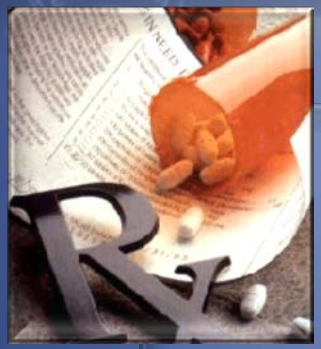
The United States Department of Justice

Drug Enforcement Administration



The Trafficking and Abuse of Prescription Controlled Substances, Legend Drugs and Over the Counter Products

Medical Board of California/California State Board of Pharmacy
Joint Forum to Promote Appropriate Prescribing and Dispensing

San Francisco, California

February 21, 2013

OR

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

- *"When Two Addictions Collide"*

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

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

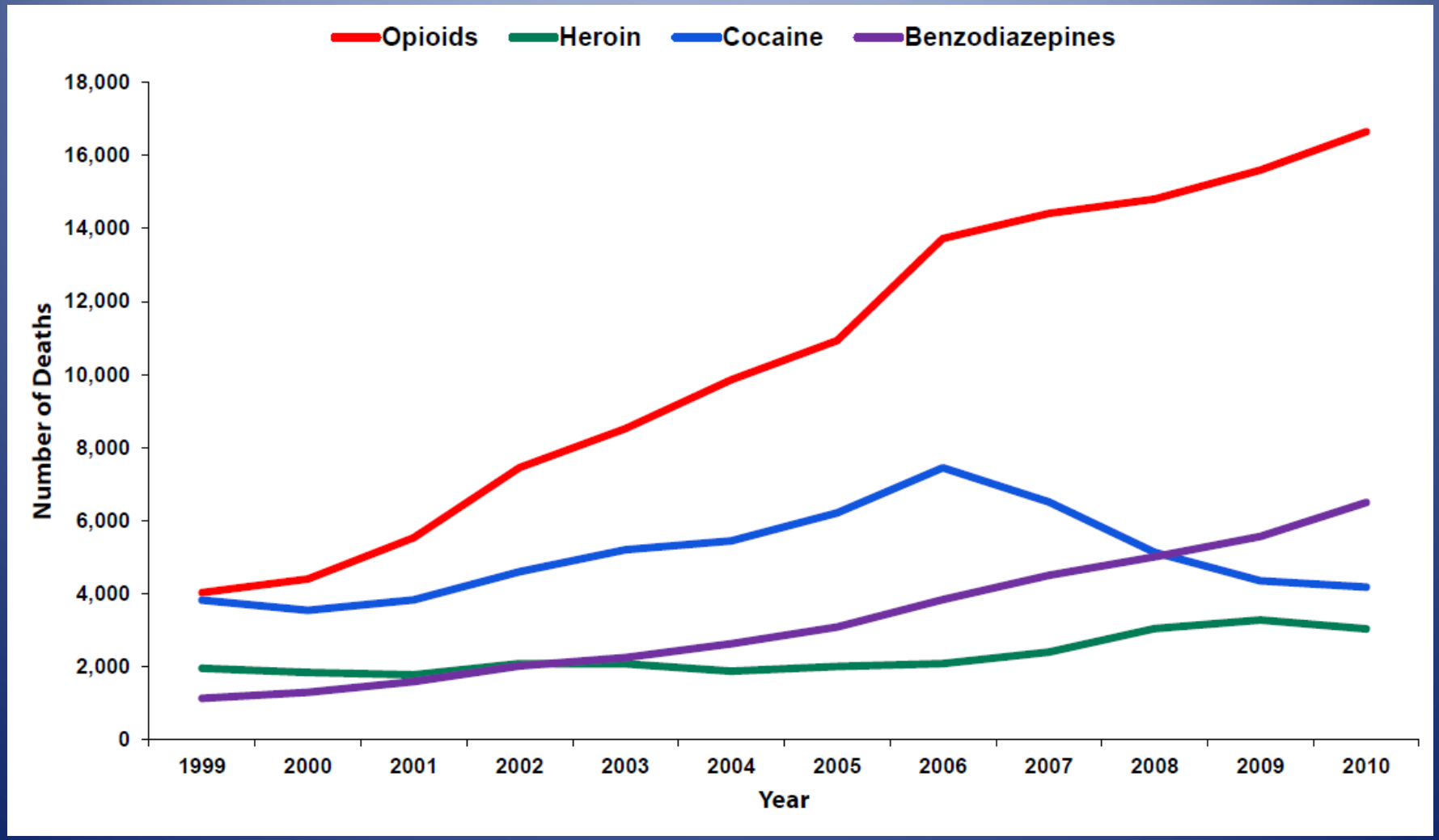
In 2010, approximately 38,329 unintentional drug overdose deaths occurred in the United States, one death every 14 minutes.

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.

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

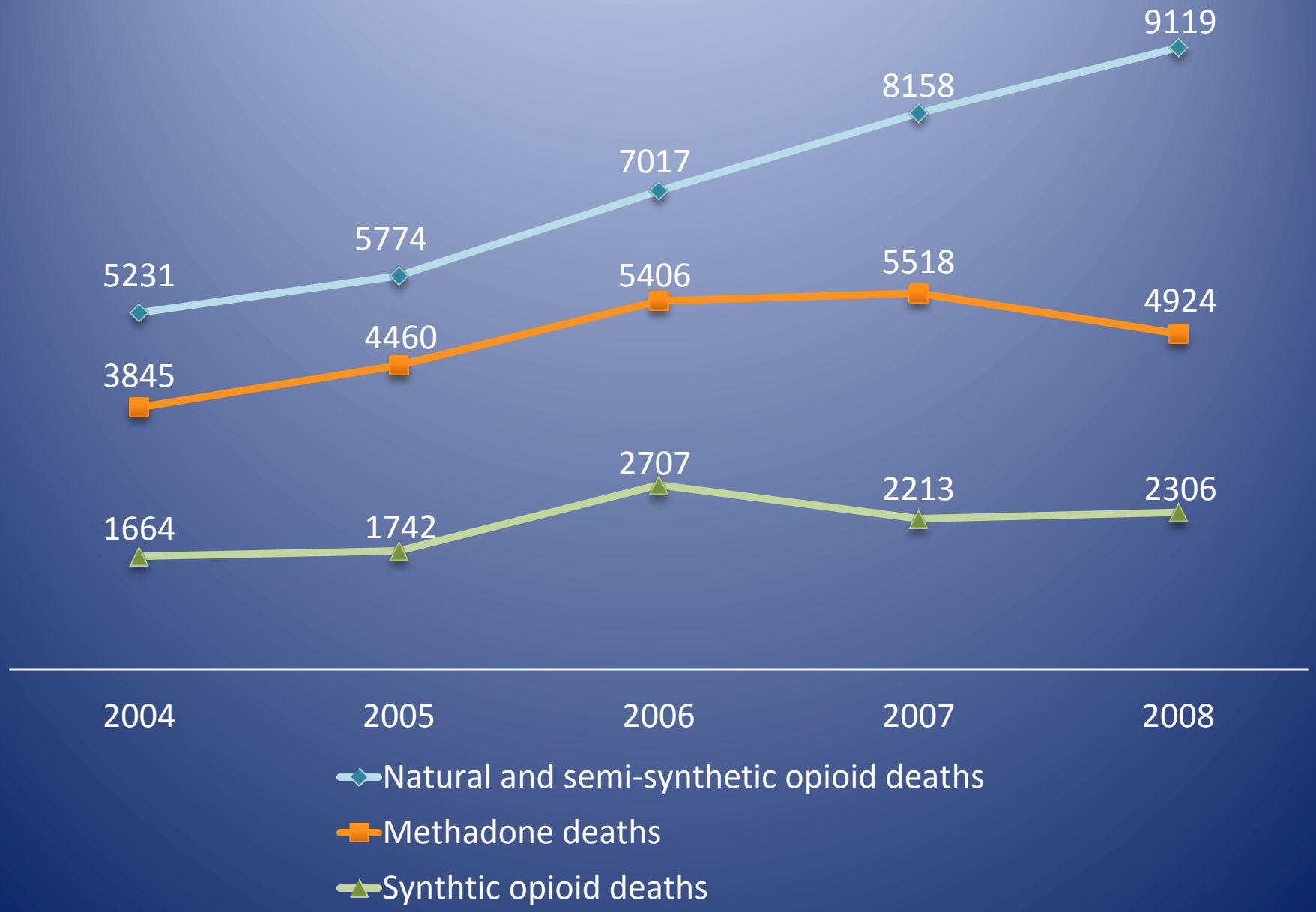
U.S. Drug Overdose Deaths by Major Drug Type, 1999-2010



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

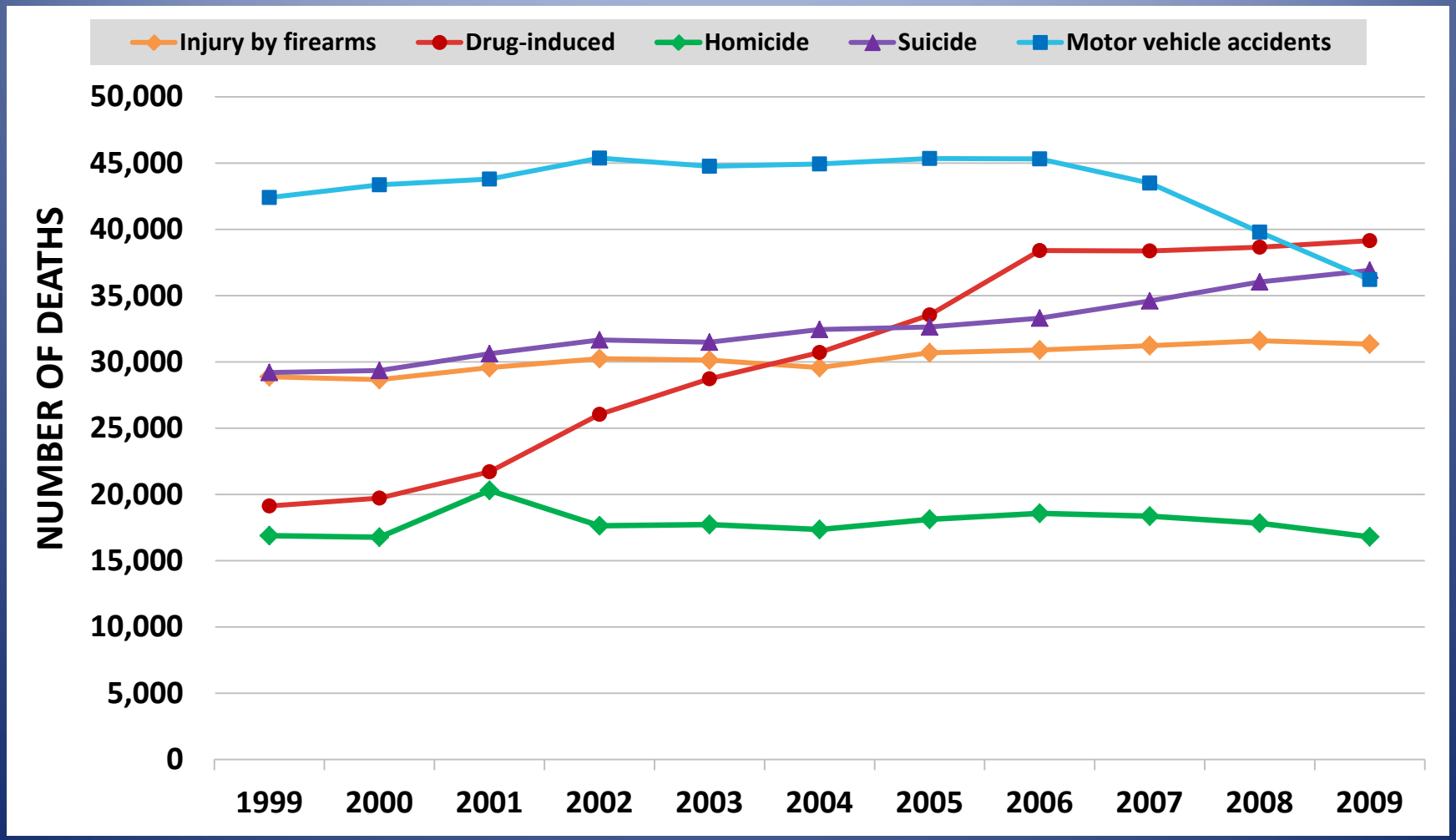
Source: CDC/NCHS, NVSS

Opioid analgesic involved in deaths



Source: NCHS Data Brief #81, December 2011

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).

2010 Current Users (Past Month) 2011

2010	2011
ANY ILLICIT DRUG: 22.6 million	ANY ILLICIT DRUG: 22.5 million
MARIJUANA: 17.4 million	MARIJUANA: 18.1 million
PSYCHOTHERAPEUTIC DRUGS: 7 million	PSYCHOTHERAPEUTIC DRUGS: 6.1 million
COCAINE: 1.5 million	COCAINE: 1.4 million
Methamphetamine 353,000	Methamphetamine 439,000
Heroin: 239,000	Heroin: 281,000

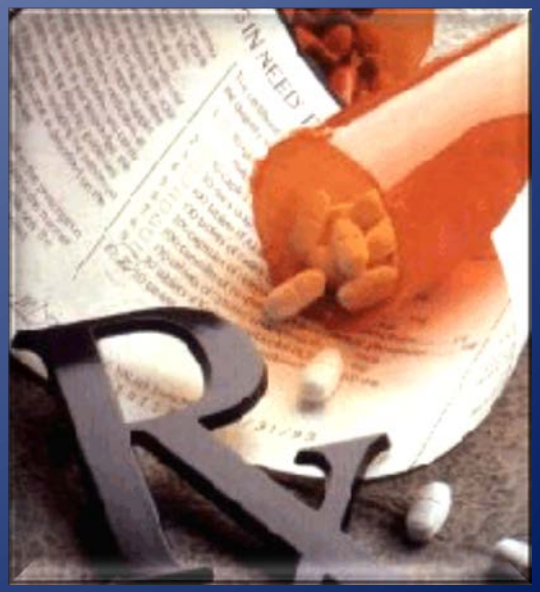
Source: 2010 & 2011NSDUH

Prescription Drug Abuse

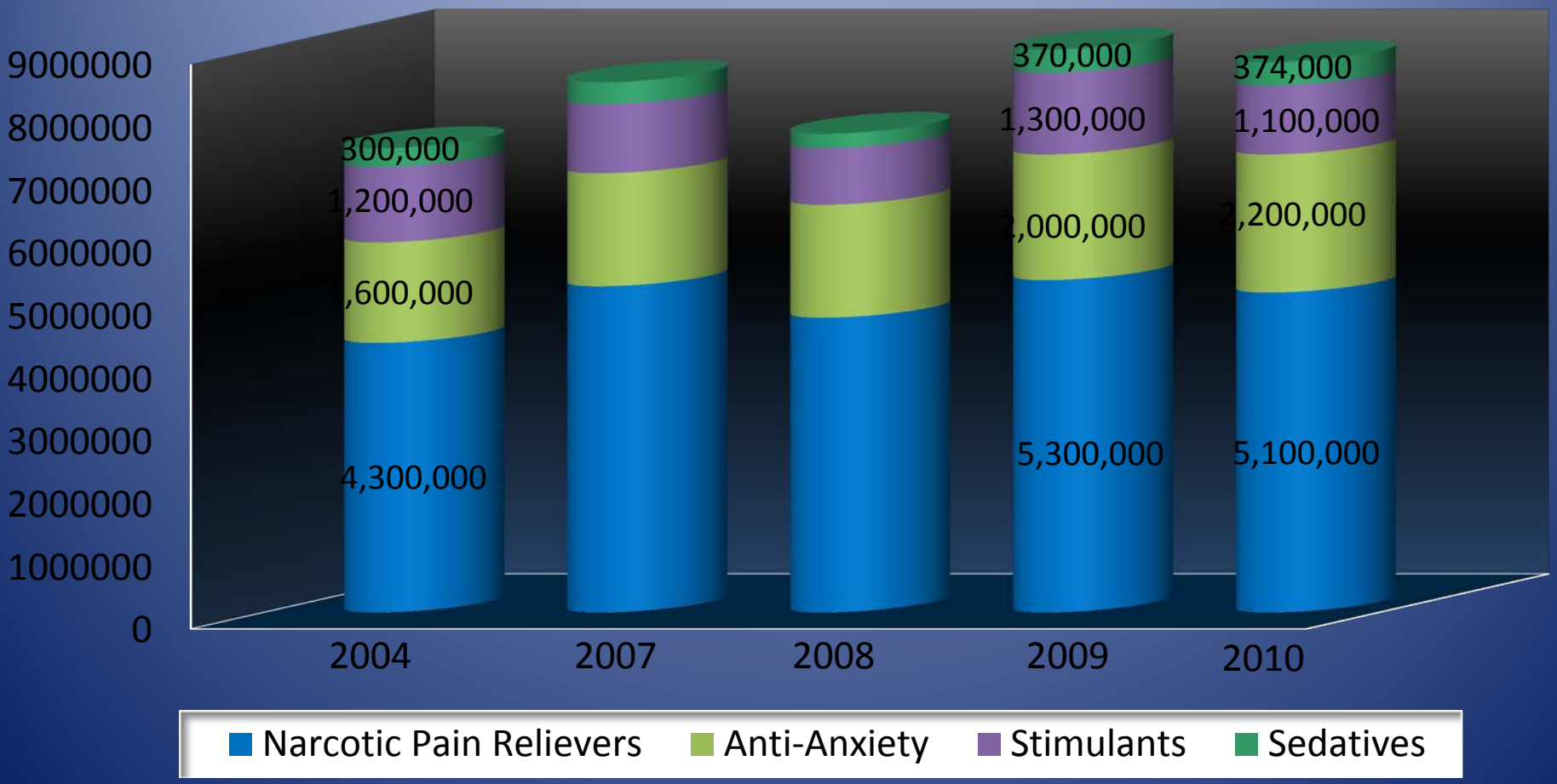
More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Heroin, and Inhalant abusers

COMBINED!!!



Scope and Extent of Problem



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

Economic Impact – The Cascading Effect

2006 estimated cost in the United States from nonmedical use of prescription opioids

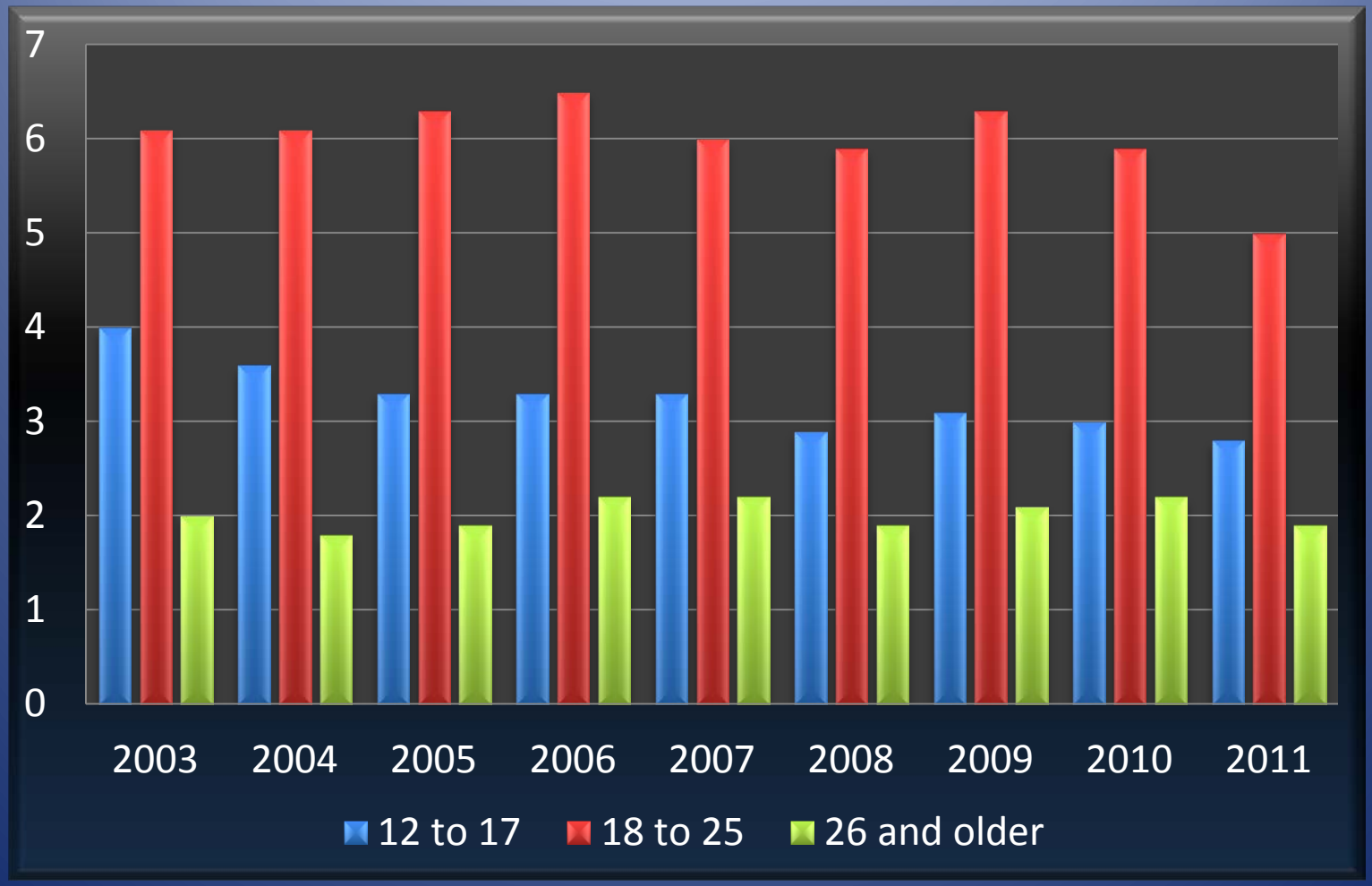
$53.4 BILLION

- $42 billion – Lost productivity
- $8.2 billion – Criminal Justice costs
- $2.2 billion – Treatment costs
- $944 million – Medical complications

Five drugs – OxyContin, oxycodone, hydrocodone, propoxyphene, and methadone accounted for two-thirds of the economic burden

Source: Clinical Journal of Pain, December 2010, University of Washington, Hansen RN; Oster, G; Edelberg, J; Woody, GE; and Sullivan, SD

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



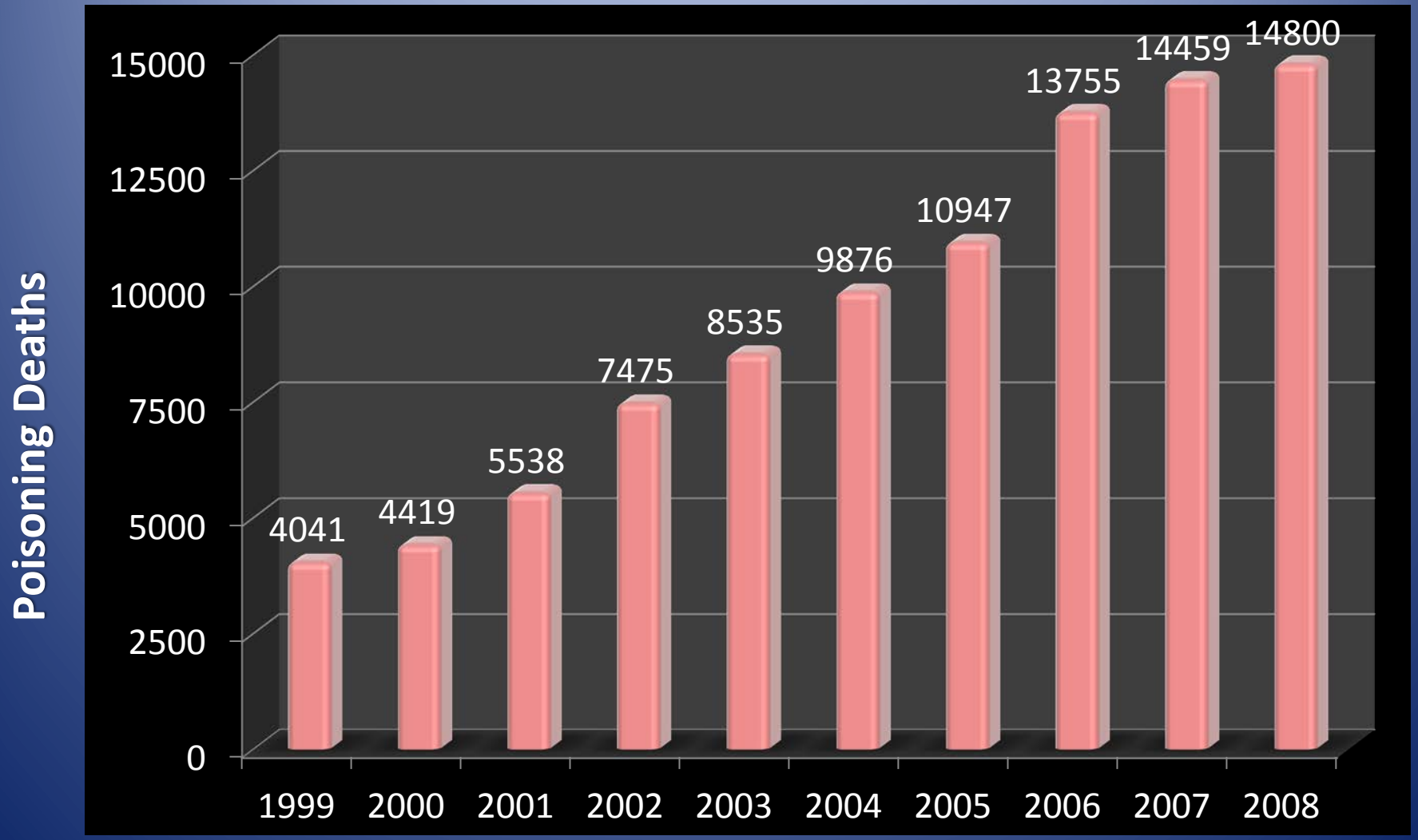
Source: 2011 National Survey on Drug Use and Health

Emergency Room Data 2004-2010

- Increase of 115%: ER visits attributable to pharmaceuticals alone
  (*i.e.*, with no other type of drug or alcohol) (626,472 to 1,345,645)
  - No Significant Change: ER visits attributable to cocaine, heroin, marijuana, or methamphetamine
- Rx Drugs most frequently implicated:
  - **Opiates/Opioids pain relievers**
    - Oxycodone products 255% increase
    - Hydrocodone products 149% increase
- Emergency room data 2004 - 2009
  - Fentanyl products 117.5% increase
  - **Insomnia or Anti-Anxiety medications**
    - Zolpidem 154.9% increase
    - Alprazolam 148.3% increase
    - Clonazepam 114.8% increase
  - **Carisoprodol 100.6% increase**
- For patients aged 20 and younger misuse/abuse of pharmaceuticals increased 45.4%
- For patients aged 20 and older the increase was 111%

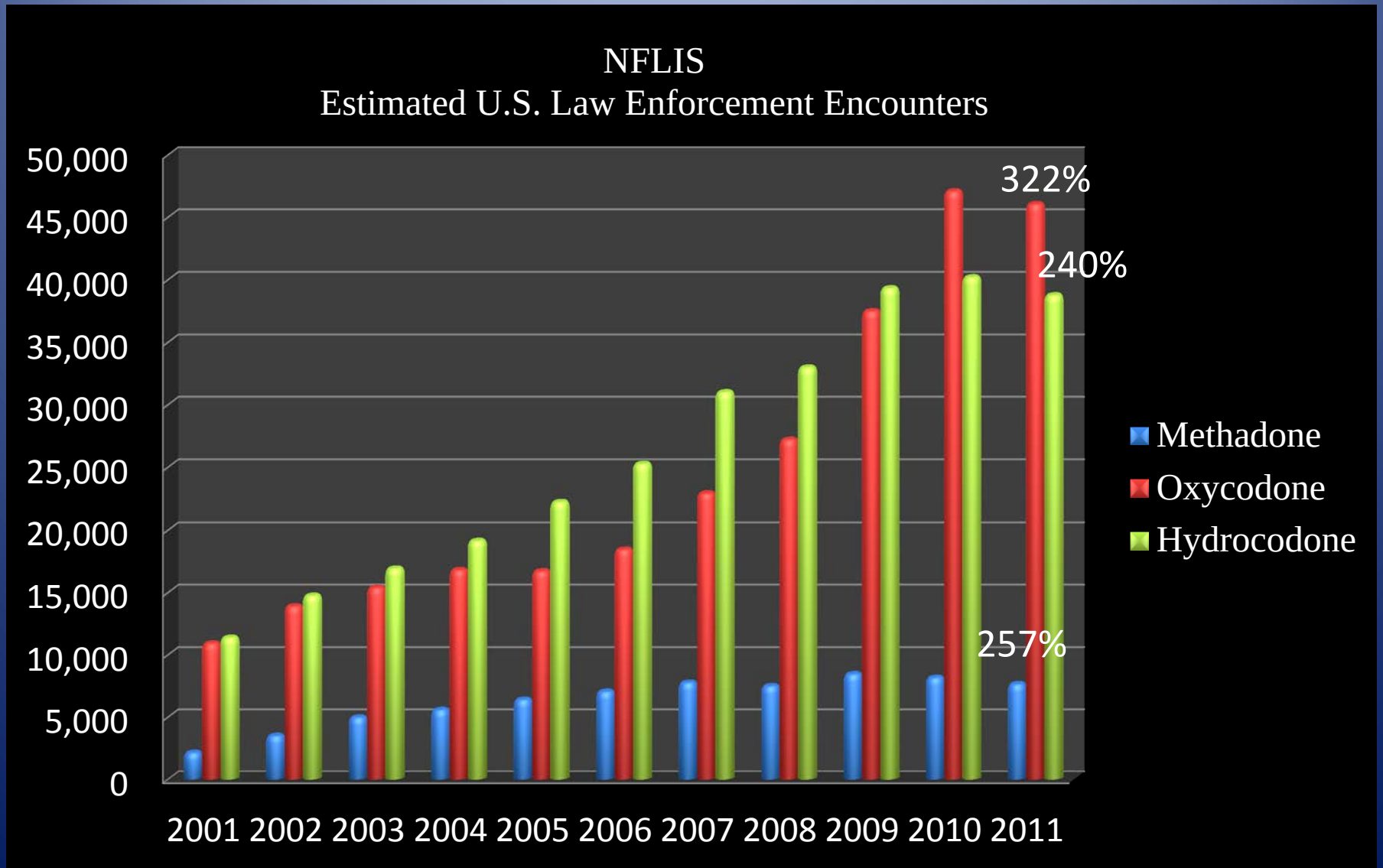
SOURCE: The DAWN Report, *Highlights of the 2009 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits*, December 28, 2010

Poisoning Deaths: Opioid Analgesics



Source: CDC/NCHS, National Vital Statistics System

Number of Forensic Cases 2001-2011



Statistical Perspective

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

Source: U.S. Census Bureau

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.

Rush Limbaugh

Steven Tyler

ABUSERS

Eminem

Brett Farve

Wrestler Benoit's doctor gets 10 years in prison

Updated 5/12/2009 2:34 PM | Comment | Recommend

Enlarge WWE via AP

Wrestler Chris Benoit strangled his wife and 7-year-old son, then hung himself in a June 2007 murder-suicide. Benoit's personal doctor Phil Astin was sentenced to 10 years in prison on Tuesday for illegally distributing prescription drugs to patients.

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

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

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

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

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

"The fact that two people did die outweighs other conditions that I must consider," Camp said.

A federal investigation found Astin wrote prescriptions without conducting physical exams and sometimes gave patients as many as four simultaneous prescriptions for Percocet. He also prescribed "cocktails" of drugs like Percocet, Oxycontin, Vicodin and Adderall.

"Medical doctors know that after a period of time, if the prescriptions are not working, you get them off," Assistant U.S. Attorney John Horn said during the hearing.

Investigators cited one case in which an unidentified female patient began receiving a combination of drugs that included Xanax from Astin in 2002. She died in June 2007, the same month authorities found Benoit and his family dead in their suburban Atlanta home.

Rush Limbaugh Arrested On Drug Charges

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

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

Prosecutors' three-year investigation of Limbaugh began after he publicly acknowledged being addicted to p
rehabilitation program. They accused Limbaugh of "doctor shopping," or illegally deceiving multiple doctors t
learning that he received about 2,000 painkillers, prescribed by four doctors in six months, at a pharmacy ne

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

Coheed and Cambria Bassist Arrested Before Gig

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

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

Rangers' Boogaard died of alcohol, oxycodone mix

Updated 5/20/2011 11:09 PM |

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

The Hennepin County Medical Examiner announced Boogaard's cause of death Friday, saying it was unclear exactly when the 28-year-old died. Boogaard was found dead in his Minneapolis apartment last
nths after he sustained a
concussio

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

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

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

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

Boogaard's agent, Ron Salcer, said it has

Friday, June 3, 2011

Michael Baze accidentally overdosed

Associated Press

LOUISVILLE, Ky. -- Jockey Michael Baze, who won more than 900 horse races in a nine-year career, died from an accidental overdose of cocaine and prescription pain medicine at Churchill Downs, the coroner's office said Friday.

The 24-year-old Baze was pronounced dead on May 10. His body was found in his vehicle near the stables at the famed Louisville track.

Jefferson County Deputy Coroner Jim Wesley said the cause of death was multiple substance intoxication. Significant amounts of cocaine and the pain medication oxymorphone were found in Baze's system, said Wesley, citing toxicology results.

Baze was facing a drug possession charge at the time of his death. The week he died, he was scheduled to appear at a preliminary hearing on a charge of first-degree possession of cocaine. He also w

Baze was arrested last Novembe
to the arrest warrant.

His mother, Teri Gibson, said the

"I honestly thought he was not d

Baze was remembered for his ki

Churchill Downs spokesman Joh
who rode only briefly at Church

Hall of Fame rider Mike Smith n
asleep.

May 08, 2012

Thomas Kinkade cause of death: alcohol, Valium

Recommend 71 0

By Ann Oldenburg, USA TODAY

Updated 2012-05-08 7:18

CAPTION By Gene Blythe, AP

An autopsy has concluded that Thomas Kinkade's death was caused by an accidental overdose.

NBC Bay Area News reported late Monday that the Santa Clara County medical examiner's autopsy is complete and reveals that Kinkade died April 6 at his California home from a combination of alcohol and prescription drugs. He was 54.

