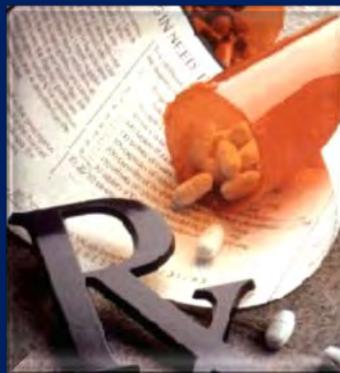




PRESCRIPTION DRUG TRAFFICKING & ABUSE TRENDS



November 16-17, 2013

Pharmacy Diversion Awareness Conference (PDAC)

Louisville, KY

Alan G. Santos, Associate Deputy Assistant Administrator,
Operations Division, Office of Diversion Control,
U.S. Drug Enforcement Administration



Disclosure Information

I have no financial relationships to disclose !!



Rx Trends Outline

- Scope of the Problem
- The Costs
- What People are Abusing
- The “CSA” – Checks & Balances
- Where People are Getting Their Drugs
(Evolution of Problem & Pill Mills)



OBJECTIVES

1. Identify current trends in pharmaceutical controlled substance abuse.
2. Describe the impact pharmacy diversion has on communities.



PRE-TEST

1. What is the most commonly prescribed controlled substance in the U.S.?
 - a. Oxycodone
 - b. Methylphenidate
 - c. Hydrocodone/APAP
 - d. Alprazolam



PRE-TEST

2. Name four common methods of diversion.



PRE-TEST

3. What combination of drugs is referred to as the “trinity”?

- A) Hydrocodone, alprazolam, and carisoprodol
- B) Promethazine with codeine, methylphenidate and carisoprodol
- C) Hydromorphone, carisoprodol and buprenorphine
- D) Methadone, diazepam and tramadol



Prescription Drug Abuse & Trafficking Trends

OR

Responding to America's Prescription Drug
Abuse Crisis

“When Two Addictions Collide”



SCOPE OF THE PROBLEM

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



Mayo Clinic Study on Prescription Drugs

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

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NEWS

Study: 70 Percent Of Americans On Prescription Drugs

June 19, 2013 12:59 PM

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

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

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

The [study](#) is uncovering valuable information

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



Not a New Problem



Laudanum is no more dangerous than many of the preparations sold as soothing syrups; it has the saving grace of the "poison" label. (By courtesy of the Committee on Interstate and Foreign Commerce.)

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45 1/2 GRAINS OPIUM and 65% ALCOHOL.

•DOSE•

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

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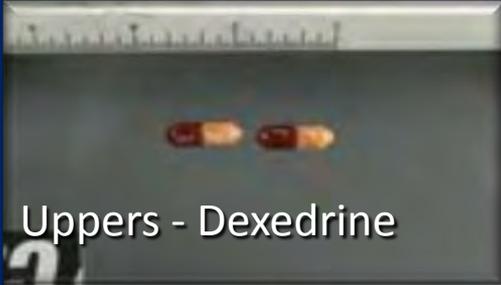
The 1960/70s/80s



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



“Ts and Blues”



Uppers - Dexedrine



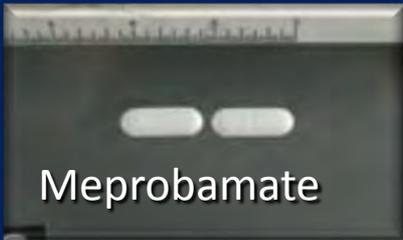
Downers - Seconal



Hydromorphone



Tylenol® w/Codeine
(acetaminophen/codeine phosphate tablets)



Meprobamate



Oxycodone/APAP

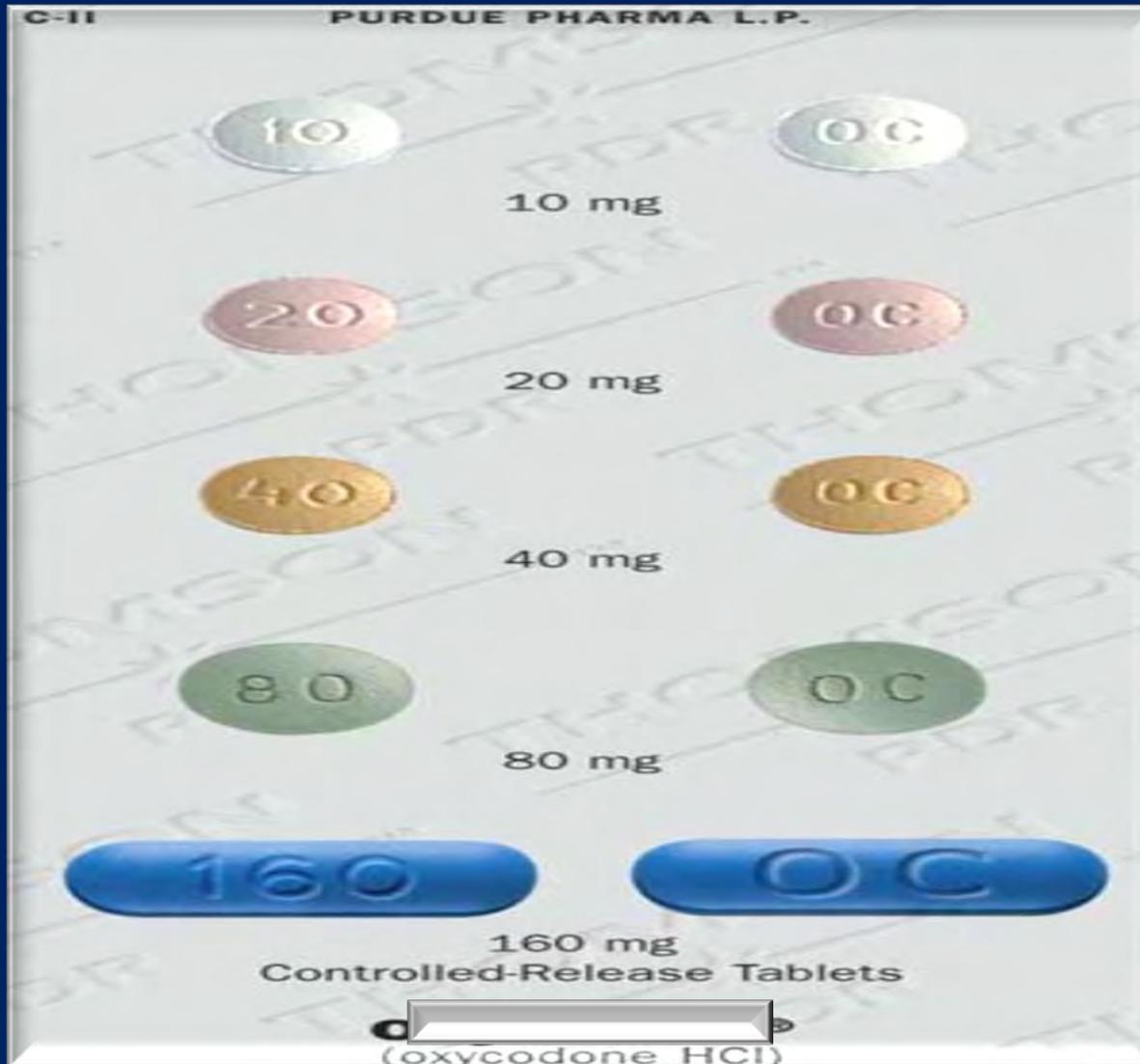


“Fours and Doors”



The 1990s

OxyContin





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

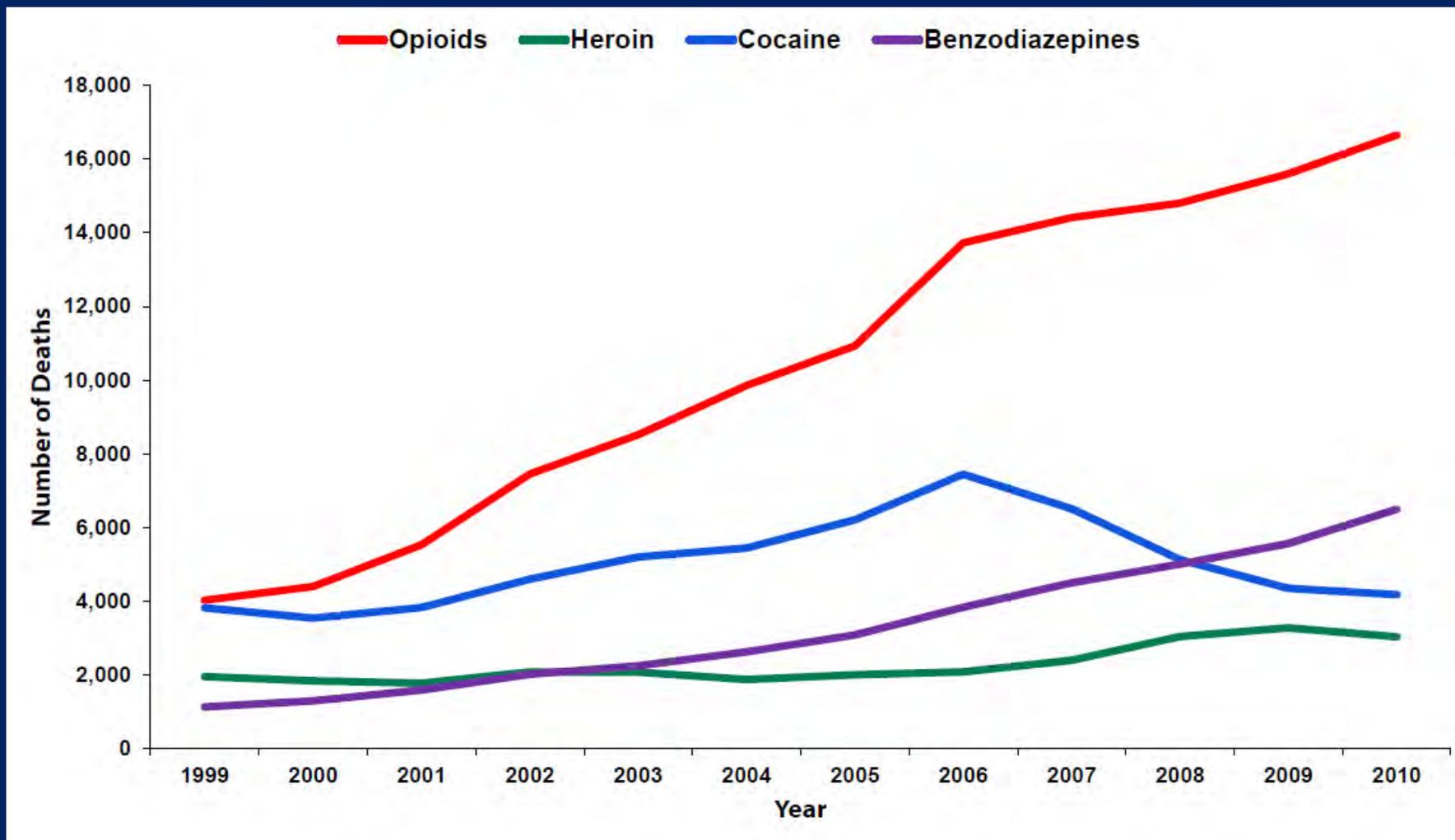
Of this number, 22,134 of these deaths were attributed to Prescription Drugs (16,651 attributed to opioid overdoses/ 75.2 %).

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)



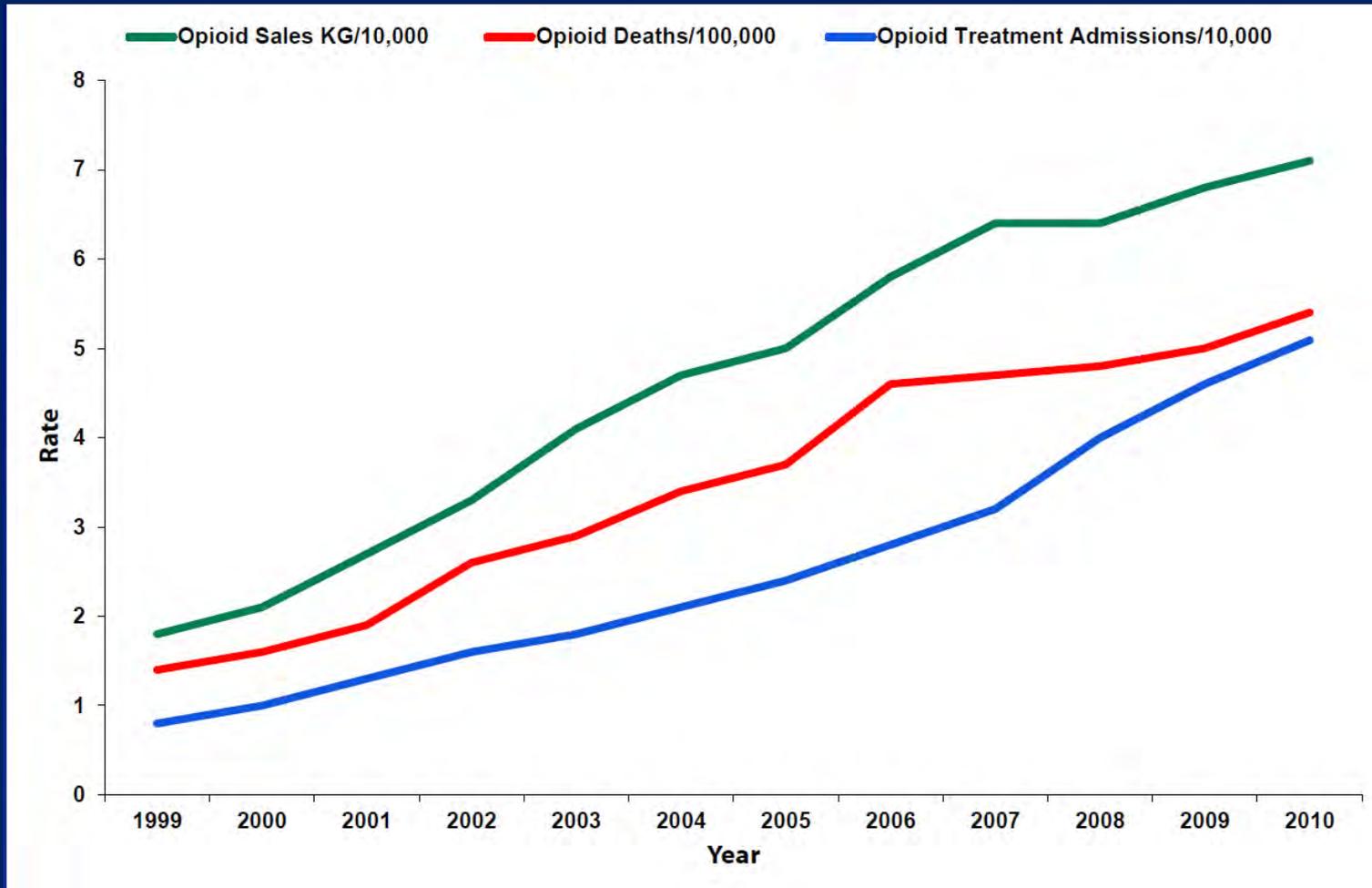
U.S. Drug Overdose Deaths by Major Drug Type, 1999-2010



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



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*



Today's Perfect Storm

- Industry is producing a wider variety of controlled substance pharmaceuticals
- Use of Medicare / Medicaid or insurance to fund drug habits
- The Information / Electronic era (i.e., web sites such as Erowid & Bluelight, social networking, blogging, twitter, text messaging, & chat rooms for instant exchanges of information)



2010 Current Users (Past Month) 2011

ANY ILLICIT DRUG:
22.6 million

MARIJUANA: 17.4 million

PSYCHOTHERAPEUTIC
DRUGS: 7 million

COCAINE: 1.5 million

Methamphetamine 353,000

Heroin: 239,000

ANY ILLICIT DRUG:
22.5 million

MARIJUANA: 18.1 million

PSYCHOTHERAPEUTIC
DRUGS: 6.1 million

COCAINE: 1.4 million

Methamphetamine 439,000

Heroin: 281,000



Prescription Drug Abuse

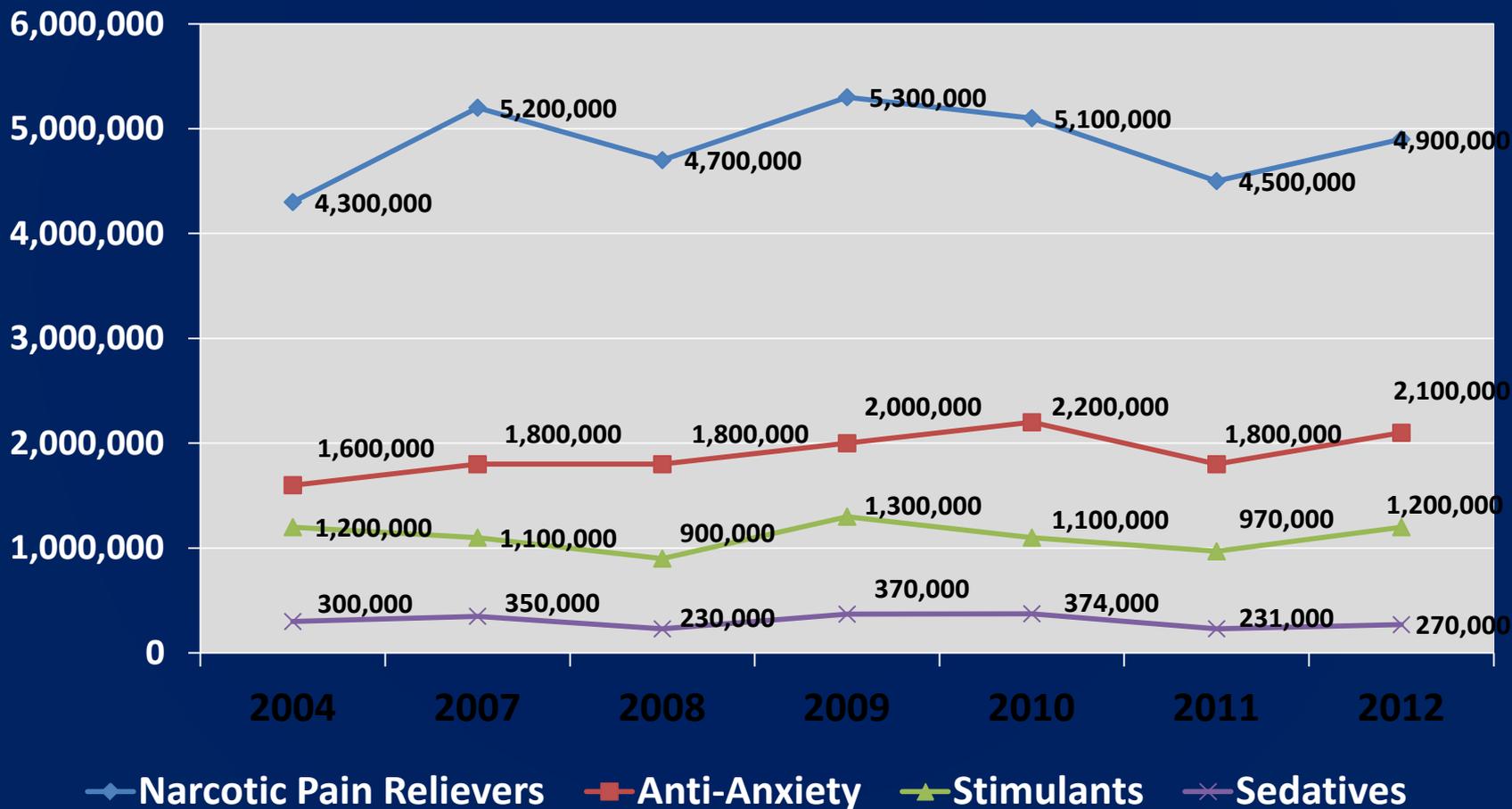
More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Methamphetamine &
Heroin abusers

COMBINED!!



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

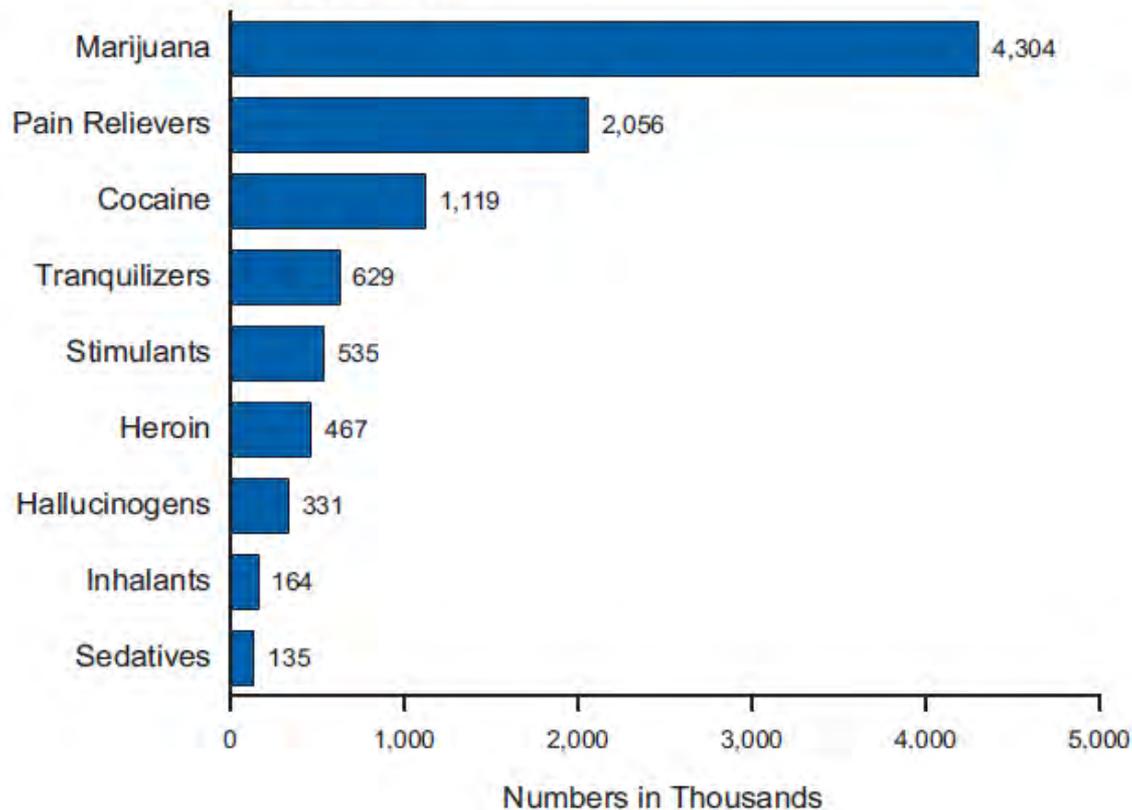


Source: 2004, 2007, 2008, 2009, 2010, 2011, 2012 National Survey on Drug Use and Health



Past Year Initiates 2012 – Ages 12 and Older

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

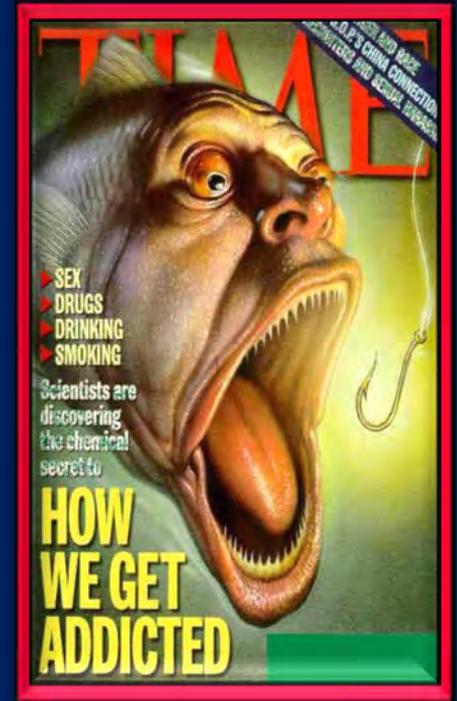


SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)



National Abuse Facts

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



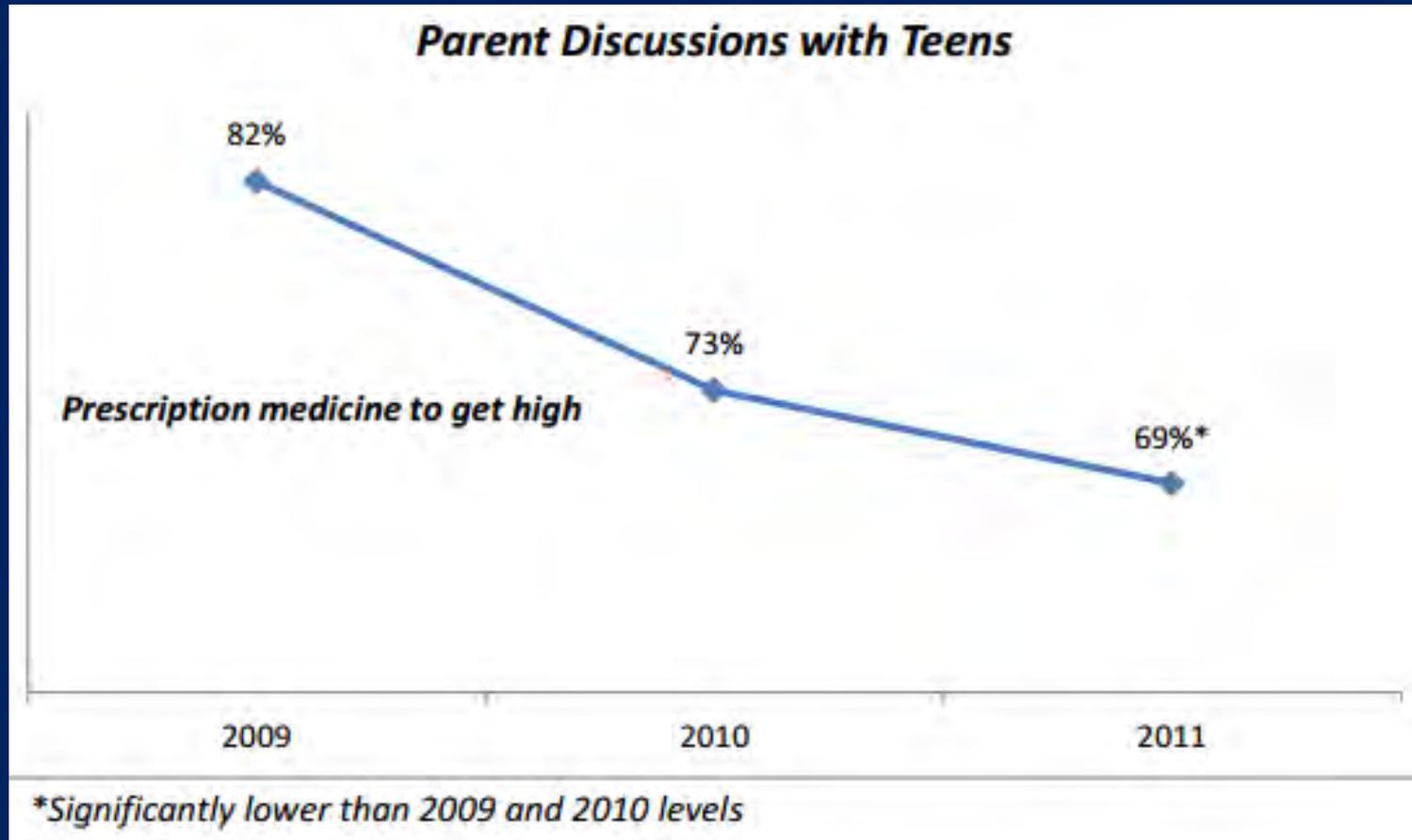
SOURCE: * 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)

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



Parents & Their Attitudes

Parents are not discussing the risks of abusing prescription drugs

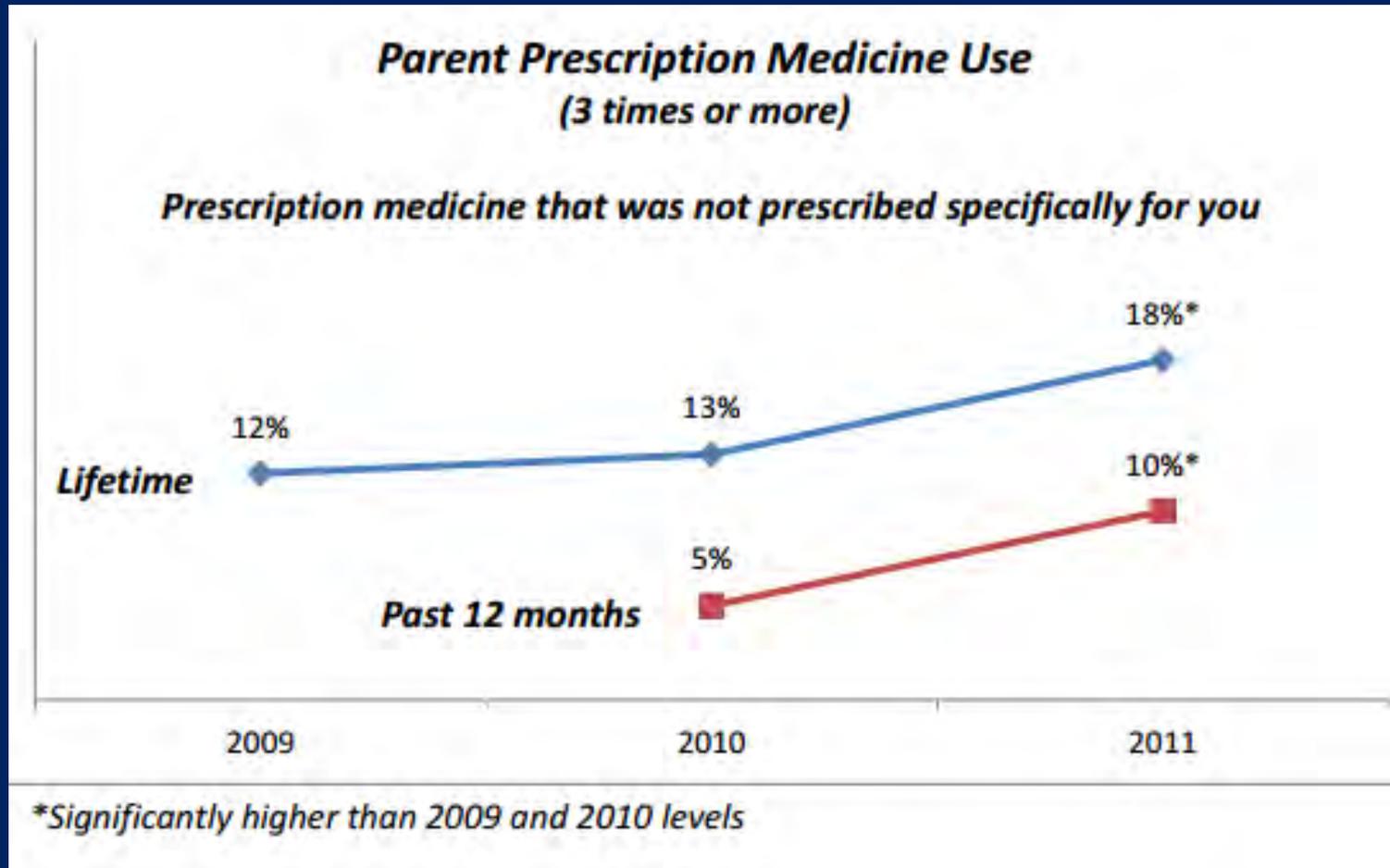


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Parents & Their Actions

Parents and their abuse of prescription drugs



U.S. Drug Enforcement Administration / Operations
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Where do kids get their information from?

