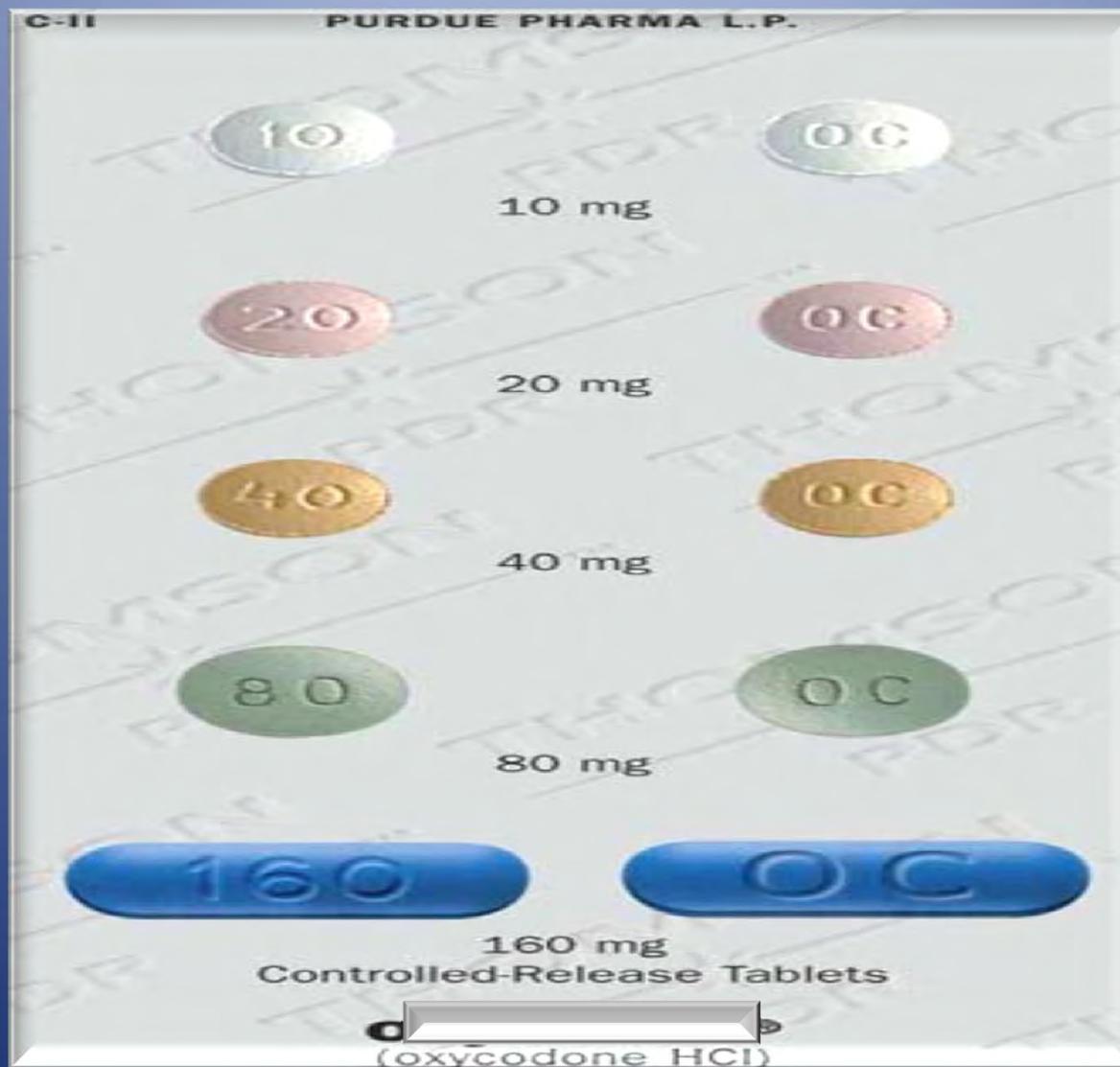
Heart Rate

BP

Respiration

The 1990s

OxyContin





Public release date: 17-Mar-2006
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Contact: Amy Jenkins
amy@jenkinspublicrelations.com
312-836-0613
American Academy of Pain Medicine

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

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

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

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

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

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

Victories and Defeats in Pain Care

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

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

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

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

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

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

Freedom to Care for Pain Patients Critical

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

The Department of Justice must "stop the abuse and diversion of prescription medicines without harming access to these medicines for people affected by pain," states Will Rowe, Executive Director, American Pain Foundation. "The DEA's failure to abide by its commitment to the pain community to pursue a balance between the war on drugs and the rights of pain patients, and also cite the more comprehensive command."

###

About the American Academy of Pain Medicine

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

About the American Pain Foundation

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

Risky Connection Blocked

McAfee has blocked your PC from making a potentially risky connection.

About This Connection
IP Address: 72.21.194.32
Program: Internet Explorer

[More](#) ▾

Do not show this alert again



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Contact: Amy Jenkins
amy@jenkinspublicrelations.com
312-836-0613
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"It is essential that we resume dialogue between the DEA and healthcare professions for the benefit of our patients and society," continues Dr. Heit. "The DEA and the healthcare professionals treating pain both have an important job to do in ensuring those who need [controlled substances] for pain receive them while preventing misuse and diversion. Only through dialogue based on and mutual trust and respect can this balance be restored."

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

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

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

Freedom to Care for Pain Patients Critical

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

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

###

About the American Academy of Pain Medicine

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

About the American Pain Foundation

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

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Dollars for Doctors

How Industry Money Reaches Physicians

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





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Families & Loved Ones

Prospective Patients

Addiction Professionals

Professionals

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[Treatment Programs](#)

[Resources](#)

[Success Stories](#)

[News & Updates](#)

Chronic Pain and Opiate Addiction

Posted on September 5, 2012



Lloyd Gordon, III, MD is the Medical Director at COPAC.

The United States has over 15,000 deaths from opiate overdoses a year and over 30,000 total drug related deaths. This is more than the number of people that die in automobile accidents. Depending on the data source, the United States consumes 80% to 90% of the legal opiates in the world. Over the past 15 years there has been a distinct change in the culture of the practice of medicine related to pain. From 1999 until 2008, I was one of the delegates of the American Society of Addiction Medicine to the American Medical Association's House of Delegates.

During this time the various pain societies were pushing for acceptance that pain was under-treated and also that the pain that was evident needed to be better treated. Most of these physicians were dedicated, compassionate, and hardworking individuals. The contemporary school of thought was that "pain medicine" was just giving opiates to people with pain but these specialists combined long-acting opiates, short-acting opiates, medium-acting opiates, anti-inflammatories, anti-

depressants, anti-convulsants, and a variety of other medicines to treat pain. This was comparable to my Internal Medicine practice when I used to treat a Type I diabetic with several different types of insulin, multiple shots through the day, multiple sliding scales, and finely adjust their medications to control their blood glucose. These dedicated pain doctors were able to design regimens that helped control their patients' chronic pain all through the day. During this time the Joint Commission stated that pain should be another vital sign. There was no question that pain had been under-treated. We in the American Society of Addiction Medicine worked closely with the Pain Societies to try to propose policy guidelines. The Pain Societies then proposed that someone who had been an opiate addict could safely take opiates for pain if they were monitored closely with a contract providing for urine drug screens, single pharmacy use, and no early refills. They talked of an entity called "pseudoaddiction" which became accepted even though there was no medical research to suggest it even existed. The Pain Societies proposed that the gold standard for treatment with opiates should be that the patient's "function" improve. In other words, the patient should get out of bed and

[Get Help Now](#)

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Recent Posts

[Diane Basner – NASW Member](#)

[Chronic Pain and Opiate Addiction](#)

[5th Annual Dog Days of Summer](#)

[COPAC Treatment Rates Reduced Change](#)

Success Stories





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 companies and the organizations that promote their drugs can put lives at risk. These painkillers have an important role in health care when prescribed and used properly, but pushing misinformation on consumers to boost profits is not only wrong, it's dangerous."

"The problem of opioid abuse is bad and getting worse," Grassley said. "Something has to change. A greater understanding of the extent to which drug makers underwrite literature on opioids is a good start. Doctors and patients should know if the medical literature and groups that guide the drugs' use are paid for by the drugs' manufacturers and if so, how much. Education on the proper use of pain medication is a key step in preventing abuse and misuse, so it's important to understand what material is out there."

The Centers for Disease Control and Prevention have declared overdoses from opioid painkillers to be a public health epidemic. Deaths from painkiller overdoses have tripled over the last decade and led to the deaths of 14,800 Americans in 2008, exceeding those caused by heroin and cocaine combined. The

Related Files

- Baucus Grassley Opioid Investigation Letter to Purdue Pharma [288.2 KB]
- Baucus Grassley Opioid Investigation Letter to Federation of State Medical Boards [278.9 KB]
- Baucus Grassley Opioid Investigation Letter to the Joint Commission [278.4 KB]
- Baucus Grassley Opioid Investigation Letter to Wisconsin Pain And Policy Studies Group [277.5 KB]
- Baucus Grassley Opioid Investigation Letter to American Academy of Pain Medicine [277.6 KB]
- Baucus Grassley Opioid Investigation Letter to American Pain Foundation [279.8 KB]
- Baucus Grassley Opioid Investigation Letter to American Pain Society [278.8 KB]
- Baucus Grassley Opioid Investigation Letter to Center for Practical Bioethics [278.3 KB]
- Baucus Grassley Opioid Investigation Letter to Johnson and



Watchdog Reports

Home » Watchdog Online » Watchdog Reports

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

By John Fauber of the Journal Sentinel

May 9, 2012

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“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.”

- Letter to Endo Pharmaceuticals
- Letter to American Pain Foundation
- Letter to American Pain Society
- Letter to American Academy of Pain Medicine



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



TOP STORIES

- Employment debate requires closer look
- Warm winter reduced heating costs 24%
- Tracing the political dividing lines over Gov. Scott Walker
- Game Blog: Brewers at Diamondbacks

MORE WATCHDOG

THE KANSAS CITY STAR
KansasCity.com

86° Intermittent clouds
91° High
68° Low
Forecast

NewHope SurgeryCenter
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Posted on Fri, May 11, 2012 11:22 PM [Read more Front Page](#)

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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
 - Former KC Chief charged with attempted murder
 - Man, 65, shoots motorcyclist in road rage incident

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Direct to Consumer Advertising

Burden on the health care delivery system

The Perfect Storm

- **Industry is producing a wider variety of controlled substance pharmaceuticals and practitioners are prescribing more.**
- **Use of Medicare / Medicaid or insurance to fund drug habits**
- **Information / Electronic era**

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

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 Abuse

- One in four teens (24%) reports having misused or abused a prescription drug at least once in their lifetime, which is approximately 5 million teens
 - In comparison, 18% of teens in 2008 and 24% of teens in 2012 reported the same
- Of those kids who said they abused prescription medications, one in five (20%) has done so before age 14
- More than a quarter of teens (27%) mistakenly believe that misusing and abusing prescription drugs is safer than using street drugs
- One in four teens (25%) says there is little or no risk in using prescription pain relievers without a prescription

Education

- Children/Teens

Information from the Internet or
their peers

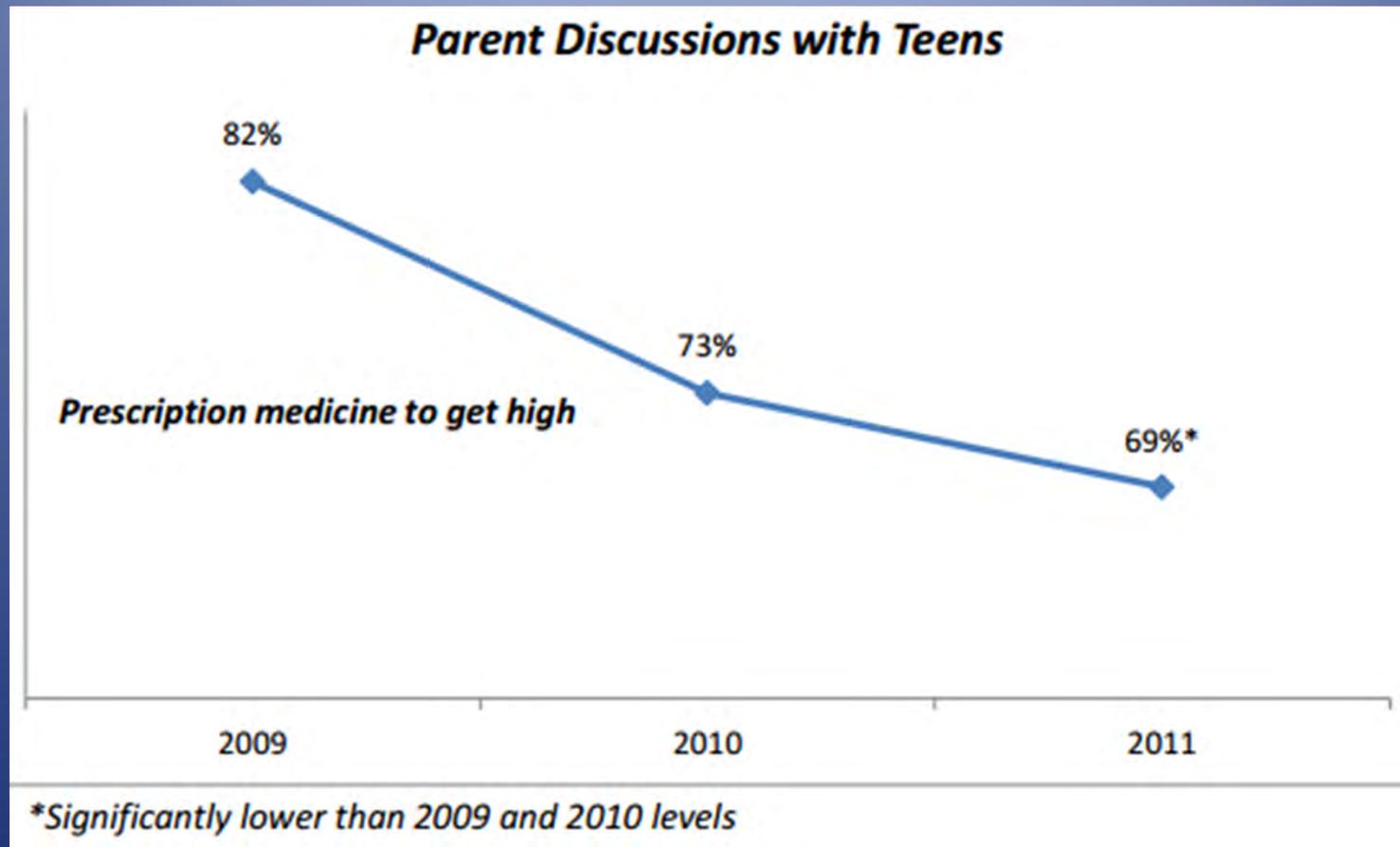
Following parents

Teens and Their Attitudes

- 1 in 4 teens (24 percent) reports having misused or abused a prescription drug at least once in their lifetime (up from 18 percent in 2008 to 24 percent in 2012), which translates to about 5 million teens. 33 percent increase over 5 year period.
- 1 in 5 (20 percent) abused before age 14.
- 27 percent mistakenly believe that using prescription drugs are “safer” than illicit drugs.
- 33 percent believe “it’s okay to use prescription drugs not prescribed to them.”
- 23 percent believe parents don’t care if caught using.

Parents & Their Attitudes

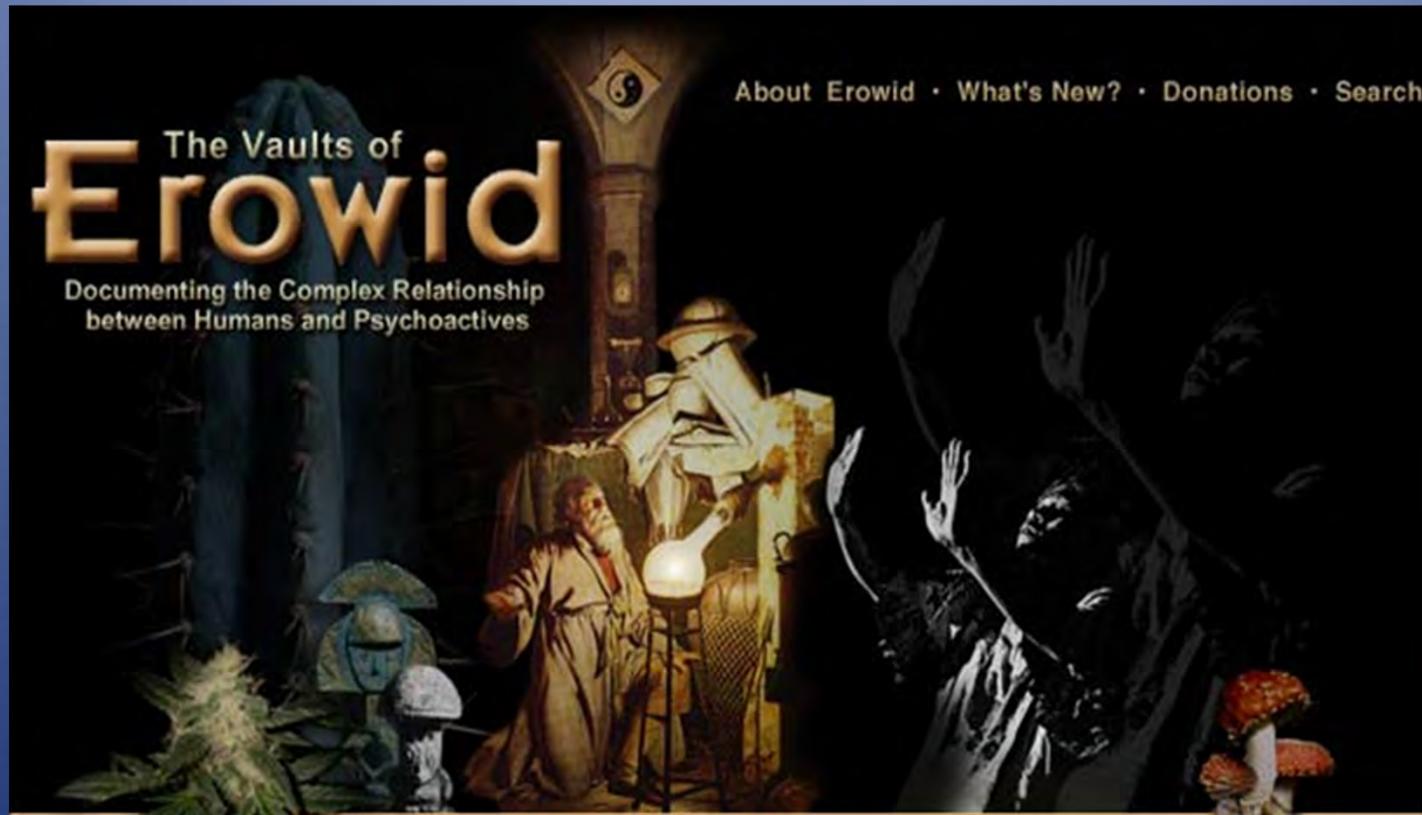
Parents are not discussing the risks of abusing prescription drugs



Source of Concerns

- 1 in 5 parents (20 percent) report that they have given their teen a prescription drug that was not prescribed to them.
- 17 percent of parents do not throw away expired medications.
- 14 percent of parents say they themselves have misused or abused prescription drugs within the past year.
- 49 percent of parents say anyone can access their medicine cabinet.

Where do kids get their information from?



Bluelight - The Front Page

www.bluelight.ru/vb/?sty

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Google BlueLight

User Name

Password

Log In

Help

Register

Remember Me?

BLUELIGHT

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Home

Forum

What's New?

Wiki

Q

The Front Page

Advanced Search

The Front Page

If this is your first visit, be sure to check out the [FAQ](#).

You may have to **register** before you can post: click the register link above to proceed. To start viewing messages, select the forum that you want to visit from the selection below.

Features

- BlueLight Wiki
- Blogs
- BlueLight Mobile
- Staff List
- Twitter
- Our own Wiki project
- Blogs from our members
- Use BlueLight on the go!
- Contact our staff members
- Follow us on Twitter

Forums

- | | |
|-----------------|-----------------------|
| Focus Forums | Australia & Asia |
| Drug FAQs | Australian Drug |
| Ecstasy | Discussion |
| Discussion | Australian Social & |
| Cannabis | Events |
| Discussion | |
| Steroid | Europe & Africa |
| Discussion | European Drug |
| Psychedelic | Discussion |
| Drugs | European Events |
| Other Drugs | |
| | North America & South |
| Drug Discussion | America |
| Drug Studies | North & South |
| Drugs in the | American Social & |
| Media | Drug Discussion |
| Basic Drug | North & South |
| Discussion | American Events |
| Advanced Drug | |
| Discussion | Pillreports.com |
| The Dark Side | Pillreports |
| Trip Reports | Discussion |
| Drug Culture | Pill Testing Q&A |

THE FRONT PAGE

Bluelight Remembers Ryan Haight, Launch of the Recovery forums

by Sebastians_ghost Published on 12-02-2013 06:45



Dear Bluelighters,

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

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



DEA Web-based Resources

www.JustThinkTwice.com

The screenshot shows the homepage of the Just Think Twice website. At the top, the URL is <http://www.justthinktwice.com/>. The main header features the logo "JUST THINK TWICE" with the tagline "YOU'VE HEARD THE FICTION. NOW LEARN THE FACTS." Below this is a navigation menu with the following items: 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 in the top right corner, with links for "Parents & Educators" and "Drug Glossary".

The main content area features a large banner for a featured article: "THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF". The article text reads: "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." Below the text is a link: "GET THE FACTS ABOUT METHAMPHETAMINE »". To the right of the text is a photo of a young woman with dark hair wearing a green jacket. Below the article text are three small images with labels: MARIJUANA, COCAINE, and METH.

On the right side of the page, there are several smaller promotional boxes. The top one says "IT'S TIME TO SHATTER THE MYTHS ABOUT DRUGS AND DRUG ABUSE" with a "Learn More" link and a "DRUG FACTS WEEK" logo. Below that is a box for "FACTS & FICTION Get the Facts". At the bottom right is a box for "TEENS TO TEENS" with the text "Advice from teens on the D.A.R.E. Youth Advisory Board" and a "READ MORE »" link.

At the bottom of the page, there is a "Did You Know?" section: "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 a web browser window displaying the homepage of www.getsmartaboutdrugs.com. The browser's address bar shows the URL. The website header features 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 is divided into several sections:

- Communities of Practice:** A large section with a blue header and a grid of dots. It contains text about PowerPoint presentations and a "Train the Trainer" module, accompanied by a "Learn more" button and a "Train the Trainer" screenshot.
- DEA Publications:** A pink box with a "READ MORE" button and an image of a publication cover.
- Watch the Videos:** A yellow box with a "VIEW" button and an image of pills labeled "dispose" and "unused Rx".

At the bottom, there are three columns:

- Latest News:** Includes a link to "See All News Stories" and two news items:
 - 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:** A yellow box featuring "Irma Perez's Story" and a snippet of text about a 14-year-old girl from Belmont, California.
- Inside DEA:** A white box with the text: "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..."

