



DEA Trends & Update

Jackson Pharmacy Diversion Awareness Conference

January 9 & 10, 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

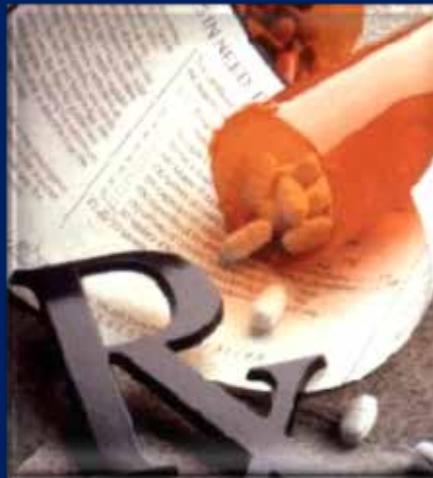


Goals and Objectives

- 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



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



Overdose

A Public Health Epidemic

- Prescription opioids are potentially dangerous drugs – overdoses involving these drugs claimed more than 175,000 lives between 1999 and 2013.



- From 1999 to 2010, a 4-fold increase in opioid sales paralleled a more than 4-fold increase in prescription opioid-involved overdose deaths.



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

NEWS

Study: 70 Percent Of Americans On Prescription Drugs

June 19, 2013 12:59 PM

Like 17k Share 1.8K View Comments



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

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

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

The [study](#) is uncovering valuable information

Ø The three most common types of prescriptions are antibiotics, antidepressants, and painkiller opioids

Ø 70% of Americans are taking at least one prescription drug

Ø More than 50% are on at least two prescriptions

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Women to stand trial in theft of drugs from Norwin Pharmacy



By Paul Perce
 Friday, March 27, 2015, 12:01 a.m.

A North Huntingdon pharmacy technician confessed she stole 180 to 600 pain pills on every shift she worked for more than a year, then handed them over to be sold on the street, according to the state attorney general's office.

Agent Andrew Sakmar testified at a preliminary hearing that former Norwin Pharmacy technician JoAnn Gruber, 53, admitted in an interview last fall that she stole "tens of thousands" of painkillers including oxycodone, Xanax and Cozart, and gave them to Michelle L. Gandy, 41, of

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Package detonated

Police detonate a suspicious package in Oakland outside of Pitt's Biomedical Science Tower (video)

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Washington County pharmacy owner charged with fraud

October 10, 2014 5:26 PM



By Madelyn Czetwinski / Pittsburgh Post-Gazette

The owner of a Pennsylvania pharmacy was charged with fraud Friday after an investigation revealed he allegedly stole \$346,000 from insurance companies by filing false prescription claims, falsified prescriptions and gave multiple patients narcotic pills, the state Attorney General's office announced Friday.

Andrew F. Kury, 61, of Washington County, has been charged with drug diversion, Medicaid fraud, insurance fraud and theft by deception, according to court records.



ADVERTISEMENT

Physician assistants, two others charged in prescription drug scheme

September 22, 2015 10:55 AM



By Andrew Goldstein / Pittsburgh Post-Gazette

Four Allegheny County residents, including two physician assistants, were charged by the state attorney general's office in a prescription drug ring, state Attorney General Kathleen Kane announced.

Dena J. Lazar, 26, of Overbrook; Jill S. Harlan, 32, of Springdale Township; Jodi L. Cantor, 50, of Bridgeville; and Brandon R. Bodnar, 29, of Carnegie, are accused of diverting prescription drugs between March and June 2015.

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



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



Consequences

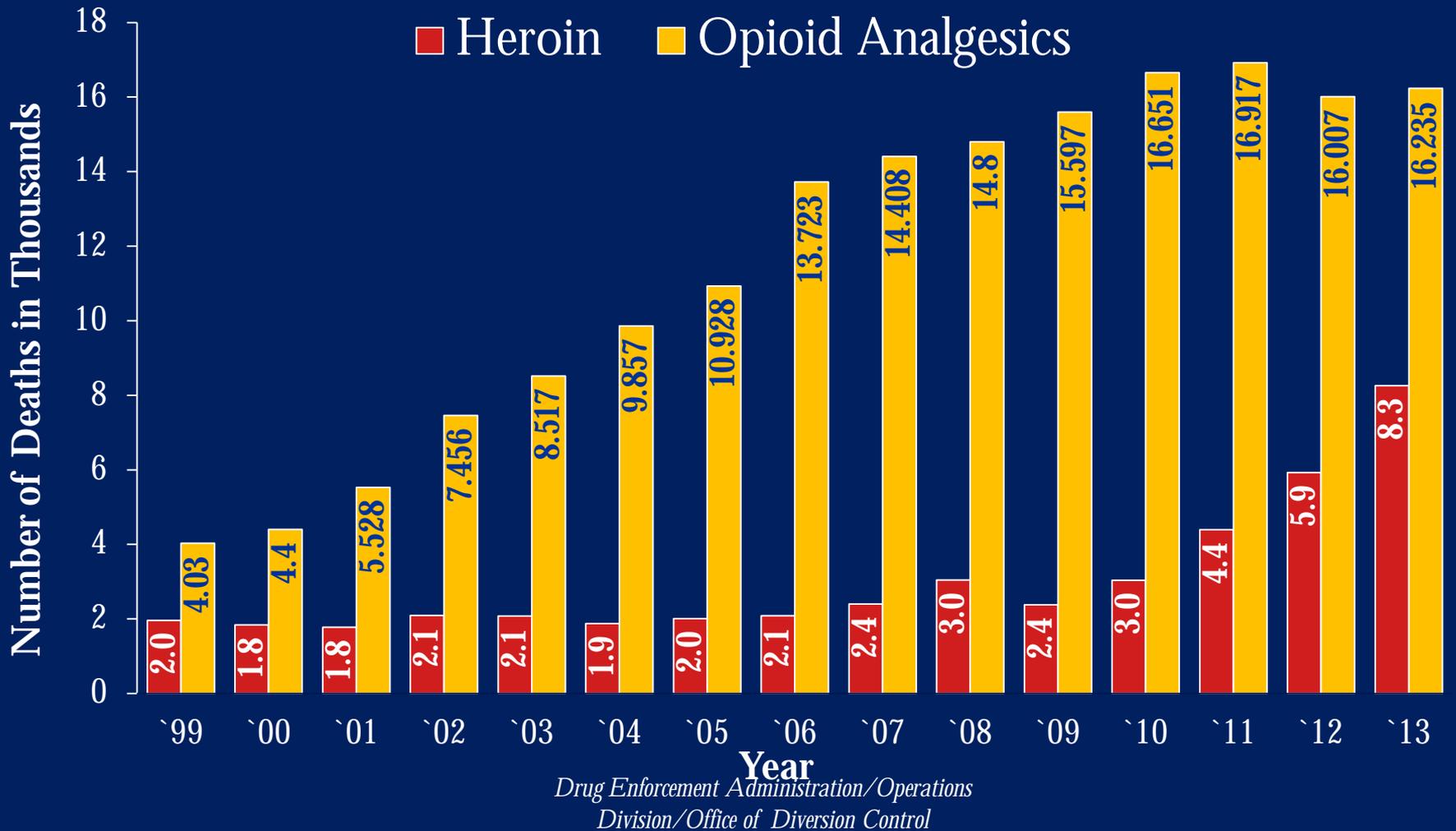
In 2011, approximately **41,340** unintentional drug overdose deaths occurred in the United States, one death every 12.45 minutes. (increased for 12th consecutive year)