← → ↻ 🏠 www.bluelight.ru/vb/

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THE FRONT PAGE 🔔

A Letter to Bluelight and MAPS Forum members From Brad Burge (MAPS) and Sebastians_Ghost (BL)

by Sebastians_ghost Published on 05-04-2013 06:57

It is with great pride and enthusiasm that we announce today a major collaboration between Bluelight.ru and the Multidisciplinary Association for Psychedelic Studies.

Through the efforts of Brad Burge, MAPS' Director of Communications, Rick Doblin, MAPS' Founder and Executive Director, Sebastians_Ghost and The_Love_Bandit of Bluelight.ru, we will soon undertake an exciting partnership to reinvigorate the MAPS forum and increase opportunities for public education about psychedelic science and medicine. The existing plaintext email MAPS Forum will be migrating to Bluelight.ru, the world's leading drug information website. We're aiming to unveil the new MAPS Forums on Bluelight shortly before the Psychedelic Science 2013 symposium in mid-April.

In the coming weeks, the MAPS Forum will no longer be linked from maps.org. Instead, MAPS will provide a link to the new MAPS Forum hosted at Bluelight. MAPS will work closely with Bluelight to encourage public participation in our new "home" at Bluelight.ru as the migration of the MAPS Forum topics is completed.

...

Forums

Focus Forums	Australia & Asia
Drug FAQs	Australian Drug Discussion
Ecstasy Discussion	Australian Social & Events
Cannabis Discussion	
Steroid Discussion	Europe & Africa
Psychedelic Drugs	European Drug Discussion
Other Drugs	European Events
Drug Discussion	North America & South America
Drug Studies	North & South American
Drugs in the Media	Social & Drug Discussion
Basic Drug Discussion	North & South American
Advanced Drug	Events

start Bluelight - The Front ...



Popularizing Controlled Substances Abuse



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

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.

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Wrestler Benoit's doctor gets 10 years in prison

Updated 5/12/2009 2:34 PM | [Comment](#) | [Recommend](#)[E-mail](#) | [Print](#) |[Enlarge](#)

WWE via AP

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.

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Rush Limbaugh Arrested On Drug Charges

Rush Limbaugh and prosecutors in the long-running prescription fraud case against him have reached a deal calling for the only charge against the conservative commentator to be dropped without a guilty plea if he continues treatment.

Limbaugh turned himself in to authorities on a warrant filed Friday charging him with possession of a controlled substance. He and his attorney Robert Barbera, a spokeswoman for the Palm Beach County Jail. He and his attorney Robert Barbera said.

Prosecutors' three-year investigation of Limbaugh began after he publicly acknowledged a rehabilitation program. They accused Limbaugh of "doctor shopping," or illegally obtaining prescriptions, learning that he received about 2,000 painkillers, prescribed by four doctors in six states.

Limbaugh, who pleaded not guilty Friday, has steadfastly denied doctor shopping and said he 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!

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 oxycodone 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 was charged with possession of a handgun.

Baze was arrested last November on a charge of possession of a handgun and possession of a controlled substance. He was released on bond after the arrest warrant.

His mother, Teri Gibson, said the jockey was a "good kid."

"I honestly thought he was not doing anything wrong," she said.

Baze was remembered for his kindness and his love of horses.

Churchill Downs spokesman John Johnson said Baze rode only briefly at Churchill Downs last year.

Hall of Fame rider Mike Smith named Baze as one of the best riders he ever rode with.

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.

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 week after he sustained a concussion.

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 been confirmed that Boogaard died of a toxic mix of alcohol and oxycodone.

May 08, 2012

Thomas Kinkadee cause of death: alcohol, Valium

By Ann Oldenburg, USA TODAY

Updated 2012-05-08 7:18

An autopsy has concluded that Thomas Kinkadee'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 Kinkadee died April 6 at his California home from a combination of alcohol and prescription drugs. He was 54.



CAPTION By Gene Blythe, AP



**Russell Jones, aka
Ol' Dirty Bastard
November 13, 2004**



**Kenneth Moore,
aka Big Moe
October 14, 2007**



**Brittany Murphy
December 20, 2009**



**Anna Nicole
Smith
February 8, 2007**



**Heath Ledger
January 22, 2008**

DEATHS



**Leslie Carter
January 31, 2012**



**Ken Caminiti
October 10, 2004**



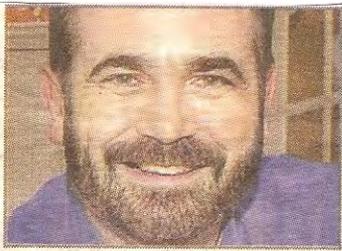
**Whitney Houston
February 11, 2012**



**Derek Boogaard
May 13, 2011**



Noelle Bush



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.



Eminem

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.



Terrence Kiel

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, 2003

Corey Haimers, Pitchmen



Corey Haim



The Costs



Economic Costs

- \$55.7 billion in costs for prescription drug abuse in 2007¹
 - \$24.7 billion in direct healthcare costs
- Opioid abusers generate, on average, annual direct health care costs 8.7 times higher than non-abusers²

1. Birnbaum HG, White, AG, Schiller M, Waldman T, et al. Societal Costs of Prescription Opioid Abuse, Dependence, and Misuse in the United States. *Pain Medicine*. 2011;12:657-667.

2. White AG, Birnbaum, HG, Mareva MN, et al. Direct Costs of Opioid Abuse in an Insured Population in the United States. *J Manag Care Pharm*. 11(6):469-479. 2005



Addicted Infants Triple in a Decade



Prescription abuse

Addicted infants triple in a decade

3.4 out of 1,000 suffer painkiller withdrawal

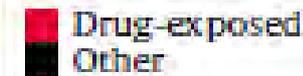
By Liz Szabo
USA TODAY

The number of babies born addicted to the class of drugs that includes prescription painkillers has nearly tripled in the past decade, according to the first national study of its kind.

About 3.4 of every 1,000 infants born in a hospital in 2009 suffered from a type of drug withdrawal commonly seen in the babies of pregnant women who abuse narcotic pain medications, the study says. It's published today in *The Journal of the American Medical Association*.

Born into addiction

Babies exposed to drugs in the womb have more health problems than other newborns.



Breathing problems



Low birthweight[†]



Feeding problems



Seizures



Source: Journal of the American Medical Association

By Frank Pompa, USA TODAY



Economic Costs

- Maternal opioid dependence can affect birth costs
- A recent study showed in 2009, the average hospital stay for opioid exposed infants with neonatal abstinence syndrome (NAS) was 16 days¹
- The hospitalization cost of treating each baby with NAS averaged \$53,400²
- State Medicaid programs paid for 77.6% of these births³

1. Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM. Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. JAMA. 2012 May 9;307(18):1934-40. Epub 2012 Apr 30
2. Ibid.
3. Ibid.



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	22,319	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

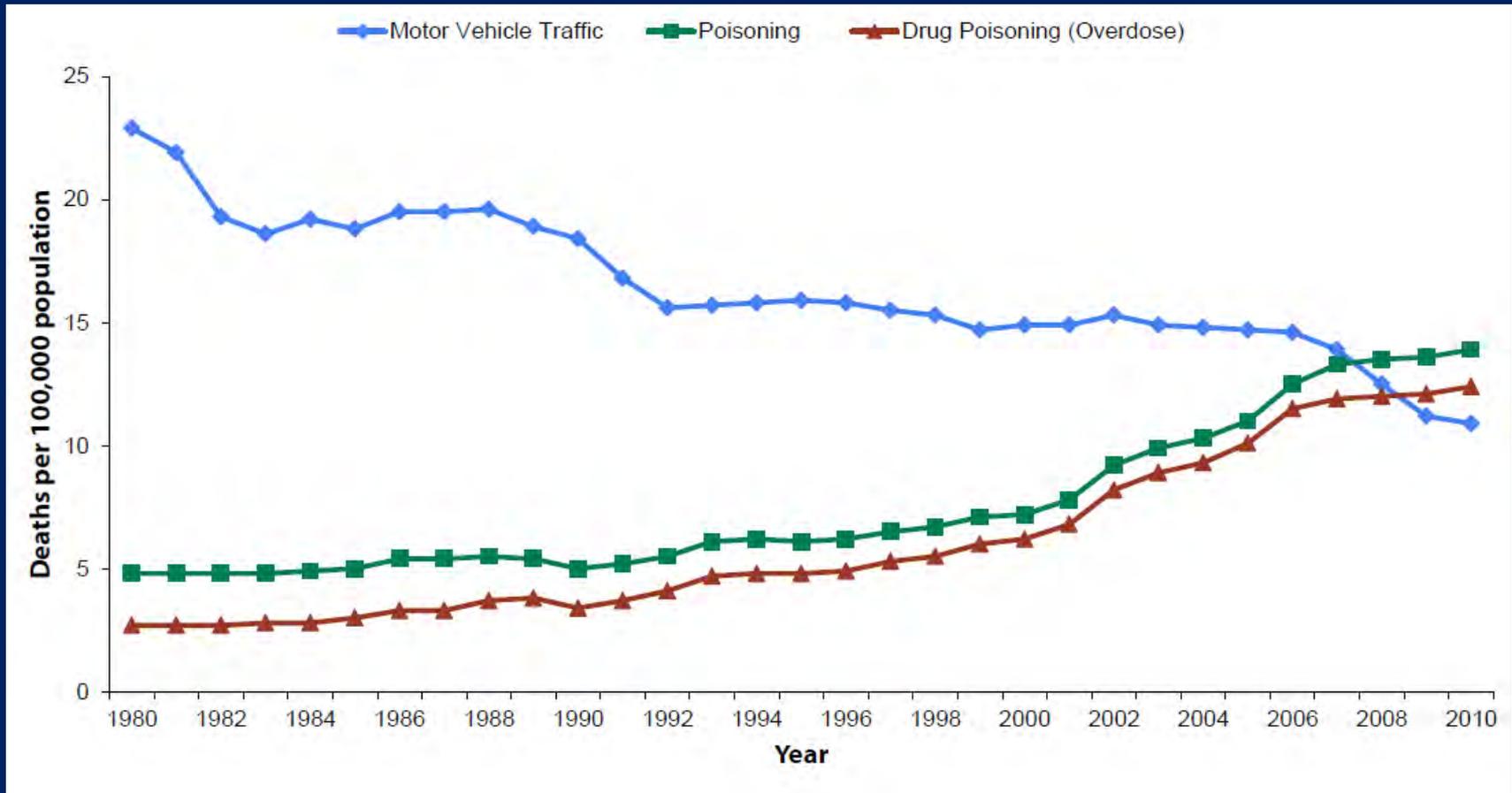


Emergency Room Visits (2004-2010)

- **Increase of 115%: ER visits attributable to pharmaceuticals** (*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**



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

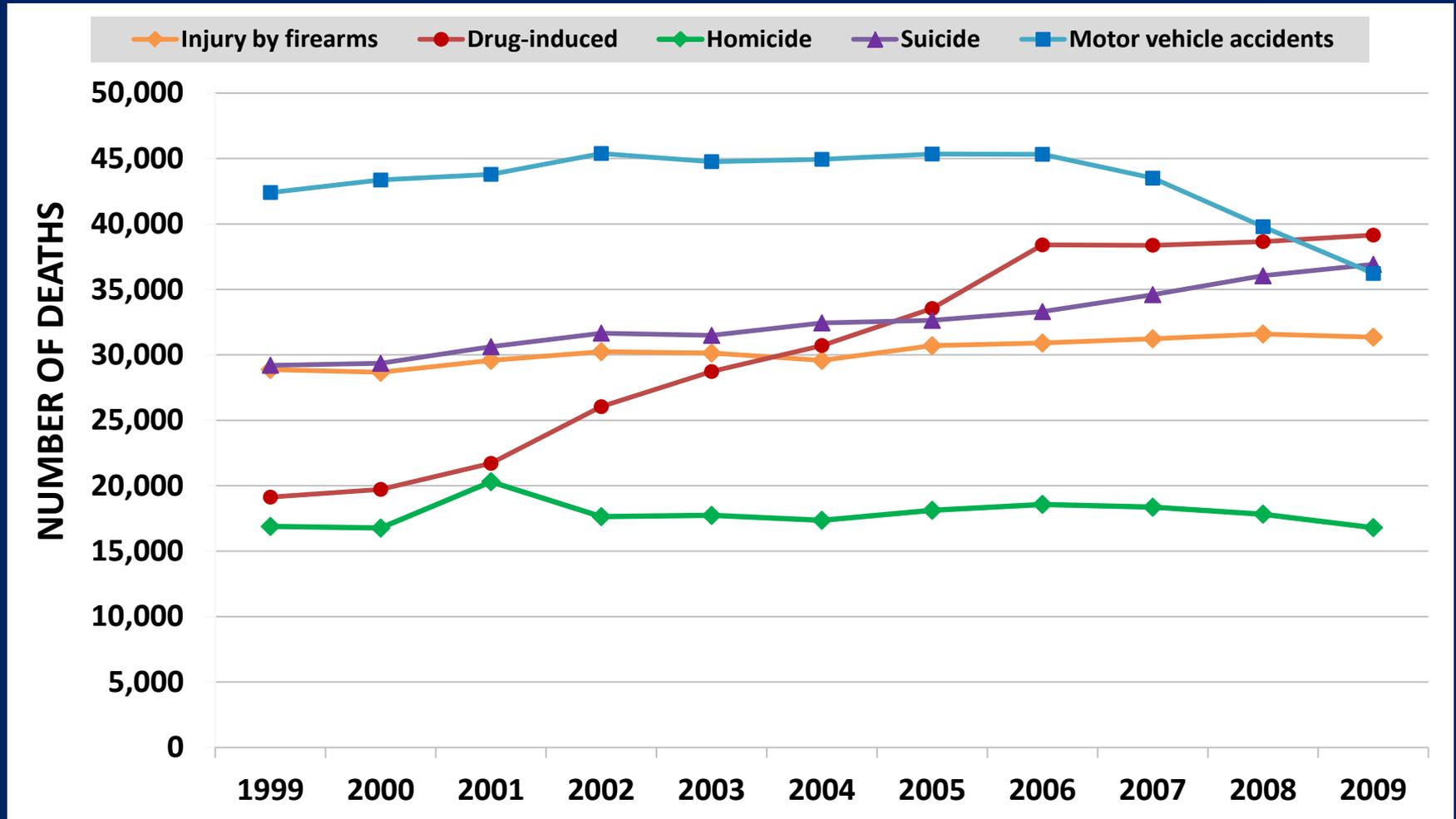


Source: CDC National Center for Health Statistics (NCHS) Data Brief, December 2011, updated with 2009 and 2010 mortality data

*U.S. Drug Enforcement Administration / Operations
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Drug-Induced Deaths vs. Other Injury Deaths (1999–2009)



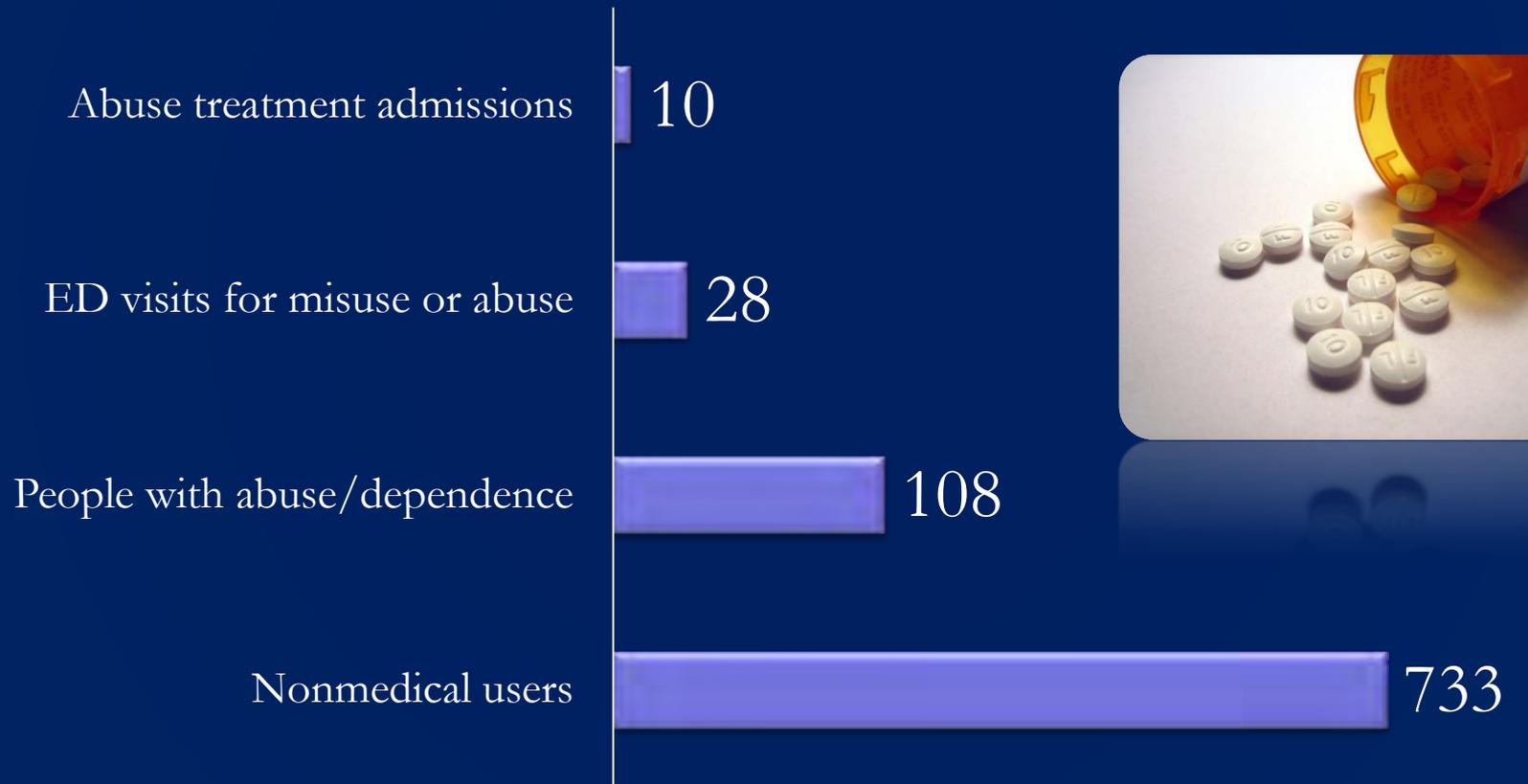
Causes of death attributable to drugs include accidental or intentional poisonings by drugs and deaths from medical conditions resulting from chronic drug use. Drug-induced causes exclude accidents, homicides, and other causes indirectly related to drug use. Not all injury cause categories are mutually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



Public Health Impact of Opiate Analgesic Abuse

For every 1 unintentional opioid overdose death in 2010, there were...



Mortality figure is for unintentional overdose deaths due to opioid analgesics in 2010, from CDC/Wonder

Treatment admissions are for with a primary cause of synthetic opioid abuse in from TEDS

Emergency department (ED) visits related to opioid analgesics in from DAWN

Abuse/dependence and nonmedical use of pain relievers in the past month are from the National Survey on Drug Use and Health



For Immediate Release Contact: Communications Office (Baucus), 202-224-4515
May 08, 2012 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 [276.4 KB]
- Baucus Grassley Opioid Investigation Letter to Wisconsin Pain And Policy Studies Group [277.6 KB]
- Baucus Grassley Opioid Investigation Letter to American Academy of Pain Medicine [277.8 KB]
- Baucus Grassley Opioid Investigation Letter to American Pain Foundation [276.8 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



Who Can Still Afford State U? **REVIEW**

THE [REDACTED] RNAL.

WSJ

How to Live Without Cable **OFF DUTY**

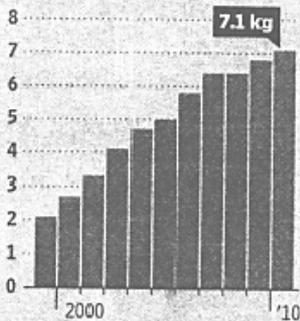
VOL. CCLX NO. 141 ***** **WEEKEND** ***** \$2.00

DOWNONES SATURDAY/SUNDAY, DECEMBER 15 - 16, 2012 WSJ.com

A Pain-Drug Champion Has Second Thoughts

On the Rise

Kilograms of opioids sold, per 10,000 people



Source: National Vital Statistics

By THOMAS CATANZARINO

It has been his second thoughts.

Two decades ago, Dr. Portenoy campaigned to help people who were long suffering because of their addiction to painkillers derived from opium.

Dr. Portenoy's success was phenomenal. Today, drugs like Vicodin, Oxycodone, and OxyContin are among the most widely prescribed pharmaceuticals in America.

Opioids are also behind the country's deadliest drug epidemic. More than

Now, Dr. Portenoy and other pain doctors who promoted the drugs say they erred by overstating the drugs' benefits and glossing over risks. "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did," Dr. Portenoy said in an interview with the Wall Street Journal. "We didn't know then what we know now."

thought, and questions whether opioids are effective against long-term chronic pain.

The change of heart among former champions of opioid use has happened

Among the assertions he and his followers made in the 1990s: Less than 1% of opioid users became addicted, the drugs

Please turn to page A12

the notice of many psychiatrists. Dr. Joseph "shocked" after outlining the risks.

of everything. "You saw other people and saying, 'Oh my God, what's going on?'"

ed they were dangerous. Opioids were long used for cancer patients. But what they could be months or years from chronic pain.



WHAT PEOPLE ARE ABUSING



Commonly Abused Controlled

Pharmaceuticals



Carisoprodol

C-IV as of 1/11/2012



Hydrocodone



OxyContin 80mg



Oxymorphone



Xanax (Alprazolam)

Photo from the Physicians Desk Reference

Alprazolam



Oxycodone 30 mg





HYDROCODONE



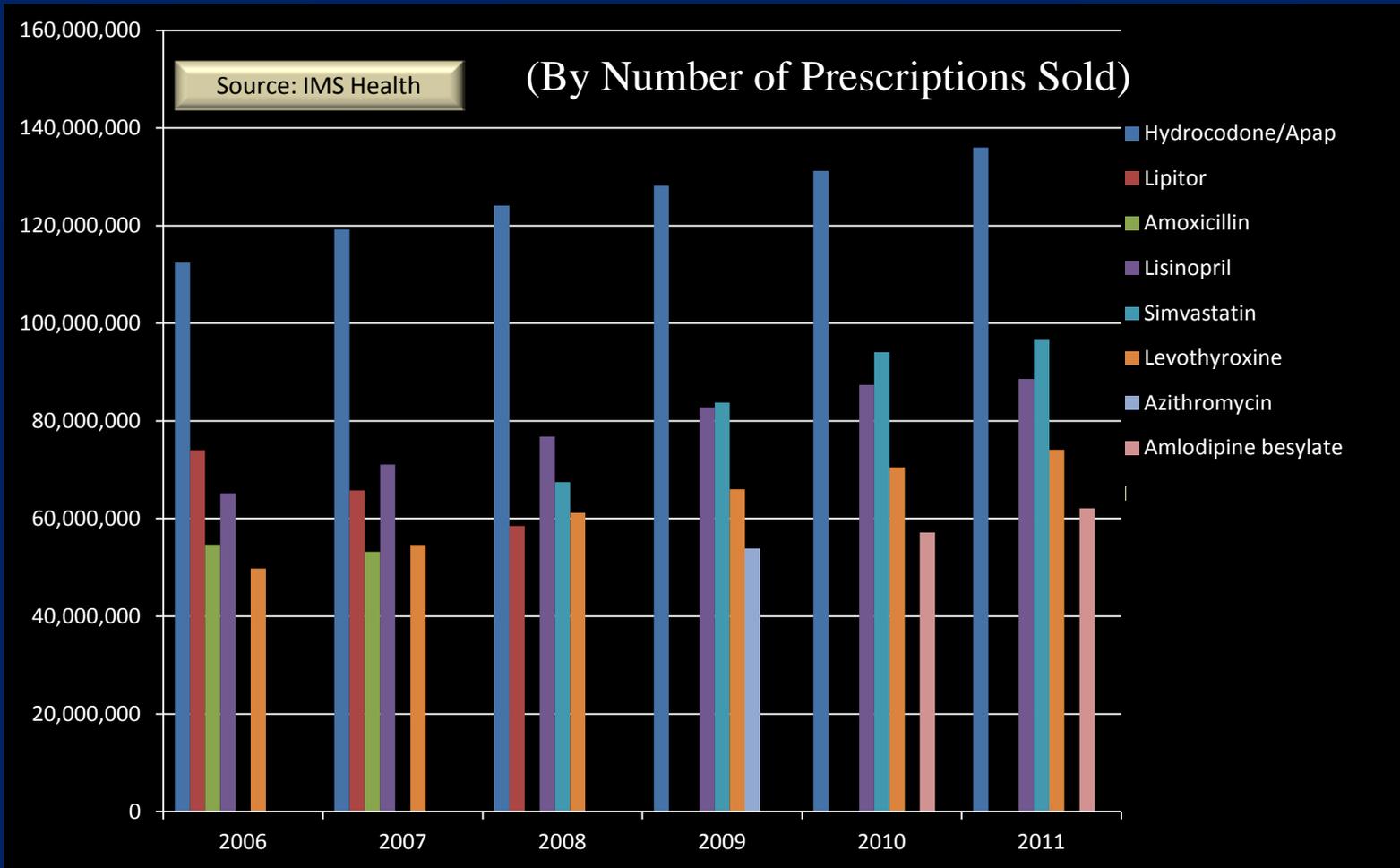
Hydrocodone

- Similarities:
 - Structurally related to codeine
 - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin[®], Lortab[®], Lorcet[®]
- Street prices: \$2 to \$10+ per tablet depending on strength & region



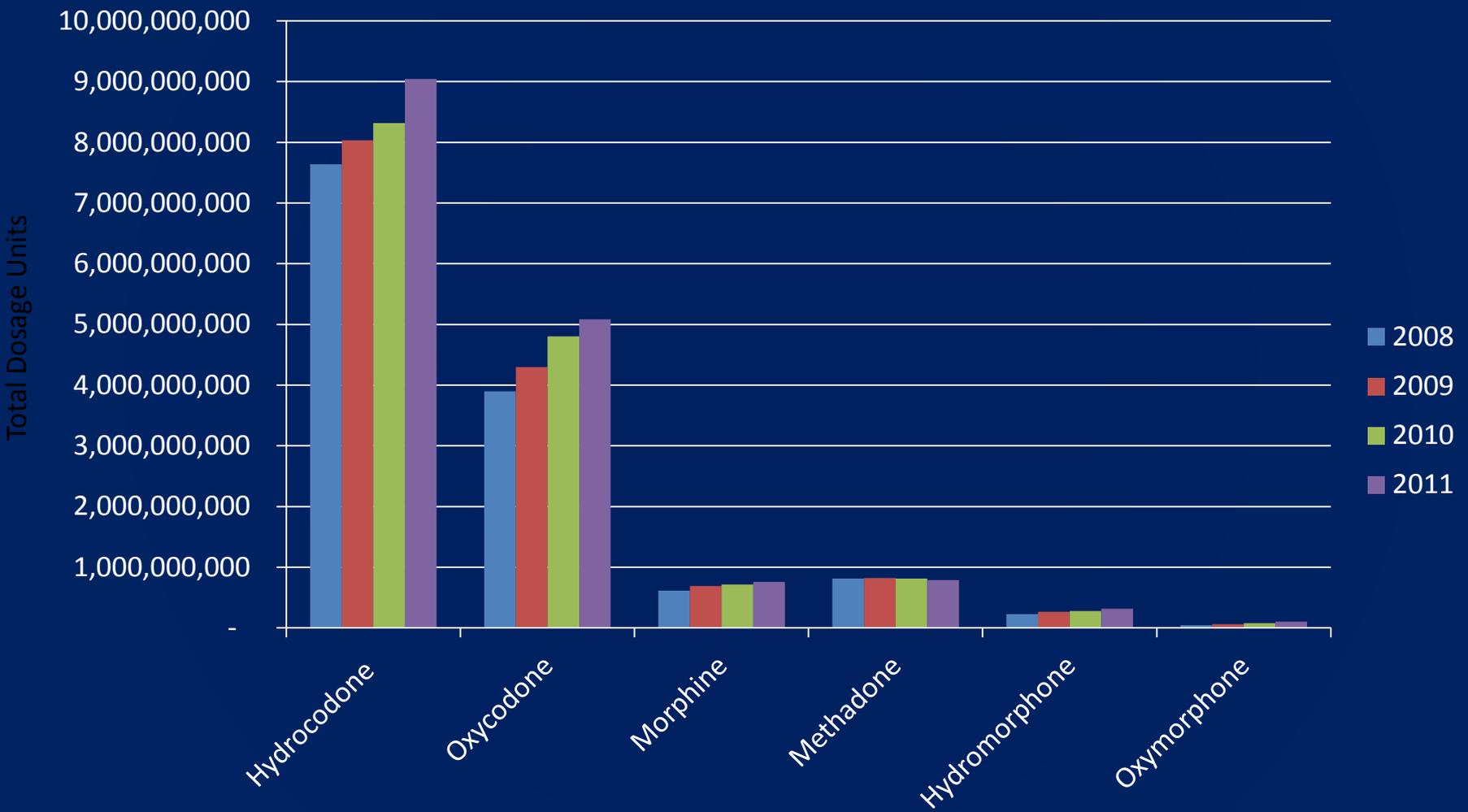


Top Five Prescription Drugs Sold in the U.S. (2006-2011)





Total U.S. Retail* Distribution of Selected Drugs January 1, 2008 – December 31, 2011



*Retail includes pharmacies, hospitals, practitioners, mid-level practitioners, teaching institutions, and narcotic treatment programs.