DEA Web-based Resources

www.DEA.gov

The screenshot displays the DEA website homepage. At the top, the URL is <http://www.justice.gov/dea/index.shtml>. The main header features the large "DEA" logo in gold, followed by "UNITED STATES Drug Enforcement Administration" and the slogan "TOUGH WORK, VITAL MISSION". A navigation bar 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 gold DEA Special Agent badge. To the right of the banner are three 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: "TOP STORY" with the headline "Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy" dated "JAN 29 (BROWNSVILLE, TEXAS)"; "TOPICS OF INTEREST" listing "DEA Fact Sheet", "Drugs of Abuse: A DEA Resource Guide", "Extension of Temporary Placement of Five Synthetic Cannabinoids", and "The DEA Position on Marijuana"; and "RESOURCE CENTER" listing "Controlled Substances Act", "DEA Museum and Visitors Center", "Doing Business with DEA", "Drug Disposal", and "Employee Assistance Program".

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 Gallegos, 30, and her husband Jose Carlos

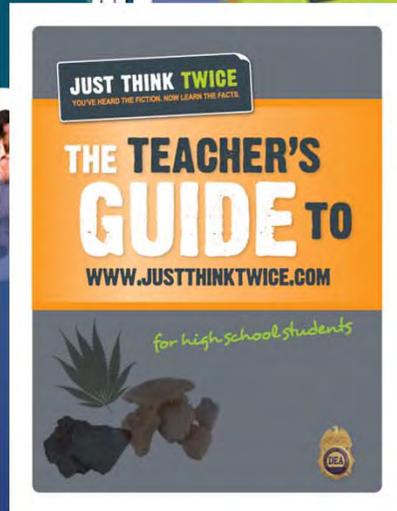
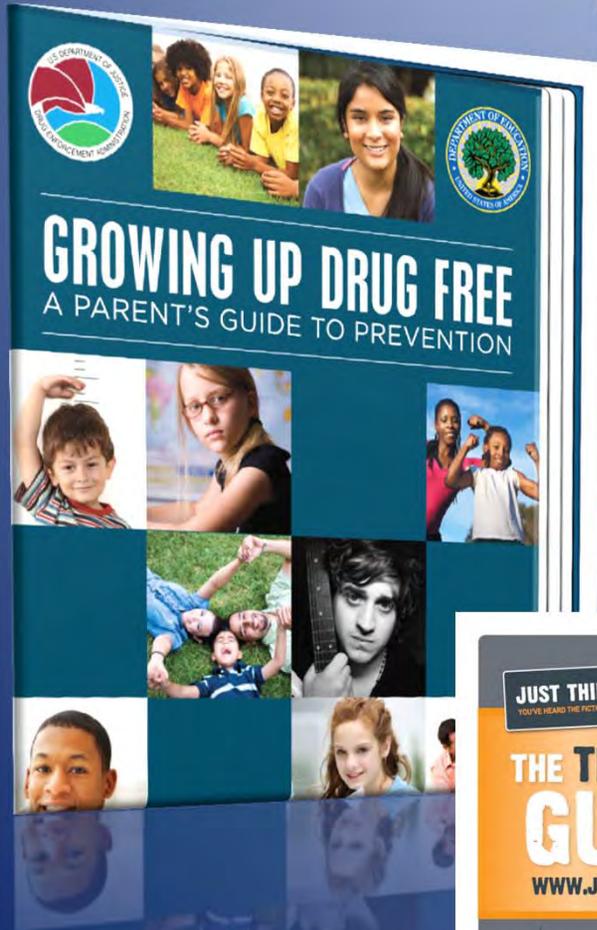
TOPICS OF INTEREST

- 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

Publications



Community Coalitions and Advocacy Groups

Education

- Physicians/Dentists/Practitioners
Prescribing habits
Mandatory opiate prescribing
continuing education?

Education

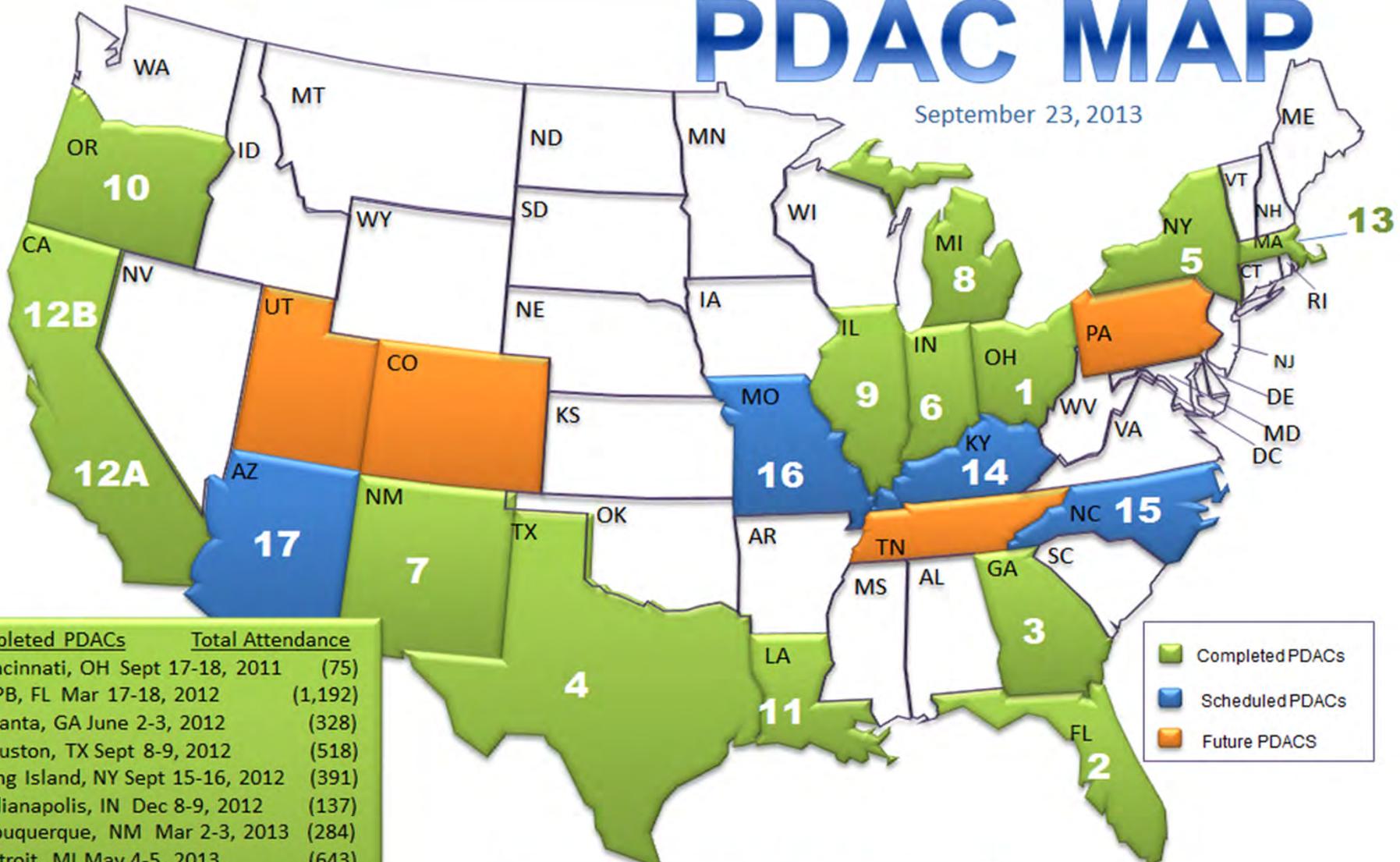
- Pharmacists

Drug Experts in the health care delivery system.

Corresponding responsibility

PDAC MAP

September 23, 2013



Completed PDACs	Total Attendance
1-Cincinnati, OH Sept 17-18, 2011	(75)
2-WPB, FL Mar 17-18, 2012	(1,192)
3-Atlanta, GA June 2-3, 2012	(328)
4-Houston, TX Sept 8-9, 2012	(518)
5-Long Island, NY Sept 15-16, 2012	(391)
6-Indianapolis, IN Dec 8-9, 2012	(137)
7-Albuquerque, NM Mar 2-3, 2013	(284)
8-Detroit, MI May 4-5, 2013	(643)
9-Chicago, IL June 22-23, 2013	(321)
10-Portland, OR July 13-14, 2013	(242)
11-Baton Rouge, LA Aug 3-4, 2013	(259)
12A-San Diego, CA Aug 16-17, 2013	(353)
12B-San Jose, CA Aug 18-19, 2013	(434)
13-Boston, MA Sep 21-22, 2013	(275)
Total attendance to date:	(5,452)

Scheduled PDACs

- 14-Louisville, KY Nov 16-17, 2013
- 15-Charlotte, NC Feb 8-9, 2014
- 16-St. Louis, MO April 5-6, 2014
- 17-Phoenix, AZ June 28-29, 2014

Completed PDACs
Scheduled PDACs
Future PDACS

Future PDACS

- Nashville, TN
- Philadelphia, PA
- Denver, CO
- Salt Lake City, UT

The Controlled Substances Act

21 United States Code

CSA Registrant Population

Current Number of
DEA Registrants.....

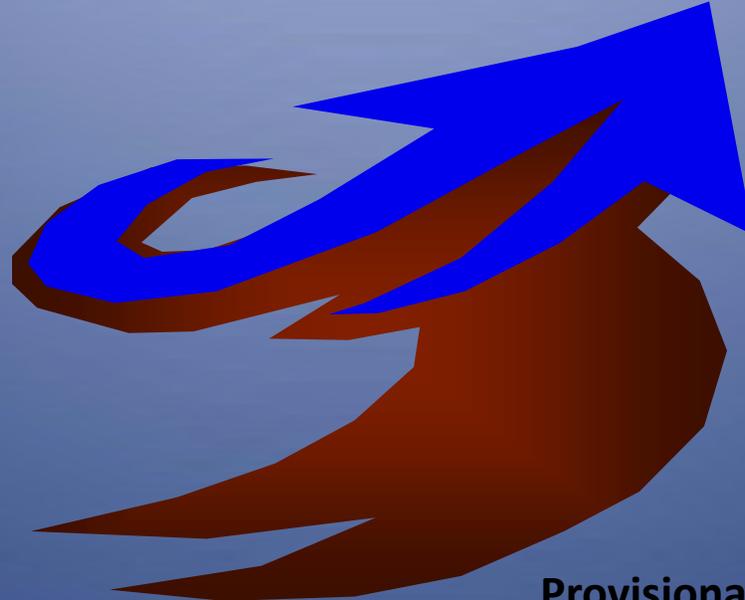
1,521,645

January 2014

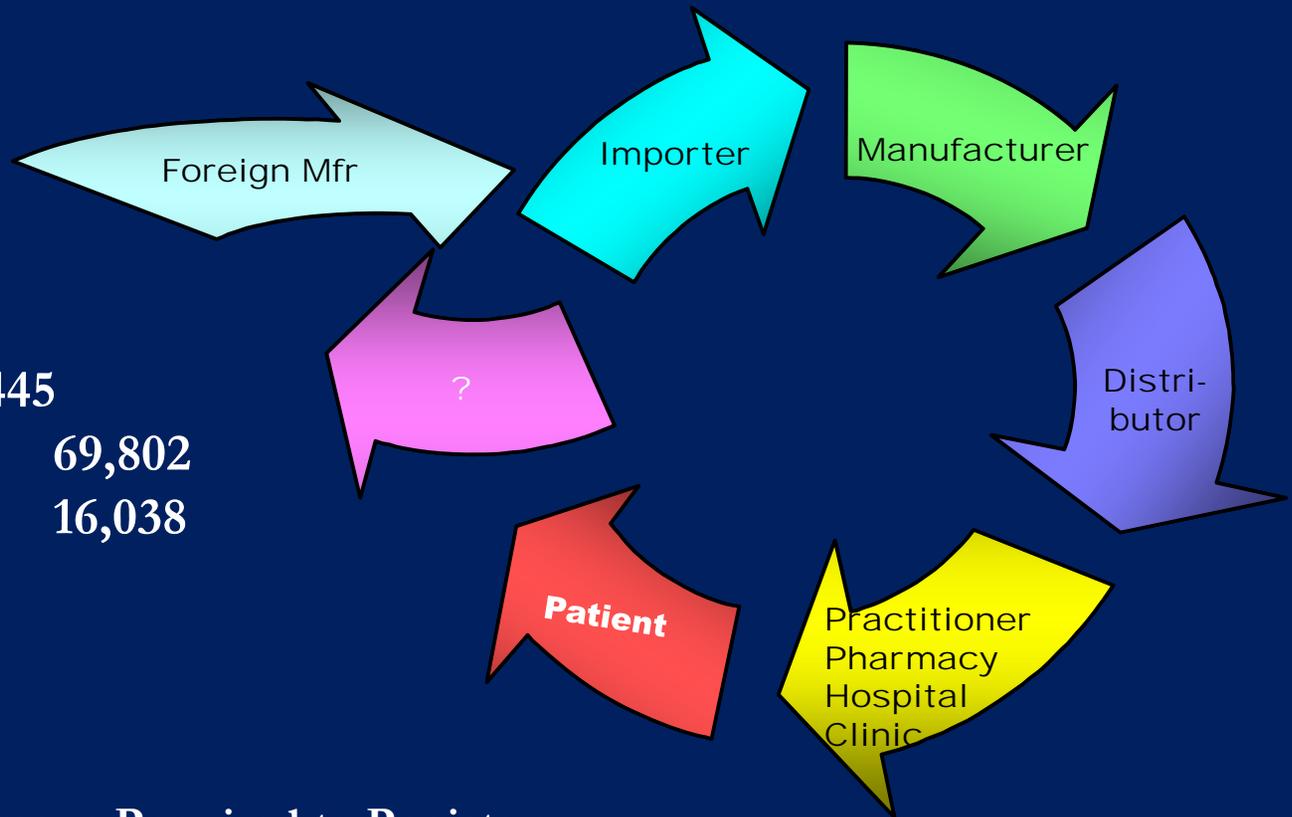
480,000

1973

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



Closed System of Distribution



1,521,645 (01/31/2014)

Practitioners: 1,177,445

Retail Pharmacies: 69,802

Hospital/Clinics: 16,038

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

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

Law: 21 USC 822 (a) (2) Persons Required to Register:

“Every person who dispenses, or who proposes to dispense any controlled substance ...”



Closed System of Distribution



Cutting off the Source of Supply

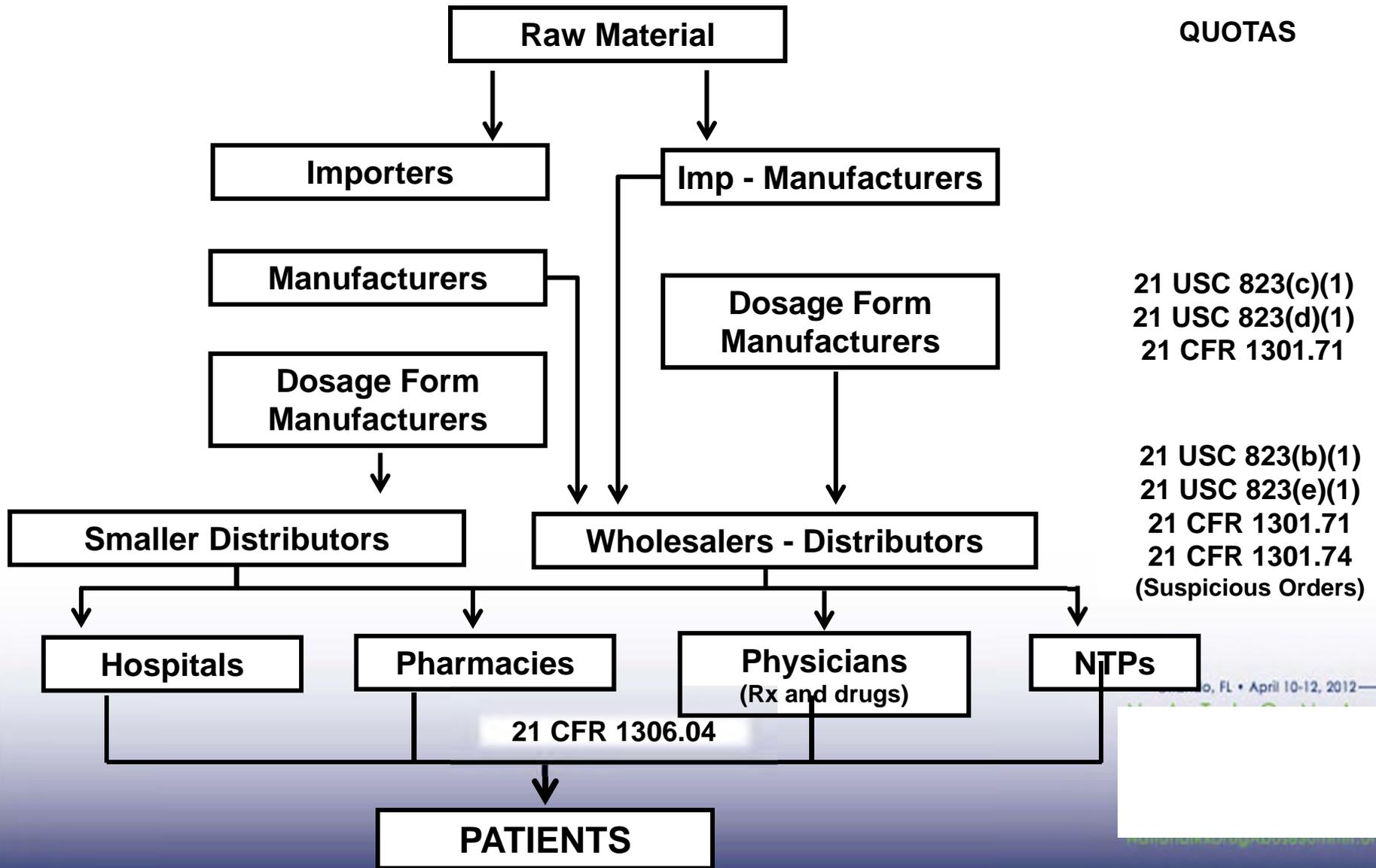


The Controlled Substances Act

Checks and Balances



The Flow of Pharmaceuticals





Diversion via the Internet



Domestic 'Rx' Flow

1. Consumer in Montana orders hydrocodone on the Internet

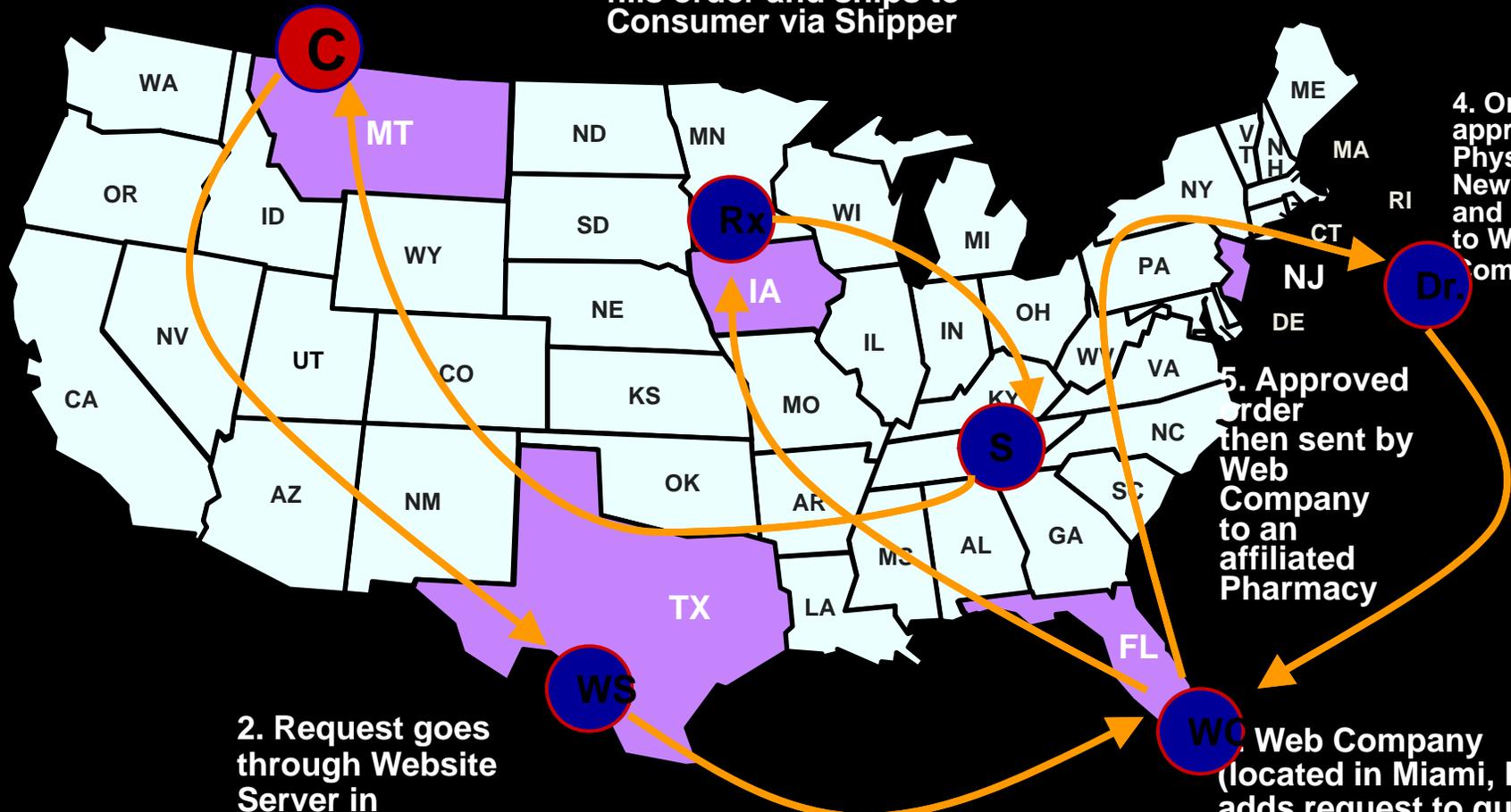
6. Pharmacy in Iowa fills order and ships to Consumer via Shipper

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

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

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

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



Checks and Balances of the CSA and the Regulatory Scheme

- Distributors of controlled substances

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



DEA Distributor Initiative

Purpose and format:

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

August 2005 – Present:

- Briefings to 81 firms with 233 locations
- Examples of civil action against distributors:
 - Cardinal Health , \$34 million civil fine
 - McKesson, \$13.25 million civil fine
 - Harvard, \$6 million civil fine
- Examples of suspension, surrender or revocation of DEA registration
 - Keysource, loss of DEA registration
 - Sunrise, loss of DEA registration

'Opiate Refugees' Caught Between Pharmacies, Suppliers And The Law

BY PATRICIA MURPHY KUOW.ORG/SEATTLE



Credit Flickr Photo/Greg McMullin

This week the state Department of Health reported that prescription drug overdose deaths are down 27 percent since 2008. But curbing fraud and abuse of powerful opiates has come at a price for some legitimate patients who say they're suffering unnecessary pain due to delays at pharmacies.

"This situation has literally brought customers to tears in our store," said Doug Hoey, CEO of the National Community Pharmacists Association, reading from comments submitted to a survey by the association's members.