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

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



Drug-Poisoning Deaths Involving Opioid Analgesics or Heroin in the US, 1999-2013

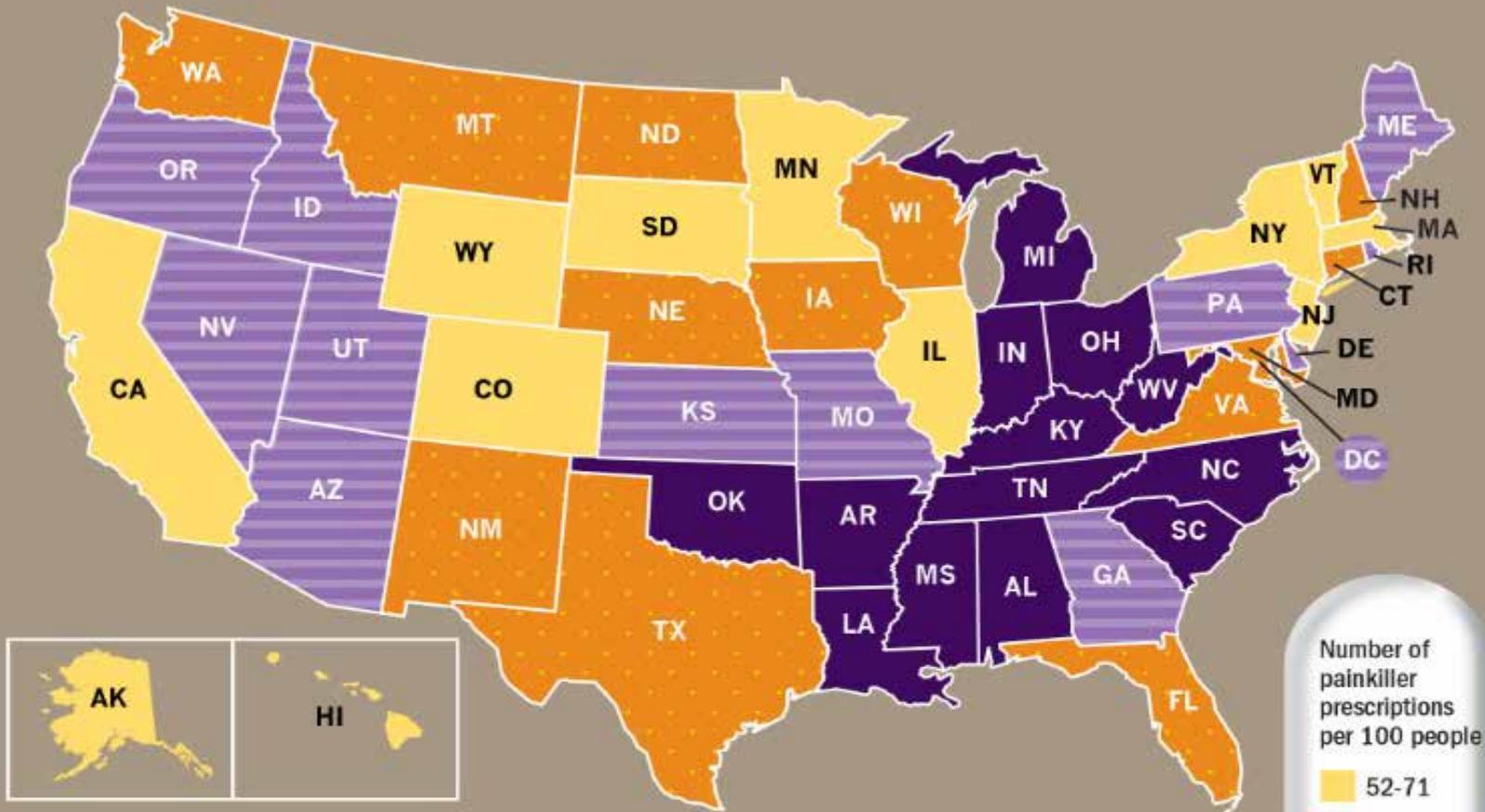




Highest Opiate Prescriptions

- 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

*Drug Enforcement Administration/Operations
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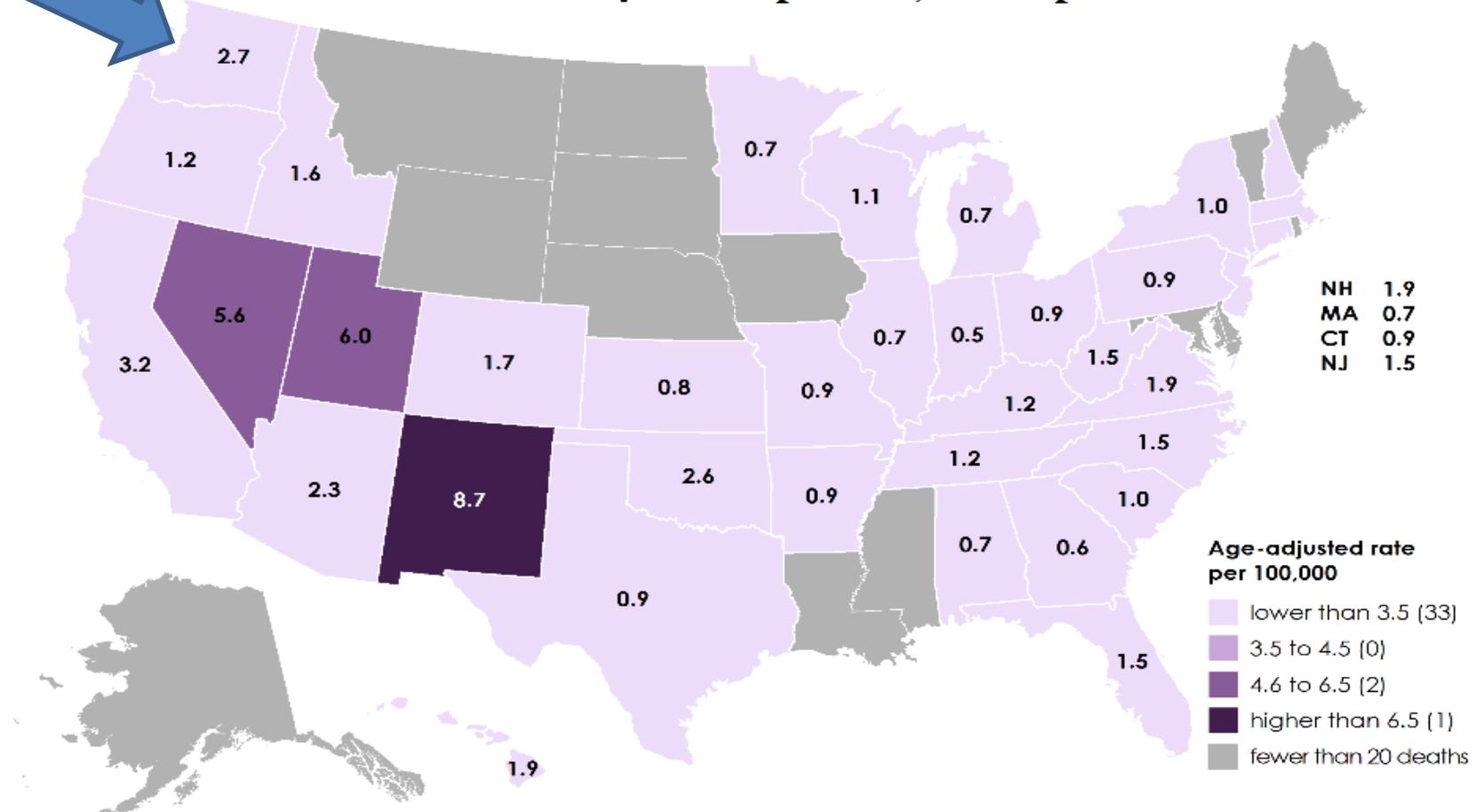
Some states have more painkiller prescriptions per person than others.

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



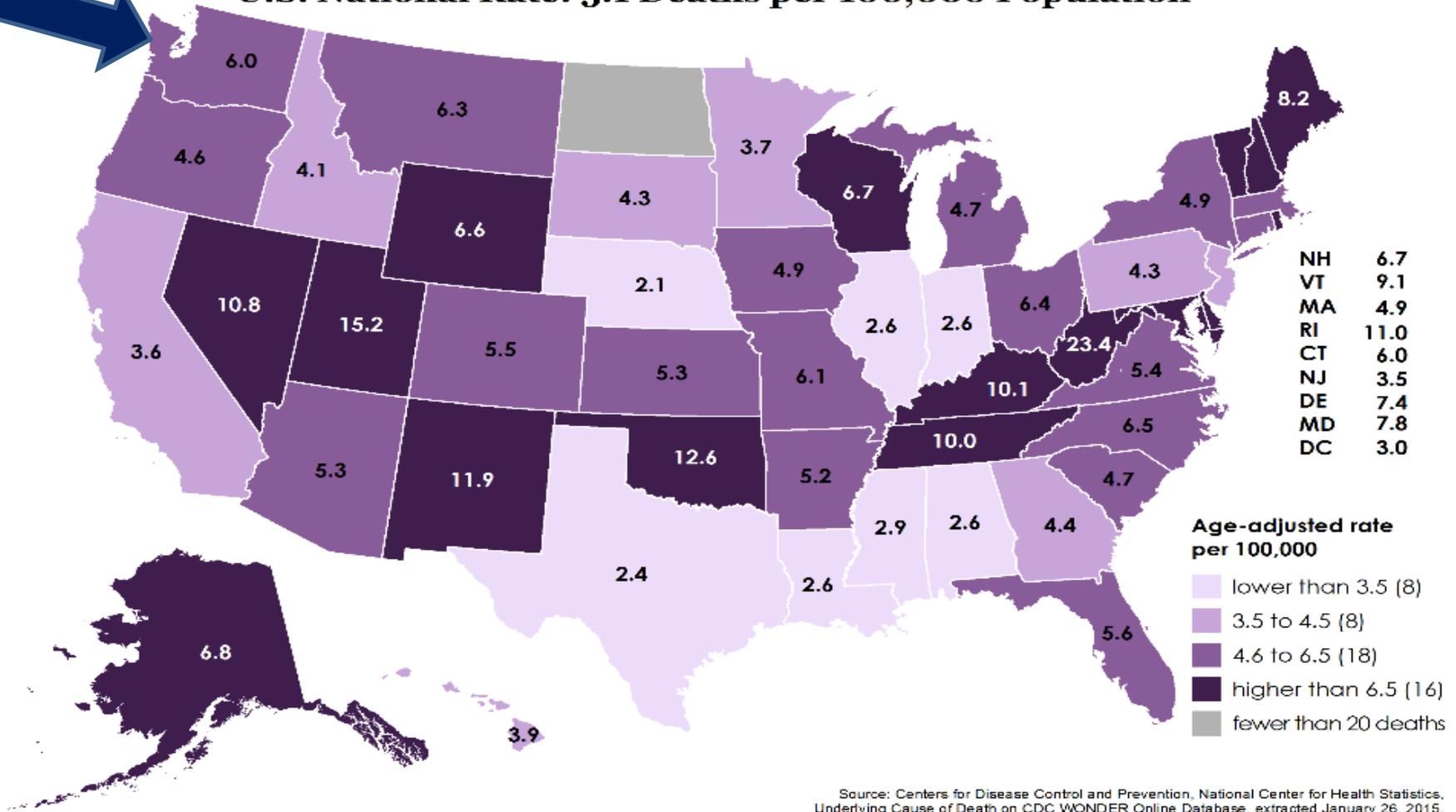
Source: Centers for Disease Control and Prevention, National Center for Health Statistics, Underlying Cause of Death on CDC WONDER Online Database, extracted January 26, 2015.

Prescription Opioid Analgesics Poisoning Deaths

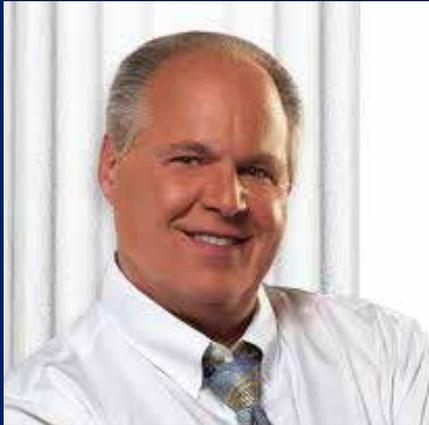


Opioid-Involved Drug Poisoning Death Rates by State, 2013

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



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.



Rush Limbaugh

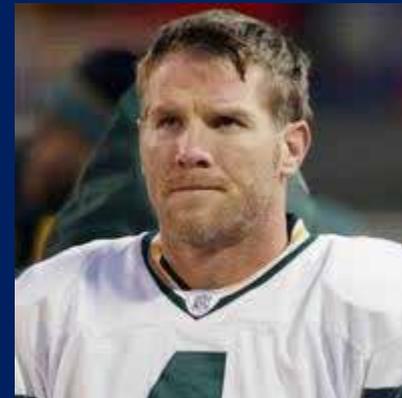


Steven Tyler

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

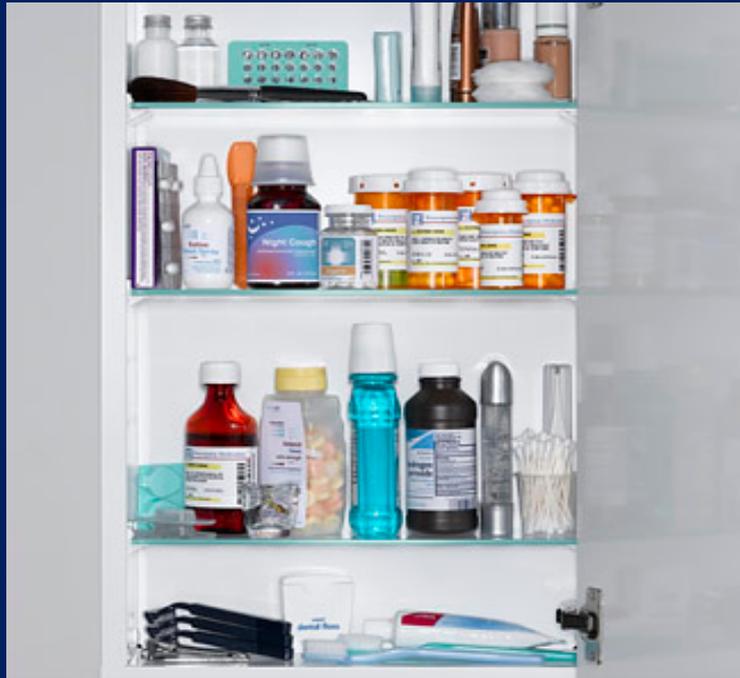


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Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

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



Violence

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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



Ready for mayhem, the brute, struts through the door.



