



DEA Trends & Update

Charleston Pharmacy Diversion Awareness Conference



February 27 & 28, 2016



The United States Department of Justice
Drug Enforcement Administration



Ruth A. Carter, Chief
Liaison & Policy Section
Office of Diversion Control



Disclosure Statement

I have no financial relationships to disclose



Goals and Objectives

- Public Health Epidemic
- Impact on Society
- Drugs of Abuse
- Criminal Activity
- The Controlled Substances Act: Checks & Balances
- Legal obligations: DEA registrant
- The DEA Response
- Miscellaneous Pharmacy Topics
- DEA Web-Based Resources



Public Health Epidemic



Ex-Pratt Mayor Gary Fields Pleads Guilty To Drug Charge

BY JEFFREY A. MORRIS | THURSDAY, SEPTEMBER 24TH 2015



CHARLESTON, W.Va. - Former Pratt Mayor Gary Fields admitted to selling the powerful prescription painkiller oxycodone.



Beckley caregiver accused of stealing prescription medications

Recommend
2.4K

50

By Paul Hess, WVVA Internet Director
Posted: Jan 29, 2016 1:13 PM EST

CONNECT



Michelle Ann Redden

BECKLEY, WV (WVVA) - Police in Raleigh County arrest a woman for allegedly stealing prescription drugs from elderly patient.

Michelle Redden is charged with four counts of obtaining a controlled substance by fraud. She is currently being held in Southern Regional Jail on \$25,000 bond.

Police say Redden worked as a homemaker for the Raleigh County Commission on Aging. The prescription drug thefts occurred over the past couple of months at a residence in the Wildwood House Complex on Autumn Lane in Beckley. The Commission on Aging were notified and "immediately took action to remove the homemaker from the residence," according to a police news release.

Redden was arrested by members of the U.S. Marshals Fugitive Task Force.

Read: [3 arrested on heroin charges in Beckley](#)

Read: [Lewisburg man sentenced on drug charges](#)

Read: [Man accused of soliciting teenager for sex enters plea](#)

- 1 arrested/ 1 wanted for violent robbery against elderly woman in McDowell County**

W.Va. pharmacist charged in multistate prescription-drug ring

Posted: Monday, December 14, 2015 10:02 pm

MARTINSBURG, W.Va. — Authorities may have disrupted a prescription-drug ring allegedly involving a Martinsburg pharmacist, a physician employee in Georgia and two Kentucky women who obtained hundreds of pills each month from a Charles Town, W.Va., pharmacy since August.

The pharmacist, David M. Wasanyi, 47, was charged last week in Jefferson County, W.Va., with conspiracy to distribute controlled substances from City Pharmacy at 82 Somerset Blvd., according to Jefferson County Magistrate Court records.





Richlands nurse practitioner admits to writing illegal prescriptions

[f Recommend](#)
195
[t](#)
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[@](#)
[✉](#)
[🗨](#)
[+](#)
8

By Paul Hess, WVVA Internet Director
Posted: Nov 25, 2015 10:50 AM EST

CONNECT



ABINGDON, VA (WVVA) A former Richlands nurse practitioner enters a plea in federal court to writing illegal prescriptions for the pain-killer oxycodone.

According to court documents, Gloria W. "Faye" Kennedy conspired with her husband Darryl Lynn Wells to distribute 3,780 oxycodone (15 mg) pills.

Kennedy was "licensed as a nurse practitioner in the state of Virginia and had prescribing privileges granted by the United States Department of Justice Drug Enforcement Administration." Between April 22, 2014 and September 3, 2015 she wrote numerous prescriptions "without a legitimate medical purpose and beyond the bounds of medical practice," to her husband and others.

On Tuesday, Kennedy entered a plea to one count of conspiring to distribute controlled substances and one count of making false statements to investigators. She is scheduled to be sentenced on March 22, 2016.

Wells entered a plea to federal drug charges earlier this month.

Read: [Doctor indicted on federal drug charges in Beckley](#)

Doctor indicted on federal drug charges in Beckley



Read: [Greenbrier County cracks down on alleged food stamp card scam](#)

Read: [West Virginia woman sues mining company, claims gender discrimination](#)

Doctor Accused of Overprescribing Pills Is Guilty of Manslaughter

By MONIQUE O. MADAN JULY 18, 2014



Dr. Stan Xuhui Li outside State Supreme Court in Manhattan on Friday. He was convicted of 200 of the 211 charges against him after a four-month trial. Anthony Lanzilote for The New York Times



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





Impact on Society





Consequences

From 2000-2014 the rate of unintentional drug overdose deaths in the United States has increased **137%**, including a **200%** increase in overdose deaths involving opioids.

During this time period nearly half a million (500,000) people have died from drug overdoses.

In 2014, approximately **47,055** unintentional drug overdose deaths occurred--one death every 11.16 minutes.

There were approximately 1½ times more drug overdose deaths in the United States than deaths from motor vehicle accidents.



Consequences

In 2014, 61% (**28,647**) of these deaths involved some type of opioid, including heroin.

In 2014, CDC indicates that there were about *19,000 “prescription opioid pain reliever deaths”.

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

**Historically, CDC has programmatically characterized all opioid pain reliever deaths (natural and semisynthetic opioids, methadone, and other synthetic opioids) as “prescription” opioid overdoses. In 2014, a sharp increase in deaths involving synthetic opioids (other than methadone) coincided with law enforcement reports of increased availability of illicitly manufactured fentanyl, a synthetic opioid. However, illicitly manufactured fentanyl cannot be distinguished from prescription fentanyl in death certificate data.*

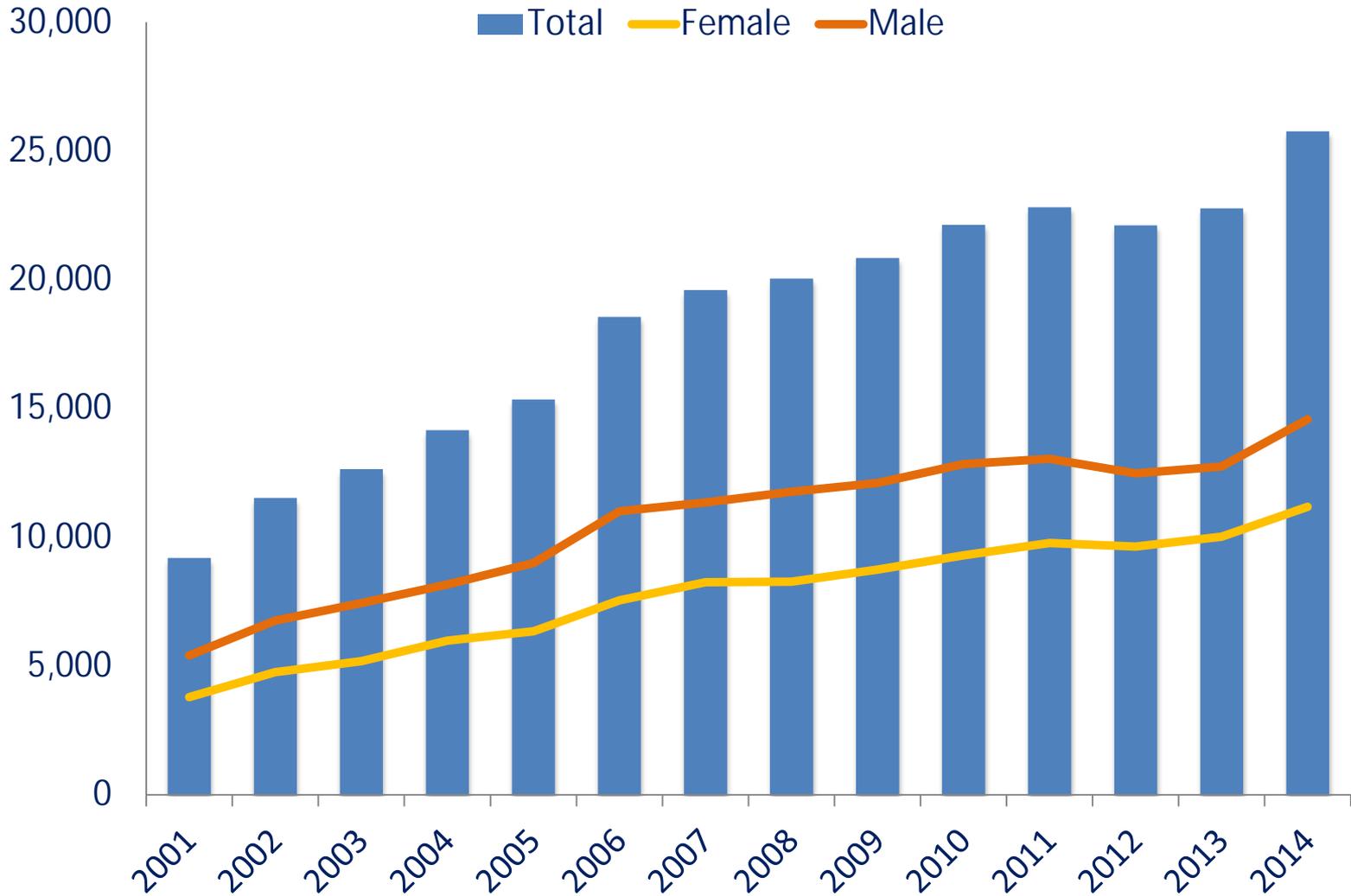
CDC National Center for Health Statistics/Morbidity and Mortality Weekly Report (MMWR); January 1, 2016