'We're Cutting It Off'

Hoey said they created the survey because of increased concerns among pharmacists who are running into problems when they order painkillers and other controlled substances from suppliers. Sometimes, he said, the drugs are just not there, and the explanation is vague.

This situation has literally brought customers to tears in our store.

"When we talk to the suppliers, they say the Drug Enforcement Agency has come in and said that 'we're supplying too many,' or 'they're watching us.' But they don't give us any guidelines on what 'watching us' means," Hoey said.

According to Hoey, the suppliers tell the pharmacists that they are reviewing what they are shipping and erring on the side of caution: "If we see anything that looks suspicious to us, we're cutting it off."

The scenario is so prevalent that patients in this situation have been dubbed "opiate refugees." Patients are forced to go from pharmacy to pharmacy trying to fill legitimate prescriptions.

Not Just A Supply Chain Issue

Some large pharmacy chains have instituted polices requiring pharmacists to ask a host of new questions before filling prescriptions. They're scrutinizing how far away a patient lives from the pharmacy and, in some cases, calling doctors to inquire about treatment plans and the number of times they've seen the patient. If every question can't be answered satisfactorily, the patient may leave empty-handed.

John Gray, president and CEO of Healthcare Distribution Management Association, said suppliers used to have a more cooperative and collaborative relationship with the Drug Enforcement Agency. But things have changed, he said. "It's all been dumped in our laps as wholesalers to make what I would consider to be law enforcement decisions as to whether or not a particular customer or account is or is not over what the DEA, in their own mind, thinks is a viable limit for Schedule II drugs they ought to be dispensing," Gray said.

Drug wholesaler, 2 pharmacies charged in DEA crackdown

By Donna Leinwand Leger, USA TODAY

Updated 15h 4m ago

Comment

Recommend 57

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Federal authorities have expanded their crackdown on painkiller abuse, charging a major health care company and two CVS pharmacies in Florida with violating their licenses to sell powerful pain pills and other drugs.



By Kiichiro Sato, 2007 AP photo

The DEA suspended Cardinal Health's controlled substances licenses on Friday for the third time in five years.

The [Drug Enforcement Administration](#) linked [Cardinal Health](#) to unusually high shipments of the controlled drugs to four pharmacies.

On Friday, the DEA suspended Cardinal's controlled substances license at its Lakeland, Fla., distribution center, which services 2,500 pharmacies in Florida, Georgia and [South Carolina](#).

A federal judge temporarily halted the suspension the same day after Cardinal, a \$1.3 billion company, said it would stop supplying the drugs to the four pharmacies. A hearing on the suspension order was set for Feb. 13 in Washington, D.C.

"We believe the DEA is wrong," CEO George Barrett said on the company's website.

The action comes as the DEA is cracking down on pill mills — rogue doctors and shady pharmacies that divert the highly addictive pills, such as oxycodone, to drug dealers.

"This is still an ongoing investigation," said DEA Special Agent David Melenkevitz, spokesman for the Miami Field Division. "We will be able to provide more information on Monday."

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On Saturday, the DEA raided two CVS pharmacies in Sanford, Fla., and suspended their licenses to dispense controlled substances.

CVS said Saturday it had taken steps with DEA's knowledge to stop filling prescriptions from doctors thought to be prescribing improperly.

"We informed a small number of Florida physicians that CVS/pharmacy will no longer fill the prescriptions they write for [Schedule II](#) narcotics," spokeswoman Carolyn Castel said in a written statement. "Distributions of oxycodone to the two Florida stores have decreased by approximately 80% in the last three months compared to the prior three months — we believe in large part due to our action."

In its suspension order, the DEA alleges that Cardinal knew or should have known that

The Company called the DEA action “a drastic overreaction” that would disrupt delivery of critical medications to hospitals and pharmacies.

illegitimate use, Barrett said. Cardinal's internal controls have flagged more than 160 pharmacies in Florida and 350 pharmacies nationwide for "suspicious order patterns," he said. Barrett said the DEA is holding the company responsible for a part of the supply

“At the time we filled these orders, the pharmacies held valid state board of pharmacy and DEA licenses,” Barrett said in a call to investors on Friday. “Pharmaceutical distributors do not influence the manufacture of controlled medicines. We do not write prescriptions. We do not dispense controlled medicines, nor do we license pharmacies. Our role is, as a distributor, a critical link in the supply chain between pharmaceutical manufacturers and pharmacies.” Cardinal CEO George Barrett

In November 2007, the DEA suspended the license for Cardinal's Auburn, Wash., distribution facility for selling 18 million hydrocodone pills in nine months to retail drugstores. The company sold 605,000 pills to one store in Burlington, Wash., over a seven-month period, the DEA said.

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**

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 (5th Cir 1979)

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

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

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

Checks and Balances Under the CSA

- 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 (5th Cir 1979)

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

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

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

E-MAIL PRINT SHARE

AMA adopts resolution on pharmacist drug inquiries

Group calls some inquiries 'inappropriate,' 'unwarranted'

JULY 8, 2013 | BY ALARIC DEARMENT

NEW YORK — Inquiries by pharmacists with doctors regarding the rationale behind prescriptions, diagnoses and treatment plans are inappropriate, according to a new resolution by the American Medical Association.

Related Content

- A look at China's retail pharmacies
- Bartell to cease filling Medicaid



Advil[®]
Take \$1 off your next purchase
SAVE NOW
THE #1 SELLING PAIN RELIEVER

NEWSLETTER REGISTRATION

The AMA adopted the resolution at its 2013 annual meeting, calling such inquiries “an interference with the practice of medicine and unwarranted”.

Potential Red Flags

Many customers receiving the same combination of prescriptions; cocktail

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

Many customers paying cash for their prescriptions

Early refills

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

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

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

Potential Red Flags

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

Overwhelming proportion of prescriptions filled by pharmacy are controlled substances

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

Verification of legitimacy not satisfied by a call to the doctor's office

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



Large-Scale Diversion

- In 2009, the average purchase for all oxycodone products for all pharmacies in US – 63,294 d.u.
- In 2010, the average was – 69,449 d.u.
- In 2009, the average purchase for all oxycodone products for the top 100 pharmacies in Florida – 1,226,460 d.u.
- In 2010, the average was – 1,261,908 d.u.

Purchases of Oxycodone 30mg

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

Violations?

What happens next.....





The DEA Inspection

- **Investigators will identify themselves and produce their official credentials**
- **Investigators will produce, either a**
 - **Notice of Inspection**
 - **Administrative Inspection Warrant**
 - **Search Warrant**

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

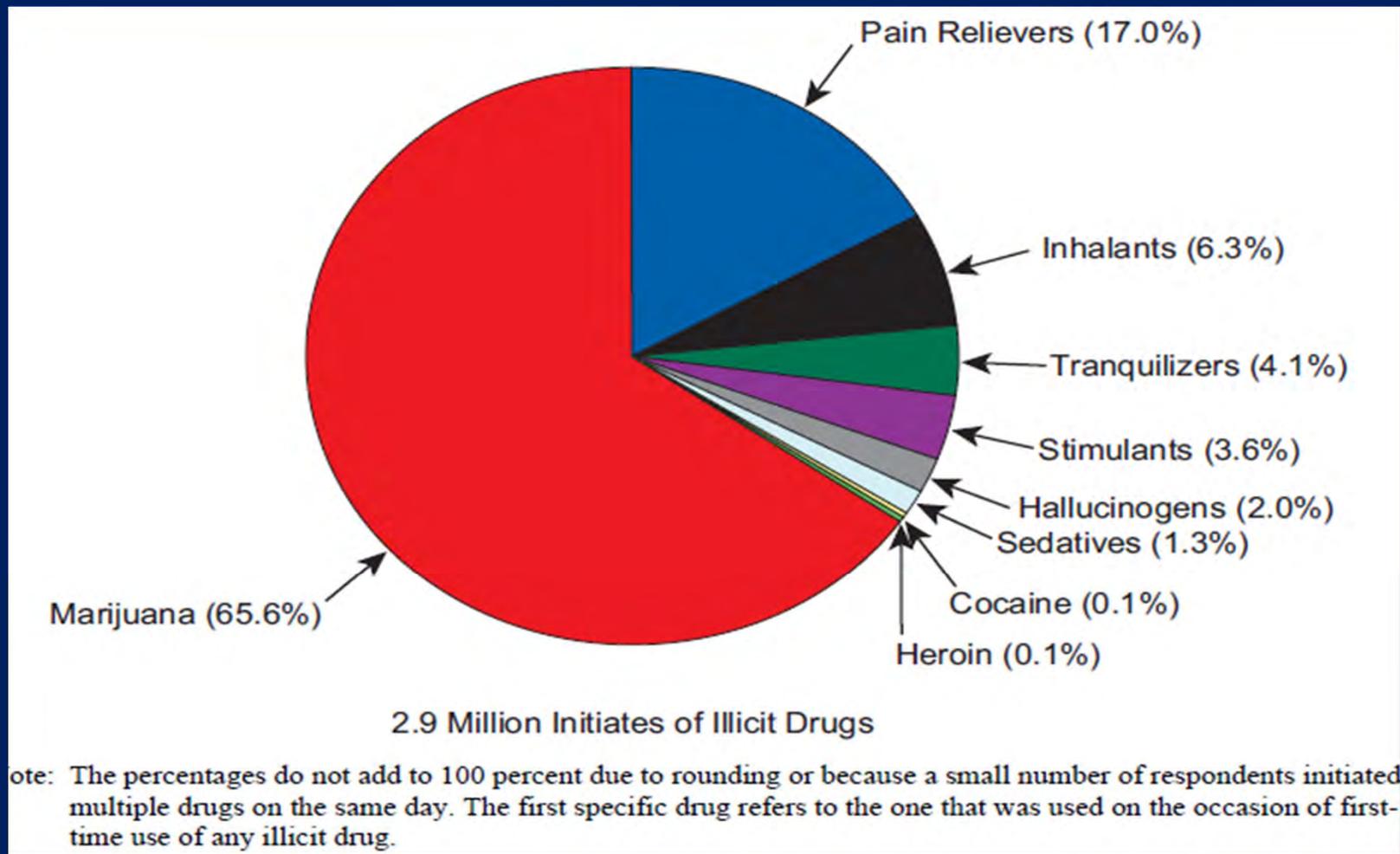
- a) Grounds –
 1. Falsification of Application
 2. Felony Conviction
 3. State License or Registration suspended, revoked or denied no longer authorized by State law
 4. Inconsistent with Public Interest
 5. Excluded from participation in Title 42 USC § 1320a-7(a) program

- b) AG discretion, may suspend any registration simultaneously with Order to Show Cause upon a finding of Imminent Danger to Public Health and Safety

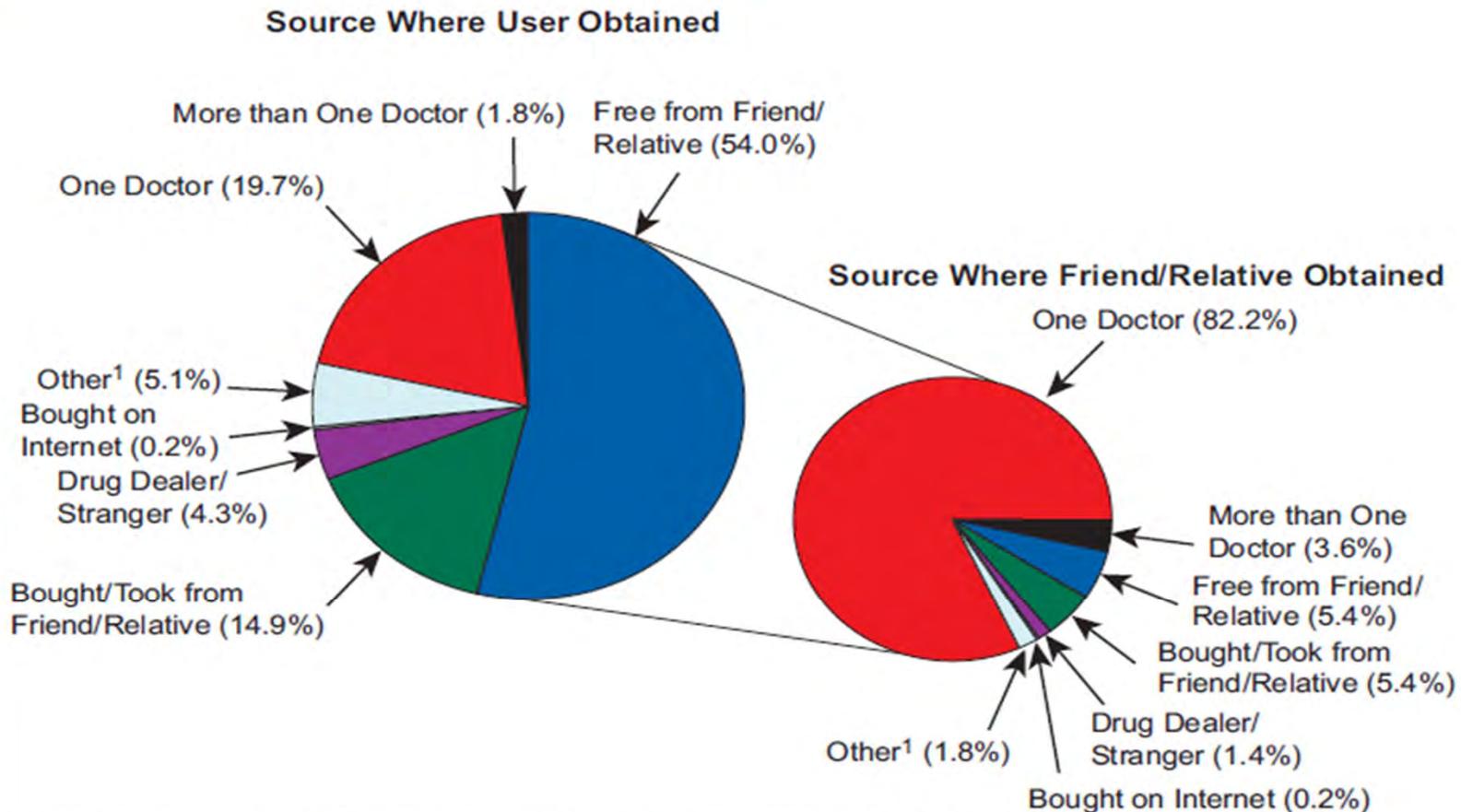
Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!

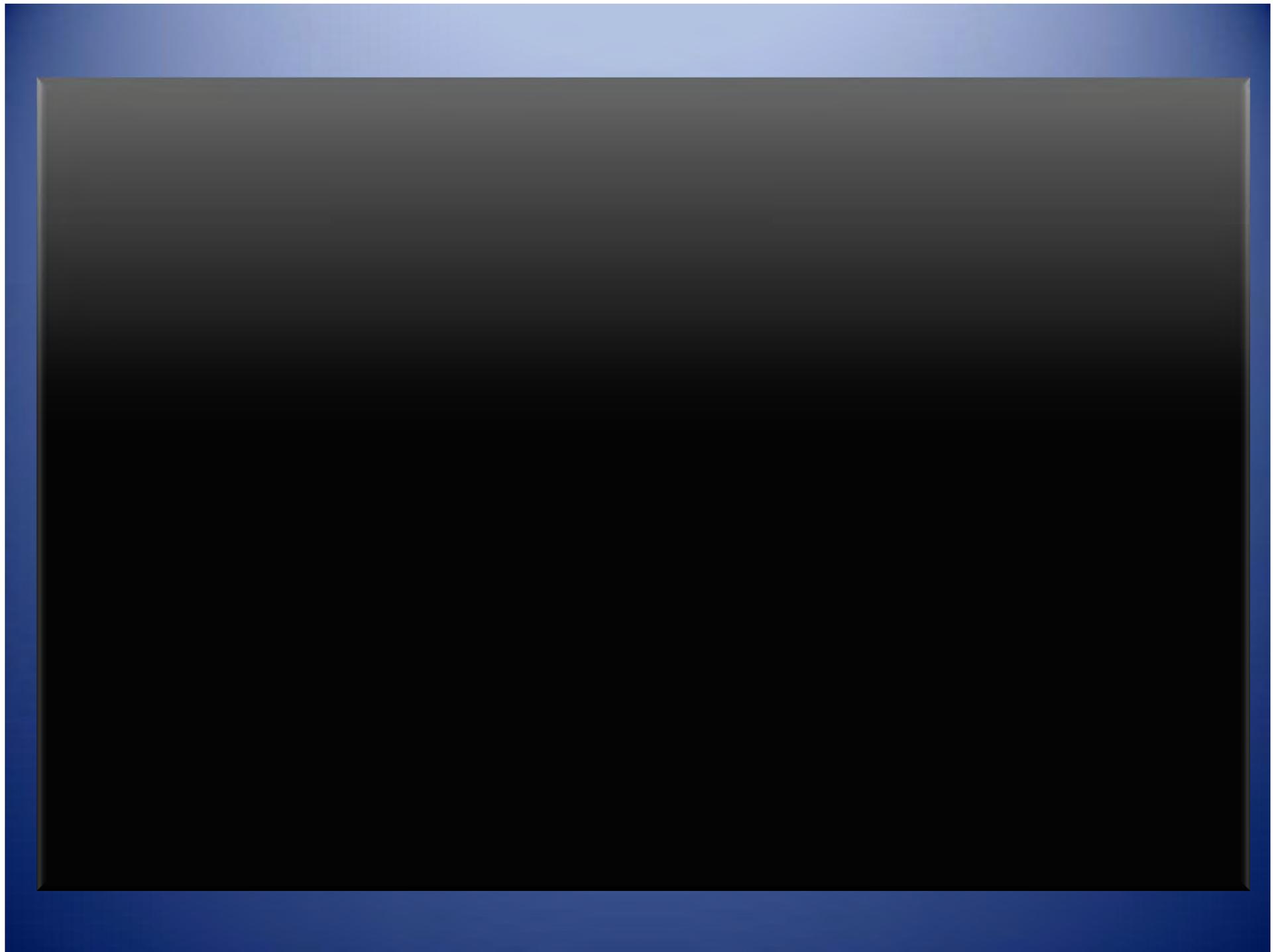
First Specific Drug Associated with Initiation of Illicit Drug Use Among Past Year Illicit Drug Initiates Aged 12 or Older: 2012



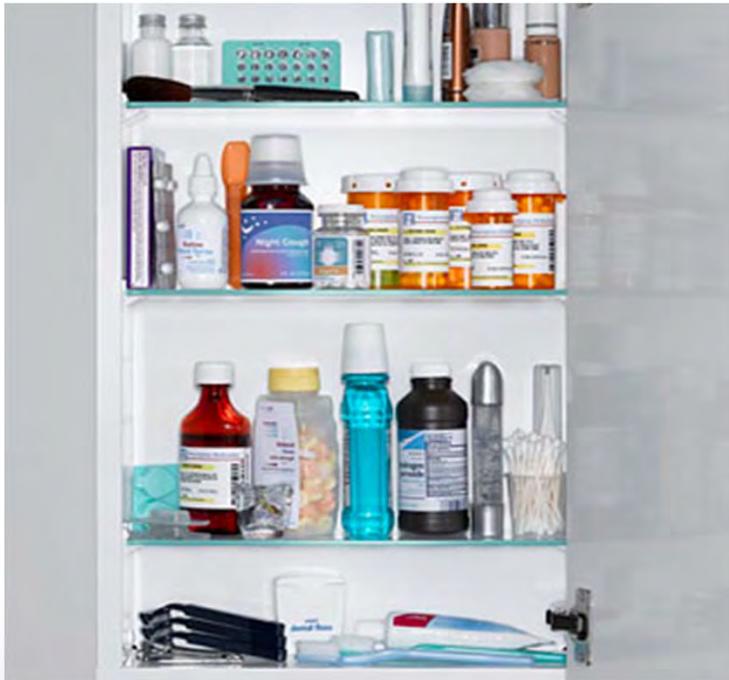
Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use Among Past Year Users Aged 12 or Older: 2011-2012



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



The Problem – Easy Access



Medicine Cabinets: Easy Access

% Agree Strongly/Somewhat	2009	2010	2011	2012
Parents Indicate: "Anyone in the house can access the medicine cabinet where I keep Rx meds"	56%	48%	59%	49%
Teens Indicate: "It's easy to get Rx drugs from parent's medicine cabinet"	63%	47%	53%	56%

Medicine Cabinets: Easy Access

- More than half of teens (56%) indicate that it's easy to get prescription drugs from their parent's medicine cabinet
- Half of parents (495) say anyone can access their medicine cabinet
- More than four in 10 teens (42%) who have misused or abused a prescription drug obtained it from their parent's medicine cabinet
- Almost half (49%) of teens who misuse or abuse prescription medicines obtained them from a friend



So Many Drugs in the Household - Why?

- Unreasonable quantities being prescribed
 - Insurance rules
- 

So Why is this important to me
(Pharmacist, Physician, Dentist, Nurse
etc.)

- Under the current law, receiving a controlled substance from a ultimate user is a violation of the CSA

Ultimate User Disposal of Medicines

National Take-Back Events: Take-back events are a good way to remove expired, unwanted, or unused medicines from the home.



Law Enforcement Collection Bins: Collection bins installed by our Law Enforcement Partners are a good way to remove expired, unwanted, or unused medicines from the home.



Disposal in Household Trash: Mix medicines (do not crush tablets or capsules) with substances such as kitty litter or used coffee grounds and place the mixture in a container such as a sealed plastic bag and throw the container in your household trash.



Disposal by Flushing: Some medicines have specific disposal instructions that indicate they should be flushed down the sink or toilet when they are no longer needed.



ONDCP Guidelines

- ONDCP guidelines for the disposal of ultimate user medications, including dispensed controlled substances (2/20/07).
- Advise public to flush medications only if the prescription label or accompanying patient information specifically states to do so.
- ONDCP recommends a minimal deactivation procedure, and disposal in common household trash.

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.