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



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



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

Chilling anatomy of drugstore massacre

He never gave them a chance. The 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

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

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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

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Pharmacist slain in Beach robbery was much beloved

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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



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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!

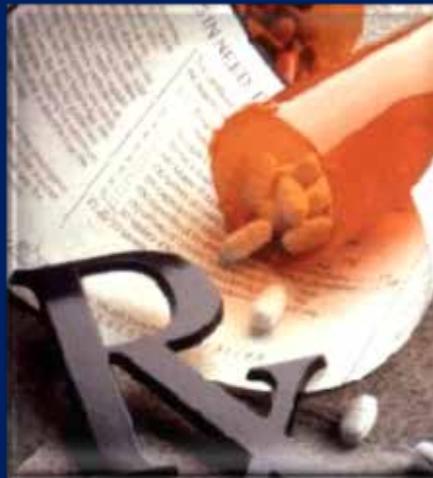
[Daily Deal](#) | [Promote your business](#)

Source:

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



Drugs of Abuse



*Drug Enforcement Administration/Operations
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Opiates



Papaver



Somniferum

Codeine

Morphine

Thebaine

Hydrocodone

Hydromorphone

Oxycodone
Hydrocodone



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

- 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%



***Most commonly prescribed
prescription medicine?***

Hydrocodone/acetaminophen



Estimated World Requirements of Narcotic Drugs 2015

Hydrocodone Top 10 List

Ø 10 Guatemala	10 kilograms
Ø 09 Mexico	10 kilograms
Ø 08 Vietnam	20 kilograms
Ø 07 China	20 kilograms
Ø 06 Denmark	25 kilograms
Ø 05 Columbia	50 kilograms
Ø 04 Syrian Republic	50 kilograms
Ø 03 Germany	60 kilograms
Ø 02 Canada	100 kilograms
Ø 01 United States	79,700 kilograms 99.5%

SOURCE: UN International Narcotics Control Board website. Estimated World Requirements of Narcotic Drugs in grams for 2015 <http://www.incb.org> . Accessed July 15, 2015



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





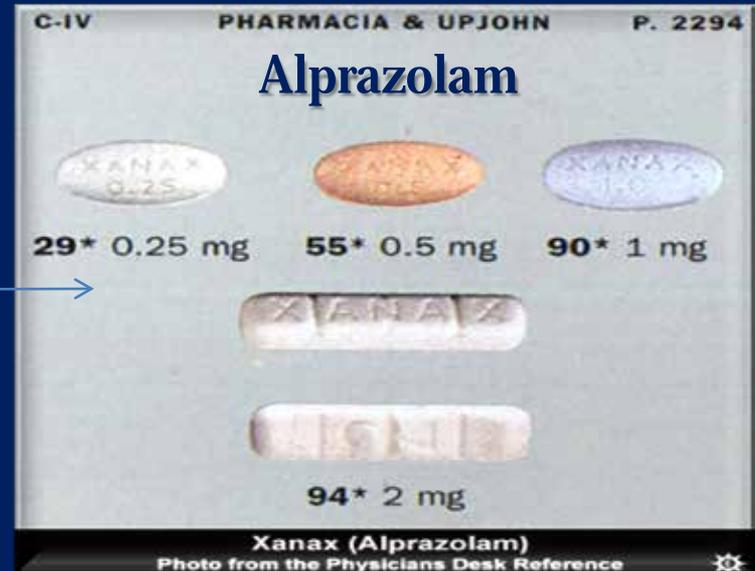
The Trinity



Opiate



Muscle Relaxant



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, light-resistant container as defined in the USP.

Roxane Laboratories, Inc.
Columbus, Ohio 43216

NDC 0054-0264-25 100 Tablets

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

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

BioCringer Technologies
Roxane Laboratories

00540 26425

10005693/02
© RLI, 2009

EXP. LOT

USUAL DOSAGE:
See package insert for prescribing information.

Dispense in a light, light-resistant container as defined in the USP with a child-resistant closure.

Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].
Rx: 1299 10 315

NDC 0527-1355-01

Lannett

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

Rx Only
100 TABLETS

Each Tablet Contains:
Hydromorphone Hydrochloride, USP 8 mg

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

Manufactured by:
Lannett Company, Inc.
Philadelphia, PA 19106

Made in the USA

0527-1355-01

LOT #
Exp. Date



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

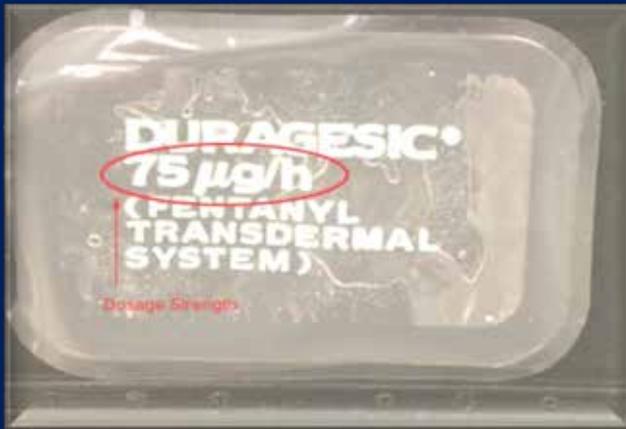


Trade Name: Dilaudid
Controlled Ingredient:
hydromorphone hydrochloride, 2 mg



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



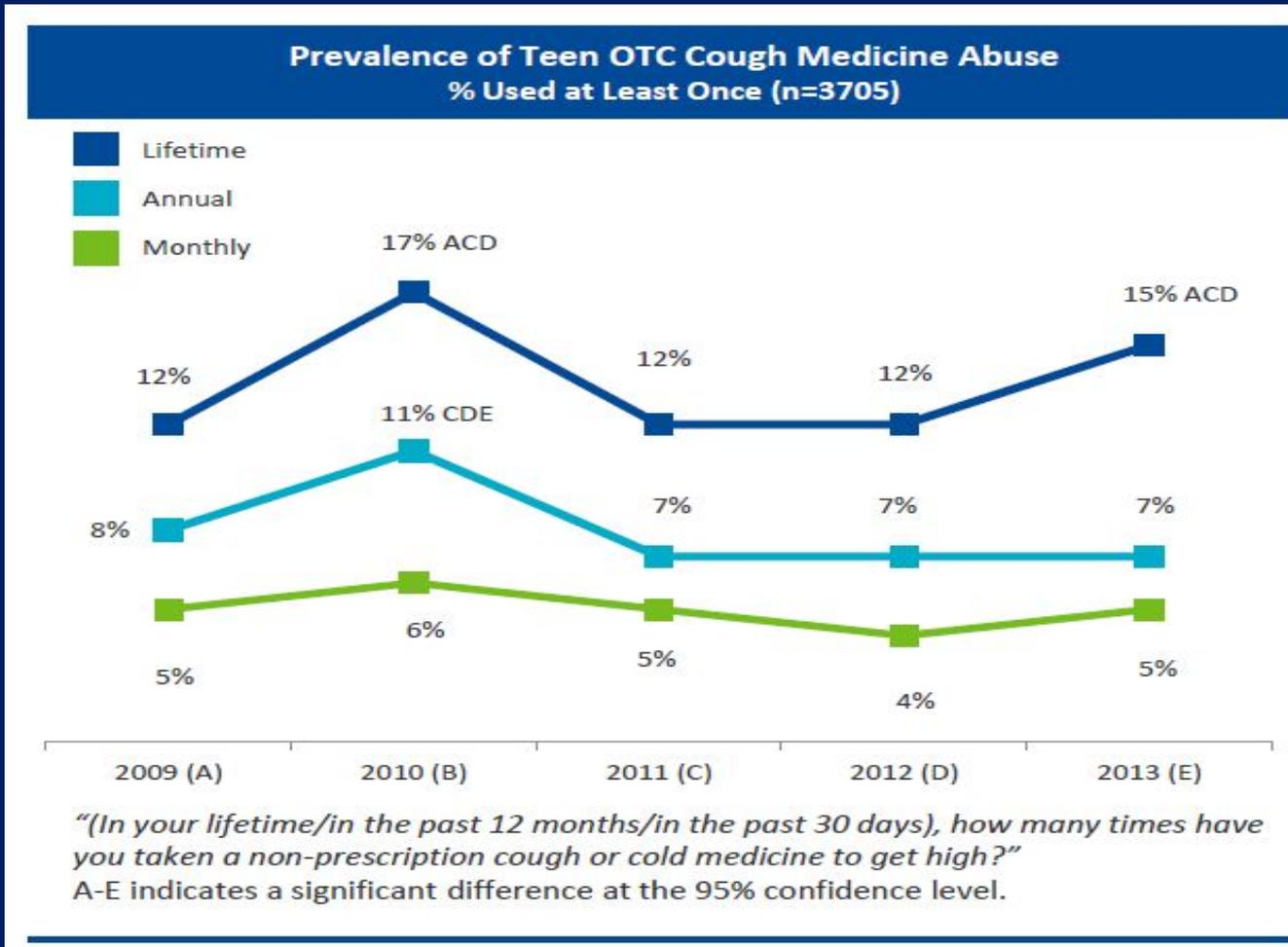
Dextromethorphan (DXM)

- 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





Methadone- 5mg & 10mg



Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg



NDC 0406-0540-34 **100 TABLETS**

METHADOSE™
 Dispersible Tablets **Ⓒ II**
 (Methadone Hydrochloride
 Tablets for Oral Suspension USP)

40 mg

Each tablet contains:
 Methadone Hydrochloride USP..... 40 mg
Rx only

Mallinckrodt

COVIDIEN™

Usual Dosage:
 See accompanying literature for dosage.

Keep tightly closed.

Dispense in a tight container (USP) with a child-resistant closure.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.,
 Hazelwood, MO 63042 USA.

3 0406-0540-34 7

100 TABLETS



Treatment of Narcotic Addiction



WHY IS IT ALSO USED AS AN ANALGESIC?

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?