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

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

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

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

DEATHS

Marilyn Monroe
August 5, 1962

Elvis Presley
August 16, 1977

Gerald Levert
November 10, 2006

Anna Nicole Smith
February 8, 2007

Heath Ledger
January 22, 2008

Michael Jackson
June 25, 2009

Luna Vachon
August 27, 2010

Michael Baze
May 10, 2011

Whitney Houston
February 11, 2012

Thomas Kinkade
April 6, 2012

Billy Mays, the late pitchman

Autopsy: Cocaine had role in his death

Hillsborough County spokeswoman Lori Hudson said nothing in the toxicology report indicated the frequency of Mays' cocaine use. Cocaine can raise arterial blood pressure, directly cause thickening of the left wall of the ventricle and accelerate the formation of atherosclerosis in the coronary arteries, the release said.

The toxicology tests also showed therapeutic amounts of painkillers hydrocodone, oxycodone and tramadol, and anti-anxiety drugs alprazolam and diazepam. Mays had suffered hip problems and was scheduled for hip-replacement surgery the day after he was found dead.

condo June 28.

Mays, 50, was a pop-culture fixture with his energetic commercials pitching gadgets and cleaning products like Orange Glo and OxiClean.

Heart disease was the primary cause of death, and a report released Friday by the medical examiner listed cocaine as a "contributory cause of death." The office said Mays last used cocaine in the few days before his death but was not under the influence of the drug when he died.

NEWSDAY, SATURDAY, AUGUST 8, 20

Westchase teachers learn a lesson: Say 'no' to mints in pill bottles

One of the mint-filled pill bottles distributed to some fourth graders at Westchase Elementary.

By JOSÉ PATIÑO GIRONA | The Tampa Tribune
Published: February 8, 2010

What two fourth-grade teachers at Westchase Elementary School apparently thought was a creative way to calm students about to take the FCAT made at least one caregiver fear the teachers were sending a different message – that taking drugs while under stress is OK.

Sandy Young walked into her grandson's fourth-grade classroom last Thursday and saw pill bottles on each students' desk. Her mind raced with questions and thoughts of disbelief.

Young said she immediately questioned Westchase Elementary fourth-grade teacher Beth Watson about the pill bottles, which were filled with pieces of small mint candy.

"She said it was nothing but some mints; it was just something special for the kids, for the FCAT to mellow them out," Young said.

Young said she was shocked and speechless and walked out of the room when Watson started the students on a math assignment.

Young said the pill bottles go against the lessons of teaching children to say no to drugs.

"We turn around and we have our teachers giving them drugs," said Young, 60, of Tampa. "I don't care if it's mints or not. ... If it's in a prescription bottle, it's a drug."

Young said the bottle reads in part: "Watson's Whiz Kid Pharmacy. Take 1 tablet by mouth EVERY 5 MINUTES to cure FCAT jitters. Repeated use may cause craft to spontaneously ooze from pores. No refills. Ms. (Deborah) Falcon's authorization required."

The school received one complaint since pill bottles were distributed on Thursday, said Linda Cobbe, a school district spokeswoman. It's believed only two fourth-grade teachers at the school distributed the pill bottles.

The principal met with the students on Monday to confirm the pill bottles contained mints that were safe to eat. The students were asked to dump the mints in a separate container and the pill bottles were thrown away, Cobbe said.

She said the bottle idea was tied to the children's book the students recently read, "George's Marvelous Medicine," about a boy who concocts potions to try to change the disposition of his cranky grandmother.

The teachers were just trying to use a creative way to get across to the students not to be stressed with the FCAT writing examination that will be administered to fourth-, eighth- and 10th-graders beginning today, Cobbe said.

"Elementary teachers do creative things to make learning fun," Cobbe said.

The teachers won't be disciplined, and it wasn't their intention to promote drug use, Cobbe said.

"I know that is not the intent of the teachers," Cobbe said. "That is not the outcome they would wish for."

Young said her grandson has been at Westchase Elementary for a year, and she hasn't had any complaints. But this experience has soured her.

It concerns her that now someone might hand her grandson a pill bottle with drugs and he might think it's OK to consume its contents.

"We as parents and grandparents have to drill it into them that this is unacceptable and hope and pray that they don't accept drugs from someone else," Young said.

Violence

Pharmacy Armed Robberies Rankings by State

January 1 thru December 31, 2011 (701)

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

Source: DEA Drug Theft & Loss Database as of January 9, 2013

Violence Related to Controlled Substance Pharmaceuticals

NEW YORK POST Page Six

TUESDAY, JUNE 21, 2011 / T-storm, 86 / Weather: P. 26 METRO EDITION www.nypost.com $1.00

ASSASSIN

Ready for mayhem, the lunatic strolls through the door.

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

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

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

Chilling anatomy of drugstore massacre

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

PAGES 4-5

NEW YORK POST Page Six

THURSDAY, JUNE 23, 2011 / T-storms, 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

Couple pleads guilty in pharmacy murders

Eyewitness News

MEDFORD (WABC) -- The suspect in the Father's Day massacre at a Long Island pharmacy pleaded guilty to murder charges Thursday. David Laffer has officially withdrawn his not guilty pleas to charges of first-degree murder and criminal use of a firearm and waived his right to appeal. Laffer killed four people at Haven Drugs in Medford before robbing the place of 10,000 hydrocodone pills.

Laffer's wife, Melinda Brady, also pleaded guilty to robbery charges. The judge announced his intention to sentence Laffer to the maximum of four life sentences with no parole, to be served consecutively, and Brady to 21 to 25 years in state prison. Formal sentencing for both husband and wife is scheduled for October 17.

Laffer and Brady were arrested June 22 in their suburban home a mile and a half from Haven Drugs, where authorities say he opened fire on the victims before jamming the backpack full of prescription painkillers.

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.

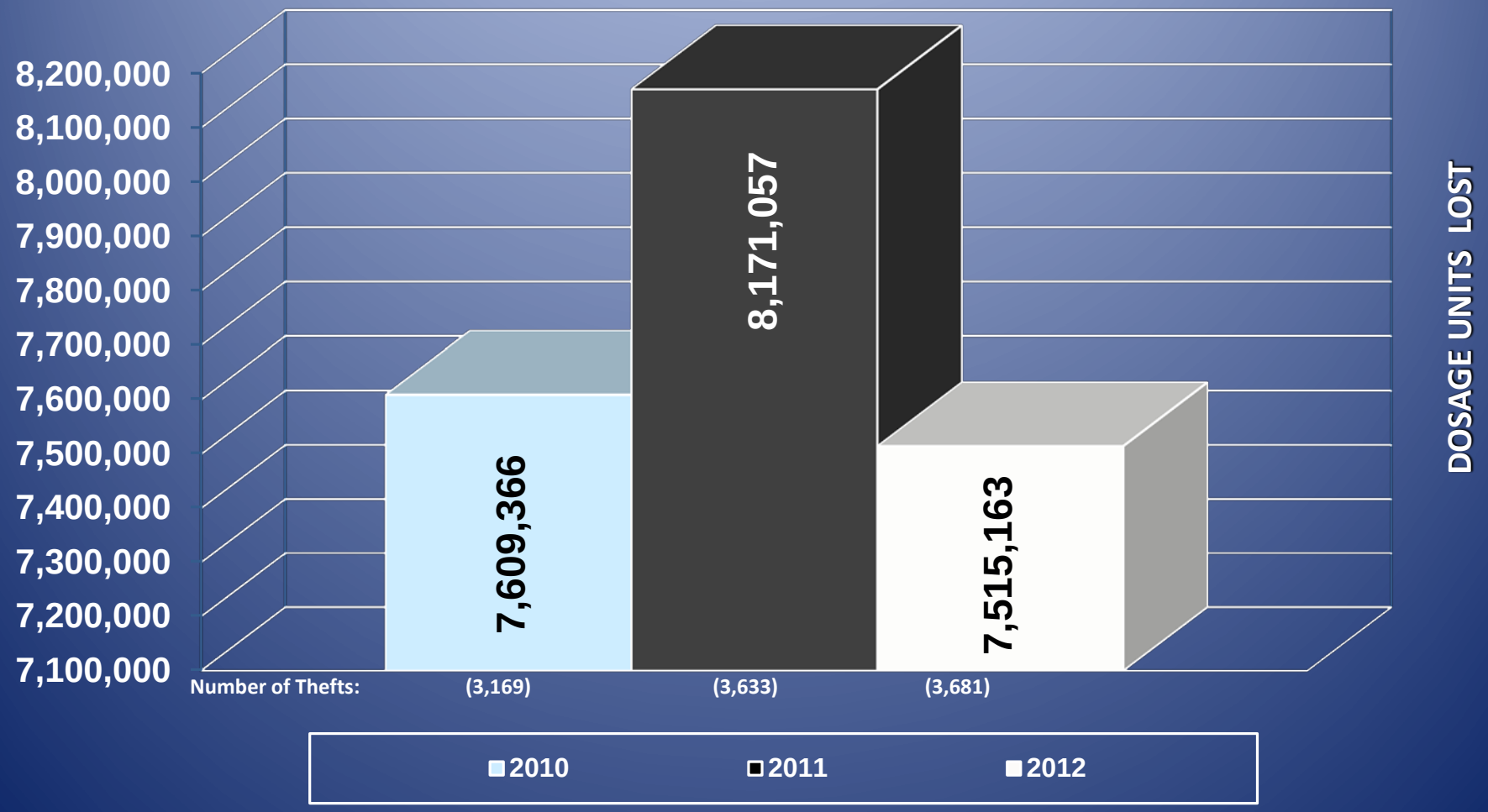
Be the first to rate: ★★★★ Click to rate

Related

Nassau

Cops: Fatal shooting at Seaford drugstore

Comparisons of Hydrocodone Reported Thefts

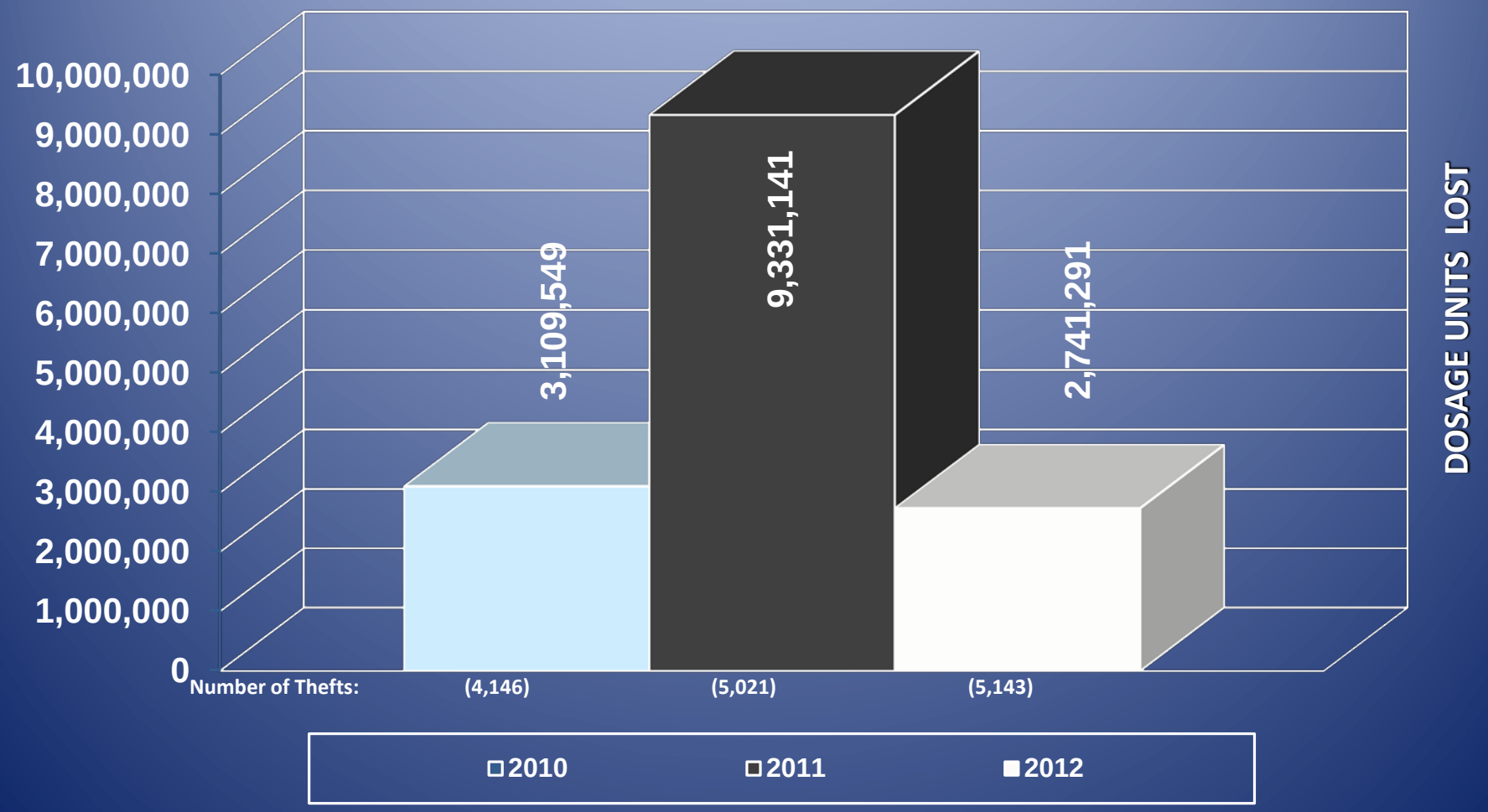


01/01/2012 – 12/31/2012

Source: Drug Theft and Loss
Date Prepared: 02/08/2013

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

Comparisons of Oxycodone Reported Thefts



01/01/2012 – 12/31/2012

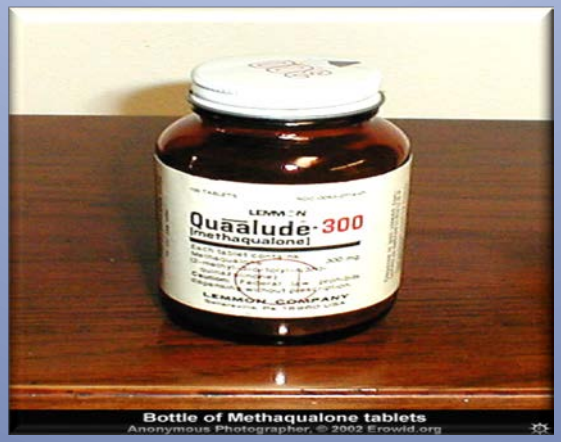
Source: Drug Theft and Loss
Date Prepared : 02/08/2013

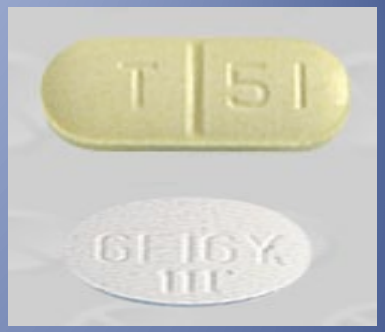
Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

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

The 1960/70s/80s

Uppers - Dexedrine





"Ts and Blues"

Downers - Seconal

Hydromorphone

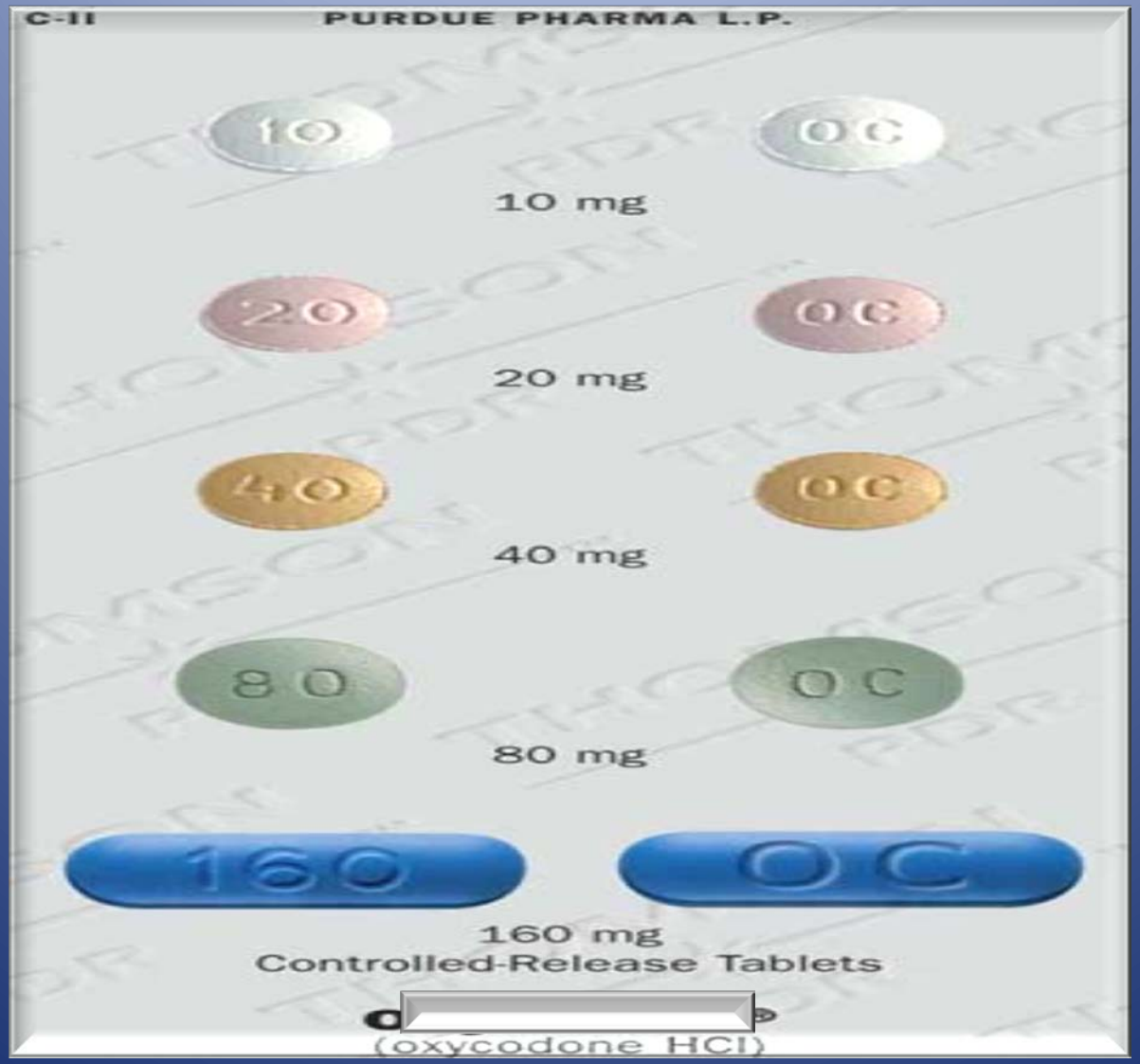
"Fours and Doors"

Meprobamate

Oxycodone/APAP

The 1990s

OxyContin



Commonly Abused Controlled Pharmaceuticals

CYCLOBENZAPRINE (FLEXERIL)

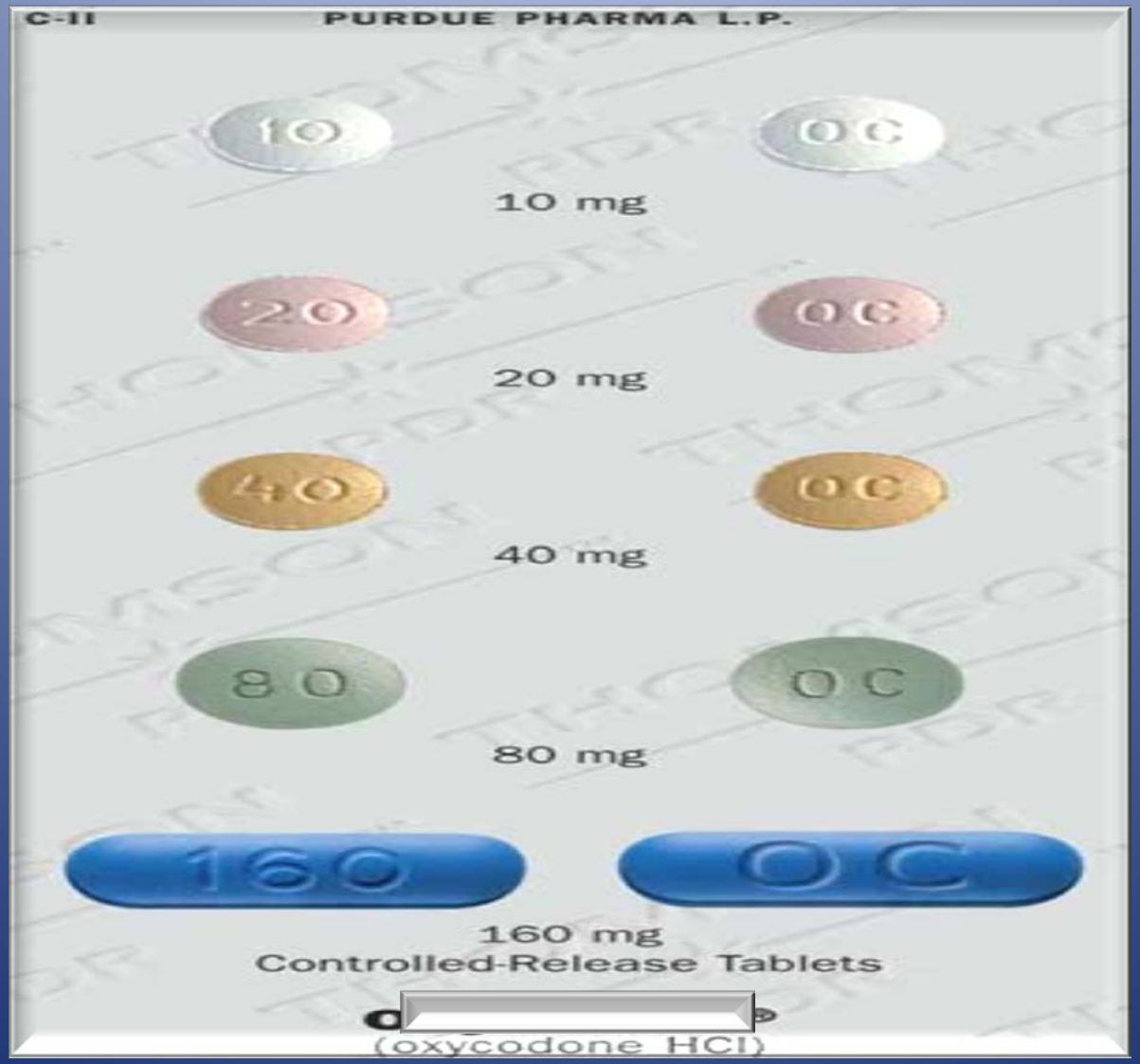
Hydrocodone

Oxycodone 30 mg

Alprazolam

The 1990s

OxyContin



Inadequate Pain Control

The Fifth Vital Sign?

Temperature

Heart Rate

BP

Respiration

http://www.eurekalert.org/pub_releases/2006-03/aaop-ecf031506.p
AOL Mail (1811) | scott fishman dea - AOL Searc... | Experts call for balance in a...
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Public release date: 17-Mar-2006
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Back To EurekAlert!

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. Contrary to recent events in Washington, we 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, Ame
commentary points to a failure on the part of the DEA in not abiding by its commitment to the pain community to pursue a balance between the war on drugs and the rights of pain patients, and also cite
assert the more comprehensive command."

###

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 qual
awareness, providing practical information, promoting research, and advocating to remove barriers and increase access to effective pain management. For more information, visit www.painfoundation.org

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Dollars for Doctors
How Industry Money Reaches Physicians

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

http://www.finance.senate.gov/newsroom/chairman/release/?id=0 | AOL Mail (1811) | us senate finance committee i... | The United States Senate C...
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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 [276.9 KB]
- Baucus Grassley Opioid Investigation Letter to the Joint Commission [278.4 KB]
- Baucus Grassley Opioid Investigation Letter to Wisconsin Pain And Policy Studies Group [277.5 KB]
- Baucus Grassley Opioid Investigation Letter to American Academy of Pain Medicine [277.6 KB]
- Baucus Grassley Opioid Investigation Letter to American 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

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Watchdog Reports

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

By John Fauber of the Journal Sentinel

May 9, 2012

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"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

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Bioethics think tank's ties to pain pill industry studied

BY ALAN BAVLEY
The Kansas City Star

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

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

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

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

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

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

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

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

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

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

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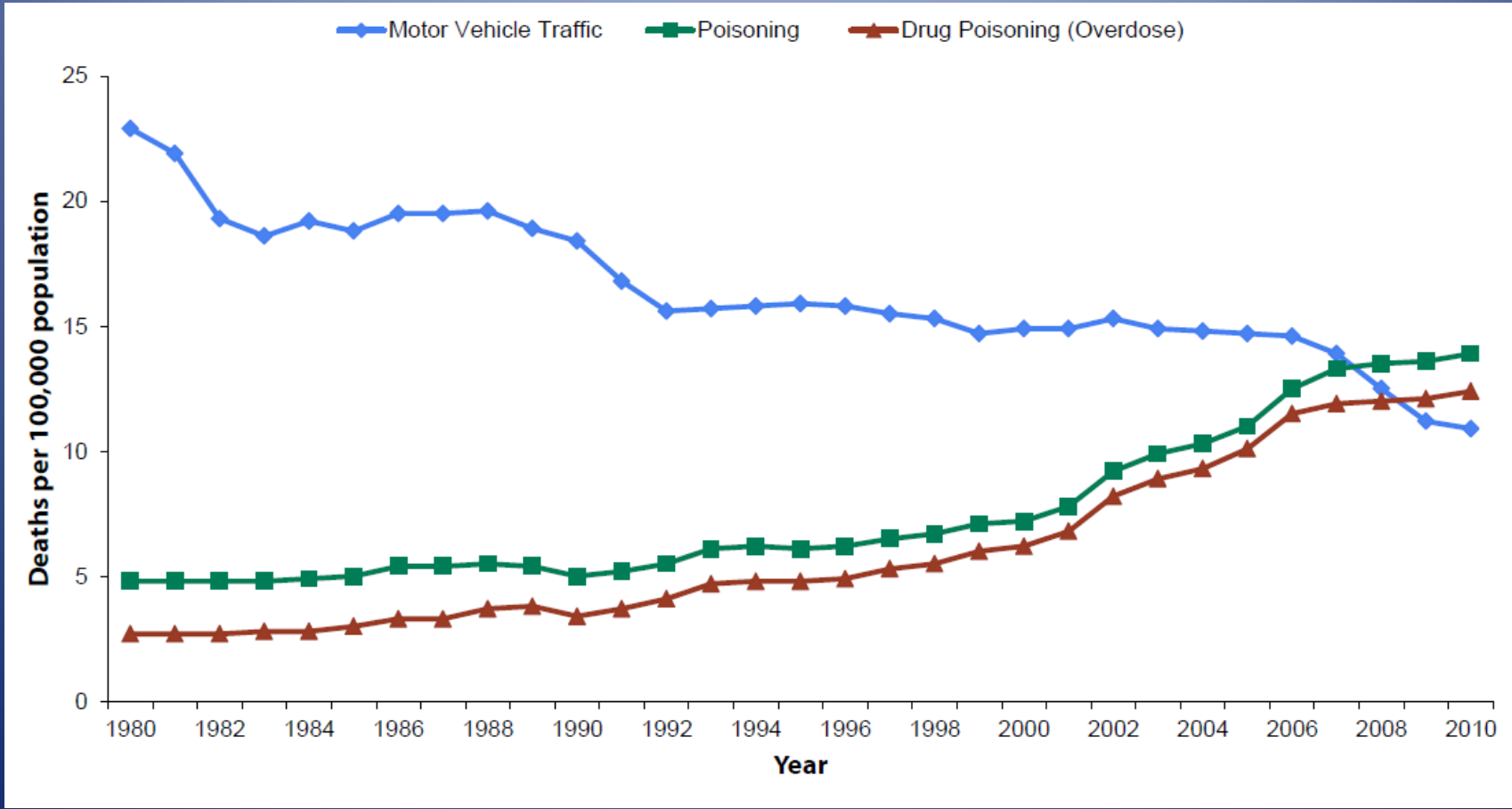
U.S. Motor Vehicle Traffic, Poisoning, and Drug Poisoning (Overdose) Death Rates, 1980-2010



Source: CDC National Center for Health Statistics (NCHS) Data Brief, December 2011, updated with 2009 and 2010 mortality data

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

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**

Drug Education

or not

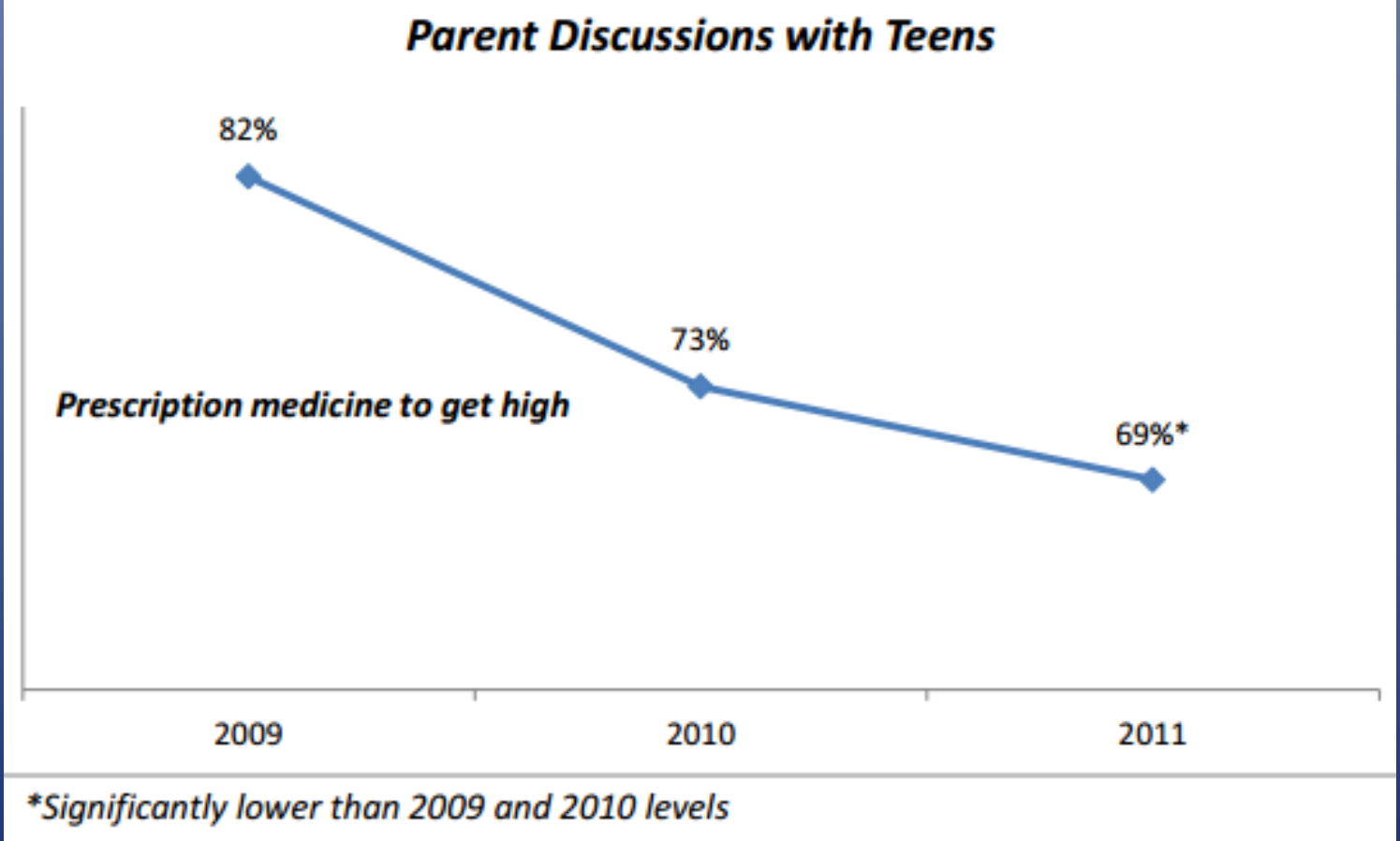
What are kids listening to… Eminem?