The Trinity



Opiate



Muscle Relaxant

Benzodiazepine



FDA Advisory Committee Votes in Favor of Hydrocodone Rescheduling

On January 25, 2013, the FDA's Drug Safety and Risk Management Advisory Committee voted yes (19-10) to recommend rescheduling of hydrocodone from Schedule III to Schedule II

U.S. Department of Health & Human Services

A to Z Index | Follow FDA | FDA Voice Blog

4. (VOTING) Based on the background materials, presentations and the discussion above, do you recommend that hydrocodone combination products be rescheduled from schedule III to schedule II of the Controlled Substances Act (CSA)? Please explain the basis for your vote.

Yes: 19 No: 10 Abstain: 0 No Voting: 0

The committee members that voted yes stated that the pharmacology and epidemiology data shows no difference between the abusability of hydrocodone combination products and other schedule II products. They believed that current controls of these products are inadequate with regard to drug abuse; and that rescheduling is a first step in ushering in a new thought process, by prescribers and patients, about the use of hydrocodone combination products. Members also thought rescheduling would reduce the amount of drug product in circulation.

The committee members that voted no stated that rescheduling would result in an increased burden to patients and decreased patient access. Members were also concerned that limited access to hydrocodone combination products may lead to increased abuse of illicit drugs (such as heroin). There was concern that increased prescribing of other schedule II products, which may have higher abuse potential, will be the net result of rescheduling. Committee members were also unsure whether or not rescheduling would address the abuse of hydrocodone combination products and that there is not sufficient data to support the rescheduling.

Please see the transcript for details of the committee discussion.

Background materials for the originally scheduled October 29-30, 2012, Drug Safety and Risk Management Advisory Committee meeting are currently available at: 2012 Meeting Materials, Drug Safety and Risk Management Advisory

FDA intends to make background material available to the public no later than 2 business days before the January 24 and 25, 2013, Drug Safety and Risk Management Advisory Committee meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting.



FDA Recommends Hydrocodone Up-Scheduling

www.newsday.com/news/nation/fda-recommends-strict-painkiller-rules-1.6316243

Newsday Is shocked the Islanders traded Matt Moulson for Thomas Vanek. search newsday.com

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Nation Newsday > News

8 Comments Like 116 Tweet 13 +1 Pin it

FDA recommends stricter painkiller rules

Originally published: October 24, 2013 7:31 PM
Updated: October 24, 2013 10:19 PM
By KEVIN DEUTSCH kevin.deutsch@newsday.com



HYDROCODONE BITARTRATE AND ACETAMINOPHEN TABLETS USP 5 mg/500 mg
Mallinckrodt

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FDA Approves Pure Hydrocodone Pain Killer

www.examiner.com/article/new-narcotic-pain-pill-zohydro-pure-hydrocodone-pain-killer-approved-by-fda

THE OIL AND GAS INDUSTRY SUPPORTS 9.8 MILLION JOBS NATIONWIDE. SEE WHAT CHEVRON IS DOING >>

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New narcotic pain pill Zohydro: Pure hydrocodone pain-killer approved by FDA

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October 27, 2013 Like 5



Zohydro, a pure hydrocodone pain pill, has just been approved for sale in the U.S. by the FDA. This pure hydrocodone pill will be classified as a Schedule II drug, much like Oxycontin and oxycodone, according to "Fox and Friends Weekend" on Sunday Oct. 27.

According to Bloomberg on Oct. 25, Hydrocodone is the narcotic pain medication found in pain pills like Vicodin.

Next article: Crypto Locker virus locks your computer files until you pay ransom

Popular Videos: Annually 1,500 Children Are Treated in ERs For Pain Medicine ODs

Advertisement: Altria Today



Oxycodone

- OxyContin controlled release formulation of Schedule II oxycodone
 - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
 - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
 - 10, 15, 20, 30, 40, 60, 80mg available

- Effects:
 - Similar to morphine in effects and potential for abuse/ dependence
 - Sold in “Cocktails” or the “Holy Trinity” (Oxycodone, Soma ® / carisoprodol, Alprazolam / Xanax®)

- Street price: Approx. \$80 per 80mg tablet

NOTE: 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.



Heroin (& Prescription Drugs)



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



Circle of Addiction & the Next Generation

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Oxycodone IR
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Hydrocodone
Lorcet®
\$5-\$7/tab

Heroin
\$15/bag





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WEDNESDAY, DECEMBER 5, 2012

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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

More suburban teens turning from pills to heroin, authorities say

By Ed Fletcher
McClatchy Newspapers

Tuesday, April 3, 2012

Text size: **A A A**

 +1 0

 Tweet 0

 Recommend

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Photo by Randy Pench/Sacramento Bee/MCT Brandon Scott, 19, of Auburn, Calif., leads a workshop at the Auburn Library regarding drugs and how they affect teens. Brandon transitioned from RX to heroin but has since gone through the Full Circle Treatment Center program and has been clean for about two years.

SACRAMENTO, Calif. – Heroin, a drug most often associated with the gritty back alleys of big cities, is making a surprising surge in suburban, affluent places.

Many new heroin addicts started as teens, abusing prescription painkillers they found in their homes, say law enforcement and public health officials.



HEROIN: NO LONGER CONFINED TO URBAN AREAS

trafficked heroin, cocaine and other drugs in the District and Montgomery and Prince George's counties.

About 4.2 percent of Maryland high school students reported trying heroin at least once in a 2011 statewide survey, up from 2.4 percent in 2007.

Former heroin addict Mike Gimbel has spent the past three decades working on substance abuse education and treatment in Maryland. He called the suburban heroin shift a "big-time trend" in the Washington area and elsewhere.

"Instead of waiting for the suburban kids to come into the city, the dealers have gone out to the suburbs," he said. "It just blows away these parents in the middle-class communities — the last drug in the world they think their kids are going to use is heroin."

The resurgence is tied to the booming market for prescription painkillers like OxyContin and Vicodin — experts say painkiller abusers often move on to heroin due to its availability and their craving for a stronger high.

Beth Kane Davidson, director of the Addiction Treatment Center at Suburban Hospital in Bethesda,



EXAMINER FILE

Montgomery and Fairfax counties have both reported spikes in heroin use.

Getting high

Percentage of Maryland high schoolers who reported using heroin:

	2011	2009	2007	2005
Males	5.7	5.8	3.7	2.8
Females	1.9	1.7	0.8	2.3
Total	4.2	4.1	2.4	2.6

SOURCE: MARYLAND YOUTH RISK BEHAVIOR SURVEY

"Instead of waiting for the suburban kids to come into the city, the dealers have gone out to the suburbs. It just blows away these parents in the middle-class communities — the last drug in the world they think their kids are going to use is heroin."

- Mike Gimbel, former heroin addict

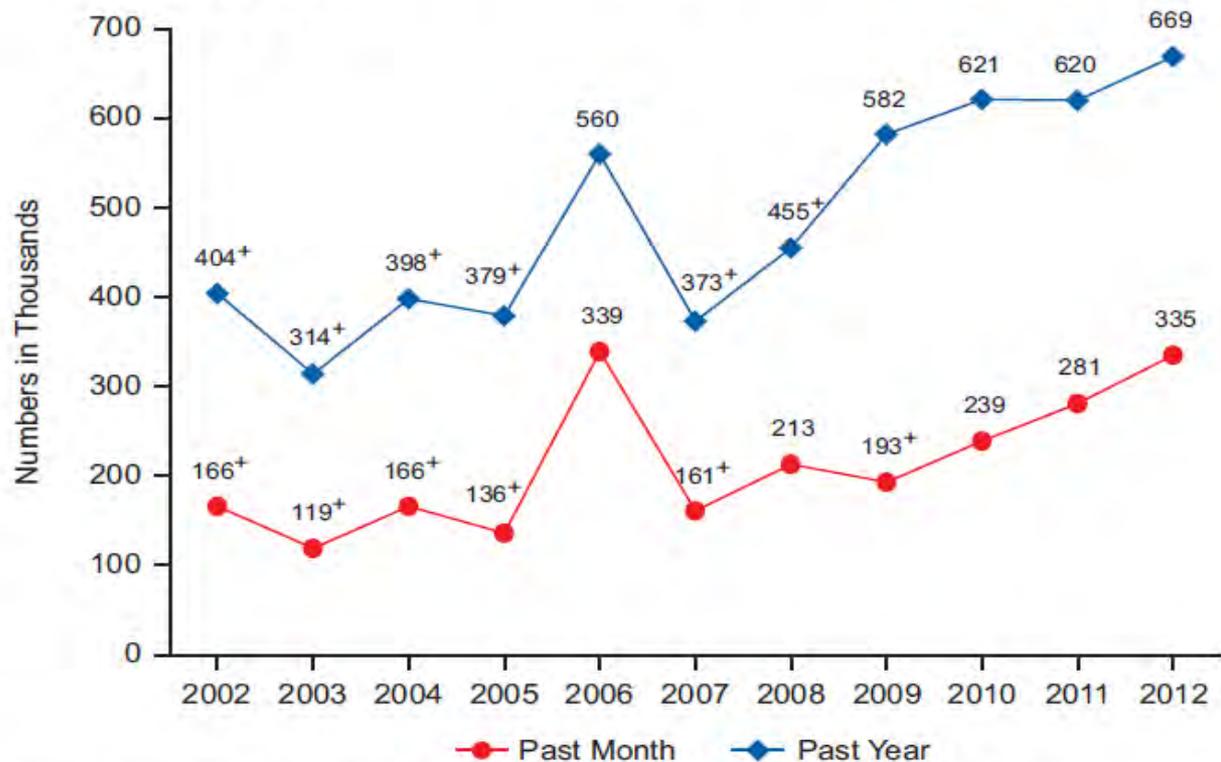
said. "And then there were times when I thought I was living in hell."

Dan Torsch died of a heroin overdose at age 24 in December 2010. Since then, his mother set up GRASP, an organization for grieving family members to connect after losing a loved one to substance abuse, along with a foundation in Dan's name to help families pay for addiction treat-



Past Month & Year Heroin Use – Ages 12 or Older (2002 – 2012)

Figure 2.4 Past Month and Past Year Heroin Use among Persons Aged 12 or Older: 2002-2012



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



Example: *“Heroin a Growing Problem in St. George”*

- St. George, Utah is known as a good place to raise a family or to retire, but aside from the wholesome image, it's fighting a newfound heroin problem.
- Police point to users like Karli Chambers: 27 year-old mother of two had been addicted to prescription drugs, then made an economic decision.
- "I couldn't afford the pills," Chambers said in an interview at the Southwest Behavioral Health Center in St. George, where she is getting counseling. "It was too much. The only thing I could find was heroin."



METHADONE





Methadone History

- Methadone was developed in 1937 in Germany as a field painkiller, in anticipation of the potential loss of the raw opium supply for drugs like morphine in the event of war.
- The Controlled Substances Act and corresponding regulations established strict rules for methadone clinics, or Narcotic Treatment Programs (NTPs).



Methadone- 5mg & 10mg



Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg





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

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?



One Pill can Kill



CE Article: JACOME, CMI, ACEFI 1 CE credit for this article

By Jonathan J. Lipman, PhD

THE METHADONE POISONING "Epidemic"

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

Name _____ Date _____
Address _____

Rx

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.





Overdose...Why?

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





Bluefield Daily Telegraph

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"Then he answered and spake to me, saying, Thus 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 KJV)

Overdose deaths Prescription drugs take deadly toll in WV

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

The report found that one-third of the prescription drugs taken during the fatal 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.

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

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

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

□ □ □

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

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

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

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

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



editorials

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, a abuse or diversion of methadone



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

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

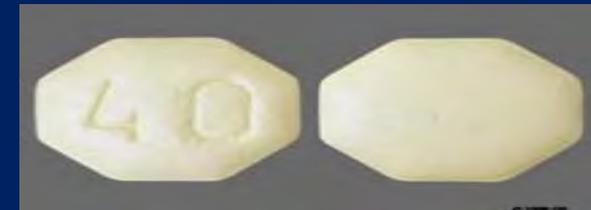
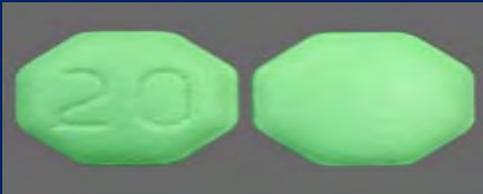
At least 29 states have prescription monitoring programs that would identify indiscriminate prescribing, doctor-shopping and other abuses. A task force established this year in Maryland is studying the possibility of establishing a similar tracking system for methadone and other controlled substances.

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



Opana ER (Oxymorphone) (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming more popular and is abused in similar fashion to oxycodone
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: \$10.00 – \$80.00





Other Narcotics

Fentanyl



Hydromorphone



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

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



Trade Name: Oxycodone
Controlled Ingredient: oxycodone hydrochloride, 100 mg

Trade Name: Oxycodone
Controlled Ingredient: oxycodone hydrochloride, 15 mg

Trade Name: Oxycodone
Controlled Ingredient: oxycodone hydrochloride, 30 mg

Trade Name: Oxycodone
Controlled Ingredient: oxycodone hydrochloride, 30 mg

Trade Name: Oxycodone
Controlled Ingredient: oxycodone hydrochloride, 100 mg

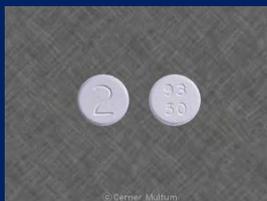
Trade Name: Oxycodone
Controlled Ingredient: oxycodone hydrochloride, 30 mg

Meperidine

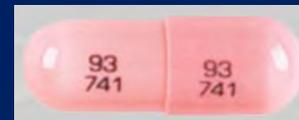


Morphine

Codeine



Propoxyphene





Benzodiazepines

Alprazolam



Clonazepam



Diazepam



Lorazepam



Midazolam



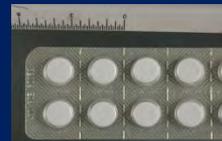
Triazolam



Temazepam



Flunitrazepam





ADHD Drugs: Ritalin® / Concerta® / Adderall®





ADHD Drugs

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

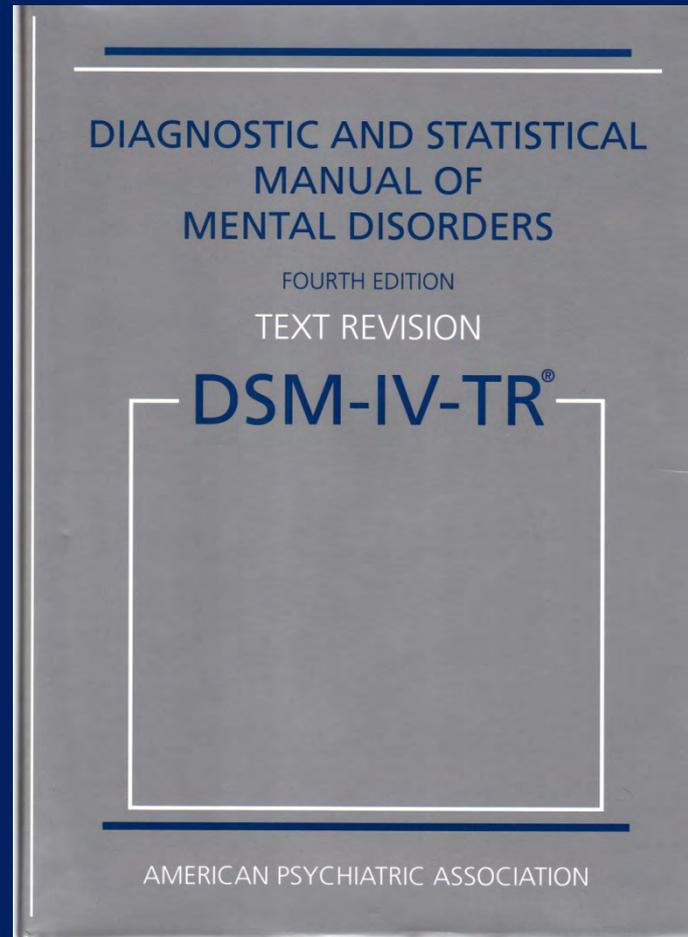


ADHD Drugs

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



Required Reading



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 disorder

- 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).



that require and poor ued, typical quate self others as-ior. Famil specially b to believe parent-ch

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-

ire als sts lar its

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

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.



Dextromethorphan (DXM)

- Cough suppressant in over 125 OTC medications (e.g., Robitussin and Coricidin)
- Bulk form on the Internet
- At high doses, has Ketamine- and PCP-like effects
- Produces physical and psychological dependence
- Deaths associated with DXM abuse





Cough Syrup Cocktails

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



PURPLE DRANK
ima grip and sip





Tramadol – Notice of Proposed Rule Making

➤ On November 4, 2013 prepared a “Notice of Proposed Rulemaking” to schedule Tramadol into schedule IV

➤ Open for 60 days of Public Comment

Federal Register / Vol. 78, No. 213 / Monday, November 4, 2013 / Proposed Rules 65923

essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Meaningful disruption means a change in production that is reasonably likely to lead to a reduction in the supply of a biological product by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

Significant disruption means a change in production that is reasonably likely to lead to a reduction in the supply of blood or blood components by a manufacturer that substantially affects the ability of the manufacturer to fill orders or meet expected demand for its product, and does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period of time.

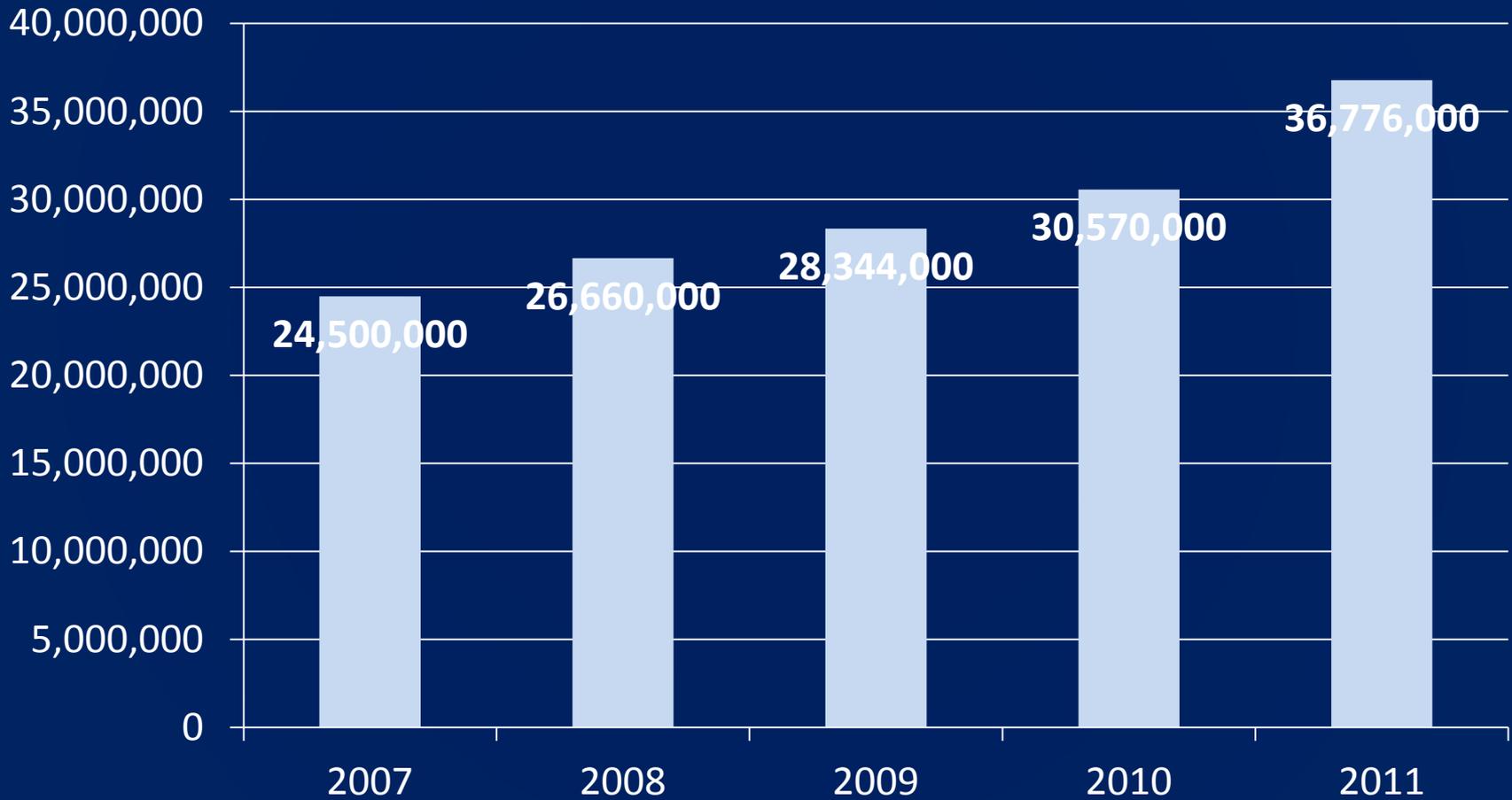
Dated: October 26, 2013.
Ledie Kux,
 Assistant Commissioner for Policy.
 [FR Doc. 2013-25956 Filed 10-31-13; 11:15 am]
 BILLING CODE 4160-01-P

DEPARTMENT OF JUSTICE
Drug Enforcement Administration
21 CFR Part 1308
 [Docket No. DEA-351]
Schedules of Controlled Substances: Placement of Tramadol Into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice of proposed rulemaking.
SUMMARY: The Drug Enforcement Administration (DEA) proposes to place the substance 2-((dimethylamino)methyl)-1-(3-methoxyphenyl)cyclohexanol, its salts, isomers, salts of isomers, and all isomeric configurations of possible forms including tramadol (the term “isomers” includes the optical and geometric isomers) into Schedule IV of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Assistant Secretary of Health of the Department of Health and Human Services (HHS) and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle tramadol.
DATES: Interested persons may file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before January 3, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period. Interested persons, defined as those “adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811),” 21 CFR 1308.01, may file a request for hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45 and 1316.47. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before December 4, 2013.
ADDRESSES: To ensure proper handling of comments, please reference “Docket No. DEA-351” on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the on-line instructions at that site for submitting comments. An electronic copy of this document and supplemental information to this proposed rule are also available at the <http://www.regulations.gov> Web site for easy reference. Paper comments that duplicate electronic submissions are not necessary. All comments submitted to <http://www.regulations.gov> will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrisette Drive, Springfield, Virginia 22152.
FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Chief, Policy Evaluation and Analysis Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone (202) 598-6812.
SUPPLEMENTARY INFORMATION: *Posting of Public Comments:* Please note that comments received in response to this NPRM are considered part of the public record and will be made available for public inspection and posted at <http://www.regulations.gov> and in the DEA’s public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.
 If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made public, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want to be made publicly available in the first paragraph of your comment and identify what information you want redacted.
 If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available.
 Comments containing personal identifying information and confidential business information identified and located as set forth above will be made available in redacted form. The Freedom of Information Act (FOIA) applies to all comments received. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the **FOR FURTHER INFORMATION CONTACT** paragraph, above.