*Email: Between CDC (Rudd) and DEA (Prevoznik) 2/18/2016



National Overdose Deaths

Number of Deaths from Prescription Drugs

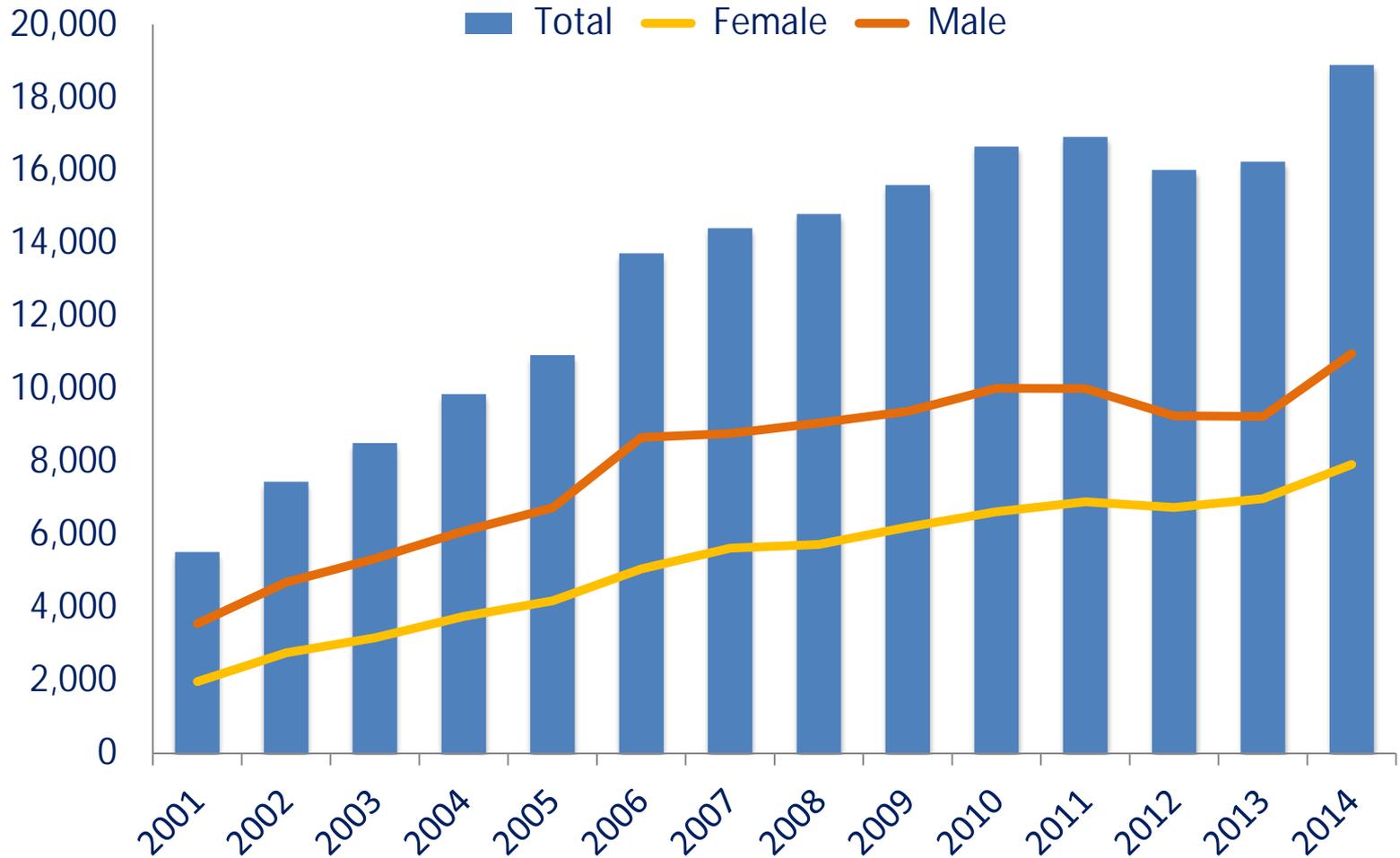


Source: National Center for Health Statistics, CDC Wonder



National Overdose Deaths

Number of Deaths from Prescription Opioid Pain Relievers

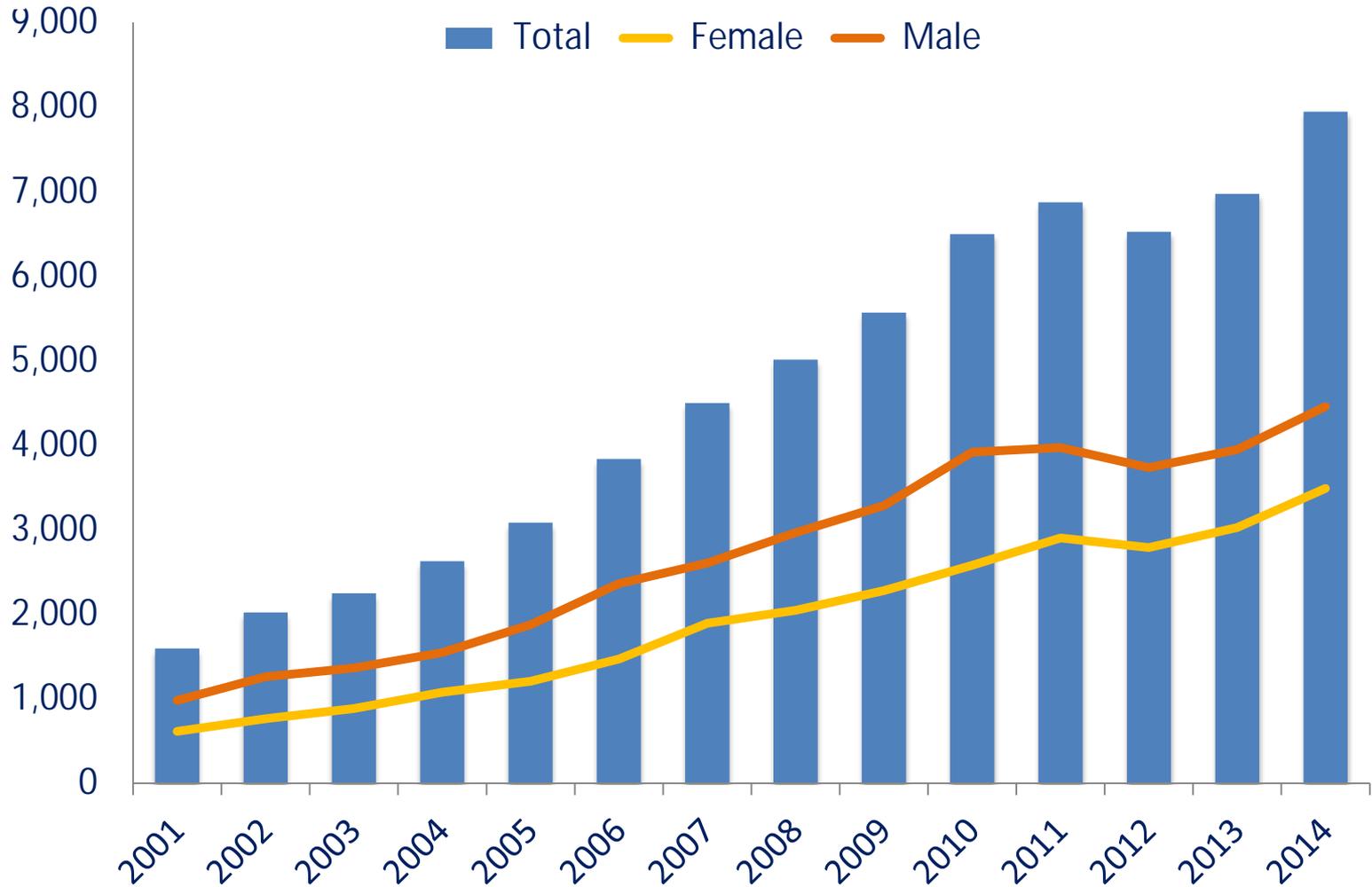


Source: National Center for Health Statistics, CDC Wonder



National Overdose Deaths

Number of Deaths from Benzodiazepines

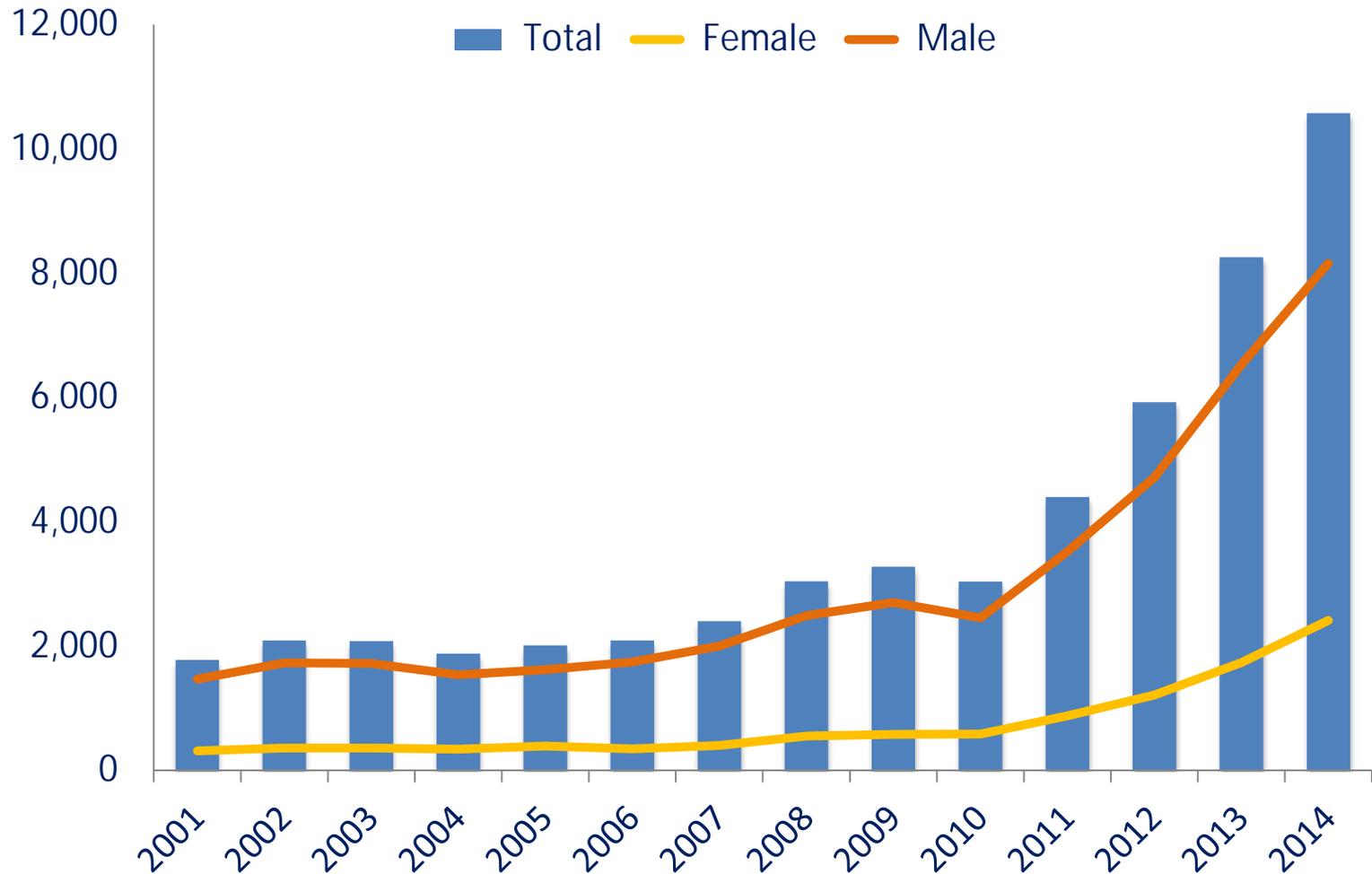


Source: National Center for Health Statistics, CDC Wonder



National Overdose Deaths

Number of Deaths from Heroin

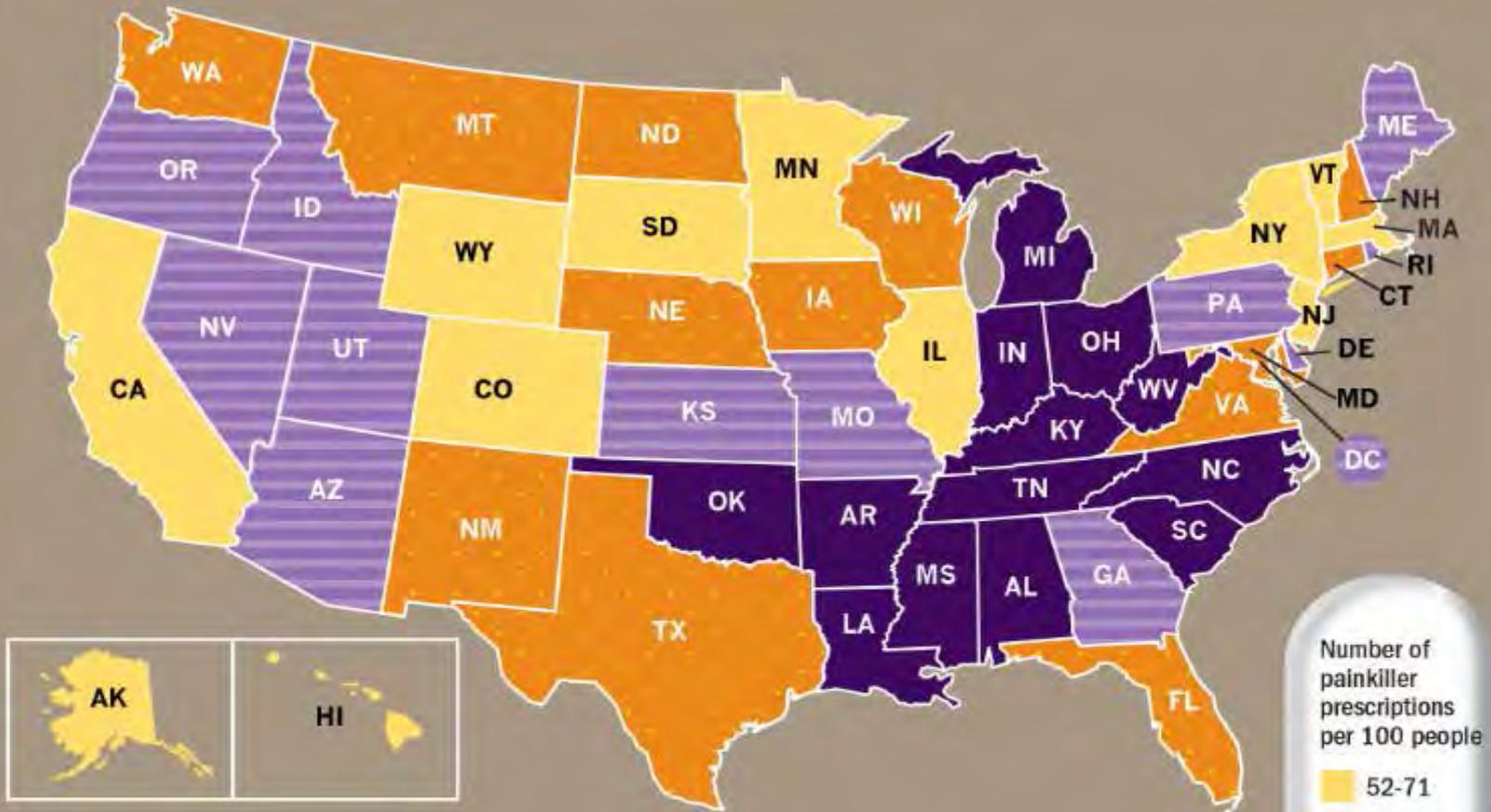


Source: National Center for Health Statistics, CDC Wonder



Highest Opiate Prescriptions

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



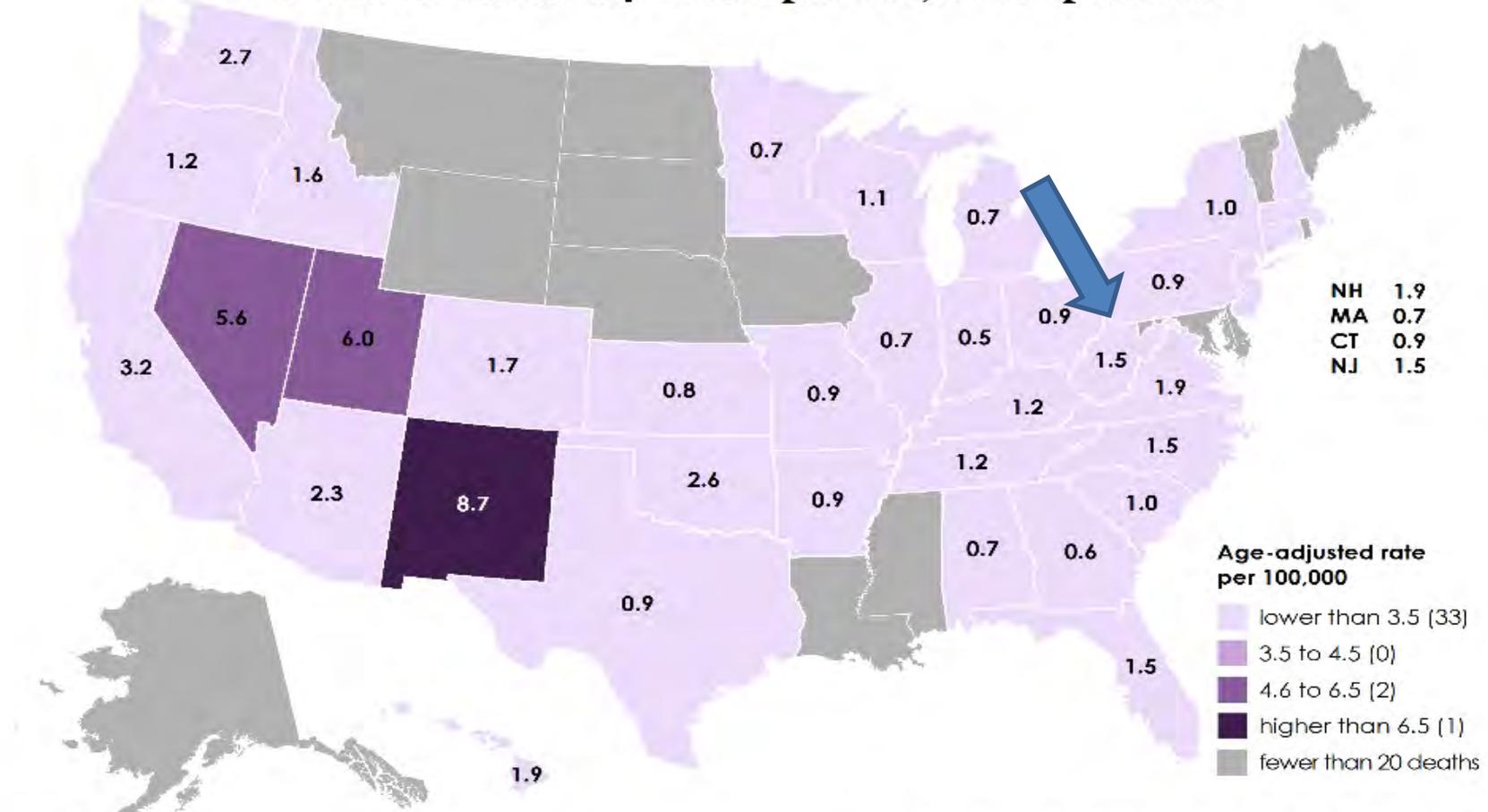
Some states have more painkiller prescriptions per person than others.