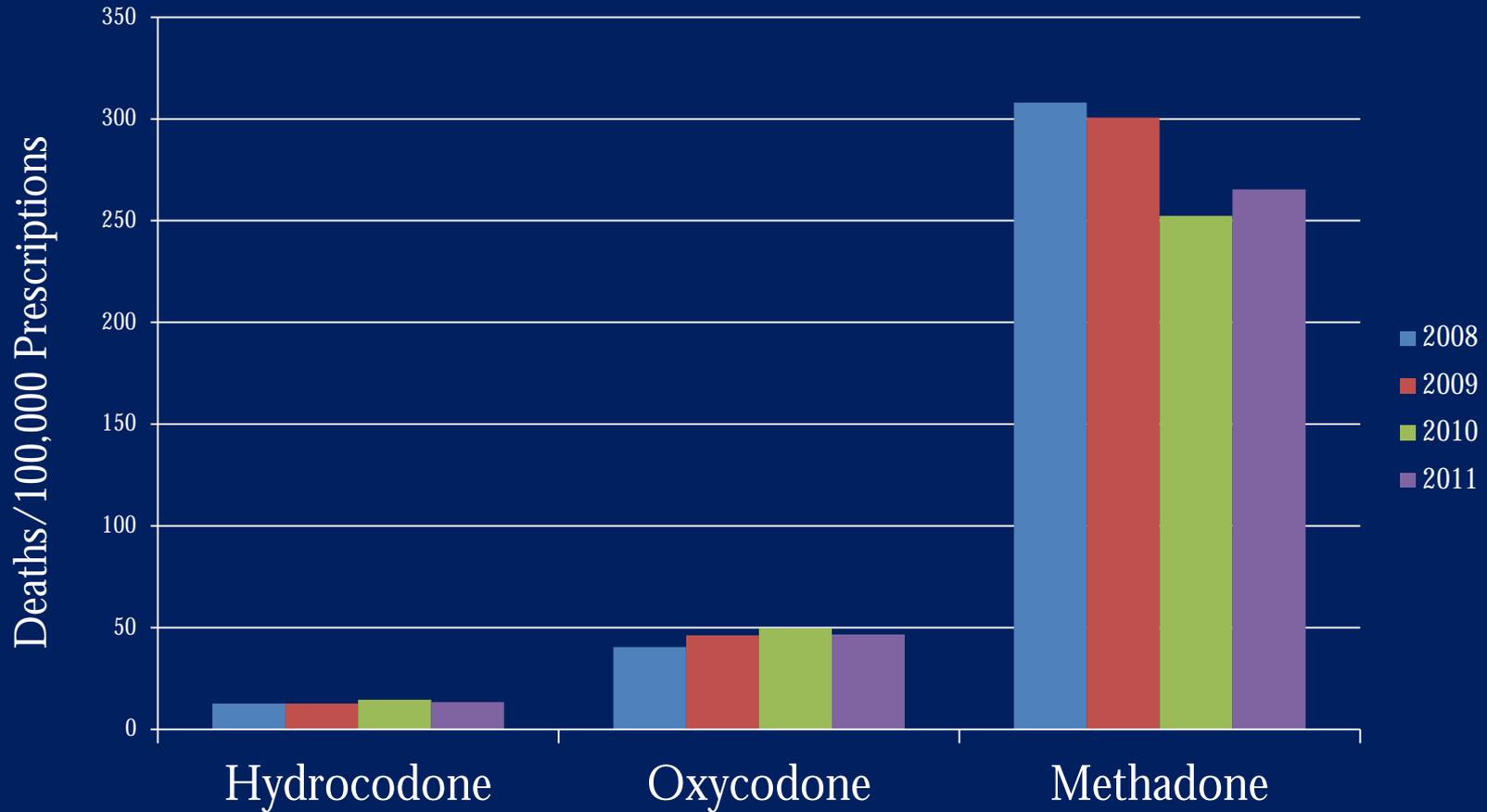


Overdose...Why?

- 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



Florida Deaths Per 100,000 Prescriptions 2008-2011



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



One Pill can Kill



CE Article: (ACCME, CMI, ACEI) 1 CE credit for this article

By Jonathan J. Lipman, PhD

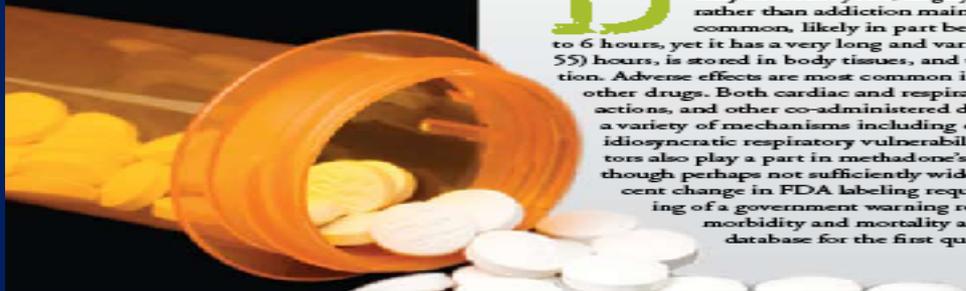
THE METHADONE POISONING "Epidemic"

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.





Prescription Opiates v. Heroin



*Drug Enforcement Administration/Operations
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Circle of Addiction & the Next Generation

Oxycodone
Combinations

Percocet®

\$7-\$10/tab

OxyContin®
\$80/tab

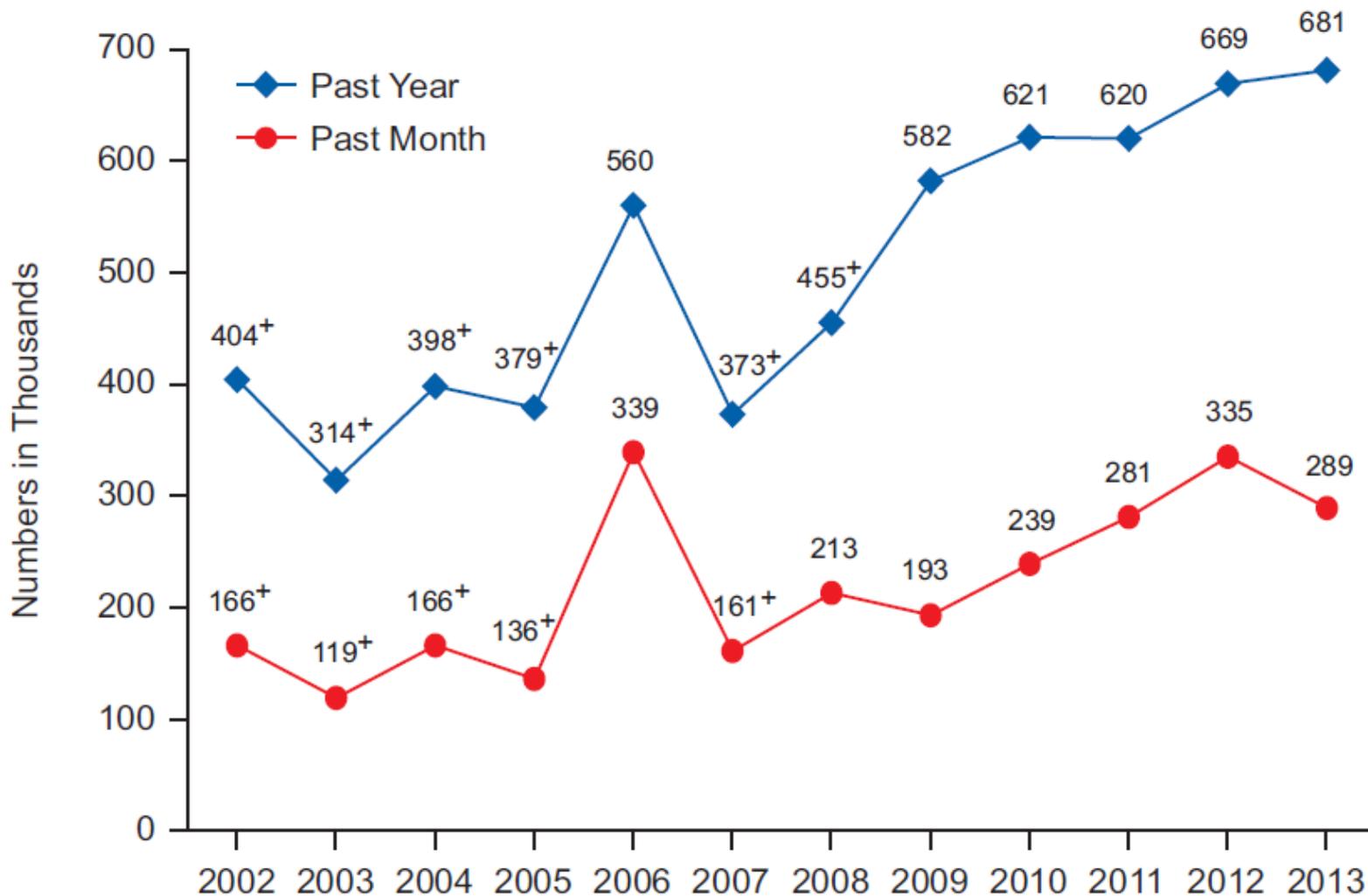
Roxicodone®
Oxycodone
IR 15mg,
30mg
\$30-\$40/tab

Hydrocodone
Lorcet®
\$5-\$7/tab

Heroin
\$15/bag



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.

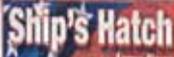


HEROIN: NO LONGER CONFINED TO URBAN AREAS


NOW OPEN
DARCARS
 See what it's like to have car bought
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 Sales & Service
 12511 Prosperity Drive • Silver Spring, MD 20904
1-888-589-3065
 www.DARCARSvolkswagen.com
 Call / Email Alex Pedron, General Sales Manager
 APedron@Darcars.com

washingtonexaminer.com

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 WEDNESDAY, DECEMBER 5, 2012


Ship's Hatch
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'Liaisons Dangereuses'
 New approach to classic P. 19


Playoff possibilities
 Schedule favors Skins P. 35

Cooling down

60°-34°
 DETAILS P. 4

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

LOCAL
FBI analyst busted

Heroin use spikes in area suburbs

Pill addicts risk deadly drug

*Drug Enforcement Administration/Operations
 Division/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. Lankeau 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





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





United States V. Alvin Yee, M.D.

CURES Data (PMP)

- During a one-year time period, Yee wrote prescriptions for a total of 876,222 dosage units of all medications combined.
- 52% of all prescriptions (458,056 dosage units) written by Yee were for oxycodone during the referenced time period.
- The top five most commonly abused and diverted prescription drugs – oxycodone, hydrocodone, alprazolam, hydromorphone, and oxymorphone – accounted for 96% of all prescriptions written by Yee.





United States V. Alvin Yee, M.D.

CURES Data (PMP)

- Of the oxycodone prescriptions written by Yee, 92% were for the strongest form of immediate release oxycodone available, 30 mg, which is also the highest in demand by both drug abusers and traffickers.
- Almost half of Yee's patients were 25 and under.





United States V. Alvin Yee, M.D.

MEDICAL OFFICE

Various Locations, Orange County, California



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, Pills / by thefrankness



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 Rodriquez, the Office Manager





Intracoastal Medical Group



A relative of Boyd's would make sure cars with out-of-state license plates didn't park at his pill mill clinic.



Intracoastal Medical Group



Boyd paid \$47,102 for this 1990 military custom truck.

According to a [online description of the monster truck](#), it has a turbocharged engine, a Hummer fabricated front end, custom handmade front and rear bumpers, a custom overhead LED light bar with a catwalk, hidden LED front driving lights, a custom bed, and, oh yeah, a 50 caliber machine gun mounted on top.