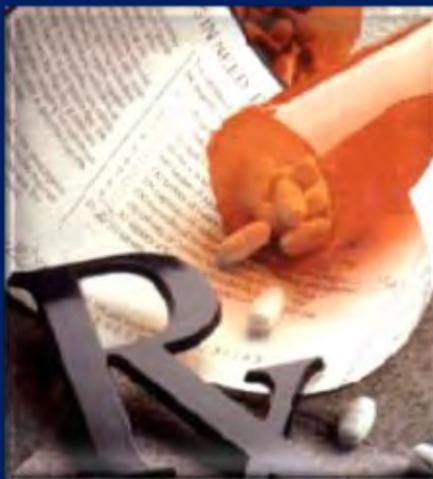
Tramadol Prescriptions



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



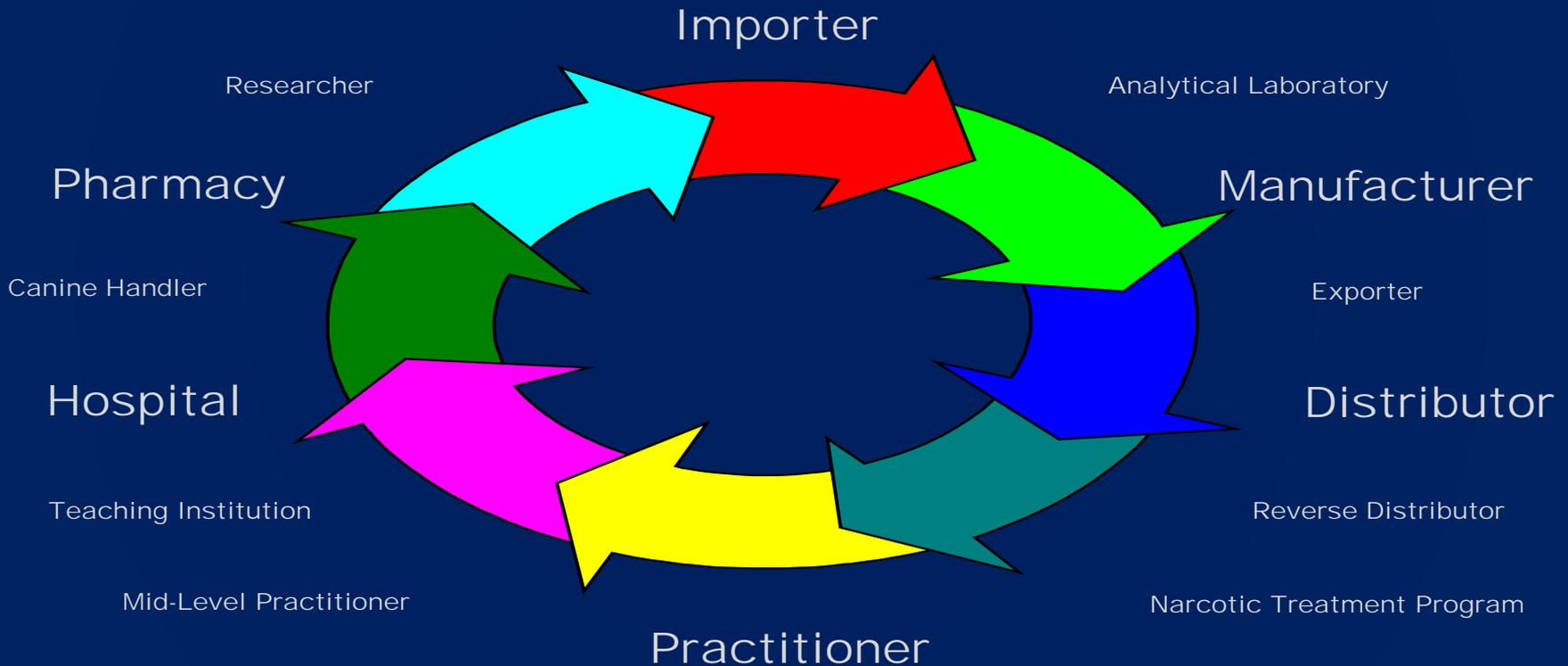
THE CSA: CHECKS & BALANCES



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



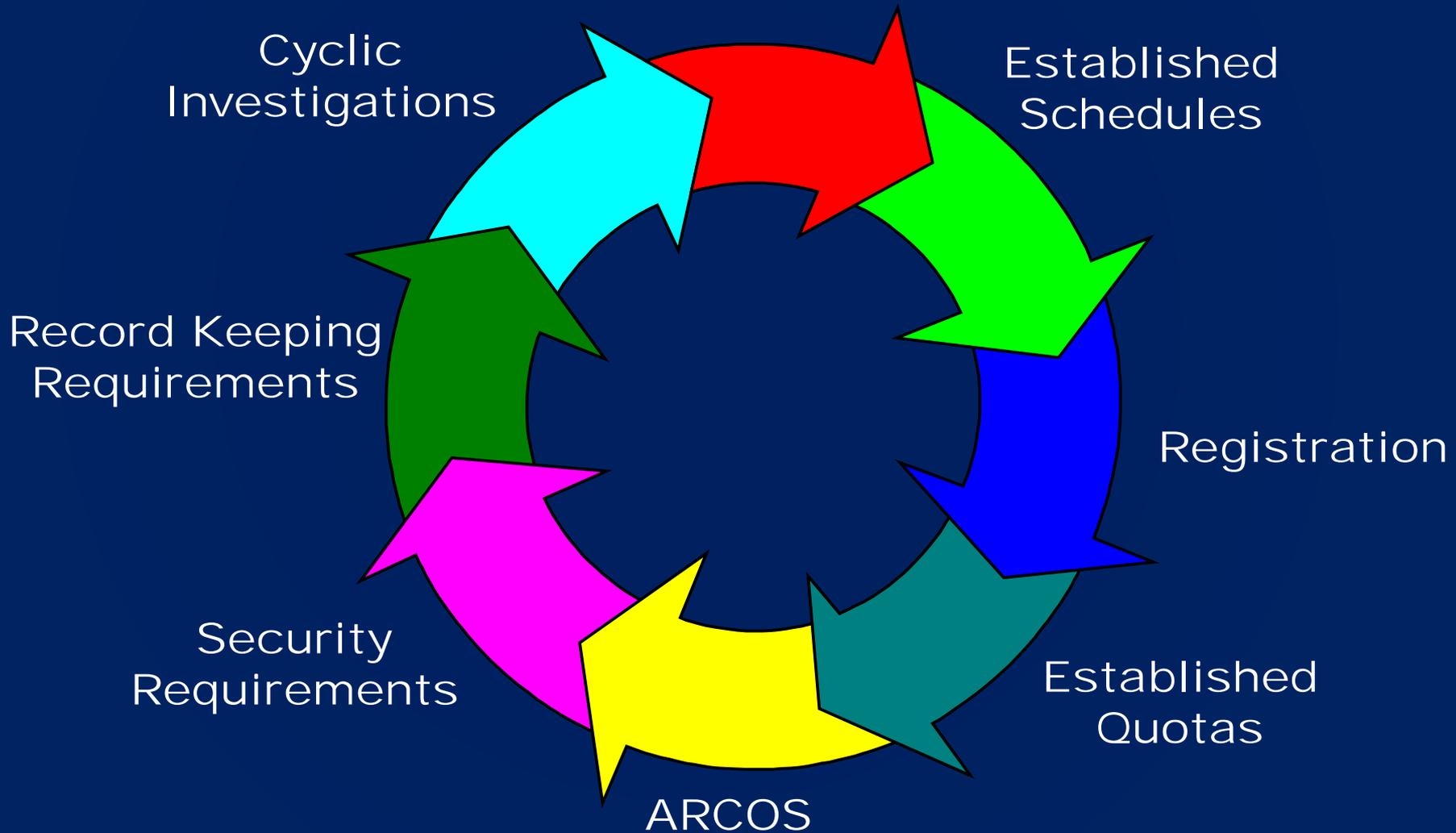
The CSA's Closed System of Distribution



1,469,821 DEA REGISTRANTS

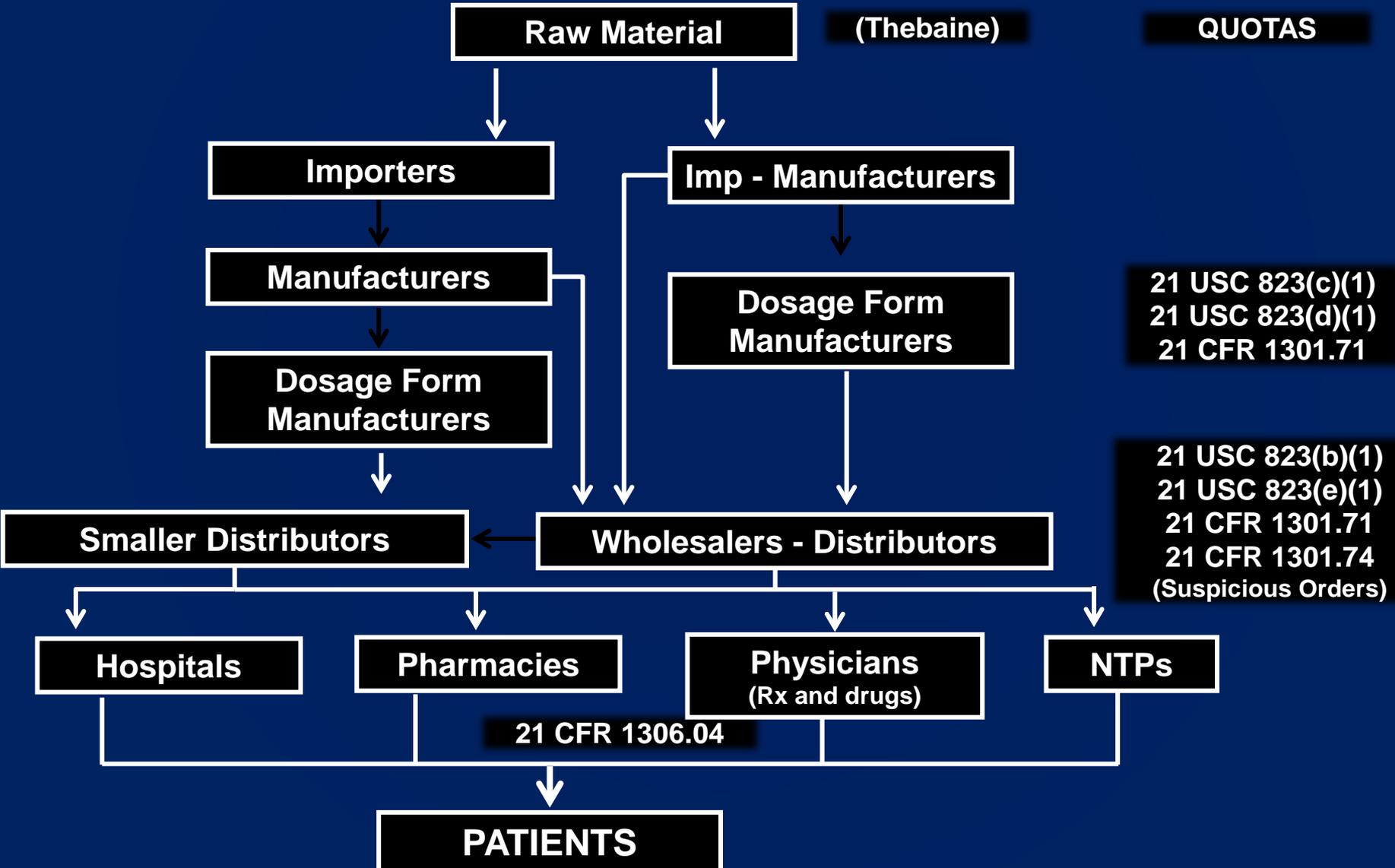


The CSA's Closed System of Distribution





The Flow of Pharmaceuticals





Checks and Balances of the CSA and the Regulatory Scheme

- Distributors of controlled substances

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



Checks and Balances Under the CSA

- Practitioners

“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.” (21 CFR §1306.04(a))

United States v Moore 423 US 122 (1975)



Checks and Balances Under the CSA

- Pharmacists – The Last Line of Defense

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



What can happen when these
checks and balances
collapse ?



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.



Large-Scale Diversion

- In 2011, the average purchase for all oxycodone products for all pharmacies in US – 74,706 d.u.
- In 2012, the average was – 73,434 d.u.
- In 2011, the average purchase for all oxycodone products for the top 100 pharmacies in Tennessee – 490,781 d.u.
- In 2012, the average was – 466,061 d.u.



WHERE PEOPLE ARE GETTING THEIR DRUGS

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

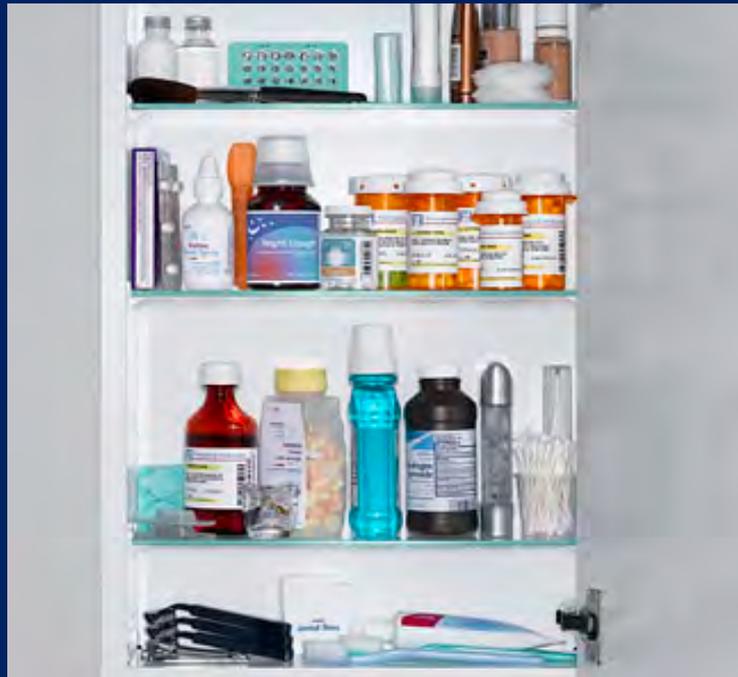


Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!



The Medicine Cabinet: The Problem of Easy Access





So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules



National Take Back Initiatives

Over 3.4 million pounds (1,733 tons) collected

- September 30, 2010: 242,383 pounds (121 tons)
- April 30, 2011: 376,593 pounds (188 tons)
- October 29, 2011: 377,086 pounds (189 tons)
- April 28, 2012: 552,161 pounds (276 tons)
- September 29, 2012: 488,395 pounds (244 tons)
- April 27, 2013: 742,497 pounds (371 tons)
- October 26, 2013: 647,211 pounds (324 tons)



Take-Back Event



Boxed, Sealed, Counted, Weighed,
Consolidated, Secured, and
Incinerated



Looking to the Future: The Secure and Responsible Drug Disposal Act of 2010

- On October 12, 2010, the President signed the “*Secure and Responsible Drug Disposal Act of 2010.*”
- This Act allows DEA to draft new regulations which permits ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.

S. 3397

One Hundred Eleventh Congress
of the
United States of America

AT THE SECOND SESSION

*Begin and held at the City of Washington on Tuesday,
the fifth day of January, two thousand and ten*

An Act

To amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Secure and Responsible Drug Disposal Act of 2010”.

SEC. 2. FINDINGS.

Congress finds the following:

(1) The nonmedical use of prescription drugs is a growing problem in the United States, particularly among teenagers.

(2) According to the Department of Justice’s 2009 National Prescription Drug Threat Assessment—

(A) the number of deaths and treatment admissions for controlled prescription drugs (CPDs) has increased significantly in recent years;

(B) unintentional overdose deaths involving prescription opioids, for example, increased 114 percent from 2001 to 2005, and the number of treatment admissions for prescription opioids increased 74 percent from 2002 to 2006; and

(C) violent crime and property crime associated with abuse and diversion of CPDs has increased in all regions of the United States over the past 5 years.

(3) According to the Office of National Drug Control Policy’s 2008 Report “Prescription for Danger”, prescription drug abuse is especially on the rise for teens—

(A) one-third of all new abusers of prescription drugs in 2006 were 12- to 17-year-olds;

(B) teens abuse prescription drugs more than any illicit drug except marijuana—more than cocaine, heroin, and methamphetamine combined; and

(C) responsible adults are in a unique position to reduce teen access to prescription drugs because the drugs often are found in the home.

(4)(A) Many State and local law enforcement agencies have established drug disposal programs (often called “take-back” programs) to facilitate the collection and destruction of unused, unwanted, or expired medications. These programs help get outdated or unused medications off household shelves and out of the reach of children and teenagers.



The Secure and Responsible Drug Disposal Act of 2010

As DEA worked to promulgate regulations to implement the Act, we have been required to consider:

- Public health and safety
- Ease and cost of program implementation
- Participation by various communities
- Diversion Control



Notice of Proposed Rulemaking for the Disposal of Controlled Substances

➤ The NPRM on disposal was published in the Federal Register on December 21, 2012

➤ Open for a 60-day public comment period / Closed February 19, 2013

➤ The Final Rule will be published in the Federal Register upon completion

75784 Federal Register / Vol. 77, No. 246 / Friday, December 21, 2012 / Proposed Rules

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305, 1307, 1317, and 1321

[Docket No. DEA-316]

RIN 1117-AB18

Disposal of Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule proposes requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users.

These regulations would implement the Secure and Responsible Drug Disposal Act of 2010 (Pub. L. 111-273) by expanding the options available to collect controlled substances from ultimate users for purposes of disposal to include take-back events, mail-back programs, and collection receptacle locations.

These proposed regulations contain specific language to continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles. These regulations propose to allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles. In addition, this proposed rule expands the authority of authorized retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities. This proposed rule also reorganizes and consolidates existing regulations on disposal, including the role of reverse distributors.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before February 19, 2013. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-316" on all electronic and written correspondence. DEA encourages all comments be submitted electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site for easy reference. Paper comments that duplicate the electronic submission are not necessary as all comments submitted to <http://www.regulations.gov> will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Office of Diversion Control (OD-DX), 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 307-4054.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and are made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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Outline

I. Executive Summary

A. Purpose of the Regulatory Action

B. Summary of the Major Provisions of the Regulatory Action

II. Background

A. Legal Authority

B. History of Disposal of Controlled Substances

C. Existing DEA Regulations

III. Prescription Drug Abuse Epidemic

IV. Scope of Proposed Rule

V. Proposed Disposal Act Implementing Regulations

A. Disposal of Controlled Substances by Ultimate Users—Authorized Persons

B. Disposal of Controlled Substances by Ultimate Users—Authorized Methods

C. Disposal of Controlled Substances by Registrants

D. Return and Recall

E. Methods of Destruction

VI. Miscellaneous Changes

VII. Regulatory Analyses

Executive Summary

Purpose of the Regulatory Action

On October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted (Pub. L. 111-273, 124 Stat. 2858). Below the Disposal Act, ultimate users who wanted to dispose of unused, unwanted, or expired controlled substance pharmaceuticals had limited disposal options. The Controlled Substances Act (CSA) only permitted ultimate users to destroy those substances themselves, for example by flushing or discarding, or to dispose of such substances by surrendering them to law enforcement or by seeking assistance from the U.S. Drug Enforcement Administration (DEA). These restrictions resulted in the accumulation of controlled substances in household medicine cabinets that were available for abuse, misuse, and accidental ingestion. The Disposal Act amended the CSA to authorize ultimate users to deliver their controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the Attorney General. 21 U.S.C. 822(g) and 828(b)(3). The Attorney General delegated responsibility for promulgating the Disposal Act implementing regulations to DEA. These proposed regulations expand the entities to which ultimate users may transfer unused, unwanted, or expired controlled substances for the purpose of disposal, as well as the methods by which such controlled substances may be collected. Specific entities may voluntarily administer any

duplicate the electronic submission are not necessary as all comments submitted to <http://www.regulations.gov> will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Office of Diversion Control (OD-DX), 8701 Morrisette Drive, Springfield, Virginia 22152.

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Doctor Shopping





Doctor Shopping: What is it ?

Practiced by both Individual “Patients Drug Seekers” & Trafficking Organizations

- Target Physicians
 - Obtain prescriptions from multiple physicians
 - Physicians who are willing to prescribe controlled substances over an extended period of time with little or no follow-up
- Target Pharmacies
 - Utilize multiple pharmacies to fill the orders to avoid suspicion
 - Pharmacies known to dispense controlled substances without asking questions are targeted



Doctor Shopping: What is it ?

Los Angeles Times

LATIMES.COM

Prescriptions like candy

The story of a Duarte doctor makes it clear a lot can go wrong between the handcuffs and the prison time.

SANDY BANKS

We're getting tough on drug dealers in Los Angeles these days, sweeping crack sellers off skid row



streets, shutting down marijuana dispensaries, prosecuting doctors who peddle prescriptions like candy to patient addicts.

But the story of Dr. Daniel Healy makes it clear that a lot can go wrong between the handcuffs and the prison time.

Healy, according to prosecutors, is a most prolific drug dealer. In 2008 alone, he illegally distributed enough prescription drugs to constitute the federal government's equivalent of more than 50 kilos of cocaine or 37,000 pounds of marijuana.

The Duarte physician ordered more Vicodin than any doctor in the nation — 1 million pills in 2008. That's 10 times the stockpile of an average pharmacy; more than his local CVS, Wal-Mart, Target and City of Hope pharmacies combined.

According to federal legal briefs, Healy made so many over-the-counter sales from his "Kind Care" medical clinic, the office had its own money-counting machine and Healy pocketed "\$3,000 to \$6,000 a day."

On the day he was arrested, police pulled over a

ghetto street dealer with a wad of cash and pocketful of crack cocaine.

That guy would have received

years in

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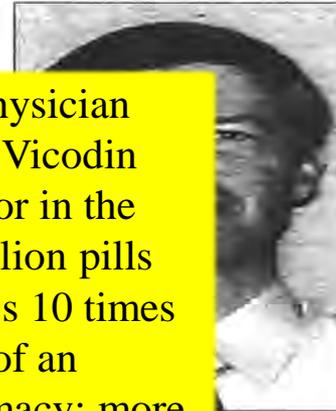
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Healy

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The Duarte physician ordered more Vicodin than any doctor in the nation — 1 million pills in 2008. That's 10 times the stockpile of an average pharmacy; more than his local CVS, Wal-Mart, Target, and City of Hope pharmacies combined.



Prosecutors Healy is a dealer.

couldn't 96 of the he year ested,

Care clinic an a "nar-

almost \$700,000 in one year: "a cash-and-carry narcotics store under the guise of providing legitimate medical treatment."

The prosecutor in the case stopped short of saying he's disappointed when I interviewed him Monday.

"Forty-eight months is a significant sentence, by any measure," said Assistant U.S. Atty. David Herzog.

The felony conviction

means Healy will lose his license. "The end result is that this defendant is no longer able to distribute narcotics into the community and never will again."

But 48 months is considerably less than the 210-month minimum term the probation report recommended. It's less, even, than the 57 months Healy's lawyer suggested would be fair.

That's a blow to DEA efforts to crack down on abuse of prescription drugs, which is rising among teens and young adults.

Nearly 7 million Americans are abusing pharmaceutical drugs — up from 3.8 million 10 years ago, and more than the number addicted to cocaine, heroin and hallucinogens. Opioid painkillers — the kind Healy dispensed — cause more overdose deaths than cocaine and heroin combined.

Blatant drug-dealing by doctors is rare. More common is doctor-shopping by patients, thefts from pharmacies, trading meds by addicts and illicit street sales by drug dealers.

That's why Healy's sentence is so disappointing.

Here's a chance to send a message to "well-meaning" doctors like Healy who might be tempted by easy money and to suffering patients who might not realize that the mild-mannered guy with the stethoscope might have more than their well-being in mind.

sandy.banks@latimes.com



Illinois Doctor Sentenced to Four Consecutive Life Sentences

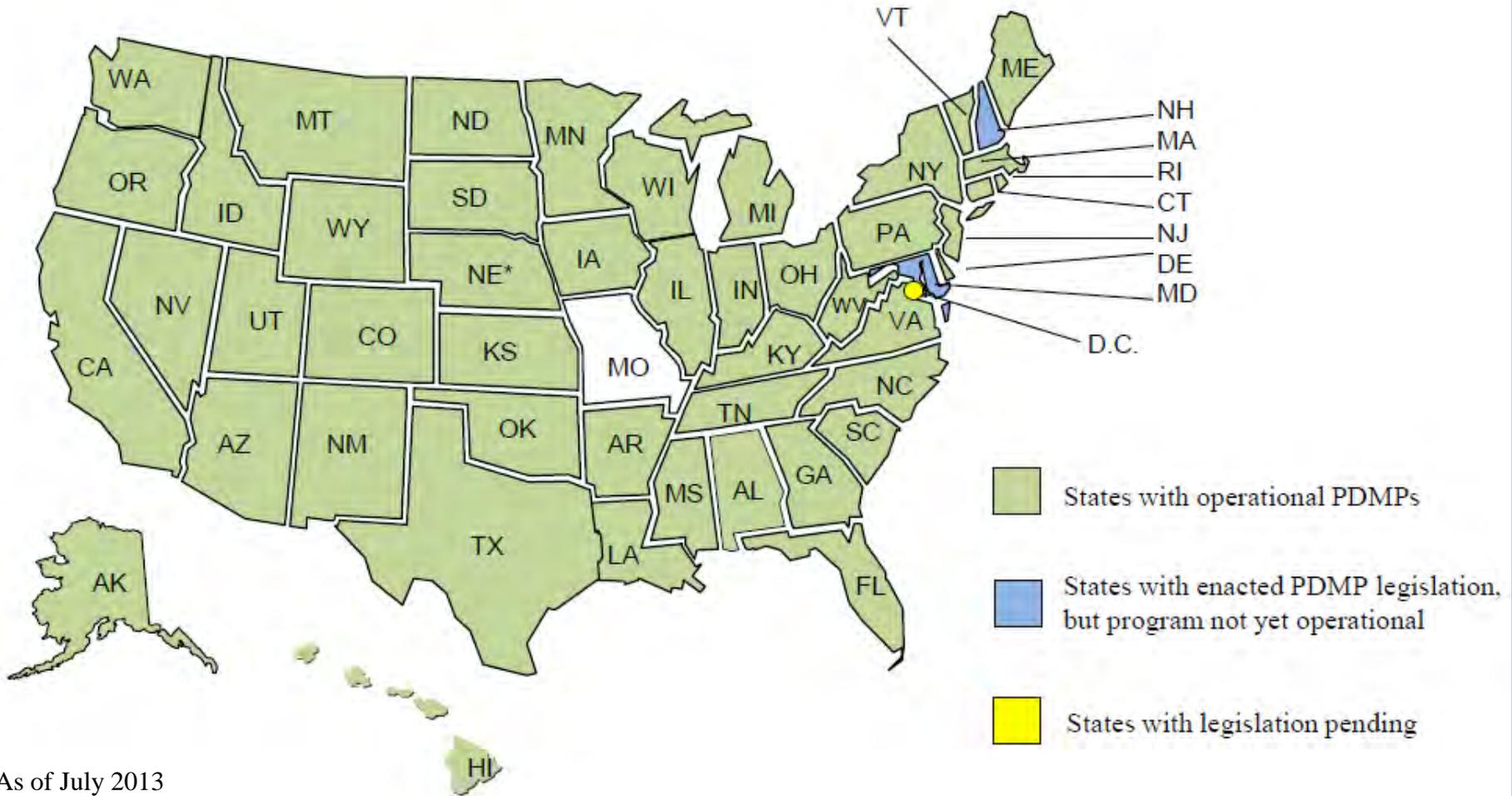


Dr. Paul H. Volkman was sentenced in the Southern District of Ohio on February 14, 2012 to four consecutive life sentences and ordered to forfeit \$1.2 million. Volkman was convicted on 12 counts of illegal distribution of controlled substances, four of which resulted in a death; one count of conspiracy to distribute controlled substances; four counts of maintaining a drug premise; and one count of possession of a firearm in furtherance of a drug trafficking crime.

From 2003 to 2005, Volkman illegally distributed over 2.5 million dosage units of Schedule II drugs, primarily oxycodone, outside the course of professional practice which resulted in the death of four people. Of the approximate one million practitioner registrants in the United States in 2004, Volkman ranked first in purchases of oxycodone.



Status of State Prescription Drug Monitoring Programs (PDMPs)



Source: The National Alliance for Model State Drug Laws (NAMSDL), www.namsdl.com. "Prescription Drug Abuse: Strategies to Stop the Epidemic (2013)"

* The operation of Nebraska's PDMP is currently being facilitated through the state's Health Information Initiative. Participation by patients, physicians, and other health care providers is voluntary.



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;

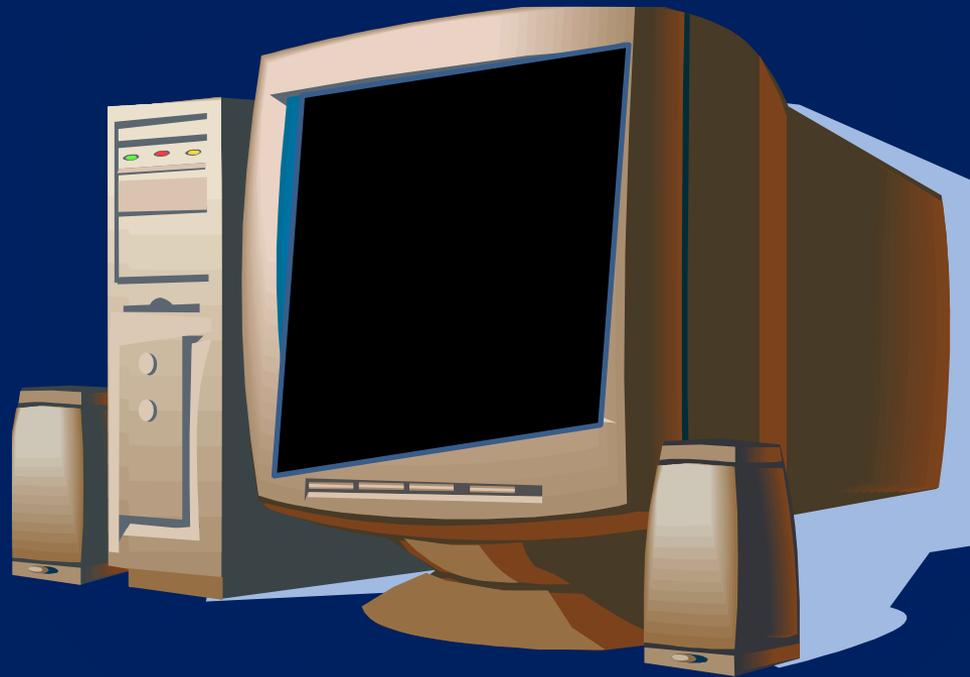
individuals driving long distances to visit physicians and/or to fill prescriptions;

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.).



The Internet



Domestic 'Rx' Flow

1. Consumer in Montana orders hydrocodone on the Internet

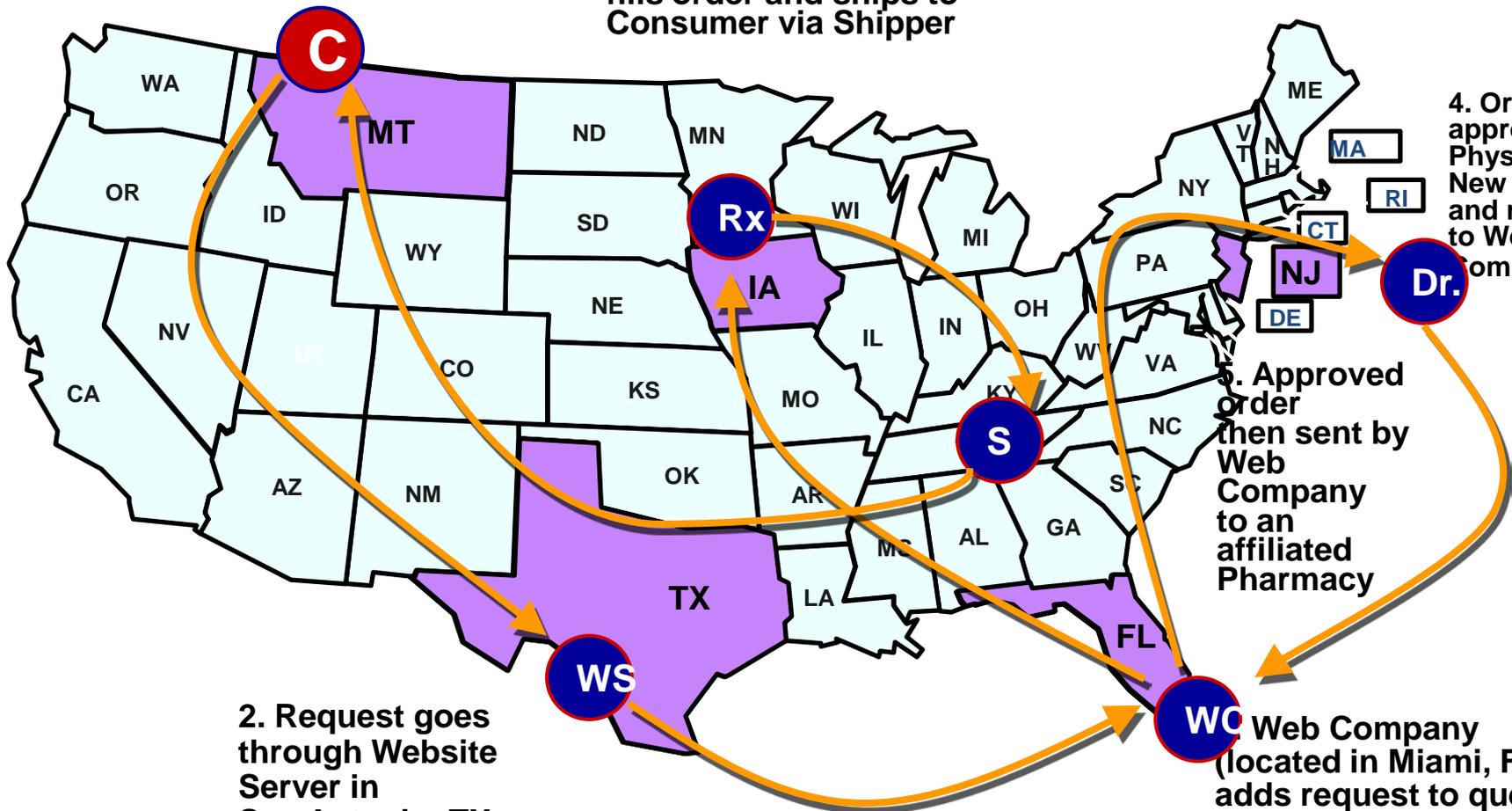
6. Pharmacy in Iowa fills order and ships to Consumer via Shipper

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

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

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

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





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	9,077,816
3		Hillsborough	TAMPA	FLORIDA	33614	8,760,876
4		Baltimore City	BALTIMORE	MARYLAND	21213	5,876,300
5		Hillsborough	TAMPA	FLORIDA	33619	5,718,200
6		Jefferson	RIVER RIDGE	LOUISIANA	70123	4,892,900
7		Hillsborough	TAMPA	FLORIDA	33634	4,733,290
8		Polk	LAKELAND	FLORIDA	33813	4,564,480
9		Hillsborough	TAMPA	FLORIDA	33612	4,220,840
10		Pinellas	CLEARWATER	FLORIDA	33759	3,819,320
11		Hillsborough	TAMPA	FLORIDA	33610	3,044,160
12				FLORIDA	33809	3,039,490
13					70123	2,750,000
14					34652	2,664,120
15					33613	1,902,900
16					33801	1,726,020
17		Hillsborough	TAMPA	FLORIDA	33612	1,619,765
18		Hillsborough	TAMPA	FLORIDA	33604	1,570,350
19		Pinellas	TARPON SPRINGS	FLORIDA	34689	1,464,900
20		Lincoln	DENVER	NORTH CAROLINA	28037	1,402,450
21		Hillsborough	TAMPA	FLORIDA	33617	1,282,800
22		Hillsborough	TAMPA	FLORIDA	33619	1,272,860
23		Polk	LAKELAND	FLORIDA	33813	1,039,400
24		Pasco	WESLEY CHAPEL	FLORIDA	33543	1,030,050
25		Iredell	MOORESVILLE	NORTH CAROLINA	28117	902,500
26		Polk	LAKELAND	FLORIDA	33815	867,800
27		Broward	HOLLYWOOD	FLORIDA	33021	865,700
28		Los Angeles	ENCINO	CALIFORNIA	91436	798,100
29		Hillsborough	TAMPA	FLORIDA	33604	793,350
30		Pasco	NEW PORT RICHEY	FLORIDA	34652	583,400
31		Ravalli	FLORENCE	MONTANA	59833	362,000
32		Hillsborough	TAMPA	FLORIDA	33619	162,000
33		Broward	DEERFIELD BEACH	FLORIDA	33441	112,600
34		Hillsborough	TAMPA	FLORIDA	33614	49,600
						2,899,021

98,566,711



One Internet Case Example Minneapolis, Minnesota





Total Forfeiture:

\$4,370,258.80



Ryan Haight Online Pharmacy Act: Internet Trafficking a Crime

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)



Ryan Haight Online Pharmacy Act: Violations

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

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



Current CSA Registrant Population

Total Population: 1,500,245

➤ Practitioner	-	1,168,919
➤ Mid-Level Practitioner	-	232,136
➤ Pharmacy	-	68,907
➤ Hospital/Clinic	-	15,921
➤ Manufacturer	-	545
➤ Distributor	-	959
➤ Researcher	-	7,164
➤ Analytical Labs	-	1,525
➤ NTP	-	1,319
➤ ADS Machine	-	564

as of 07/31/2013



**What took the place of internet
controlled substance distribution?**

Where did it all go?