Prescription Opioid Analgesics Poisoning Deaths



Opioid-Involved Drug Poisoning Death Rates by State, 1999

U.S. National Rate: 1.4 Deaths per 100,000 Population



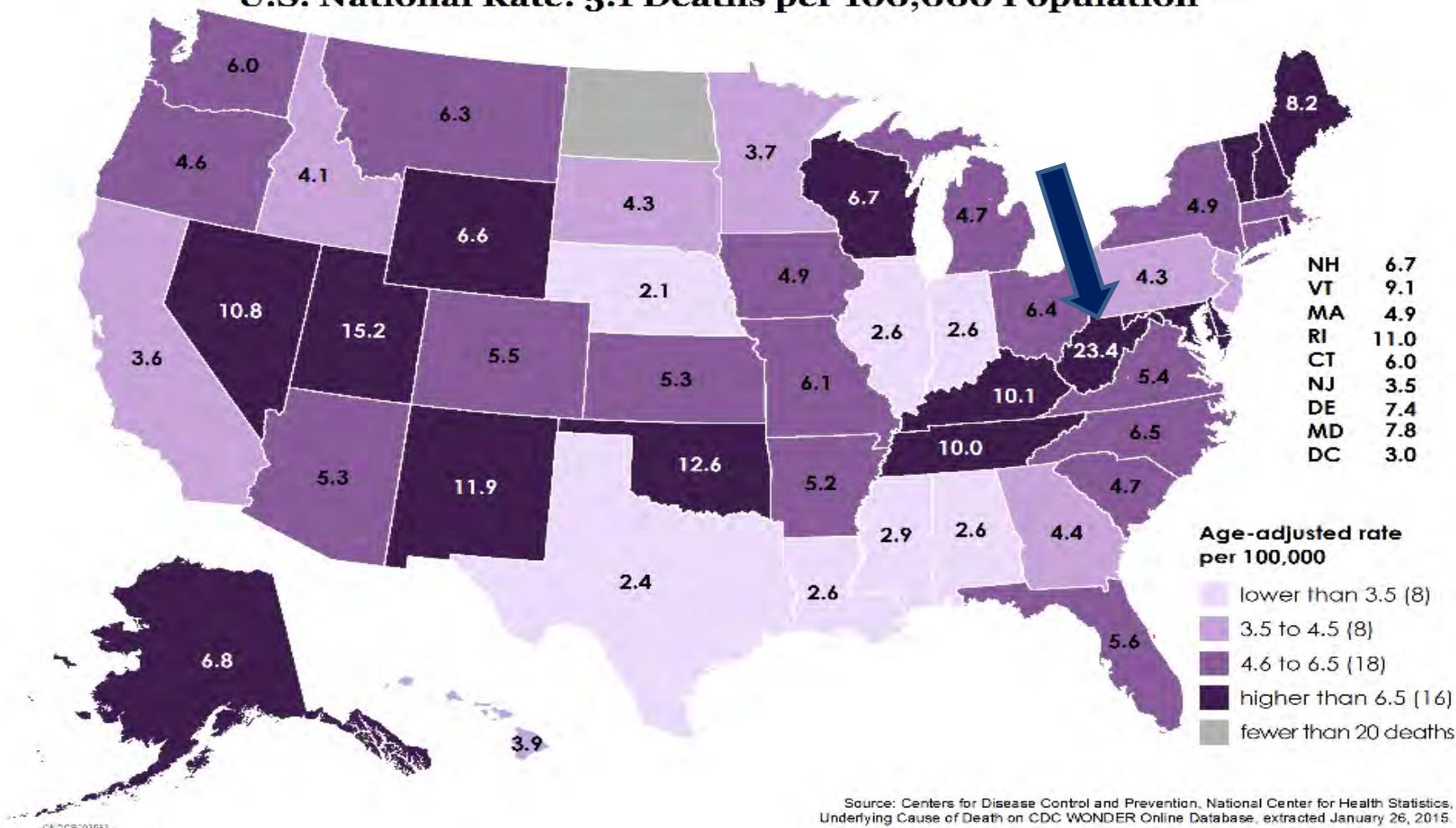
Source: Centers for Disease Control and Prevention, National Center for Health Statistics, Underlying Cause of Death on CDC WONDER Online Database, extracted January 26, 2015.

Prescription Opioid Analgesics Poisoning Deaths



Opioid-Involved Drug Poisoning Death Rates by State, 2013

U.S. National Rate: 5.1 Deaths per 100,000 Population





Rush Limbaugh



Steven Tyler

Pharmaceutical Abuse



Eminem



Brett Farve



Marilyn Monroe
August 5, 1962



Elvis Presley
August 16, 1977



Gerald Levert
November 10, 2006



**Anna Nicole
Smith**
February 8, 2007



Heath Ledger
January 22, 2008

DEATHS



Michael Jackson
June 25, 2009



Luna Vachon
August 27, 2010



Michael Baze
May 10, 2011



Whitney Houston
February 11, 2012



Thomas Kinkadee
April 6, 2012



Our Youth

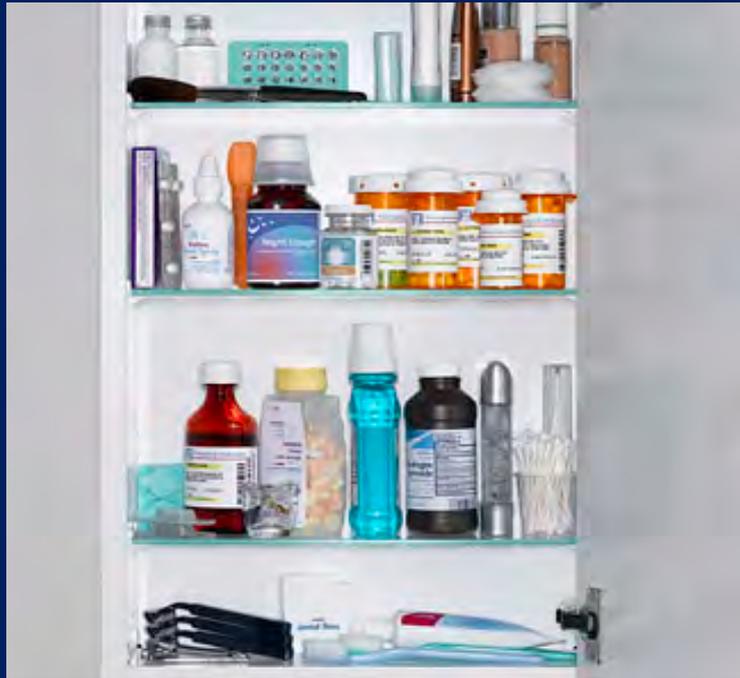


U.S. Drug Enforcement Administration
Office of Diversion Control



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

Friends and Family...For Free!!





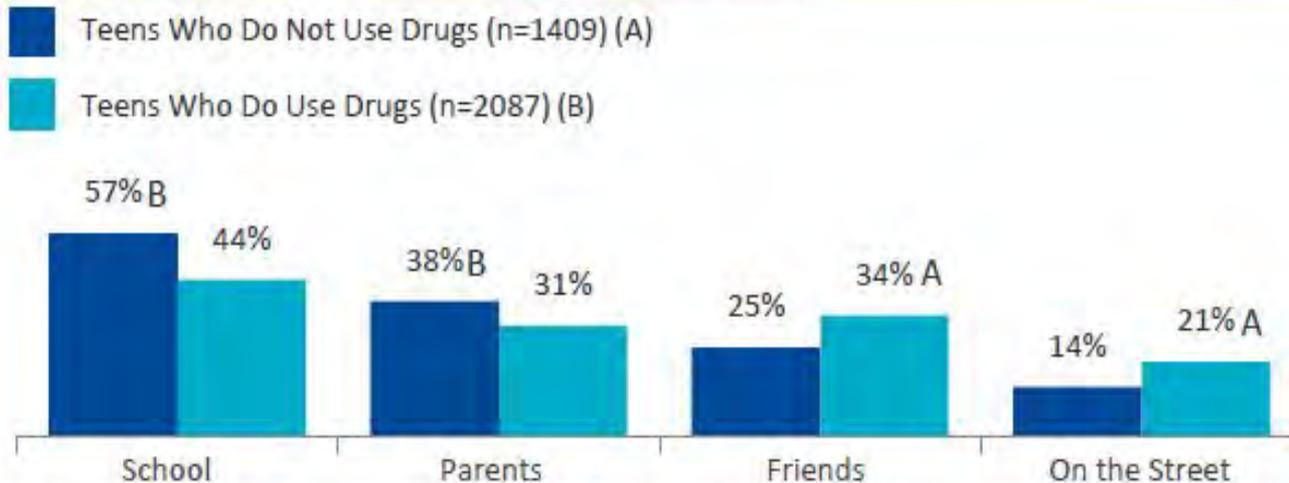
Medicine Cabinets: Easy Access

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



Where our kids learn about drugs!

Learned About Risk of Drugs From Following Sources by Teen Drug Use (% A lot) (n=3705)



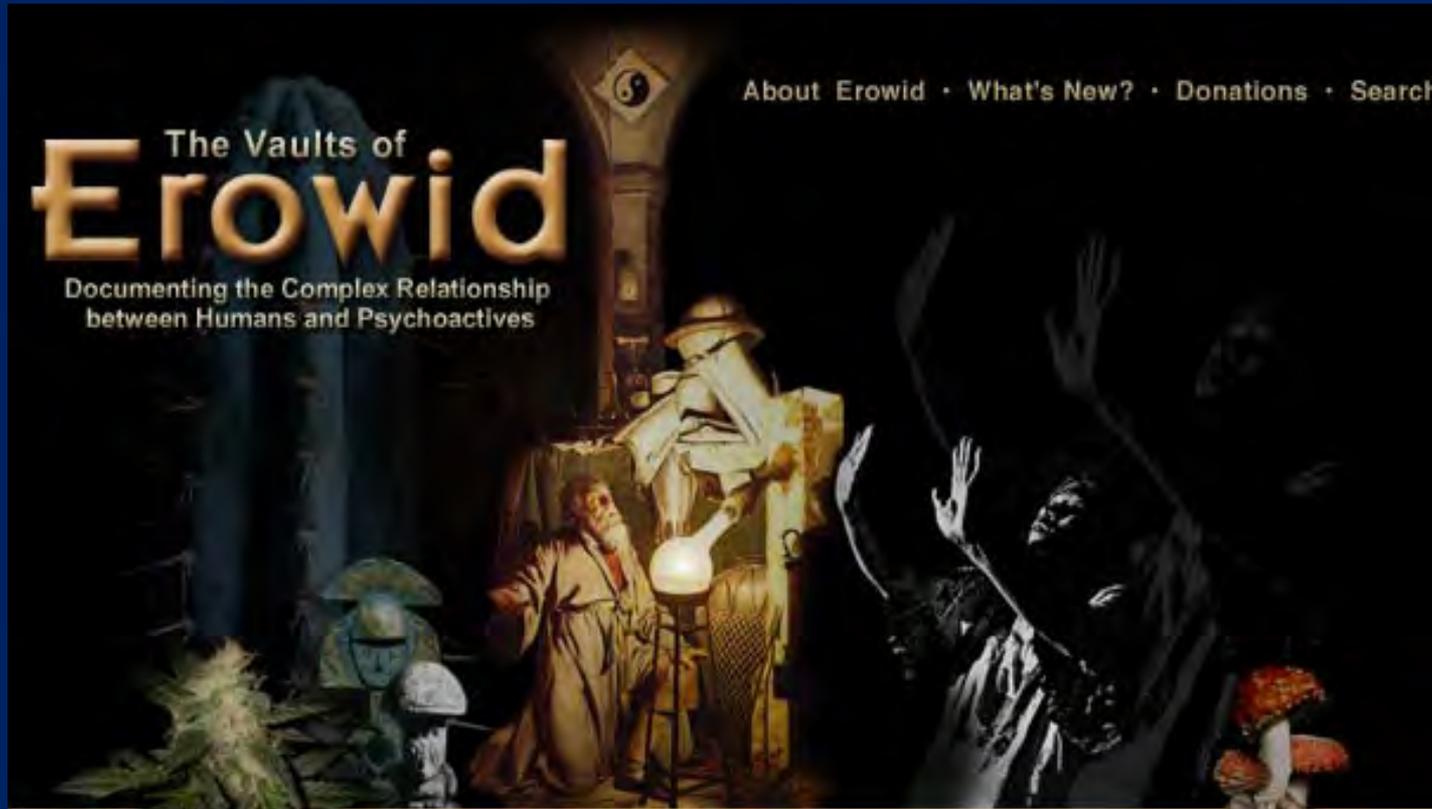
A-B indicates a significant difference at the 95% confidence level.

“How much have you learned about the risks of drugs from each of the following:”

Partnership for Drug-Free Kids | The Partnership Attitude Tracking Study | Teens & Parents 2013



Where else do our kids get their information from? www.erowid.org





Where do kids get their information from? www.bluelight.org

← → ↻ ↵ www.bluelight.ru/vb/

GoogleBluelight

User Name Password Log in Help Register
Remember Me?

BLUELIGHT

HARM REDUCTION WORKSHOP with BLUELIGHT
PSYCHEDELIC SCIENCE 2013 APRIL 18TH REGISTER NOW
OAKLAND MARRIOTT CITY CENTER • CALIFORNIA

Home Forum What's New? Wiki

The Front Page Advanced Search

The Front Page

If this is your first visit, be sure to check out the FAQ.
You may have to register before you can post: click the register link above to proceed. To start viewing messages, select the forum that you want to visit from the selection below.