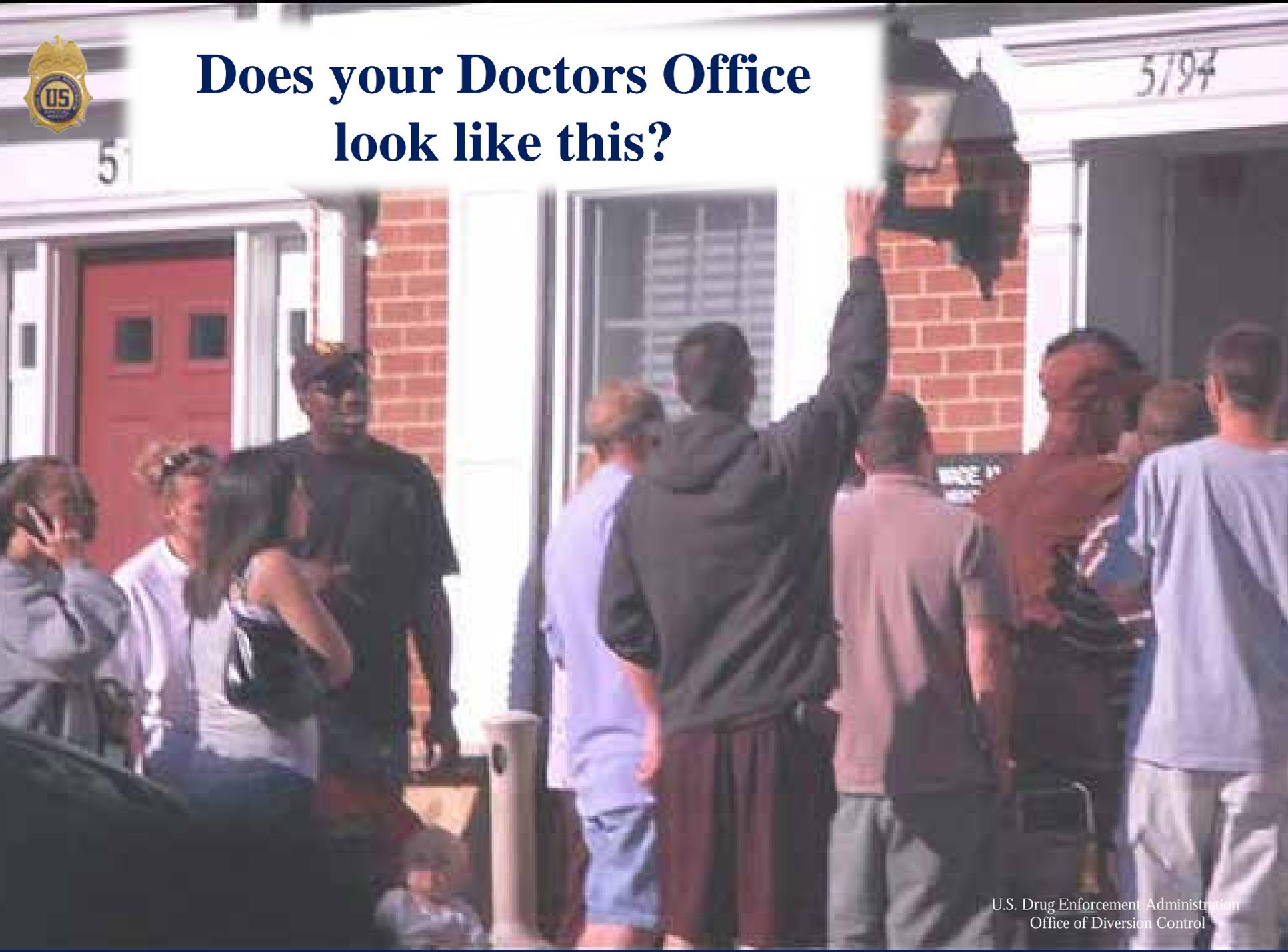


Investigative Results

- **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?

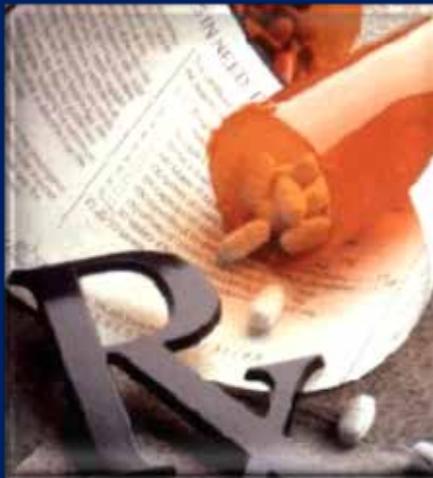








The Controlled Substances Act: Checks & Balances



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



Mission

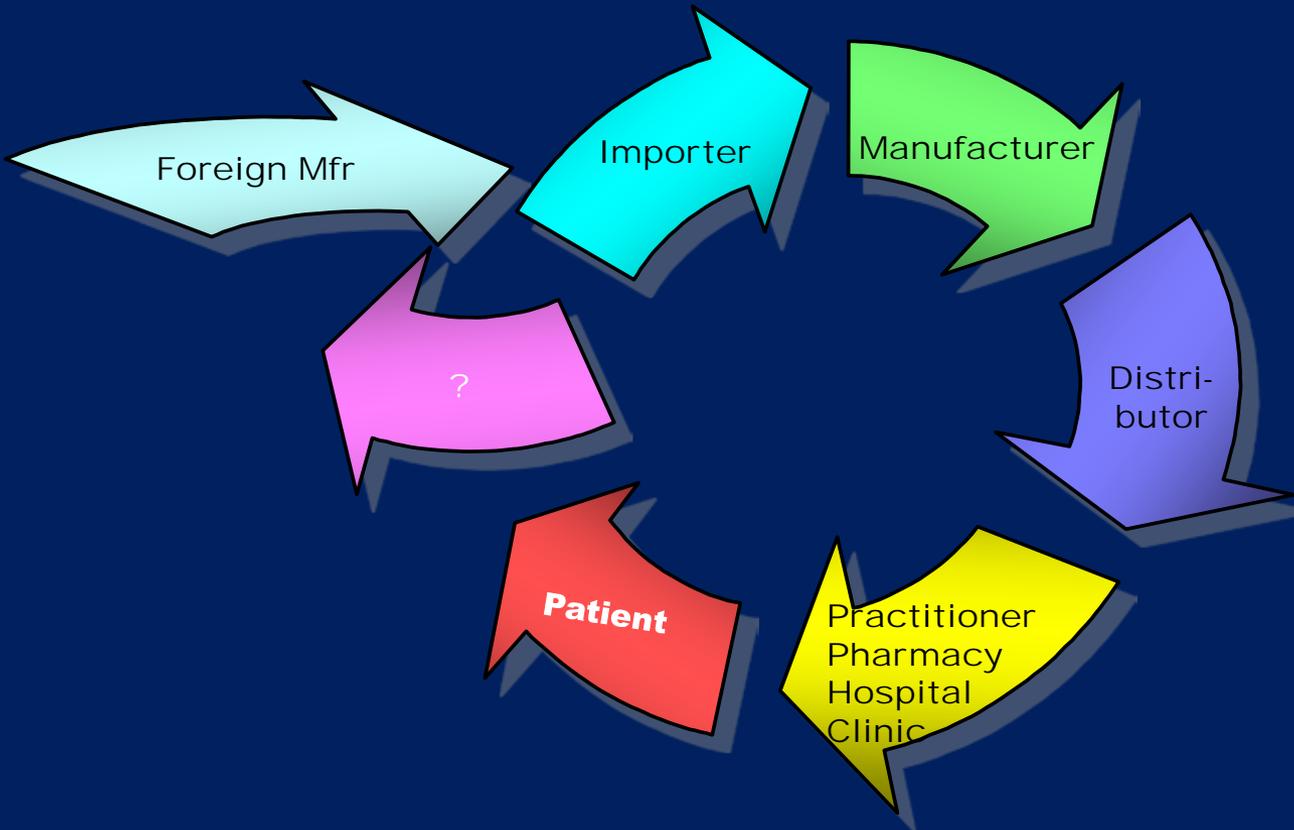
The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

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



Closed System of Distribution

The DEA is responsible for:

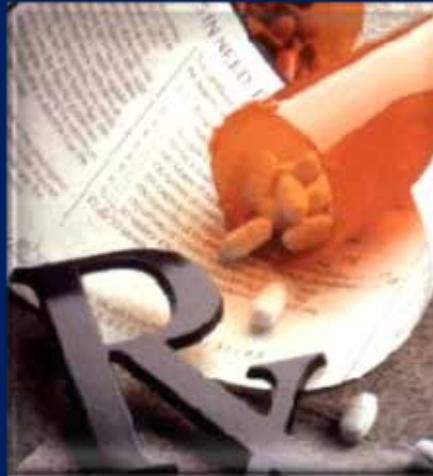
- the oversight of the system
- the integrity of the system
- the protection of the public health and safety



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



Legal Obligations: DEA Registrant



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



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)

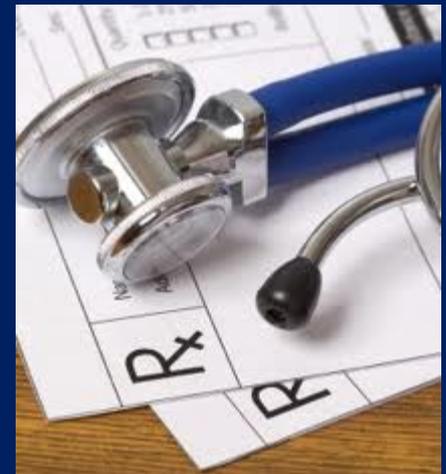


Prescriptions

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.

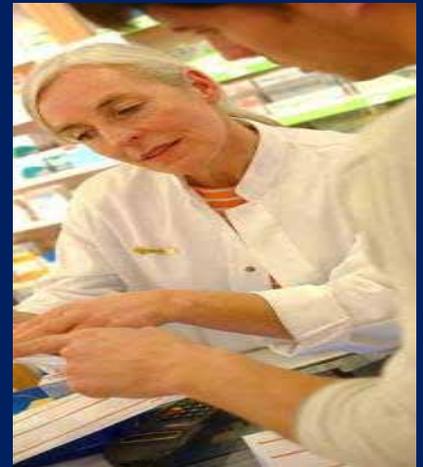
21 CFR § 1306.04(a)





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



*Drug Enforcement Administration/Operations
Division/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 circular emblem 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 is located in the top right corner with a 'GO' button. Below the logo and search bar is a navigation menu with links for HOME, ABOUT, PROGRAMS, PUBLICATIONS, NEWS, MEETINGS, and CONTACT. A secondary navigation bar includes links for BOARDS OF PHARMACY, MEMBERS, PHARMACISTS, STUDENTS, TECHNICIANS, GOVERNMENT AFFAIRS, and CONSUMERS. A chat bubble icon is present with the text 'QUESTIONS? CHAT IS AVAILABLE'. The main content area features a 'Meet the NABP Executive Committee' section with a photo of Edward O. McGinley, MBA, RPh, and a text block about the 2015-2016 Executive Committee. To the right is a large red banner for the 'redflag' campaign with the headline 'Do You Know What a Doctor Shopper Looks Like?' and a paragraph about prescription drug abuse. Below the banner are four orange buttons: 'Red Flags for Pharmacists', 'Verified Pharmacy Program', 'DRE Monitor', and 'Safe Online Pharmacies'. At the bottom, there is a 'NEWSROOM HEADLINES' section with a 'SEE MORE' link.

NABP
NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Search the site... **GO**

[e-Profile Login and ID Quick Search](#)

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QUESTIONS? **CHAT IS AVAILABLE**

Meet the NABP Executive Committee



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

2015-2016 Executive Committee

Officers

Chairperson – Joseph L. Adams, RPh
President – Edward O. McGinley, 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.



