



DEA Trends & Update

Pittsburgh Pharmacy Diversion Awareness Conference

December 10 & 11, 2015



The United States Department of Justice
Drug Enforcement Administration



Thomas W. Prevoznik,
Unit Chief Liaison
Office of Diversion Control



Disclosure Statement

I have no financial relationships to disclose

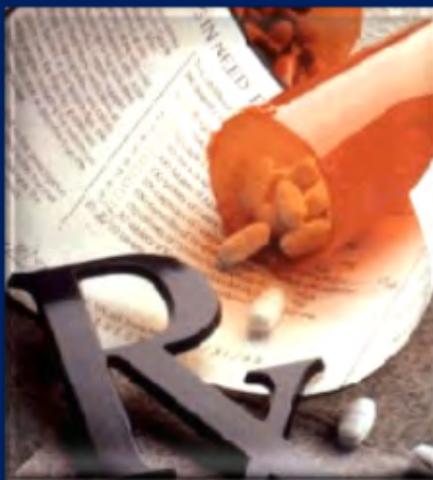


Goals and Objectives

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



Public Health Epidemic



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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.



In four years of medical school, students receive, on average, only 11 hours of pain medication training.

VS

11 hours





Mayo Clinic Study on Prescription Drugs

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

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NEWS

Study: 70 Percent Of Americans On Prescription Drugs

June 19, 2013 12:59 PM

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

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

The [study](#) is uncovering valuable information

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

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

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Women to stand trial in theft of drugs from Norwin Pharmacy



By [Paul Pierce](#)
 Friday, March 27, 2015, 12:01 a.m.

A North Huntingdon pharmacy technician confessed she stole 160 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 Michele I. (Gant) 1 of

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Package detonated

Police detonate a suspicious package in Oakland outside of FBI's Biomedical Research Tower Friday

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Washington County pharmacy owner charged with fraud

October 10, 2014 8:26 PM



By Madelyn Czobiniak / 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. Kuzy, 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



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Consequences

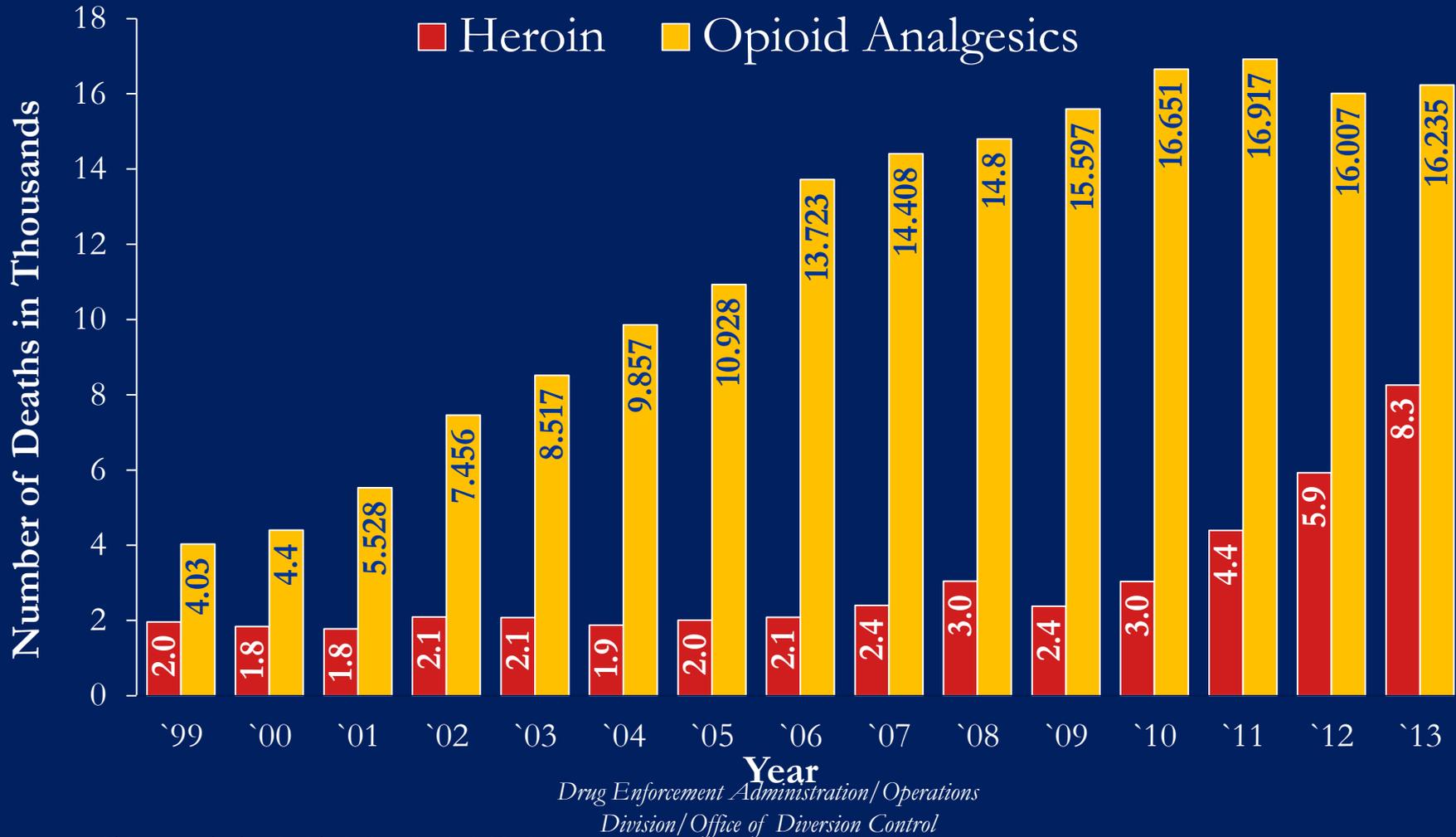
In 2011, approximately **41,340** unintentional drug overdose deaths occurred in the United States, one death every 12.45 minutes. (increased for 12th consecutive year)