Features

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

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

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.

...



Violence



*U.S. Drug Enforcement Administration
Office of Diversion Control*



Armed Robbery

- Ø Keep calm – Do as directed
- Ø Do not challenge the bad actor – give him what he wants
- Ø Let him leave the store without any intervention.
- Ø As soon as he clears the store lock the door, call 911 and check on your customers/patients
- Ø Write down any observations (clothing, height, weight, distinguishing features) while it is fresh in your mind
- Ø Armed Robbery is an act of desperation. No amount of drug loss is worth your life or the life of your patients



Violence Related to Controlled Substance Pharmaceuticals

ASSASSIN



Chilling anatomy of drugstore massacre

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

PAGES 4-5

DRUGSTORE MASSACRE



Husband and wife busted in Rx-slay horror

PAIN KILLER

David Laffer is the man caught on video wearing a fake beard (top) who slaughtered four people in a pharmacy to fund his wife Melissa's addiction, cops said yesterday.

PAGES 4-5

33

comments

Slain Lansing Rite Aid pharmacist, father of toddler may not have known attacker



Michael Nana Baffour Addo was a well-liked pharmacist at Rite Aid in the Frandor Shopping Center in Lansing. (Courtesy photo)



By Melissa Anders | manders@mlive.com

Follow on Twitter

on May 13, 2014 at 4:14 PM, updated May 14, 2014 at 5:38 PM

Print

Tweet

2.7k

Like

LANSING — Michael Addo, known as a friendly Rite Aid pharmacist with a "million dollar smile," had a toddler and wife in Ghana, where he hoped

RITE AID AND EAST LANSING SHOOTING CASE

Do you know a WWII vet?



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

... Read more about the project

Source:
http://www.mlive.com/lansing-news/index.ssf/2014/05/michael_addo_rite_aid_frandor.html

[HOME](#) » [NEWS](#)

Pharmacist slain in Beach robbery was much beloved

[+](#) Share 829 [f](#) 777 [t](#) 34 [in](#) 18 [p](#) 0 [g+](#) 2



1 OF 10 PHOTOS: Shannon Rogers lays flowers near the store on Monday, April 14, 2014. Rogers said she just met the store's owner, David Kilgore, this weekend. Rogers, who called Kilgore "awesome," said he let her park her car at the store so she could spend a day at the beach. Police said Kilgore died after an attempted robbery in his drugstore Monday morning. (Brian J. Clark | The Virginian-Pilot)

[View all 10 photos](#) | [Buy Pilot photos](#)

By Stacy Parker
The Virginian-Pilot
© April 15, 2014

VIRGINIA BEACH

When pharmacist David Kilgore left Rite Aid three-plus years ago, customers transferred their prescriptions to his new, small independent business.

They admired the way he connected with them on a personal level.

Monday, they placed flowers at his pharmacy's doorstep after learning the 46-year-old was shot during a morning robbery and later died.

"It was always, 'Hey Pete, how you doing?'" said Peter Carlson, who dropped off a colorful bouquet at Beach Pharmacy on Monday evening.

Related: [Suspect identified, charged with murder](#)

The pharmacist was working at Rite Aid on Laskin Road near the Oceanfront when development



The Kroger Co. Family of Stores

Find valuable coupons, savings and more! [>](#)

PilotOnline.com
DAILY DEAL
50% DISCOUNT
BUY NOW FOR \$10 **A \$20 VALUE**
And Get \$20 Worth of Tasty Food at Ocean House Waterfront Dining!

[Daily Deal](#) | [Promote your business](#)

Source:

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



Pharmacy Armed Robberies

January 1 thru August 31, 2015

Ø U.S. (Nationwide) – 853

Ø State of West Virginia – 10

West Virginia Counties	Number of Pharmacy Thefts
KANAWHA	4
MONONGALIA	2
JEFFERSON	1
BRAXTON	1
PUTNAM	1
MARION	1
No Reported Armed Robberies in remaining counties	



Drugs of Abuse





Opiates

*Drug Enforcement Administration
Office of Diversion Control*



Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen



INTERNATIONAL NARCOTICS CONTROL BOARD



Narcotic Drugs
Stupéfiants
Estupefacientes
2014

Estimated World Requirements for 2015
Statistics for 2013

Évaluations des besoins du monde pour 2015
Statistiques pour 2013

Previsiones de las necesidades mundiales para 2015
Estadísticas de 2013



UNITED NATIONS

*U.S. Drug Enforcement Administration
Office of Diversion Control*

- INCB Annual Report
Narcotic Drugs
- Estimated World
Requirements for
2015
- Statistics for 2013



International Narcotics Control Board: Comments on Reported Statistics on Narcotic Drugs

The United States was the country with the highest consumption of the following drugs:

2013	DRUG	2012
99%	Hydrocodone	99%
78%	Oxycodone	82%
57%	Morphine	57%
51%	Hydromorphone	42%
51%	Methadone	49%
31.5%	Fentanyl	37%



Hydrocodone

Ø Hydrocodone / Acetaminophen (toxicity)

Ø Similarities:

- Structurally related to codeine
- Equal to morphine in producing opiate-like effects

Ø Brand Names: Vicodin[®], Lortab[®], Lorcet[®]

Ø Currently, combination products are Schedule III

Ø **October 6, 2014 moved to SCHEDULE II**

Ø “Cocktail” or “Trinity”

- Ø Hydrocodone
- Ø Soma[®] / carisoprodol
- Ø Alprazolam / Xanax[®]

Ø Street prices: \$2 to \$10+ per tablet depending on strength & region



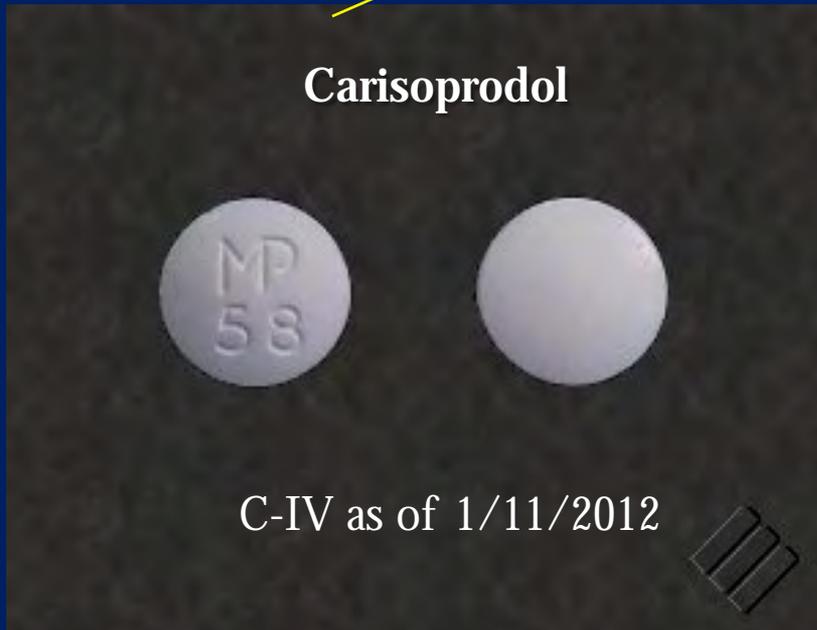


The Trinity



Hydrocodone

Opiate



Carisoprodol

C-IV as of 1/11/2012

Muscle Relaxant



Alprazolam

Benzodiazepine

OXYCODONE





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 ® / 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.



Oxycodone HCL CR *(OxyContin[®]) Reformulation*





New OxyContin® OP



08-27-2010, 01:11 AM

#17

[mz.mary420](#)

Member



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

well just got ours and they suck! when snorted the pill balls up in your nose and gets stuck, so i tried sucking on one and it did ok, but tastes nasty. No way you can shoot them as metioned in a previous post. havent tried smoking it yet, kinda in a hole money wise, it cost me over \$700.00 to get my 80s filled and i probably wont even get half my money back 😞

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



08-27-2010, 06:09 AM

#18

[mephist00](#)

Member



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

ya my friend has tried to smoke the new ones... said its very harsh on the lungs and throat..

so far the only way ive been able to beat the time release, is use a hose clamp to grind it very fine, and snort it.. it doesnt gel up like you would think (doesnt gel up like the football shaped generic 40's do anyways) it just kinda turns snotty.. but if you can get it down fast it seems to work ok

Quote:

Originally Posted by **stalk**

I've come to the conclusion it's because these psychedelic visions are simply vibrating on a higher, or different, spectrum of frequencies that normally the monkey does not perceive.

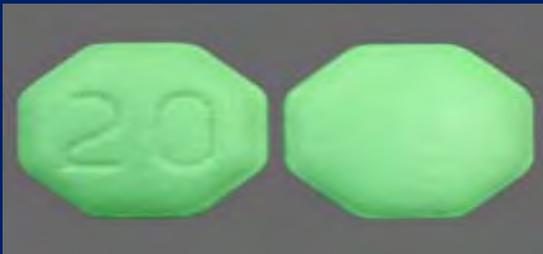


Oxymorphone Extended Release

Opana ER[®] (Schedule II)

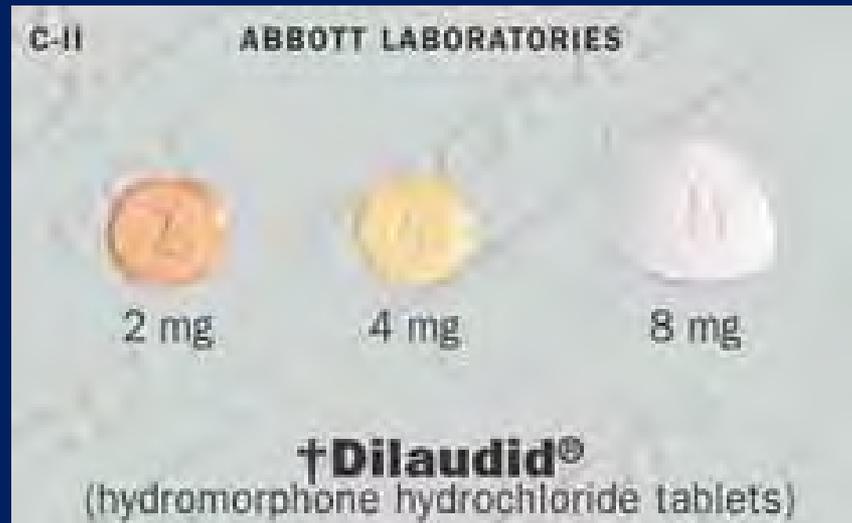
Ø Opana ER[®] - (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming popular and is abused in similar fashion to oxycodone ; August 2010 (Los Angeles FD TDS)
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: \$10.00 – \$80.00





Hydromorphone



Usual Dose: See package insert

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

Roxane Laboratories, Inc.
Columbus, Ohio 43216

NDC 0054-0264-25 100 Tablets

HYDROMORPHONE HYDROCHLORIDE **C-II**
Tablets, USP

4 mg

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

Roxane Laboratories

10054026425

EXP. LOT

10005693002
© RLI, 2009

USUAL DOSAGE:
See package insert for prescribing information.
Dispense in a light-resistant container, as defined in the USP, with a child-resistant device.
Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].
Rx Only 10 313

NDC 0527-1355-01

Lannett

HYDROMORPHONE HYDROCHLORIDE **C-II**
TABLETS, USP

8 mg

Rx Only
100 TABLETS

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

Inert Ingredients:
Anhydrous Lactose, Lactose Monohydrate, USP, 100 Mesh, Avicel®

Manufactured by:
Lannett Company, Inc.
Pittsburgh, PA 15109

Made in the USA

0527-1355-01



Other Opiates of Interest



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



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



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 30 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 30 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 100 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 60 mg



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



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

Fentanyl



Fentora®



Actiq®

- Ø Fentanyl Patches
- Ø Fentanyl Citrate dispensed in a berry flavored lollipop-type unit
- Ø Fentanyl is 100 times more potent than morphine
- Ø Intended to be used for chronic cancer pain & only for people who are tolerant to prescription opioid (narcotic) pain medicines
- Ø Abused for its intense euphoric effects



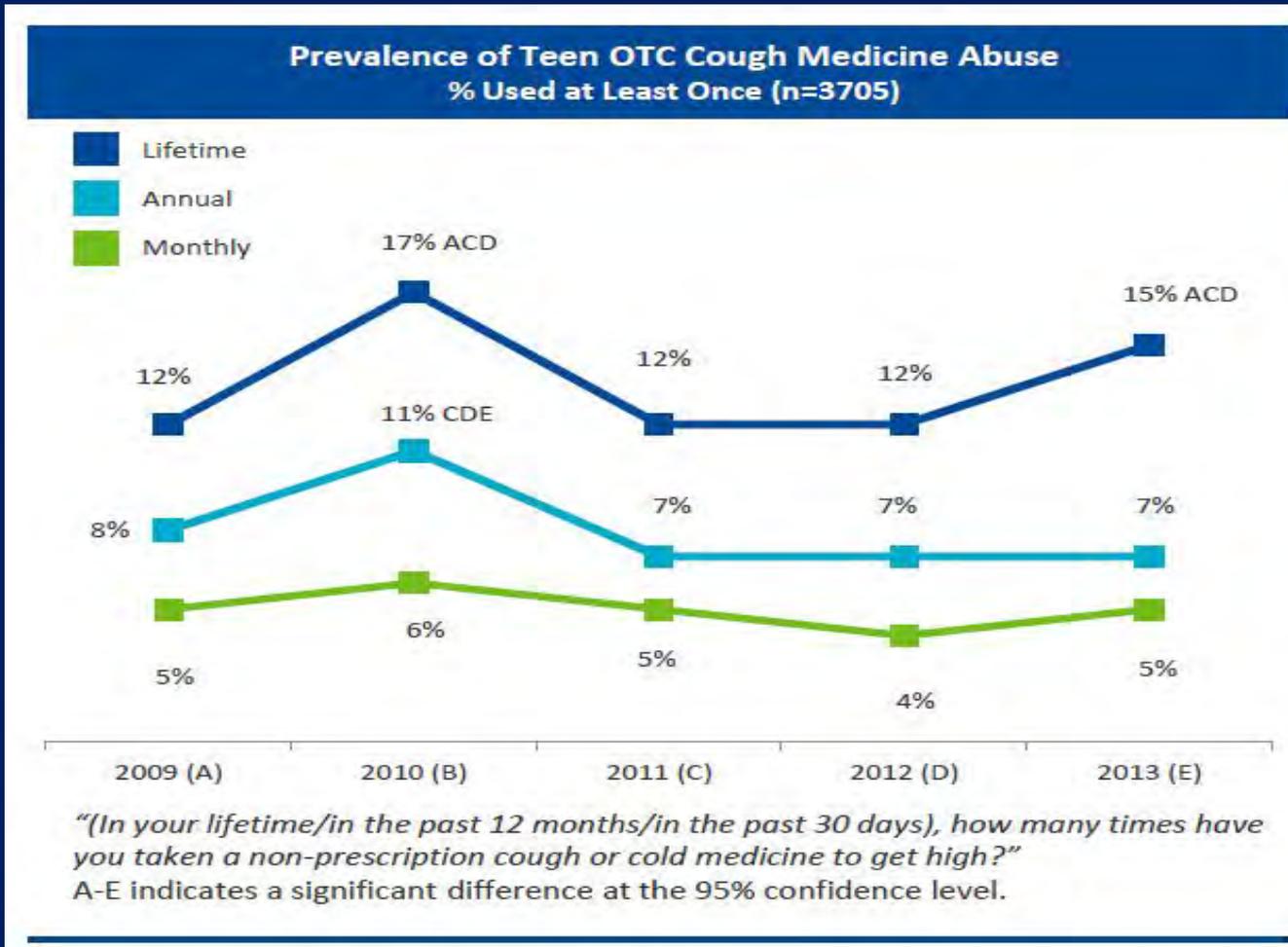
Dextromethorphan (DXM)

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





Teen OTC Cough Medicine Misuse and Abuse





Cough Syrup Cocktails

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



PURPLE DRANK
ima grip and sip





METHADONE



*U.S. Drug Enforcement Administration
Office of Diversion Control*



Methadone- 5mg & 10mg



Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg





Treatment of Narcotic Addiction



WHY IS IT ALSO USED AS AN ANALGESIC?