Red Flags for Pharmacists **Verified Pharmacy Program** **DRE Monitor** **Safe Online Pharmacies**

NEWSROOM HEADLINES [SEE MORE](#)



Practical Application of the Controlled Substances Act to the Current Rogue Pain Clinic Situation



CVS Florida

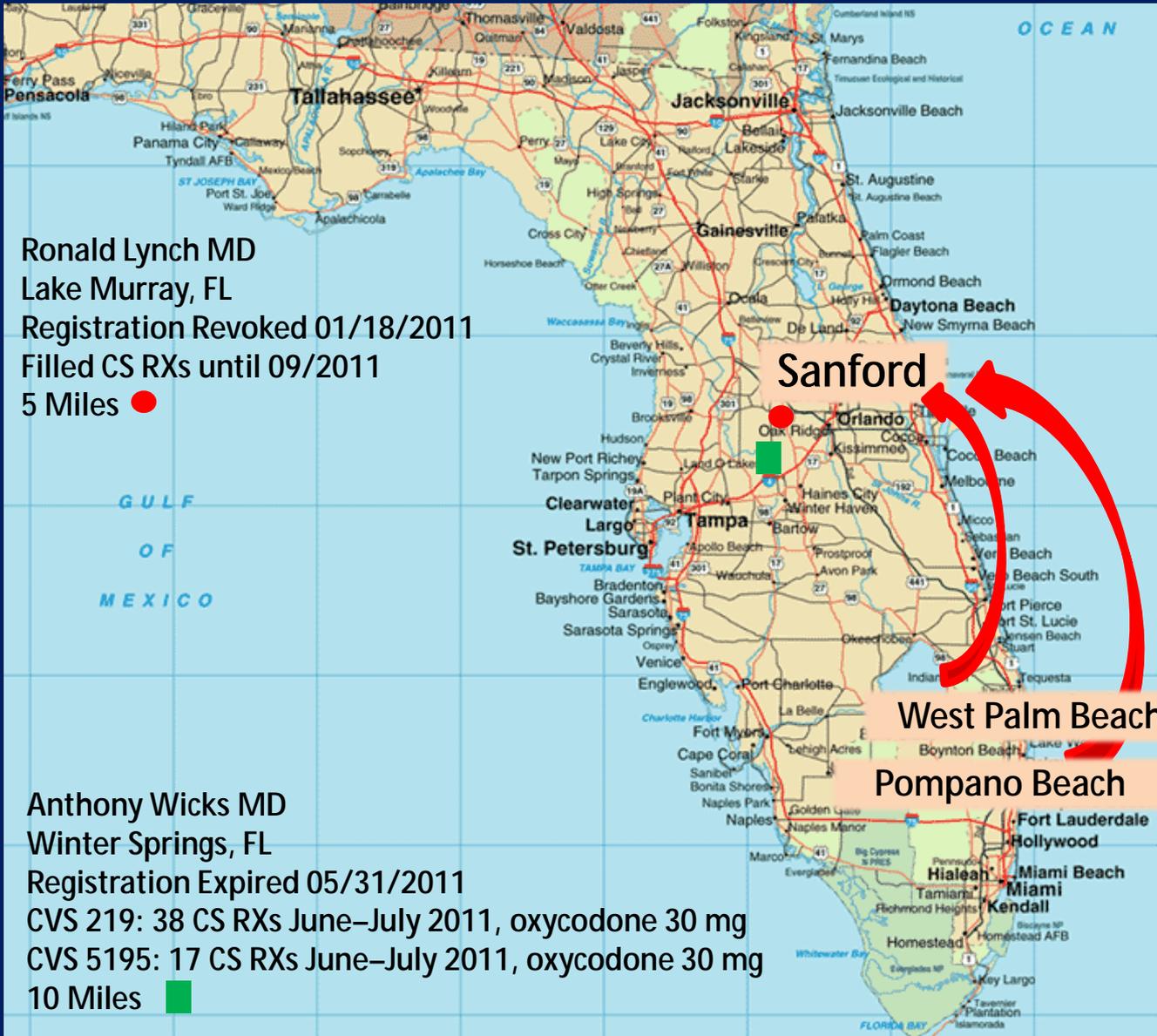
CVS
Sanford, FL
Store #219
Store #5195

Ronald Lynch MD
Lake Murray, FL
Registration Revoked 01/18/2011
Filled CS RXs until 09/2011
5 Miles ●

Carlos Gonzales MD
West Palm Beach, FL
184 Miles

Anthony Wicks MD
Winter Springs, FL
Registration Expired 05/31/2011
CVS 219: 38 CS RXs June–July 2011, oxycodone 30 mg
CVS 5195: 17 CS RXs June–July 2011, oxycodone 30 mg
10 Miles ■

Jack Danton DO
Pompano Beach, FL
216 Miles





Cardinal Florida

During 2011, Cardinal Lakeland supplied 6 of the sixteen pharmacies with DEA registrations within the city limits of Sanford, FL, with approximately 3,144,120 units of oxycodone

Sanford Population – 53,570
58 units per resident

Of the 3,144,120 units
3,012,500 units (96%) went to
CVS #5195 and #219

CVS #5195, Sanford, FL
1.2 million units in 2011
1 chain store within 2 miles
purchased 25,700 units for
2011

CVS #219, Sanford, FL
1.8 million units in 2011
Two chain stores within 1 mile
collectively purchased 207,000
units



Gulf Coast Pharmacy
Ft. Myers, FL
2009 – 231,740
2010 – 724,500
2011 (Sept.) – 1,097,300

Caredmed Pharmacy
d/b/a Brooks Pharmacy
Bonita Springs, FL
2009 – 213,100
2010 – 1,073,540
2011 (Sept.) – 2,063,100



Other Cardinal Issues

- Ø Didn't follow its own suspicious monitoring program – sales visits based on red flag trigger
- Ø No on-site visits to chain retailers even though it was part of their suspicious ordering monitoring policies
- Ø Low numbers of suspicious orders reported – none for either CVS pharmacy except for 1 report filed for CVS 219 after an AIW was served at the Cardinal Lakeland facility
- Ø Comparison of the 2008 ISO and 2011 ISO revealed the same concerns. Different drugs involved, but the same story...high volume sales without appropriate due diligence
- Ø Cardinal Lakeland customers received, on average, 5,364 units per month between 10/01/08 and 12/31/2011. In contrast, CVS 5195 received 58,223 units per month; Caremed received 59,264 units per month; Gulf Coast received 96,644 units per month and CVS 219 received 137,994 units per month



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



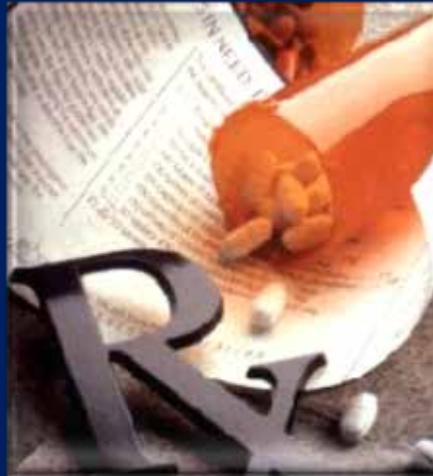
Purchases of Oxycodone 30mg

Ø In 2009, 44% of all oxycodone 30mg products were distributed to Florida

Ø In 2010, 43% of all oxycodone 30mg products were distributed to Florida



The DEA Response



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



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

Ø Enforcement is just as important as....

Ø Prevention/Education

Ø Treatment







Community Partnerships

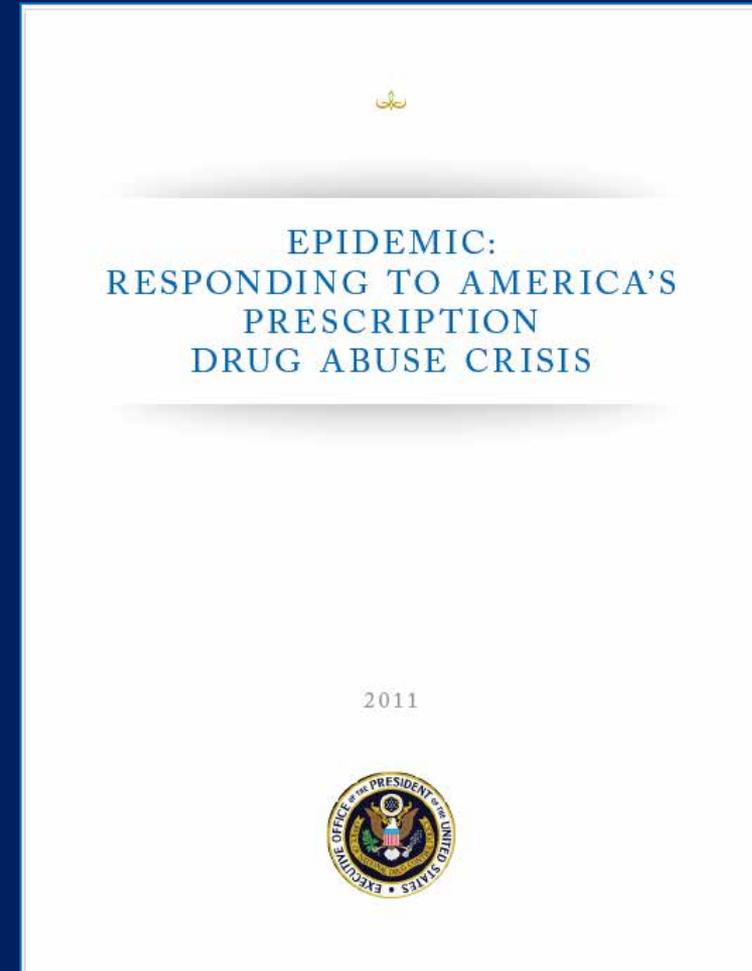


- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education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

Distributor Initiative

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

August 1, 2005 – January 7, 2016: Briefings to **84** firms with **279** registrations