'Vike'

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

Parents & Their Attitudes

Parents are not discussing the risks of abusing prescription drugs

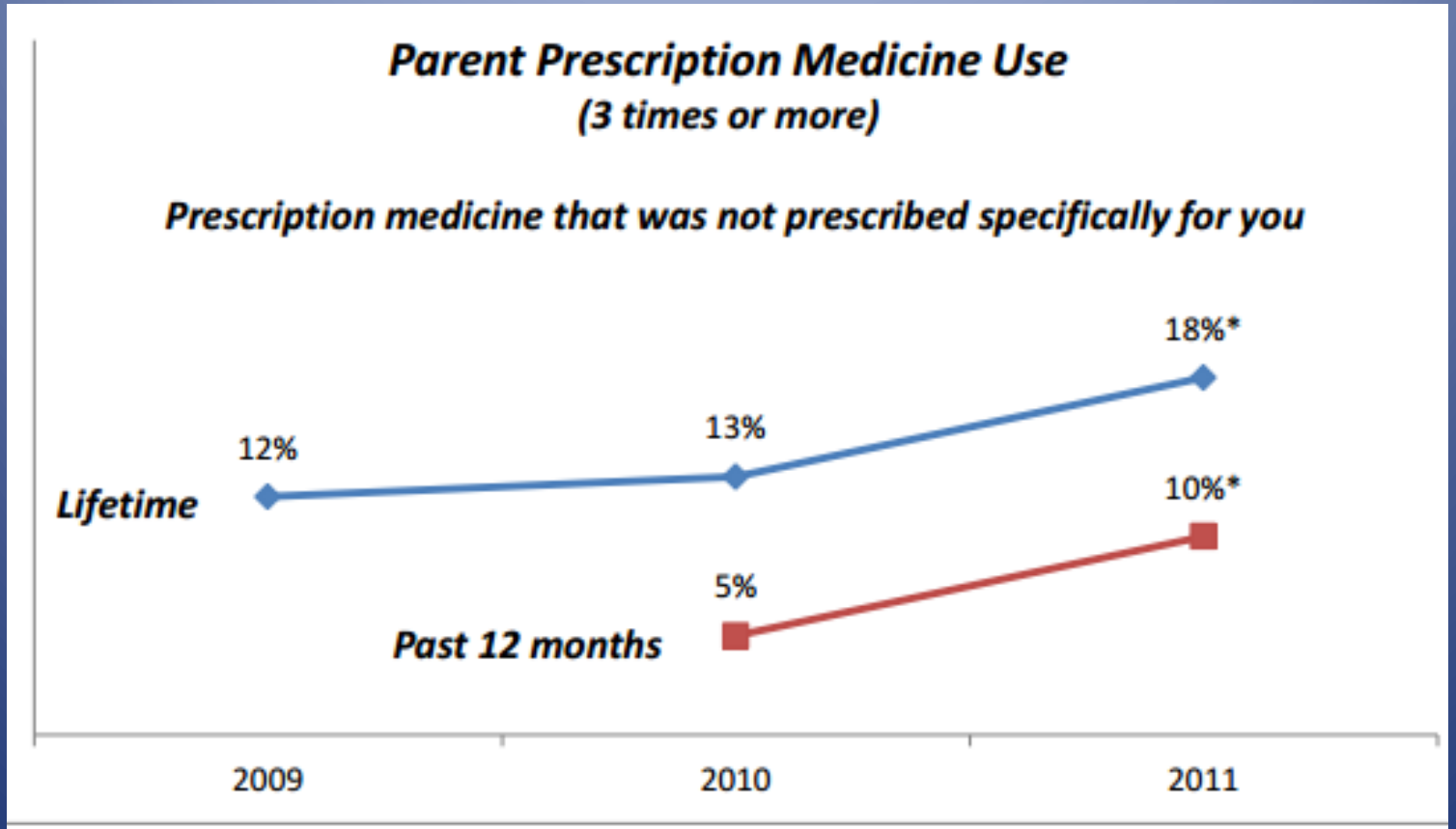


U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control

Source: 2011 Partnership Attitude Tracking Study

Parents & Their Actions

Parents and their abuse of prescription drugs

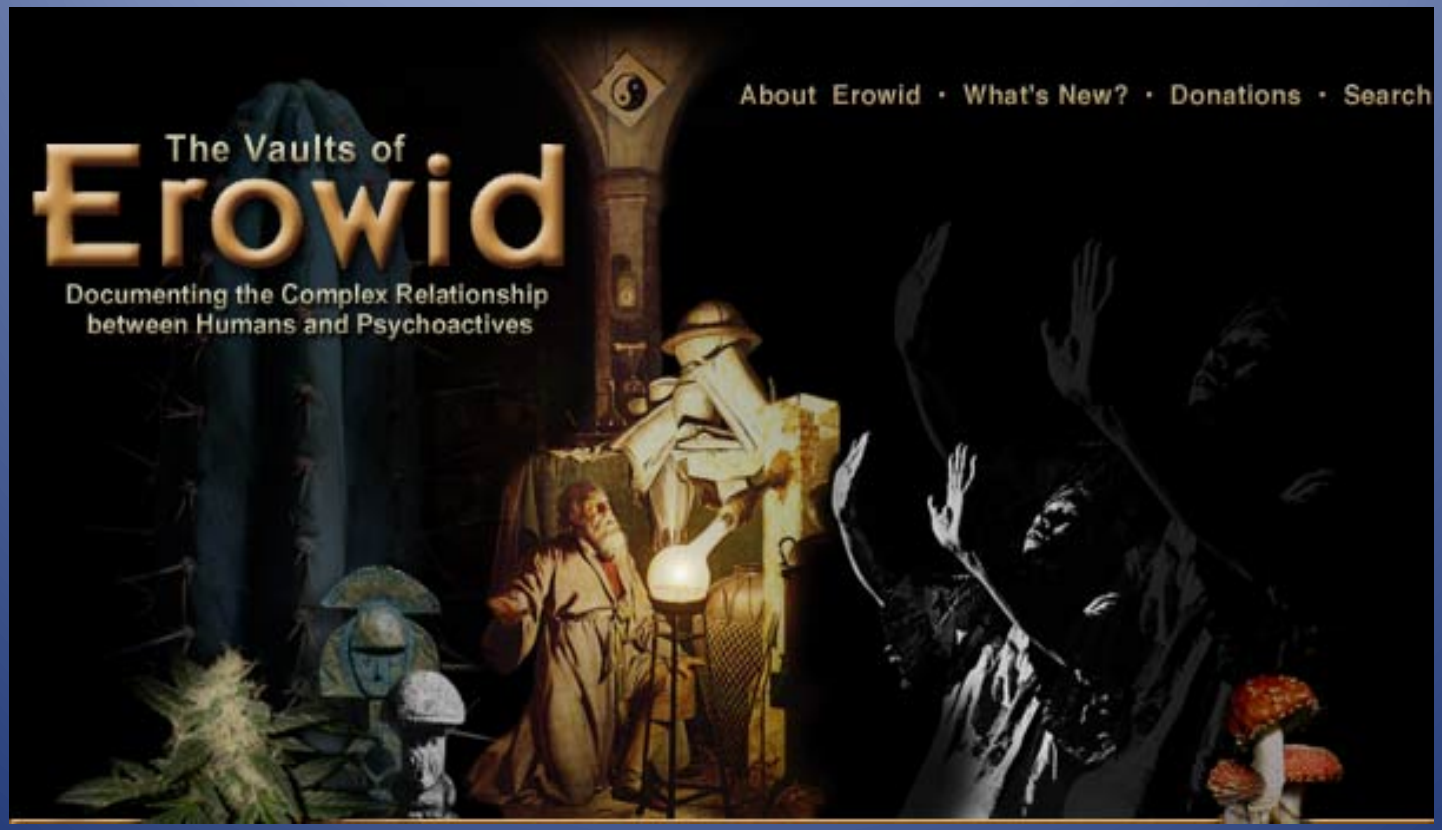


*Significantly higher than 2009 and 2010 levels

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

Source: 2011 Partnership Attitude Tracking Study

Where do kids get their information from?



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

- Enforcement is just as important as….
- Prevention/Education
- Treatment
- TREATMENT!!!!

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

DEA Response

Enforcement

- Regulatory/Administrative/Civil/Criminal
- Stepped-up inspection program
- TDS program

National Take-back Initiative

- Proposed regulations

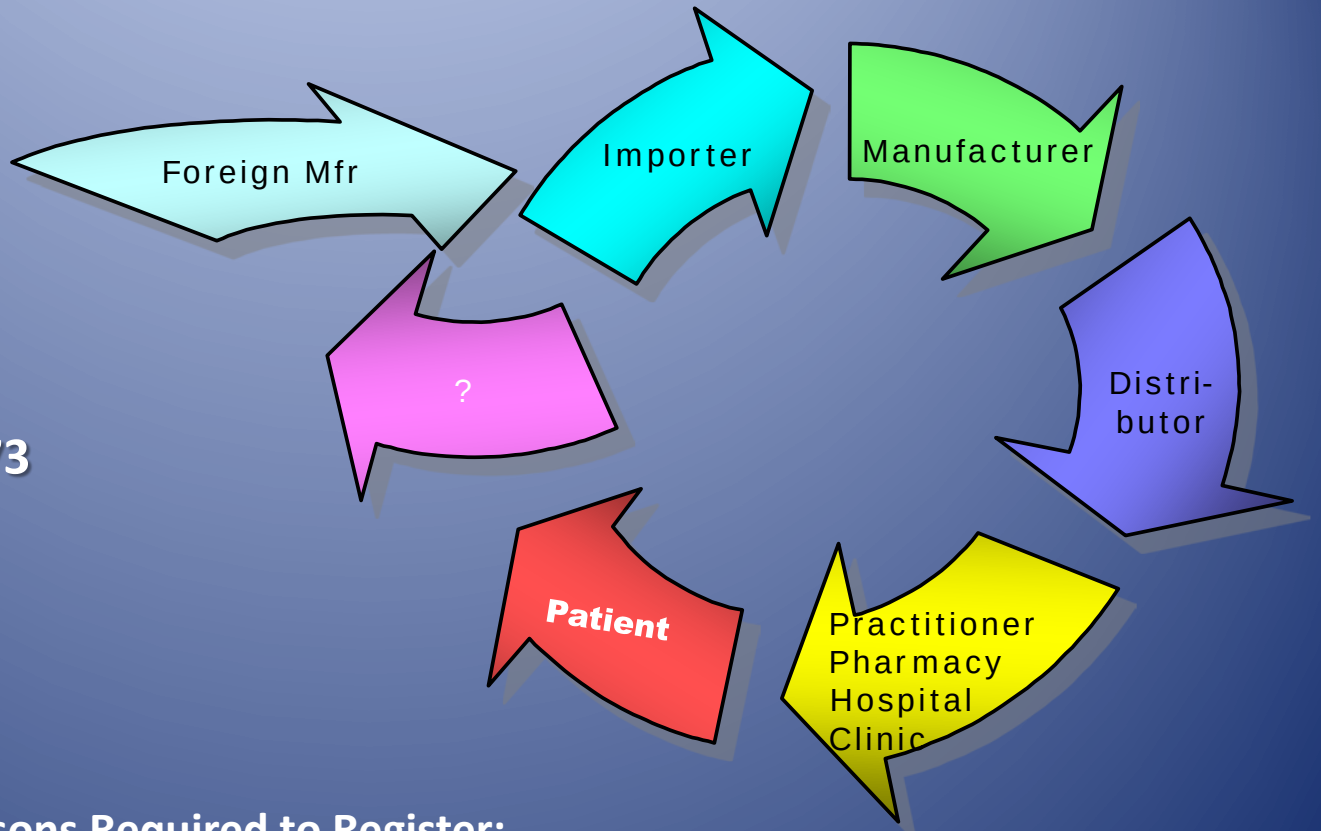
Education

- Pharmacist Diversion Awareness Conferences (PDAC)
- Participation in conferences for healthcare professionals
- Registrant conferences

The Controlled Substances Act

21 United States Code

Closed System of Distribution

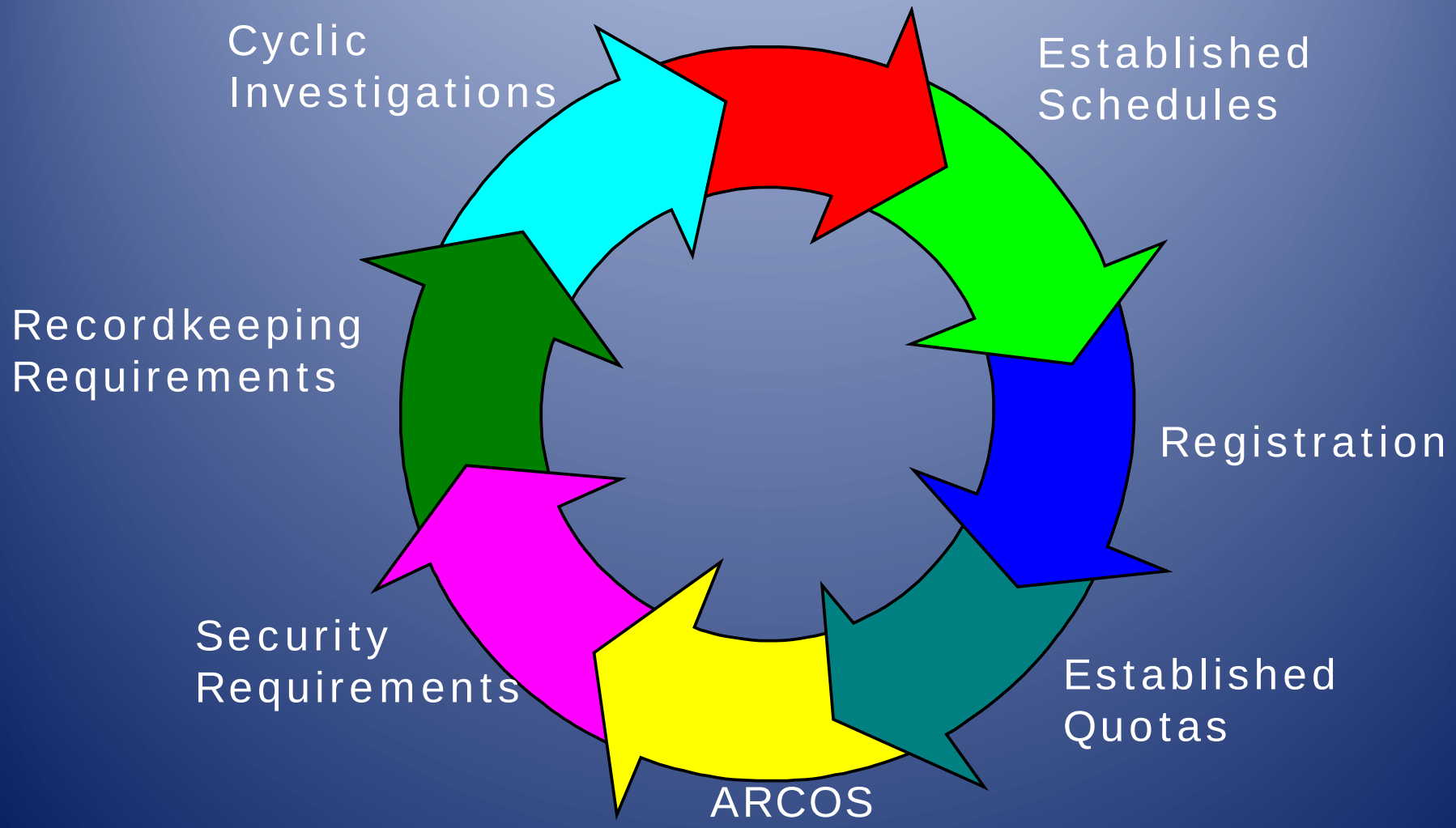


1,469,638 (01/22/13)
Practitioners 1,149,498
Retail Pharmacies 68,473
Hospital/Clinics 15,849

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 ..."

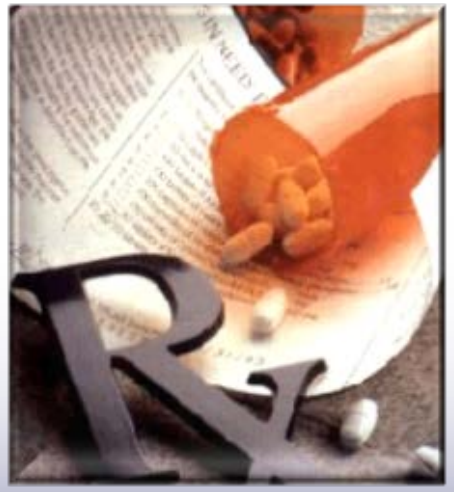
Closed System of Distribution



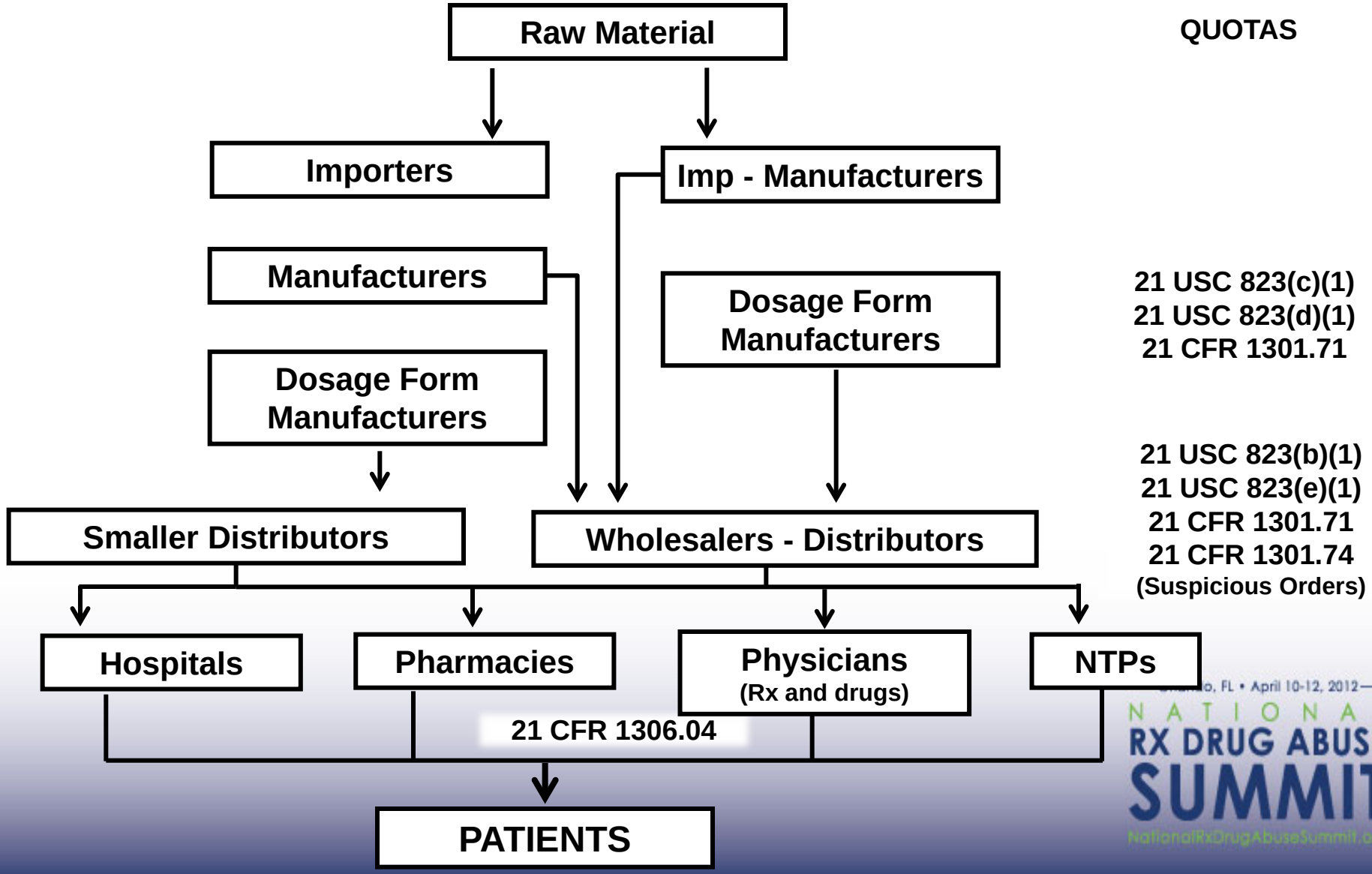
Cutting off the Source of Supply

The Controlled Substances Act

Checks and Balances



The Flow of Pharmaceuticals



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Checks and Balances of the CSA and the Regulatory Scheme

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

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

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**

Drug wholesaler, 2 pharmacies charged in DEA crackdown

By Donna Leinwand Leger, USA TODAY

Updated 15h 4m ago

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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.

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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."

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.

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

Checks and Balances Under the CSA

- **<u>Practitioners</u>**

"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)***

Checks and Balances Under the CSA

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

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

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

Drug Dealers Masquerading as Doctors

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

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

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

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

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

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

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

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

0-12, 2012
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Violations?

What happens next.....

Notice of Inspection

- You may refuse the inspection and require an AIW or SW.
  - Explain the NOI and provide a copy
  - Explain the purpose of the visit
  - Request to inspect the registered location and the controlled substance records
  - Receipt provided for records obtained
  - Conducted between normal business hours

Administrative Inspection Warrant

- Reviewed by an Assistant United States Attorney
- Executed by a United States Magistrate Judge
- Served with a copy of the AIW
- Controlled substances records obtained and a receipt provided
- Conducted between normal business hours

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

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

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The Medicine Cabinet
and
the Problem of Pharmaceutical Controlled Substance Disposal

The Problem – Easy Access

So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules

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.

Law Enforcement

- **Law enforcement officers, acting to enforce laws regarding the abandonment of controlled substances, may receive controlled substances from ultimate users.**
- **Law enforcement must safeguard the controlled substances and ensure that they are destroyed properly.**
- **Law enforcement must be present during the destruction of the controlled substances.**

National Take Back Initiative
April 27, 2013

SUMMIT
NationalRxDrugAbuseSummit.org

Nationwide Take-back Initiative

- **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**

Next Nationwide Take-back Event

April 27, 2013

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.

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.

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.

Medicine	*Active Ingredient*
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)	Oxymorphone Hydrochloride
Opana ER, tablets (extended release)	Oxymorphone 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

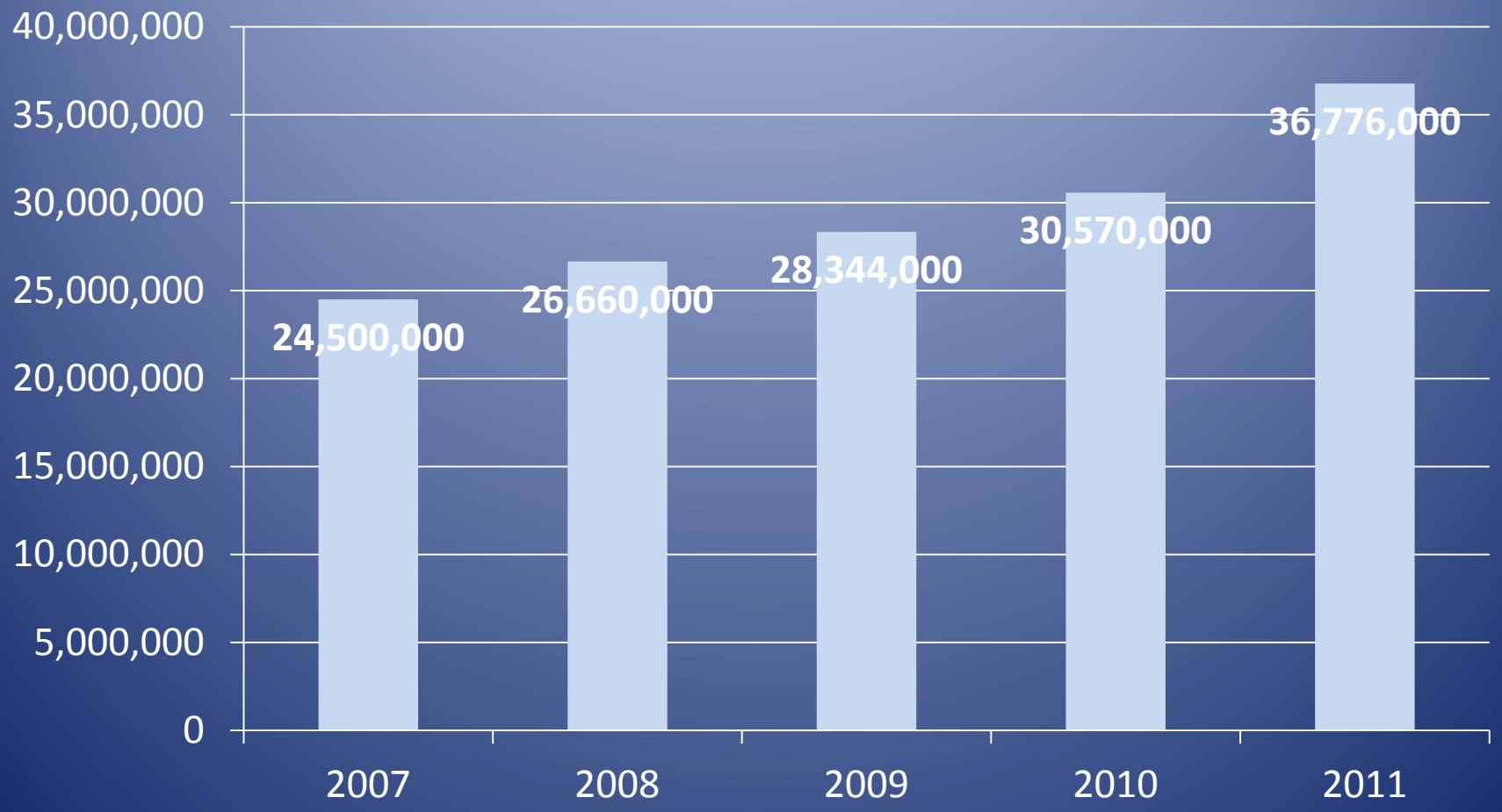
Legend Drugs v. Controlled Substances

Legend Pharmaceuticals

Non-Controlled Substances

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

Tramadol Prescriptions



Source: IMS Health National Prescription Audit Plus downloaded 6/5/2012

NFLIS Estimated Tramadol Reports

and Percentage of Total Narcotic Analgesics

January – June

Year (Jan – June)	Estimated Reports	% of Total Narcotic Analgesics
2009	557	0.99%
2010	704	1.04%
2011	720	1.09%
2012	957	1.50%

Source: U.S. Drug Enforcement Administration, Office of Diversion Control. National Forensic Laboratory Information System (NFLIS): Midyear Reports (2009-2012).

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

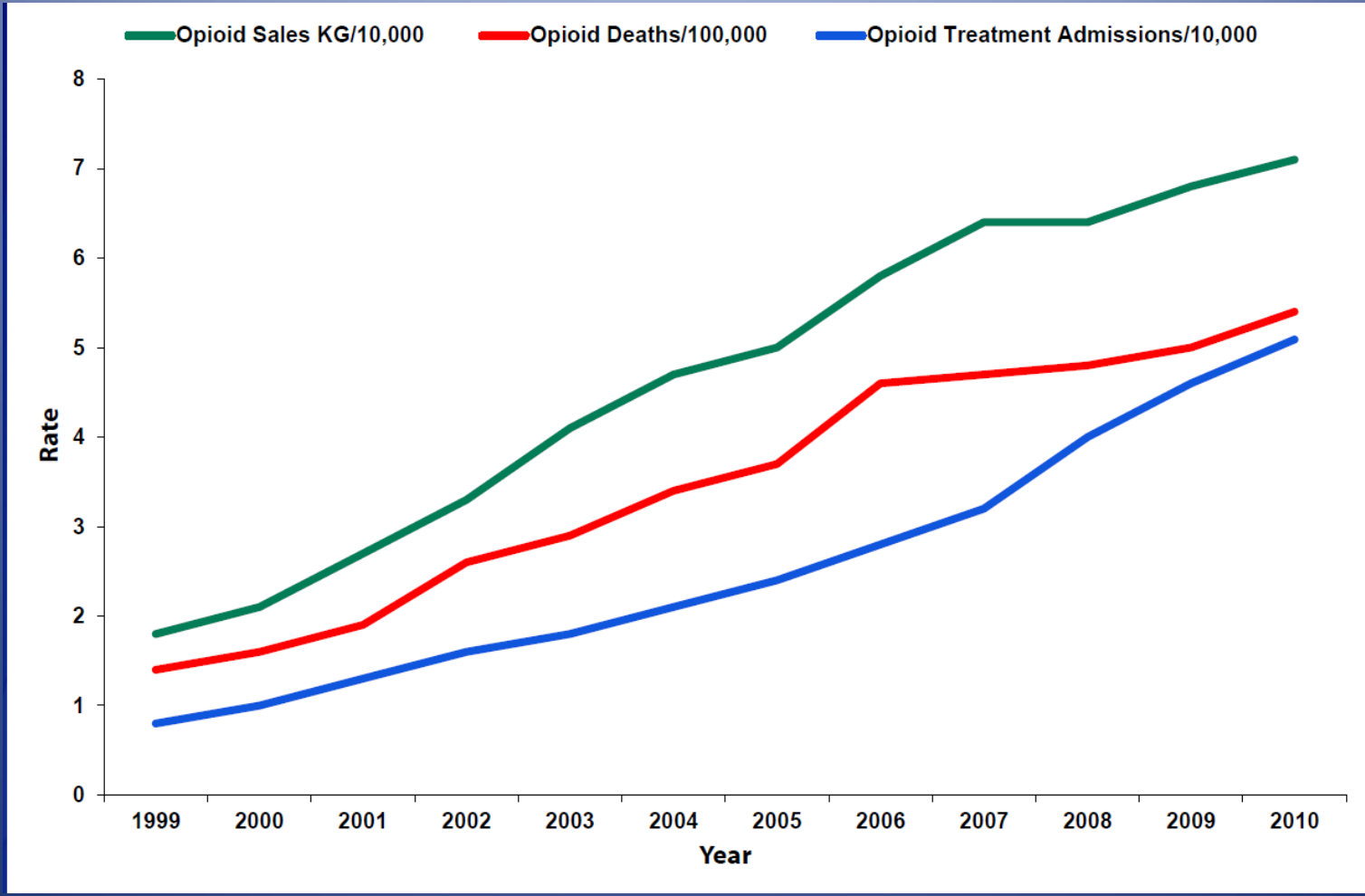
Prescription Requirements

	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



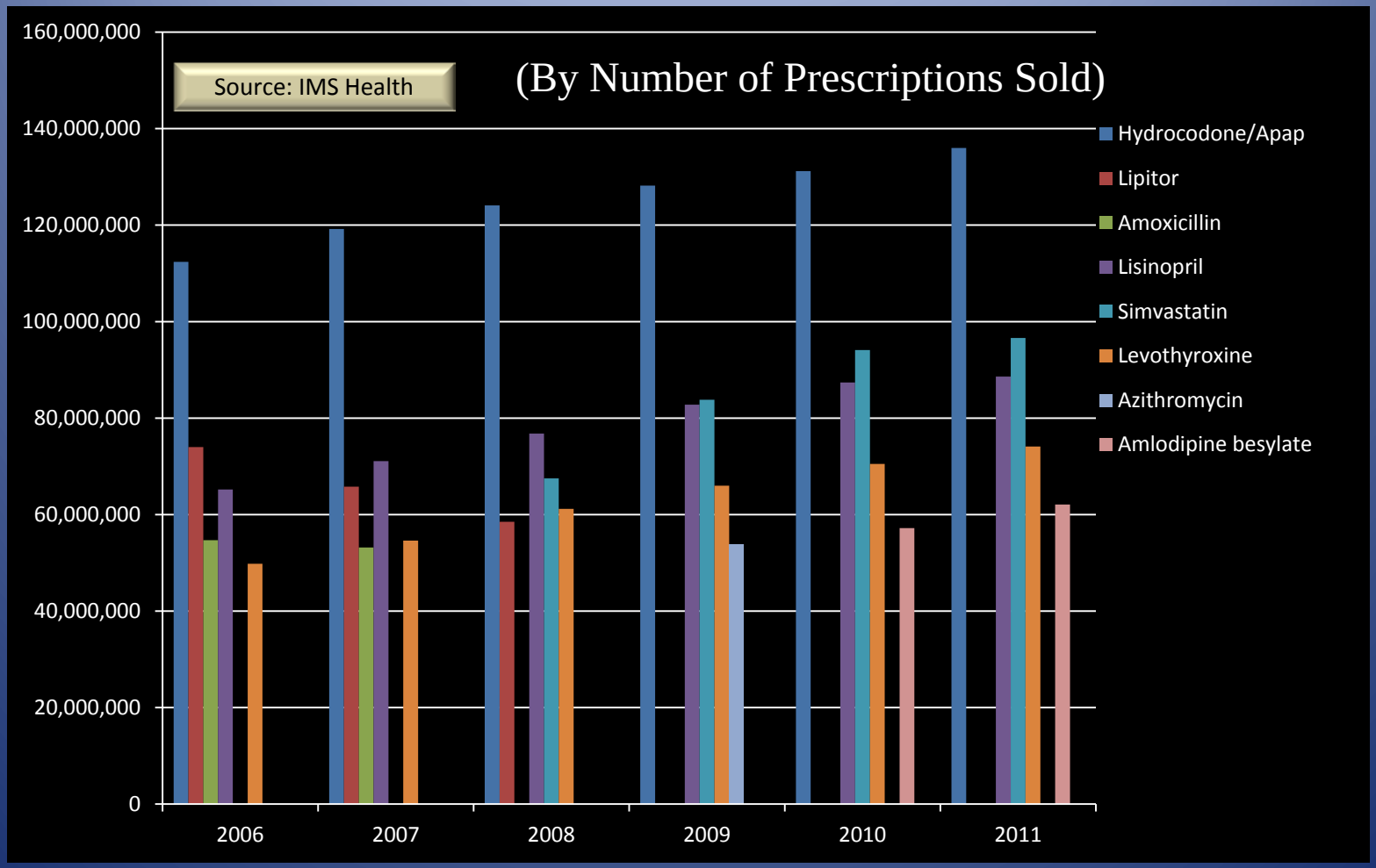
Source: National Vital Statistics System (NVSS), DEA's Automation of Reports and Consolidated Orders System, SAMHSA's Treatment Episode Data Set

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

Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen

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



Top 25 U.S. Pharmaceutical Products Dispensed by Prescription*

Total RX in Millions

		2007	2008	2009	2010	2011
Total US Prescription Market		3,825	3,866	3,949	3,993	4,024
1	hydrocodone/acetaminophen	119.2	124.1	128.2	131.2	136.0
2	simvastatin	47.9	67.5	83.8	94.1	96.6
3	lisinopril	71.1	76.8	82.8	87.4	88.6
4	levothyroxine sodium	54.6	61.2	66.0	70.5	74.1
5	amlodipine besylate	27.9	44.6	51.3	57.2	62.1
6	omeprazole (RX)	26.6	35.1	45.4	53.4	59.3
7	azithromycin	46.3	51.0	53.8	52.6	55.3
8	amoxicillin	53.2	50.9	52.4	52.3	53.8
9	metformin HCL	40.2	42.3	44.3	46.9	48.4
10	hydrochlorothiazide	48.5	48.5	47.9	47.8	48.1
11	alprazolam	39.8	41.7	43.9	46.3	47.8
12	furosemide	44.2	44.1	43.5	43.4	42.1
13	Lipitor®	65.8	58.5	51.7	45.3	40.8
14	zolpidem tartrate	16.0	29.9	35.1	38.0	39.4
15	metoprolol tartrate	31.6	32.6	41.1	38.9	37.8
16	citalopram HBR	17.8	22.4	27.1	32.1	37.7
17	sertraline HCL	31.6	32.7	34.2	35.7	37.2
18	metoprolol succinate	21.0	41.5	26.9	33.0	34.5
19	prednisone	25.9	27.1	27.8	28.7	33.7
20	atenolol	44.7	41.8	39.3	36.3	33.3
21	gabapentin	20.0	22.2	25.4	29.3	33.2
22	tramadol HCL	19.1	21.8	24.1	26.8	32.9
23	oxycodone/acetaminophen	25.9	28.4	30.2	31.9	32.8
24	ibuprofen (RX)	27.7	28.5	30.3	31.1	32.6
25	warfarin sodium	28.8	30.2	31.6	32.0	30.9