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?



Overdose...Why?

Ø Patients not taking the drug as directed

Ø Physicians not properly prescribing the drug

Ø Non medical users ingesting with other substances

Ø Opiate naive



Prescription Opiates v. Heroin





Circle of Addiction & the Next Generation

Oxycodone
Combinations

Percocet®

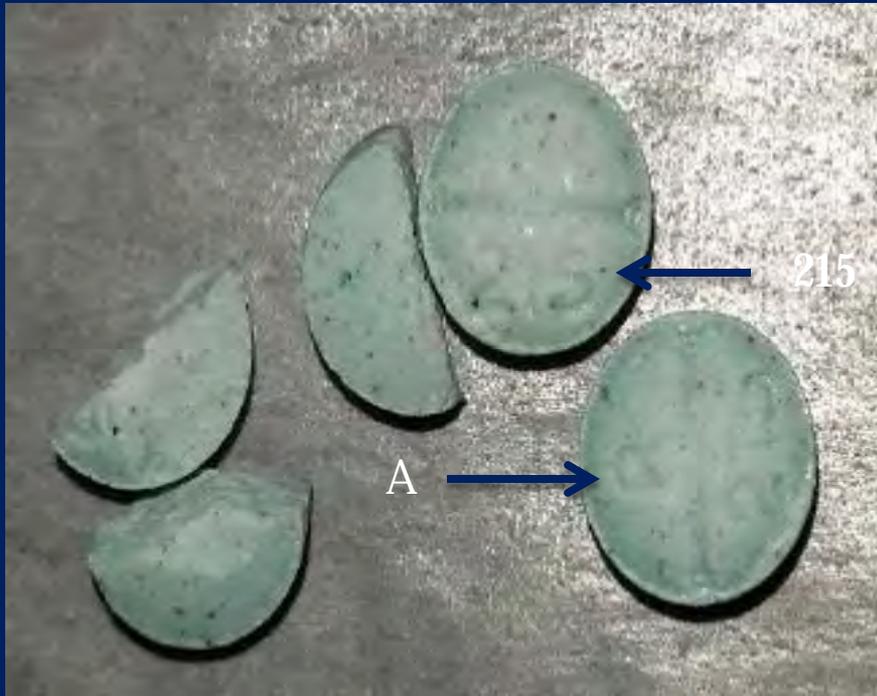
\$7-\$10/tab

OxyContin®
\$80/tab

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

Hydrocodone
Lorcet®
\$5-\$7/tab

Heroin
\$15/bag



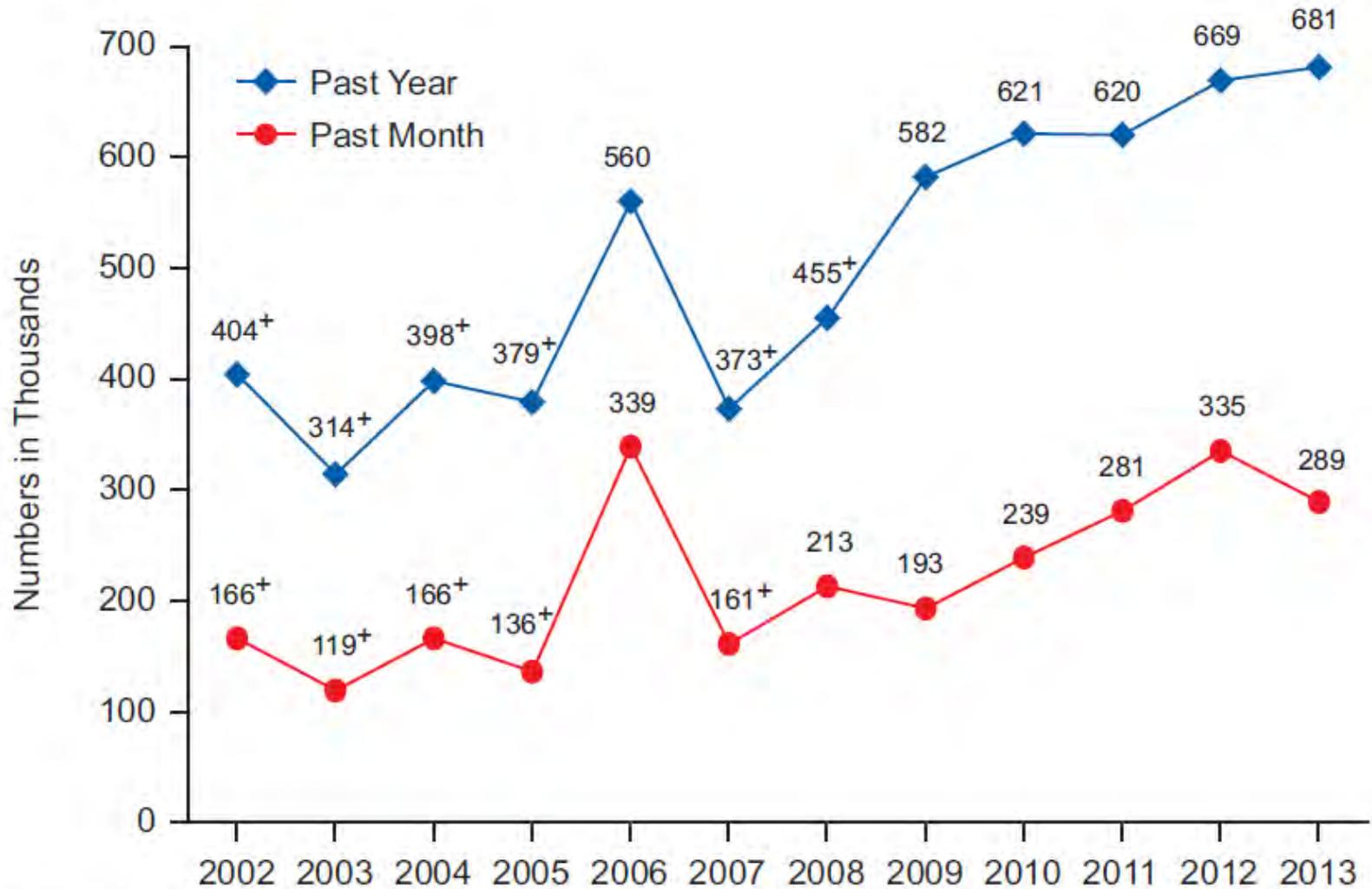
Heroin Seizure



Pharmaceutical Oxycodone 30mg



Past Month and Past Year Heroin Use Among Persons Aged 12 or Older: 2002-2013



⁺ Difference between this estimate and the 2013 estimate is statistically significant at the .05 level.



HEROIN: NO LONGER CONFINED TO URBAN AREAS


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 See what it's like to drive our best
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 Call / Email: Alan Pedron, General Sales Manager
 APedron@darcars.com

washingtonexaminer.com

The Examiner
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 WEDNESDAY, DECEMBER 5, 2012

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 Gifts, Flag Cases,
 Presentation Clocks
703.413.6209
 www.shipshatch.com
 Located in the Shops at Crystal City


'Liaisons Dangereuses'
 New approach to classic P. 19


Playoff possibilities
 Schedule favors Skins P. 35

Cooling down

60°-34°
 DETAILS P. 4

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

LOCAL
FBI analyst busted

Heroin use spikes in area suburbs

Pill addicts risk deadly drug

U.S. Drug Enforcement Administration
 Office of Diversion Control



Non-medical Prescription Opioid Users Who Try Heroin

- Prescription opioid use is a risk factor for heroin use. Approximately 4 out of 5 recent heroin initiates ages 12-49 used prescription opioids non-medically before heroin initiation.¹
- Transition from prescription opioid abuse to heroin use is relatively rare; approximately 4 percent of prescription opioid abuse initiates begin using heroin within five years of their initiation of prescription opioid abuse.²
- Injection-drug users report that tolerance motivates them to try heroin.³
- New research shows that heroin's effects, price, availability, and ease of use motivate heroin users who formerly used prescription opioids.⁴



1. Muhuri, P.K. Gfroerer, J., Davies, C. (2013). Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. SAMHSA CBHSQ Data Review (August).
2. Ibid
3. Lanckenau SE, et al. (2012). Initiation into prescription opioid misuse amongst young injection drug users. Int J Drug Policy. 2012 Jan;23(1):37-44. Epub 2011 Jun 20.
4. Cicero TJ, Ellis MS, Surratt HL, Kurtz SP. The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years. JAMA Psychiatry. Published online May 28, 2014. doi:10.1001/jamapsychiatry.2014.366



Criminal Activity



Egregious Activity (Not on the fringes)



United States V. Alvin Yee, M.D.

Dr. Alvin Yee



*U.S. Drug Enforcement Administration
Office of Diversion Control*





United States V. Alvin Yee, M.D.

Overview

- Dr. Yee primarily met with his “patients” in Starbucks cafes throughout Orange County, California.
- He would see up to a dozen patients each night between 7:00 and 11:00 p.m. and wrote these “patients” prescriptions, primarily for opiates, in exchange for cash.
- Yee pled guilty to distributing millions of dollars in oxycodone, oxymorphone, hydrocodone, hydromorphone, Adderall® and alprazolam outside the course of professional practice and without a legitimate medical purpose



DOCTOR SOLD PRESCRIPTIONS AT STARBUCKS

By *StopOxy* · Comments Comments Off

It was never our intention to to become a watchdog website that would use our outlet to humiliate unethical doctors criminals.

Yet recently we are reading some stories that compel us to provide as much of a "comeuppance" as we can to shady and unethical doctors like



Alvin Ming-Czech Yee of Mission Viejo (medical practice was in Irvine).

This "doctor" sat in a Starbucks Coffee Shop and sold prescriptions for OxyContin - also known as "legal heroin" (or also known as "the prescription drug that is shattering families in record numbers)."

Again, let us reiterate that Dr. Yee **would perform his examinations in Starbucks.** the "examinations" would last about a minute. Yee would meet up with a dozen people per night in Starbucks throughout Orange County. The "examinations" drug deals consisted of taking blood pressure and



Pain Clinics



Operation "As the Pill Turns"

Ft. Lauderdale, FL

Dr. Vijay Chowdhary and Jason Boyd



Chowdhary



Jason Boyd



Intracoastal Medical Group

Rogue Pain Clinic – Ft. Lauderdale, FL

Ft. Lauderdale, FL

- **1 ½ year long Title III investigation targeting Intracoastal Medical Group, a Rouge Pain Clinic in Ft. Lauderdale.**
- **Jason RODRIGUEZ and Jason BOYD both convicted felons were involved in operating the pain clinic.**
- **7 undercover agents were introduced into the clinic as prescription pill buyers, pain clinic patients and a pain clinic sponsor.**
- **Agents executed 4 federal search warrants and arrested 7 people on federal drug and money laundering charges.**
- **Seized during the enforcement action were 18 vehicles and approximately \$900,000 in assets.**



Intracoastal Medical Group

- Jason Boyd, the Pain Clinic Owner



Jason Boyd: A Florida Pill Mill Poster Boy

July 9, 2013 | 12 Comments | in DEA, (Hits: 7 by thefrankies)



Between his late Twenties and early Thirties, Jason Boyd tried his hand at several drug trades. He dabbled in cocaine, hydrocodone, LSD, marijuana, MDMA, methamphetamine, and steroids between 1996 and 2002, according to his criminal court records in Broward County, Florida.

It didn't get him very far, except for free trips to the county jail on petty drug charges for slinging nickel-and-dime quantities of illicit narcotics.

However, by the time he turned 38 in 2008, Boyd had found his calling in the Sunshine State's lucratively addictive prescription pill mill racket, according to a July 3 20-count federal indictment against him and six other co-conspirators accused of operating a bogus pain management clinic in Fort Lauderdale, Florida, that collected \$4.2 million from the illegal sale of Oxycodone, Ambien, and prescription Motrin during a two year period.

His criminal defense lawyer Fred Haddad did not return a message seeking comment about Boyd, his criminal history, and the current charges against him. Boyd, along with four of his co-defendants, are in federal custody pending their bond hearings.