DEA Registrant Initiatives

Pharmacy Diversion Awareness Conference

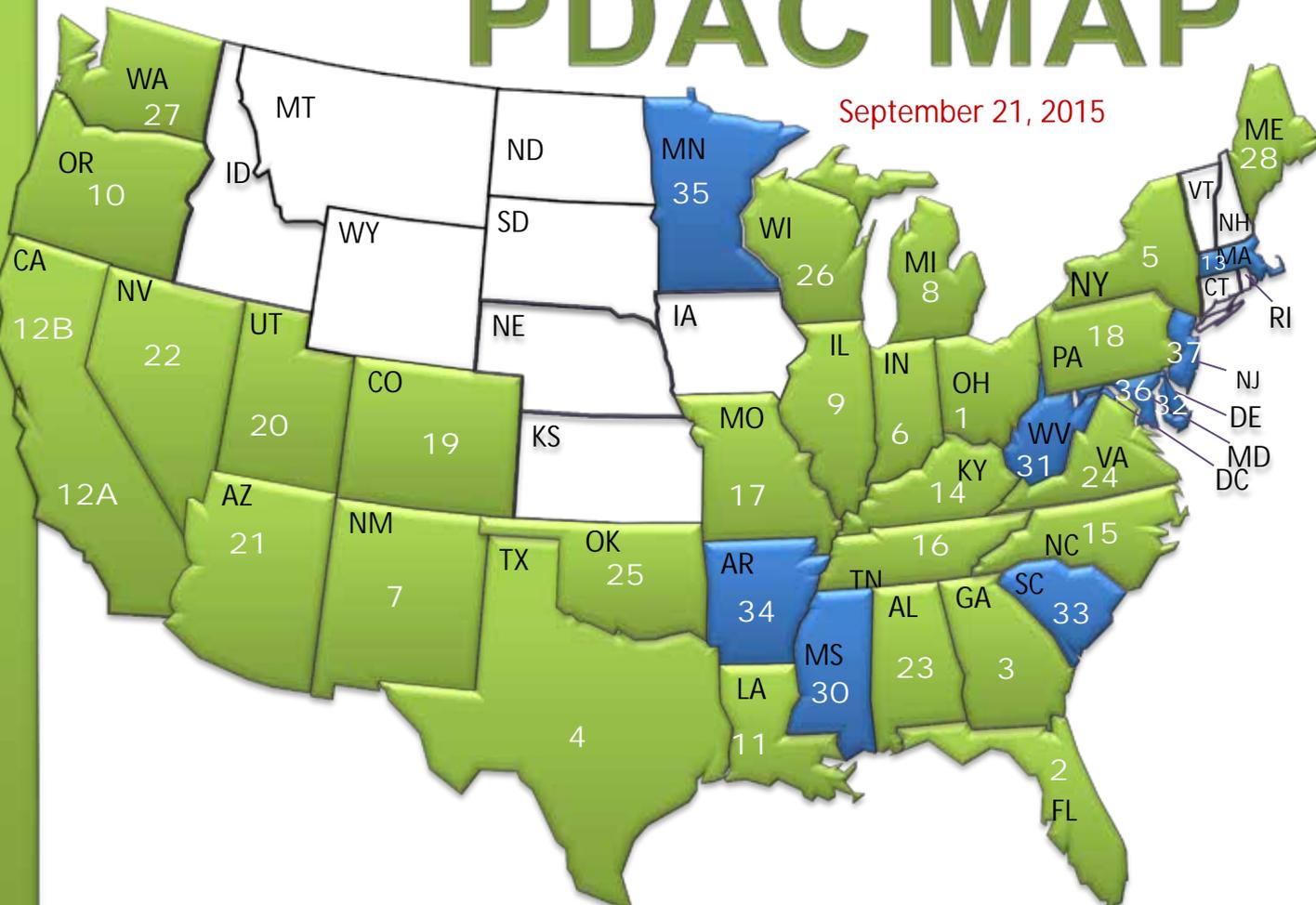
This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity

PDAC MAP

September 21, 2015

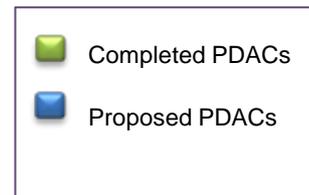
Completed PDACs

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
Total Attendance To Date	9,218



Proposed FY-2016 PDACs

- 29-Pittsburg, PA December 10 & 11, 2015
- 30-Jackson, MS January 9 & 10, 2016
- 31-Charleston, WV February 27 & 28, 2016
- 32-Wilmington, Delaware March 19 & 20, 2016
- 33-Charleston, South Carolina April 2016
- 34-Little Rock, Arkansas May 2016
- 35-Minneapolis/St. Paul, Minnesota July 2016
- 36-Towson, Maryland August 2016
- 37-New Brunswick, New Jersey September 2016





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.

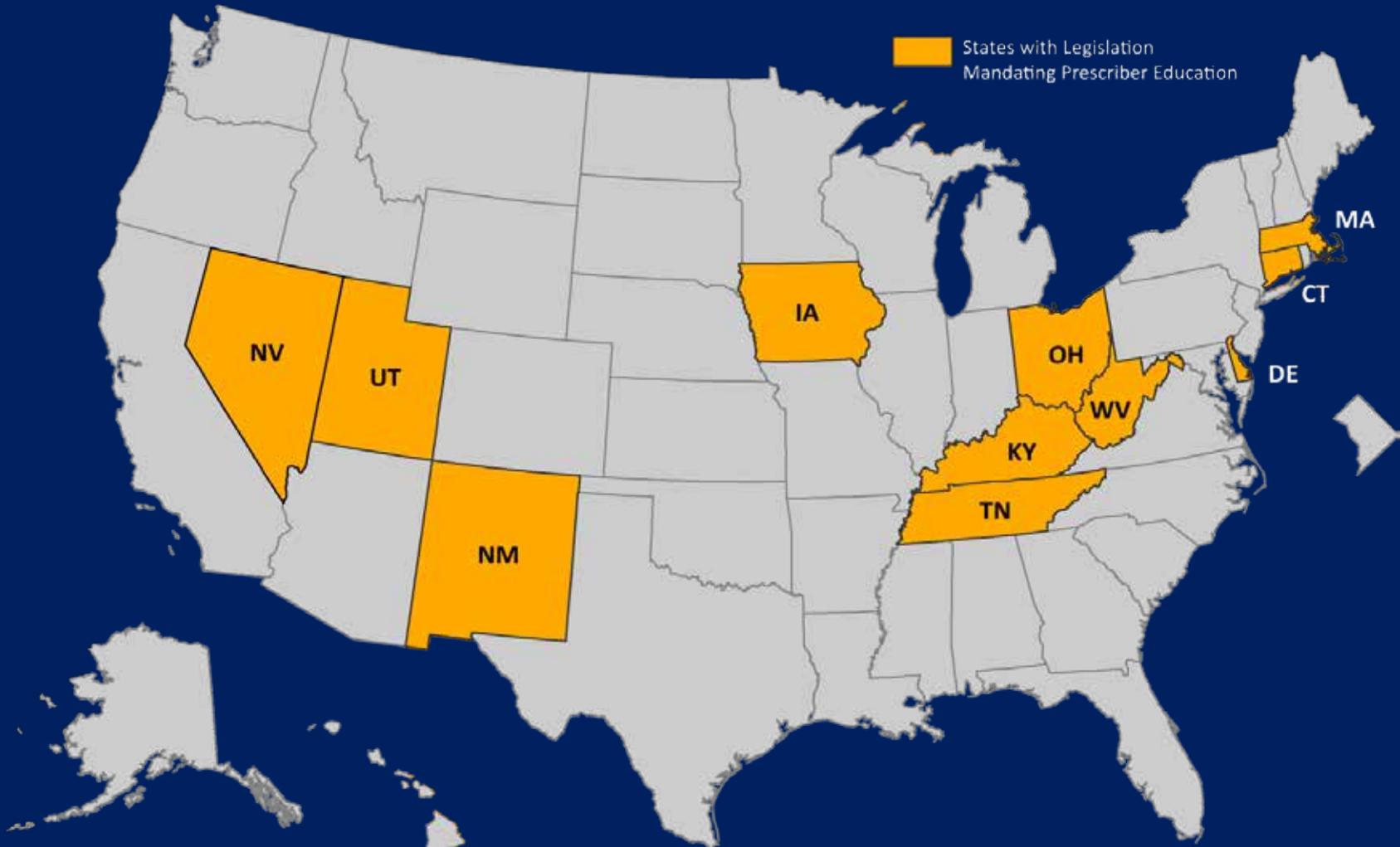


Scheduled Investigations

- 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.

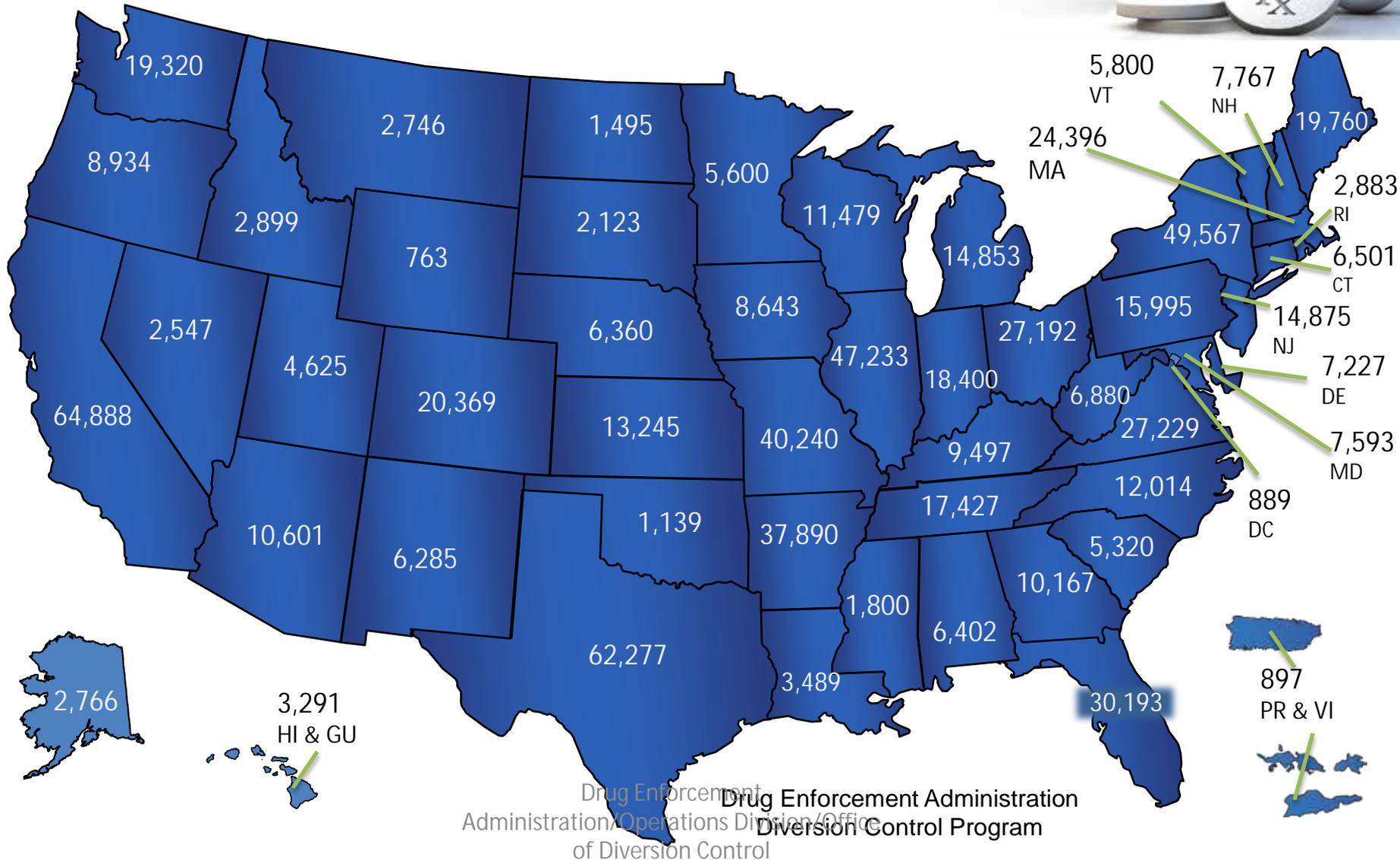


10:00 AM – 2:00 PM

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

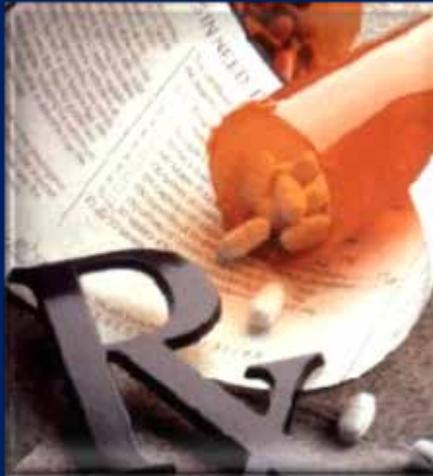
10th National Take Back Day: **September 26, 2015**