*Source: ims National Prescription Audit™

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Updated February 23, 2013

Top 50 Generic Drugs by Total Prescriptions 2010

Rank	Drug	Total Rxs	Change from Previous Year	Rank	Drug	Total Rxs	Change from Previous Year
1	Hydrocodone/APAP	122,806,850	2.10%	26	Lorazepam	23,428,627	3.70%
2	Lisinopril	76,901,813	4.30%	27	Warfarin	23,388,338	1.50%
3	Simvastatin	76,771,821	4.90%	28	Clonazepam	23,085,065	4.00%
4	Levothyroxine	68,222,152	8.20%	29	Fluticasone nasal	22,447,832	19.70%
5	Amoxicillin	51,083,822	-0.60%	30	Cyclobenzaprine	22,240,071	7.30%
6	Amlodipine besylate	50,186,652	11.70%	31	Cephalexin	21,943,482	2.70%
7	Azithromycin	48,756,188	-2.10%	32	Trimethoprim/sulfa	21,345,723	4.50%
8	Alprazolam	46,201,182	3.90%	33	Fexofenadine	20,430,430	27.50%
9	Hydrochlorothiazide	45,838,017	-0.80%	34	Amoxicillin/pot clav	20,234,873	1.20%
10	Omeprazole	44,795,175	15.40%	35	Ciprofloxacin HCl	20,063,382	1.80%
11	Metformin	41,932,689	4.70%	36	Pravastatin	20,026,786	17.90%
12	Furosemide oral	36,583,895	-0.10%	37	Trazodone HCl	18,786,495	6.50%
13	Metoprolol tartrate	34,707,807	-0.50%	38	Lovastatin	17,509,951	13.50%
14	Atenolol	33,839,806	-11.00%	39	Triamterene/HCTZ	17,201,037	-7.00%
15	Sertraline	33,409,838	8.90%	40	Carvedilol	16,681,336	8.30%
16	Metoprolol succinate	32,224,000	12.00%	41	Alendronate	16,177,014	-6.90%
17	Zolpidem tartrate	29,719,569	-2.80%	42	Ranitidine HCl	14,699,414	6.60%
18	Oxycodone/APAP	28,705,243	6.80%	43	Meloxicam	14,645,167	2.90%
19	Citalopram HBR	27,993,635	9.40%	44	Diazepam	14,584,147	7.10%
20	Gabapentin	26,865,557	14.00%	45	Naproxen	14,297,759	10.30%
21	Ibuprofen	26,256,548	3.20%	46	Propoxyphene-N/APAP	14,274,354	-18.70%
22	Prednisone oral	25,529,463	-2.70%	47	Fluconazole	13,938,887	4.60%
23	Tramadol	25,527,796	10.30%	48	Methylprednisolone tabs	13,659,852	11.30%
24	Lisinopril/HCTZ	24,538,247	8.00%	49	Doxycycline	13,199,430	1.90%
25	Fluoxetine	24,473,994	6.80%	50	Paroxetine	12,979,366	-14.40%

Source: SDI's Vector®: National, June 2011
Date Prepared: 03/06/2012

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

State Ranking* - Hydrocodone January 1 – December 31, 2011

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	405,692,065	12	IL	92,977,840	23	VA	55,100,651	34	CO	18,452,400	45	AK	6,041,200
2	TX	340,313,340	13	FL	90,012,630	24	WV	50,784,470	35	NM	17,284,770	46	WY	3,655,570
3	MI	172,654,340	14	NC	86,619,248	25	OR	49,989,655	36	NE	17,208,499	47	RI	3,571,380
4	AL	134,461,800	15	LA	82,584,490	26	WI	45,882,760	37	MA	15,920,820	48	VT	2,103,920
5	KY	129,026,114	16	MS	77,669,630	27	MN	32,918,294	38	MD	15,372,420	49	NH	1,740,840
6	TN	122,258,515	17	PA	76,070,466	28	UT	31,039,500	39	MT	11,065,910	50	PR	1274220
7	GA	111,364,050	18	IN	64,032,062	29	IA	29,605,860	40	SD	9,212,040	51	DE	823780
8	OK	102,103,000	19	AR	63,705,310	30	AZ	29,201,725	41	ND	9,067,980	52	DC	653,430
9	OH	94,175,600	20	WA	62,896,030	31	NJ	20,979,530	42	HI	8,500,500	53	VI	408,000
10	MO	93,914,780	21	KS	59,379,830	32	ID	20,976,760	43	CT	8,372,250	54	GU	196,300
11	NY	93,900,590	22	SC	55,883,580	33	NE	20,409,240	44	ME	7,924,050			

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit (01/16/2013)

State Ranking* - Hydrocodone January 1– December 31, 2011

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	26,596,905	12	MD	1,056,089	23	OH	531,337	34	MN	214,474	45	MT	61,460
2	GA	3,650,814	13	VA	1,034,924	24	NJ	522,515	35	ND	186,249	46	SD	58,412
3	IL	2,535,828	14	TX	1,002,407	25	CT	408,858	36	IA	164,389	47	ME	48,402
4	FL	2,448,494	15	KY	965,850	26	OR	382,882	37	DE	150,950	48	RI	29,827
5	NV	2,435,532	16	CO	940,617	27	WI	376,634	38	KS	139,620	49	DC	28,654
6	TN	2,429,834	17	NY	690,759	28	HI	376,252	39	KS	132,850	50	VT	26800
7	PA	1,837,008	18	SC	655,614	29	LA	371,093	40	UT	111,602	51	NH	22472
8	AL	1,454,378	19	MO	649,763	30	MI	366,637	41	WV	99,190	52	GU	6,200
9	IN	1,326,323	20	WA	596,102	31	ID	247,450	42	AR	97,303	53	RP	2,200
10	AZ	1,161,886	21	OK	594,602	32	AK	235,769	43	NE	78,756	54	VI	1,800
11	MI	1,062,674	22	NC	581,264	33	NM	226,786	44	WY	70,360			

** Business Activity - Practitioners*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit (01/16/2013)

State Ranking* - Hydrocodone January 1– September 30, 2012

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	23,776,920	12	MD	741,978	23	OH	346,787	34	AK	159,271	45	NE	50,104
2	GA	2,409,068	13	TX	701,126	24	HI	345,827	35	MN	139,325	46	SD	42,280
3	IL	2,050,379	14	CO	620,493	25	MS	330,759	36	IA	112,594	47	ME	37,500
4	TN	1,647,726	15	NV	564,154	26	NJ	325,776	37	ND	106,930	48	RI	22,667
5	PA	1,646,148	16	NC	500,302	27	WA	310,658	38	KS	93,795	49	DC	21,110
6	AL	1,324,943	17	MO	493,318	28	WI	266,806	39	DE	85,458	50	VT	14,900
7	MI	883,366	18	NY	456,281	29	LA	244,062	40	UT	79,160	51	NH	11,818
8	IN	850,550	19	OK	408,606	30	OR	224,877	41	MA	69,290	52	GU	3,500
9	VA	812,750	20	KY	405,044	31	ID	176,600	42	WY	68,450	53	PR	2,500
10	AZ	806,259	21	SC	374,024	32	WV	167,788	43	AR	66,270	54	VI	700
11	FL	754,979	22	CT	360,517	33	NM	161,810	44	MT	54,800	55	AS	0

** Business Activity - Practitioners*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit (01/16/2013)

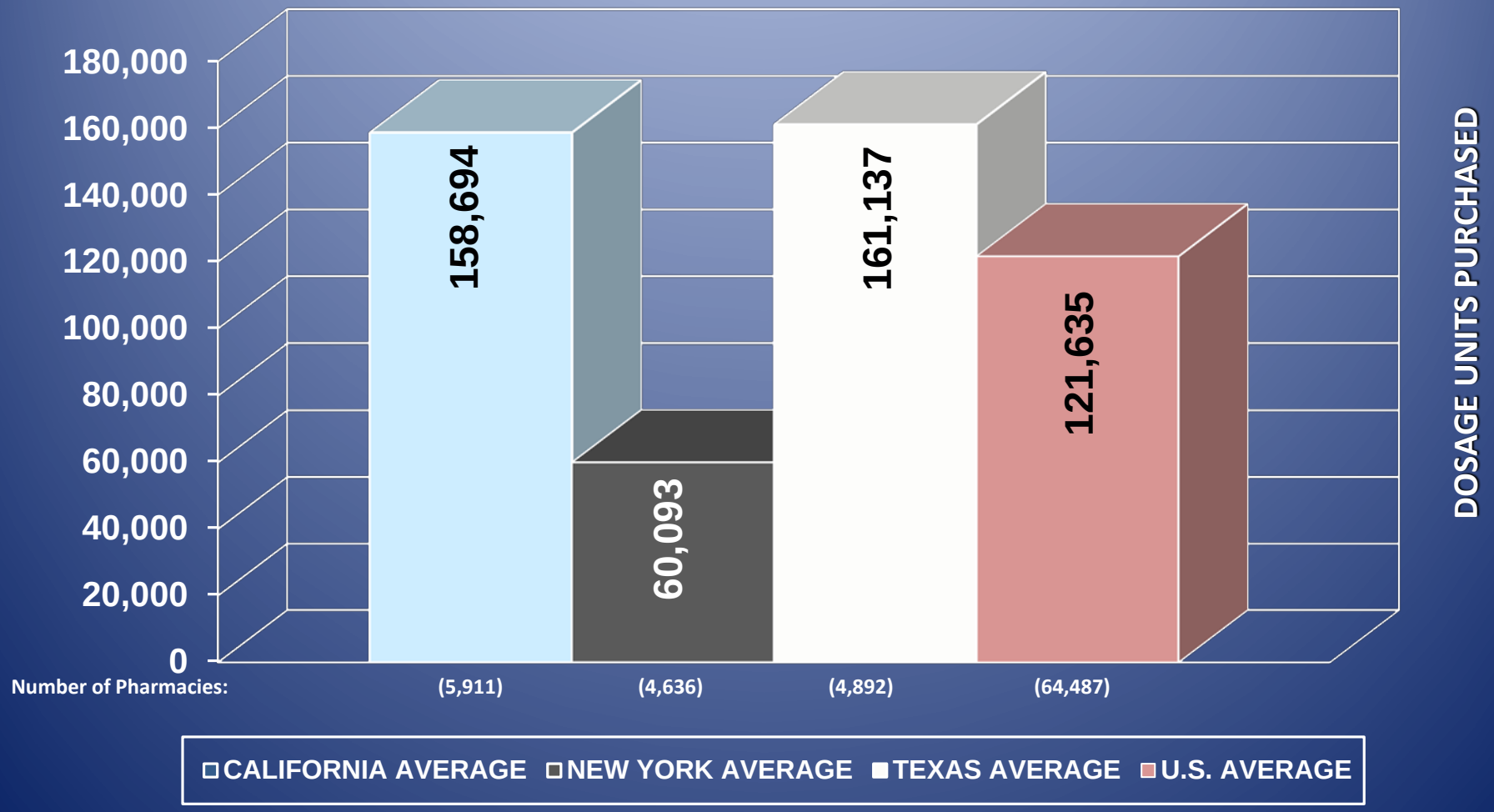
State Ranking* - Hydrocodone January 1 – September 30, 2012

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	752,243,210	12	PA	179,880,349	23	MS	95,040,930	34	MA	45,146,650	45	NH	11,372,160
2	TX	616,744,356	13	KY	174,997,631	24	AR	91,577,120	35	MD	39,757,136	46	WY	9,801,690
3	TN	372,321,936	14	NC	168,721,190	25	OR	89,644,605	36	ID	39,144,850	47	AK	8,914,452
4	MI	316,860,884	15	MO	155,533,410	26	WI	83,864,540	37	NM	34,014,930	48	ND	8,192,140
5	FL	272,756,535	16	OK	142,561,470	27	KS	72,465,169	38	NE	28,350,230	49	DE	7,154,030
6	IL	233,059,530	17	LA	128,601,625	28	WV	68,151,620	39	CT	26,188,240	50	VT	5,672,450
7	OH	224,079,845	18	SC	119,274,940	29	CO	60,518,800	40	ME	22,443,390	51	DC	1,795,600
8	IN	216,475,192	19	NV	117,109,135	30	IA	53,580,034	41	MT	20,483,720	52	PR	1,421,520
9	GA	197,245,775	20	WA	113,082,770	31	MN	53,502,119	42	RI	15,836,670	53	VI	344,030
10	NY	191,672,460	21	VA	111,391,716	32	UT	46,820,190	43	HI	14,422,340	54	GU	183,400
11	AL	190,924,530	22	AZ	108,617,660	33	NJ	46,479,750	44	SD	12,077,710	55	AS	0

** Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit (01/16/2013)

2010
Comparisons of Hydrocodone Sales to Pharmacies

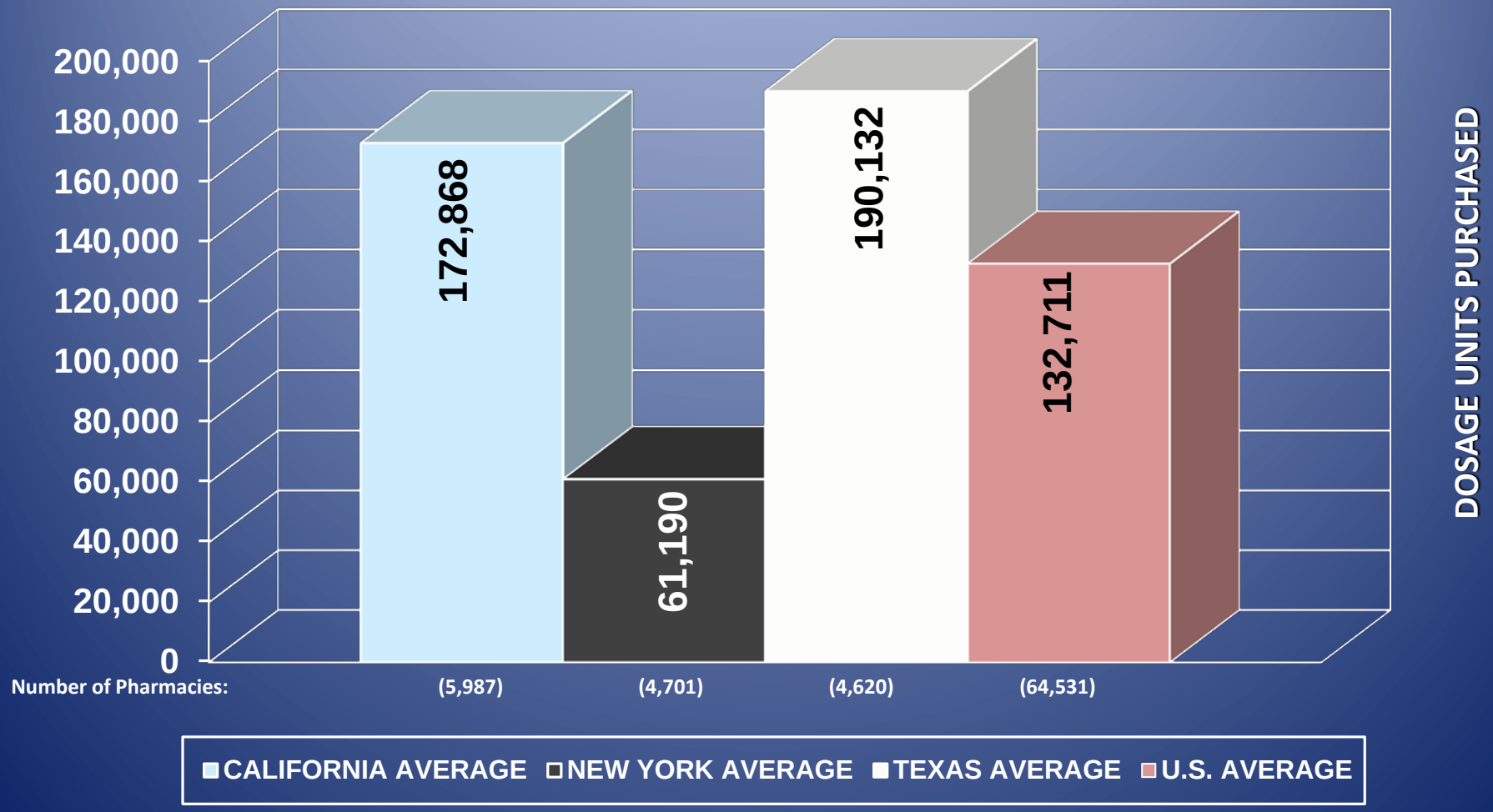


Source: ARCOS

Date Prepared: 10/26/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

2011
Comparisons of Hydrocodone Sales to Pharmacies

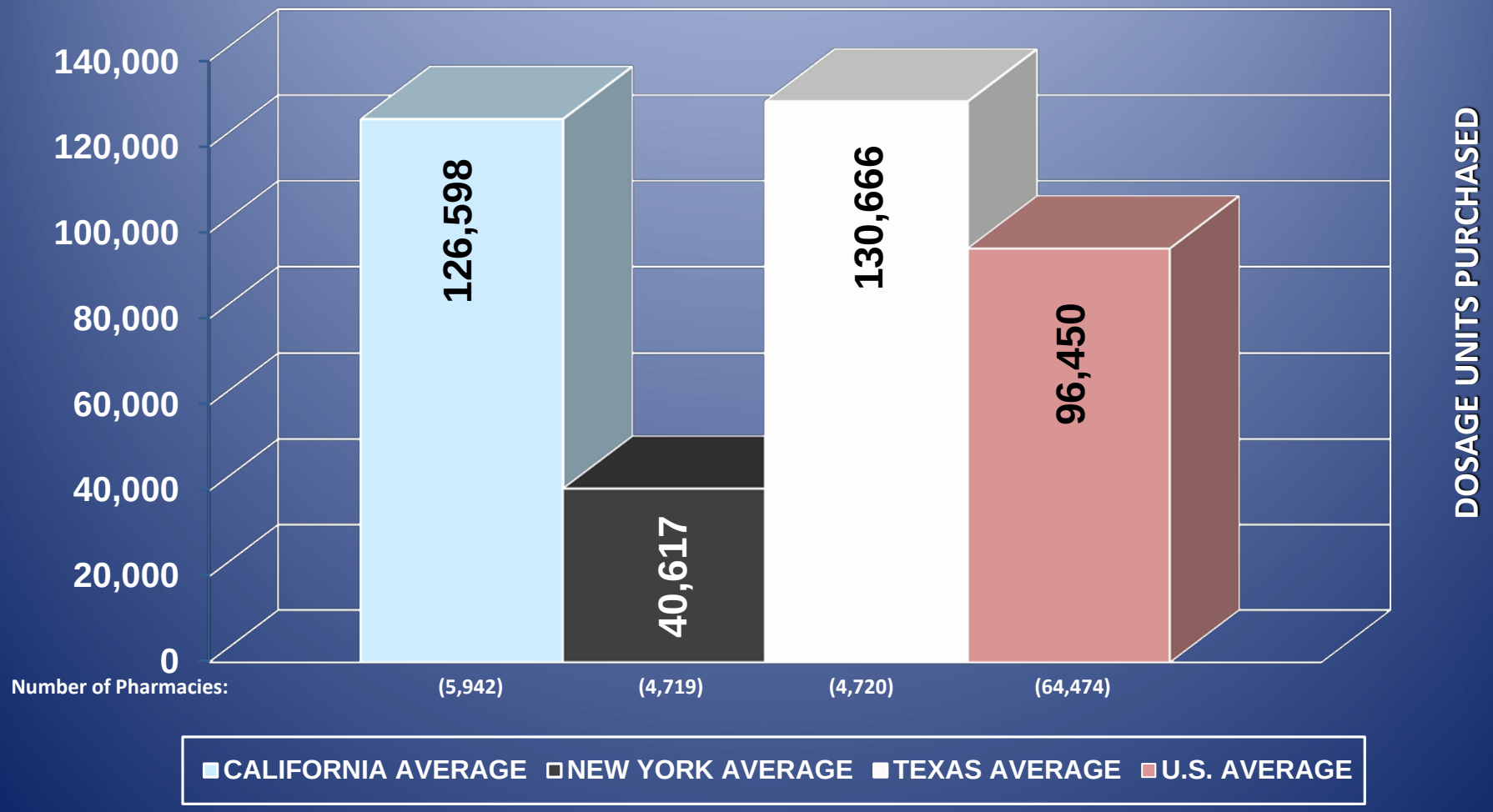


Source: ARCOS

Date Prepared: 10/26/2012

Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

January 1 – September 30, 2012
Comparisons of Hydrocodone Sales to Pharmacies



Source: ARCOS

Date Prepared : 01/16/2013

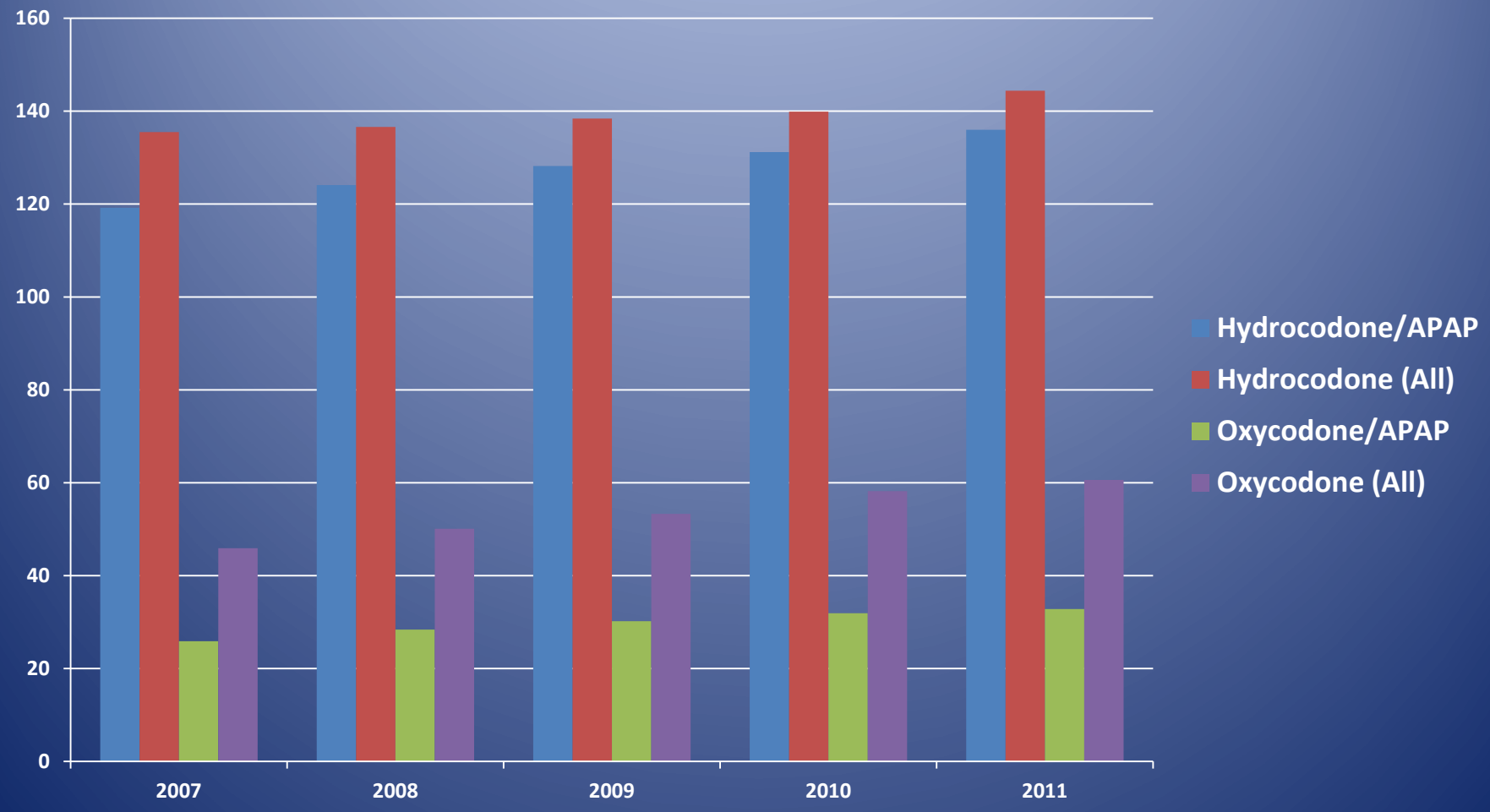
Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

National Poison Data System (Formerly known as Toxic Exposure Surveillance System) – Total Annual Mentions of Toxic Exposures

	Hydrocodone	Oxycodone
2001	15,191	9,480
2002	17,429	10,515
2003	19,578	11,254
2004	22,654	12,603
2005	22,229	13,191
2006	22319	13,473
2007	24,558	15,069
2008	26,306	17,256
2009	27,753	18,396
2010	28,310	19,363
2011	30,792	19,423

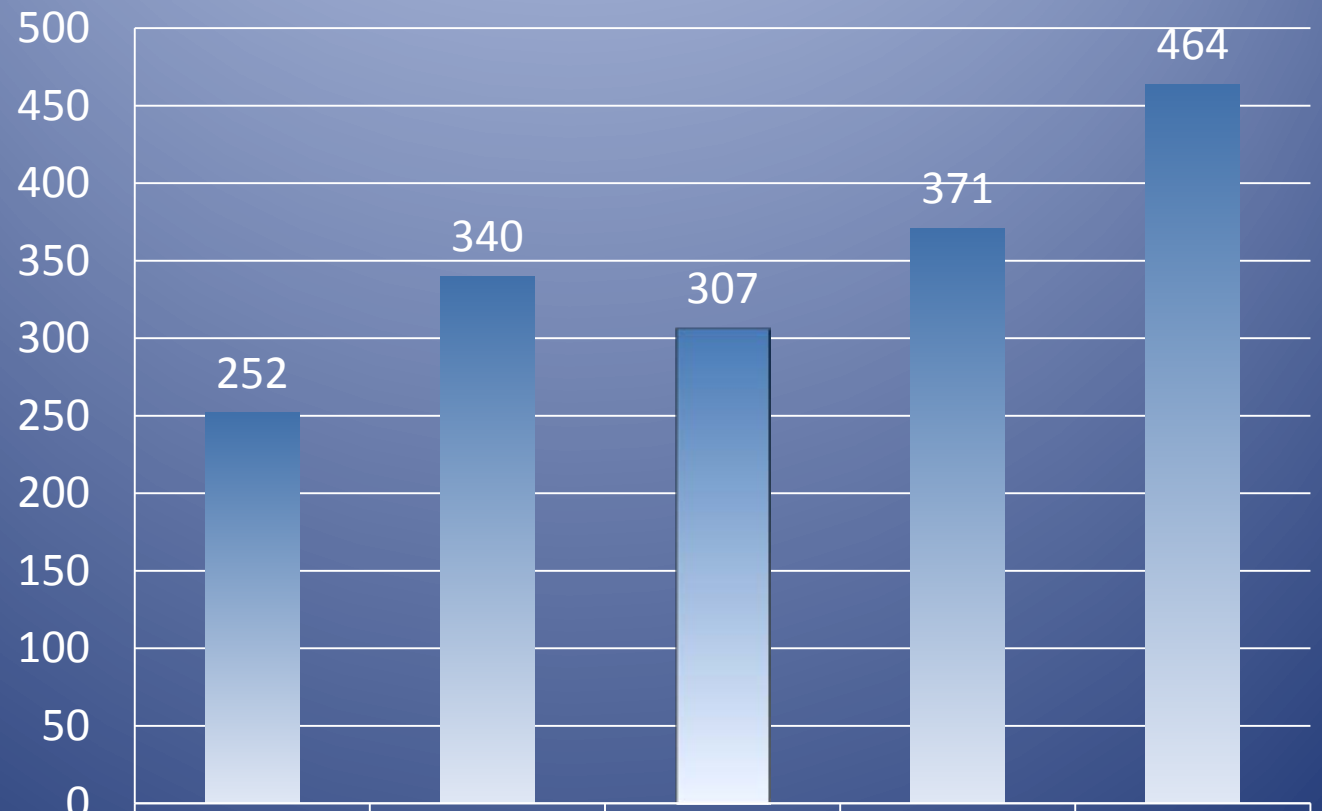
U.S. Dispensed Prescriptions

(IMS Data, Total RX's in Millions)



Source: IMS Health: National Prescription Audit

Diversion Hydrocodone Cases*
FY2008 thru 2012



	FY2008	FY2009	FY2010	FY2011	FY2012
Hydrocodone Cases	252	340	307	371	464

*Source: SMARTS

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

Factors determinative of control or removal from schedules (21 USC 811(c))

(1) Its actual or relative potential for abuse
(2) Scientific evidence of its pharmacologic effect, if known
(3) The state of current scientific knowledge regarding the drug or other substance
(4) Its history and current pattern of abuse
(5) The scope, duration and significance of abuse
(6) What, if any, risk there is to public health
(7) Its psychic or physiological dependence liability
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter

Schedule II

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

Schedule III

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

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

"Abuse" is not defined in the CSA

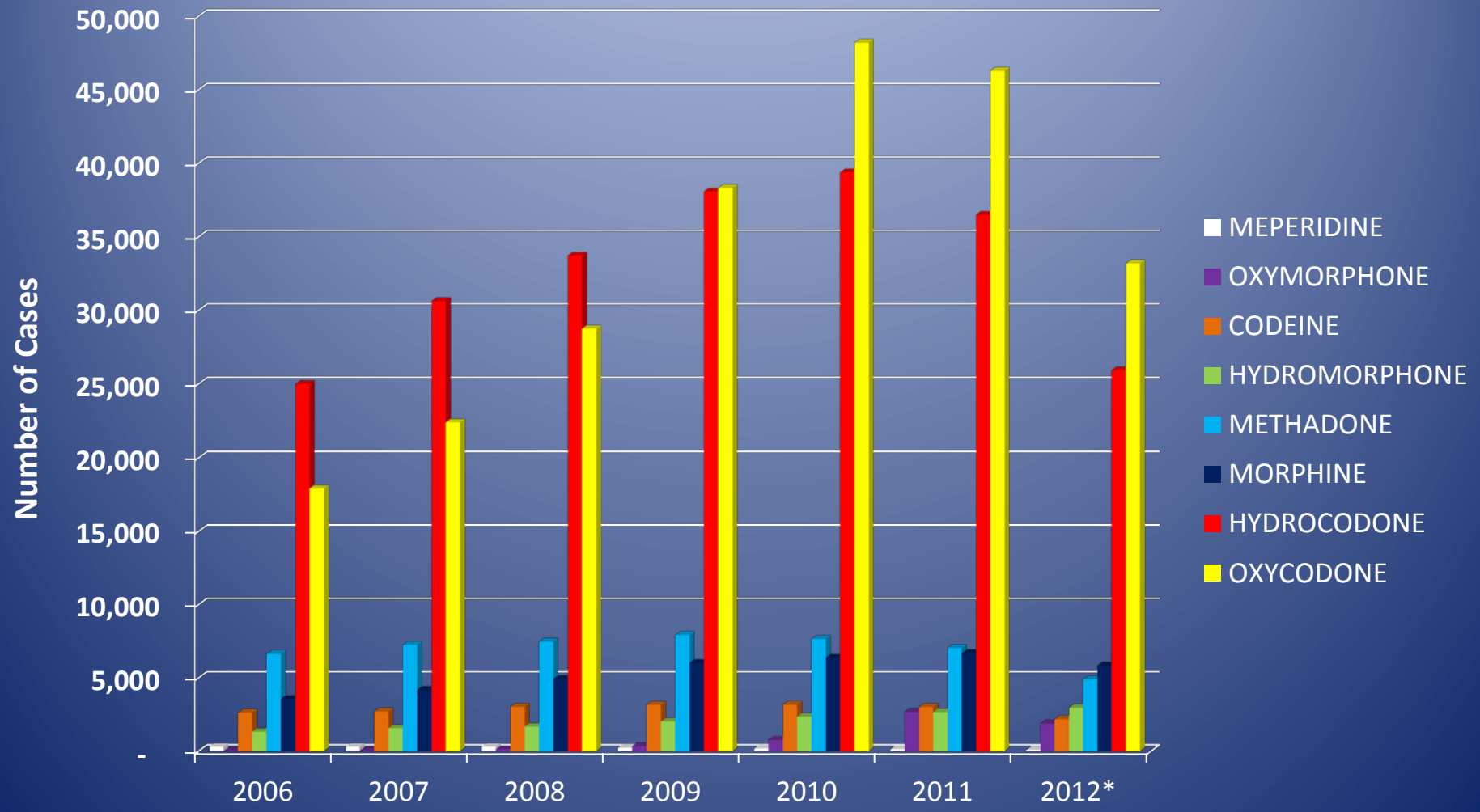
The legislative history suggests the following in determining whether a particular drug or substance has a potential for abuse[1] :

a. Individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or
b. There is a significant diversion of the drug or other substance from legitimate drug channels; or
c. Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or
d. The drug is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has substantial capability of creating hazards to the health of the user or to the safety of the community. Of course, evidence of actual abuse of a substance is indicative that a drug has potential for abuse

1. (Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No 91-1444, 91st Cong., Sess.1 (1970) reprinted in U.S.C.C.A.N. 4566,4603):

NFLIS Cases

(Federal, State, and Local)



*2012 data is still being submitted, data queried on 1/22/2013

NFLIS Encounters

(Federal, State, and Local)

*2012 data is still being submitted, data queried 1/22/2013

National Poison Data System (Formerly known as Toxic Exposure Surveillance System) – Total Annual Mentions of Toxic Exposures

	Hydrocodone	Oxycodone
2001	15,191	9,480
2002	17,429	10,515
2003	19,578	11,254
2004	22,654	12,603
2005	22,229	13,191
2006	22319	13,473
2007	24,558	15,069
2008	26,306	17,256
2009	27,753	18,396
2010	28,310	19,363

OXYCODONE

State Ranking - Oxycodone

Total Dosage Units Sold to Retail

January 1, 2010 – December 31, 2011

2011			2010		
STATE	RANK	TOTAL DOSAGE UNITS	RANK	TOTAL DOSAGE UNITS	% CHANGE 2010 to 2011
FL	1	525,338,986	1	650,885,860	-24%
PA	2	311,529,433	2	288,870,043	7%
NY	3	299,937,485	4	266,896,986	11%
CA	4	295,022,496	5	261,181,184	11%
OH	5	289,383,062	3	282,936,529	2%
NC	6	222,189,039	6	201,693,238	9%
NJ	7	195,014,871	7	179,311,163	8%
AZ	8	173,034,663	8	154,633,084	11%
TN	9	158,340,886	11	141,889,292	10%
WA	10	153,748,970	9	151,249,822	2%
MA	11	151,947,593	10	146,314,057	4%
MD	12	149,086,425	12	141,639,892	5%
GA	13	142,133,490	13	125,986,084	11%
VA	14	131,740,301	14	118,068,618	10%
CO	15	112,194,642	17	100,227,545	11%
MO	16	109,876,292	18	99,979,350	9%
WI	17	108,480,463	16	100,329,263	8%
OR	18	107,116,456	15	101,389,306	5%
KY	19	94,901,418	19	81,873,088	14%
IN	20	90,455,351	20	80,726,827	11%
MI	21	82,434,611	21	73,164,053	11%
SC	22	79,359,293	23	71,450,580	10%
MN	23	76,127,137	24	69,549,000	9%
CT	24	74,439,138	22	71,531,918	4%
NV	25	70,560,182	25	63,270,105	10%
TX	26	69,676,107	26	62,437,942	10%
AL	27	61,157,797	28	51,216,443	16%
OK	28	57,706,857	27	52,363,292	9%