Nationwide Take-back Initiative

Over 3.4 million pounds (1,733 tons) collected

- On **September 30, 2010**, **122 tons** of prescription drugs collected
- On **April 30, 2011**, **188 tons** of prescription drugs collected
- On **October 29, 2011**, **189 tons** of prescription drugs collected
- On **April 28, 2012**, approximately **276 tons** of prescription drugs collected
- On **September 29, 2012**, approximately **244 tons** of prescription drugs collected
- On **April 27, 2013**, approximately **376 tons** of prescription drugs collected
- On **October 26, 2013**, approximately **324 tons** of prescription drugs collected

National Take Back Day

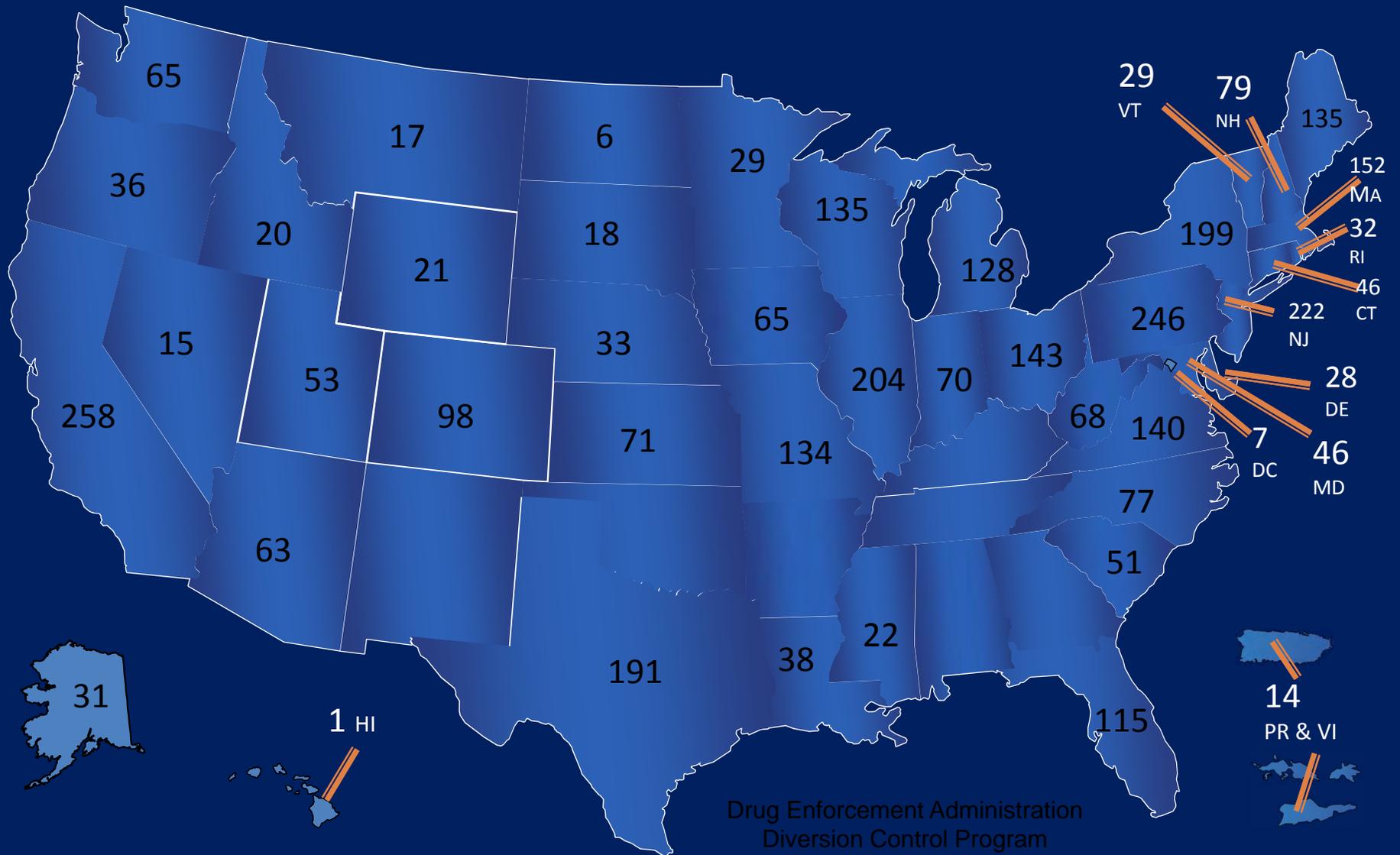
October 26, 2013

4,114 Agencies; 5,683 Sites
647,211 Pounds Collected (324 Tons)



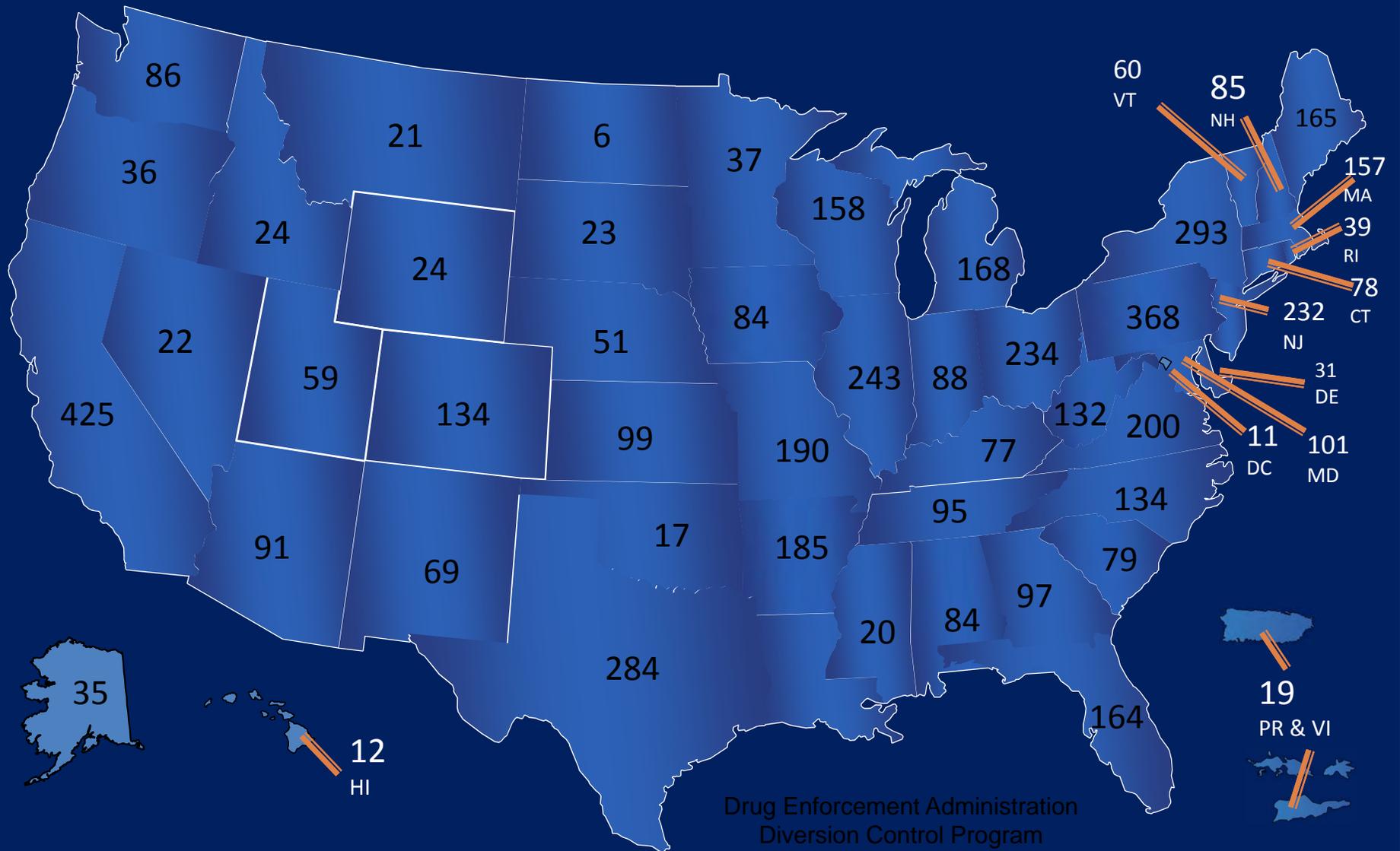
National Take Back Day: October 26, 2013

Total Law Enforcement Participation: 4,114



National Take Back Day: October 26, 2013

Total Collection Sites: 5,683



Secure and Responsible Drug Disposal Act of 2010

- Enacted in October 2010 (Pub. L. 111-273, codified at 21 U.S.C. 822(g) and 823(b)(3))
- Act allows an ultimate user to “deliver” a controlled substance “to another person for the purpose of disposal” in accordance with regulations issued by DEA
- If the ultimate user dies while in lawful possession of the controlled substance, then any person lawfully entitled to dispose of the decedent’s property may deliver the controlled substance to another person for the purpose of disposal.
- DEA may also, by regulation, authorize long term care facilities (LTCFs) to dispose of controlled substances on behalf of ultimate users who reside or have resided at the LTCF.
- DEA is working to promulgate regulations to implement this Act. DEA must consider:
 - Public health and safety
 - Ease and cost of program implementation
 - Participation by various communities
 - Diversion Control
- Participation is voluntary. DEA may not require any person to establish or operate a delivery or disposal program.

Notice of Proposed Rulemaking

PROZAC (?) FISH



MEDICINES RECOMMENDED FOR DISPOSAL BY FLUSHING

This list from FDA tells you what expired, unwanted, or unused medicines you should flush down the sink or toilet to help prevent danger to people and pets in the home. Flushing these medicines will get rid of them right away and help keep your family and pets safe.

FDA continually evaluates medicines for safety risks and will update the list as needed.

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

*These medicines have generic versions available or are only available in generic formulations.

List revised: January 2012

Pharmaceuticals

Legend Drugs v.
Controlled Substances

Legend Pharmaceuticals



Non-Controlled Substances

- Analgesic:
 - Tramadol (Ultram®), Ultracet®)
- Muscle Relaxant:
 - Cyclobenzaprine (Flexeril®)

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

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.

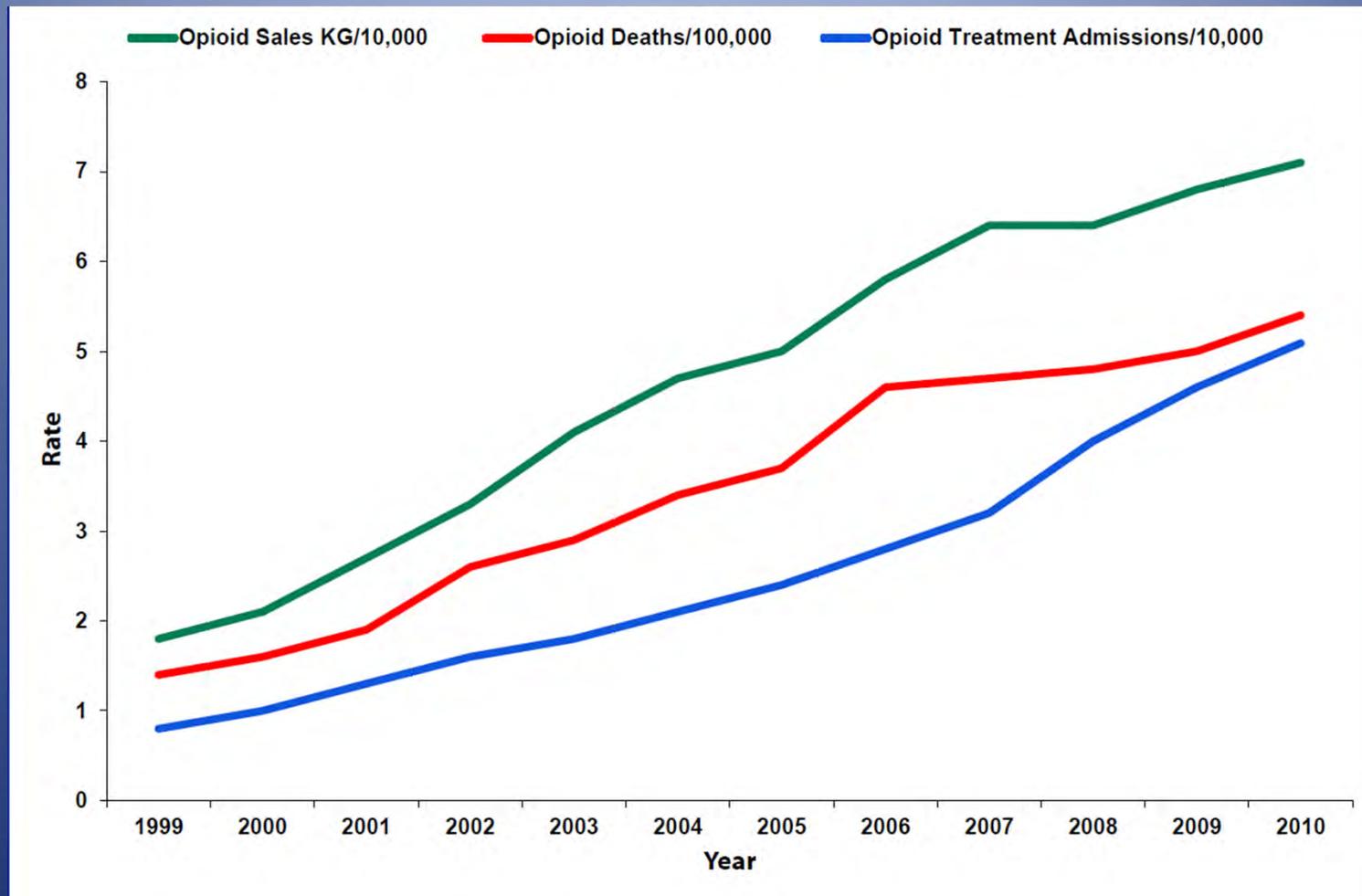
** A signed, hard copy of the prescription must be presented before the medication is dispensed.

*** 72 hour time limitation.

With medical authorization, up to 5 in 6 months.

Opiates

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

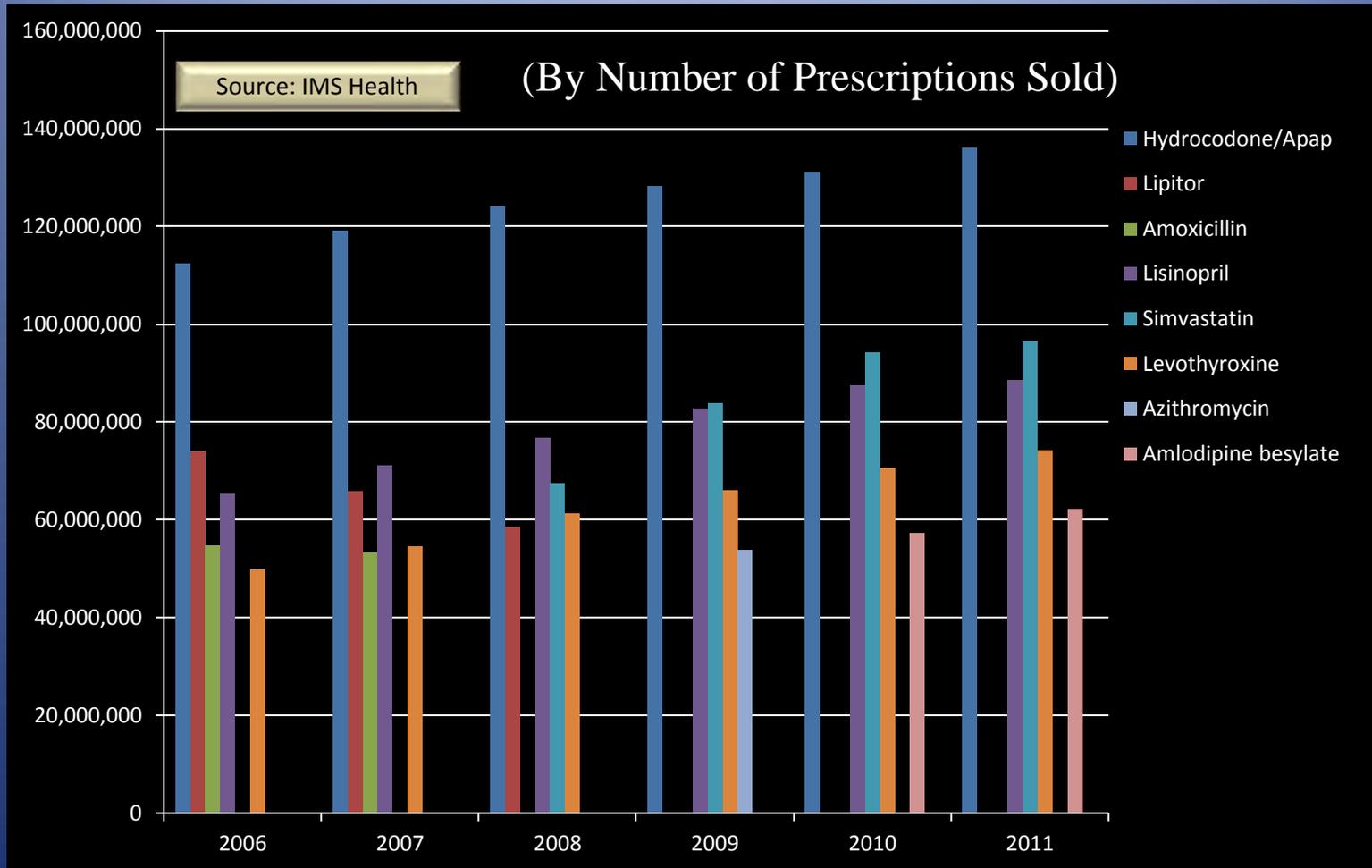


Source: National Vital Statistics System (NVSS),
DEA's Automation of Reports and
Consolidated Orders System, SAMHSA's
Treatment Episode Data Set

*Most commonly prescribed prescription
medicine?*

Hydrocodone/acetaminophen

Top Five Prescription Drugs Sold in the U.S. (2006-2011)





Hydrocodone, APAP C-III

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



Hydrocodone Combinations

- CSA defines hydrocodone substance as Schedule II, while its combination products as Schedule III.
- DEA has received a petition to reschedule CIII hydrocodone combination products to CII.
- In 2004, DEA completed an initial review forwarded the data to DHHS with a request for scientific and medical evaluation and scheduling recommendation.
- In 2008, HHS provided a scientific and medical evaluation
- In 2009, DEA sent additional data to FDA/HHS and requested a scientific and medical evaluation.

Procedures to control a substance

- DEA receives a petition from an interested party (proceedings may also be initiated at the request of the AG or Secretary of HHS)
- Petition is reviewed and accepted
- DEA conducts initial 8-factor analysis review
- Documents and material gathered during the initial review and analysis of petition is sent to HHS/FDA with a request for a scientific and medical evaluation and a recommendation as to whether the drug should be controlled
- The recommendation and review document is received back from HHS/FDA

Schedule II

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

Schedule III

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

Approval of Single Entity
Extended Release Hydrocodone



OxyContin[®] (Schedule II)

- Controlled release formulation of Schedule II oxycodone
 - The controlled release method of delivery allows for a longer duration of drug action so it contains much larger doses of oxycodone
 - Abusers easily compromise the controlled release formulation by crushing the tablets for a powerful morphine-like high
 - Street Slang: “Hillbilly Heroin”
 - 10, 15, 20, 30, 40, 60, 80mg available
- Effects:
 - Similar to morphine in effects and potential for abuse/ dependence
- Street price: Approx. \$80 per 80mg tablet
- New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.

OxyContin[®] Change



New OxyContin[®] 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 metioned in a previous post. havent tried smoking it yet, kinda in a hole money wise, it cost me over \$700.00 to get my 80s filled and i probably wont even get half my money back 😞

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

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

Percocet



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

Percodan



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

Tylox



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



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

Roxicodone



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



- 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



Fentora®

Actiq®



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.

NDC 0054-0264-25 100 Tablets

HYDROMORPHONE HYDROCHLORIDE **C II**
Tablets, USP
4 mg

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

Roxane Laboratories, Inc.
Columbus, Ohio 43216

Roxane Laboratories

EXP. LOT

00540 26425

10005693/02
© RLI, 2009

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°-25°C (68°-77°F) [See USP Controlled Room Temperature].
Rev. 12/99 10-213

NDC 0327-1355-01

Lannett

HYDROMORPHONE HYDROCHLORIDE **C II**
TABLETS, USP
8 mg

Rx Only
100 TABLETS

Each Tablet Contains:
Hydromorphone Hydrochloride, USP 8 mg

Inactive Ingredients:
Anhydrous Lactose, Lactose Monohydrate, and Magnesium Stearate

Manufactured by:
Lannett Company, Inc.
Philadelphia, PA 19136

Made in the USA

0327-1355-01

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



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”

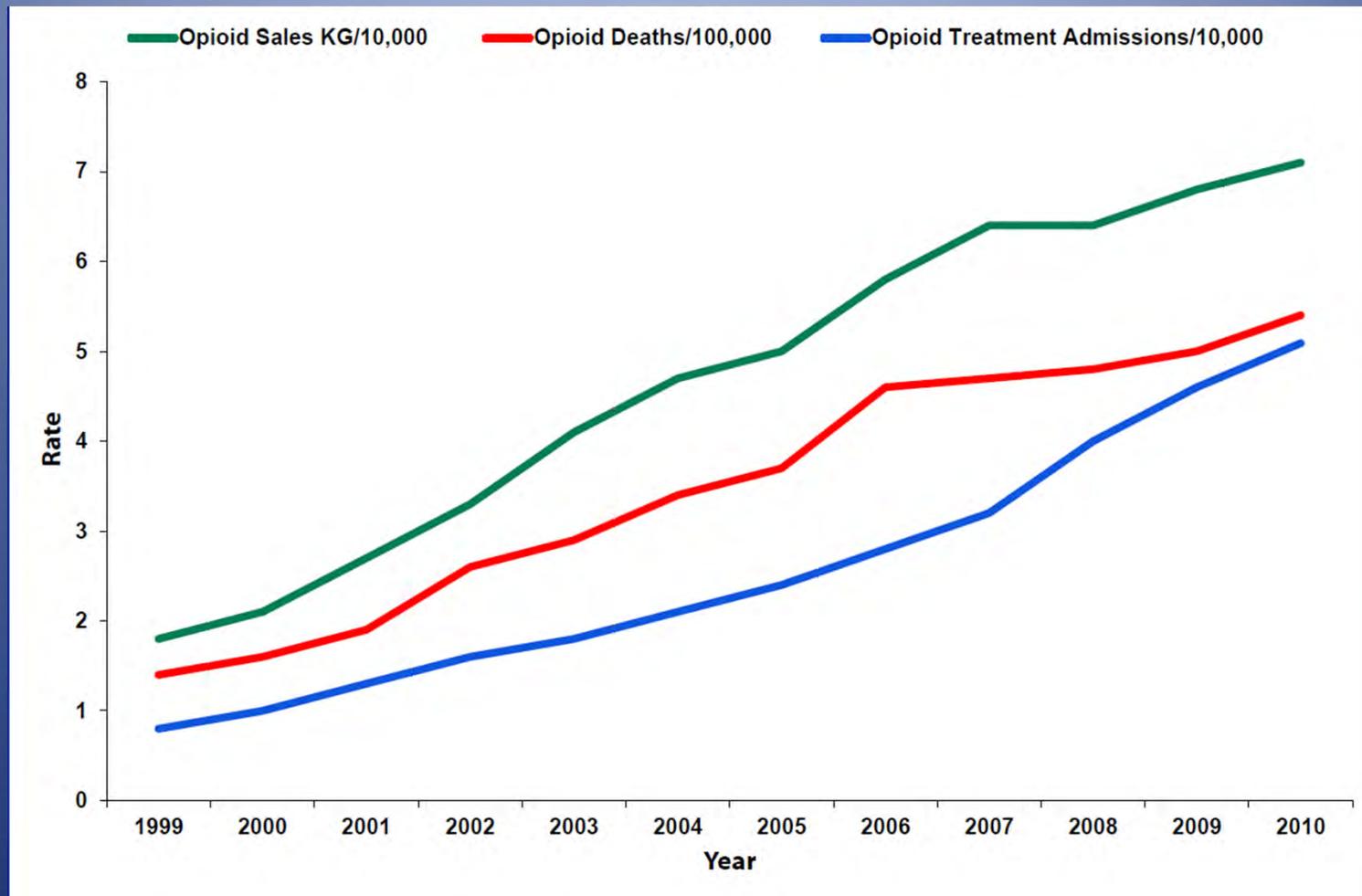


PURPLE DRANK
ima grip and sip



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®

OxyContin®
\$80/tab

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Oxycodone IR
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\$30-\$40/tab