Normal Practitioner / Patient Relationship

Practitioners

“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.” (21 CFR §1306.04(a))

United States v Moore 423 US 122 (1975)



The Florida “Migration”: Was this Normal ??

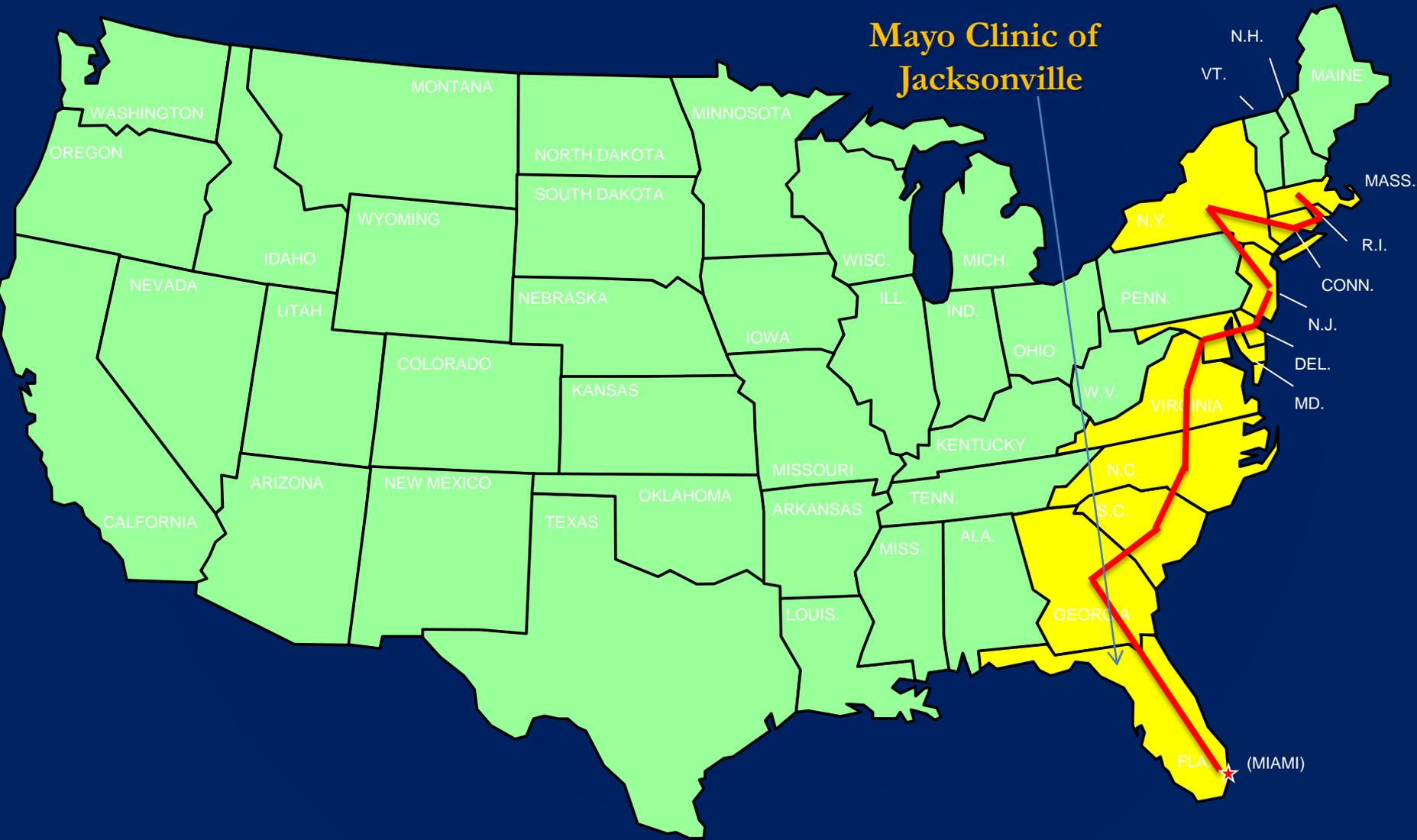
Vast majority of the “patients” visiting Florida “pain clinics” came from out-of-state:

- Georgia
- Kentucky
- Tennessee
- Ohio
- Massachusetts
- New Jersey
- North and South Carolina
- Virginia
- West Virginia



THE MIGRATION

Mayo Clinic of
Jacksonville





“short waits or
we will pay you”



“earn \$\$\$ for
patient referrals” (sic)

PAIN CENTER OF BROWARD

LOW PRICES ON MEDS!

2 DOCTORS ON THE PREMISES MEANS NO WAITS

- Be on time for your appointment and we guarantee short waits or we will pay you!! (Details at front desk)
- Still use the Patient Loyalty Program to earn FREE Visits
- Still earn \$\$\$ for patient referrals
- **SAME FRIENDLY STAFF AND OWNER**

SAVE \$\$
With Our Patient Loyalty Program

\$100 OFF
Initial Visit w/ Ad

Walk-Ins Welcome at 12 Noon Daily.

CALL TODAY FOR APPOINTMENT
954.491.8034

5459 N. FEDERAL HWY • FORT LAUDERDALE, FL 33308
(4 BLOCKS NORTH OF COMMERCIAL)



When you get in, make sure you follow the Instructions !!





All the Instructions

PLEASE
HAVE
EXACT
CHANGE

CASH ONLY

NO CREDIT
CARDS OR
CHECKS
ALLOWED.

SORRY FOR
THE
INCONVIENCE



All of your weapons !!!!!





Including the knives !!!!





Finally, get your script (s) !!





Make sure you pack them properly for the trip home (which is often out of state) !





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; each subsequent visit is \$150 to \$200
- Average 120-180 30mg oxycodone tablets per visit



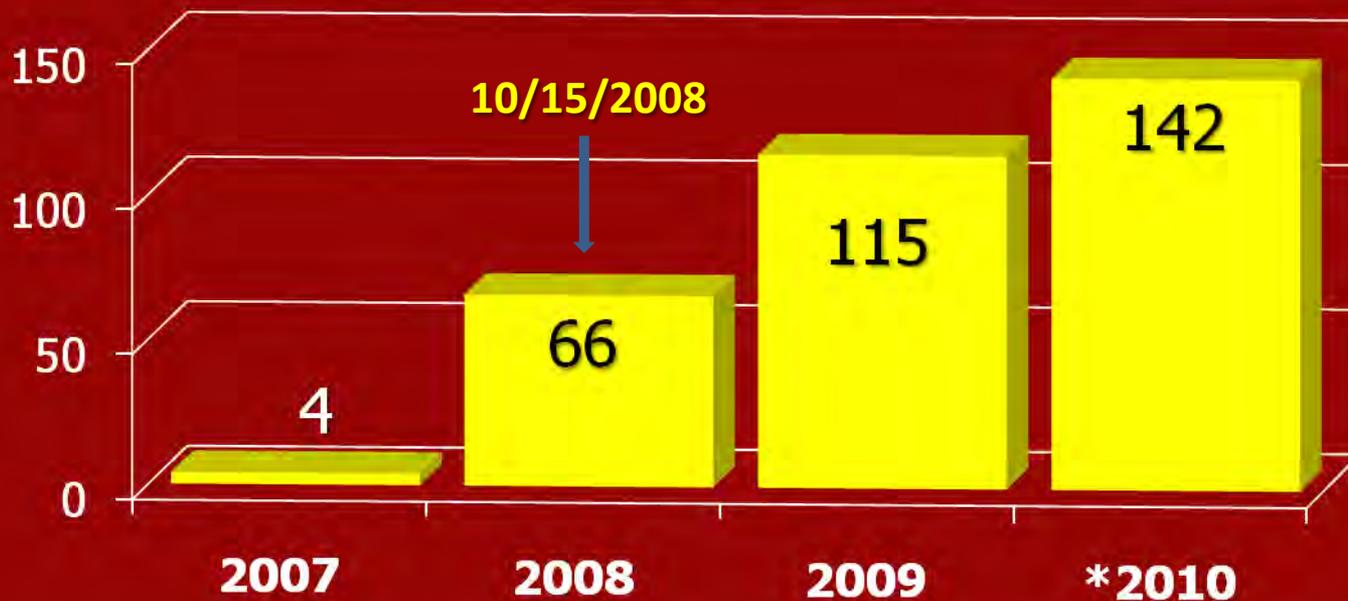
Cost of Drugs

- The ‘cocktail’ prescriptions go for \$650 to \$1,000
- According to medical experts, most clinics do not require sufficient medical history and tests for proper prescribing of Schedule II substances
- Each oxycodone 30mg tablet costs \$1.75 to \$2.50 at the clinics
 - On the street in Florida, that pill can be re-sold for \$7 to \$15
 - Outside of Florida, it can be re-sold for \$25 to \$30 (\$1 per mg)



Explosion of South Florida Pain Clinics

Estimated Number of Broward County 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.



Where to Find Doctors - Craigslist ??

****PHYSICIAN NEEDED, START IMMEDIATELY** (WEST PALM BEACH, FLORIDA)**

Date: 2010-03-03, 5:22PM EST

Reply to: job-gekbz-1627117891@craigslist.org [Errors when replying to ads?]

****PHYSICIAN NEEDED, START IMMEDIATELY****

M.D. / D.O. FOR CONTINUING CARE / PAIN MANAGEMENT CENTER

- FULL TIME & PART TIME POSITIONS ARE AVAILABLE – START IMMEDIATELY!

- Experience in Pain Management is preferred but NOT necessary. We will train if needed!

- GREAT Compensation (\$12,000+ PER WEEK!!!)

- Position may include Medical Director for facility

- Doctor's need to have their Dispensing License or can obtain one

- Perfect opportunity for a M.D. / D.O. / or Retiree

- Please send resume with salary requirements to: DPerezWPM@Gmail.com

ALL INQUIRES CONTACT: DPerezWPM@Gmail.com OR CALL 561-253-4038

DOCTOR'S NEEDED (MIAMI)

Date: 2010-02-21, 6:50PM EST

Reply to: doctor247@hotmail.com [Errors when replying to ads?]

CAN EARN OVER \$500 DOLLARS AN HOUR

FLEXIBLE HOURS

WEEKDAYS .WEEKENDS OR BOTH

YOU MAKE YOUR OWN SCHEDULE

CONTACT ERIC TEL 305 710-0013

CAN SEND US YOUR CV AT doctor247@hotmail.com

· Location: MIAMI

· Compensation: can earn over \$500 dollars an hour

· This is a part-time job.

· Principals only. Recruiters, please don't contact this job poster.

· Phone calls about this job are ok.

· Please do not contact job poster about other services, products or commercial interests.



Why is this happening?



Its All About Profit

- 
- The background of the slide is a photograph of several stacks of US one hundred dollar bills. The bills are fanned out, showing the top of one bill in each stack. The stacks are arranged in a way that creates a sense of depth and abundance. The lighting is warm, highlighting the texture of the paper and the intricate details of the currency.
- One case in Florida owner/operator of pain clinic allegedly generated \$40 million in drug proceeds
 - Houston investigation \$41.5 million in assets



Its All About Profit

- Another case in Florida - pain clinic operation paid his doctors:
 - \$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



The Washington Post

Feds raid Fla. pill mills; arrest docs, owners

By CURT ANDERSON
The Associated Press
Wednesday, February 23, 2011; 5:23 PM

WESTON, Fla. -- U.S. Drug Enforcement Administration agents and local police swept across South Florida on Wednesday making arrests as part of a lengthy undercover operation into illegal pill mills that dispense huge amounts of powerful prescription drugs across the nation.

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February 23, 2011

Agents Raid Florida Clinics in Drug Crackdown

By DON VAN NATTA Jr.

MIAMI — Drug Enforcement Administration agents and other law enforcement officials on Wednesday raided six South Florida pain clinics accused of illegally dispensing potent prescription drugs across the United States. Twenty-two people, including trafficking charges.

The Palm Beach Post

[Print this page](#) [Close](#)

11 arrested in Palm Beach County as part of multi-agency pill mill raid

In Palm Beach County, the raids focused on five doctors in four pain clinics.

By CYNTHIA ROLDAN AND MICHAEL LAFORGIA

Palm Beach Post Staff Writers

Updated: 11:20 a.m. Thursday, Feb. 24, 2011
Posted: 9:57 a.m. Wednesday, Feb. 23, 2011

Operators of four crooked pain clinics in Palm Beach County made millions of dollars by peddling pills to patients with trumped up injuries, rewarding themselves with boats, exotic cars and real estate while rates of overdose deaths and drug-dealing soared, state prosecutors alleged in court documents made public Wednesday.



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

Buy Pharmacies or
Move to Other
States!

Beef prices on the way up

Low cattle supplies, strong foreign demand for U.S. beef help fuel price boost. 1B.

Preserving pets after death growing popular as an option

Taxidermist Daniel Ross acknowledges it's a controversial topic, but says the owners "aren't weird, they just really love their pets." 3A.

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0 5

Crossword, Sudoku 5D
Editorial/Forum 6-7A
Market trends 6B
Marketplace Today 5D
State-by-state 7A
TV listings 6D

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USA TODAY Snapshots®

A bite into dental costs

Average out-of-pocket costs Americans say they pay for dental procedures:



Source: Consumer Reports

By Rachel Huggins and Karl Gelles, USA TODAY

cartoonish persona, self-promotion and a criminal record of pump-and-dump stock fraud.

The former computer hacker is the principle figure behind Megaupload, which U.S. prosecutors charge was a global empire that reaped a mega-fortune from illegal digital distribution of movies, songs and other copyright works.

In a New Zealand jail awaiting extradition to the USA on charges of racketeering, money-

Dotcom's flamboyant life of riches and creating one of the Web's most popular and controversial sites — a site that came into the government's cross-hairs two years ago after a complaint from the Motion Picture Association of America.

In the days after Dotcom's arrest, the case has triggered an angry response from the hacker

Please see COVER STORY next page ►

Dealers creative in oxycodone bid

They try to open pill mills after Florida targets

By Donna Leinwand Leger
USA TODAY

Drug dealers are finding ways around new laws that have shut down on "pill mills" dispensing powerful painkillers such as oxycodone. In Florida, hundreds of people have tried to open pharmacies after being barred doctors from dispensing narcotics directly from their homes and forced patients to fill their prescriptions at pharmacies. Some have moved their operations to states with more lenient laws, while others have moved their operations to states with more lenient laws.

"Traffickers adapt to situations," says Mark Trouville, special agent in charge of the Drug Enforcement Administration's field offices in Florida. "We knew once we put pressure on the pill mills, the wrong people would start opening pharmacies."

Florida was the nation's center of prescription-painkiller distribution until the state enacted laws last year aimed at pill mills — clinics where doctors perform cursory examinations on people with dubious injuries and dispense addictive painkillers.

Since then, the number of Florida doctors among the nation's top 100 oxycodone-purchasing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenkevitz says.

Applications for non-chain pharmacies jumped about 80% in 2011 — to 381 — from a typical year before the crackdown, Trouville says.

"Traffickers adapt to situations," says Mark Trouville, Special Agent in charge of the Drug Enforcement Administration's field offices in Florida. "We knew once we put pressure on the pill mills, the wrong people would start opening pharmacies."

with the DEA and be dispense controlled substances. The DEA can deny an application if an applicant has a criminal record or find a connection to a person whose activity poses a health and safety risk.

pharmacy applicants in applications in 2011. They feel the squeeze, he says.

Some pharmacies are able to get prescriptions to people recruited to get prescriptions. "They're not selling aspirin," Trouville says, "they're selling nothing but an empty pillproof window."

Some applicants turned down by the DEA try their luck in Georgia, where Allen, director of the state's Drug and Narcotics Agency,

of new non-chain drugstore applications, about 95% have some connection to Florida, he says.

"The people come completely out of left field without any pharmacy background and open a pharmacy in a sleazy strip mall right down the road from a pain clinic," Allen says. "You do a cursory background on them, and they're living in a doublewide in Pembroke Pines, Fla."

The DEA is working with the state to inspect pharmacies, says Barbara Heath of the DEA's Atlanta field division. She expects problem pharmacies to emerge in North Carolina and Tennessee as they are pushed out of Georgia.



"Year of the Woman"

since

member; Gingrich has fallen by 8.

Gingrich fares less well than Texas Gov. Rick Warren, who trails Obama by 7 points, 51%-44%. Paul, who trails Obama by 7 points, 51%-44%. former Pennsylvania senator Rick Warren, who also trails by 7 points, 51%-44%.

"Gingrich's efforts to win the nomination have set back his effort in the general election," says political scientist James M. Jacobs of the University of Minnesota. He says the appeal to Tea Party conservatives has pushed him out of the mainstream of American politics.

The Swing States survey focuses on the nation's most competitive battleground states: Florida, Iowa, Michigan, Nevada, New Hampshire, New Mexico, North Carolina, Ohio, Pennsylvania, Virginia and Wisconsin.

The findings presumably reflect the impact of attacks on Gingrich's temperament and leadership by Romney and other prominent Tea Party figures from Arizona Sen. John McCain to former majority leader Bob Dole. The poll shows the speaker has drawn fierce fire since he was elected in South Carolina primary on Jan. 21 at the top of national polls.

In Florida, which holds its primary on Tuesday, Romney led Gingrich in a Marist poll Sunday by 15 points, 42%-27%.

Gingrich blamed his fall on Romney and his allies. "His policy of carpet bombing his opponents," he said on *Fox News Sunday*. "It has an impact on Romney, campaigning in Naples, Fla. Gingrich should 'look in the mirror' and see his support has dropped."

Voters in both parties rate Romney higher than Gingrich on a series of positive issues.

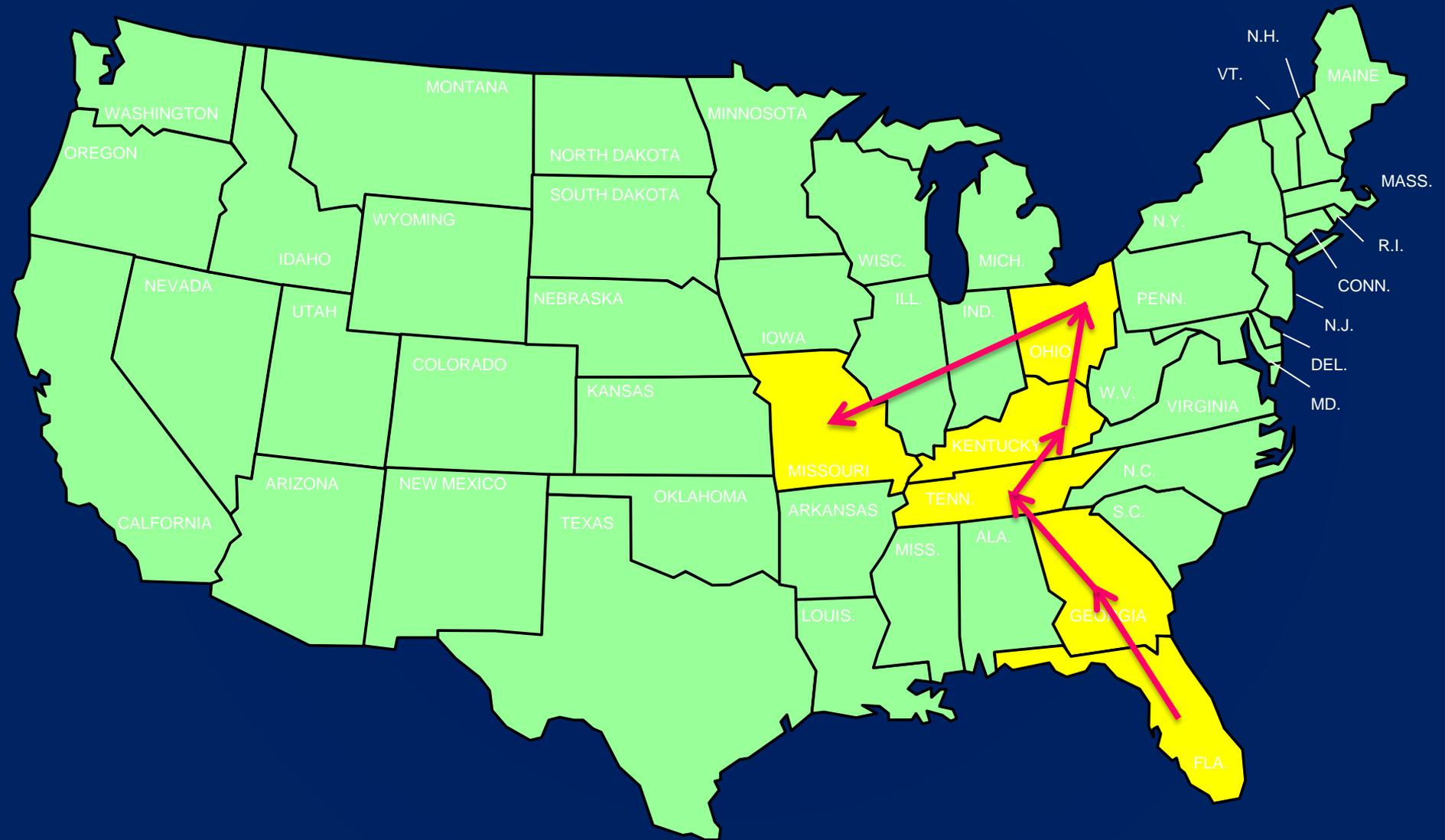
Nearly six in 10 say Romney has better leadership qualities than Gingrich; 42% say Gingrich has those qualities. 42% percent call Romney sincere and a good listener, while 31% say that of Gingrich.

Neither does particularly well on whether they understand the problems Americans face in their daily lives: 44% say they do, while 31% say they do not. The survey that applies to each.

The survey of 737 registered voters was conducted through Saturday has a margin of error of 3 percentage points.



MIGRATION OF PAIN CLINICS





Georgia Example: Traditional Pain Management Clinics

Years prior to 2009-2010: 15-20 legitimate clinics

- Almost all owned by Physicians
- Accept insurance, Medicaid, Medicare, etc.
- Patients need appointments
- Follow pain management guidelines
- Patients get a complete physical workup & exam
- Use physical therapy, other treatment methods
- Prescribed drugs usually include non-narcotics

Now approximately 125 rogue clinics

~110-115

~10-15





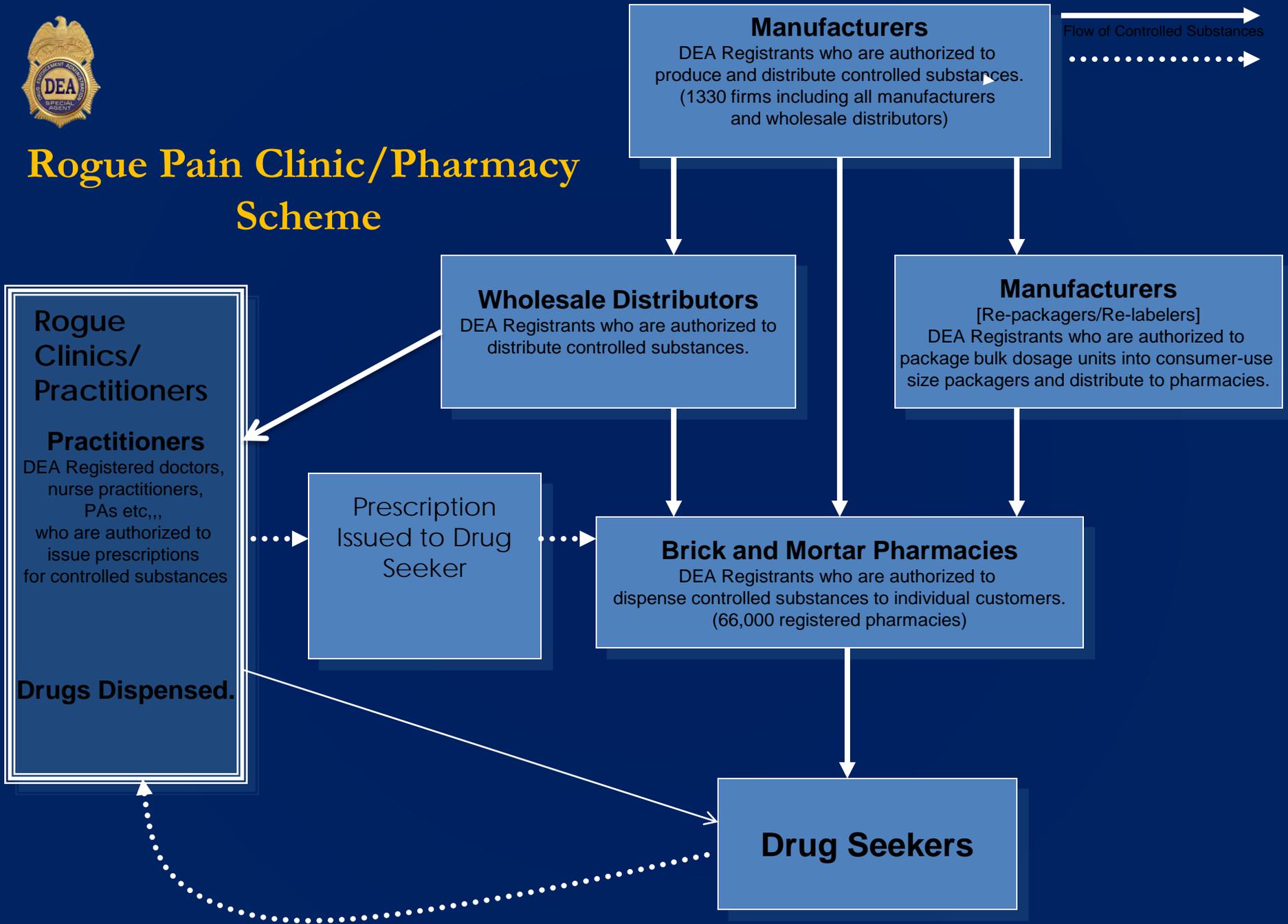
Georgia Pain Pill Clinics

In 2012 – approximately 125 rogue clinics owned by non-physicians, and the owners:

- Are from another state
- Many are convicted felons
- Usually owned or operated a pain clinic in another state.
- Have ties to some type of organized crime
- If from Florida, left not because of the Florida PMP, but due to new Pain Clinic restrictions and no dispensing



Rogue Pain Clinic/Pharmacy Scheme





Cutting off the Source of Supply





First Prong: Increased Enforcement Efforts

- Currently 58 operational Tactical Diversion Squads (TDS) throughout the United States (66 total approved).
- These TDS enforcement groups incorporate the skill sets of DEA Special Agents, Diversion Investigators, other federal law enforcement, and state and local Task Force Officers.



Second Prong: Renewed Focus on Regulatory Oversight

- Increased regulatory efforts throughout the U.S.
(to include increases in frequency of inspections)
- Investigating/Inspecting all new and renewal pharmacy applications submitted in Florida.
- Investigating/Inspecting existing pharmacies registrations



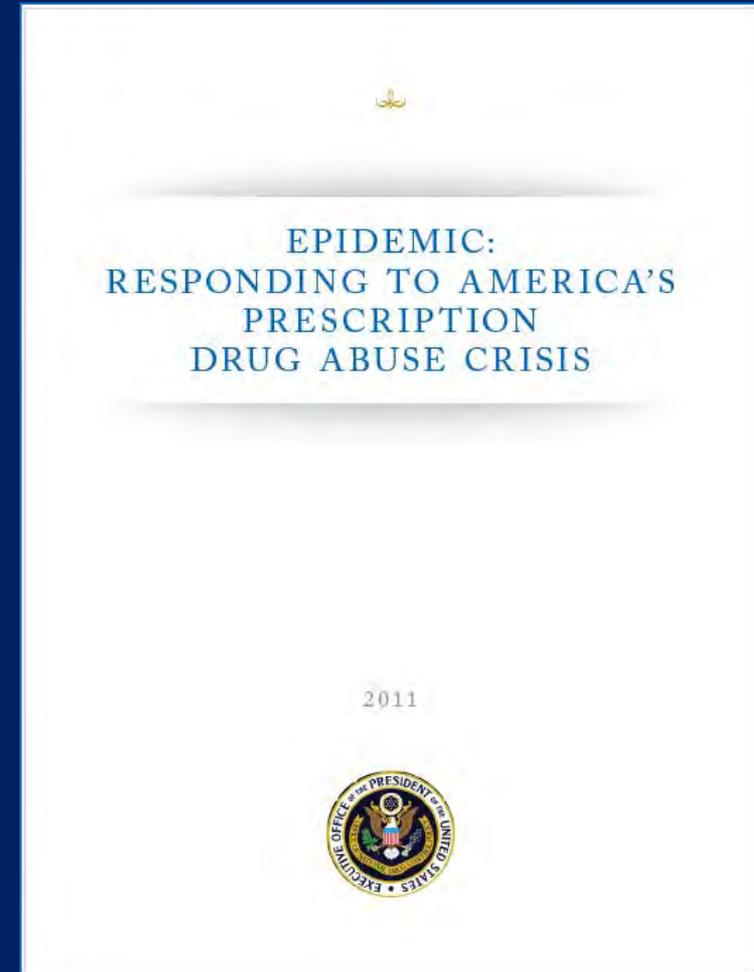
We will not arrest our way out of this problem!!!!!!