2011			2010		
STATE	RANK	TOTAL DOSAGE UNITS	RANK	TOTAL DOSAGE UNITS	% CHANGE 2010 to 2011
LA	29	56,074,553	29	49,599,949	12%
UT	30	50,697,974	30	47,895,830	6%
NM	31	48,896,260	31	45,697,500	7%
IL	32	47,700,128	33	42,805,010	10%
WV	33	45,830,170	32	42,911,440	6%
AR	34	42,524,552	34	39,873,970	6%
KS	35	41,646,268	36	37,315,942	10%
DE	36	39,956,010	35	37,620,204	6%
ME	37	35,748,190	37	34,383,060	4%
NH	38	30,851,640	38	29,799,340	3%
MS	39	28,293,808	40	24,573,192	13%
IA	40	27,996,044	39	25,805,582	8%
RI	41	20,227,440	42	18,148,220	10%
HI	42	20,153,440	41	18,897,498	6%
ID	43	17,952,864	45	15,583,792	13%
MT	44	17,228,940	43	16,533,080	4%
NE	45	17,225,401	44	16,154,094	6%
AK	46	13,325,196	48	12,287,550	8%
PR	47	12,810,809	46	12,525,590	2%
VT	48	12,534,921	47	12,422,380	1%
DC	49	9,269,620	49	8,839,300	5%
WY	50	9,016,202	50	8,530,680	5%
SD	51	8,535,958	51	8,025,872	6%
ND	52	7,632,423	52	6,598,122	14%
GUAM	53	511,440	53	463,800	9%
VIR ISL	54	288,500	54	301,080	-4%
AM SAM	55	42,800	55	50,200	-17%
TOTAL DU's		**5,055,904,995**		**4,804,706,841**	**5%**

Source: ARCOS
Date Prepared: 03/06/2012

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

Other Oxycodone Products

Percocet

Percodan

Tylox

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

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

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

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

Roxicodone

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

Opiates v. Heroin

Circle of Addiction & the Next Generation

Oxycodone Combinations
Percocet®
$7-$10/tab

OxyContin®
$80/tab

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

Hydrocodone
Lorcet®
$5-$7/tab

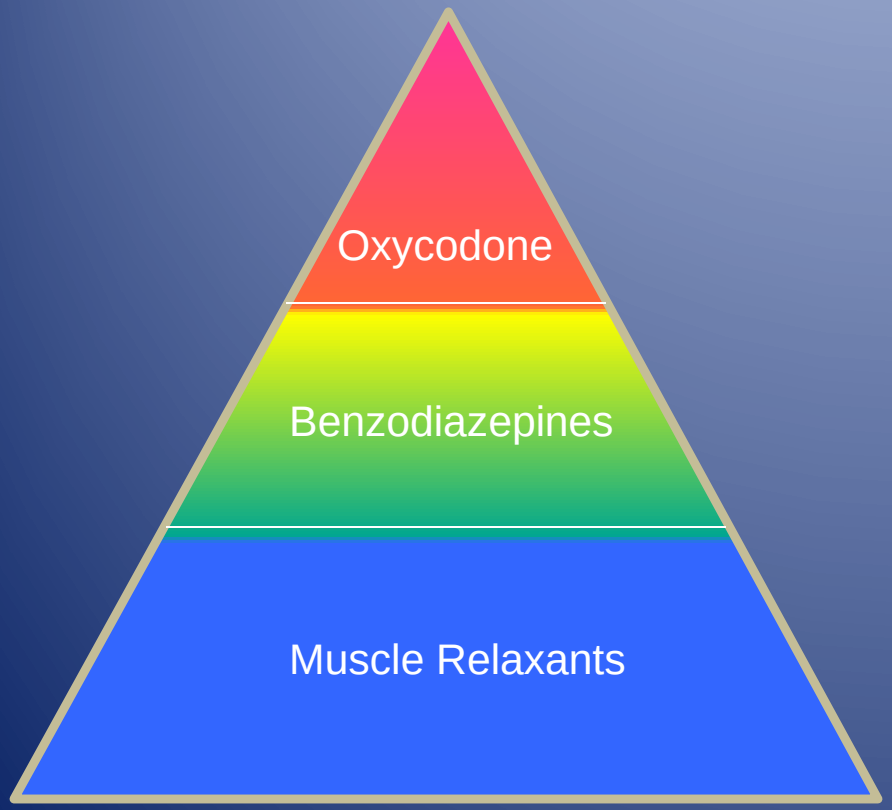
Heroin
$10/bag

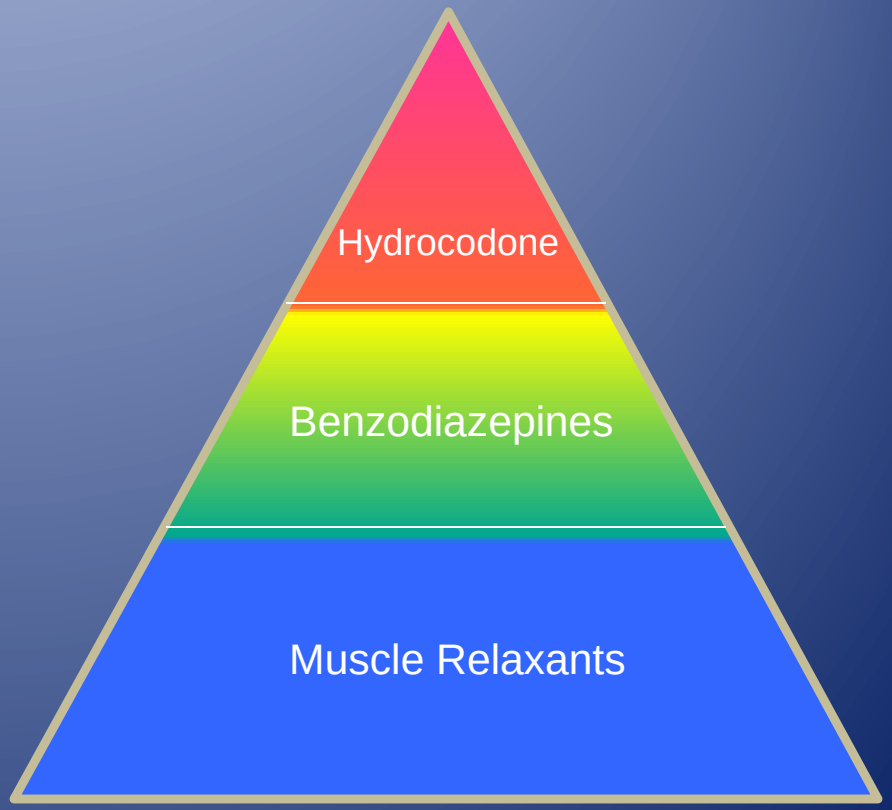
The Trinity

Opiate

Muscle Relaxant

Benzodiazepine


Oxycodone
Benzodiazepines
Muscle Relaxants


Hydrocodone
Benzodiazepines
Muscle Relaxants

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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

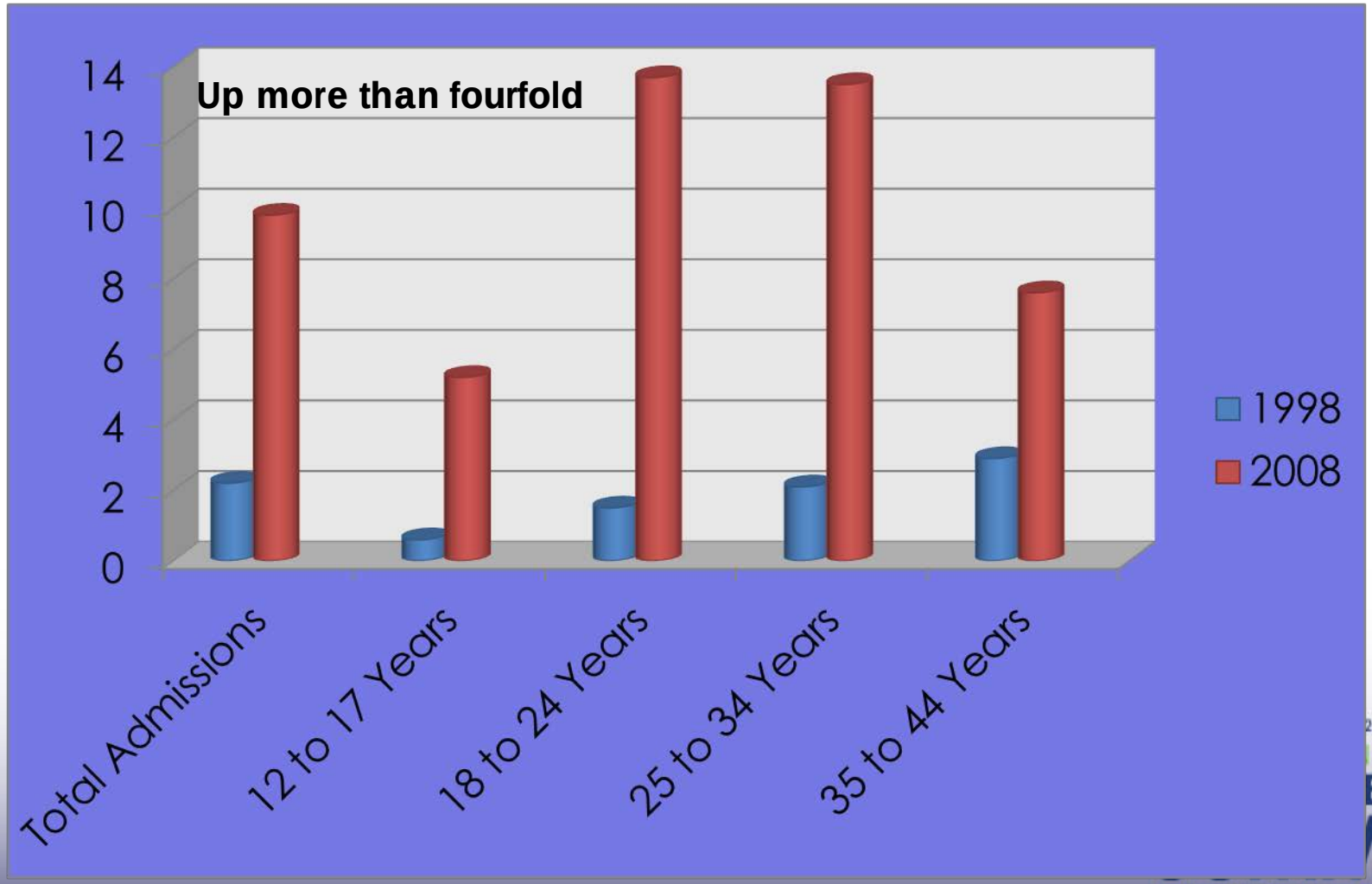
LOCAL

FBI analyst busted

Heroin use spikes in area suburbs

Pill addicts risk deadly drug

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

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
Stephanie Perry, Managing 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 ARJV)

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 2008 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 482 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 incidents 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.

Aron 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 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.

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.

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 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.

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

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.

480 Greenley Road
Sonora, CA 95370

The Union Democrat

SINCE 1854

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 Sonora 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.

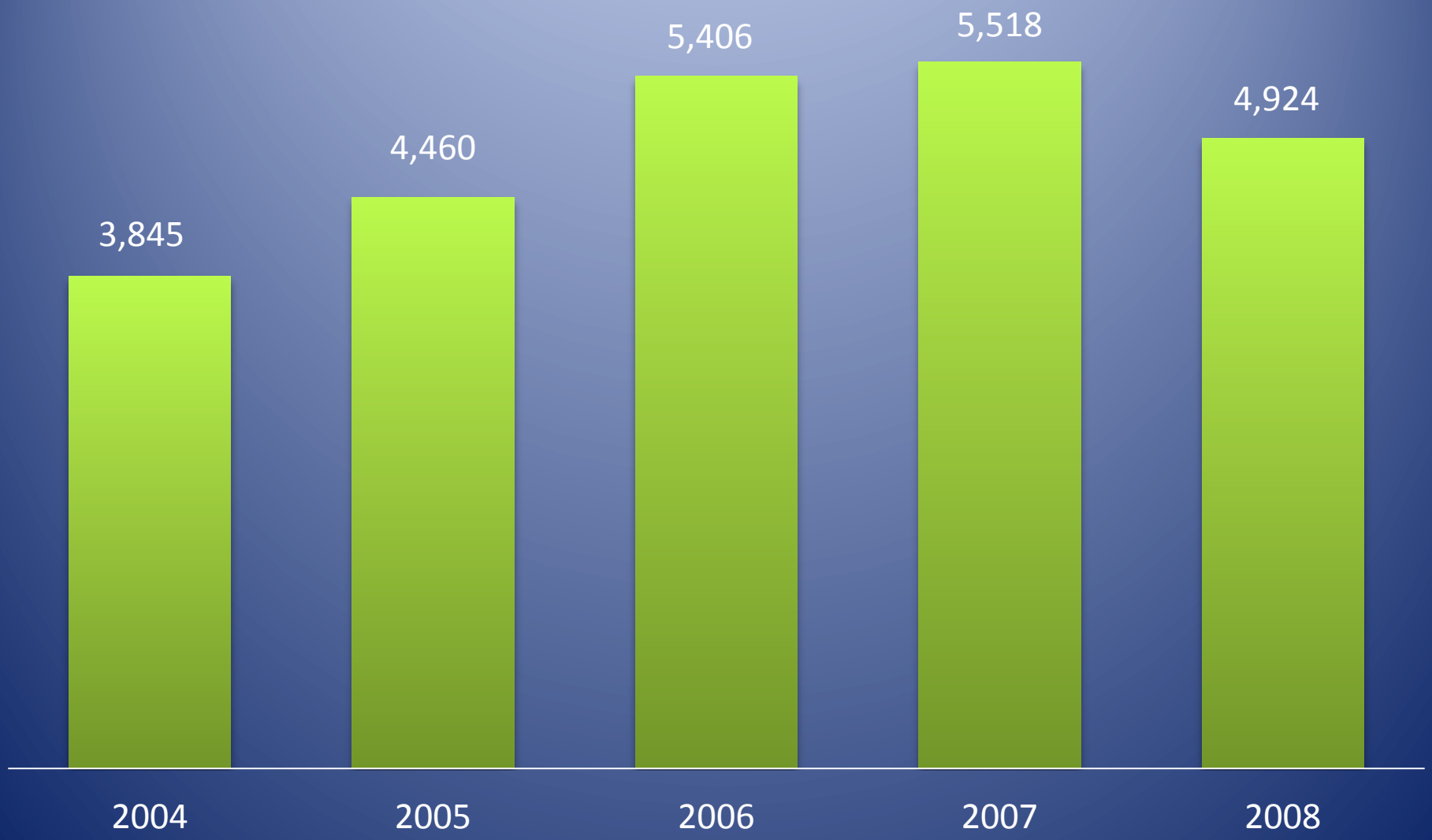
There were three suicides in 2007. The number could be higher, however, because there were some drug-related cases in which there wasn't enough

SEE DEATHS/B

ER visits involving Nonmedical Use of Methadone

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

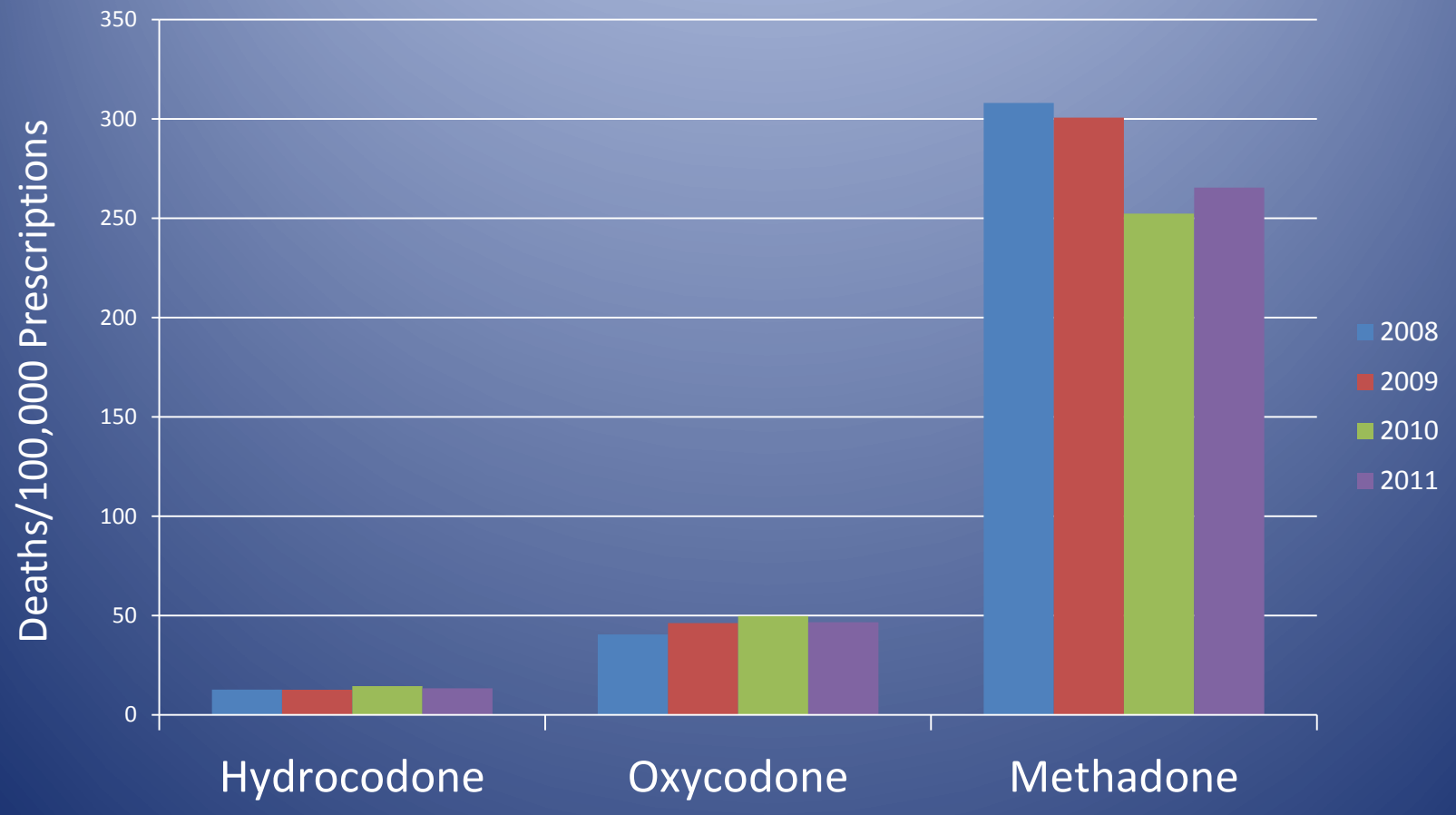
Deaths involving Methadone



Source: NCHS Data Brief #81, December 2011

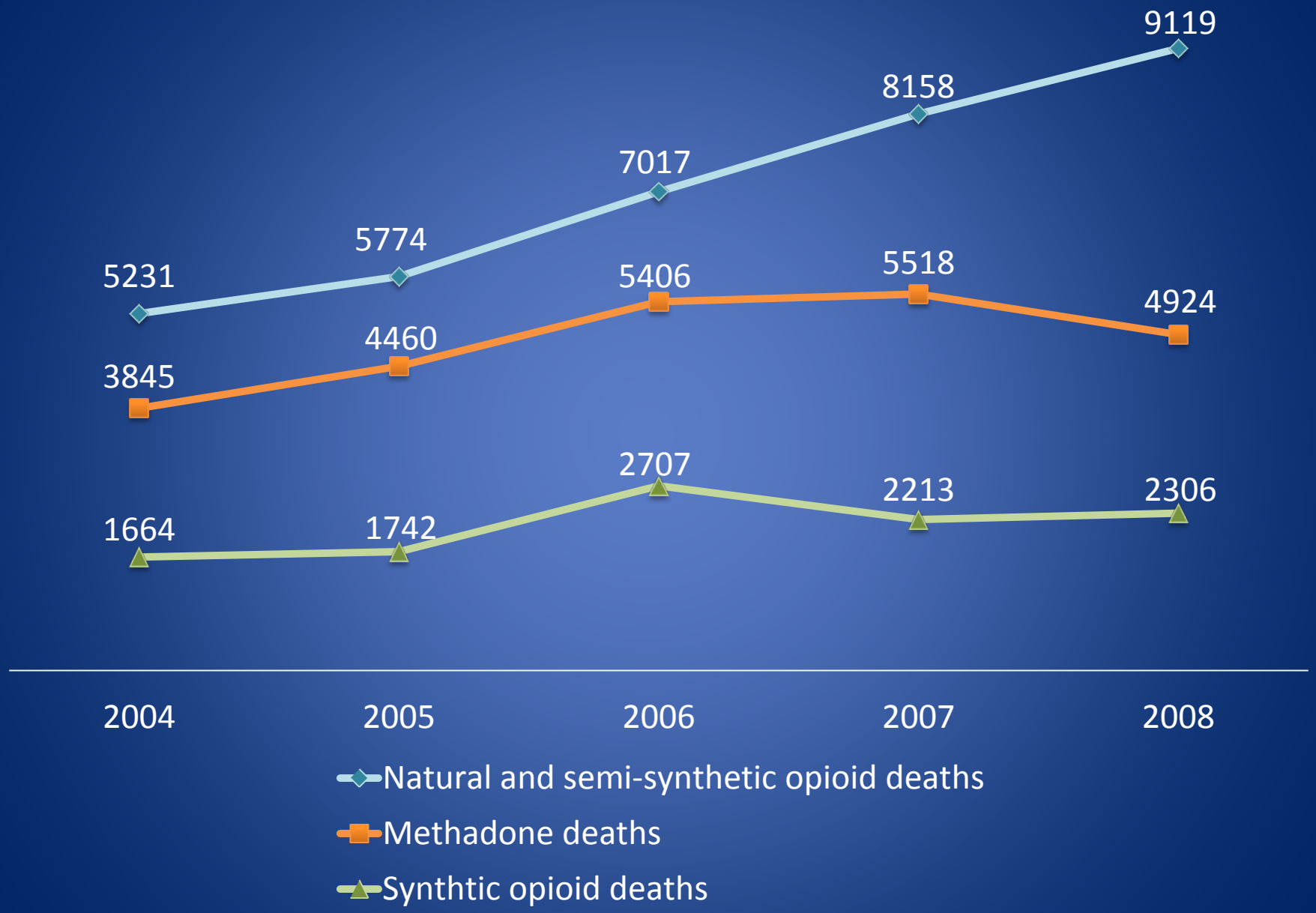
Florida Deaths Per 100,000 Prescriptions

2008-2011



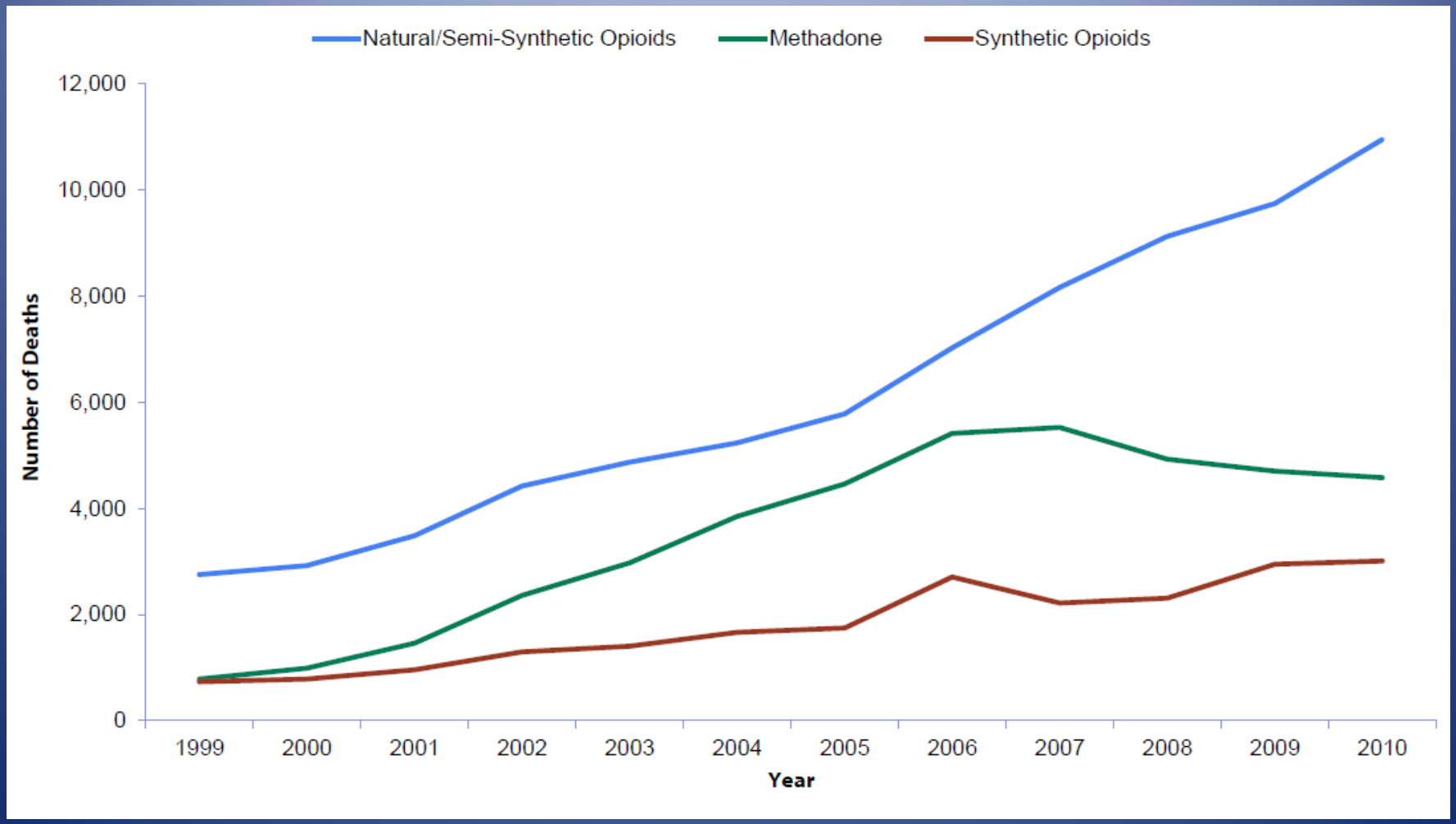
- Sources:
- Death Data : Florida Department of Law Enforcement, "Drugs Identified in Deceased Persons by Florida Medical Examiners"
- Prescription Data: IMS Exponent, State Level: Florida Retail Prescription Data

Opioid analgesic involved in deaths



Source: NCHS Data Brief #81, December 2011

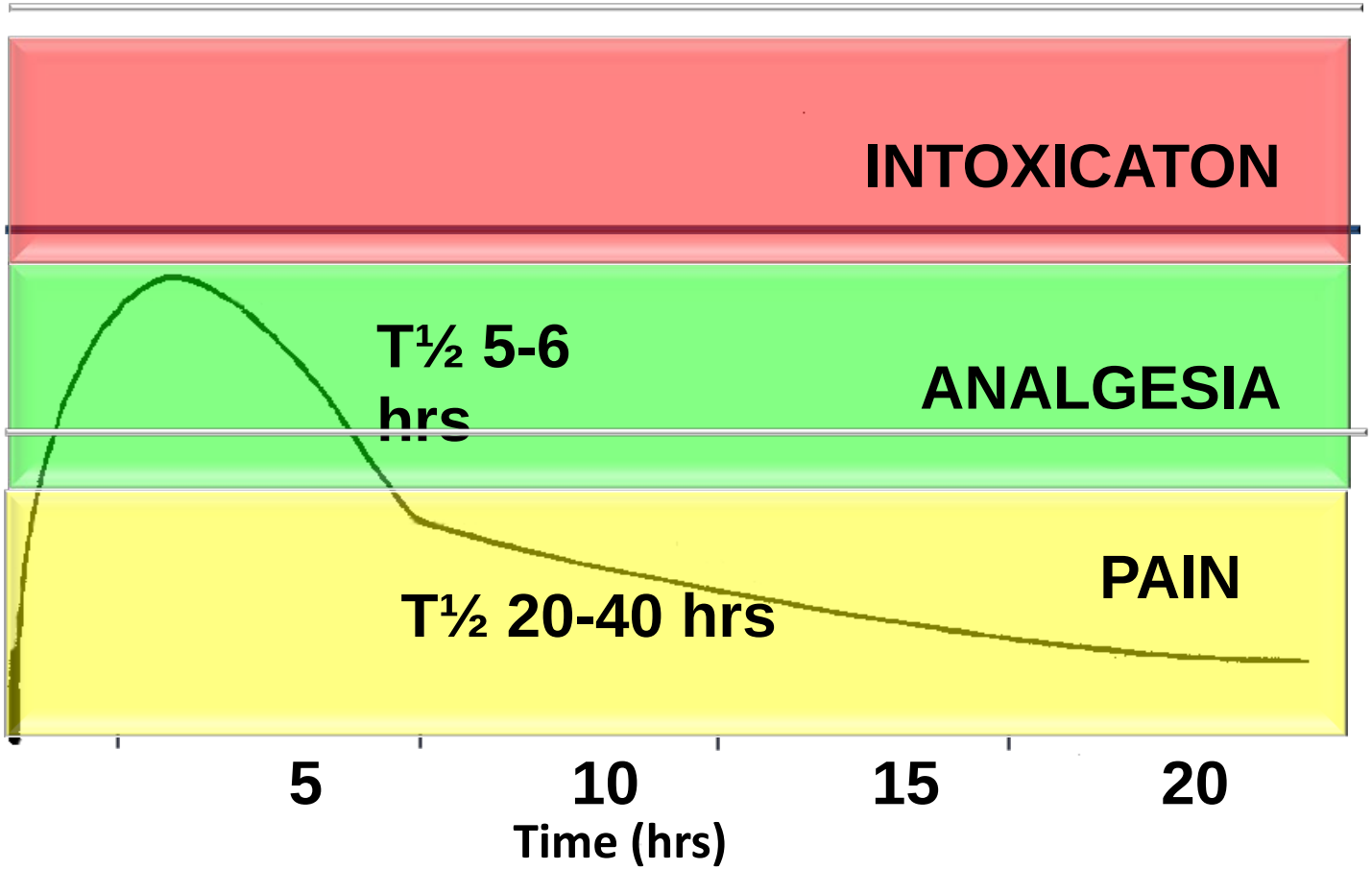
U.S. Drug Overdose Deaths by Type of Opioid Involved, 1999-2010



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

Source: 2010 NVSS Mortality File

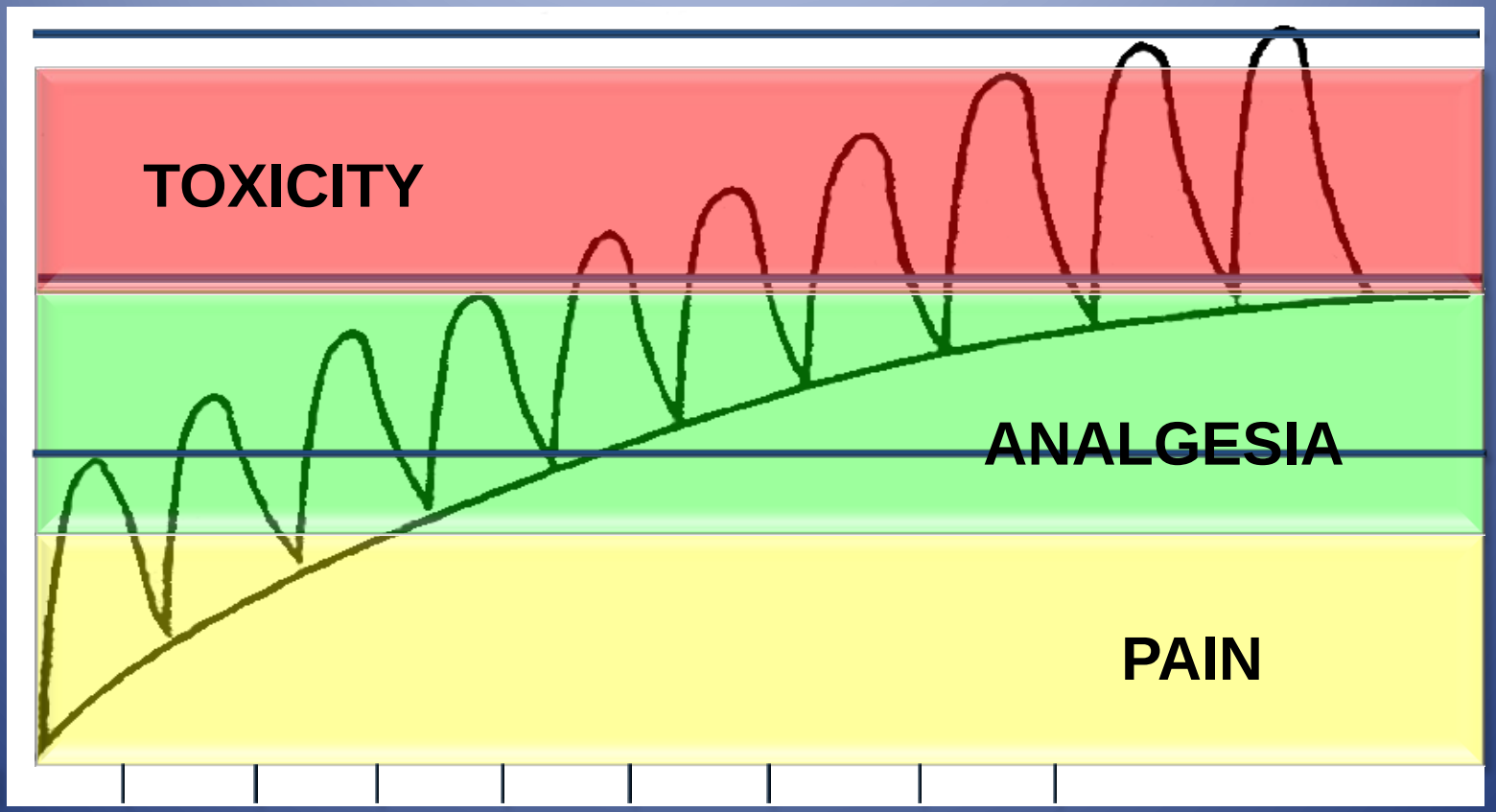
Methadone Single Dose Kinetics



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 form 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 form 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: |ACCME, CMI, ACFEI 1 CE credit for this article