A burly 6'5" man weighing 330 pounds, Boyd has a rap sheet dating back to 1990. He's been arrested by various police departments in Broward County on a variety of charges from grand theft to possession of MDMA with intent to sell to illegal possession of a firearm by a convicted felon. In one case, he was arrested on October 17, 1997 by Pembroke Pines Police for allegedly trafficking a general store of illicit narcotics, including LSD, marijuana, anabolic steroids, and hydrocodone. He also has a 2003 federal felony conviction for identity and credit card fraud.



Jason Boyd



Intracoastal Medical Group

- **Jason Rodriguez, the Office Manager**





Investigative Results

- **In May 2014, five defendants from Intracoastal Medical Group were sentenced in Ft. Lauderdale, Florida for Conspiracy to Distribute**
- **Dr. Vijay CHOWDHARY was sentenced to 24 month's incarceration and a \$25,000 fine.**
- **Physician's Assistant Harish CHOWDHARY was sentenced to 48 month's incarceration.**
- **Pain clinic owner Jason BOYD (also charged with Money Laundering) received 84 months.**
- **Office manager Jason RODRIGUEZ was sentenced to 168 months incarceration.**
- **Facilitator Amanda BOZER received four years' probation.**



Does your Doctors Office look like this?





The Controlled Substances Act: Checks & Balances





Mission

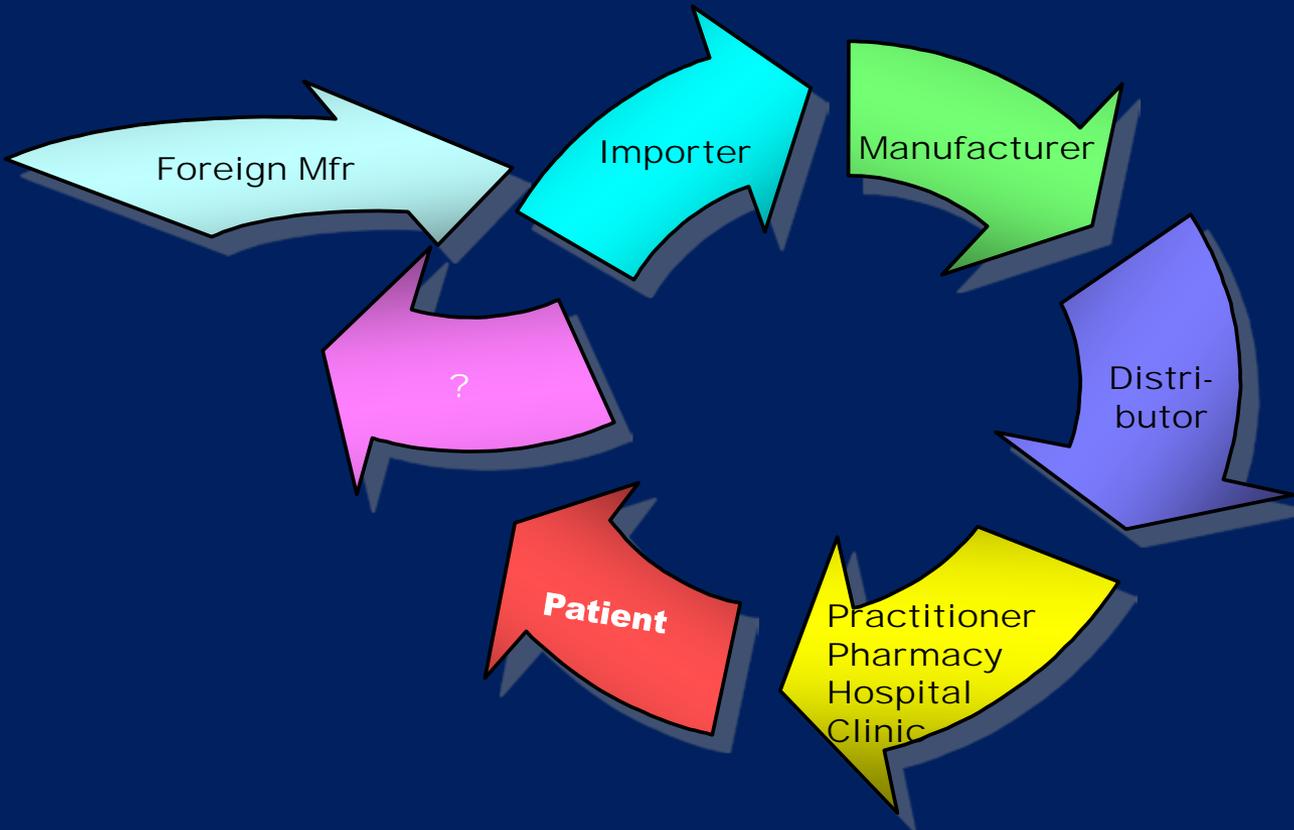
The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

while ...

ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs



Closed System of Distribution

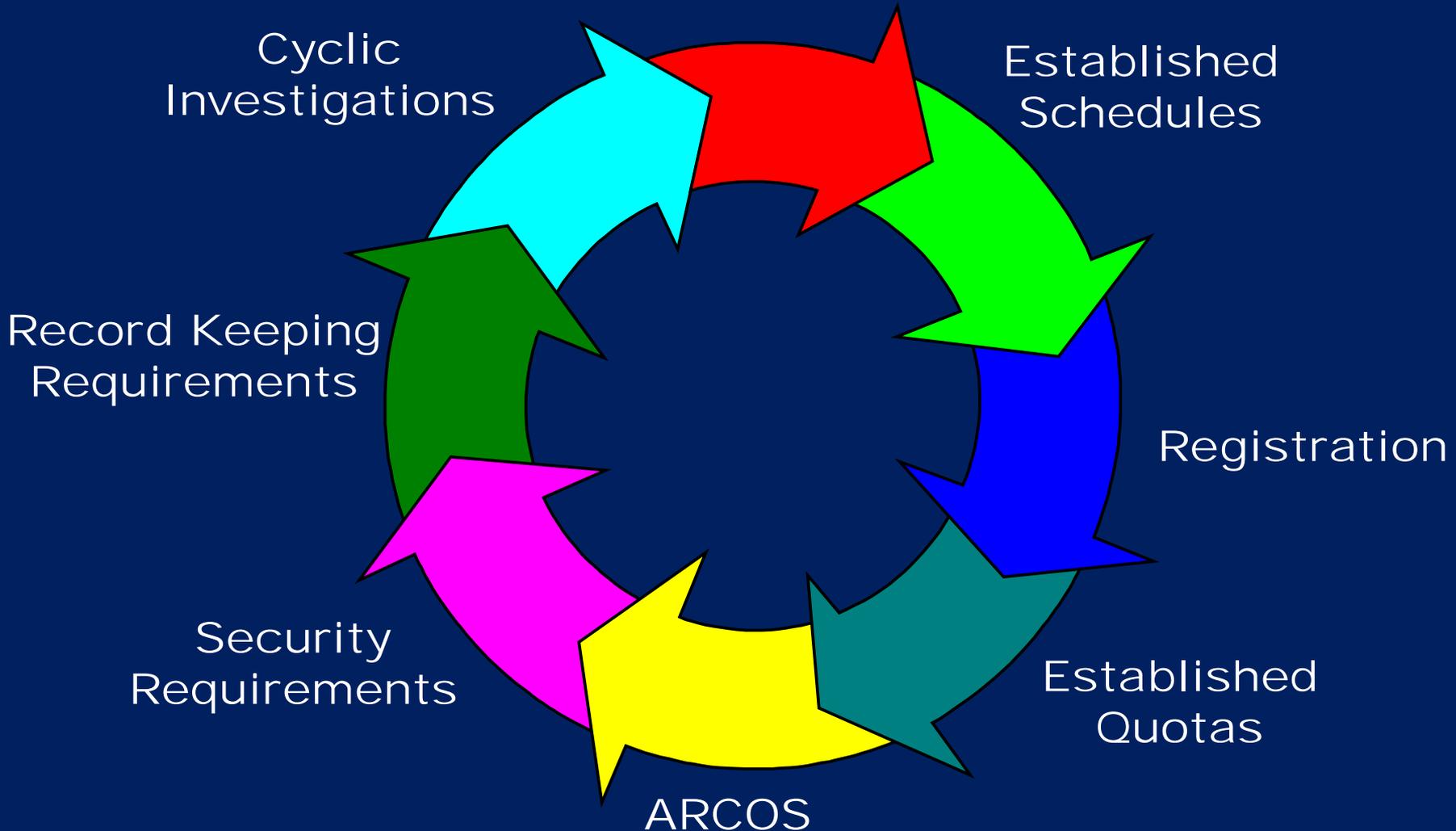


1,604,158 (09/04/2015)

- **Practitioners:** 1,221,972
- **Retail Pharmacies:** 71,439
- **Hospital/Clinics:** 16,500



The CSA's Closed System of Distribution





Closed System of Distribution

The DEA is responsible for:

- the oversight of the system
- the integrity of the system
- the protection of the public health and safety





Legal Obligations: DEA Registrant





Effective Controls

In order to determine whether a registrant has provided **effective controls** against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the **physical security controls** and **operating procedures** necessary to **prevent diversion**.

21 CFR § 1301.71(a)



Suspicious Orders

Non-practitioners 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(b)



Prescriptions

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 his professional practice.

21 CFR § 1306.04(a)

United States v Moore 423 US 122 (1975)





Corresponding Responsibility

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

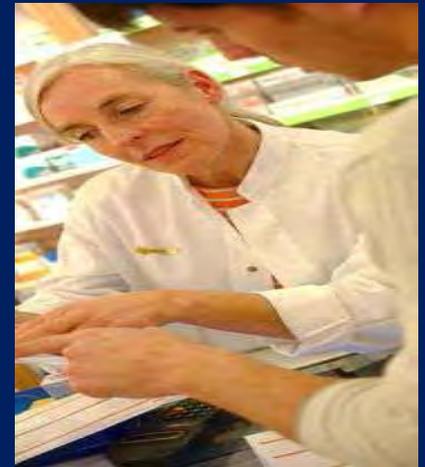
21 CFR § 1306.04(a)





Corresponding Responsibility

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate.
- When a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!





The Last Line of Defense



*U.S. Drug Enforcement Administration
Office of Diversion Control*



Potential Red Flags

Many customers receiving the same combination of prescriptions; cocktail

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

Many customers paying cash for their prescriptions

Early refills

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

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



Potential Red Flags continued

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.).

Overwhelming proportion of prescriptions filled by pharmacy are controlled substances

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

Verification of legitimacy not satisfied by a call to the doctors office



Red Flag?

What happens next?

You attempt to resolve...



Resolution is comprised of many factors

- Verification of a valid practitioner DEA number ! It is not, however, the end of the pharmacist's duty. Invalid DEA number = Invalid RX
- Resolution cannot be based solely on patient ID and prescriber verification.
- You must use your professional judgment, training and experience...we all make mistakes
- Knowledge and history with the patient
- Circumstances of prescription presentation
- Experience with the prescribing practitioner
- It does not require a call to the practitioner for every CS RX
- This is not an all-inclusive list...



Who do I call to report a practitioner?

- Ø State Board of Pharmacy/Medicine/Nursing/Dental
- Ø State/County/Local Police
- Ø DEA local office and Tactical Diversion Squad
- Ø Health department
- Ø HHS OIG if Medicare/Medicaid fraud

www.nabp.net

The screenshot shows the NABP website homepage. At the top left is the NABP logo, a red circle with a caduceus and the letters 'S' and 'P'. To its right is the text 'NABP NATIONAL ASSOCIATION OF BOARDS OF PHARMACY'. A search bar with a 'GO' button is in the top right. Below the logo is a navigation menu with links: HOME, ABOUT, PROGRAMS, PUBLICATIONS, NEWS, MEETINGS, CONTACT. A secondary menu below that includes: BOARDS OF PHARMACY, MEMBERS, PHARMACISTS, COUNCIL, TECHS/COMPS, GOVERNING BODIES, COORDINATORS. A green banner on the left says 'QUESTIONIST CHAT IS AVAILABLE'. Below that is a section titled 'Meet the NABP Executive Committee' featuring a photo of Edward O. McOrley and text about the 2015-2016 committee inauguration. To the right is a large red banner for 'redflag' with the text 'Do You Know What a Doctor Shopper Looks Like?' and a paragraph about prescription drug abuse. Below the red banner is a navigation bar with four orange buttons: 'Red Flags for Pharmacists', 'Verified Pharmacy Program', 'DE Monitor', and 'Safe Dollar Pharmacies'. At the bottom left is a section for the '2015-2016 Executive Committee' with a 'View' button and names of committee members. At the bottom right is a 'NEWSROOM HEADLINES' section with a 'VIEW ALL' button.

NABP
NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Search the Site **GO**

Profile Login and Quick Search

HOME ABOUT PROGRAMS PUBLICATIONS NEWS MEETINGS CONTACT

BOARDS OF PHARMACY MEMBERS PHARMACISTS COUNCIL TECHS/COMPS GOVERNING BODIES COORDINATORS

QUESTIONIST CHAT IS AVAILABLE

Meet the NABP Executive Committee

The 2015-2016 NABP Executive Committee, including President Edward O. McOrley, MBA, RPh, were inaugurated at the 111th Annual Meeting. [Learn More](#)

2015-2016 Executive Committee

[View](#)

Chairperson – Joseph L. Adams, RPh
President – Edward O. McOrley, MBA, RPh
President-Elect – Hal Ward, MBA, RPh

Do You Know What a Doctor Shopper Looks Like?

Americans abuse prescription drugs more than cocaine, heroin, and hallucinogens combined. The "Red Flags" video helps pharmacists identify the warning signs of prescription drug abuse and diversion.

redflag

Red Flags for Pharmacists Verified Pharmacy Program DE Monitor Safe Dollar Pharmacies

NEWSROOM HEADLINES [VIEW ALL](#)



The DEA Response





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

Ø Enforcement is just as important as....