- Enforcement is just as important as....
- Prevention/Education
- Treatment



Prescription Drug Abuse Prevention Plan

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





DEA Web-based Resources

Office of Diversion Control

www.deadiversion.usdoj.gov

The screenshot shows the homepage of the DEA Office of Diversion Control. At the top, it features the U.S. Department of Justice Drug Enforcement Administration logo and the text "Office of Diversion Control". Below this, there are several navigation and informational sections:

- Home**: Includes links for Registration, Reporting, Info & Legal Resources, and Inside Diversion Control.
- Got Drugs?**: A section with a "Got Drugs?" banner and a "Disaster Relief" banner.
- What's New**: A list of recent news items, including "Leo A. Ryan, M.D., Doctor and Leader" (May 19, 2015), "A Pharmacy of Controlled Substances" (May 15, 2015), "T.O. RX Pharmacy, Dispenser and Dealer" (May 8, 2015), "U.S. & B. Pharm., Inc." (April 23, 2015), "Allied Amputees, Inc." (April 23, 2015), "DCAS Navajo, LLC" (April 23, 2015), "Realty Trust/Trustee" (April 18, 2015), "Cannabis, Inc." (April 16, 2015), "U.S. Health Care" (April 16, 2015), "Nebraska Data Pharmacist" (April 16, 2015), "Elyria Corporation" (April 16, 2015), "Rhodes, Inc." (April 16, 2015), "American Pharmaceutical Chemicals, Inc." (April 16, 2015), "Mackinac, LLC" (April 16, 2015), "National Center for Medical Products Research, LLC" (April 16, 2015), "In-Home of Controlled Substances" (April 16, 2015), "In-Home of Controlled Substances" (April 16, 2015), "DC-Dev, LLC" (April 16, 2015), "60-Day Notice of Disposition Required" (April 16, 2015), and "Gary Albert Shaver, M.D., Doctor" (April 16, 2015).
- Report Illicit Pharmaceutical Activities**: A prominent section with the phone number 1-877-RX-ABUSE and 1-877-792-2873, accompanied by an image of a pill bottle.
- Registration Support**: A section titled "Registration Number Toll Free: 1-800-882-9539 (8:30 am-6:00 pm EST)" with a "More" link.
- Upcoming Meetings**: A section listing "Pharmacy Diversion Awareness Conference" and "New Jersey and New York Area Regulators".
- Hurricane Sandy**: A section with a message for New Jersey and New York Area Regulators.
- Quick Links**: A list of links including "Home", "About Us", "Registration", "Reporting", "Legal Resources", "FAQ", "Contact Us", "Site Map", and "Search".
- FAQ**: A section titled "FAQ" with a list of questions and answers.



DEA Web-based Resources

www.DEA.gov

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

- Header:** "DEA" in large gold letters, "UNITED STATES Drug Enforcement Administration" in white, and the slogan "TOUGH WORK, VITAL MISSION".
- Navigation Menu:** HOME, ABOUT, CAREERS, OPERATIONS, DRUG INFO, PREVENTION, PRESS ROOM.
- Main Content Area:**
 - Left: "Tough Work, Vital Mission The Facts About DEA" with a blue graphic of a hand holding a pen.
 - Center: A large gold DEA badge.
 - Right: Three resource boxes: "Drug Facts for Today's Teens" (JustThinkTwice.com), "A DEA Resource for Parents" (GetSmartAboutDrugs.com), and "Wall of Honor" (DEA Remembers).
- Bottom Section:** Three columns: "TOP STORY", "TOPICS OF INTEREST", and "RESOURCE CENTER".

TOP STORY

Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy

JAN 29 (BROWNSVILLE, TEXAS)

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

TOPICS OF INTEREST

- DEA Fact Sheet
- Drugs of Abuse: A DEA Resource Guide
- Extension of Temporary Placement of Five Synthetic Cannabinoids
- The DEA Position on Marijuana

RESOURCE CENTER

- Controlled Substances Act
- DEA Museum and Visitors Center
- Doing Business with DEA
- Drug Disposal
- Employee Assistance Program



DEA Web-based Resources

www.JustThinkTwice.com

The screenshot shows the homepage of the Just Think Twice website. At the top, a navigation bar includes links for "HOME" (return home), "DRUG FACTS" (learn the truth), "FACTS & FICTION" (know the difference), "CONSEQUENCES" (life changing events), "TEENS TO TEENS" (sharing our experience), and "INSIDE DEA" (find out more). A search bar is also present. The main content area features a large banner for "THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF" with a photo of a young woman. Below this banner are three buttons for "MARIJUANA", "COCAINE", and "METH". To the right, there are three smaller promotional boxes: "IT'S TIME TO SHATTER THE MYTHS ABOUT DRUGS AND DRUG ABUSE" with a "Learn More" link, "FACTS & FICTION Get the Facts", and "TEENS TO TEENS" with a "READ MORE" link. The footer contains a "Did You Know?" fact about "meth mouth".

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

Parents & Educators | Drug Glossary

SEARCH

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

THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF?

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

[GET THE FACTS ABOUT METHAMPHETAMINE »](#)

MARIJUANA | COCAINE | METH

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

FACTS & FICTION
Get the Facts

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

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



DEA Web-based Resources

www.GetSmartAboutDrugs.com

The screenshot shows the website's layout with a navigation menu and several content sections:

- Navigation:** Home, Identify, Prevent, Help, Hot Topics, DEA in the Community, Communities of Practice, Search.
- Communities of Practice:** A section titled "COMMUNITIES of PRACTICE" featuring a "Train the Trainer" module. Text: "The new Communities of Practice section includes three PowerPoint presentations about drug abuse and awareness and an online Train the Trainer module that provides presenters with techniques to effectively deliver the presentations." Includes a "Learn more" button and "BACK STOP NEXT" navigation.
- DEA Publications:** A section titled "DEA Publications" with the text "Download or request Drugs of Abuse and Prescription for Disaster." and a "READ MORE" button.
- Watch the Videos:** A section titled "Watch the Videos" with the text "View videos to learn how to keep your family safe, including ways to avoid prescription drug abuse." and a "VIEW" button.
- Latest News:** A section titled "Latest News" with a link "See All News Stories".
 - Drug Court Offers Hope for the Future:** "Jan 22, 2013 The Columbia River Partnerships for Change, a nonprofit in Oregon, is seeing tremendous success with its three drug court programs: adult treatment, juvenile treatment, and families restored."
 - ER Visits Tied to Energy Drinks Double Since 2007:** "Jan 16, 2013 Hospitals around the country have seen a gradual uptick in the number of emergency room visits involving energy drinks."
- Voices:** A section titled "Voices" featuring "Irma Perez's Story". Text: "Irma was a 14 year old girl from Belmont, California who took an Ecstasy pill on April 23, 2004. She became sick immediately—vomiting and writhing in pain—yet her friends did not seek medical help for her. Instead, they gave..."
- Inside DEA:** A section titled "Inside DEA" with the text: "The men and women of DEA aren't just drug enforcement agents—we're parents, grandparents, brothers and sisters. We've seen how drugs rob young people of their promise and dreams, and how entire families are affected by a child's drug abuse..."



Thank You / Questions



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



Synthetic Drug Trafficking & Abuse Trends



November 16-17, 2013

Pharmacy Diversion Awareness Conference (PDAC)

Louisville, KY

Alan G. Santos, Associate Deputy Assistant Administrator,
Operations Division, Office of Diversion Control,
U.S. Drug Enforcement Administration



Outline

Designer Synthetic Drugs: Defining What They Are

- Synthetic Cannabinoids
- Synthetic Cathinones
- Other Synthetic Compounds

Scope of the Problem

- Global Overview of Threat
- U.S. Overview & Experience

Control Efforts: Using All the “Tools Available

- State
- Federal
- International



Designer Drugs: A Tough Problem

Targeting emerging psychoactive designer synthetic drugs [i.e. synthetic cannabinoids (the synthetic marijuana compounds), synthetic cathinones (the synthetic stimulants), and other emerging synthetic compounds] is a priority for DEA.

But it's a tough public health & safety challenge!



Designer Synthetic Drugs: Defining What They Are

*U.S. Drug Enforcement Administration / Operations
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Designer Drugs Purported as “Legal” Highs

Designer Drugs have rapidly emerged as “legal” alternatives to internationally controlled drugs (such as marijuana, cocaine, methamphetamine, & MDMA) causing similar effects, with the potential to pose serious risks to public health and safety.



Where did they come from ?

A highly regarded Medicinal Chemist Dr. F. Ivy Carroll and colleagues stated in a recent publication:

Throughout the drug discovery process, pharmaceutical companies, academic institutions, research institutions, and other organizations publish their studies in scientific journals, books, and patents. This information exchange, which is essential to the legitimate scientific enterprise, can be, and is, used by clandestine chemists who duplicate the technical sophistication used by the research community to manufacture and market a seemingly endless variety of analogs of so-called designer drugs.



Where did they come from ?

- Substances rejected due to poor therapeutic potential
- Scientific literature excavated to identify substances
- No industrial or medical use for these substances
- Often characterized as being “research compounds” (the only research being undertaken is to determine their abuse potential for sale to consumer market)





Proliferation of Designer Drugs

- Increasingly popular among recreational drug users
- Internet sales
- Head shops/Smoke shops
- Promoted by discussion boards – self studies



**Armed with medical research and fueled by Chinese factories
And YouTube, a band of outlaws has
Created a dangerous multibillion-dollar industry**



Synthetic Cannabinoids

*U.S. Drug Enforcement Administration / Operations
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Synthetic Cannabinoids

- A “cannabinoid” is a class of chemical compounds in the marijuana plant that are structurally related.
- “Synthetic cannabinoids” are a large family of chemically unrelated structures functionally (biologically) similar to THC, the active principle of marijuana.
- They may have less, equivalent or more pharmacologic (psychoactive) activity than THC.



Synthetic Cannabinoids

- Synthetic Cannabinoids are sold in retail stores, on the internet, and in “head shops” as “Herbal Incense” or “Potpourri”
- Smoked alone or as a component of herbal products
- Abusers report a potent cannabis-like effect





Adverse Health Effects

Multiple deaths have been connected to the abuse of these substances alone and with other substances on-board.

Psychological	Anxiety, aggressive behavior, agitation, confusion, dysphoria, paranoia, agitation, irritation, panic attacks, intense hallucinations
Neurological	Seizures, loss of consciousness
Cardiovascular	Tachycardia, hypertension, chest pain, cardiac ischemia
Metabolic	Hypokalemia, hyperglycemia
Gastrointestinal	Nausea, vomiting
Autonomic	Fever, mydriasis
Other	Conjunctivitis



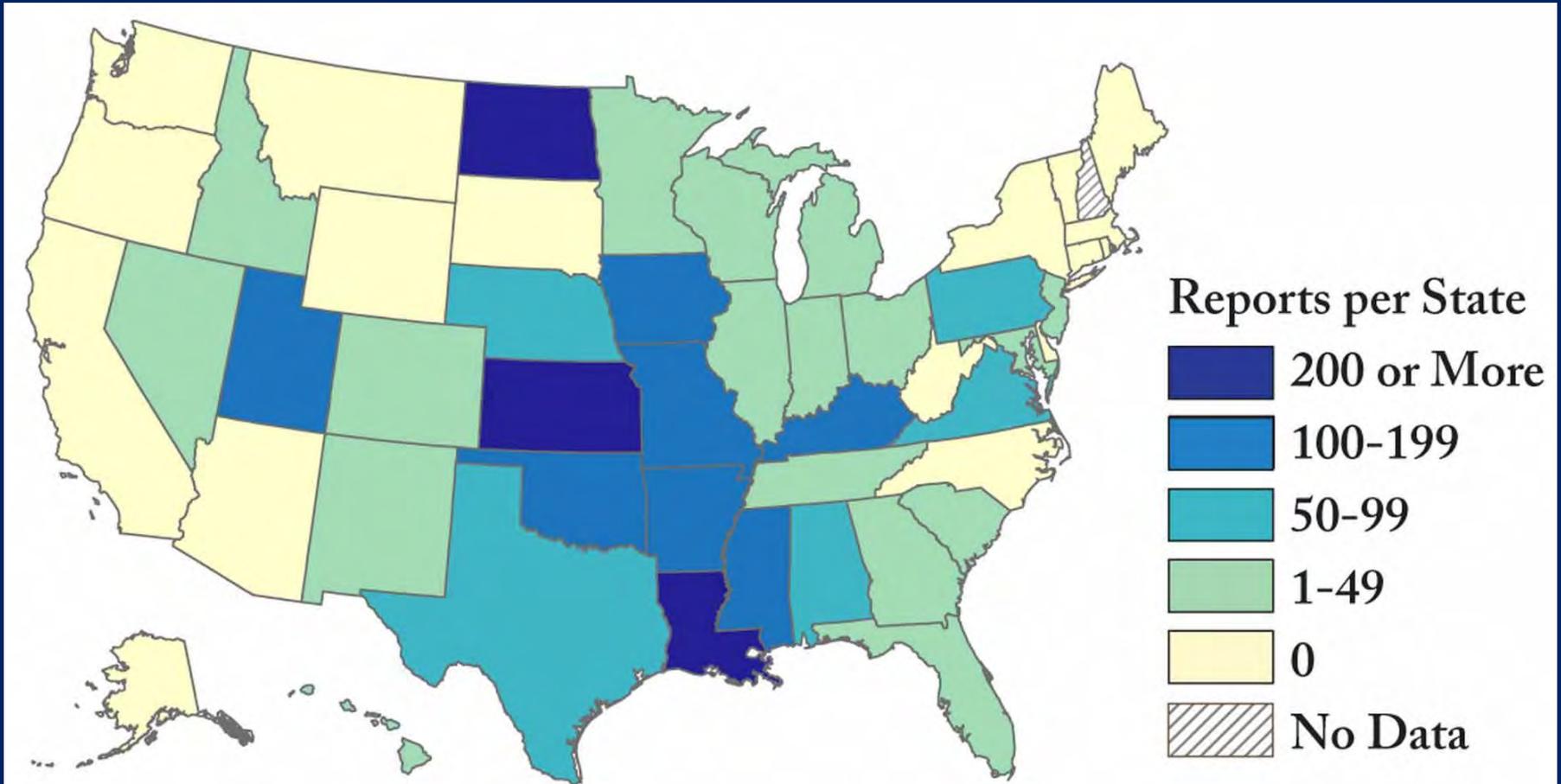
Synthetic Cannabinoids

- Unregulated and unlicensed industry (many manufacturers)
- Full disclosure of ingredients typically not present
- Batch to batch variance (i.e., “Hot Spots”)



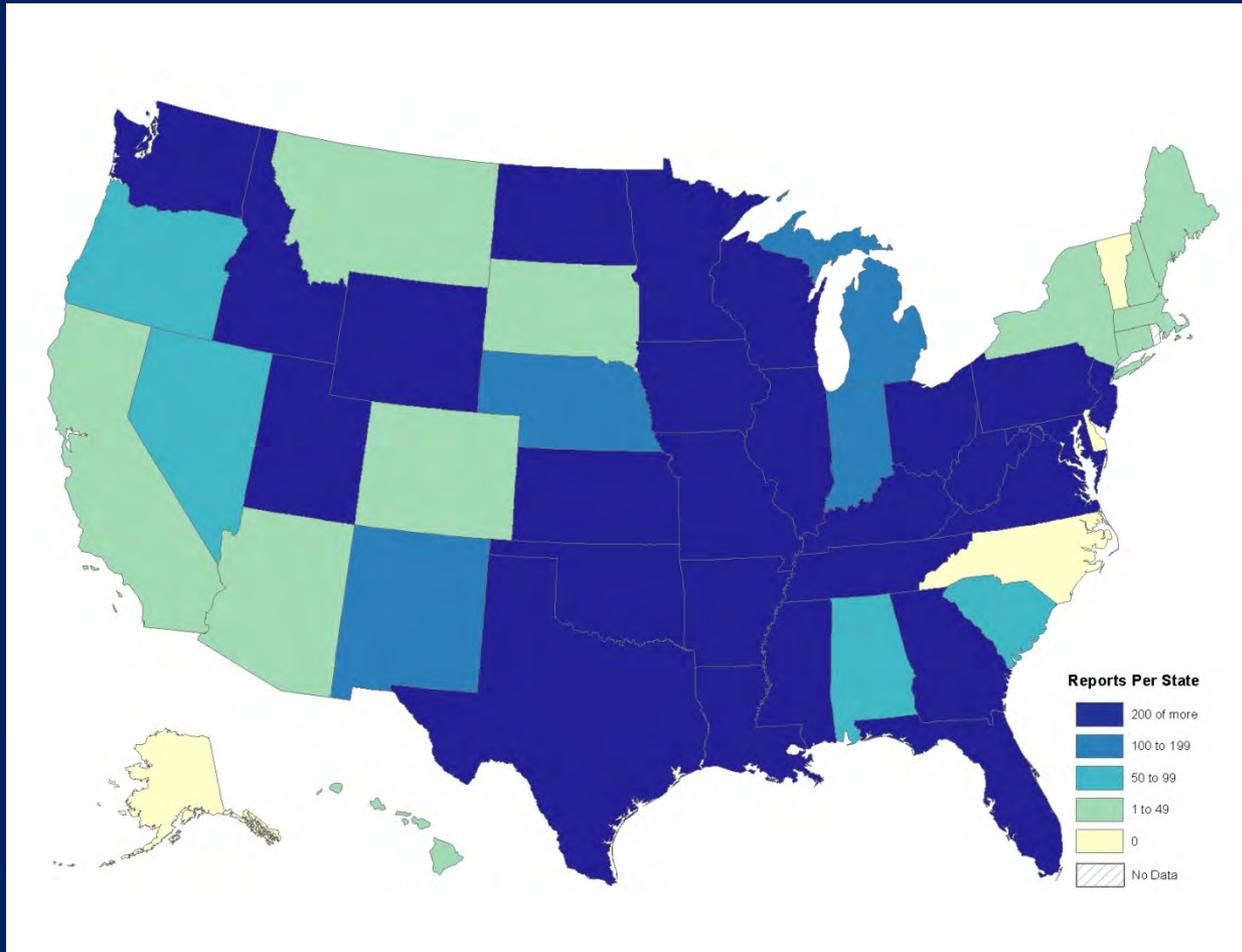


Synthetic Cannabinoids, by State, 2010



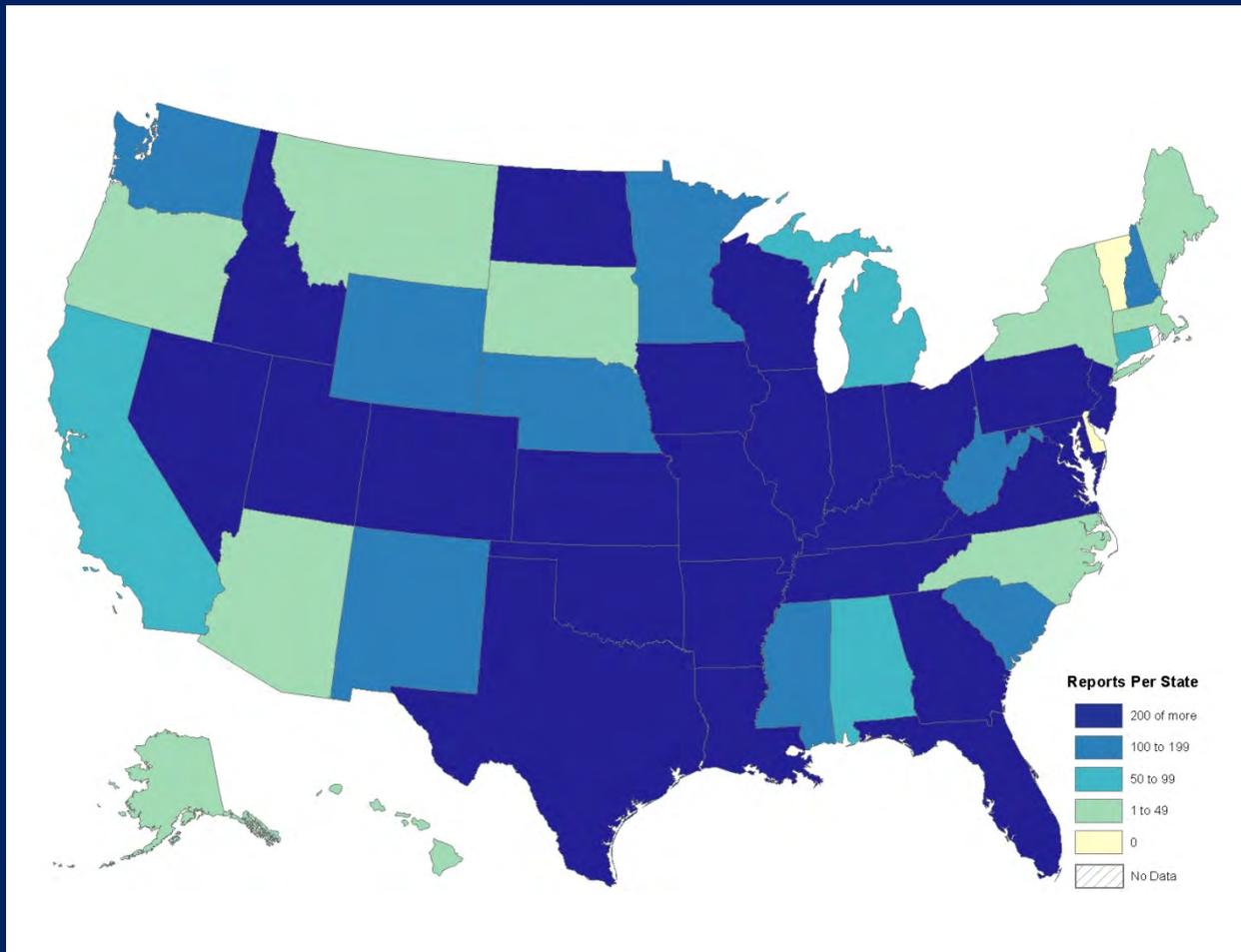


Synthetic Cannabinoids, by State, 2011





Synthetic Cannabinoids, by State, 2012





Synthetic Cathinones

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Synthetic Cathinones

- Structurally and pharmacologically similar to amphetamine, Ecstasy (MDMA), cathinone, and other related substances.
- Are central nervous system (CNS) stimulants and have stimulant and psychoactive properties similar to schedule I and II amphetamine type stimulants.
- Synthetic cathinones are sold in retail stores, on the internet, and in “head shops” as “bath salts”, “plant food”, or “jewelry cleaner”



Adverse Health Effects

Synthetic cathinone users commonly report cardiac, psychiatric, and neurological signs and symptoms with death.



Cardiovascular	palpitations, tachycardia, chest pain, vasoconstriction, myocardial infarction
Psychological	Aggressive behavior, anger, anxiety, agitation, auditory and visual hallucinations, depression, dysphoria, empathy, euphoria, fatigue, formication, increased energy, concentration, panic attacks, paranoia, perceptual disorders, restlessness, self-mutilation, suicidal ideation
Neurological	Seizures, tremor, dizziness, memory loss, cerebral edema, headache, lightheadedness
Musculoskeletal	Arthralgia, extremity changes (coldness, discoloration, numbness, tingling), muscular tension, cramping
Gastrointestinal	Abdominal pain, anorexia, nausea, vomiting
Pulmonary	Shortness of breath
Ear Nose Throat	Dry mouth, nasal pain, tinnitus



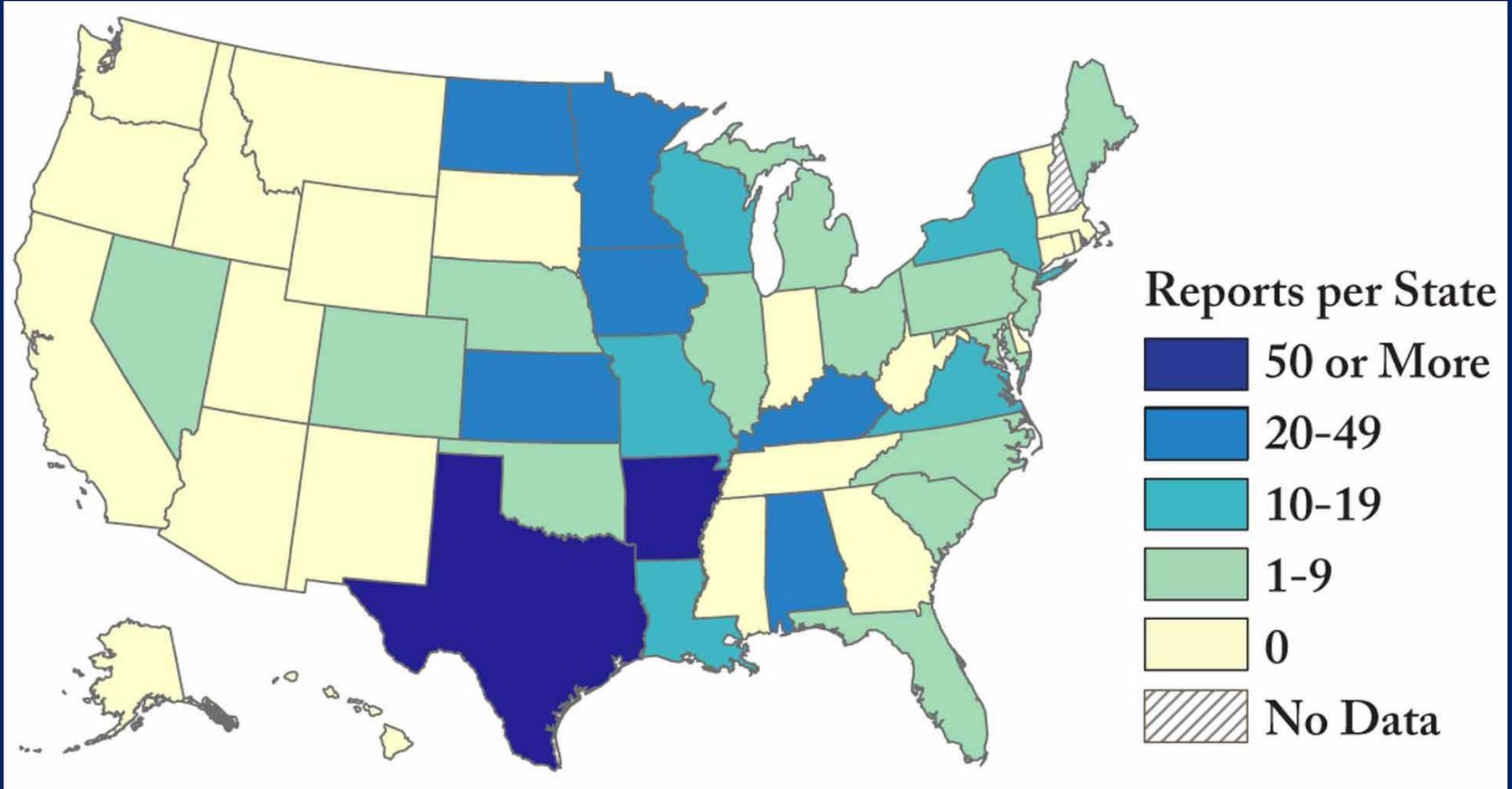
Synthetic Cathinones

- Like the cannabinoids, unregulated and unlicensed industry (many manufacturers)
- Full disclosure of ingredients typically not present
- Significant batch to batch variances (i.e., “Hot Spots”)