By Jonathan J. Lipman, PhD

THE METHADONE POISONING "Epidemic"

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

Name _____

Address _____ Date _____

Rx

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

Other FDA Approved Drugs for Narcotic Addiction Treatment

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

Other Opiates of Interest

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

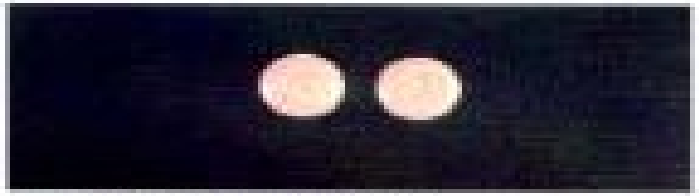
Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 15 mg

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

State Ranking* - Hydromorphone January – June 2012

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	21,228,360	12	IL	4,421,736	23	IN	2,448,208	34	NH	1,011,318	45	ND	393,136
2	FL	19,061,912	13	NC	4,252,436	24	SC	2,082,112	35	DE	990,800	46	RI	389,840
3	NY	9,697,706	14	MA	4,007,506	25	IA	1,861,184	36	UT	872,202	47	HI	360,900
4	TX	7,461,462	15	CO	3,851,846	26	OK	1,625,362	37	VT	806,448	48	AK	349,586
5	VA	5,922,402	16	OR	3,242,616	27	AL	1,601,898	38	NM	797,552	49	WY	311,412
6	PA	5,865,658	17	CT	3,212,408	28	WI	1,526,180	39	MT	782,800	50	DC	239,606
7	WA	5,005,016	18	GA	3,180,576	29	NV	1,498,220	40	ID	768,354	51	SD	235,004
8	OH	4,873,528	19	MO	3,166,810	30	KS	1,435,180	41	WV	743,716	52	PR	26,300
9	MI	4,682,560	20	AZ	3,061,366	31	LA	1,344,362	42	ME	740,870	53	GU	13,300
10	MD	4,506,456	21	MN	2,497,782	32	AR	1,315,256	43	MS	731,290	54	VI	5,800
11	NJ	4,482,783	22	TN	2,473,281	33	KY	1,214,538	44	NE	522,898	55	AS	0

** Business Activity - Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit

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®

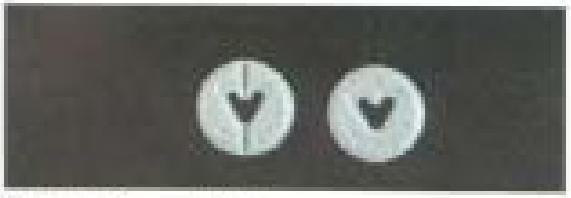
Dextromethorphan (DXM)

- 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

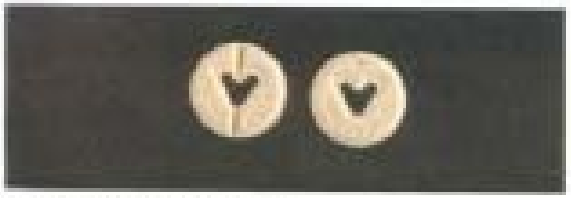
Cough Syrup Cocktails

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

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 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**

Xanax (Alprazolam)
Photo from the Physicians Desk Reference

* Source IMS Health

** Source Verispan VONA

Stimulants

Amphetamine Salts C-II

- Adderall C-II

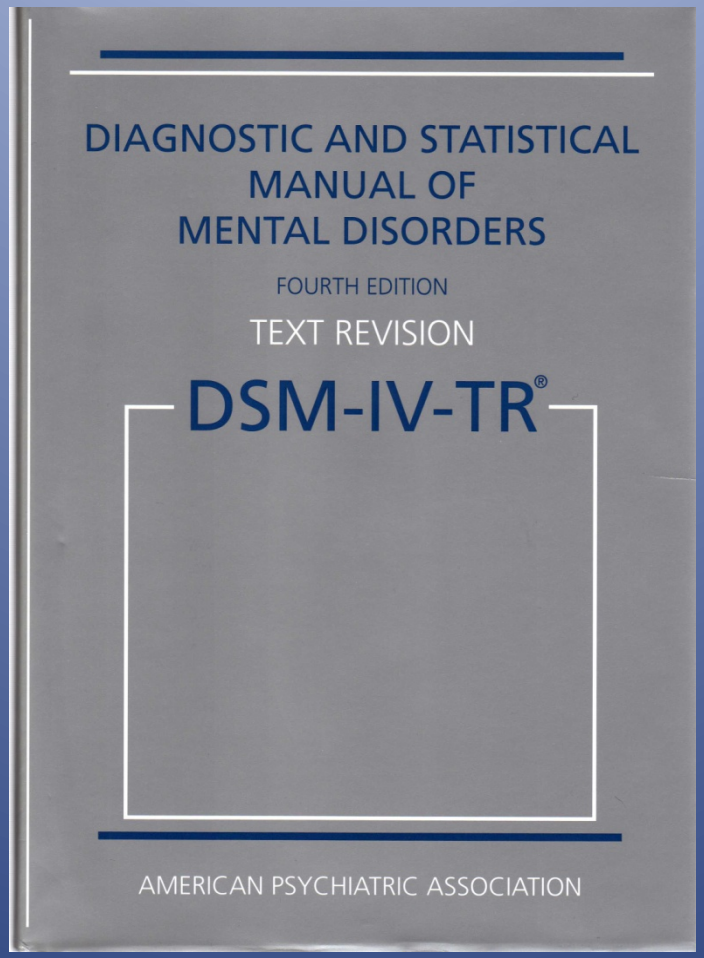
Methylphenidate C-II

- Ritalin®
- Concerta®

Ritalin® / Concerta® / Adderall

- Used legitimately to treat ADHD
- Used non-medically to get high and as an academic "performance-enhancer" to improve memory and improve concentration – gain the edge
  - Higher GPA
  - Higher SAT / ACT score
  - Get that scholarship

REQUIRED READING



Attention-Deficit and Disruptive Behavior Disorders

Attention-Deficit/Hyperactivity Disorder

Diagnostic Features

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)

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

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

(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

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

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).

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

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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-

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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.

Lisdexamfetamine (Vyvanse®)

- Lisdexamfetamine is a new chemical entity consisting of d-amphetamine (schedule II) covalently bound to the amino acid, L-lysine.
- Lisdexamfetamine per se is pharmacologically inactive.
- Upon oral ingestion, the lysine moiety is cleaved in the gastrointestinal system releasing d-amphetamine. Thus, lisdexamfetamine is a “pro-drug” for d-amphetamine.
- Pharmacology and abuse potential of lisdexamfetamine are similar to d-amphetamine.

Methods of Diversion

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

Where are the Pharmaceuticals Coming From?

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

Prescription Fraud

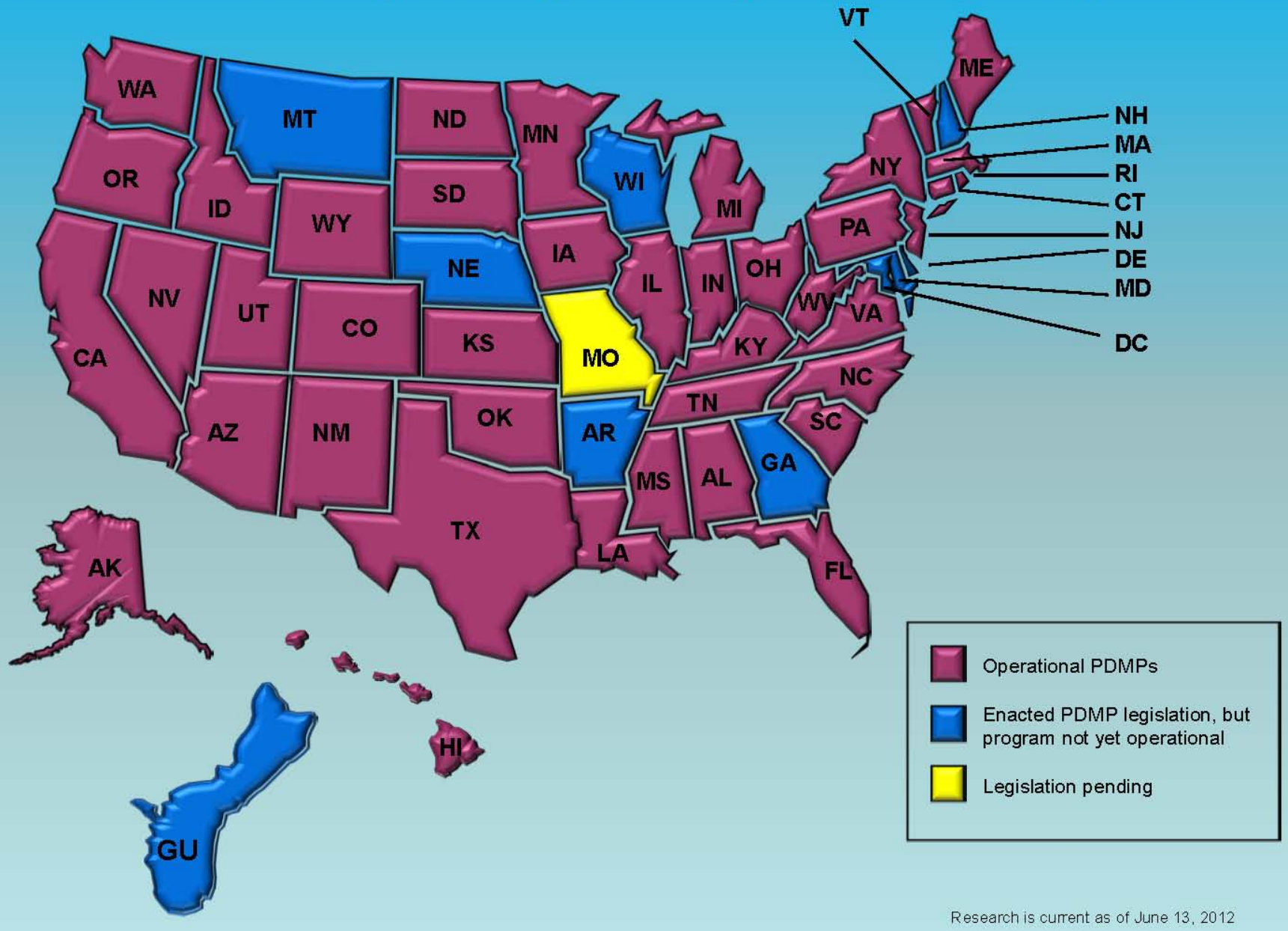
- **Fake prescriptions**
  - Highly organized
  - Use real physician name and DEA Registrant Number
    - Contact Information false or “fake office”
      - (change locations often to avoid detection)
  - Prescription printing services utilized
    - Not required to ask questions or verify information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

Doctor Shopping

Prescription Drug Monitoring Programs

Alliance of States with Prescription Monitoring Programs

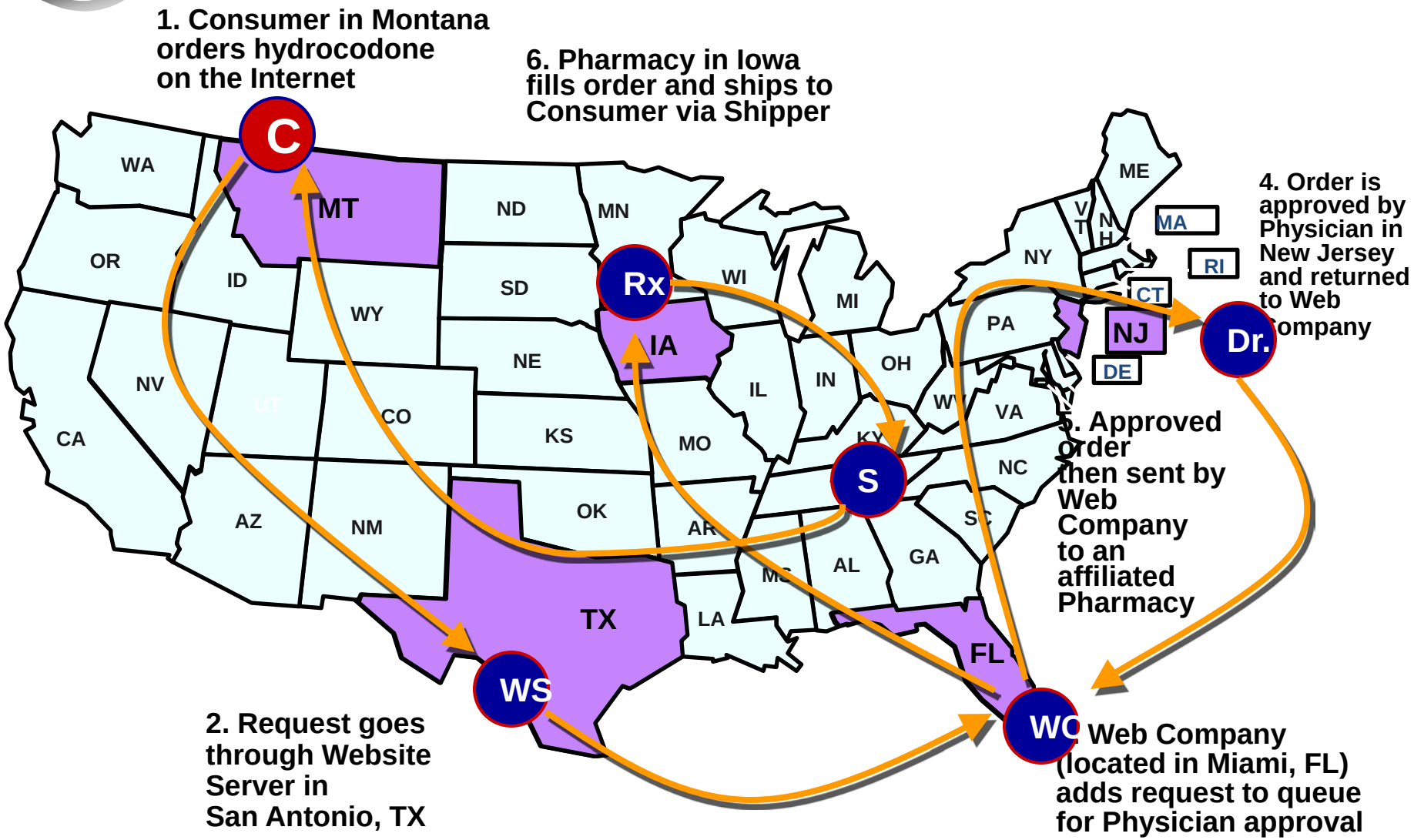
Status of Prescription Drug Monitoring Programs (PDMPs)



Research is current as of June 13, 2012

Diversion via the Internet

Domestic ‘R_X’ Flow



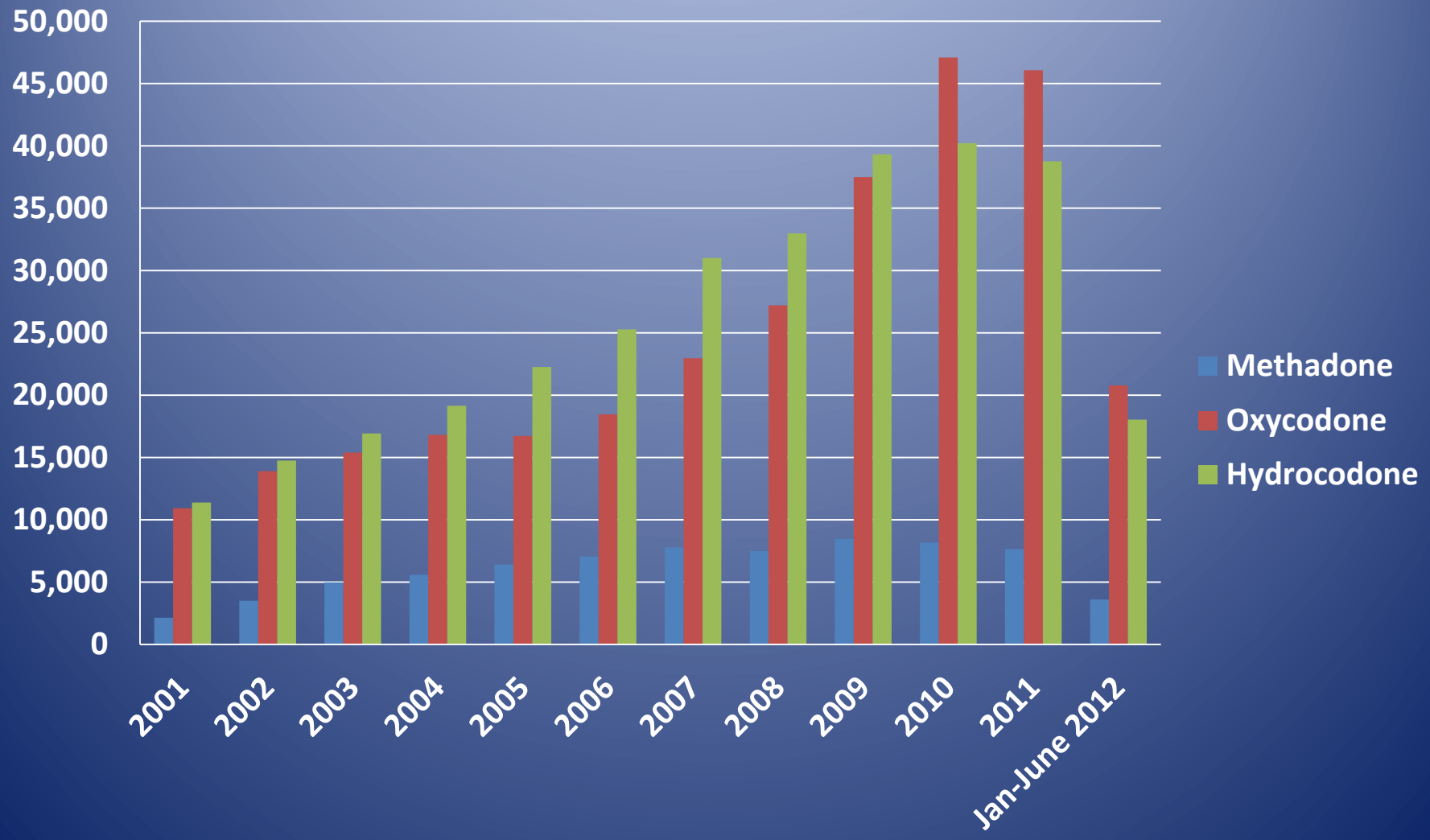
Purchases of hydrocodone by Known and Suspected Rogue Internet Pharmacies
January 1, 2006 – December 31, 2006

1			Hillsborough	TAMPA	FLORIDA	33614	15,596,380
2			Pinellas	CLEARWATER	FLORIDA	33765	9,077,818
3			Hillsborough	TAMPA	FLORIDA	33614	8,760,876
4			Baltimore City	BALTIMORE	MARYLAND	21213	5,876,300
5			Hillsborough	TAMPA	FLORIDA	33619	5,718,200
6			Jefferson	RIVER RIDGE	LOUISIANA	70123	4,892,900
7			Hillsborough	TAMPA	FLORIDA	33634	4,733,290
8			Polk	LAKELAND	FLORIDA	33813	4,564,480
9			Hillsborough	TAMPA	FLORIDA	33612	4,220,840
10			Pinellas	CLEARWATER	FLORIDA	33759	3,819,320
11			Hillsborough	TAMPA	FLORIDA	33610	3,044,160
12					FLORIDA	33809	3,039,490
13						70123	2,750,000
14						34652	2,664,120
15						33613	1,902,900
16					FLORIDA	33801	1,726,020
17			Hillsborough	TAMPA	FLORIDA	33612	1,619,765
18			Hillsborough	TAMPA	FLORIDA	33604	1,570,350
19			Pinellas	TARPON SPRINGS	FLORIDA	34689	1,464,900
20			Lincoln	DENVER	NORTH CAROLINA	28037	1,402,450
21			Hillsborough	TAMPA	FLORIDA	33617	1,282,800
22			Hillsborough	TAMPA	FLORIDA	33619	1,272,860
23			Polk	LAKELAND	FLORIDA	33813	1,039,400
24			Pasco	WESLEY CHAPEL	FLORIDA	33543	1,030,050
25			Iredell	MOORESVILLE	NORTH CAROLINA	28117	902,500
26			Polk	LAKELAND	FLORIDA	33815	867,800
27			Broward	HOLLYWOOD	FLORIDA	33021	865,700
28			Los Angeles	ENCINO	CALIFORNIA	91436	798,100
29			Hillsborough	TAMPA	FLORIDA	33604	793,350
30			Pasco	NEW PORT RICHEY	FLORIDA	34652	583,400
31			Ravalli	FLORENCE	MONTANA	59833	362,000
32			Hillsborough	TAMPA	FLORIDA	33619	162,000
33			Broward	DEERFIELD BEACH	FLORIDA	33441	112,600
34			Hillsborough	TAMPA	FLORIDA	33614	49,600
							2,899,021

98,566,711

Date Prepared: 03/07/2007 Source: ARCOS

National Forensic Laboratory Information System (NFLIS) State and Local Law Enforcement Cases



Yearly estimates are published in NFLIS Annual Report (2001-2011) and NFLIS 2012 Midyear Report

NFLIS Drug Cases
(State and Local)

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	Jan-June 2012
Methadone	2,145	3,508	4,986	5,594	6,409	7,053	7,778	7,500	8,459	8,173	7,658	3,613
Oxycodone	10,926	13,906	15,396	16,818	16,721	18,456	22,960	27,207	37,489	47,088	46,065	20,787
Hydrocodone	11,386	14,756	16,933	19,147	22,259	25,272	31,007	32,985	39,326	40,206	38,765	18,033
Morphine	1,725	2,180	2,687	2,801	3,171	3,637	4,337	4,757	5,986	5,986	6,931	3,696
Codeine	2,959	3,070	3,116	3,354	2,743	2,787	2,962	3,026	3,439	3,390	3,530	1,599
Meperidine	465	425	343	268	258	294	283	251	244	167	151	64

Yearly estimates published in NFLIS Annual Report (2001-2011) and NFLIS 2012 Midyear Report

NFLIS Data

Federal, State and Local Cases:

	2006	2007	2008	2009	2010	2011	2012*
MEPERIDINE	312	301	316	237	193	150	84
OXYMORPHONE	17	45	129	344	781	2,689	1,881
CODEINE	2,631	2,707	3,038	3,177	3,181	3,014	2,194
HYDROMORPHONE	1,333	1,570	1,680	2,024	2,355	2,675	2,969
METHADONE	6,640	7,262	7,485	7,922	7,645	7,059	4,890
MORPHINE	3,563	4,189	4,930	6,037	6,385	6,690	5,849
HYDROCODONE	24,984	30,637	33,731	38,082	39,381	36,512	25,926
OXYCODONE	17,927	22,425	28,756	38,330	48,197	46,296	33,196

Federal, State and Local Reports:

	2006	2007	2008	2009	2010	2011	2012*
MEPERIDINE	342	332	339	274	268	159	94
OXYMORPHONE	17	47	139	387	868	3,045	2,086
CODEINE	2,978	3,059	3,478	3,629	3,646	3,398	2,455
HYDROMORPHONE	1,426	1,687	1,827	2,234	2,609	2,990	3,272
METHADONE	7,124	7,899	8,400	8,783	8,481	7,737	5,351
MORPHINE	4,036	4,685	5,731	7,104	7,440	7,768	6,657
HYDROCODONE	27,927	34,449	38,422	44,074	45,625	42,751	29,944
OXYCODONE	21,155	26,478	34,652	46,575	60,223	57,668	40,973

*2012 data is still being submitted, queried on 1/22/2013

New Felony Offense
Internet Trafficking
10/15/2008

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

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

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

What has been the reaction????

Per Se Violations

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

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

Traffickers Adapt

Switch to overseas sites outside of U.S. regulatory authority

Non-controlled drugs

Current CSA Registrant Population

Total Population: 1,469,821

- Practitioner - 1,148,956
- Mid-Level Practitioner - 222,773
- Pharmacy - 68,526
- Hospital/Clinic - 15,860
- Teaching Institution - 315
- Manufacturer - 544
- Distributor - 919
- Researcher - 9,642
- Analytical Labs - 1,511
- NTP - 1,310
- Importer/Exporter - 474
- ADS Machine - 404
- Chemicals - 1,056

2/08/2013

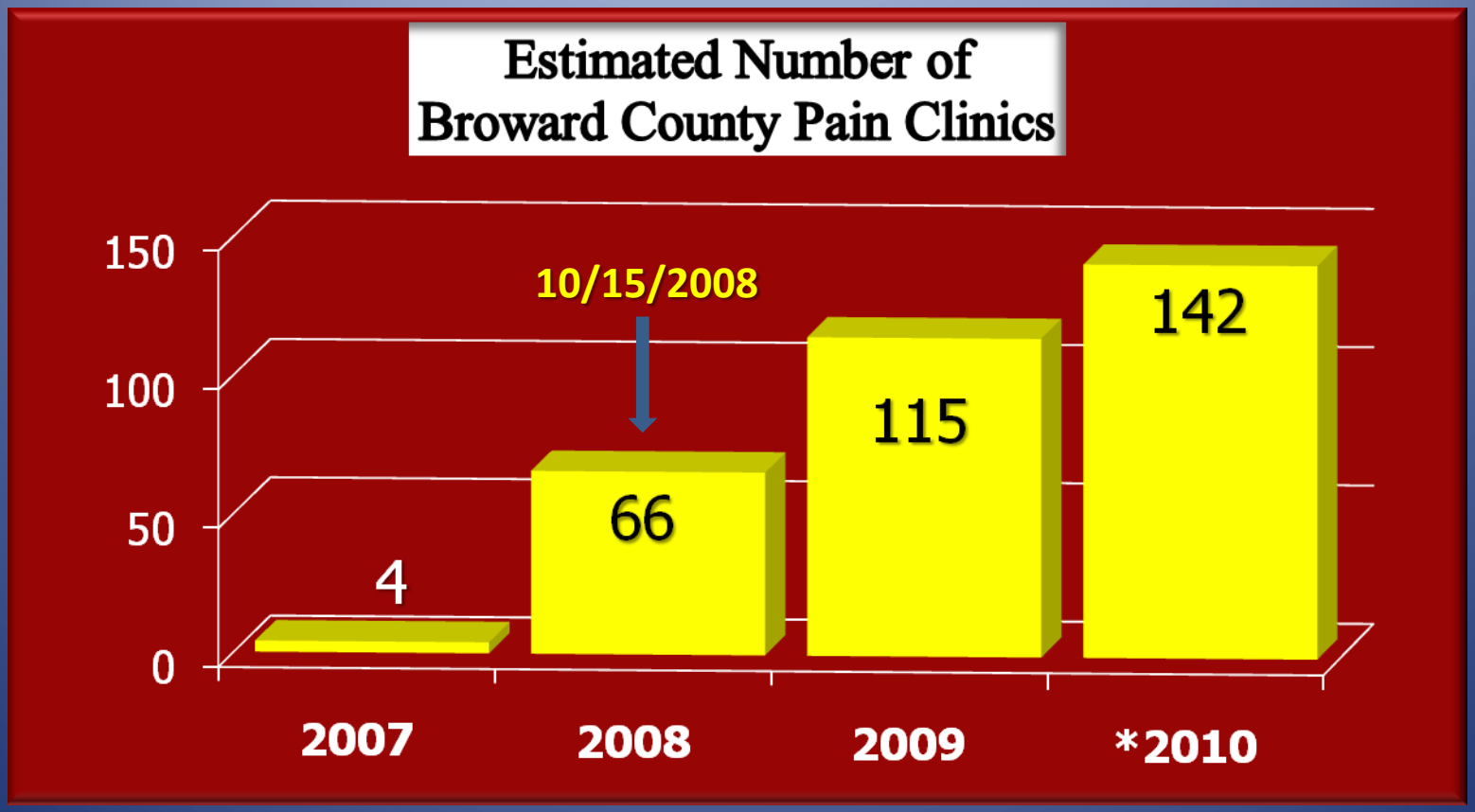
SOOOO…How many have applied for registration for Internet Pharmacy Operations?????

39 applications filed
20 withdrawn
7 applications filed in error
12 pending
No applications approved thus far

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

Explosion of South Florida Pain Clinics – All Providers (Current and Closed)

- All/State of Florida: 1,501

- Broward County: 236
- Miami-Dade County: 156
- Palm Beach County: 161
- Hillsborough County (Tampa area): 214

As of February 12, 2013.

Explosion of South Florida Pain Clinics – Currently Licensed Providers

- All/State of Florida: 390

- Broward County: 60
- Miami-Dade County: 46
- Palm Beach County: 32
- Hillsborough County (Tampa area): 63

As of February 12, 2013.