Hydrocodone
Lorcet®
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\$10/bag



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WEDNESDAY, DECEMBER 5, 2012

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'Liaisons Dangereuses'
New approach to classic P. 19



Playoff possibilities
Schedule favors Skins P. 35

Cooling down



60° 34°
DETAILS P. 4

POLITICS

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

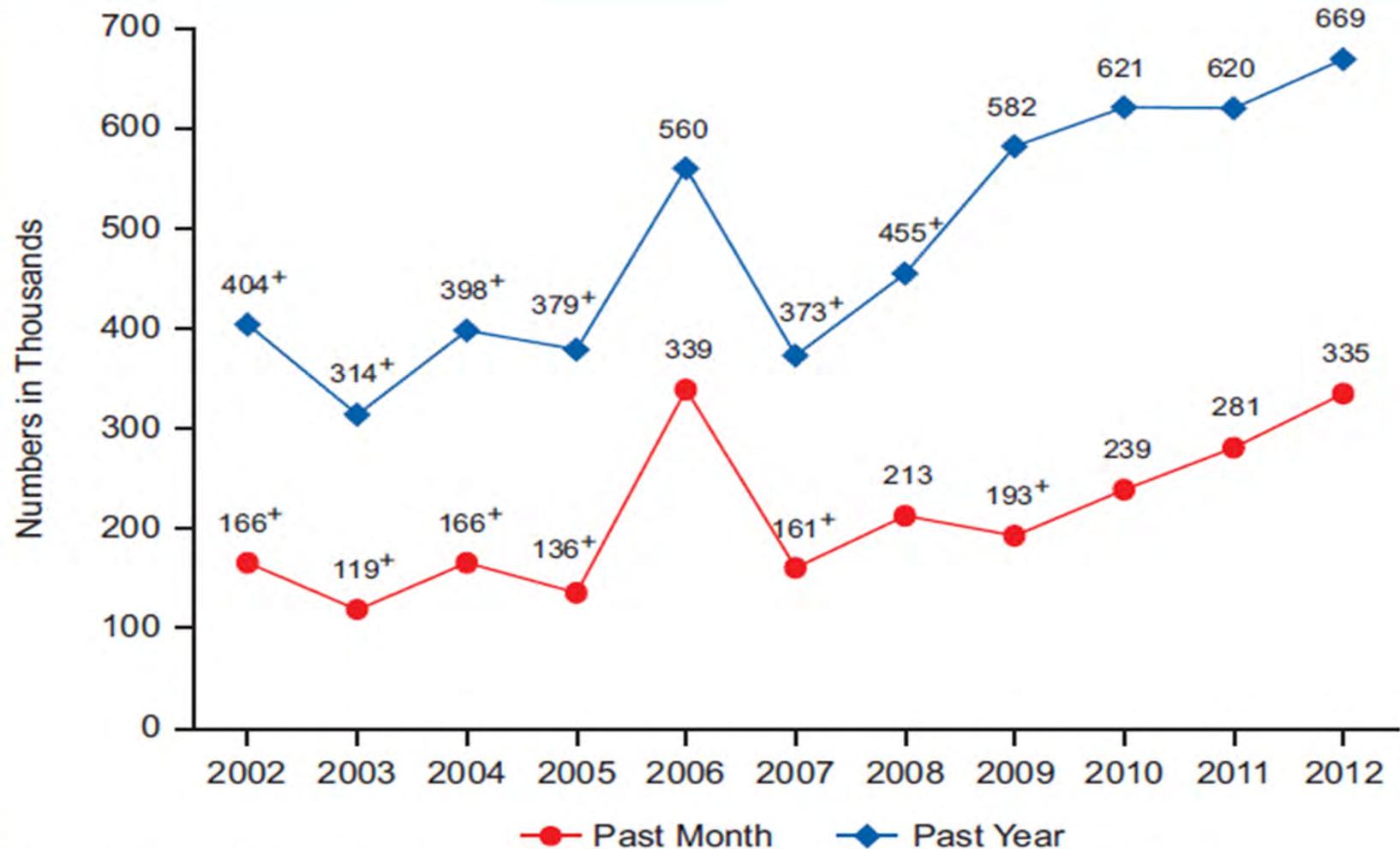
LOCAL

FBI analyst busted

Heroin use spikes in area suburbs

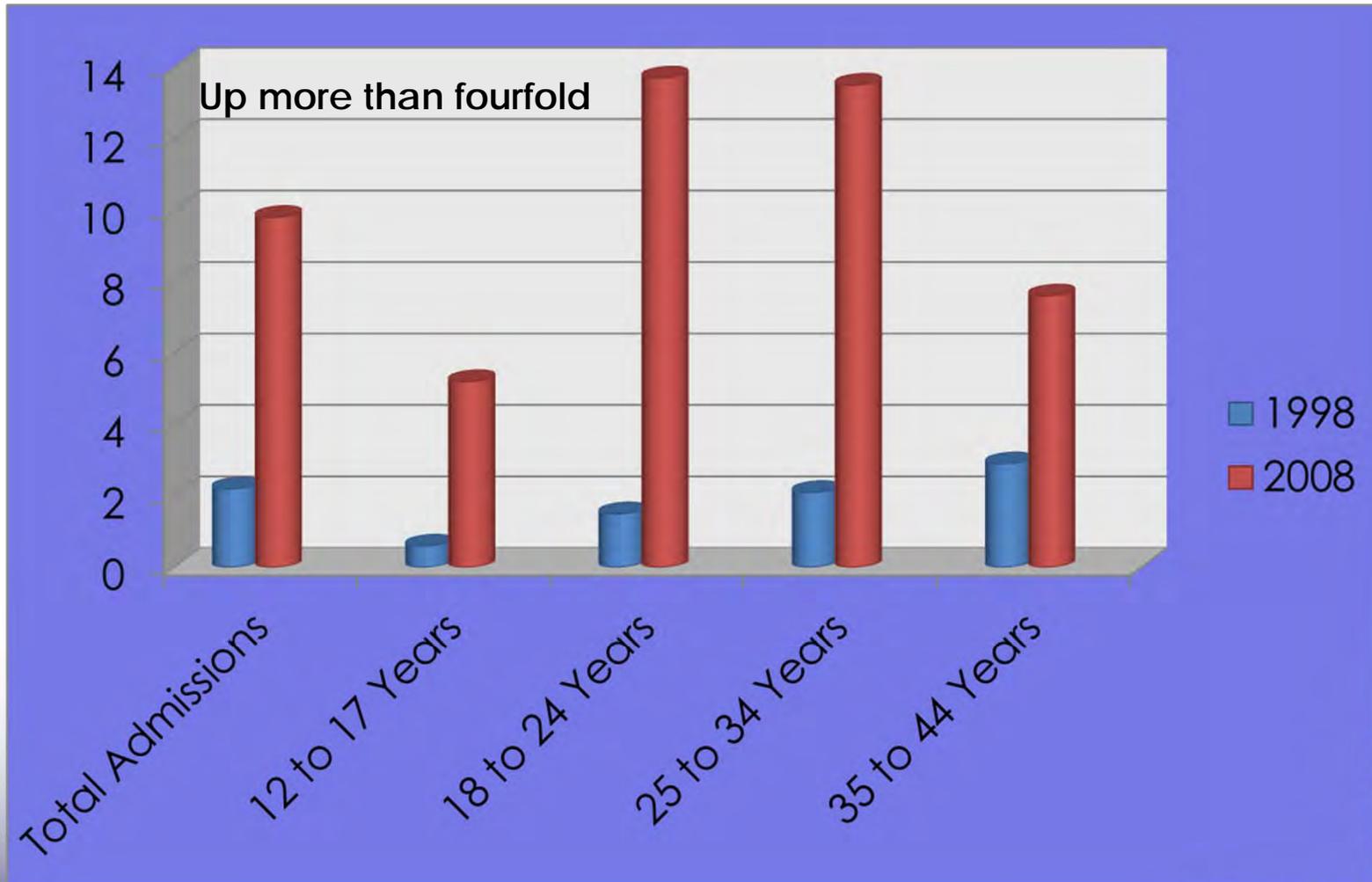
Pill addicts risk deadly drug

Past Month and Past Year Heroin Use Among Persons Aged 12 or Older: 2002-2012



Source: Substance Abuse and Mental Health Services Administration (SAMHSA)
Difference between this estimate and the 2012 estimate is statistically significant at the .05 level.

*Substance Abuse Treatment Admissions
within Specific Age Groups That Reported
Any Pain Reliever Abuse: 1998-2008*



Source: SAMSHA Treatment Episode Data Set, 1998-2008 released July 15, 2010

NationalRxDrugAbuse3

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

METHADONE

CDC Vital Signs Report July 2012

Almost one-third of prescription painkiller overdose deaths involve methadone.

Six times as many people died of methadone overdoses in 2009 than a decade before.

More than 15,500 people die every year of prescription drug overdoses, and nearly one-third of those overdoses involve the drug methadone, according to a recent [CDC Vital Signs report](#).

Researchers found that while methadone accounts for only 2 percent of painkiller prescriptions in the United States, it is involved in more than 30 percent of prescription painkiller overdose deaths.

Methadone has been used for decades to treat drug addiction, but in recent years it has been increasingly prescribed to relieve pain. As methadone prescriptions for pain have increased so have methadone-related fatal overdoses.

CDC results showed that six times as many people died of methadone overdoses in 2009 as died in 1999.

WHY IS IT ALSO USED AS AN ANALGESIC???????

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?



Methadone- 5mg & 10mg



Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg



Bluefield Daily Telegraph

William "Randy" Deason
Publisher

Thomas A. Colley
Executive Editor

Spencer Perry Managing Editor

Special Editor
Sports Editor

Ann Hunt
City Writer

Steve Givens Bill Archer
City Editor News Editor

"Then he answered and spoke to me, saying, This is the word of the LORD to Zerubbabel, saying, Not by might nor by power, but by my spirit, said the LORD of hosts."

(Zechariah 4:6 A&JV)

Overdose deaths Prescription drugs take deadly toll in WV

An alarming new study has found that prescription drugs killed more people in West Virginia in 2010 than illegal drugs. According to the report, nine out of the 10 accidental overdose deaths reported in the Mountain State involved prescription drugs. Researchers in a joint state-federal study came to the troubling conclusion after studying 432 accidental overdose autopsy reports, excluding suicides and overdoses, the Associated Press reported.

The report found that one-third of the prescription drugs taken during the fatal accidents were being used as a result of a prescription issued by a doctor within the last 30 days. The report found fewer than one in four of the deaths involved illegal narcotics.

Ann Hall, a Centers for Disease Control Epidemic Intelligence Service Officer for the West Virginia Department of Health and Human Resources, said there is a perception among some citizens that just because narcotics are legal and prescribed drugs, they are somehow safer.

The report found that methadone contributed to one of three deaths, or more than any other prescription drug. However, the report found that only 10 of the overdose victims were enrolled in a methadone clinic for drug-abuse treatment.

The report found that other opioid drugs frequently linked to accidental overdose deaths included hydrocodone

□ □ □

We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.

and oxycodone. The two narcotics contributed to one in five deaths. Morphine contributed to about one in seven deaths, the report found. Anti-anxiety drugs were found in 43 percent of the deaths.

While law enforcement officials have been fighting the illegal drug scourge in our region for years, accidental overdose deaths associated with the misuse of prescription narcotics now represents an emerging epidemic for the Mountain State.

The alarming new study from the West Virginia Department of Health and Human Resources should be viewed as a call to action for our community. We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.

We must act now to educate our community. If we fail to act, the number of accidental overdose deaths in the state and the region could continue to rise. It will take a combined effort of public education and law enforcement cooperation to reduce these alarming statistics.

Rising methadone deaths

Our view: Baltimore public health officials are trying to find out if treatment for chronic pain sufferers accounts for increase in methadone overdoses

THE JUNE LETTER FROM THE BALTIMORE HEALTH DEPARTMENT alerted physicians, nurses and other providers to a significant increase in methadone-related overdose deaths. The letter from Dr. Laura Herrera, a deputy city health commissioner, raised the possibility that the overdoses involved prescriptions for pain. It was a cautionary reminder that health care providers should educate their patients about the proper use of methadone and the lethal risks of taking extra doses.

Dr. Herrera was right to be concerned: Methadone-overdose deaths of city residents have risen from seven in 1995 to 74 in 2007. In 2007, the last year for which statistics are available, there was a 23 percent increase in such deaths over the previous year. The city deaths coincide with a similarly disturbing fivefold increase in methadone-related deaths nationally between 1999 and 2005. But proving that the use of methadone as a pain reliever caused these deaths isn't easy — no one tracks how many physicians prescribe methadone to relieve chronic pain from cancer or arthritis, for example.

Prescribing methadone has been an accepted form of treatment for chronic pain for some time, according to pain specialists at Johns Hopkins Hospital and the University of Maryland Medical Center. They add that they have seen no methadone-related deaths among their patients. Methadone used for pain treatment is prescribed in pill form; its risk stems from the drug's potency and its lingering presence in the body once its pain-relieving function has ceased. An extra dose could slow down a patient's breathing, resulting in coma or death.

To identify the extent of the problem and the patients most at risk, the city Health Department has reviewed data from the medical examiner's office. It also has asked the quasi-public city agency that oversees drug treatment in Baltimore to cross check methadone overdose victims against its patient rosters. That's a critical aspect of the review because it could uncover misuse, abuse or diversion of methadone



Methadone tablets in a cup. BALTIMORE SUN PHOTO: JED WIRSCHING

from drug treatment centers. Or it could lend credence to the prevailing view that more training is required for private physicians who prescribe methadone for pain.

At least 29 states have prescription monitoring programs that would identify indiscriminate prescribing, doctor-shopping and other abuses. A task force established this year in Maryland is studying the possibility of establishing a similar tracking system for methadone and other controlled substances.

Until then, Dr. Herrera and her colleagues at the Health Department have moved expeditiously and forthrightly to unravel this mystery. The results of their findings are the key to understanding and reversing this disturbing trend.

400 Greenley Road
Sonoma, CA 95370



The Union Democrat

THE MOTHER LODE'S LEADING INFORMATION SOURCE

Report finds trends in child deaths

By ALISHA WYMAN
The Union Democrat

Prescription drug abuse, suicide and vehicle accidents were the most prevalent causes of death last year among children and young adults in Tuolumne County, according to a recently-released report.

The Child Death Review Team, made up of officials from the Sheriff's Office, the Sonoma Police Department, the Public Health Department, Child Welfare Services and other agencies, examined 11 deaths of youths through age 25. Most were teens and young adults.

One of the concerning trends was a

rise in abuse of prescription drugs, particularly methadone, Sheriff's spokesman Lt. Dan Bressler said.

"What we're finding is even small amounts of methadone mixed with alcohol can cause death," he said. "It doesn't take much."

Three young people died of accidental overdose in 2007, two of which

involved a mixture of alcohol and methadone, a painkiller also used to help with withdrawals of harsher drugs such as heroin.

Tuolumne County isn't the only area to see a rise in prescription drug abuse, said Dr. Todd Stolp, county public health officer.

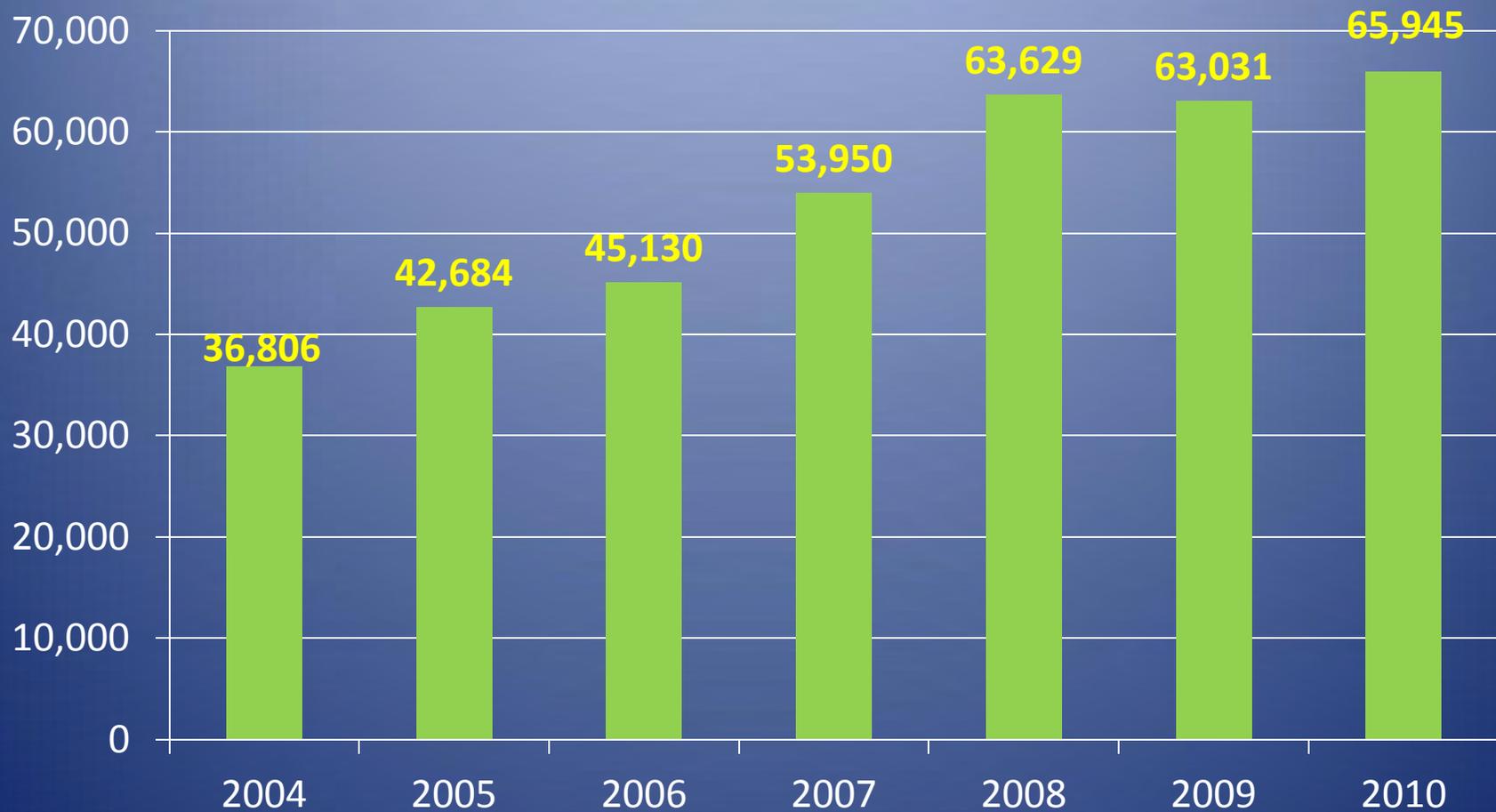
"It's a national issue, but we're in the

process of identifying the extent of the problem and how to address the problem," he said.

There were three suicides in 2007. The number could be higher, however, because there were some drug-related cases in which there wasn't enough

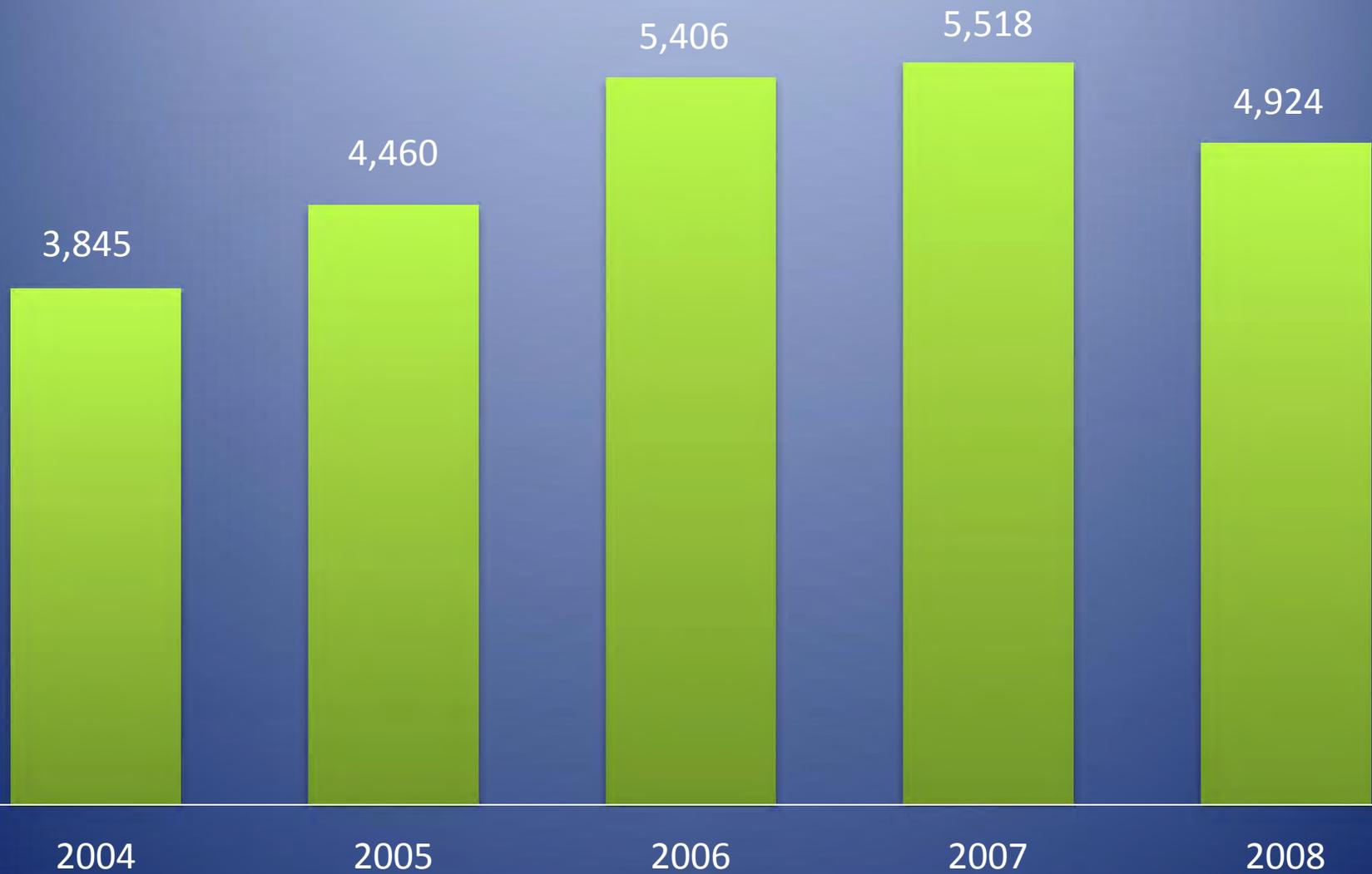
SEE DEATHS PAGE 10

ER visits involving Nonmedical Use of Methadone



Source: Drug Abuse Warning Network (DAWN) 2010 National Estimates of Drug-Related Emergency Department Visits, 2004-2010