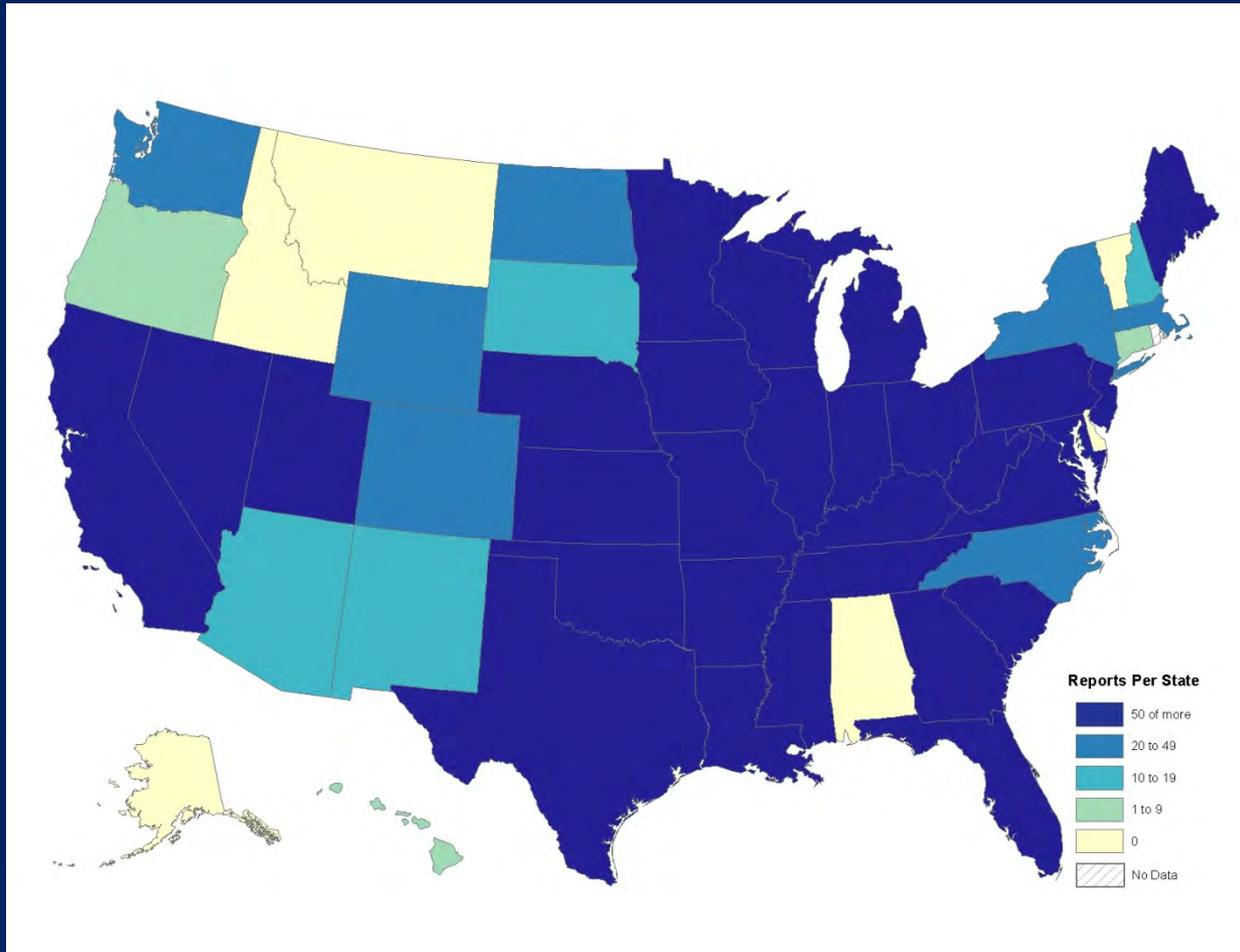


Synthetic Cathinones, by State, 2010



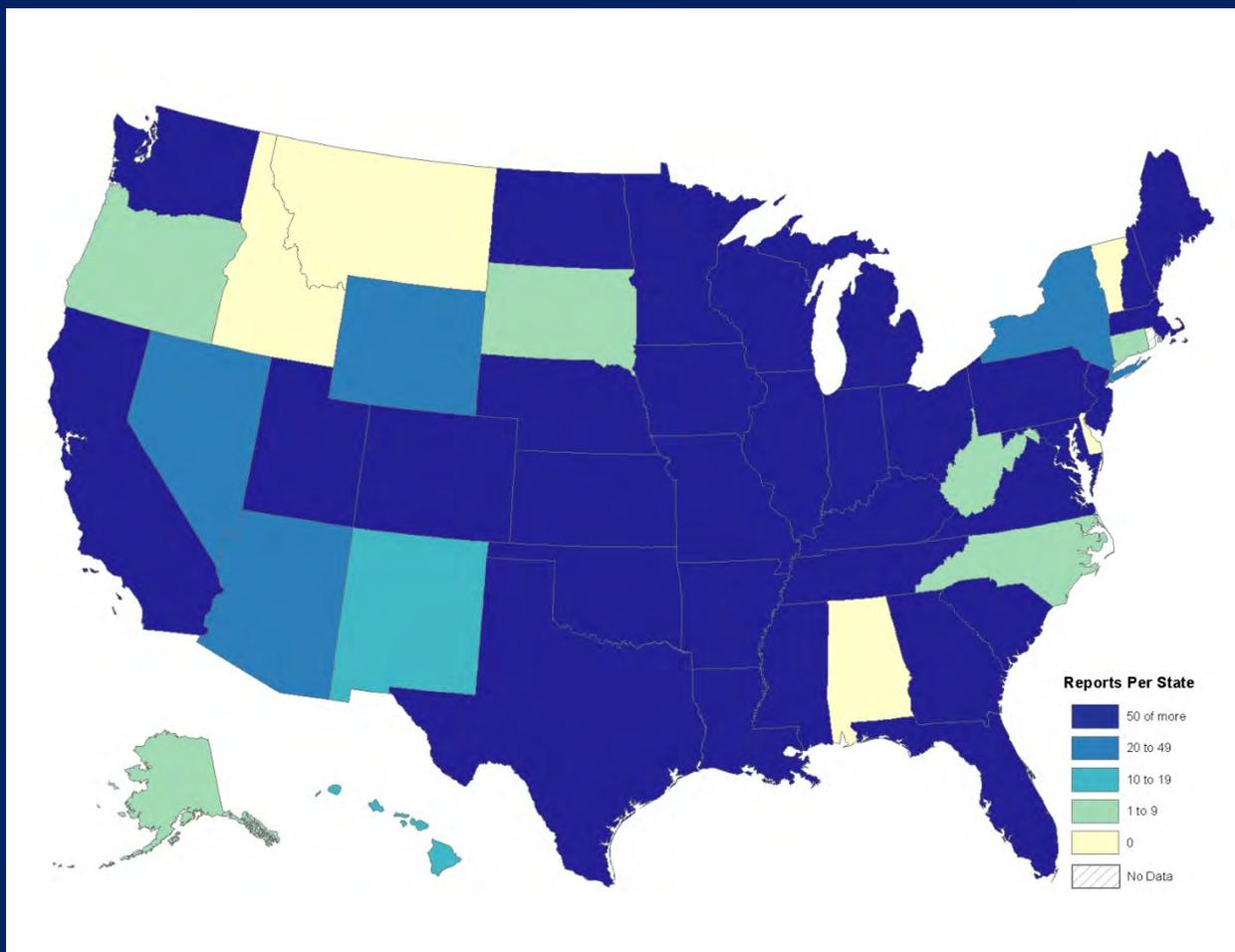


Synthetic Cathinones, by State, 2011





Synthetic Cathinones, by State, 2012





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Dance drug molly now linked to **FOURTH** overdose as police fear killer tainted batch has spread throughout East Coast

- Mary 'Shelley' Goldsmith, 19, died August 31 at one of Washington, DC's largest nightclubs
- While toxicology results are pending, the honors student's father admits Shelley was likely on 'molly,' a term for MDMA or ecstasy
- Olivia Rotondo, 20, and Jeffrey Russ, 23, died at New York City's Electric Zoo dance party after taking the drug
- Brittany Flannigan, 19, from New Hampshire, died August 28 after apparently overdosing on MDMA at a Boston concert

Site Web

TO ENJOY FREE TIME?

GLACIER EXPRESS

BOOK NOW

Switzerland. RAIL EUROPE
by train, bus and boat.

The advertisement features a red and white train crossing a bridge over a valley. The text 'GLACIER EXPRESS' is written in large, bold letters across the train. Below the train, there is a 'BOOK NOW' button. At the bottom, the RailEurope logo is displayed, including the Swiss flag and the text 'Switzerland. by train, bus and boat. RAIL EUROPE'.



What is “Molly”?

- “Molly” – a synthetic designer drug
 - Originally - a street name for pure MDMA (Ecstasy)
 - Currently - a street name for a drug, that has the same effects as MDMA





Other Synthetic Compounds

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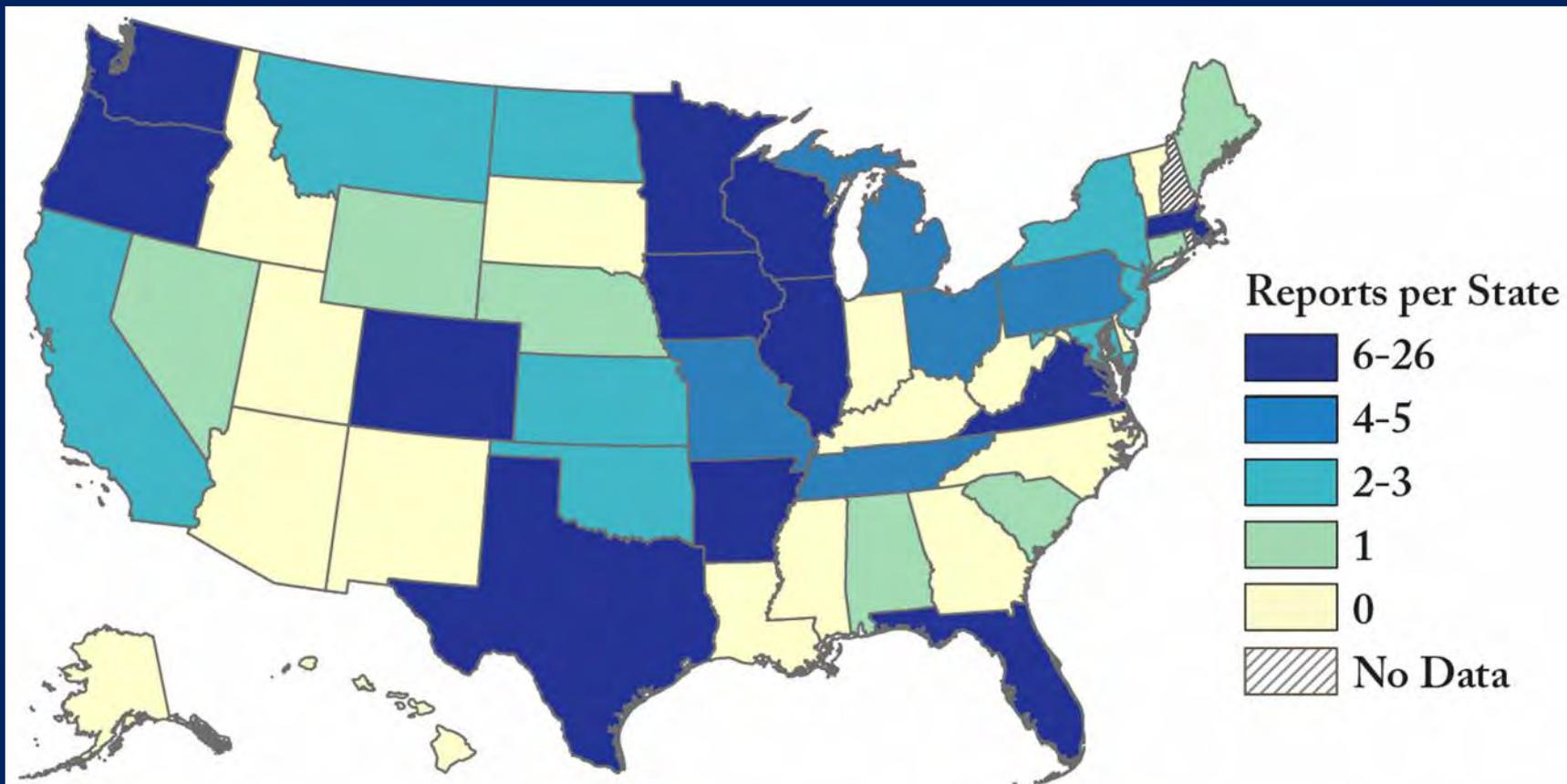
Phenethylamines

- Are a class of substances with documented psychoactive and stimulant effects / Includes the '2C series' compounds / Abused orally and encountered on "blotter paper" and in "dropper bottles" / Possibly mistaken for LSD / Linked to deaths



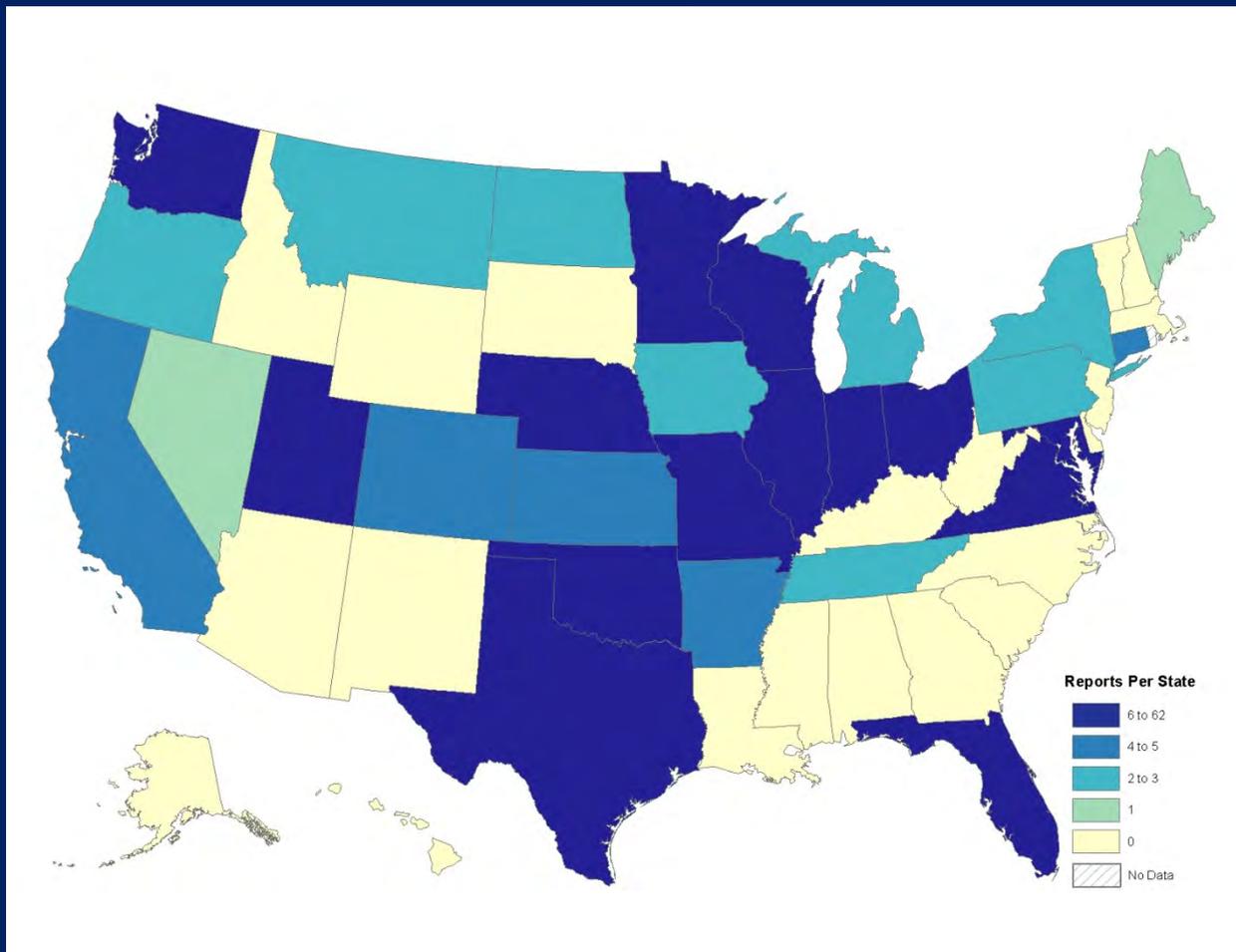


2C-Phenethylamine Reports, by State, 2010



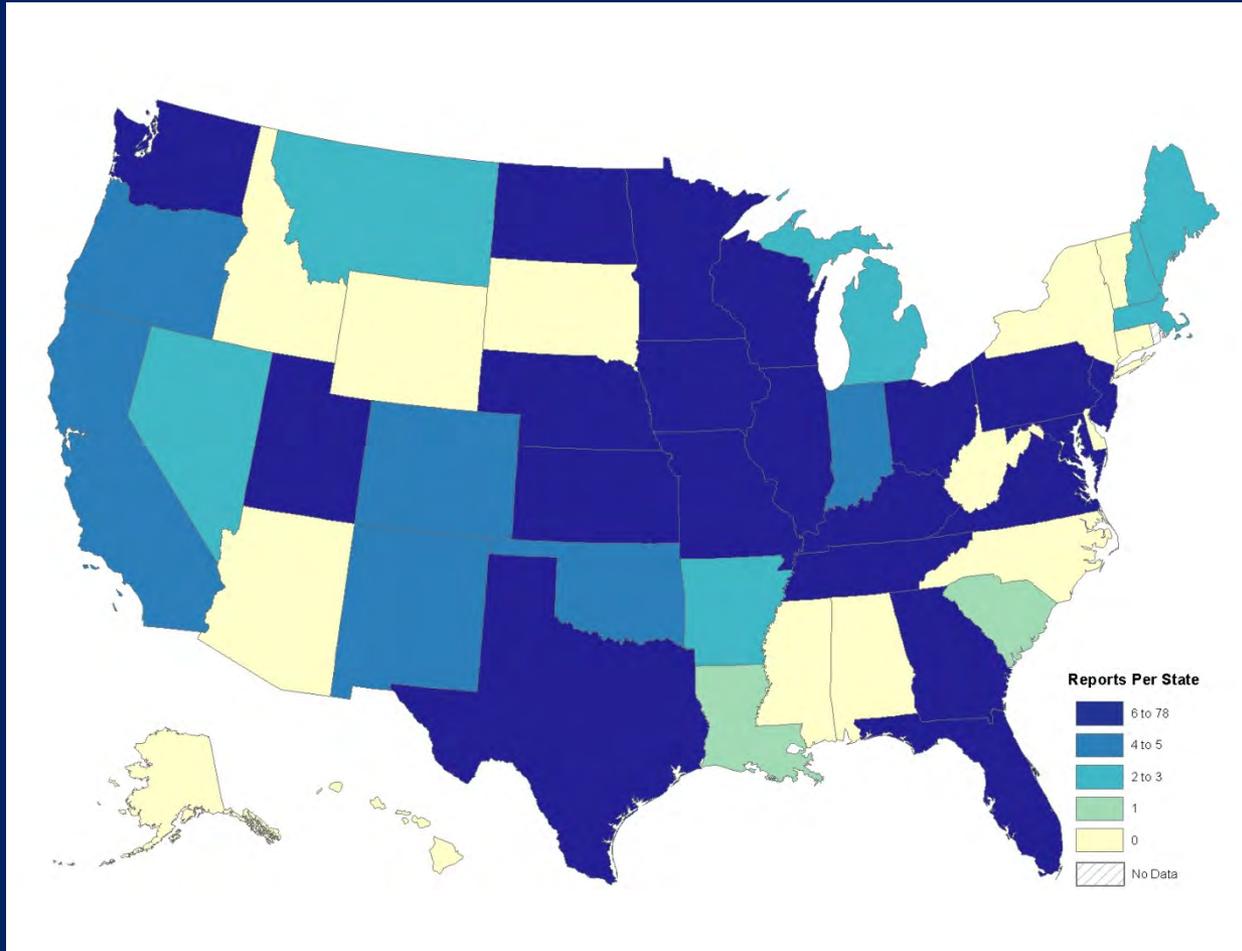


2C-Phenethylamine Reports, by State, 2011





2C-Phenethylamine Reports, by State, 2012





Piperizines

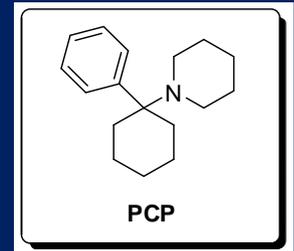
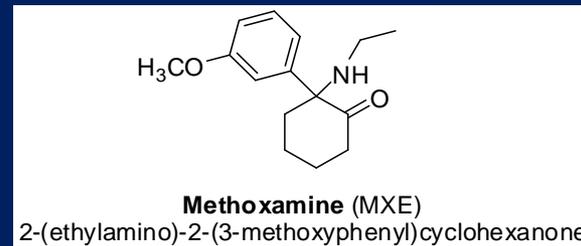
- Have hallucinogenic properties as well as often being referred to as amphetamine-like / Tableted and frequently sold as 'ecstasy' (BZP-TFMPP combination abused to mimic the effects)





Methoxamine (MXE)

- Dissociative (mind altering effects) and depression of pain
- Effects similar to PCP
- Encountered on designer drug market
- International increase in ketamine abuse
- Deaths attributed to the substance



CBP Photo



Problems with All Synthetic / Designer Drugs

- Marketed to teens and young adults
- Easily attainable in retail environments and via the internet
- Unknown ingredient(s)
- No consistency in manufacturing process
- Not tested for human consumption / Unknown short & long term effects!!
- No known dosage – not FDA approved
- Synergistic effects likely when mixed with other drugs or alcohol





Scope of the Problem

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Global Overview of the Threat

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A global problem
that constitutes a
significant public
health threat
to many nations !!!



UNODC

United Nations Office on Drugs and Crime

**The challenge of
new psychoactive substances**



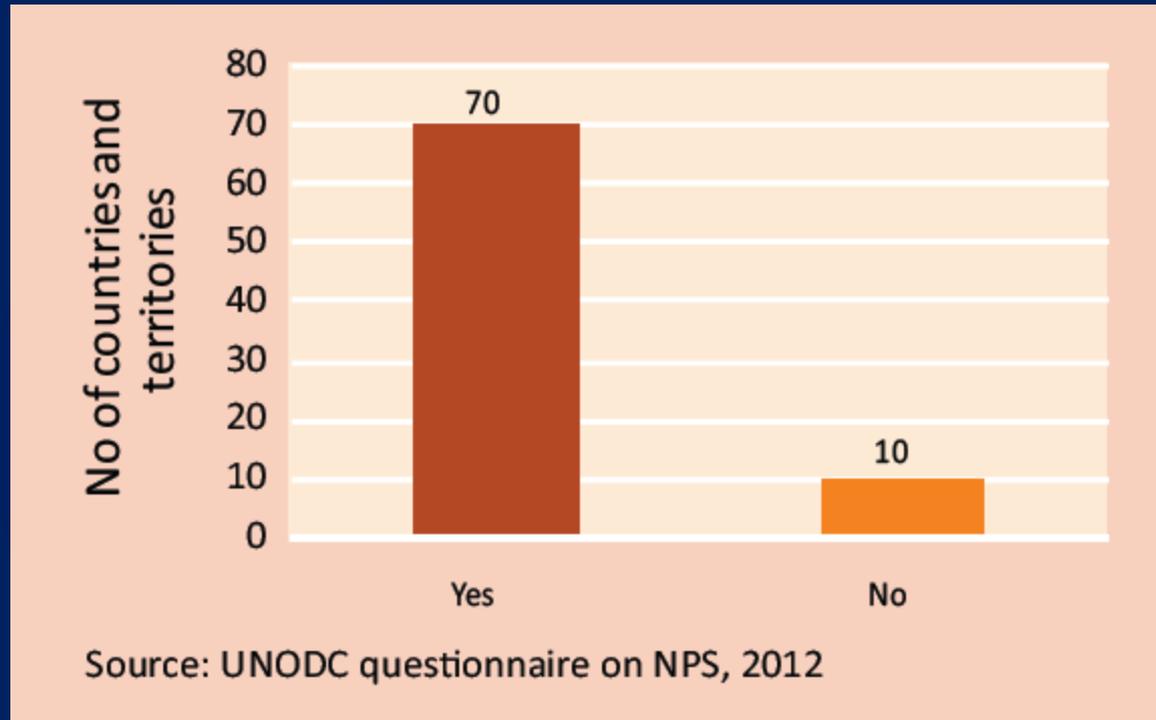
Global SMART Programme

2013

*U.S. Drug Enforcement Administration / Operations
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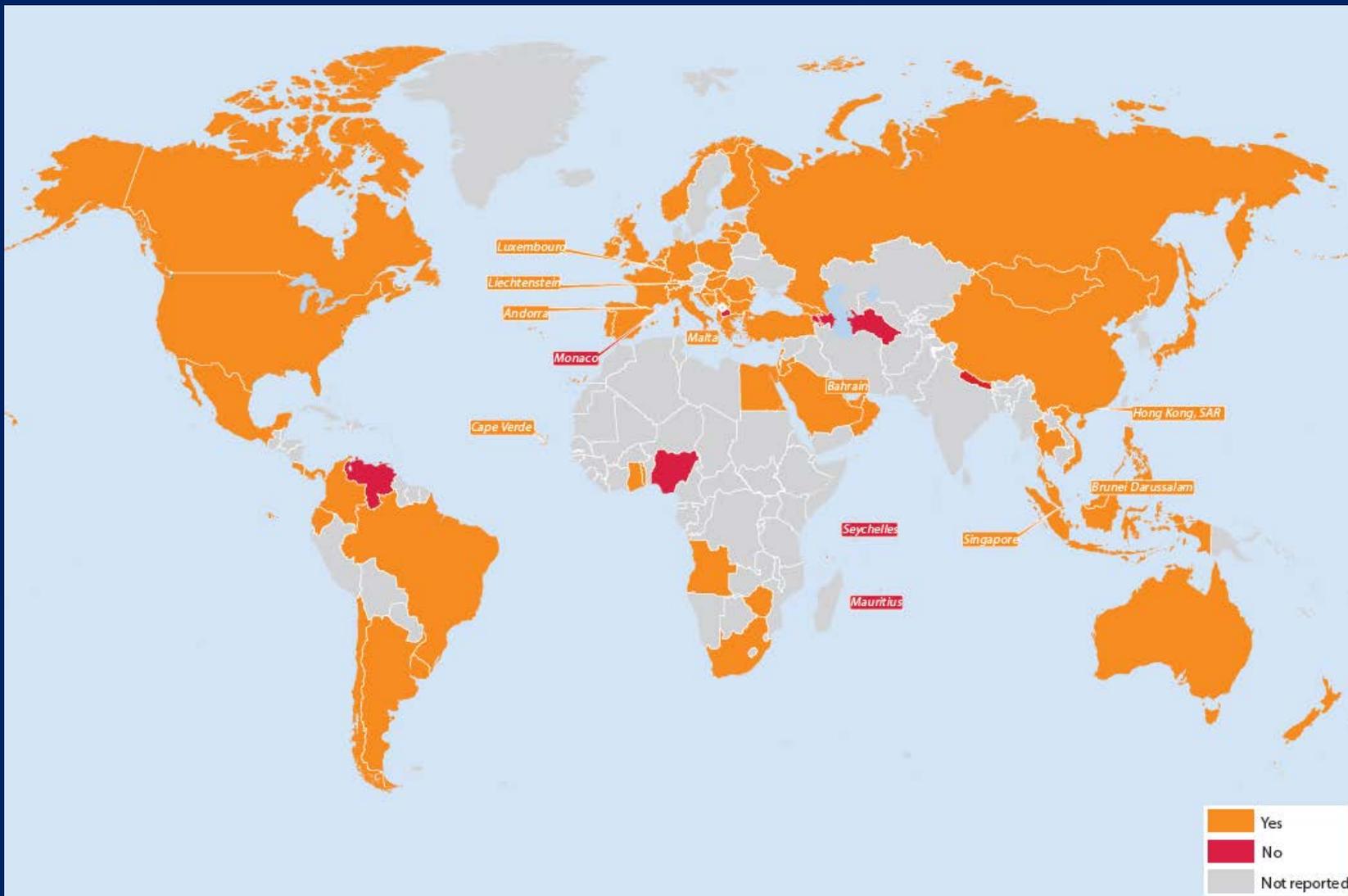
Global Synthetic Drug Use



Of the nations surveyed, 87 % (70 out of 80) indicate that NPS are available in their respective drug markets.

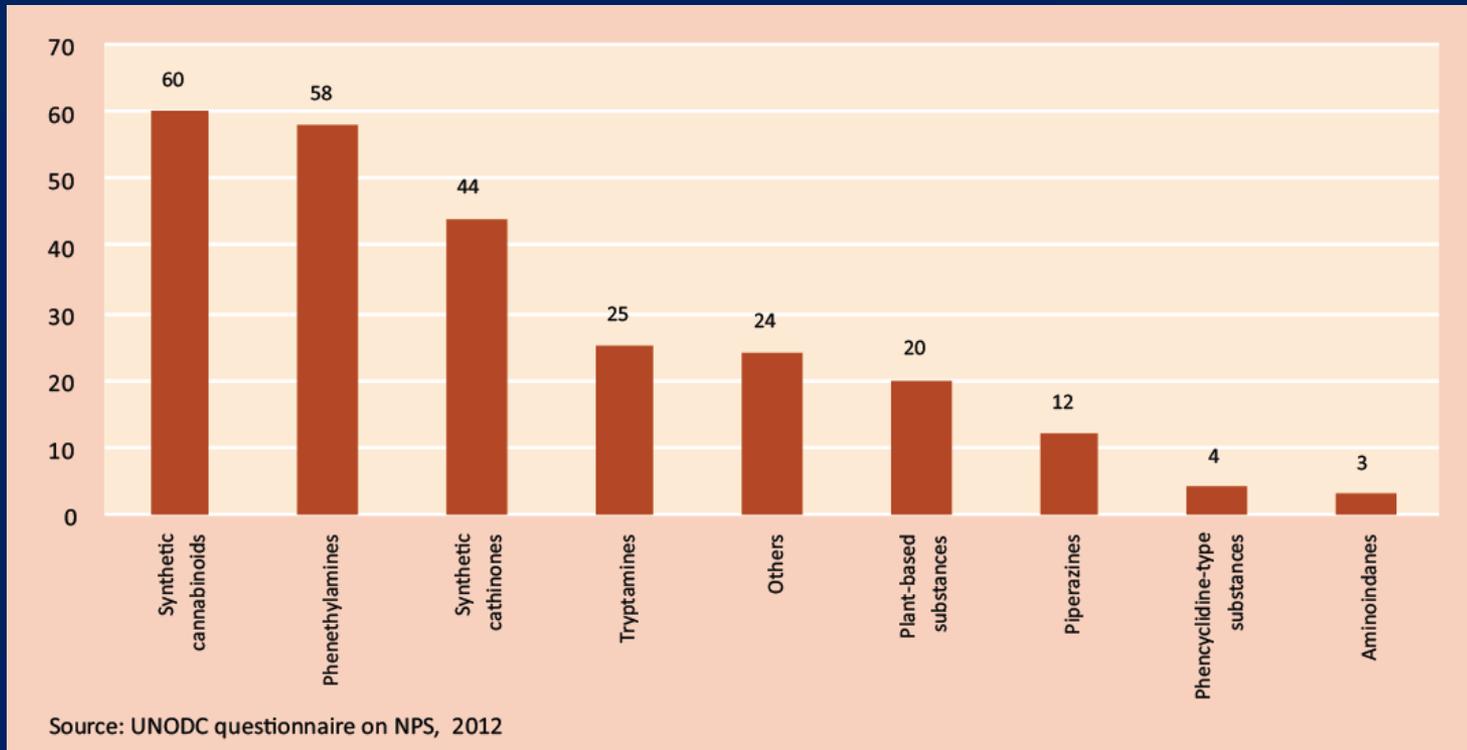


Global Synthetic Drug Use





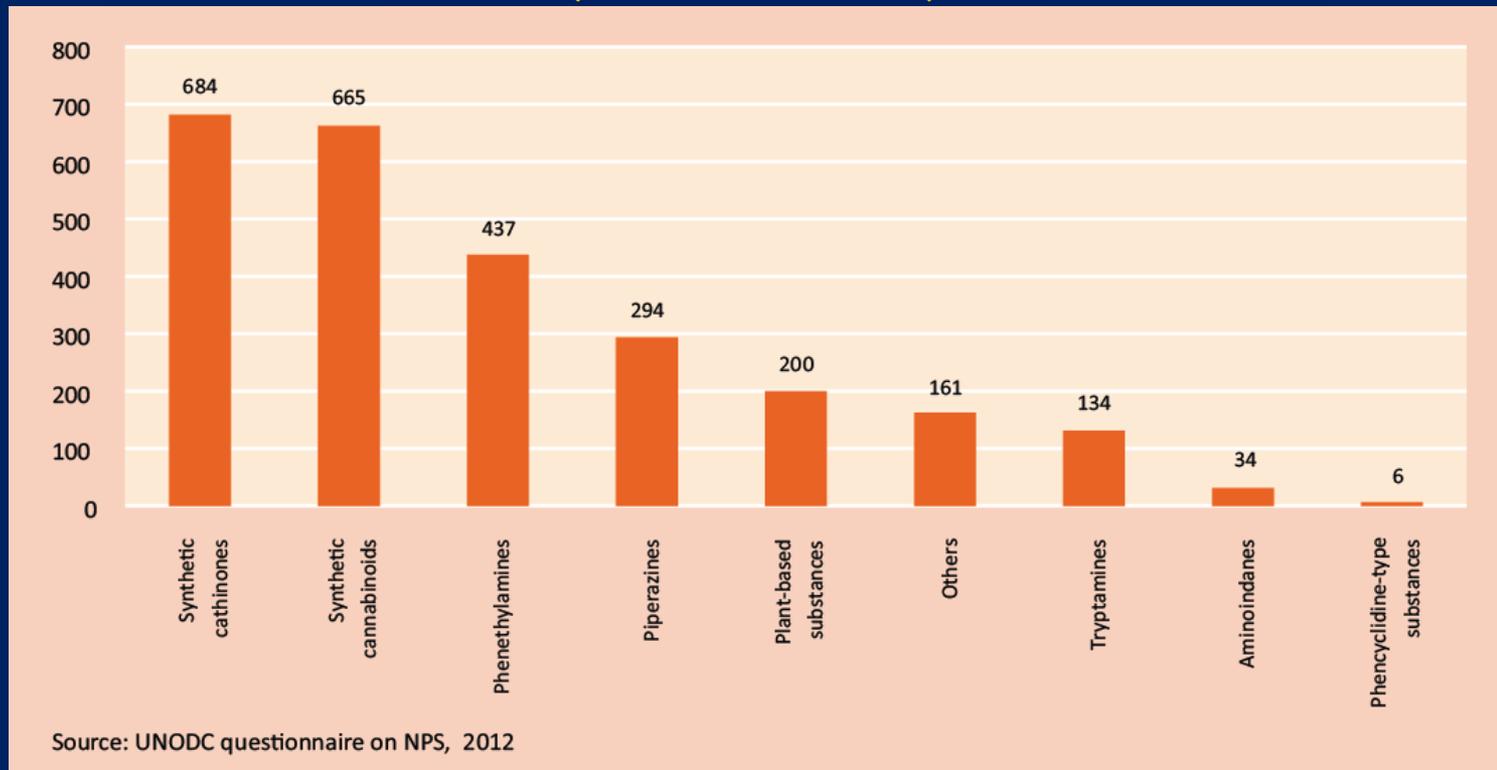
Number of NPS on Global Markets (2009-2012)



A total of 251 NPS (including ketamine) were reported to UNODC by 40 countries and territories up to 2012.