NFLIS – Federal, State, and local cases reported

	Hydrocodone	Oxycodone
2002	9,376	8,288
2003	12,130	9,715
2004	16,401	13,492
2005	21,190	14,643
2006	24,984	17,927
2007	30,637	22,425
Ryan-Haight **2008**	33,731	28,756
2009	38,082	38,330
2010	39,380	48,197
2011	36,954	46,452
2012	28,695*	35,781*

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

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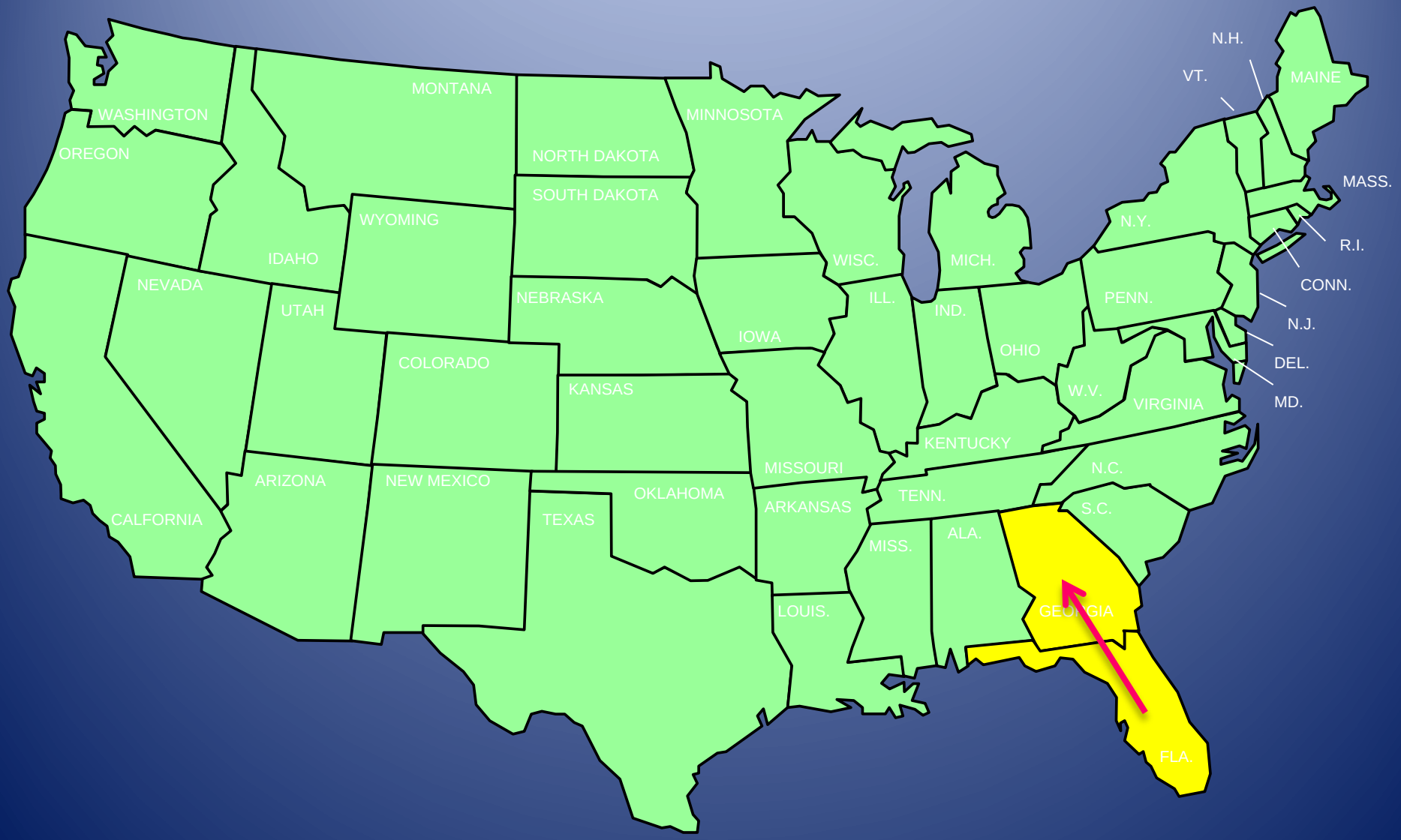
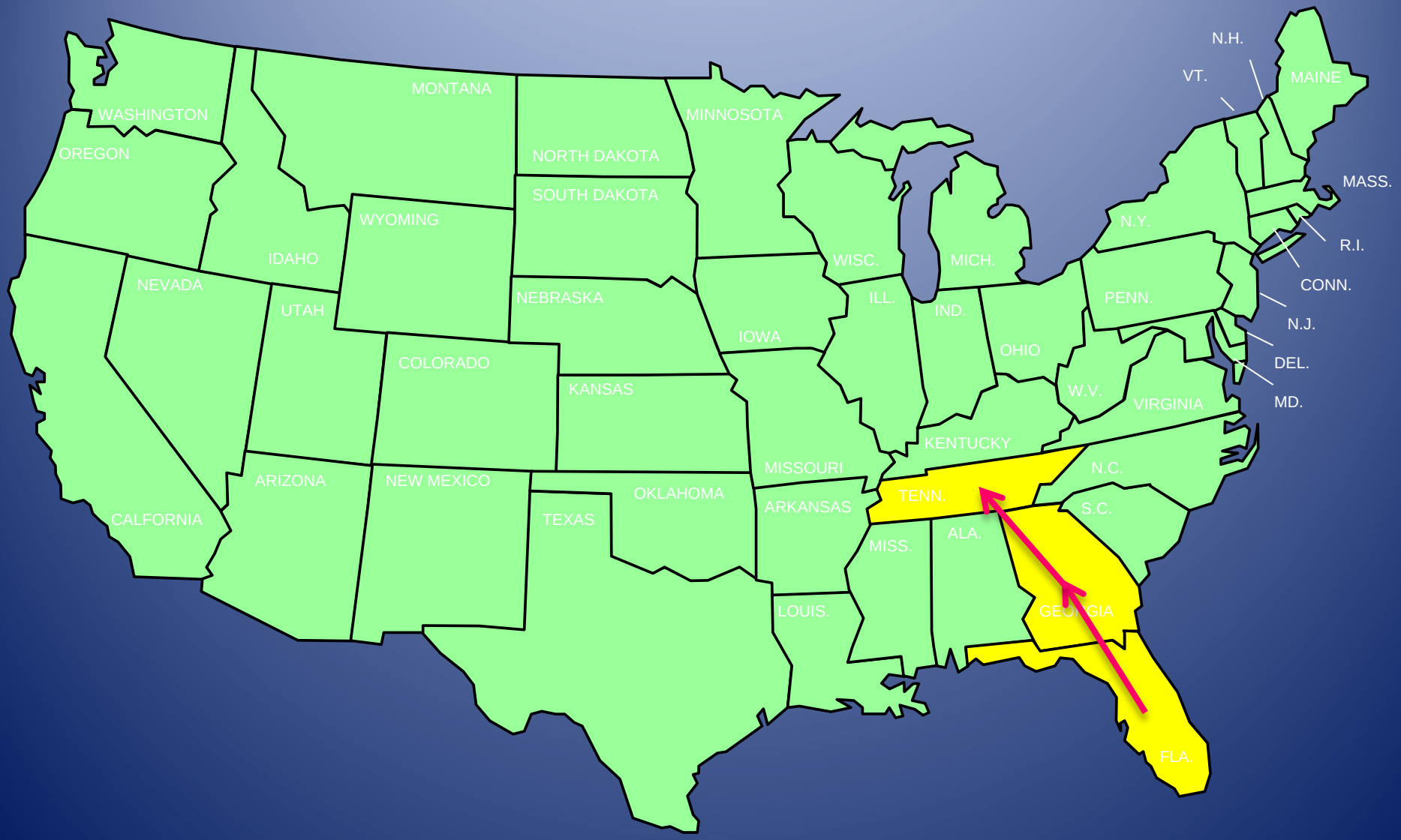
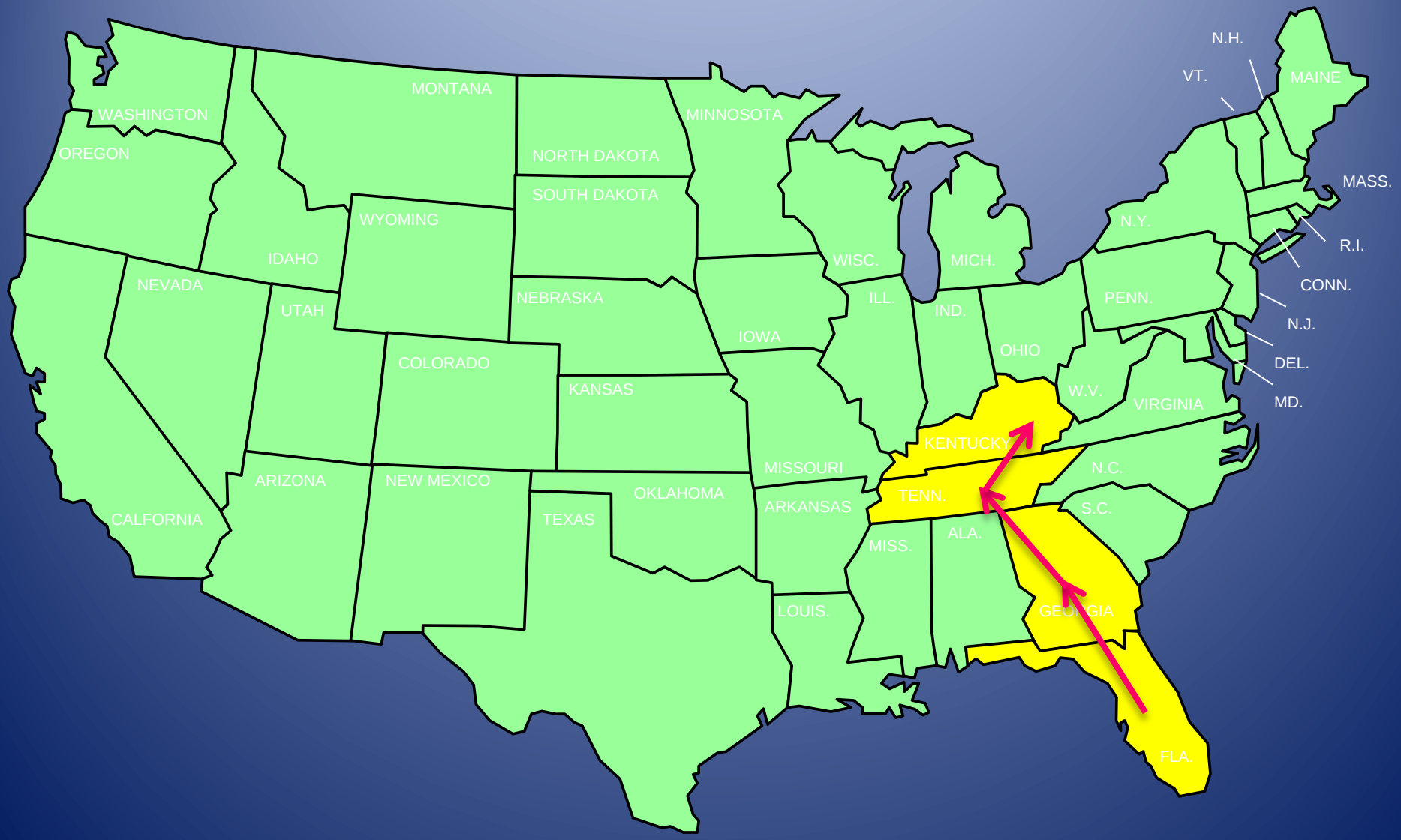
MIGRATION OF PAIN CLINICS



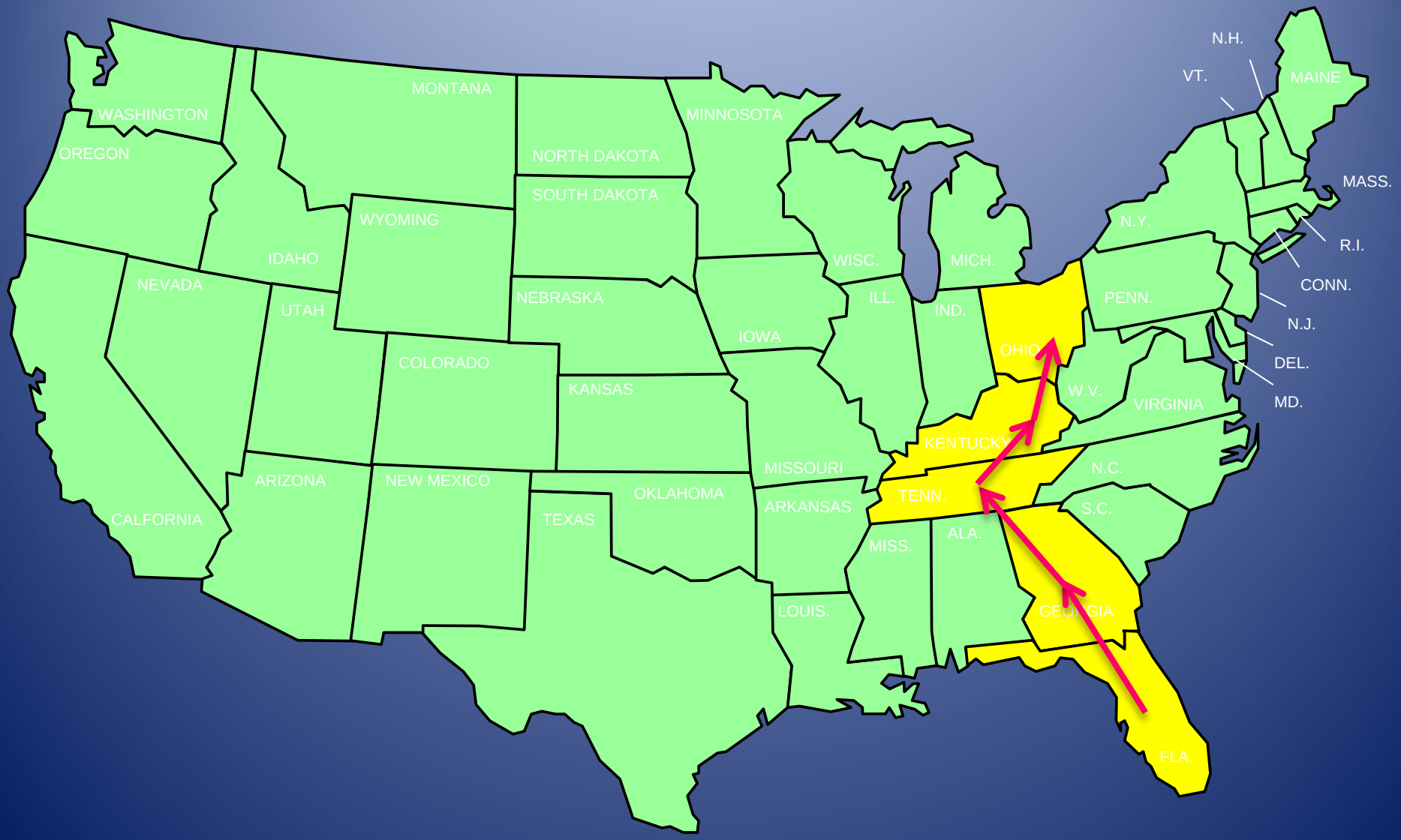
MIGRATION OF PAIN CLINICS



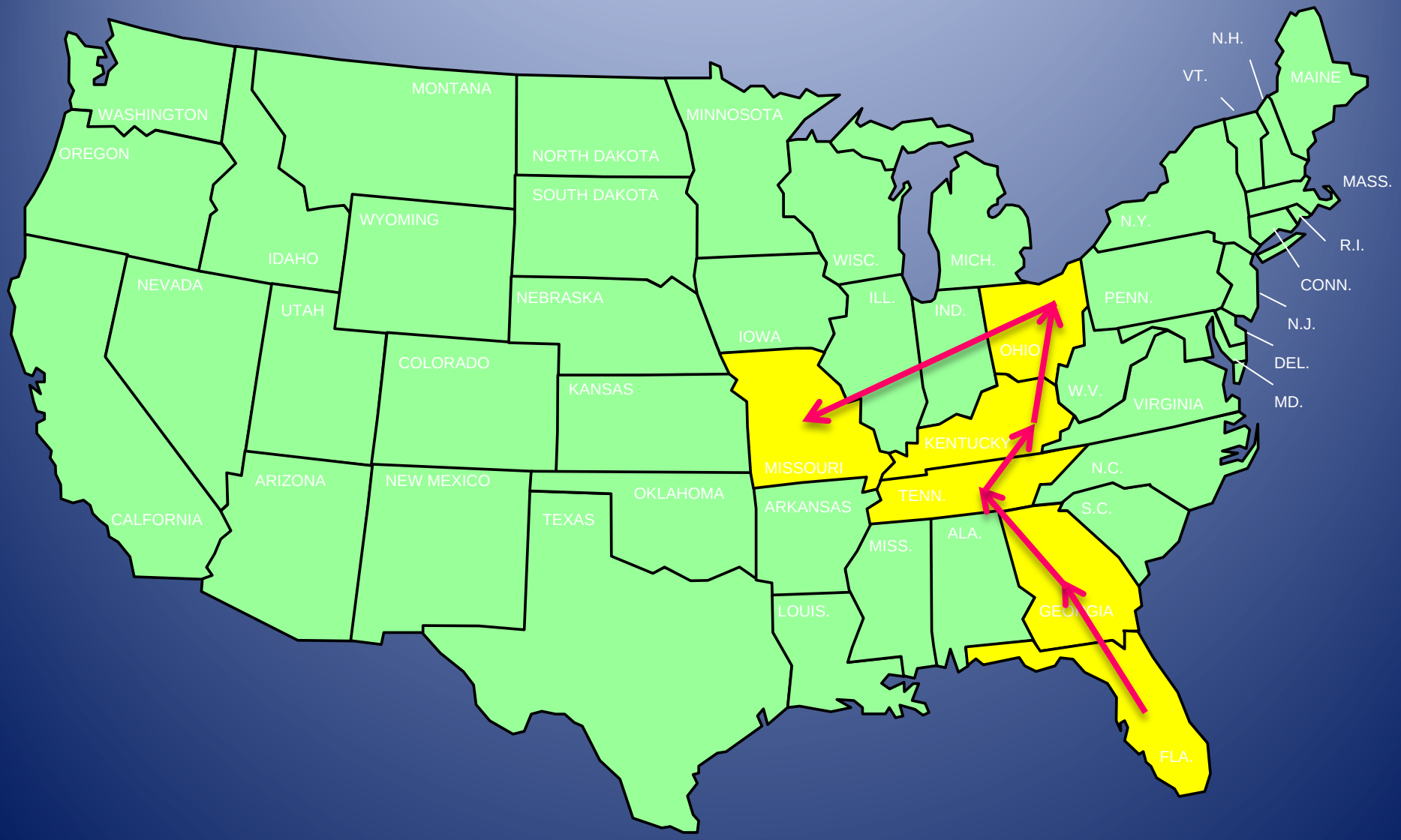
MIGRATION OF PAIN CLINICS



MIGRATION OF PAIN CLINICS



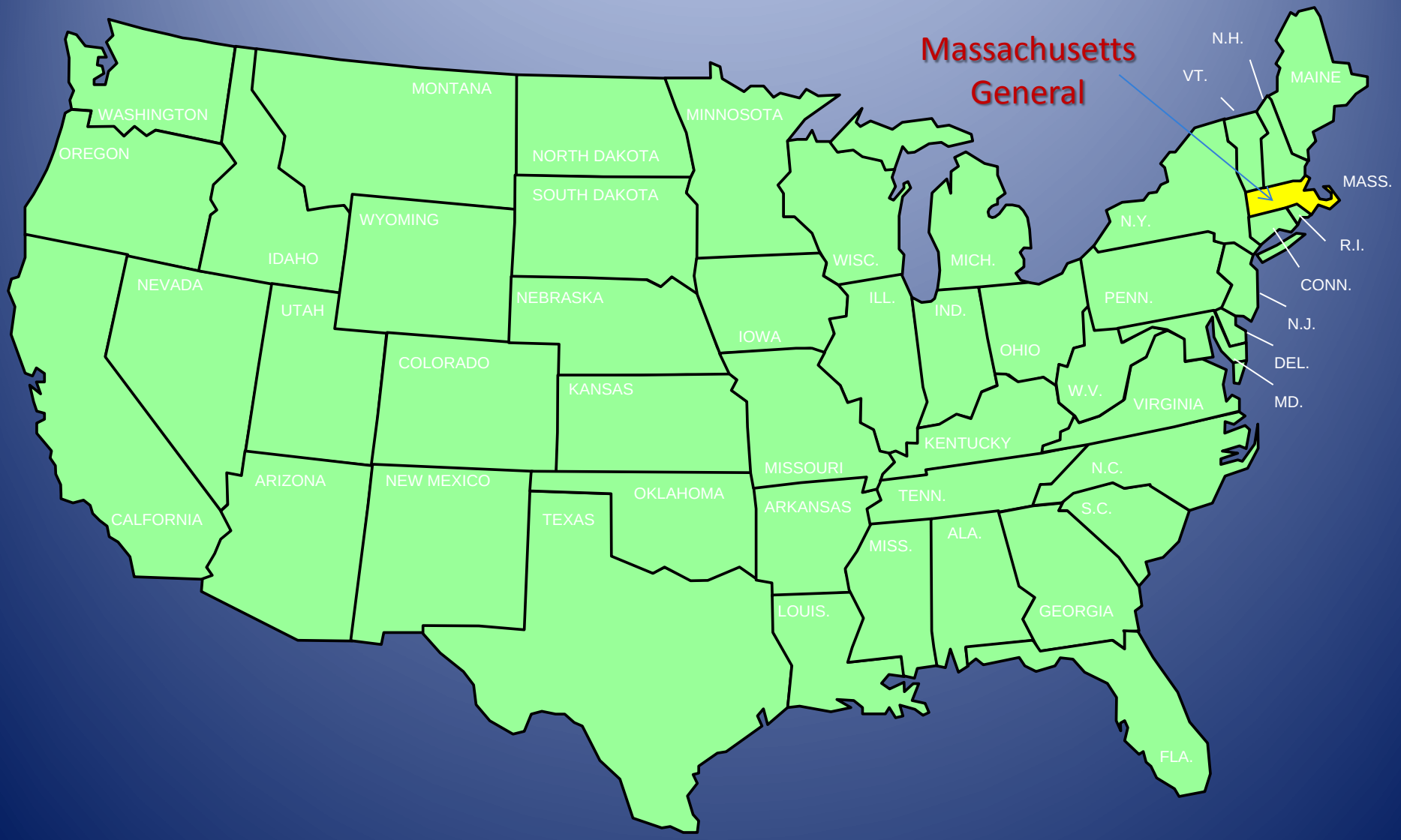
MIGRATION OF PAIN CLINICS



‘The Florida Migration’

- Vast majority of ‘patients’ visiting Florida “pain clinics”come from out-of-state:
  - Georgia
  - Kentucky
  - Tennessee
  - Ohio
  - Massachusetts
  - New Jersey
  - North and South Carolina
  - Virginia
  - West Virginia

THE MIGRATION



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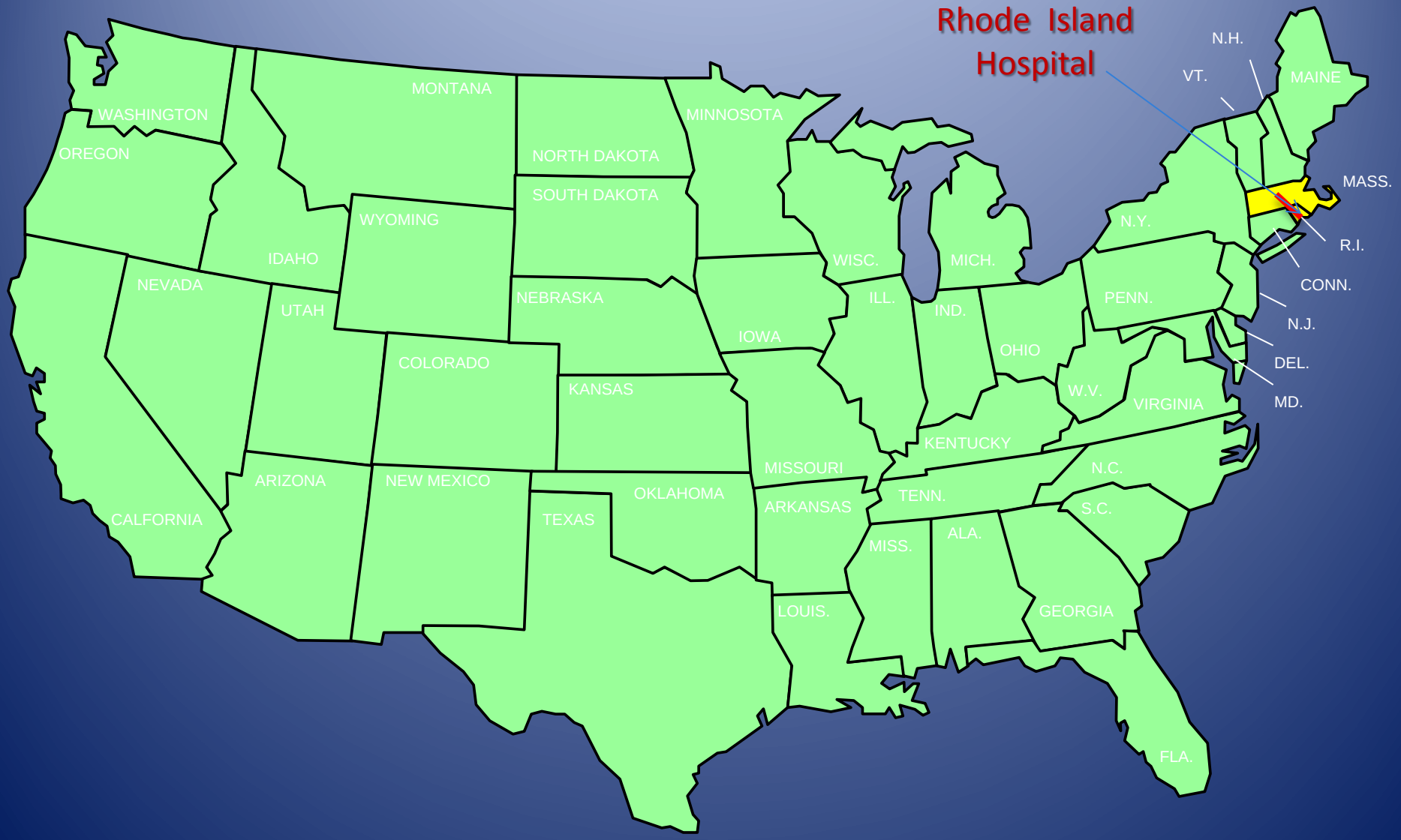
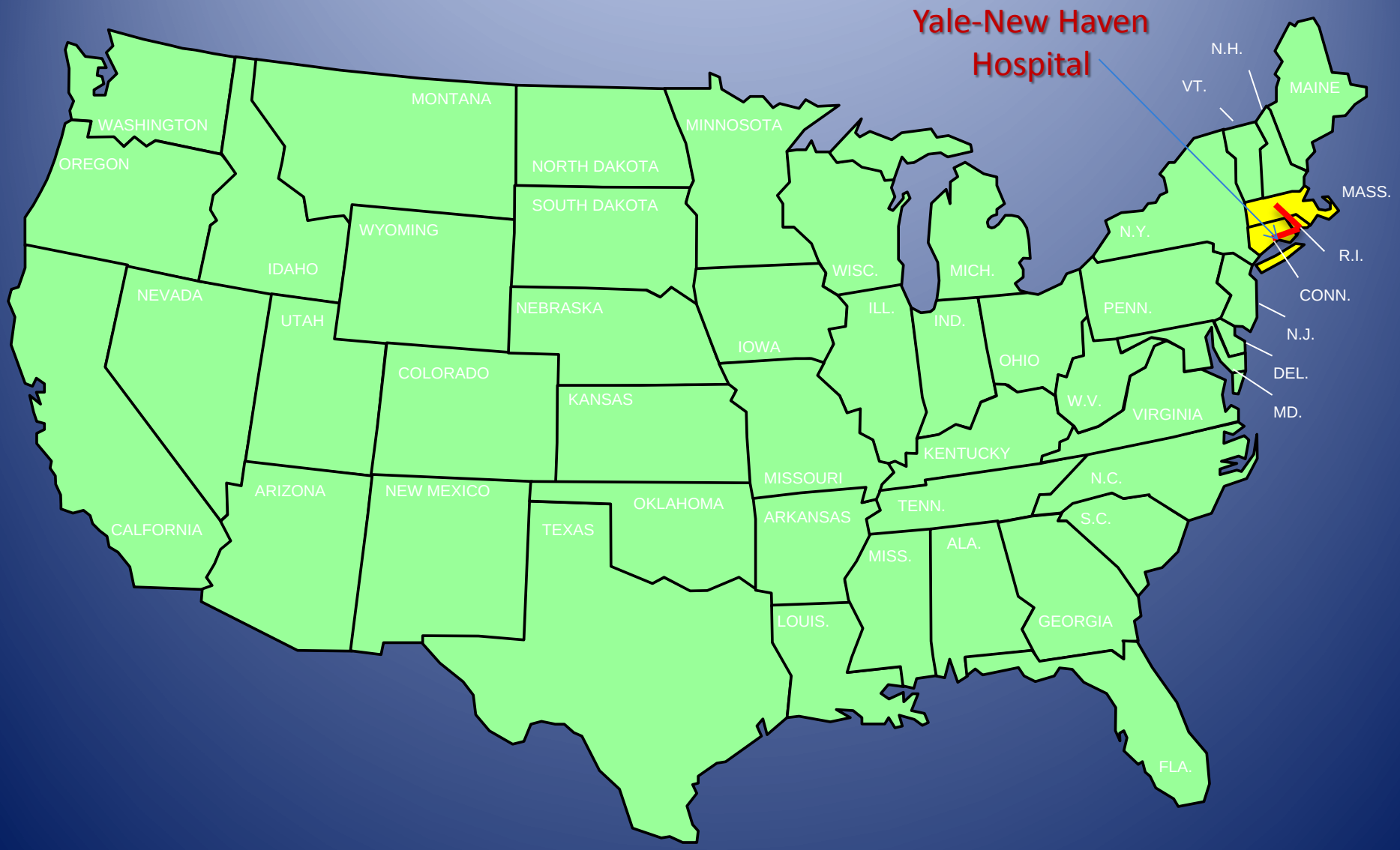
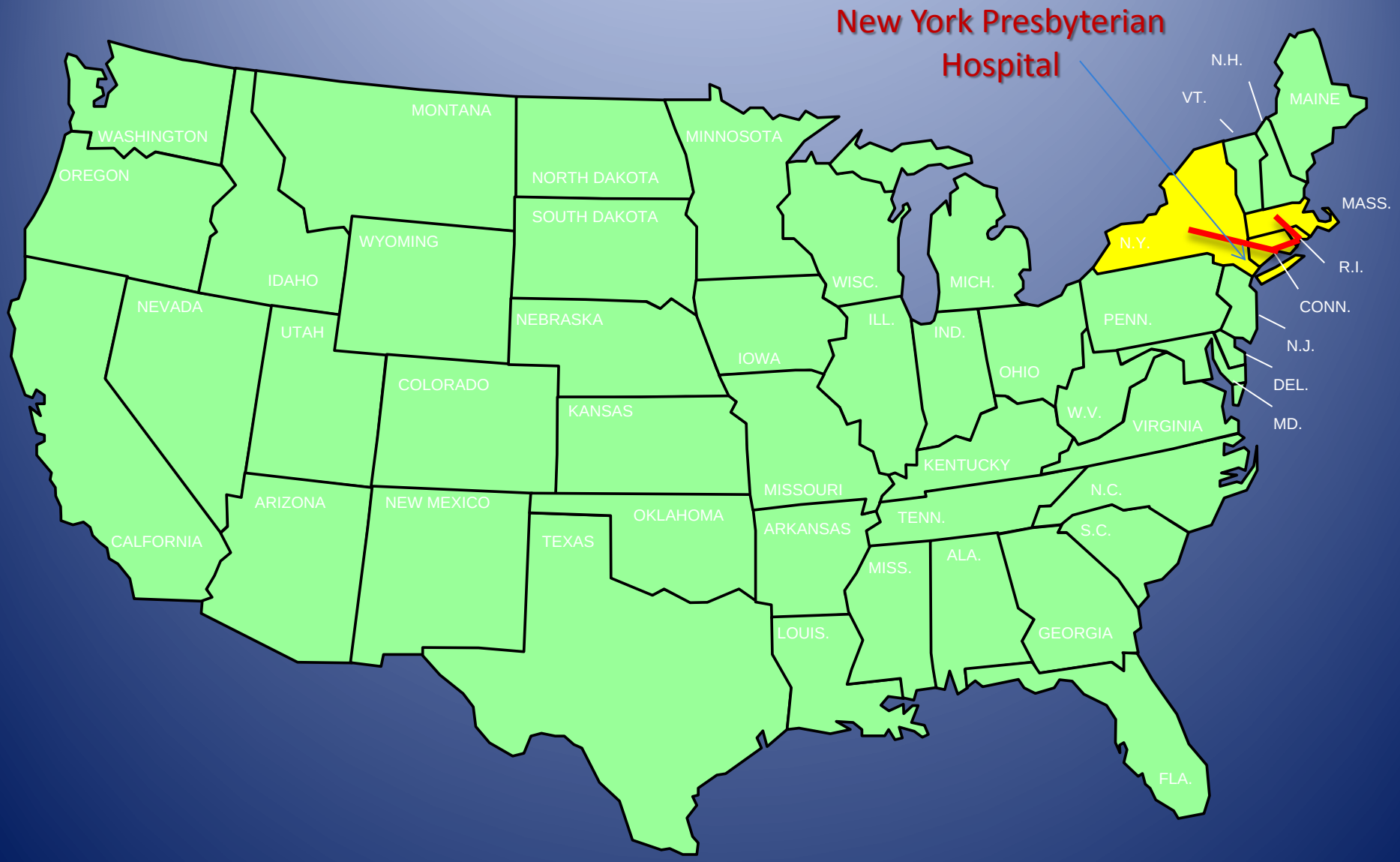


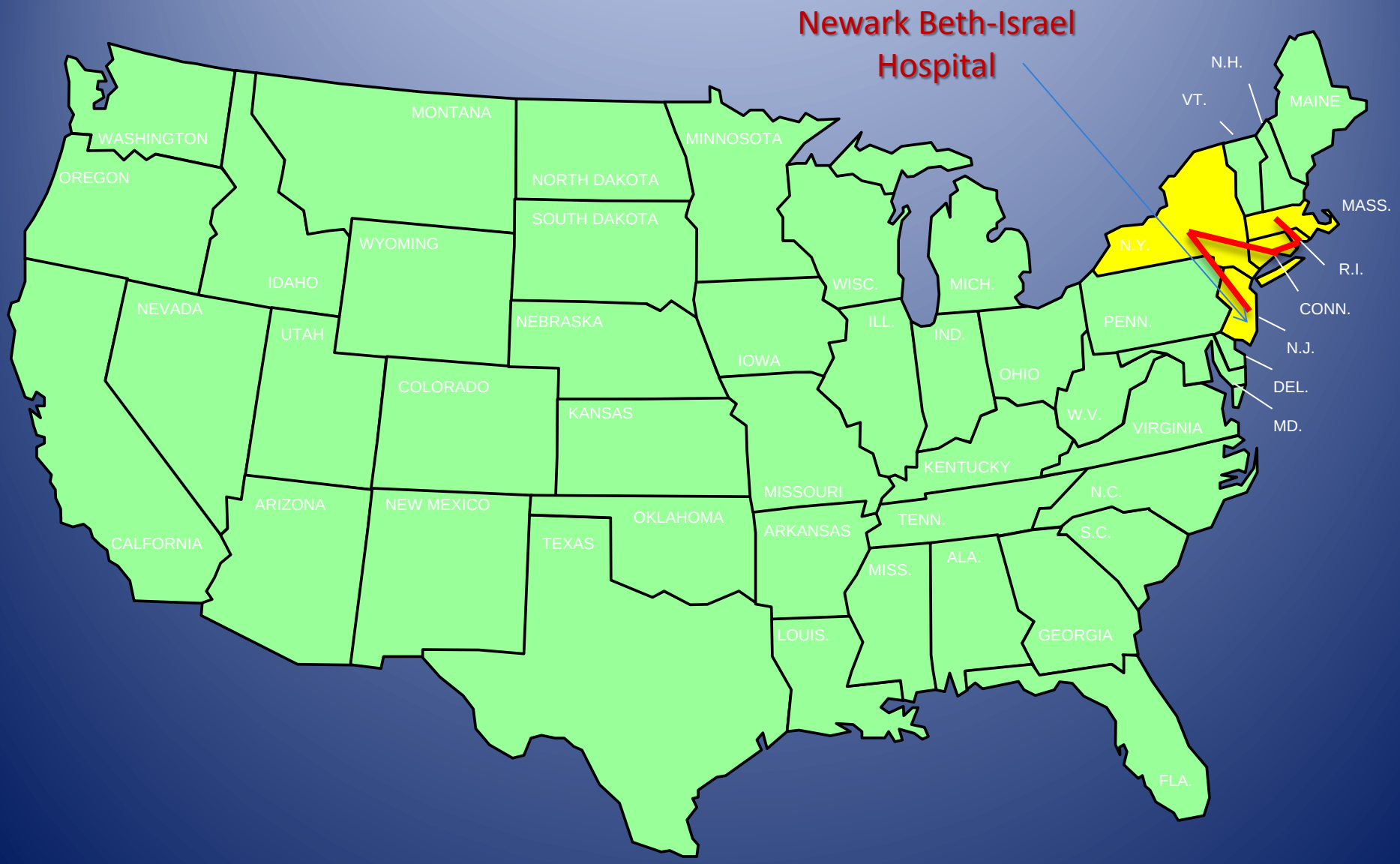
THE MIGRATION



THE MIGRATION



THE MIGRATION



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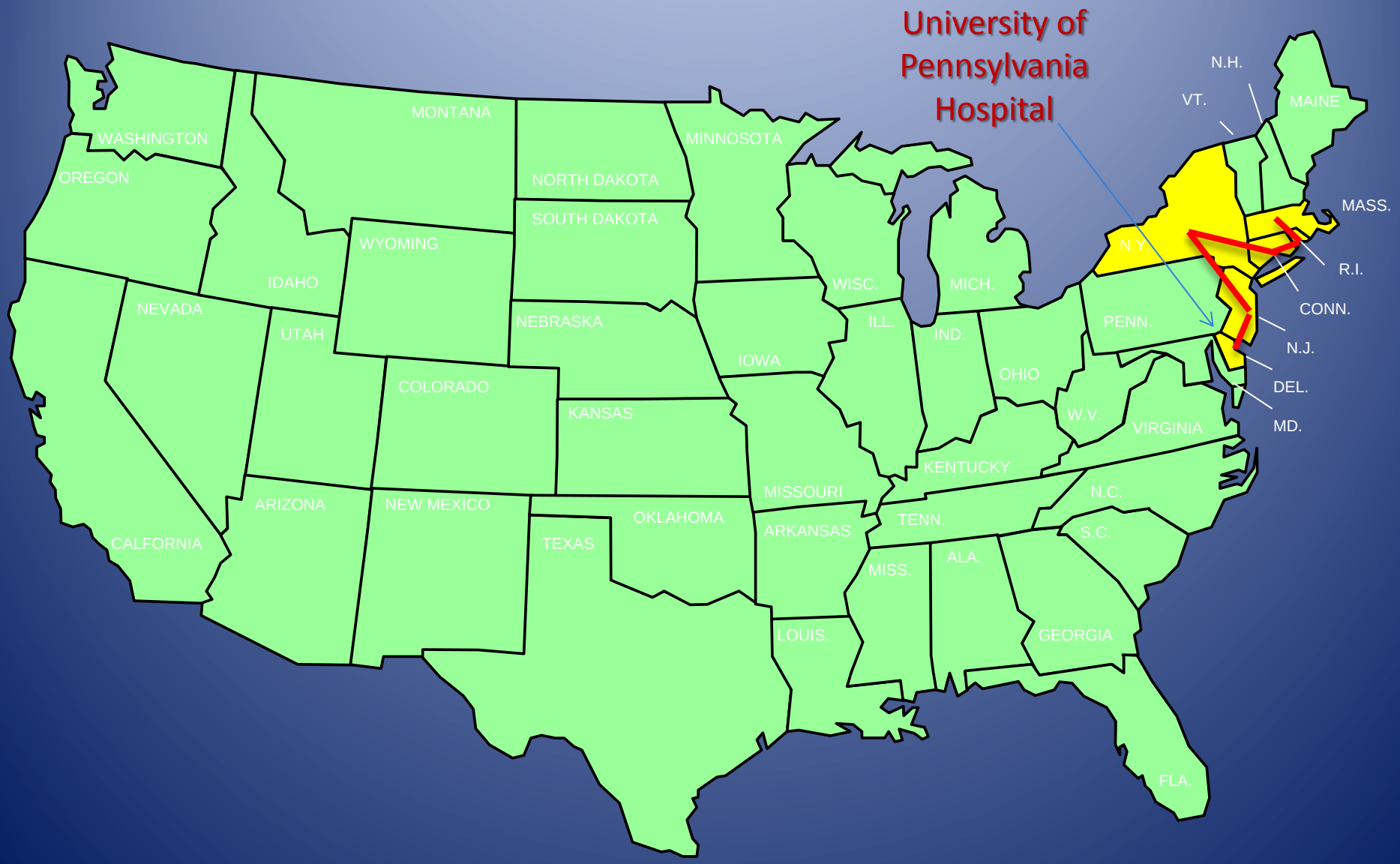