Ø Prevention/Education

Ø Treatment







Community Partnerships

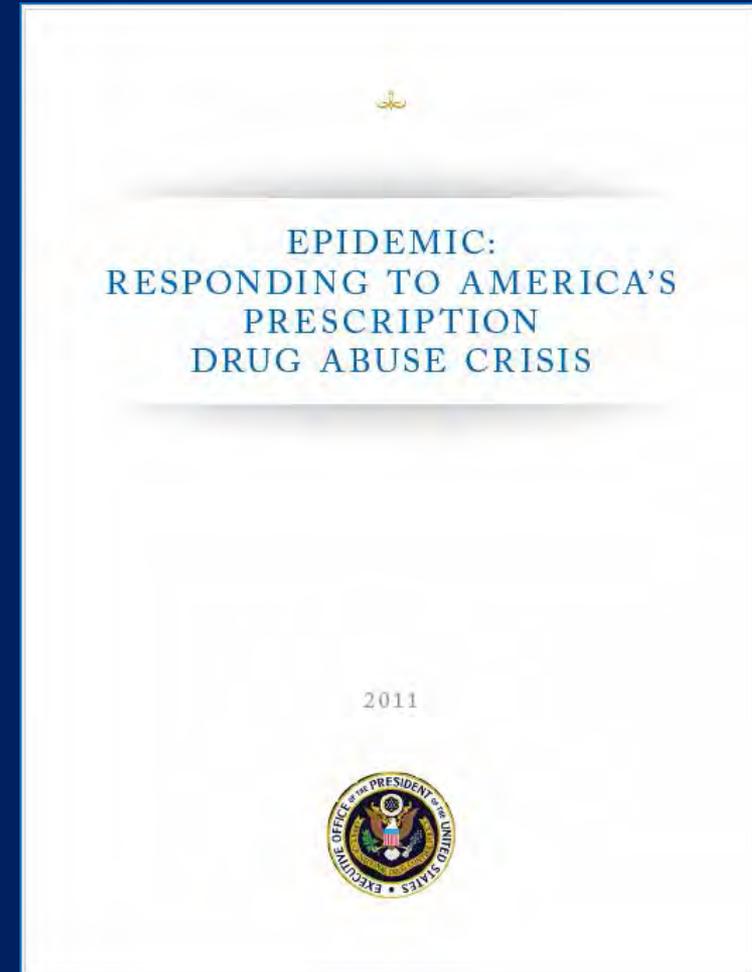


- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education and prevention efforts.



Prescription Drug Abuse Prevention Plan

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





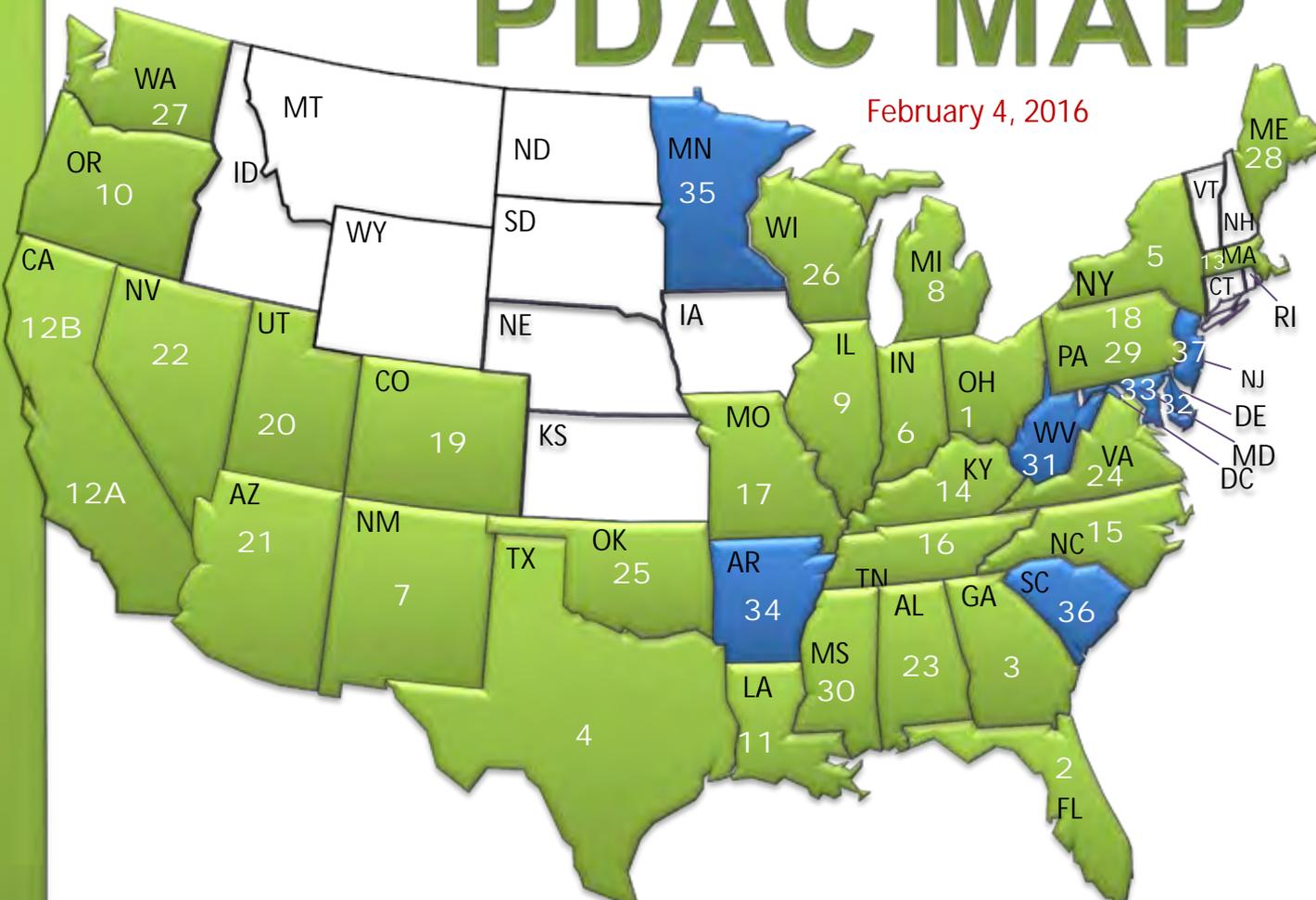
DEA Registrant Initiatives

Pharmacy Diversion Awareness Conference

This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity

PDAC MAP

February 4, 2016



Completed PDACs	Attendance
FY-2011	
1-Cincinnati, OH 9/17-18/11	75
FY-2011 Total Attendance	75
FY-2012	
2-WPB, FL 3/17-18/12	1,192
3-Atlanta, GA 6/2-3/12	328
4-Houston, TX 9/8-9/12	518
5-Long Island, NY 9/15-16/12	391
FY-2012 Total Attendance	2,429
FY-2013	
6-Indianapolis, IN 12/8-9/12	137
7-Albuquerque, NM 3/2-3/13	284
8-Detroit, MI 5/4-5/13	643
9-Chicago, IL 6/22-23/13	321
10-Portland, OR 7/13-14/13	242
11-Baton Rouge, LA 8/3-4/13	259
12A-San Diego, CA 8/16-17/13	353
12B-San Jose, CA 8/18-19/13	434
13-Boston, MA 9/21-22/13	275
FY-2013 Total Attendance	2,948
FY-2014	
14-Louisville, KY 11/16-17/13	149
15-Charlotte, NC 2/8-9/14	513
16-Knoxville, TN 3/22-23/14	246
17-St. Louis, MO 4/5-6/14	224
18-Philadelphia, PA 7/12-13/14	276
19-Denver, CO 8/2-3/14	174
20-SLC, UT 8/23-24/14	355
21-Phoenix, AZ 9/13-14/14	259
FY-2014 Total Attendance	2,196
FY-2015	
22-Las Vegas, NV 2/7-8/15	193
23-Birmingham, AL 3/28-29/15	296
24-Norfolk, VA 5/30-31/15	410
25-Oklahoma City 6/27-28/15	253
26-Milwaukee, WI 7/25-26/15	114
27-Seattle, WA 8/8-8/9/15	210
28-Portland, ME 9/12-9/13/15	94
FY-2015 Total Attendance	1,570
FY-2016	
29-Pittsburgh, PA 12/10-11/15	196
30-Jackson, MS 1/9-10/116	185
Total Attendance To Date	9,599

Proposed FY-2016 PDACs

- 31-Charleston, WV February 27 & 28, 2016
- 32-Wilmington, Delaware March 19 & 20, 2016
- 33-Towson, Maryland April 17 & 18, 2016
- 34-Little Rock, Arkansas June 15 & 16, 2016
- 35-Minneapolis/St. Paul, Minnesota July 16 & 17, 2016
- 36-Charleston, South Carolina August 2016
- 37-New Brunswick, New Jersey September 2016

- Completed PDACs
- Proposed PDACs



DEA Registrant Initiatives

- The Federation of State Medical Boards (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public
- DEA and FSMB are currently working on developing strategies to work more effectively and jointly on indiscriminate prescriber investigations in order to facilitate the administrative process to take action against those that are a threat to the public health and welfare quickly, and at the same time not jeopardize a criminal investigation



DEA Registrant Initiatives

“Stakeholders’ Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances”

- Represents the medical, pharmacist, and supply chain spectrum highlighting the challenges and “red flag” warning signs related to prescribing and dispensing controlled substance prescriptions
- The goal was to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose, as well as to provide guidance on which red flag warning signs warrant further scrutiny
- NABP along with 10 national associations and 6 major pharmaceutical firms were the coalition of stakeholders of this document.

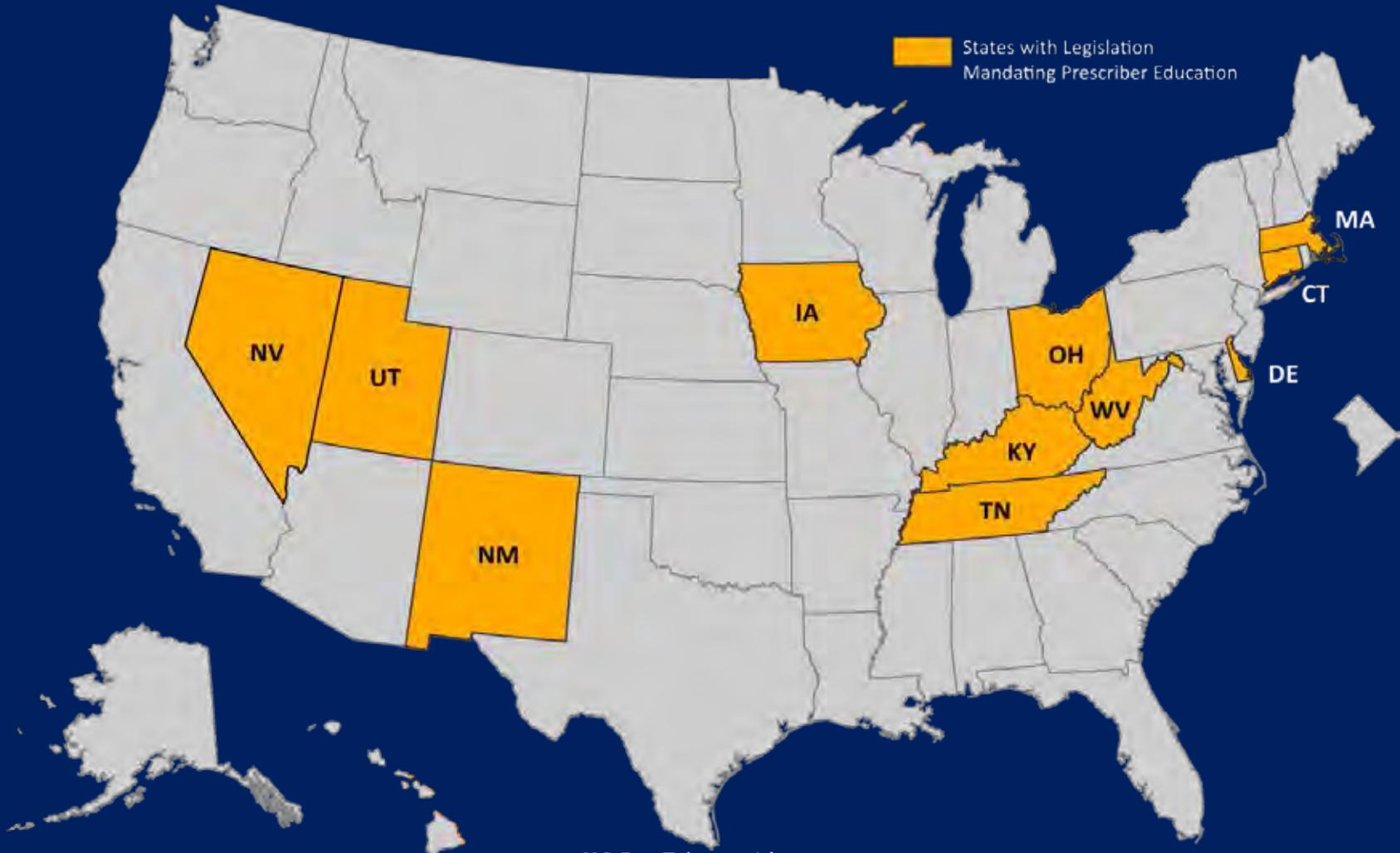


Scheduled Investigations

- Increase in the number of DEA registrants that are required to be investigated to ensure compliance with the Controlled Substances Act and its implementing regulations
- Increase in the frequency of the regulatory investigations
- Verification investigations of customers and suppliers



Since 2011, Eleven States have Passed Legislation Mandating Prescriber Education





National Take Back Initiative

April 30, 2016

Got **Drugs?**

Turn in your
unused or expired
medication for safe disposal
Saturday **April 30, 2016**

Click here
for a collection
site near you.