Number of NPS in Global Markets (2009-2012)



At the global level, most reports pertaining to NPS concern synthetic cathinones, with 684 reports, followed by synthetic cannabinoids with 665 reports



Trend of NPS Seizures (2009 – 2012)

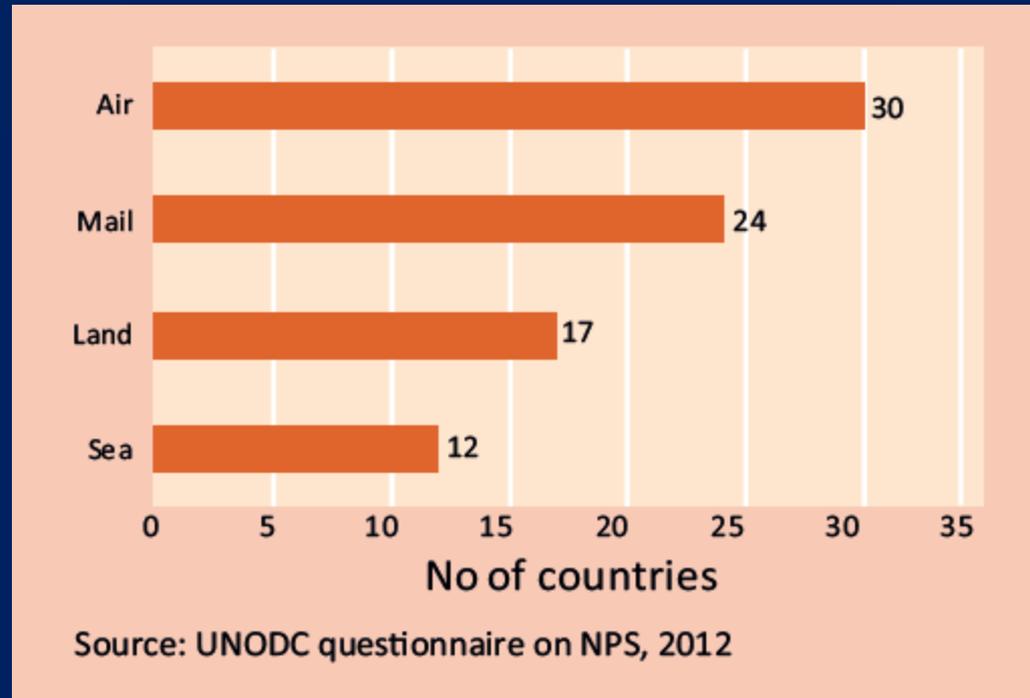
NPS group	2009	2010	2011	2012
Synthetic cannabinoids	↑	↑	↑	↑
Synthetic cathinones	↑	↑	↑	↔
Ketamine	↔	↔	↔	↔
Phenethylamines	↔	↑	↔	↔
Piperazines	↑	↔	↔	↓
Plant-based substances	↑	↑	↑	↔
Miscellaneous	-	↑	↑	↑

↑= Increasing, ↓= Decreasing, ↔ =Stable, - unknown
Source: UNODC questionnaire on NPS, 2012 and ARQ

Trends for the seven NPS groups fluctuate.
Seizures of ketamine, phenethylamines and piperazines stable
Rising trends for synthetic cannabinoids, cathinones,
and plant-based substances



NPS Trafficking Modes



The mode of trafficking named by most respondents was trafficking by air (30 countries) followed by trafficking by mail (24 countries), without any regional variations.

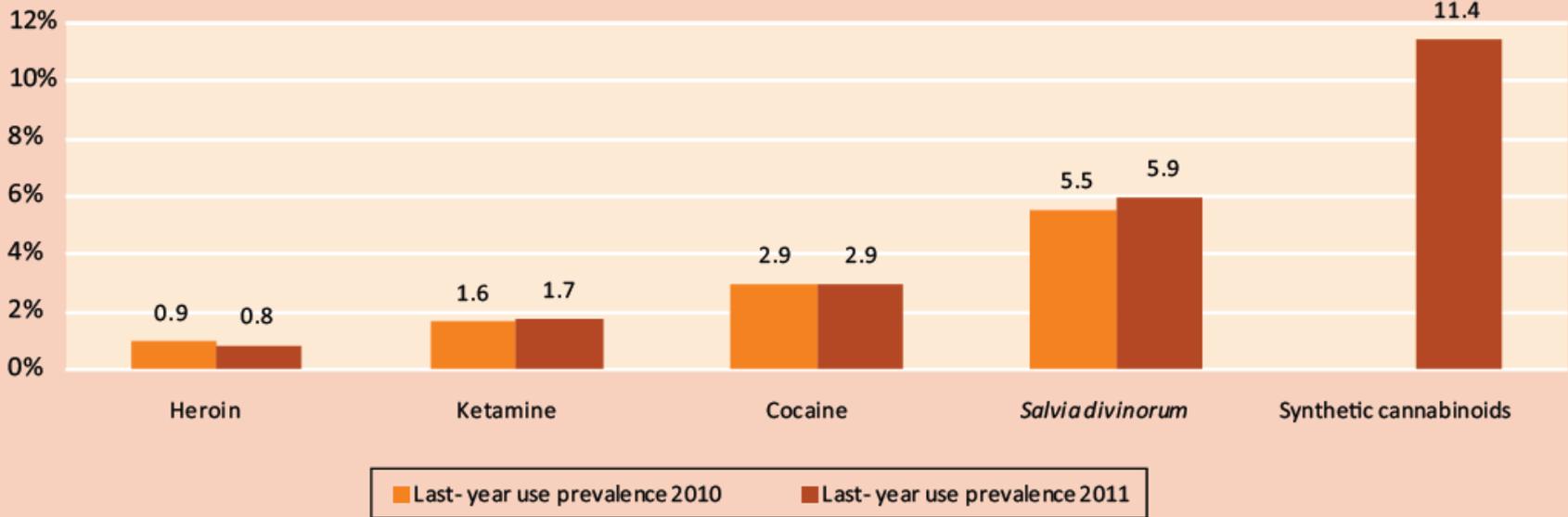


U. S. Overview & Experience

*U.S. Drug Enforcement Administration / Operations
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United States: Prevalence of Drug and NPS Use Among 12th Graders (2010 – 2011)



Source: data from the MTF Survey 2010-2011

Base: 12th graders %

Question on synthetic cannabinoids was introduced in 2011 for the first time



Identified Synthetic Compounds in the U.S.

As of October 15, 2013, the U.S. has encountered:

- 99 synthetic cannabinoids
- 52 synthetic cathinones
- 89 other compounds (2C compounds, tryptamines, piperazines, etc.)

240 Compounds and Counting !!!!



‘Spice’ makers alter recipes to sidestep state laws banning synthetic marijuana



Rob Ostermaier/Daily Press - Police show what they suspect is "spice," confiscated during a raid on Outer Edge Gifts in Hampton, Va., on April 5.

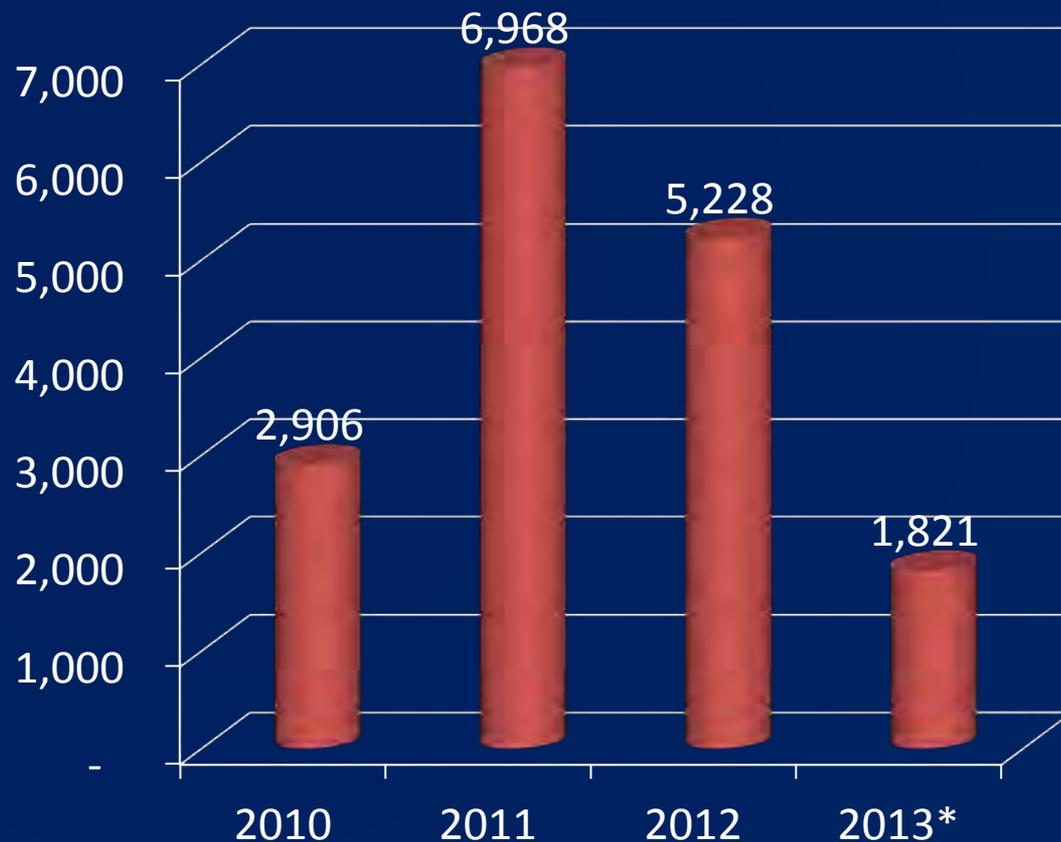


Calls to U.S. Poison Control Centers

American Association of
Poison Control Centers
(AAPCC) Reporting

Calls to poison control
centers for exposures to
synthetic marijuana
(synthetic cannabinoids)

Synthetic Cannabinoids





Calls to U.S. Poison Control Centers

American Association of
Poison Control Centers
(AAPCC) Reporting

Calls to poison control
centers for exposures to
bath salts (synthetic
cathinones)

Synthetic Cathinones





Public Safety Concerns

- Driving Under the Influence of Drugs (DUIDs) with fatalities
- Suicides
- Homicide-Suicide
- Overdoses
 - Emergency Department visits
 - First Responders
- Drugs abused to evade drug screens
 - 30-35% of juveniles in drug court tested positive
 - Individuals subjected to routine drug screens
 - Probationer / parolees



First Responder Encounters

- Altered mental status presents as severe panic attacks, agitation, paranoia, hallucinations, and violent behavior (e.g., self-mutilation, suicide attempts, and homicidal activity). (Spiller *et al.*, *Clinical Toxicology* 2011)
 - climbing into the attic of the home with a gun to kill demons that were hiding
 - breaking all the windows in a house and wandering barefoot through the broken glass
 - jumping out of a window to flee from non-existent pursuers; requiring electrical shock (Taser) and eight responders to initially subdue the patient
 - repeatedly firing guns out of the house windows at “strangers” who were not there

- Bath salts use tied to three Bangor (Maine) deaths. (Richter, *JEMS* 2012)

- Bath salt abuse: new designer drug keeps EMS crews busy nationwide. (Nevin, *JEMS* 2011)



First Responders (Cont.)

Drug Endangered Children:

- Leaving a **2-year-old daughter** in the middle of a highway because she had demons (Spiller *et al.*, *Clinical Toxicology* 2011)
- A drug-intoxicated couple hallucinated they were being burglarized, began shooting into walls. Officers found weapons in every room, and a paranoid parent huddled inside the bathroom with **two young children** and a loaded .357 Magnum (Macher, *American Jails* 2011)
- Northeast PA, couple charged with multiple offenses for stabbing at “90-people living in their walls” with **5-year old present** (*Times-Leader.com*, Mar 21, 2011)



Synthetic Drug “Manufacturing Facility”?



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*U.S. Drug Enforcement Administration / Operations
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Ready to Ship...





Control Efforts: Using all the “Tools” Available



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Synthetic Drugs: U.S. State Controls

- 
- A light blue outline map of the United States is centered on the slide, showing the borders of all 50 states and the District of Columbia. The map is semi-transparent, allowing the text to be visible through it.
- Legislation
 - Department of Health
 - Pharmacy Board
 - Consumer Affairs Dept.



U.S. Federal Scheduling & Rescheduling Procedures

Placement of a substance into one of the U.S. Federal Controlled Substance Act (CSA) schedules can be done by statute or through the administrative process.

- **Statute:** Congress may designate a substance a controlled substance or reschedule a drug within the scheduling hierarchy by passing legislation. This, by far, is the easiest method in which to add, remove or transfer a substance between schedules.
- **Administrative Process:** The Attorney General, by rule, (using his administrative authority) to add, remove or transfer a substance between schedules. **The legal definition of control, “...means to add a drug or other substance, or immediate precursor, to a schedule...whether by transfer of another schedule or otherwise”. 21 USC 802(5)**



Federal Temporary Scheduling

- Because of the lack of effective legislative controls to combat the synthetic problem early on, federally we looked to temporary scheduling as a solution
- Requires an AG finding (delegated down to DEA) that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety
- ...and the substance is not listed in any other schedule in Section 21 USC 812 or no exemption or approval is in effect under the FDCA



Federal Temporary Scheduling (Comprehensive Crime Control Act of 1984)

As set forth under 21 U.S.C 811(h), three factors (4, 5 &6) under the CSA (21 U.S.C. 811(c)) are to be considered in the evaluation

1. Its actual or relative potential for abuse
2. Scientific evidence of its pharmacological effects
3. The state of current scientific knowledge regarding the 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 the public health
7. Its psychic or physiological dependence liability
8. Whether the substance is an immediate precursor of a substance already controlled



Federal Temporary Scheduling Process

- DEA collects information from law enforcement and public health officials regarding encounters and evaluates this information relative to the three factors required for temporary scheduling.
- Once sufficient information has been collected, a letter is transmitted from DEA to the U.S. Department of Health & Human Services (DHHS) to communicate intention to temporary schedule [and to verify no active new drug applications (NDAs) or investigations drug applications (INDs) for the proposed substances filed].



Federal Temporary Scheduling Process

- DEA letter of intent to DHHS, solicits a comment to control these substances within 30 days. Based on the DHHS response, a “Notice of Intent” can be published in the U.S. Federal Register with a “Final Order” published at minimum 30-days after the “Notice of Intent”.
- As there is no “comment period” provided for temporary scheduling, civil and criminal sanctions applicable to the manufacture, possession, importation, and exportation are effective upon publication of the “Final Order”.



U.S. Federal Temporary Scheduling Actions to Date Relative to Synthetic Drugs

21858

Federal Register / Vol. 78, No. 71 / Friday, April 12, 2013 / Proposed Rules

Issued in Washington, DC, on April 4, 2013.

Gary A. Noenk,

Manager, Airspace Policy and ATC

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IFR Doc. 2013-08546 (Filed 4-11-13; 8:45 am)

BILING CODE 4010-13-D

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-373]

Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cannabinoids into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice of Intent.

SUMMARY: The Deputy Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of intent to temporarily schedule three synthetic cannabinoids into the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(b). The substances are 1-pentyl-1H-indol-3-yl(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), 1-(5-fluoro-pentyl)-1H-indol-3-yl(2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11) and N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (APINACA, AKB48). This action is based on a finding by the Deputy Administrator that the placement of these synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Any final order will be published in the Federal Register and may not be issued prior to May 13, 2013. Any final order will impose the administrative, civil, and criminal sanctions and regulatory controls of Schedule I substances under the CSA on the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152, telephone (202) 307-7165.

SUPPLEMENTARY INFORMATION:

Background

Section 201 of the CSA (21 U.S.C. 811) provides the Attorney General with

the authority to temporarily place a substance into Schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(h)(1), the Attorney General may extend the temporary scheduling up to one year.

When the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no exemption or approval in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) for the substance. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of DEA, who in turn has delegated her authority to the Deputy Administrator of DEA, 28 CFR 0.100, Appendix to Subpart E.

Section 201(b)(4) of the CSA (21 U.S.C. 811(b)(4)) requires the Deputy Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into Schedule I of the CSA.¹ The Deputy Administrator has transmitted notice of his intent to place UR-144, XLR11, and AKB48 in Schedule I on a temporary basis to the Assistant Secretary by letter dated February 14, 2013. The Assistant Secretary responded to this notice by letter dated March 14, 2013 (received by DEA on March 21, 2013), and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for UR-144, XLR11, or AKB48. The Assistant Secretary also stated that HHS has no objection to the temporary placement of UR-144, XLR11 or AKB48 into Schedule I of the CSA. DEA has taken into consideration the Assistant Secretary's comments. As UR-144, XLR11, and AKB48 are not currently listed in any schedule under the CSA, and as no exemptions or approvals are in effect for UR-144,

XLR11, and AKB48 under Section 505 of the FD&C Act (21 U.S.C. 355), DEA believes that the conditions of 21 U.S.C. 811(b)(1) have been satisfied. Any additional comments submitted by the Assistant Secretary in response to this notification shall also be taken into consideration before a final order is published. 21 U.S.C. 811(h)(1).

To make a finding that placing a substance temporarily into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Deputy Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA (21 U.S.C. 811(c)). These factors are as follows: the substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(c)(4)-(6). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(b)(3).

A substance meeting the statutory requirements for temporary scheduling (21 U.S.C. 811(b)(1)) may only be placed in Schedule I. Substances in Schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States (U.S.), and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for UR-144, XLR11, and AKB48 indicate that these three synthetic cannabinoids have a high potential for abuse, no currently accepted medical use in treatment in the U.S., and a lack of accepted safety for use under medical supervision.

Synthetic Cannabinoids

While synthetic cannabinoids have been developed over the last 30 years for research purposes to investigate the cannabinoid system, no scientific literature referring to UR-144, XLR11 or AKB48 was available prior to these drug identification in the illicit market. In addition, no legitimate non-research uses have been identified for these synthetic cannabinoids nor have they been approved by FDA for human consumption. These synthetic cannabinoids, of which 1-pentyl-1H-indol-3-yl(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144), 1-(5-fluoro-pentyl)-1H-indol-3-yl(2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144; XLR11), and N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (APINACA, AKB48) are representative, are so termed for their Δ^9 -tetrahydrocannabinol (THC)-like

¹ Because the Secretary of the Department of Health and Human Services (HHS) has delegated to the Assistant Secretary for Health the Department of Health and Human Services the authority to make domestic drug scheduling recommendations, for purposes of this Notice of Intent, all subsequent references to "Secretary" have been replaced with "Assistant Secretary." As set forth in a memorandum of understanding entered into by HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the Controlled Substances Act (CSA), with the concurrence of NIDA. 50 FR 9638.

1-pentyl-3-(2,2,3,3-tetramethylcyclopropyl)indole (UR-144), 1-(5-fluoro-pentyl)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; XLR11) and N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (APINACA, AKB48)

Background Information and Evaluation of 'Three Factor Analysis' (Factors 4, 5 and 6) for Temporary Scheduling

Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537

April 2013

Introduction

Since 2009, there has been a marked increase in the law enforcement encounters of various synthetic cannabinoids in the United States. Both law enforcement and public health reports suggest the sustained popularity of these substances in the designer drug market, most commonly abused as plant material adulterants. These associated products are often being sold as incense and labeled 'not for human consumption'. Additionally, these products are marketed as a 'legal high' or 'legal alternative to marijuana' and are readily available over the internet, in head shops, or sold in convenience stores.

These substances have no accepted medical use in the United States and have been reported to produce adverse effects in humans. Chronic abuse of synthetic cannabinoids in general has been linked to adverse health effects including signs of addiction and withdrawal (Zimmermann et al., 2009; Muller et al., 2010), as well as numerous reports of emergency room admissions resulting from their abuse (Forrester et al., 2011; Hermanns-Clausen et al., 2012; SAMHSA, 2012).

1-pentyl-3-(2,2,3,3-tetramethylcyclopropyl)indole (UR-144), 1-(5-fluoro-pentyl)-3-(2,2,3,3-tetramethylcyclopropyl)indole (5-fluoro-UR-144; XLR11) and N-(1-adamantyl)-1-pentyl-1H-indazole-3-carboxamide (APINACA, AKB48) are synthetic cannabinoids (Figure 1) and are pharmacologically similar to the Schedule I hallucinogen delta-9-tetrahydrocannabinol (Δ^9 -THC). UR-144 was first developed as a research tool by Abbott laboratories (Frost et al., 2010). XLR11 and AKB48 were not designed as research tools, however began showing up in seizures as early as 2009. From January 2009 through April 03, 2013 according to the System to Retrieve Information on Drug



U.S. Federal Temporary Scheduling Actions Relative to Synthetic Drugs

To date, 8 Synthetic Cannabinoids, 3 Synthetic Cathinone, and 3 Phenethylamine Compounds have been controlled or in the process of being controlled

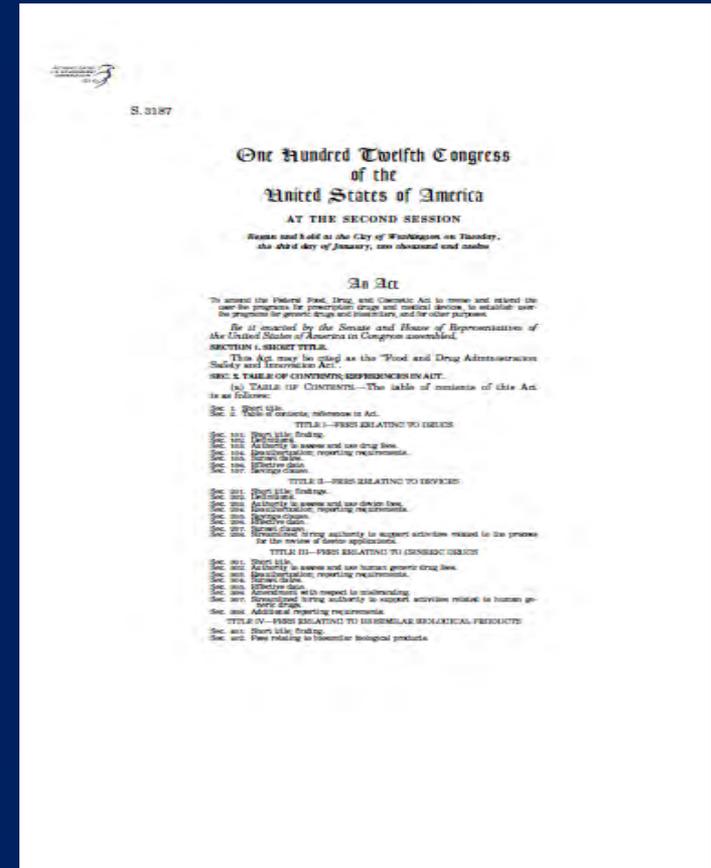
- 5 Cannabinoid Compounds (March 2011 Final Order)
- 3 Cathinone Compounds (October 2011 Final Order)
- 3 Cannabinoid Compounds (May 2013 Final Order)
- 3 Phenethylamine Compounds [i.e. “NBOMe” products (October 2013 Notice of Intent)]



U.S. Synthetic Drug Abuse Prevention Act of 2012

On July 9, 2012, the President signed the Synthetic Drug Abuse Prevention Act of 2012 (Public Law 112-144)

➤ The law controlled 26 compounds into schedule I





U.S. Synthetic Drug Abuse Prevention Act of 2012

- Defined the term “Cannabimimetic Agent” [any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist].
- Extends the maximum time that DEA may temporarily control a substance.
- Initial time period for temporary scheduling increased from 12 to 24 months / Extension period increased from 6 months to 12 months.



U.S. Synthetic Drug Abuse and Prevention Act 2012

Cannabinoids

- | | |
|--------------------------------|-------------|
| 1) AM2201 | 8) JWH-200 |
| 2) AM694 | 9) JWH-019 |
| 3) CP-47,497 | 10) JWH-250 |
| 4) CP-47,497 –
C8 homologue | 11) JWH-122 |
| 5) JWH-018 | 12) JWH-203 |
| 6) JWH-073 | 13) JWH-398 |
| 7) JWH-081 | 14) SR-19 |
| | 15) SR-18 |

Cathinones

- 1) Mephedrone
- 2) MDPV

Phenethylamines

- 1) 2C-E
- 2) 2C-D
- 3) 2C-C
- 4) 2C-I
- 5) 2C-T-2
- 6) 2C-T-4
- 7) 2C-H
- 8) 2C-N
- 9) 2C-P



The Way Forward on the International Front

- Working to identify major foreign based sources
- Working to sensitize partner nations regarding the threat and the need for international controls
- Continue to work bilaterally and with international partners to look at coordinating global outreach and cooperation



The Way Forward on the International Front / CND Resolutions

Enhancing International Cooperation in the Identification & Reporting of NPS (E/CN.7/2013/L.2/ March 2013)

United Nations E/CN.7/2013/L.2/Rev.1
 **Economic and Social Council** Distr.: Limited
14 March 2013
Original: English

Commission on Narcotic Drugs
Fifty-sixth session
Vienna, 11-15 March 2013
Agenda item 4
Implementation of the international drug control treaties

Australia, Croatia, El Salvador, Finland, Hungary, Israel, Japan, Mexico, New Zealand, Peru, Russian Federation, Thailand, Turkey, Ukraine, United Kingdom of Great Britain and Northern Ireland and United States of America: revised draft resolution

Enhancing international cooperation in the identification and reporting of new psychoactive substances

The Commission on Narcotic Drugs,

Recalling its resolution 48/1 of 11 March 2005, on promoting the sharing of information on emerging trends in the abuse of and trafficking in substances not controlled under the international drug control conventions,

Recalling also its resolution 53/11 of 12 March 2010, on promoting the sharing of information on the potential abuse of and trafficking in synthetic cannabinoid receptor agonists,

Recalling further its resolution 53/13 of 12 March 2010 on the use of "poppers" as an emerging trend in drug abuse in some regions,

Recalling its resolution 55/1 of 16 March 2012, on promoting international cooperation in responding to the challenges posed by new psychoactive substances,

Reiterating its concern at the number of potentially dangerous new psychoactive substances that continue to be marketed as legal alternatives to internationally controlled drugs, circumventing existing controls,

Concerned that emerging new psychoactive substances may have effects similar to those of internationally controlled drugs and may pose risks to public health and safety, and noting the need for additional data on the effects of these substances to be collected and shared.

V.13-81852 (E)





The Way Forward on the International Front / CND Resolutions

Major Tenants of Resolution:

- *Encourages* nations to take a comprehensive and coordinated approach to the detection, analysis, and identification of NPS
- *Urges* nations to share with one another information on the identification of NPS using, where appropriate, existing national and regional early warning systems and networks
- *Urges* nations to include information on the potential adverse impacts and risks to public health and safety of new psychoactive substances through prevention & awareness to counter public perceptions on NPS



The Way Forward on the International Front / CND Resolutions

Major Tenants of Resolution (Continued):

- *Encourages* nations, and relevant international institutions, to share and exchange ideas, best practices, and experiences regarding new laws, regulations and restrictions, to attack the NPS issue
- *Urges* the UNODC to continue to develop a voluntary electronic portal for national forensic and/or drug testing laboratories to enable timely and comprehensive sharing of information on NPS (an early warning system)



Thank You

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