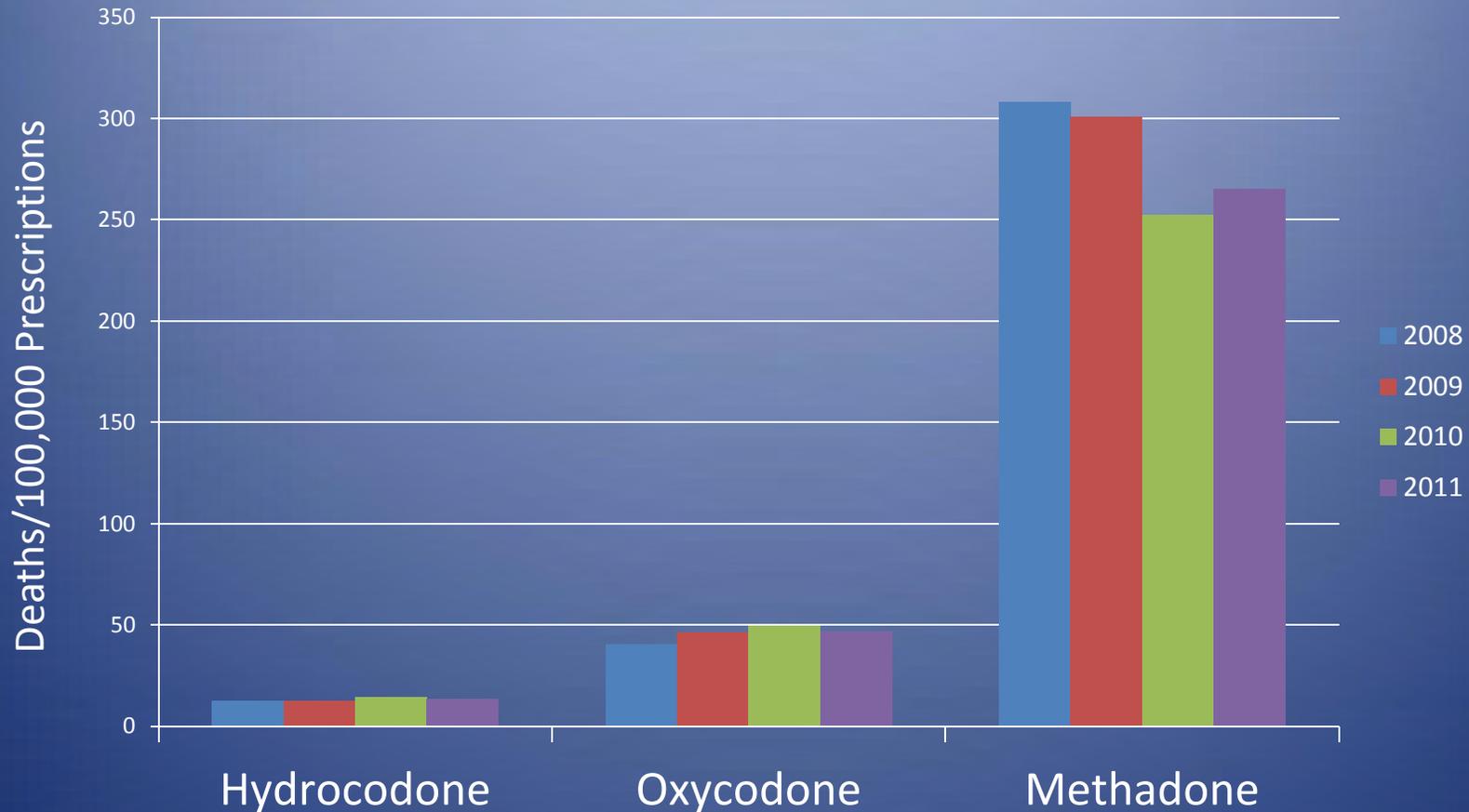
Deaths involving Methadone



Source: NCHS Data Brief #81, December 2011

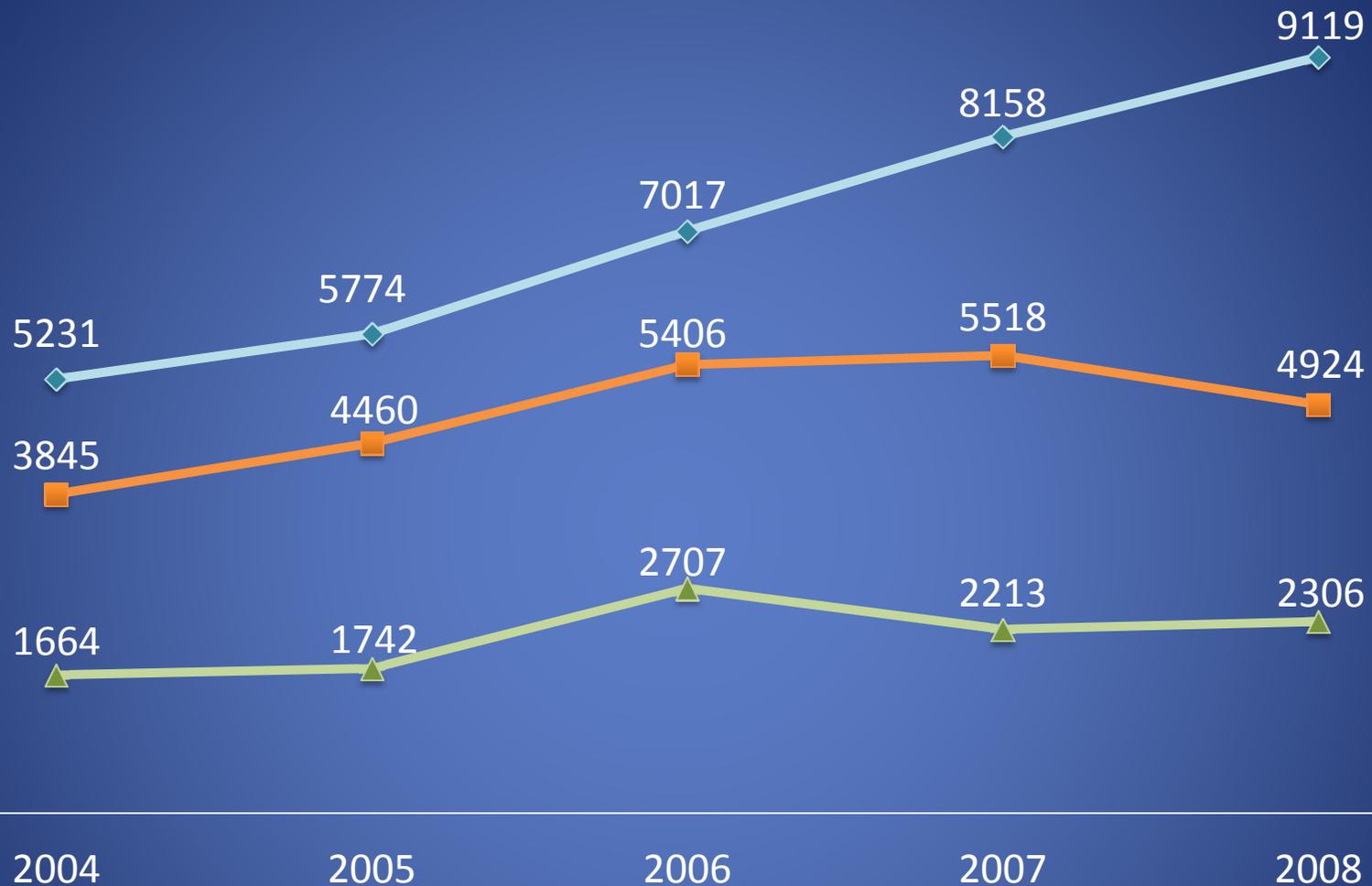
Florida Deaths Per 100,000 Prescriptions

2008-2011



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

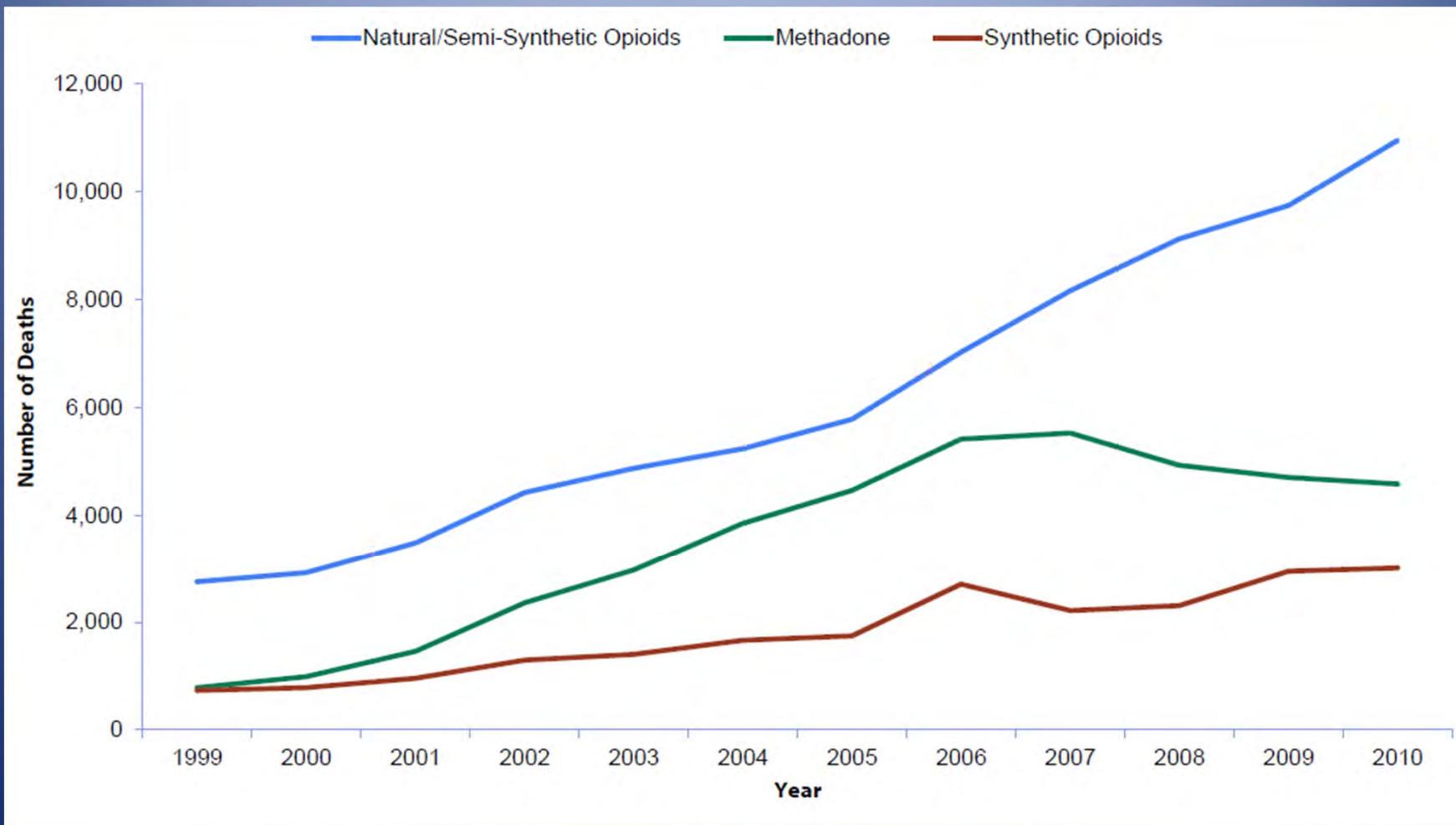
Opioid analgesic involved in deaths



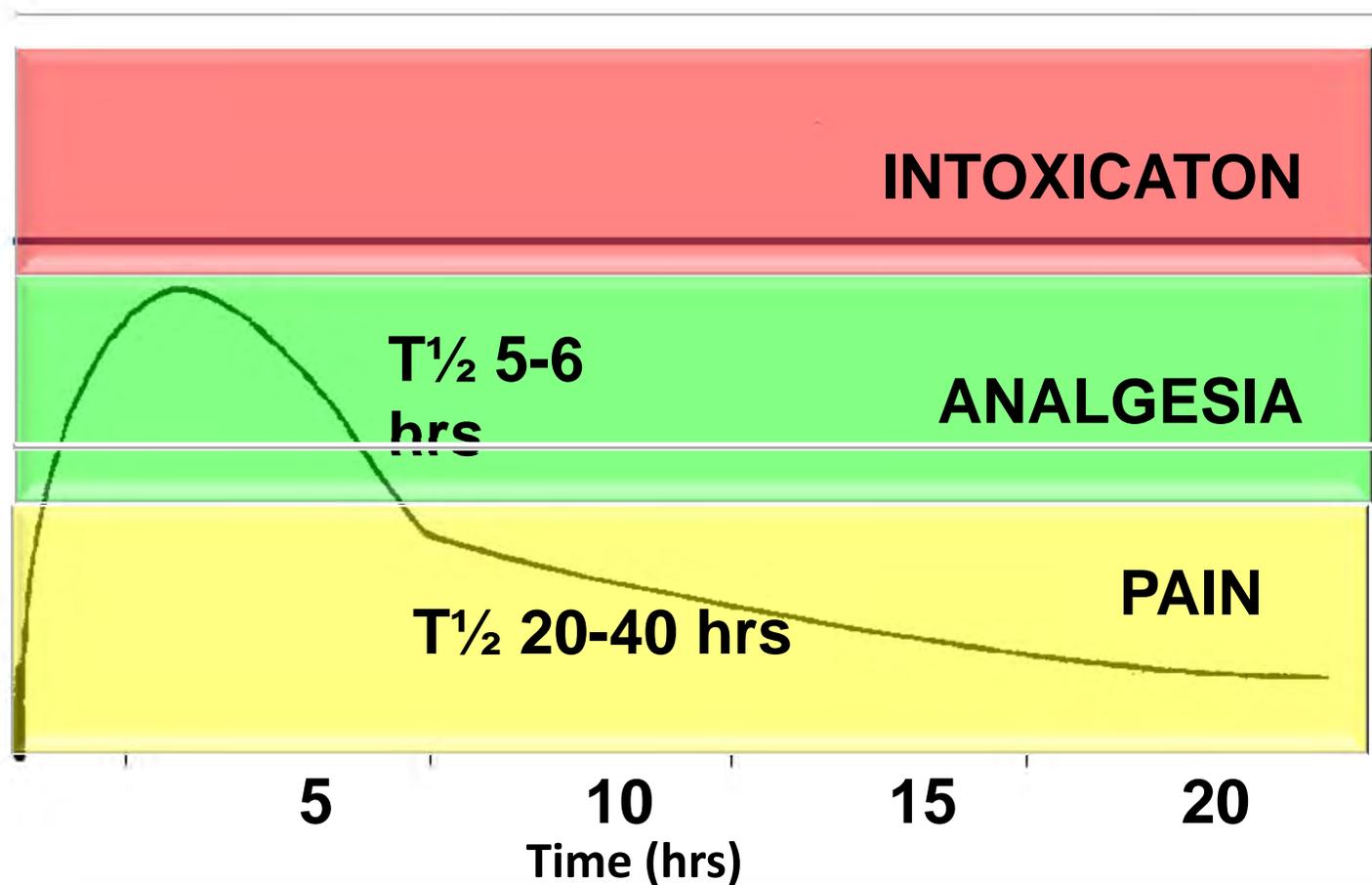
- ◆ Natural and semi-synthetic opioid deaths
- Methadone deaths
- ▲ Synthetic opioid deaths

Source: NCHS Data Brief #81, December 2011

U.S. Drug Overdose Deaths by Type of Opioid Involved, 1999-2010



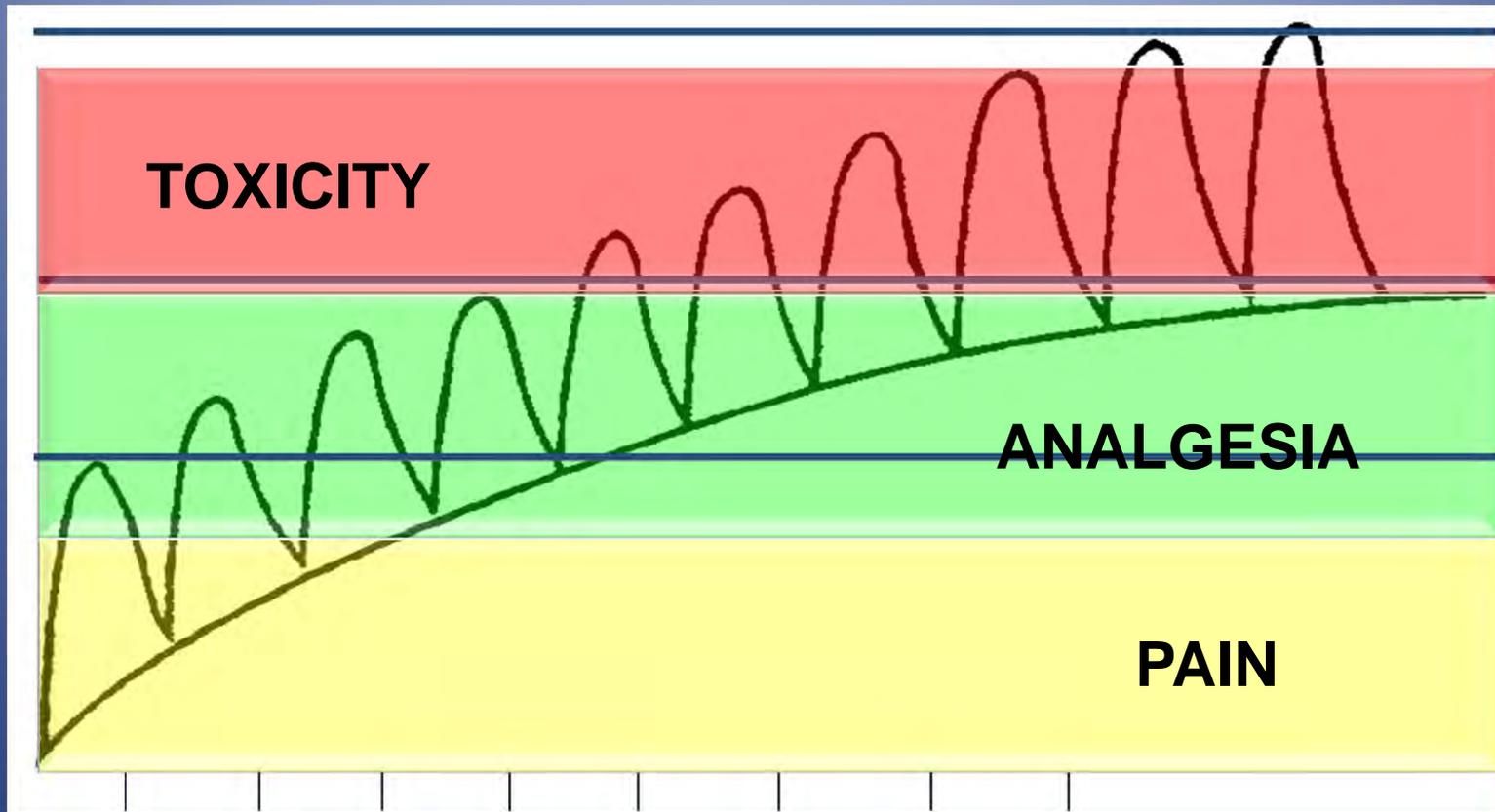
Methadone Single Dose Kinetics



Ref: Nilsson MI, et al. Acta anaesth. scand 1982, Suppl 74, 66-69

Source: Resource Manual for CME course entitled "*Prescribing Opioids for Chronic Pain*" – Offered by the New England Chapters of the American Society of Addiction Medicine with support from CSAT, SAMHSA

Fixed Methadone Dose Interval



Dosage intervals

Ref: Nilsson MI, et al. Acta anaesth. scand 1982, Suppl 74, 66-69

Source: Resource Manual for CME course entitled *"Prescribing Opioids for Chronic Pain"* – Offered by the New England Chapters of the American Society of Addiction Medicine with support from CSAT, SAMHSA

Methadone – Drug Interactions

- CNS depressants (e.g., alcohol, anesthetics, sedatives, other opioids) - Additive effect
- Antiretroviral drugs have variable interactions
- CYP3A4 inhibitors (some antifungal agents, macrolide antibiotics, and SSRIs) – Inhibits elimination
- Grapefruit juice inhibits methadone elimination
- Smoking enhances (CYP1A2) methadone elimination
- Self-inducer – Enhances (3.5 fold between 1st dose and steady state) its own elimination
- Anticonvulsants – Enhances methadone elimination

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, ACEP 1 CE credit for this article

By Jonathan J. Lipman, PhD

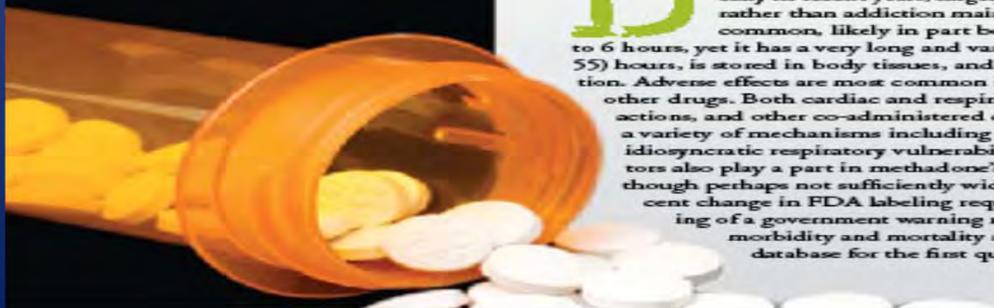
THE METHADONE POISONING "Epidemic"