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





Miscellaneous Pharmacy Topics



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



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

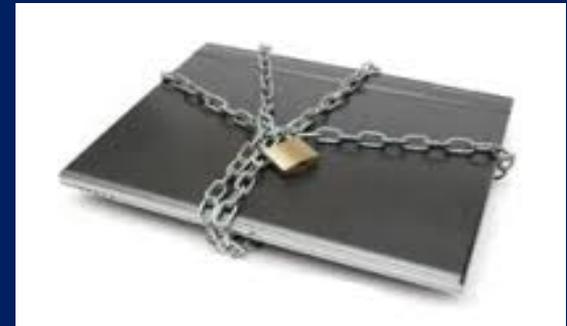
21 CFR § 1306.12(b)



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 and sell the drugs in the form of a distribution to any DEA Registrant – including practitioner office.
- Violation of DEA and FDA regulations



Abandoned Controlled Substances

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

79 FR 53546 (Disposal Final Rule)



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:
 - Manufacturers
 - Distributors
 - Reverse Distributors
 - Narcotic Treatment Programs
 - Hospitals/clinics with an on-site pharmacy
 - Retail Pharmacies21 CFR § 1317.40

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



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:

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



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 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 Receptacle Inner Liner

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

21 CFR § 1317.60(a)



Mail-Back Program

Requirements of mail-back program

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

21 CFR § 1317.70 (b)



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



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



Pharmaceutical Wastage

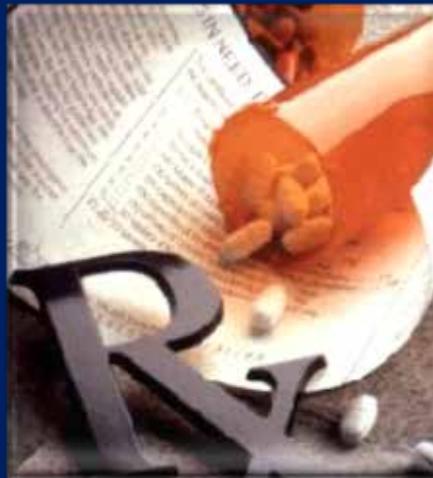


Pharmaceutical Wastage

- 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.deaDiversion.usdoj.gov



DEA Web-Based Resources



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



DEA Web-based Resources

Office of Diversion Control

www.deadiversion.usdoj.gov

U.S. Department of Justice Drug Enforcement Administration
Office of Diversion Control

Contact Us | Site Map | Search

Home
Registration
Reporting
Info & Legal Resources
Trade Diversion Control

Got Drugs?

EMERGENCY Disaster Relief ALERT

Extortion SCAM

Regulations.gov

The voice in Federal decision making

Good Medicine, Bad Behavior

Drug Diversion in America

To view PDF documents
Get **FOUR EADER**

External links included in this website should still be considered for an official acknowledgment of the views of the author.

Report Illicit Pharmaceutical Activities

1-877-RX-ABUSE
1-877-792-2873

Quick Links

- Search Applications Online
- New Applications Online
- Duplicate Certificate Request
- Registration Validation
- Registration Change Request
- Other Forms
- GDCA
- GDCA Form 106 - Report Theft or Loss of Controlled Substance
- Controlled Subst Act 1005 (CNSA)
- Cases Against Counterfeit
- Mailbox Addresses for Tablets Subject to the C-17111
- Electronic Prescriptions for Controlled Substances
- Pharmacies A Message
- Members and Directs
- Drug Diversion - Test Cases
- Chemical Control Program
- Medical Message
- Webinars & Trn

What's New

- Lac A James, M.D., Chemist and CDCA (May 13, 2013)
- John G. Zarovits, M.D., Chemist and CDCA (May 10, 2013)
- Schedule of Controlled Substances, Department of Medicines and Schedule 12 (May 6, 2013)
- Top 50 Pharmacies, Doctors and Order (May 3, 2013)
- Licensed (April 25, 2013)
- Pharm. Control Services, Inc. (April 23, 2013)
- Pharm. Trade Institute (April 23, 2013)
- Wolff's Laboratories, Inc. (April 23, 2013)
- S & B Pharma, Inc. (April 23, 2013)
- Altech Associates, Inc. (April 23, 2013)
- DCAR-Naturel, LLC (April 23, 2013)
- Cayman Chemical Company (April 23, 2013)
- Rhodes Technologies (April 18, 2013)
- Genstar LTD., Inc. (April 16, 2013)
- Amex. Control Services, Inc. (ACS) (April 16, 2013)
- US Healthcare (April 16, 2013)
- Nebuta, Inc. (April 16, 2013)
- Novo Corporation (April 16, 2013)
- Rhodes Technologies (April 16, 2013)
- American Pharmaceutical Chemicals, Inc. (April 16, 2013)
- BAKEL, LLC (April 16, 2013)
- Novo Corporation (April 16, 2013)
- Schedule of Controlled Substances, Temporary Department of Trade and Consumer Protection (April 12, 2013)
- Schedule of Controlled Substances, Department of Medicines and Schedule 1 (April 12, 2013)
- 60-Day Notice - Comments Requested National Drug Trade Service Laboratory With Changes of a Pharmacy Acquired Collection (April 9, 2013)
- 60-Day Notice - Comments Requested Prescription Dispensing for Just 1 and 2 mg. Clonidine (April 9, 2013)
- www.Adm. Servs., M.D., Chemist and CDCA (March 28, 2013)

Registration Support

Registration Number Toll Free: 1-800-882-9539 (8:30 am-6:00 pm EST)

Save time by applying for and/or renewing your DCA Registration online. Data will be entered through a secure connection to the CDMPF online web application system.

Minimum requirements: Credit Card and a web browser that supports 128-bit encryption.

Online Renewal Plan for Registrants

Email Registration Questions to: DEA.Registration.Help@usdoj.gov
Email Questions with Registration: 800.882.9539

Upcoming Meetings

- Pharmacy Diversion Awareness Conference
- Manufacturers/Wholesaler/Dispensary Conference

Hurricane Sandy

Message for New Jersey and New York Area Registrants - As you know, Hurricane Sandy impacted the New Jersey and New York areas particularly hard. Some of the DEA's offices in these two states have also been impacted by the storm. If you are not able to contact your local DEA Field Division you may direct any questions or problems with your registration to DEA's main-call center at 1-800-882-9539 (hours of operation see line 800) to 8:00pm EST. Thank you for your patience.

FAQ

- ARCOS
- Controlled Substance Online System (COSOS)
- DEA Form 224 Other Forms
- Electronic Prescriptions for Controlled Substances
- Division of Multiple Jurisdictions for Schedule II Controlled Substances
- License Transfer
- Manufacturers' Questions
- Overdose
- Pharmacist Drug Monitoring System
- Pharmacy
- Registration Procedures



DEA Web-based Resources

www.DEA.gov

The screenshot displays the DEA website homepage. At the top left is the DEA seal. The main header features the text 'DEA UNITED STATES Drug Enforcement Administration' and the slogan 'TOUGH WORK, VITAL MISSION'. A navigation menu includes links for HOME, ABOUT, CAREERS, OPERATIONS, DRUG INFO, PREVENTION, and PRESS ROOM. The central banner area contains the slogan 'Tough Work, Vital Mission The Facts About DEA' and a large image of the DEA seal. To the right of the banner are three featured resource boxes: 'Drug Facts for Today's Teens' (JustThinkTwice.com), 'A DEA Resource for Parents' (GetSmartAboutDrugs.com), and 'Wall of Honor' (DEA Remembers). Below the banner are three columns of content: 'TOP STORY' with a headline about a couple's sentences for cocaine trafficking; 'TOPICS OF INTEREST' with links to fact sheets and guides; and 'RESOURCE CENTER' with links to various legal and support resources.

DEA UNITED STATES Drug Enforcement Administration
TOUGH WORK, VITAL MISSION

HOME ABOUT CAREERS OPERATIONS DRUG INFO PREVENTION PRESS ROOM

Tough Work, Vital Mission
The Facts About DEA

Drug Facts for Today's Teens
JustThinkTwice.com

A DEA Resource for Parents
GetSmartAboutDrugs.com

Wall of Honor
DEA Remembers

TOP STORY

Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy

JAN 29 (BROWNSVILLE, TEXAS)

Norma Alicia Gallardo, 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 left, there is a navigation bar with the following items: HOME (return home), DRUG FACTS (learn the truth), FACTS & FICTION (know the difference), CONSEQUENCES (life changing events), TEENS TO TEENS (sharing our experience), and INSIDE DEA (find out more). To the right of this bar is a search box and links for "Parents & Educators" and "Drug Glossary".

The main content area features a large banner for "THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF". The text below the banner reads: "Maybe you've heard it's made of the same stuff as cold medicine. Well, that's not all. Some of the ingredients used to make meth include battery acid, gasoline, and drain cleaner." Below this text is a link: "GET THE FACTS ABOUT METHAMPHETAMINE".

Below the banner are three buttons: MARIJUANA, COCAINE, and METH. To the right of the banner is a photo of a young woman with short brown hair wearing a green jacket.

On the right side of the page, there are three additional sections: "IT'S TIME TO SMATTER THE MYTHS ABOUT DRUGS AND DRUG ABUSE" with a "Learn More" link and a "DRUG FACTS" icon; "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: "Combine toxic chemicals with neglected hygiene, and you get a condition called 'meth mouth'—rotten and decaying teeth."



DEA Web-based Resources

www.GetSmartAboutDrugs.com

The screenshot shows a web browser window displaying the homepage of www.getsmartaboutdrugs.com. The browser's address bar shows the URL. The website header features the DEA logo and the text 'GetSmartAboutDrugs A DEA Resource for Parents'. A navigation menu includes links for Home, Identify, Prevent, Help, Hot Topics, DEA in the Community, and Communities of Practice. The main content area is divided into several sections: a 'Communities of Practice' section with a text block and a 'Learn more' button; a 'DEA Publications' section with a 'READ MORE' button; and a 'Watch the Videos' section with a 'VIEW' button. Below these are three columns: 'Latest News' with two news items, 'Voices' with 'Irma Perez's Story', and 'Inside DEA' with a paragraph about DEA agents and parents.

http://www.getsmartaboutdrugs.com

Get Smart About Drugs

Email Page Print Page Font Size Contact Us

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

BACK STOP NEXT

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

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