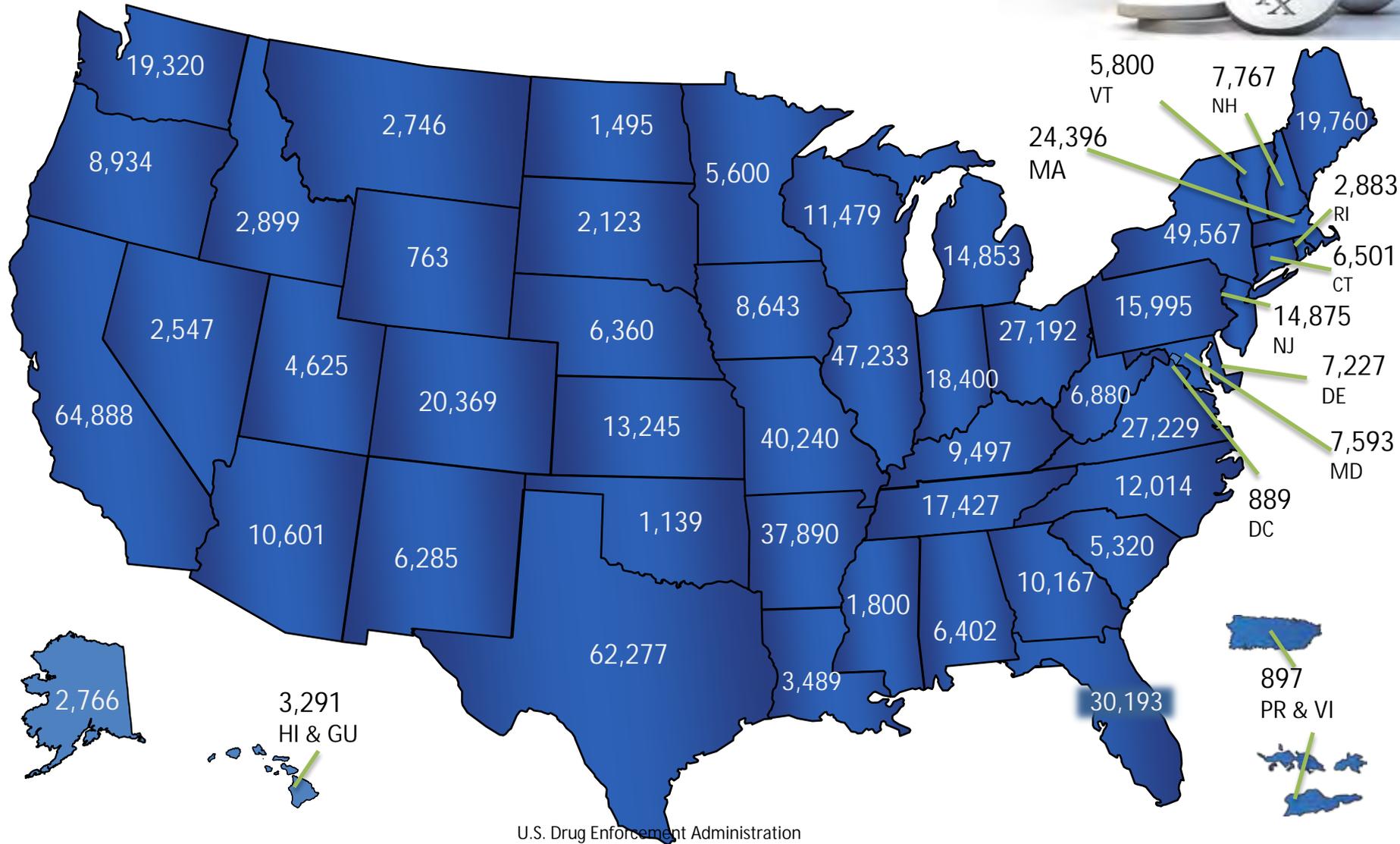


10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration
Office of Diversion Control

10th National Take Back Day: **September 26, 2015**

Total Weight Collected (pounds): 742,771 (371 Tons)





Miscellaneous Pharmacy Topics





Changes to a Schedule II Prescription

Pharmacist may change:

- Patient's address upon verification
- Dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner.
 - Consultation should be noted on the prescription
 - Must be in compliance with state law/regulation/policy

Pharmacy may not make changes:

- Patient's name
- Controlled substance prescribed (except for generic substitution permitted by state law), or
- Prescriber's signature



Multiple Prescriptions

Schedule II Controlled Substances

- Individual practitioner may issue multiple prescriptions which authorizes patient to receive 90-day supply of C-II
 - § Each separate prescription is for legitimate medical purpose issued by practitioner acting in usual course of professional practice
 - § Written instructions on each prescription indicating earliest date it can be filled
 - § Doesn't cause undue risk of diversion by patient
 - § Compliance with all other elements of CSA and state laws

21 CFR § 1306.12(b)



Faxed Prescription vs. EPCS

- True electronic prescriptions are transmitted as **electronic data files** to the pharmacy, whose application imports the data file into its database.
- A system that allows the prescriber to “sign” his/her name does **NOT** conform to EPCS regulations.
- A facsimile with a written signature is **NOT** an electronic Rx.

21 CFR § 1306.05(d)





Hospice & LTCF Prescriptions

Schedule II narcotic substances may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile

§ Practitioner (or agent) must note it is hospice patient

§ Facsimile serves as original written prescription

21 CFR § 1306.11(f), (g) & 1306.13(b)

Schedule III-V prescription

- Written prescription signed by a practitioner, or
- Facsimile of a written, signed prescription transmitted by the practitioner (or agent) to the pharmacy, or
- Oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist



Distribution by Pharmacy to Practitioner

- Practitioner registered to dispense may distribute a quantity of such substance to another practitioner for general dispensing
 - Purchaser must be registered with DEA
 - Schedule III-V - records by purchaser and receiver must conform to 21 CFR § 1304.22(c)
 - Schedule I or II - an order form must be used and must conform to 21 CFR § 1305
 - Total number of controlled substances dispensed cannot exceed 5% of total controlled substances dispensed

21 CFR § 1307.11(a)(1)



Repackaging by Pharmacy

- Practitioner can prepare, compound, package, or label in the course of his professional practice
21 CFR § 1300.01(b)
- Pharmacy can **NOT** repackage drugs (ie 100 ct bottle packaged in smaller size bottles) and sell the drugs in the form of a distribution to any DEA Registrant – including practitioner office.
- Violation of DEA and FDA regulations



Secure and Responsible Drug Disposal Act of 2010



The Problem: Easy Access





Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner

21 USC § 822(f) & (g)

- Registrants authorized to collect:
 - Ø Manufacturers
 - Ø Distributors
 - Ø Reverse Distributors
 - Ø Narcotic Treatment Programs
 - Ø Hospitals/clinics with an on-site pharmacy
 - Ø Retail Pharmacies

Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.

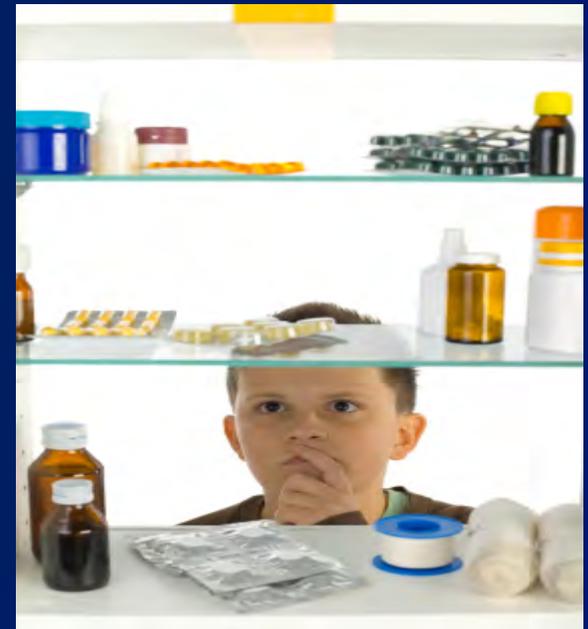
21 CFR § 1317.40



Secure and Responsible Drug Disposal Act of 2010

- ü Ultimate users now have more locations where they can securely, safely, responsibly, and conveniently dispose of their unwanted pharmaceutical controlled substances.

- ü Expected benefit to the public by:
 - Decreasing the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
 - Protecting the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users.





Ultimate User

Ultimate user means as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”

21 USC § 802(27)

Ultimate user methods of destruction prior to Disposal rule:

- ü Disposal in Trash (ONDCP method); or
- ü Flushing (FDA opioids and select CSs)
- ü National Take-back Event (DEA)
- ü Transfer to Law Enforcement
- ü (Police Station Receptacles or local Take-back events)
- ü DEA



Secure and Responsible Drug Disposal Act of 2010

- Regulations did not limit the ways that ultimate users may dispose of pharmaceutical controlled substances ...**they expanded them**
- Any method of pharmaceutical disposal that was valid for **ultimate users** prior to these regulations remains valid
- Participation is voluntary
- The DEA may not require any person to establish or operate a disposal program

21 USC § 822(g)(2)



Secure and Responsible Drug Disposal Act of 2010

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



Law Enforcement

- Law Enforcement may continue to conduct take-back events.
- Any person may partner with Law Enforcement.
- Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- Authorized collection receptacles and inner liners “should” be used.



21 CFR §§ 1317.35 and 1317.65



Collection



Collection

Collection means to receive a controlled substance for the purpose of destruction from an:

- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC § 822(g)(3) & (4) and 21 CFR § 1300.01(b)





Collection Receptacles



Collection Receptacles

- Ultimate users *shall* put the substances directly into the collection receptacle.
- Controlled and non-controlled substances may be comingled.
- Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Registrants shall not dispose of stock/inventory in collection receptacles.

21 CFR § 1317.75(b) and (c)



Collection at LTCF

A registered hospital/clinic with an on-site pharmacy or a registered retail pharmacy may request modification of their registration to become an authorized collector to maintain a collection receptacle at a LTCF

21 CFR § 1317.80

Request must include:

- Name and physical location of each LTCF at which a collection receptacle will be operated

No fee is required for this modification request

21 CFR § 1301.51(b)(2) and (c)



Collection Receptacle Location

- **Registered location** – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
- **LTCF** – located in secure area regularly monitored by LTCF employees.
- **Hospital/clinic** – located in an area regularly monitored by employees---**not** in proximity of where emergency or urgent care is provided.
- **NTP** – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)



Design of Collection Receptacles





Design of Collection Receptacles

- Securely fastened to a permanent structure.
- Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.

21 CFR § 1317.75(e)





Design of Collection Receptacles

- Outer container must display a sign stating only Schedule II-V and non-controlled substances are acceptable substances.
- Substances **Not Permitted** to be collected:
 - **Schedule I** controlled substances,
 - Controlled substances that were **not lawfully possessed** by the ultimate user, and
 - All other illicit substances (including **marijuana in states like CO and WA**)

21 CFR § 1317.75(e)



Collection Receptacle Inner Liner

- ü Waterproof, tamper-evident, and tear-resistant.
- ü Removable and sealable upon removal without emptying or touching contents.
- ü Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- ü Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- ü Outside of liner shall have permanent, unique ID number.

21 CFR § 1317.60(a)



Mail-Back Program

Requirements of mail-back program

- Ø Only lawfully possessed schedules II-V controlled substances may be collected
- Ø Controlled and non-controlled substances may be collected together
- Ø Must have method of on-site destruction

21 CFR § 1317.70 (b)



Registrant Disposal



Registrant Disposal - Inventory

Practitioner & Non-Practitioner may **dispose of inventory**:

- Prompt on-site destruction
- Prompt delivery to **reverse distributor** by **common or contract carrier** or reverse distributor pick-up
- Return and recall : Prompt delivery by common or contract carrier or pick-up at the registered location

Practitioner may **also** request assistance from the SAC

Non-practitioner may **also** transport by its own means

21 CFR § 1317.05(a) and (b)



DEA Form 41

- Form 41 shall be used to record the destruction of all controlled substances, including controlled substances acquired from collectors.
 - The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.
 - Exceptions for DEA Form 41:
 - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
 - Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41

21 CFR § 1304.21(e)



Abandoned Controlled Substances

- Circumstances when there is no authorized person to dispose of controlled substances
 - Ø School
 - Ø Summer camp
 - Ø Hospital
- Return to ultimate user is not feasible
- Options
 - Ø Contact law enforcement or DEA
 - Ø Destroy on-site

79 FR 53546 (Disposal Final Rule)



Pharmaceutical Wastage



Pharmaceutical Wastage

- Not subject to 21 CFR Part 1317
 - Destruction does not have to be “non-retrievable”
 - DEA Form 41 must not be utilized
- Dispensing must be recorded as a record
21 CFR § 1304.22(c)
- Clarification memorandum on DEA website at www.deaDiversions.usdoj.gov



DEA Web-Based Resources



*Drug Enforcement Administration/Operations
Division/Office of Diversion Control*



DEA Web-based Resources

www.DEA.gov

justice.gov

DEA.gov / Home

DEA

UNITED STATES
Drug Enforcement Administration

TOUGH WORK, VITAL MISSION

HOME ABOUT CAREERS OPERATIONS DRUG INFO PREVENTION PRESS ROOM

Tough Work, Vital Mission
The Facts About DEA

Drug Facts for Today's Teens
JustThinkTwice.com

A DEA Resource for Parents
GetSmartAboutDrugs.com

Wall of Honor
DEA Remembers

TOP STORY

Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy

JAN 29 (BROWNSVILLE, TEXAS)

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

TOPICS OF INTEREST

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

RESOURCE CENTER

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



DEA Web-based Resources

www.JustThinkTwice.com

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

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** *fact out more*

THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF

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

GET THE FACTS ABOUT METHAMPHETAMINE

MARIJUANA | COCAINE | METH

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

FACTS & FICTION
Get the Facts

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

Did You Know? Combine toxic chemicals with neglected hygiene, and you get a condition called "meth mouth"—rotten and decaying teeth.
[READ MORE](#)



DEA Web-based Resources

www.GetSmartAboutDrugs.com



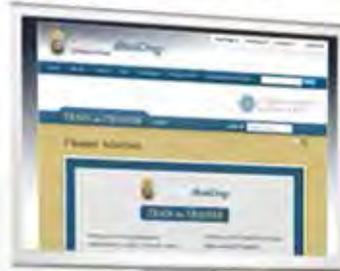
GetSmartAboutDrugs
A DEA Resource for Parents

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

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

[Learn more](#)

COMMUNITIES of PRACTICE



DEA Publications

Download or request
Drugs of Abuse and
Prescription for Disaster

[READ MORE](#)

Watch the Videos

View videos to learn how
to keep your family safe,
including ways to avoid
prescription drug abuse

[VIEW](#)



Latest News [See All News Stories](#)

Drug Court Offers Hope for the Future

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

ER Visits Tied to Energy Drinks Double Since 2007

Jan 16, 2013 Hospitals around the country have seen a gradual uptick in the number of emergency room visits involving energy drinks.

Voices

Irma Perez's Story

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

Inside DEA

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



Ruth.A.Carter@usdoj.gov

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