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

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

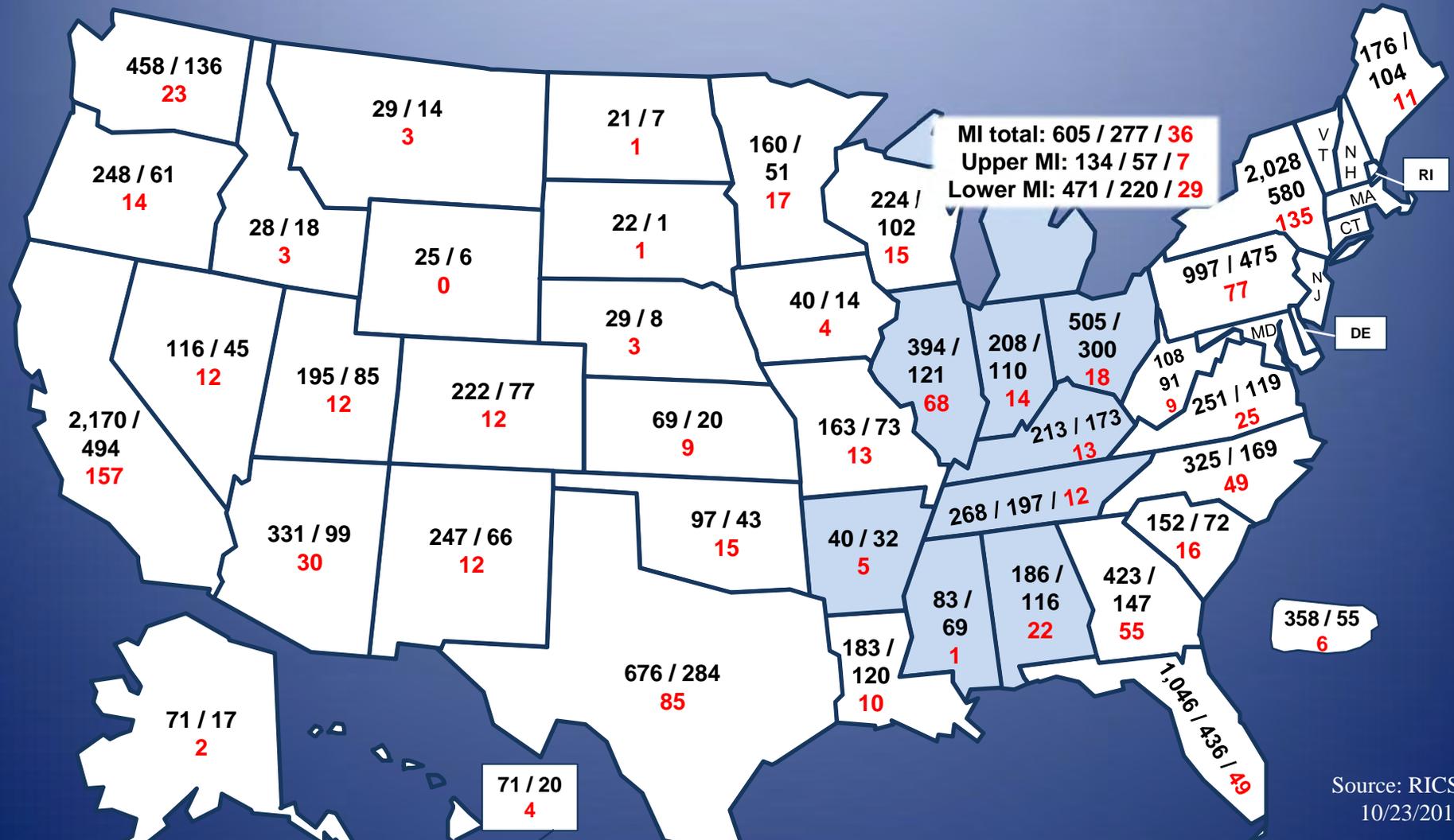


Other FDA Approved Drugs for Narcotic Addiction Treatment

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



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



Key: 1st number = DW 30
 2nd number = DW 100
 3rd number = NTP

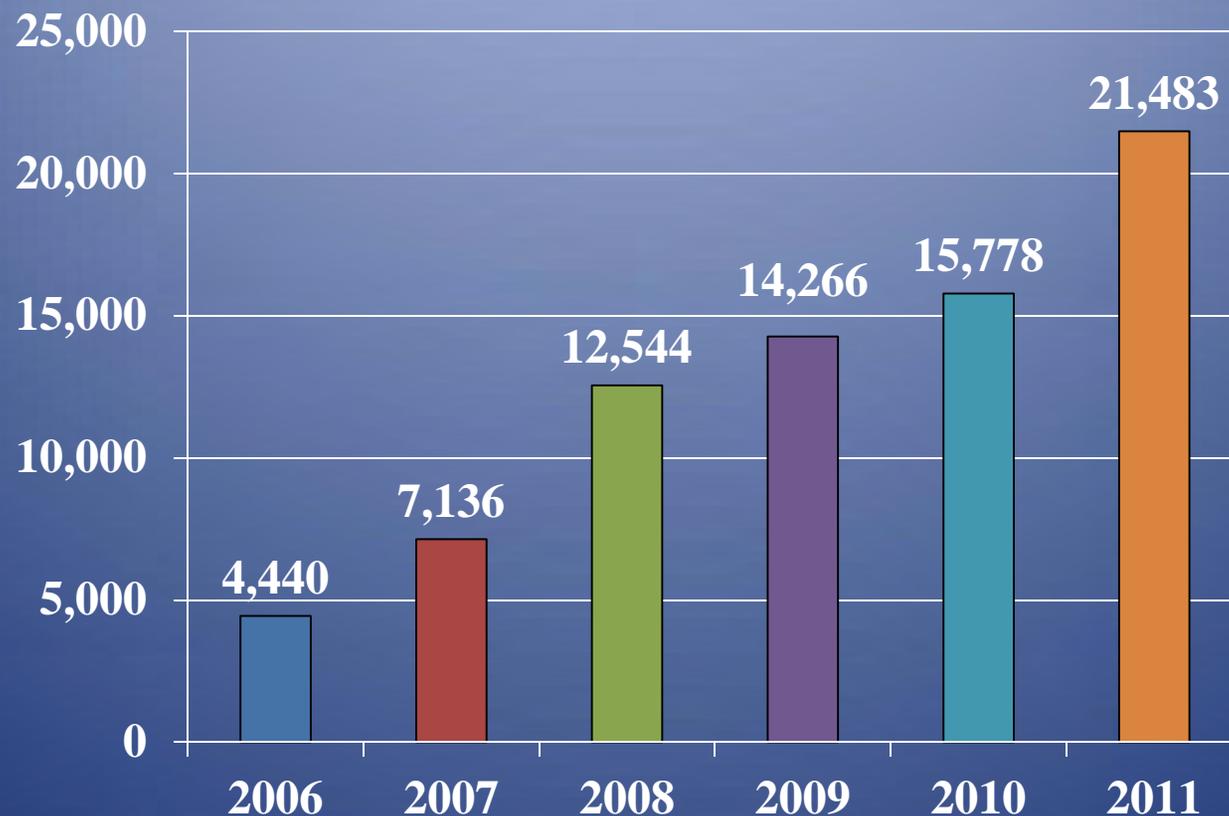
State	DW30	DW100	NTPs
VT	132	40	10
NH	59	34	8
MA	790	380	60

State	DW30	DW100	NTPs
CT	320	147	38
RI	113	60	17
NJ	622	265	36

State	DW30	DW100	NTPs
DE	55	26	9
MD	557	233	66
DC	69	15	5

Source: RICS,
10/23/2013

Emergency Department (ED) Visits Involving Buprenorphine: 2005 - 2011



Source: SAMHSA's Drug Abuse Warning Network, 2011: National Estimates of Drug-Related Emergency Department Visits, published May 2013

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[®] (Z-bars)

C IV

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

* Source IMS Health

** Source Verispan VONA





Stimulants

Amphetamine Salts C-II

- Adderall C-II

Methylphenidate C-II

- Ritalin®
- Concerta®

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

Parents' Lax Attitudes and Permissiveness

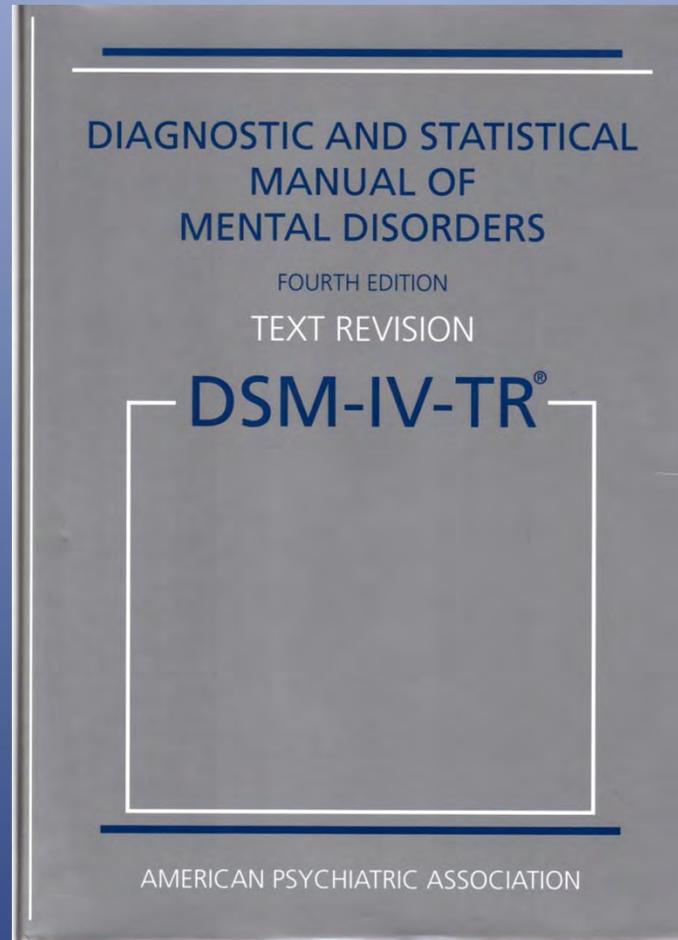
- Approximately 29% of parents surveyed say they believe ADHD medication can improve a child's academic or testing performance, even if the teen does not have ADHD



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

REQUIRED READING



Attention-Deficit and Disruptive Behavior Disorders

Attention-Deficit/Hyperactivity Disorder

Diagnostic Features

The essential feature of Attention-Deficit/Hyperactivity Disorder is a persistent pattern of inattention and/or hyperactivity-impulsivity that is more frequently displayed and more severe than is typically observed in individuals at a comparable level of development (Criterion A). Some hyperactive-impulsive or inattentive symptoms that cause impairment must have been present before age 7 years, although many individuals are diagnosed after the symptoms have been present for a number of years, especially in the case of individuals with the Predominantly Inattentive Type (Criterion B). Some impairment from the symptoms must be present in at least two settings (e.g., at home and at school or work) (Criterion C). There must be clear evidence of interference with developmentally appropriate social, academic, or occupational functioning (Criterion D). The disturbance does not occur exclusively during the course of a Pervasive Developmental Disorder, Schizophrenia, or other Psychotic Disorder and is not better accounted for by another mental disorder (e.g., a Mood Disorder, Anxiety Disorder, Dissociative Disorder, or Personality Disorder) (Criterion E).

Inattention may be manifest in academic, occupational, or social situations. Individuals with this disorder may fail to give close attention to details or may make careless mistakes in schoolwork or other tasks (Criterion A1a). Work is often messy and performed carelessly and without considered thought. Individuals often have difficulty sustaining attention in tasks or play activities and often find it hard to persist with tasks until completion (Criterion A1b). They often appear as if their mind is elsewhere or as if they are not listening or did not hear what has just been said (Criterion A1c). There may be frequent shifts from one uncompleted activity to another. Individuals diagnosed with this disorder may begin a task, move on to another, then turn to yet something else, prior to completing any one task. They often do not follow through on requests or instructions and fail to complete schoolwork, chores, or other duties (Criterion A1d). Failure to complete tasks should be considered in making this diagnosis only if it is due to inattention as opposed to other possible reasons (e.g., failure to understand instructions, defiance). These individuals often have difficulties organizing tasks and activities (Criterion A1e). Tasks that require sustained mental effort are experienced as unpleasant and markedly aversive. As a result, these individuals typically avoid or have a strong dislike for activities that demand sustained self-application and mental effort or that require organizational demands or close concentration (e.g., homework or paperwork) (Criterion A1f). This avoidance must be due to the person's difficulties with attention and not due to a primary oppositional attitude, although secondary oppositionalism may also occur. Work habits are often disorganized and the materials necessary for doing the task are often scattered, lost, or carelessly handled and damaged (Criterion A1g). Individuals with this disorder

Diagnostic criteria for Attention-Deficit/Hyperactivity Disorder

A. Either (1) or (2):

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

Inattention

- (a) often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities
- (b) often has difficulty sustaining attention in tasks or play activities
- (c) often does not seem to listen when spoken to directly
- (d) often does not follow through on instructions and fails to finish schoolwork, chores, or duties in the workplace (not due to oppositional behavior or failure to understand instructions)
- (e) often has difficulty organizing tasks and activities
- (f) often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (such as schoolwork or homework)
- (g) often loses things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools)
- (h) is often easily distracted by extraneous stimuli
- (i) is often forgetful in daily activities

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

Hyperactivity

- (a) often fidgets with hands or feet or squirms in seat
- (b) often leaves seat in classroom or in other situations in which remaining seated is expected
- (c) often runs about or climbs excessively in situations in which it is inappropriate (in adolescents or adults, may be limited to subjective feelings of restlessness)
- (d) often has difficulty playing or engaging in leisure activities quietly
- (e) is often "on the go" or often acts as if "driven by a motor"
- (f) often talks excessively

Impulsivity

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

- B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.
- C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).

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with successful treatment. On average, individuals with Attention-Deficit/Hyperactivity Disorder obtain less schooling than their peers and have poorer vocational achievement. Also, on average, intellectual level, as assessed by individual IQ tests, is several points lower in children with this disorder compared with peers. At the same time, great variability in IQ is evidenced: individuals with Attention-Deficit/Hyperactivity Disorder may show intellectual development in the above-average or gifted range. In its severe form, the disorder is markedly impairing, affecting social, familial, and scholastic adjustment. All three subtypes are associated with significant impairment. Academic deficits and school-related problems tend to be most pronounced in the types marked by inattention (Predominantly Inattentive and Combined Types), whereas peer rejection and, to a lesser extent, accidental injury are most salient in the types marked by hyperactivity and impulsivity (Predominantly Hyperactive-Impulsive and Combined Types). Individuals with the Predominantly Inattentive Type tend to be socially passive and appear to be neglected, rather than rejected, by peers.

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

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

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

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

ical assessment of Attention-Deficit/Hyperactivity Disorder. Tests that require effortful mental processing have been noted to be abnormal in groups of individuals with Attention-Deficit/Hyperactivity Disorder compared with peers, but these tests are not of demonstrated utility when one is trying to determine whether a particular individual has the disorder. It is not yet known what fundamental cognitive deficits are responsible for such group differences.

Associated physical examination findings and general medical conditions. There are no specific physical features associated with Attention-Deficit/Hyperactivity Disorder, although minor physical anomalies (e.g., hypertelorism, highly arched palate, low-set ears) may occur at a higher rate than in the general population. There may also be a higher rate of accidental physical injury.

Specific Culture, Age, and Gender Features

Attention-Deficit/Hyperactivity Disorder is known to occur in various cultures, with variations in reported prevalence among Western countries probably arising more from different diagnostic practices than from differences in clinical presentation.

It is difficult to establish this diagnosis in children younger than age 4 or 5 years, because their characteristic behavior is much more variable than that of older children and may include features that are similar to symptoms of Attention-Deficit/Hyperactivity Disorder. Furthermore, symptoms of inattention in toddlers or preschool children are often not readily observed because young children typically experience few demands for sustained attention. However, even the attention of toddlers can be held in a variety of situations (e.g., the average 2- or 3-year-old child can typically sit with an adult looking through picture books). Young children with Attention-Deficit/Hyperactivity Disorder move excessively and typically are difficult to contain. Inquiring about a wide variety of behaviors in a young child may be helpful in ensuring that a full clinical picture has been obtained. Substantial impairment has been demonstrated in preschool-age children with Attention-Deficit/Hyperactivity Disorder. In school-age children, symptoms of inattention affect classroom work and academic performance. Impulsive symptoms may also lead to the breaking of familial, interpersonal, and educational rules. Symptoms of Attention-Deficit/Hyperactivity Disorder are typically at their most prominent during the elementary grades. As children mature, symptoms usually become less conspicuous. By late childhood and early adolescence, signs of excessive gross motor activity (e.g., excessive running and climbing, not remaining seated) are less common, and hyperactivity symptoms may be confined to fidgetiness or an inner feeling of jitteriness or restlessness. In adulthood, restlessness may lead to difficulty in participating in sedentary activities and to avoiding pastimes or occupations that provide limited opportunity for spontaneous movement (e.g., desk jobs). Social dysfunction in adults appears to be especially likely in those who had additional concurrent diagnoses in childhood. Caution should be exercised in making the diagnosis of Attention-Deficit/Hyperactivity Disorder in adults solely on the basis of the adult's recall of being inattentive or hyperactive as a child, because the validity of such retrospective data is often problematic. Although supporting information may not always be available, corroborating information from other informants (including prior school records) is helpful for improving the accuracy of the diagnosis.



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



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



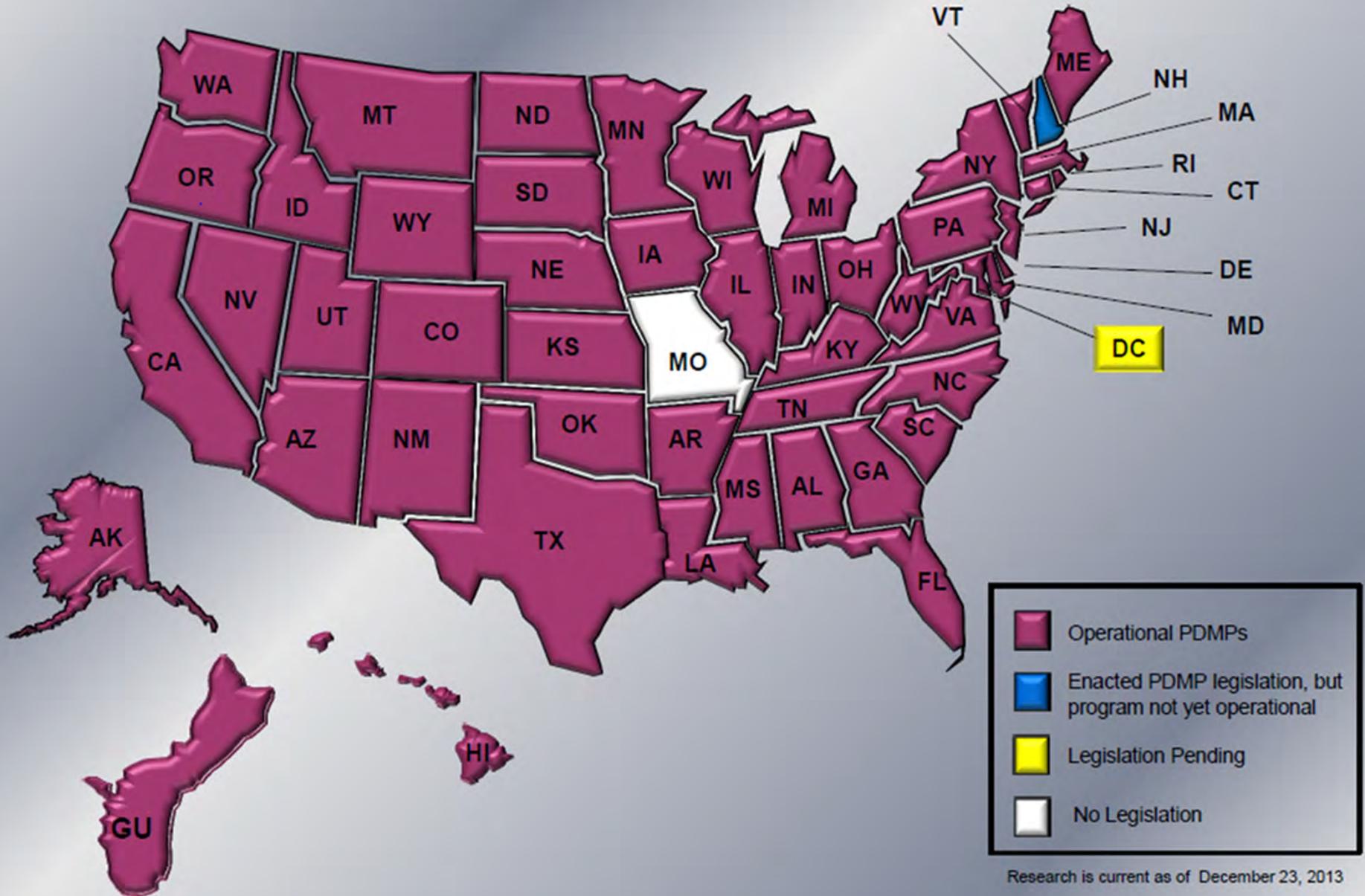
Doctor Shopping



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?

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

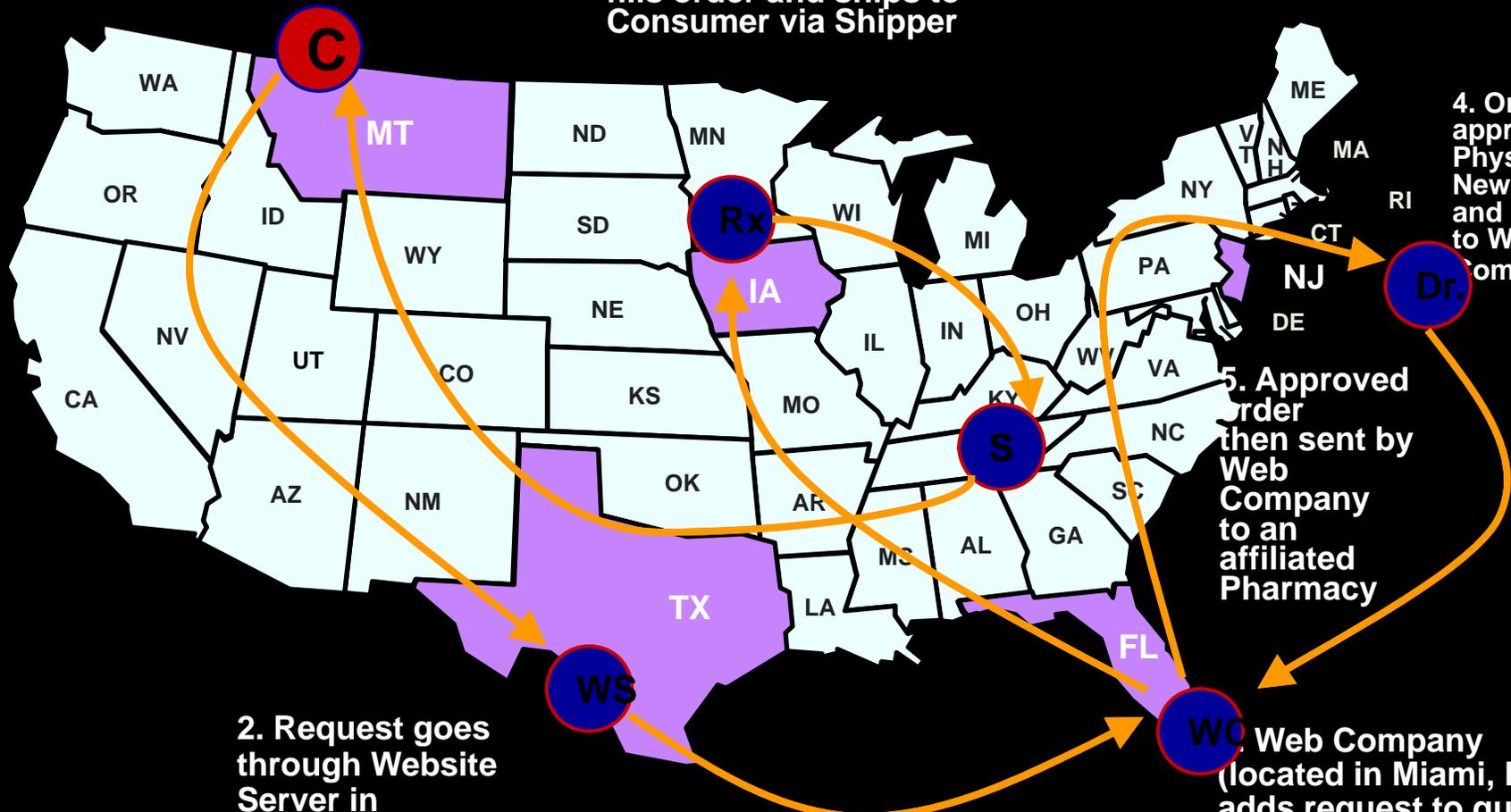
6. Pharmacy in Iowa fills order and ships to Consumer via Shipper

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

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

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

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



New Felony Offense
Internet Trafficking
10/15/2008

What has been the reaction????