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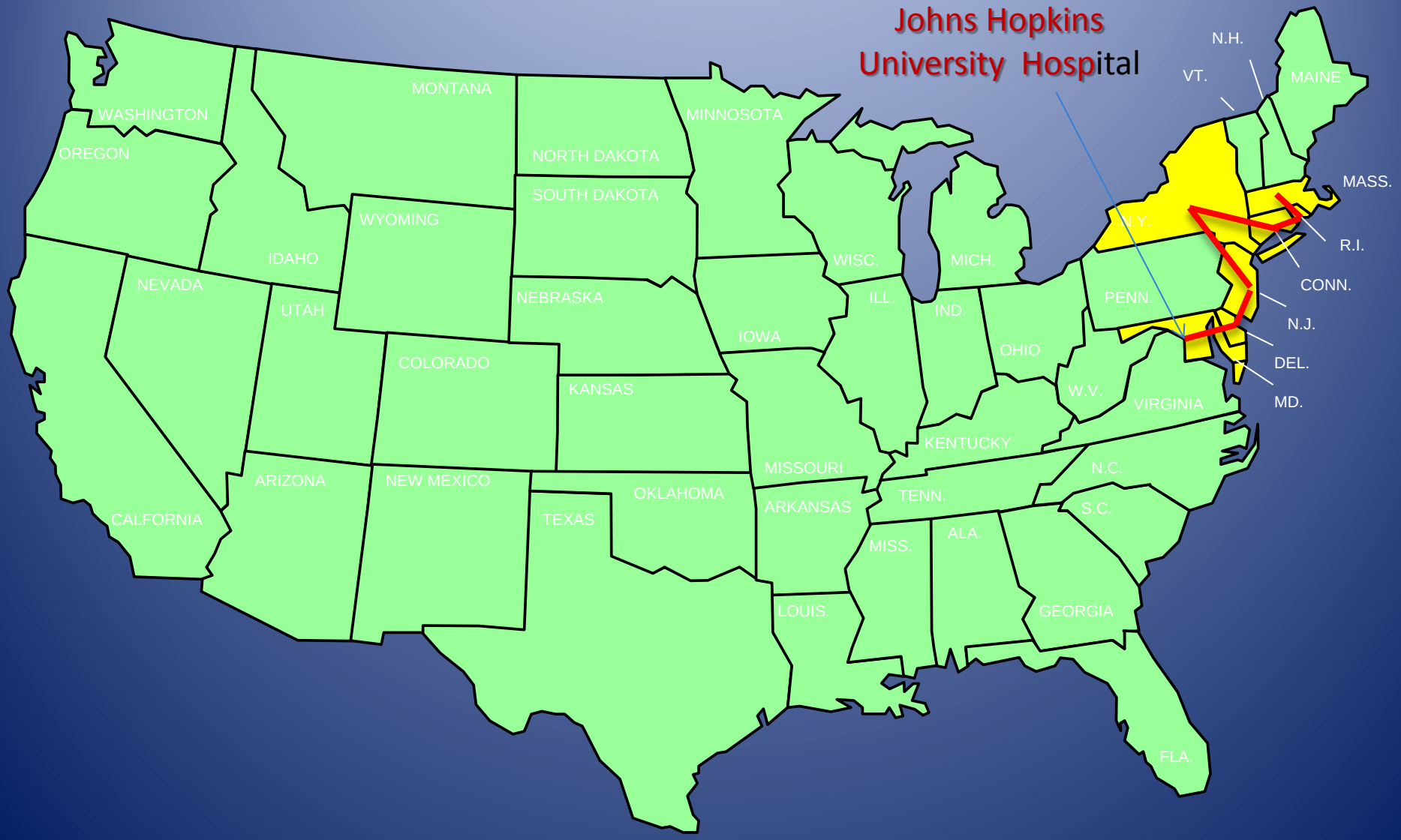

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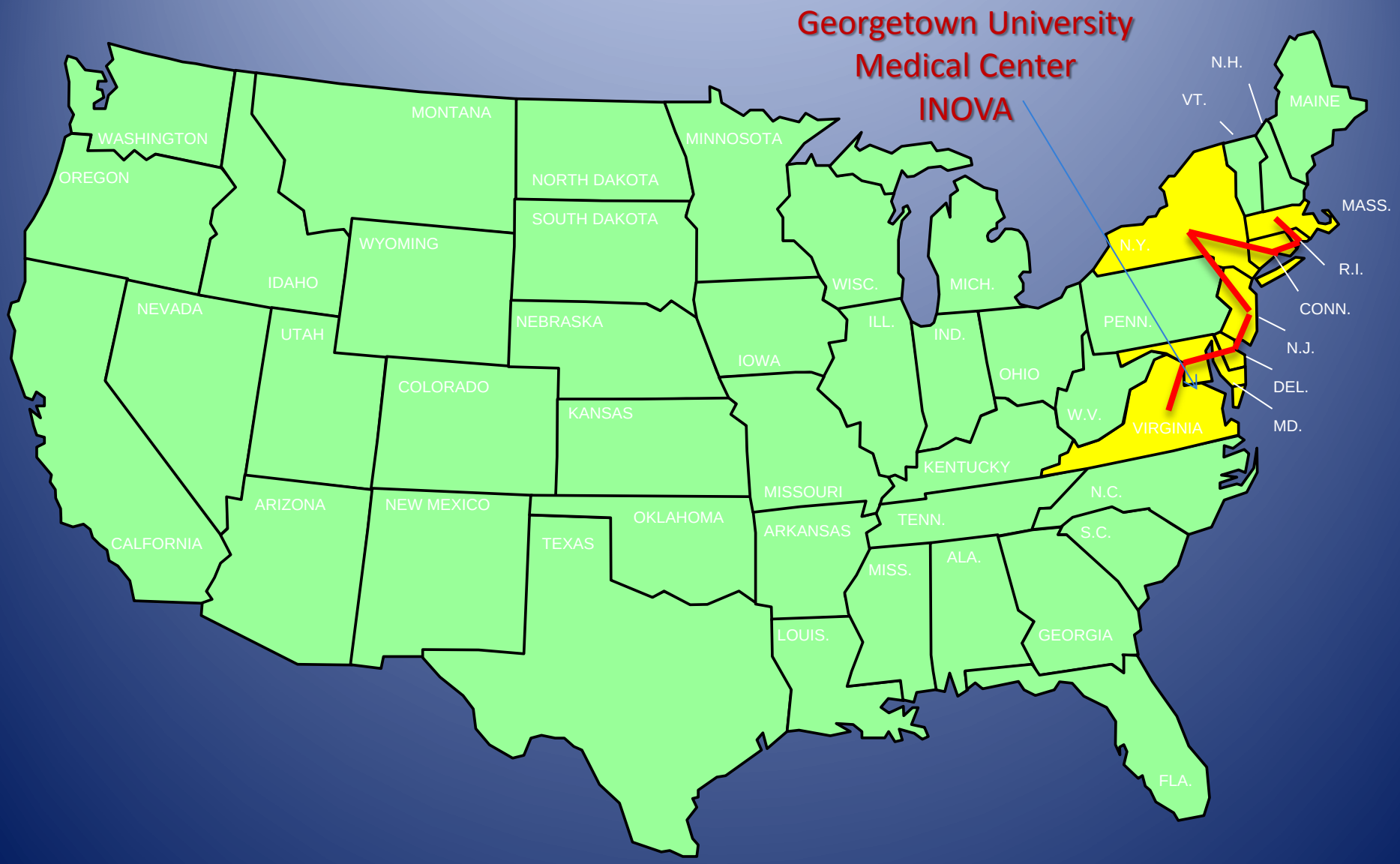

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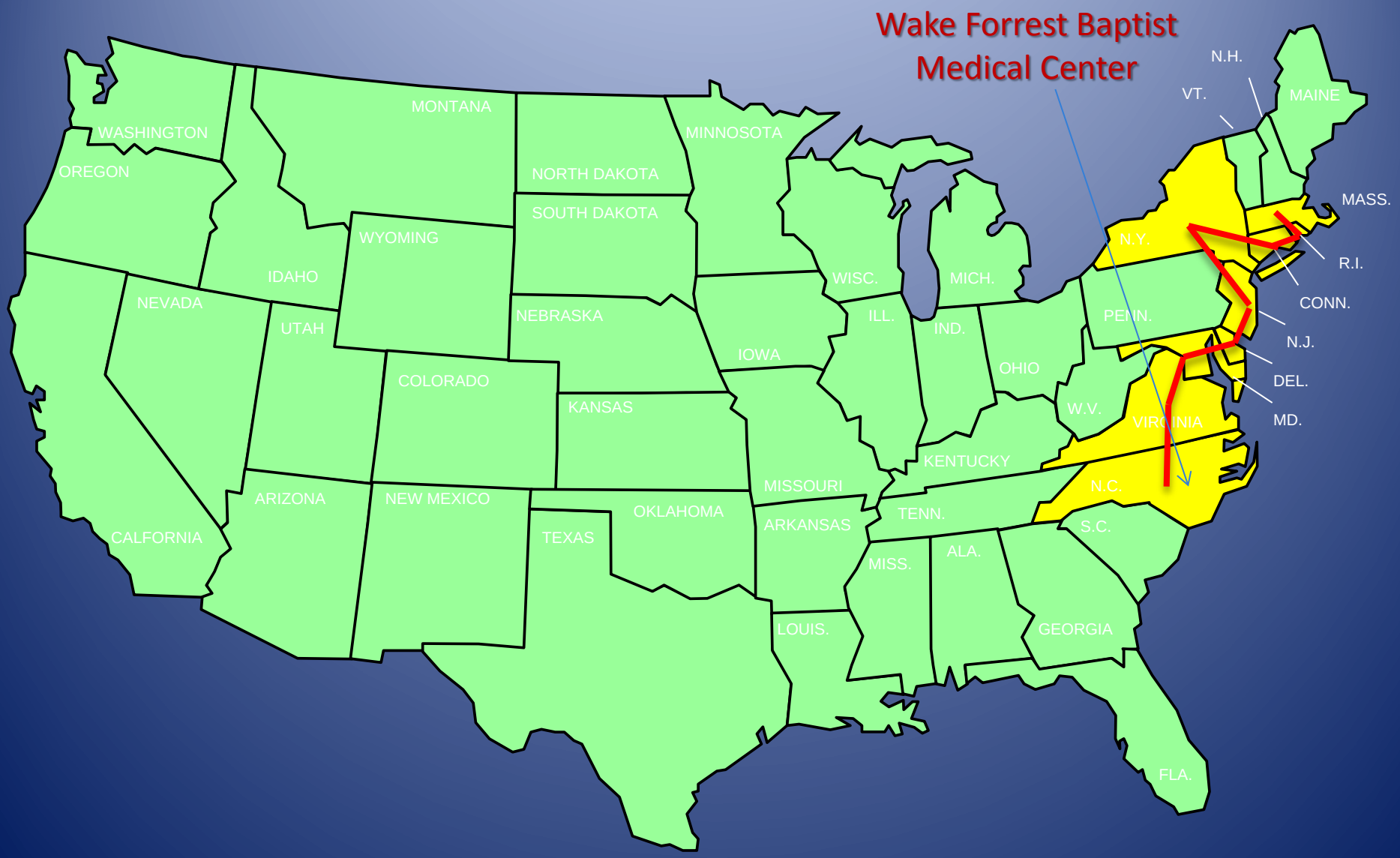

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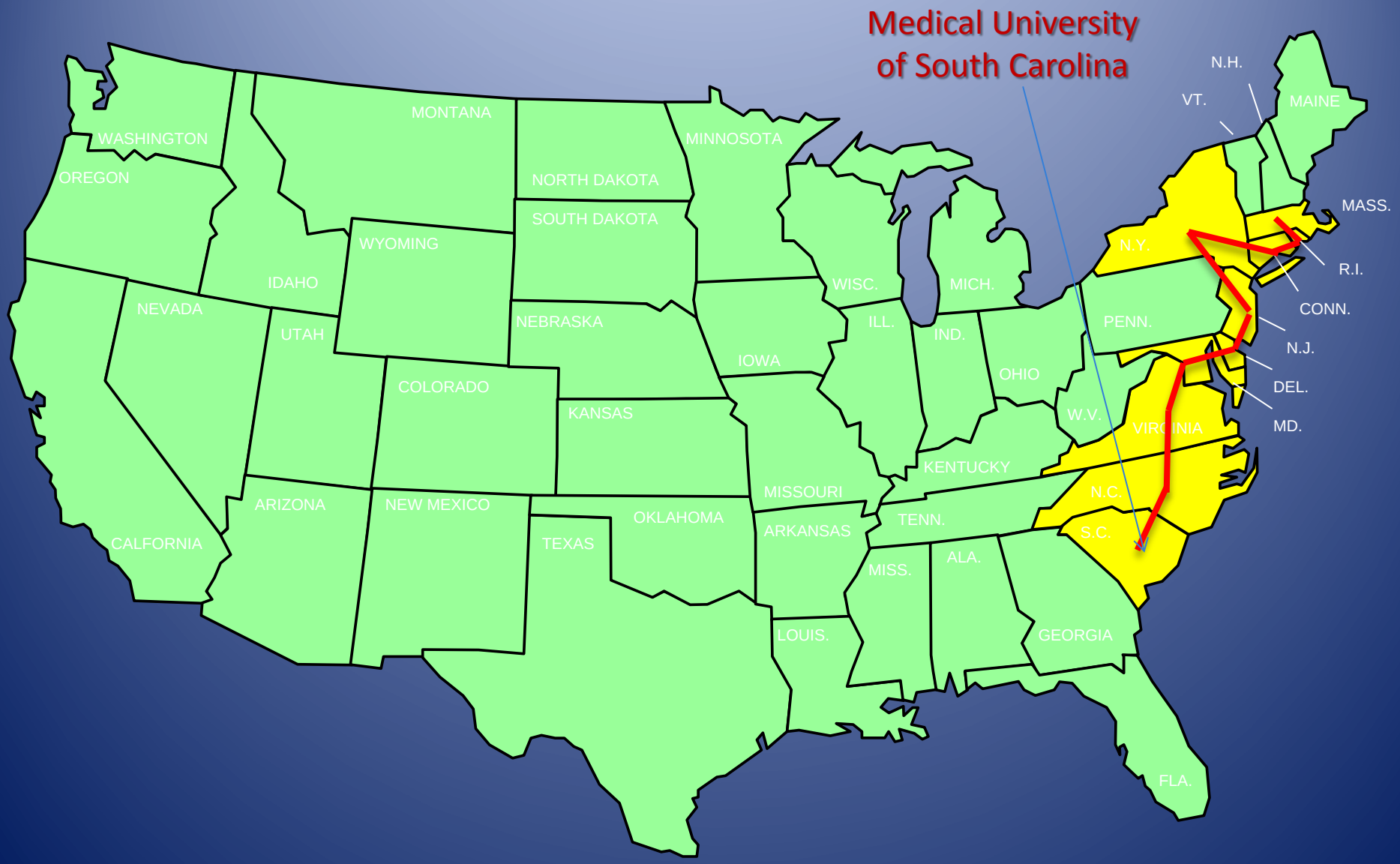

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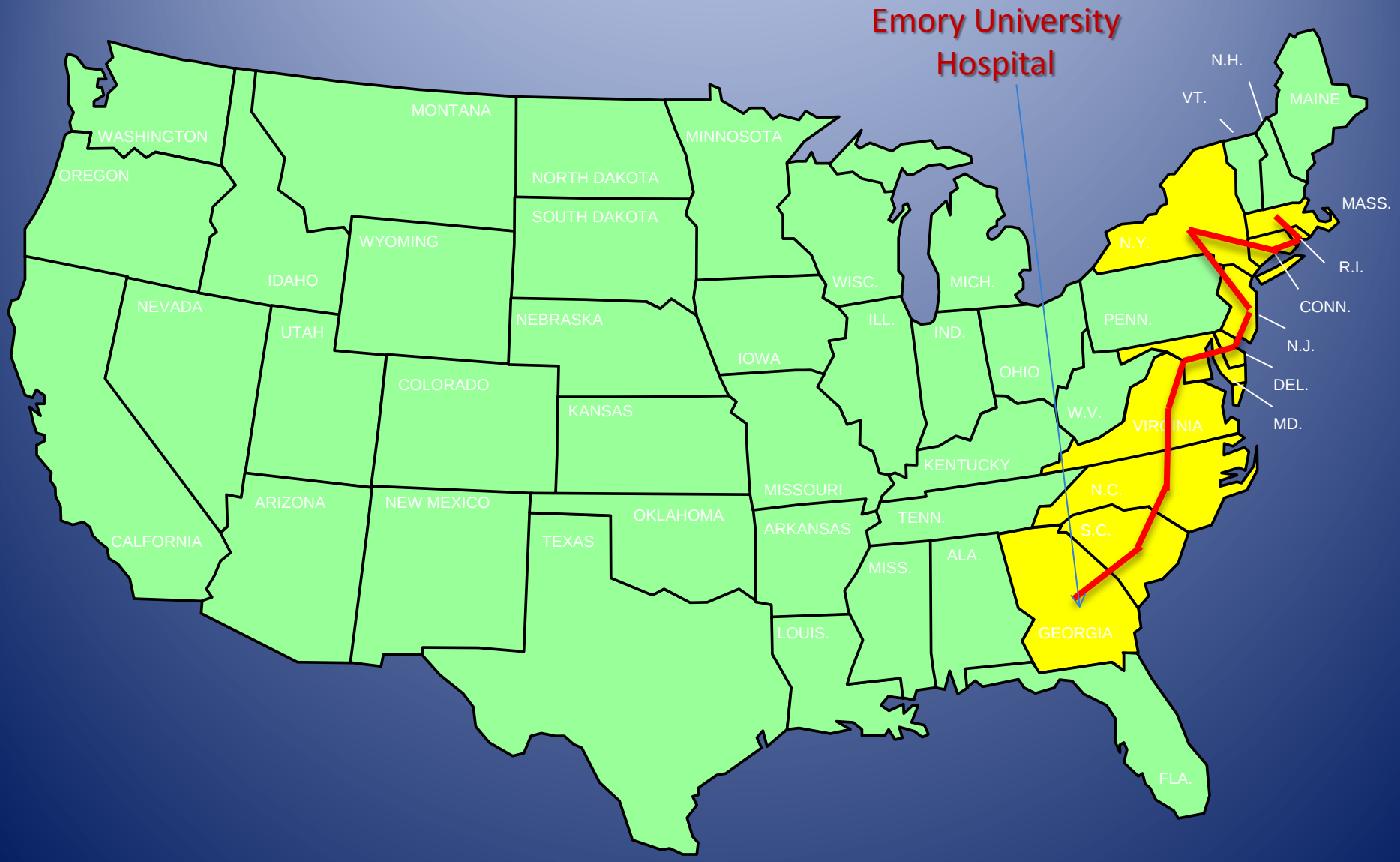

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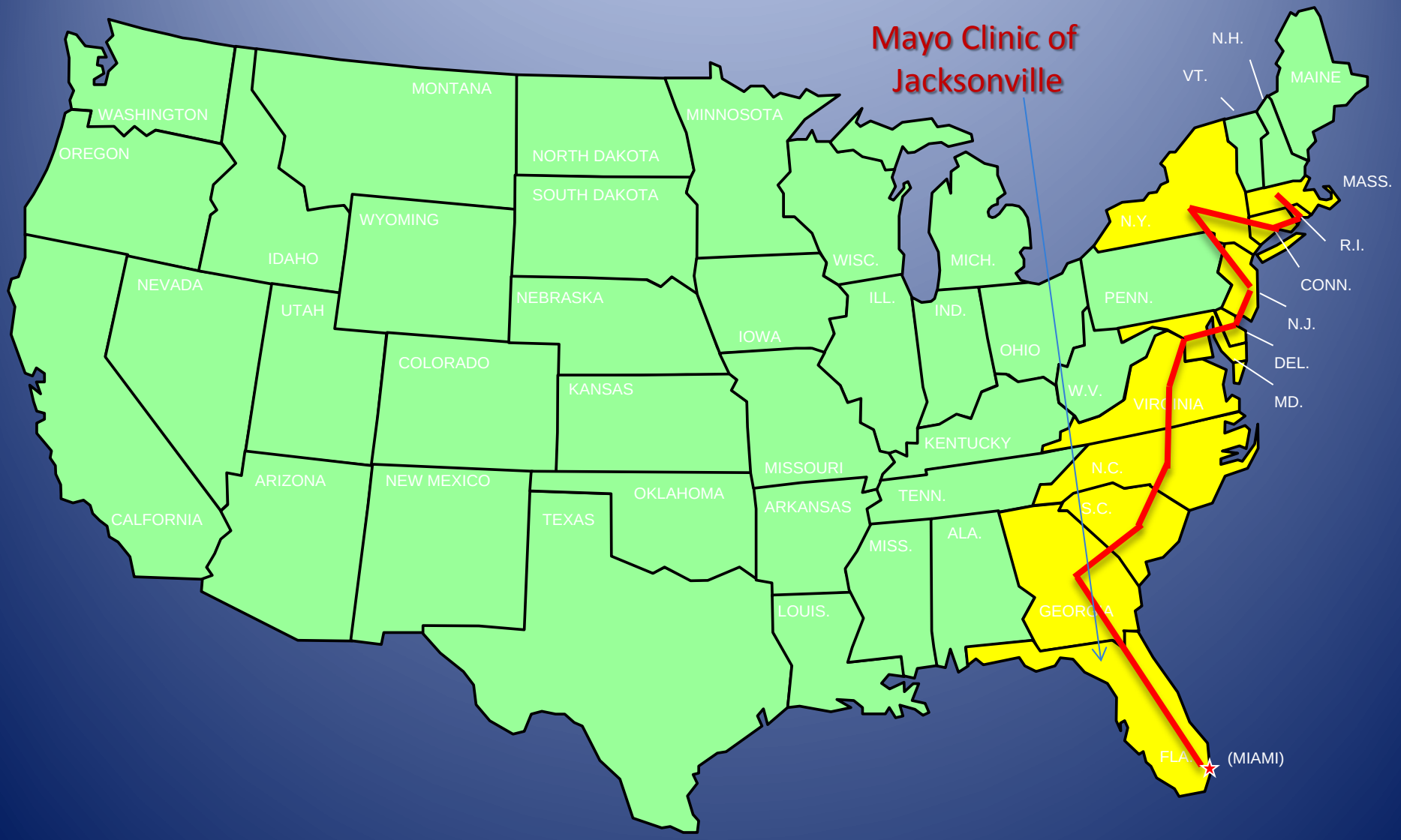


Drugs Prescribed

- 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

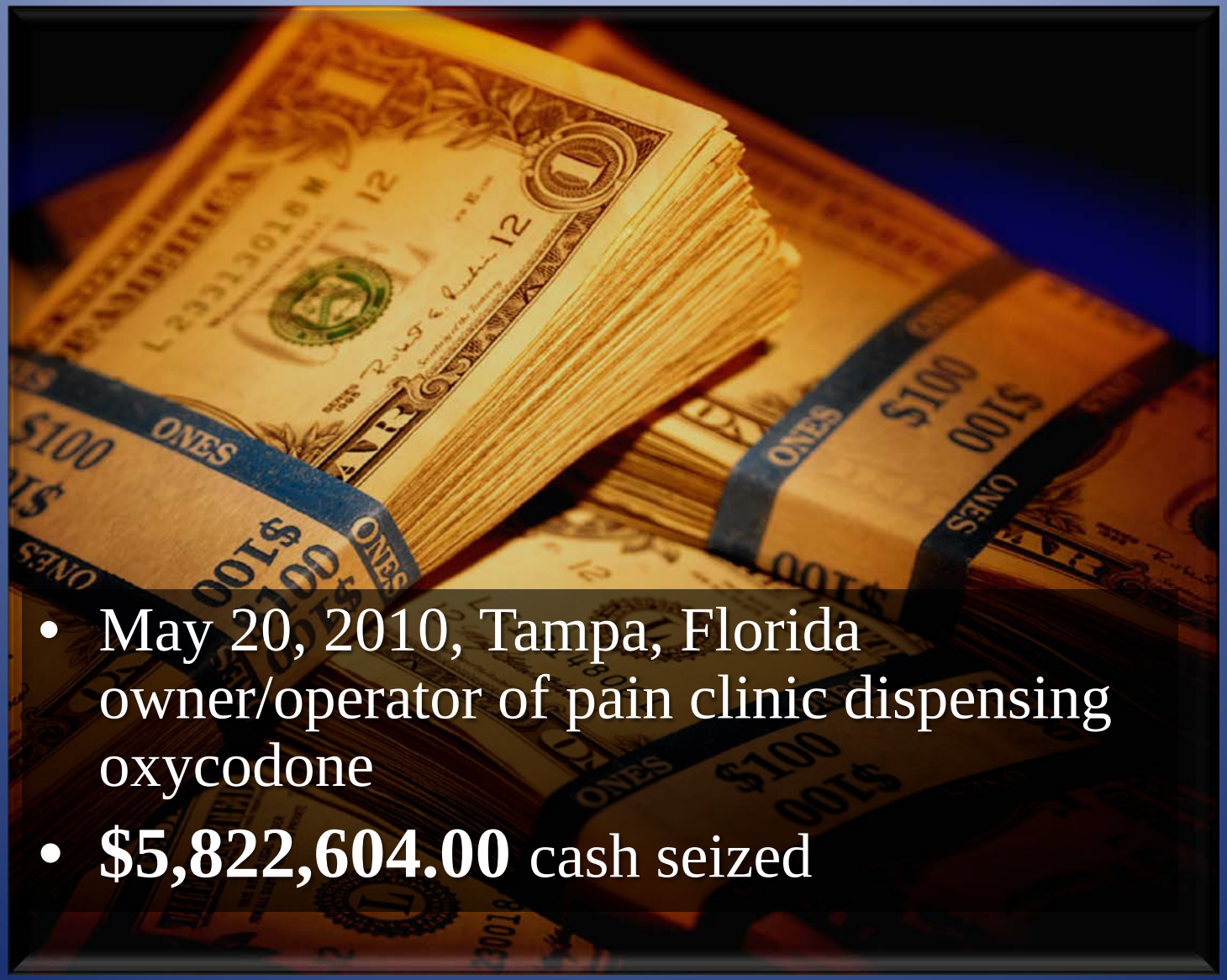
- Price varies if medication is dispensed or if customers receive prescriptions
- Some clinics advertise in alternative newspapers citing discounts for new patients such as 'buy one get one free‘ or “50% off with this ad”
- Typically, initial office visit is $250 or more; each subsequent visit may exceed $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?

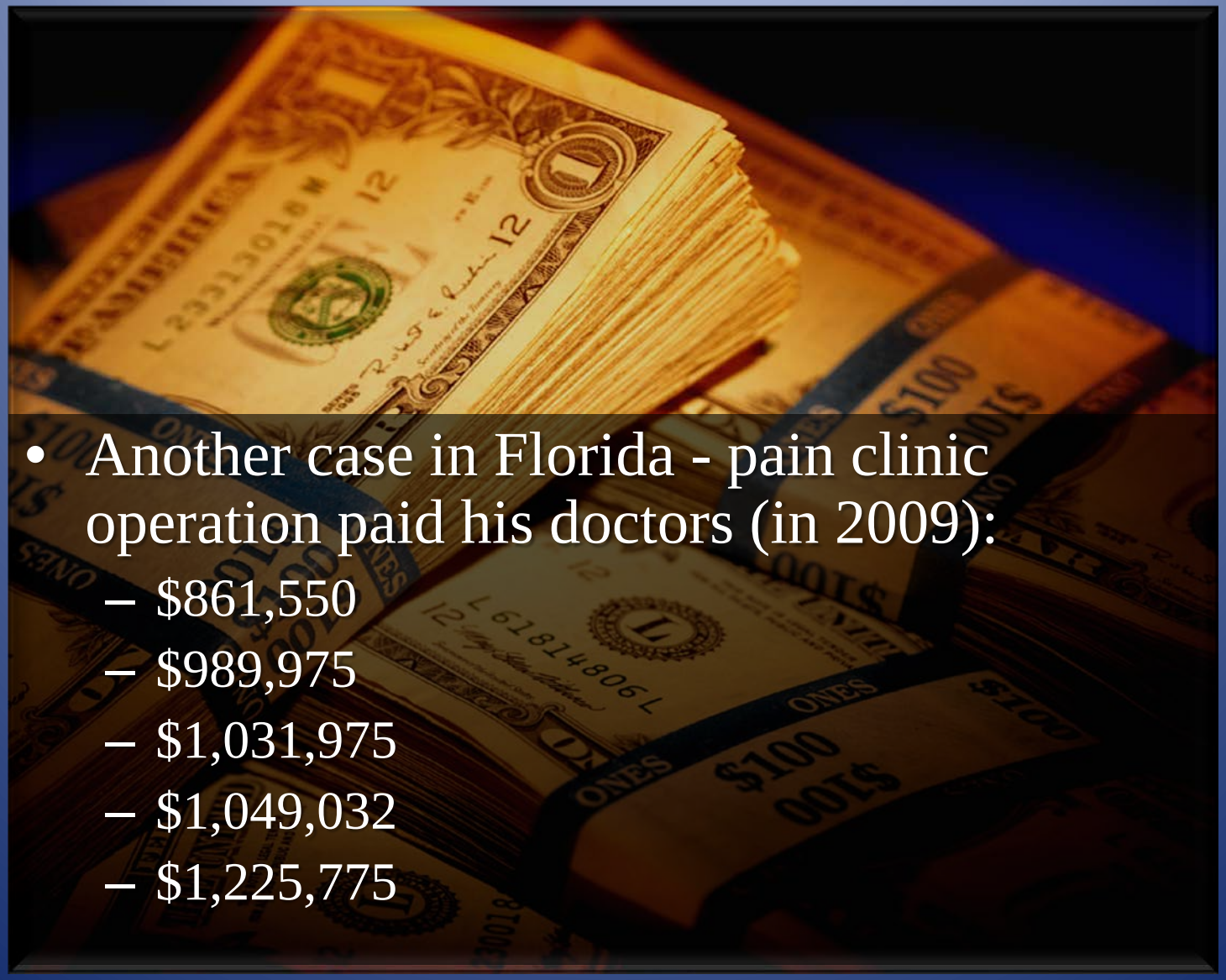


- May 20, 2010, Tampa, Florida owner/operator of pain clinic dispensing oxycodone
- **$5,822,604.00** cash seized

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

Clinic response to the Florida legislation prohibiting the sale of CS from pain clinics?

Buy Pharmacies!

Who is Applying?

- An individual who is tied to Organized Crime
- An individual who works at Boston Market
- An individual whose father owns a pain clinic
- An individual whose mother works at a pain clinic
- An individual whose father is a doctor at a pain clinic
- An individual who is a bartender/exotic dancer
- An individual who is a truck driver
- An individual who is retired from the dry wall business
- An individual who is a secretary at a pain clinic
- An individual who runs a lawn care business

Response

Enforcement and Regulatory Action

- Investigating/Inspecting all new and renewal pharmacy applications submitted in Florida
- Investigating/Inspecting existing pharmacies registrations
- Results
  - Withdrawal of applications
  - Orders To Show Cause (OTSC) issued against applications
  - Immediate Suspension Orders (ISO) issued as appropriate

The Last Line of Defense

Potential Red Flags

Many customers receiving the same combination of prescriptions

Many customers receiving the same strength of controlled substances;

Many customers paying cash for their prescriptions;

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

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

What's the Cost?
Deaths Associated with Rx Drugs in Florida

Reports of Rx Drugs Detected in Deceased Persons and Cause of Death								% Increase 2005-2010
DRUG	2005	2006	2007	2008	2009	2010	2011	
Methadone	620	716	785	693	720	694	691	
Oxycodone	340	496	705	941	1,185	1,516	1,247	266.7%
Hydrocodone	221	236	264	270	265	315	307	
Benzodiazepines	574	553	743	929	1,099	1,304	1,950*	
Morphine	247	229	255	300	302	262	345	
TOTAL	2,002	2,230	2,752	3,133	3,571	4,091		

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

SOURCE: Florida Medical Examiner's Commission

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; Inflexxion, 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

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
US
SPECIAL AGENT

Thank You!