Per Se Violations

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

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

Current CSA Registrant Population

Total Population: 1,521,645

➤ Practitioner	-	1,177,445
➤ Mid-Level Practitioner	-	244,344
➤ Pharmacy	-	69,802
➤ Hospital/Clinic	-	16,038
➤ Teaching Institution		315
➤ Manufacturer	-	540
➤ Distributor	-	839
➤ Researcher	-	7,300
➤ Analytical Labs	-	1,524
➤ NTP	-	1,347
➤ Importer/Exporter		474
➤ ADS Machine	-	742
➤ Chemicals	-	1,056

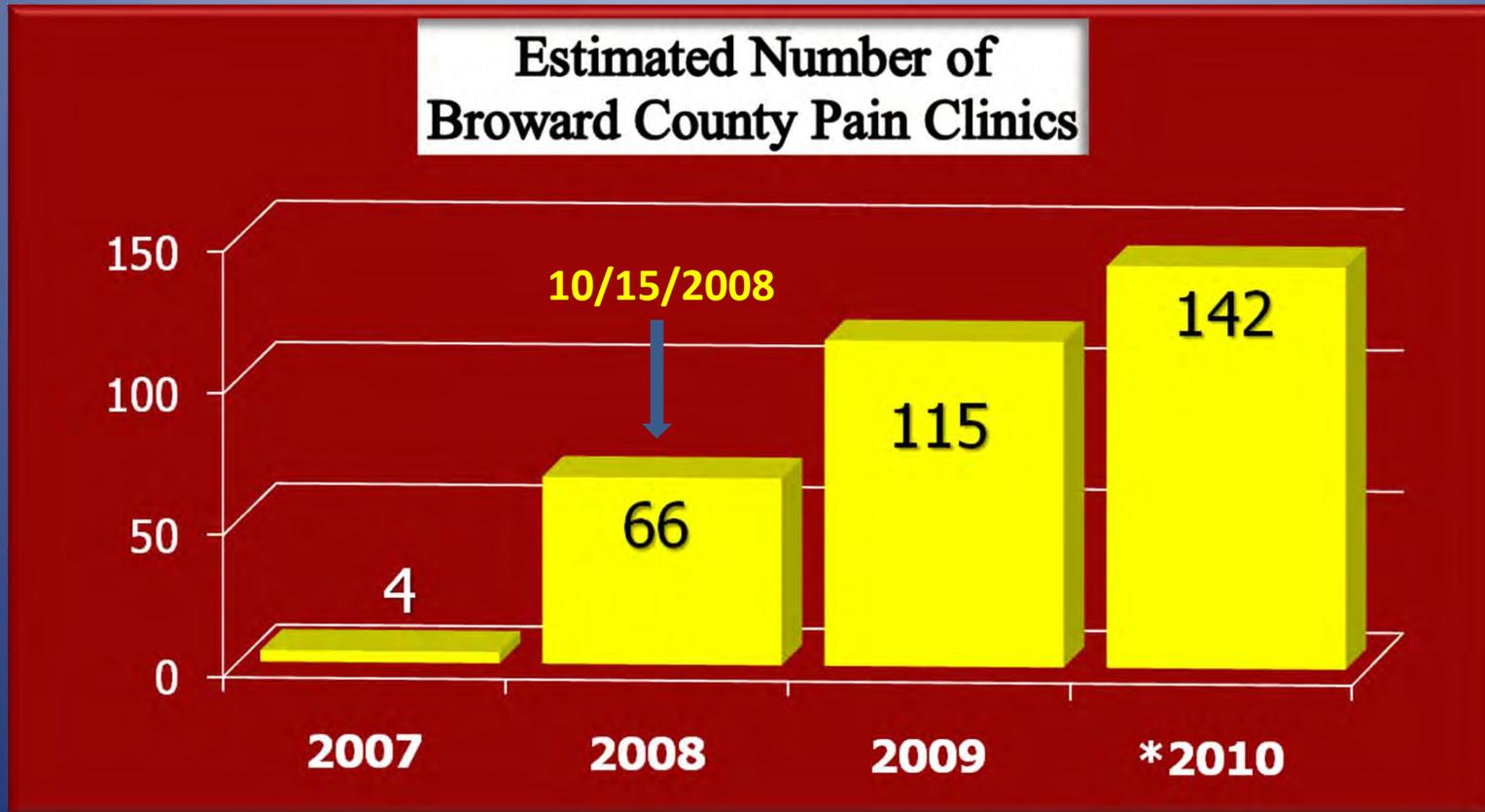
2/08/2014

*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

Medical Care ?

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

Increased Law Enforcement Pressure

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

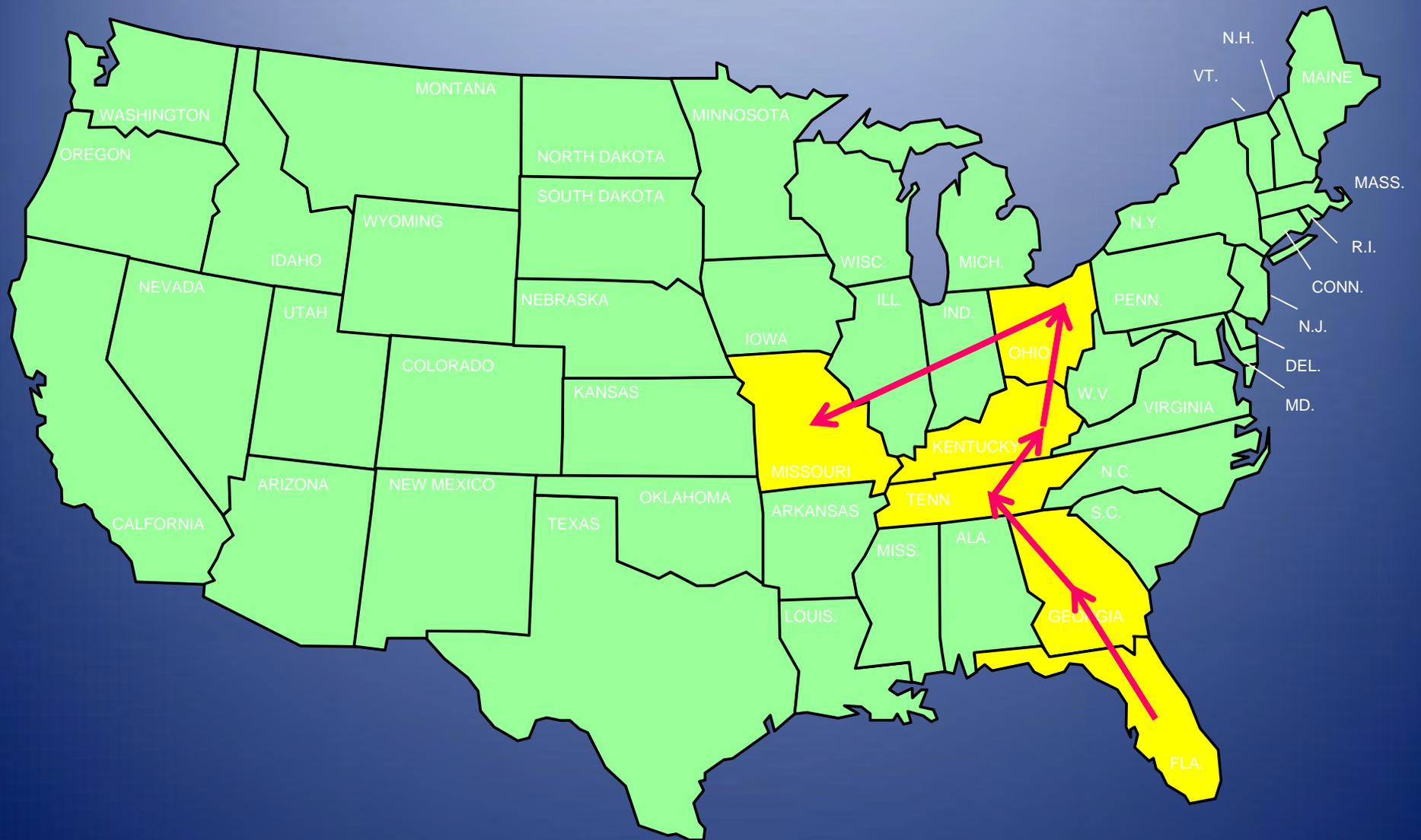
MIGRATION OF PAIN CLINICS



MIGRATION OF PAIN CLINICS



MIGRATION OF PAIN CLINICS



Drugs Prescribed

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

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

Average Charges for a Clinic Visit

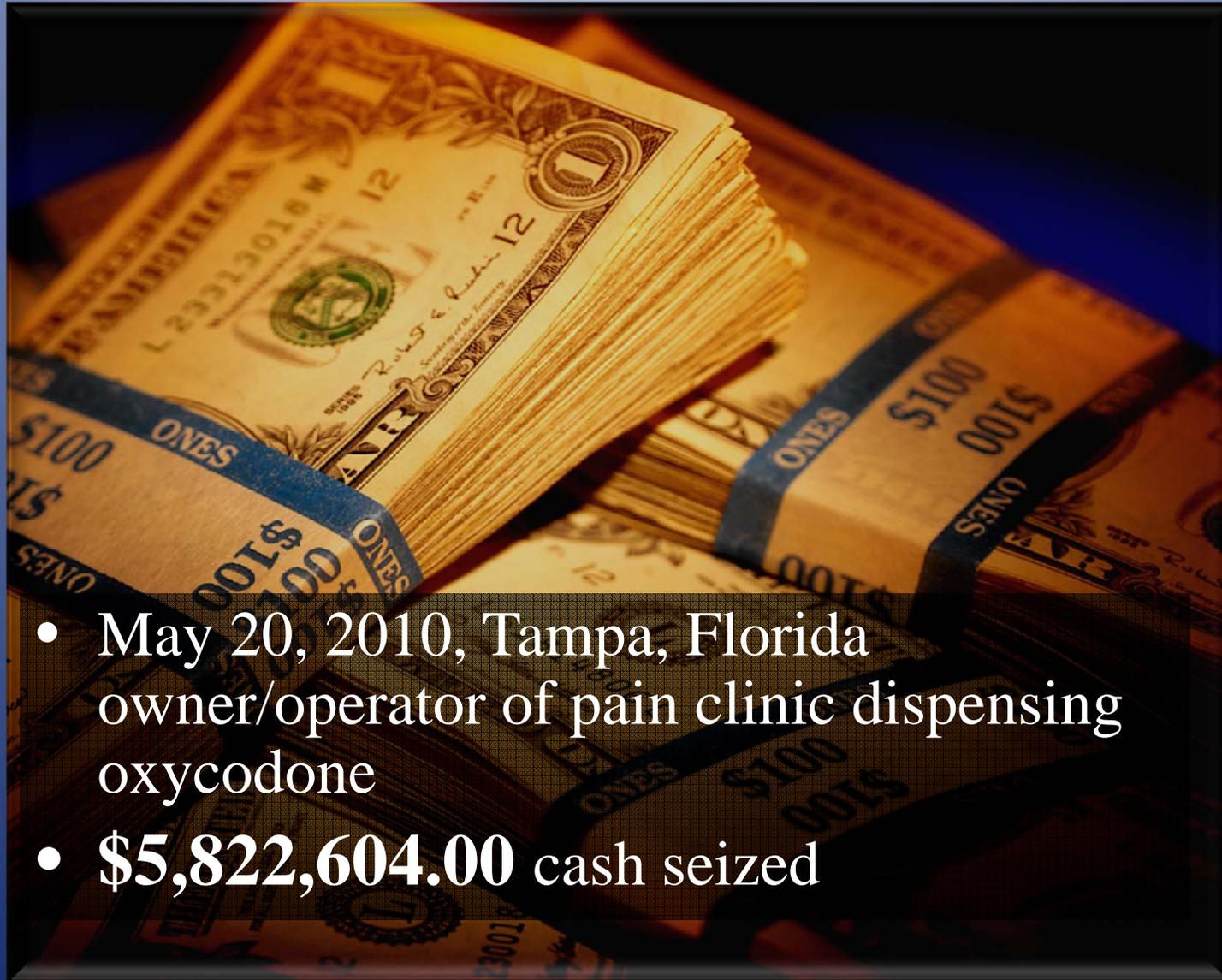
- Price varies if medication is dispensed or if customers receive prescriptions
- Some clinics advertise in alternative newspapers citing discounts for new patients such as 'buy one get one free' or "50% off with this ad"
- Typically, initial office visit is \$250 or more; each subsequent visit may exceed \$200
- Prescriptions average 120-180 30mg oxycodone tablets per visit

Cost of Drugs

- According to medical experts, most clinics do not require sufficient medical history and tests for proper prescribing of Schedule II substances
- Oxycodone 30mg immediate release tablets cost approximately \$30.00 to \$40.00 per tablet on the street depending on the sale location in the U.S. (\$1 per mg or more)

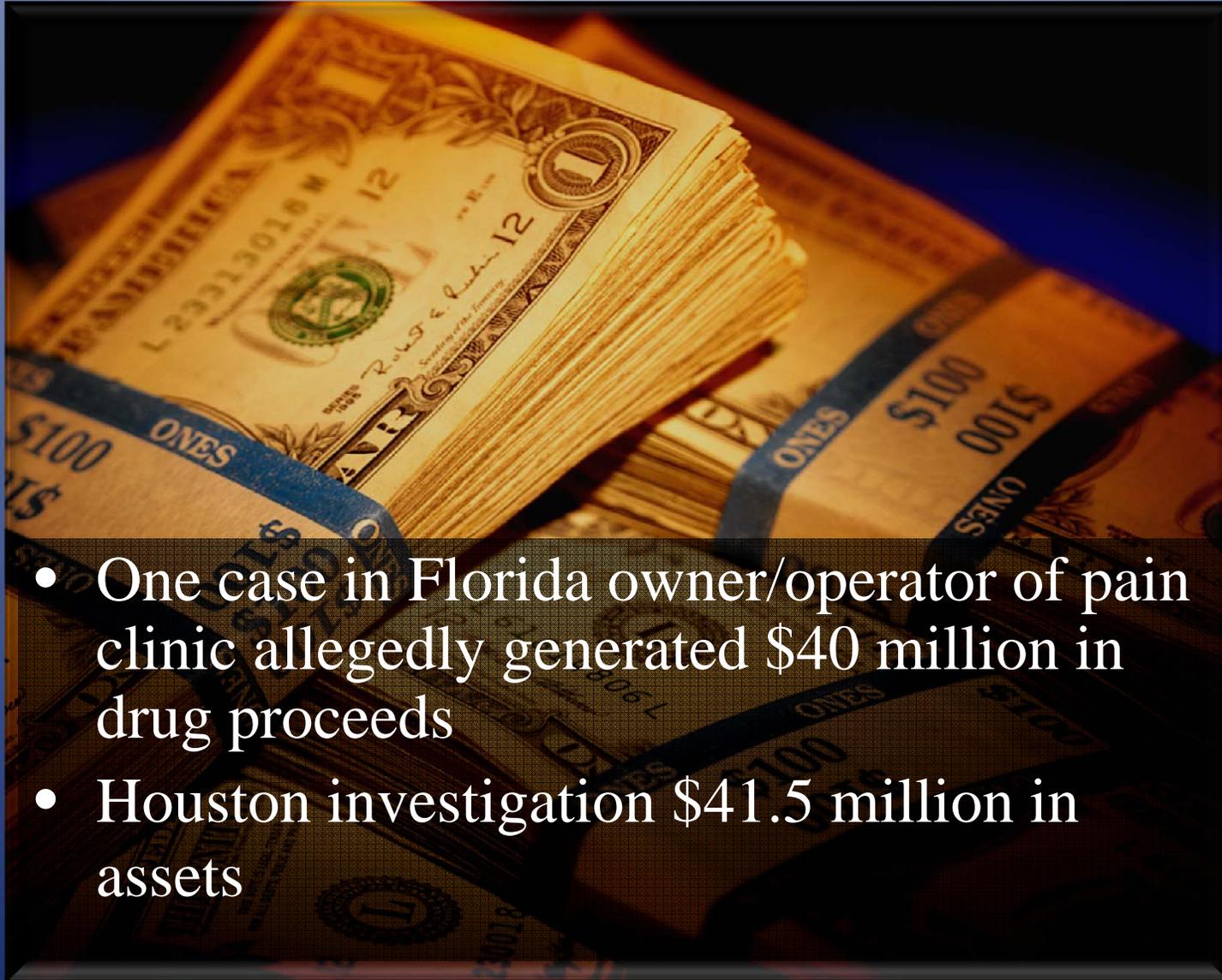
Why is this happening?

What's the Profit?



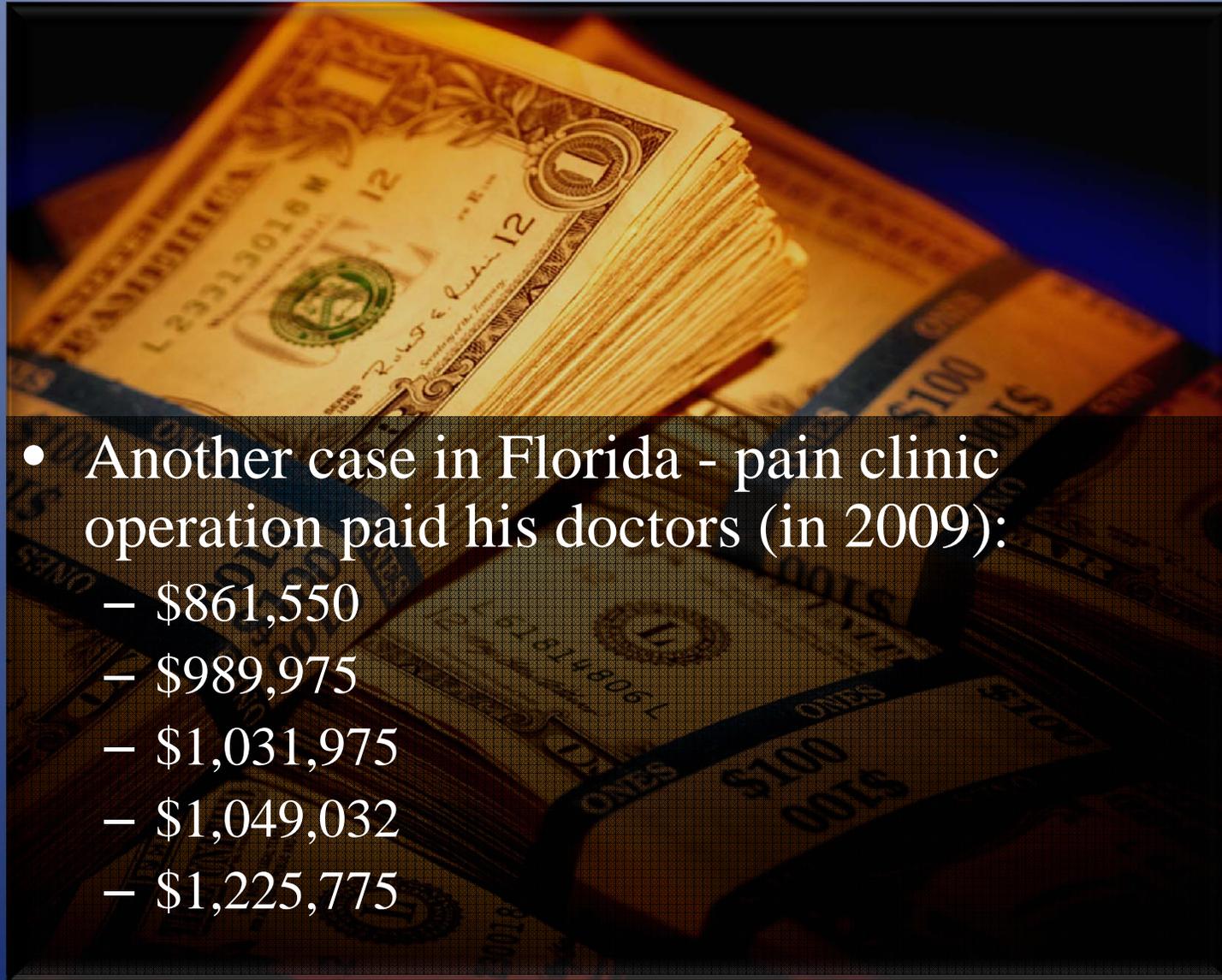
- May 20, 2010, Tampa, Florida owner/operator of pain clinic dispensing oxycodone
- **\$5,822,604.00** cash seized

What's the Profit?



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

What's the Profit?



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

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

Reaction

- Shift from dispensing physicians to prescribing physicians
- New pharmacy applications in Florida increased dramatically in 2010

National Association of Chain Drug Store Response

Patient Advocate, Healthcare Groups Urge Congress to Address Prescription Drug Diversion and Abuse
November 16, 2012

Alexandria, Va. – The National Association of Chain Drug Stores (NACDS) joined pain care advocacy and other healthcare organizations in urging Members of Congress to help address the problem of prescription drug diversion and abuse.

In a letter to the U.S. Senate Health, Education, Labor and Pensions (HELP) Committee, U.S. Judiciary Committee, U.S. House Committee on Judiciary and the U.S. House Energy and Commerce Committee, the organizations urged Congress to create a commission or advisory group to bring together all government agency stakeholders to address the problem.

The groups wrote, “[We] are committed to partnering with law enforcement agencies, policymakers, and others to work on viable strategies to solve the problems of prescription drug diversion and abuse. Although numerous groups and state and federal entities are working to reduce these problems, success remains difficult to achieve. One challenge is that many of these groups and entities are not working in a coordinated manner.”

The letter emphasized the importance of reducing prescription drug diversion and abuse without negatively impacting legitimate patient access and care.

“While appropriate policies must empower law enforcement officials to act aggressively against individuals and entities actually engaging in diversion or abuse, diversion/abuse control actions must be balanced against the needs of healthcare providers to provide care to legitimate patients. We must ensure that legitimate patients receive critical medicines without interruption,” the groups stated in the letter.

In addition to NACDS, the following organizations signed the letter: American Academy of Pain Management (AAPM); American Society for Pain Management Nursing (ASPMN); Center for Practical Bioethics; Inflexion, Inc.; International Nurses Society on Addictions (IntNSA); National Association of Directors of Nursing Administration in Long Term Care (NADONA/LTC); National Fibromyalgia & Chronic Pain Association; *Pain Treatment Topics*; Purdue Pharma L.P.; U.S. Pain Foundation, Virginia Cancer Pain Initiative Inc.

These groups are committed to ensuring patient access to medications they need to help manage their pain, ranging from a variety of health-related issues and diseases. This letter to Congress further stresses the need to find a solution for this problem – and to do so expeditiously.

“Due to the urgent nature of the problems associated with prescription drug diversion and abuse, the advisory group’s recommendations should be provided to Congress within one year of its creation or enactment,” the groups concluded in the letter.



Questions



Thank You!