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

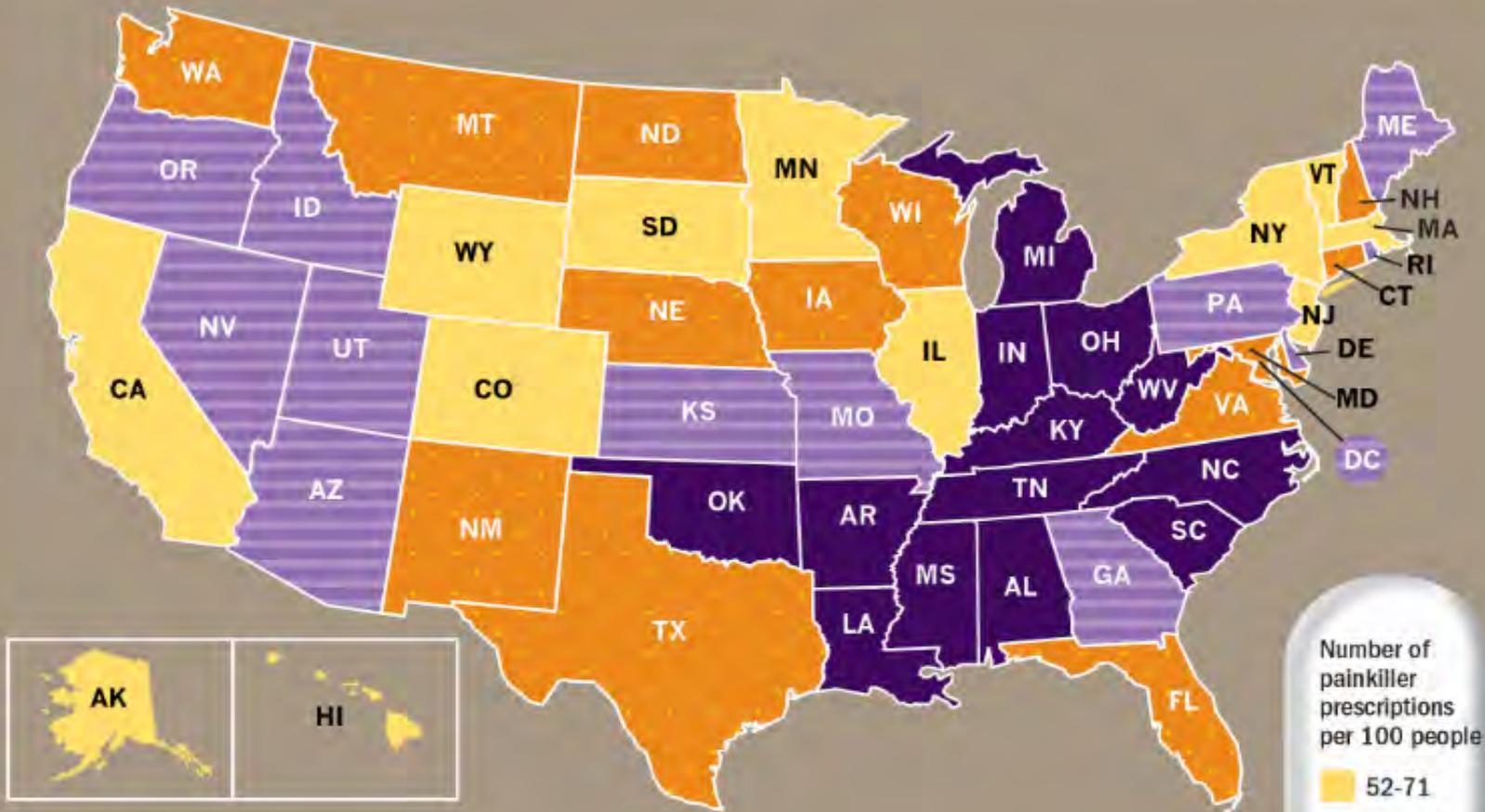




Highest Opiate Prescriptions

- 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

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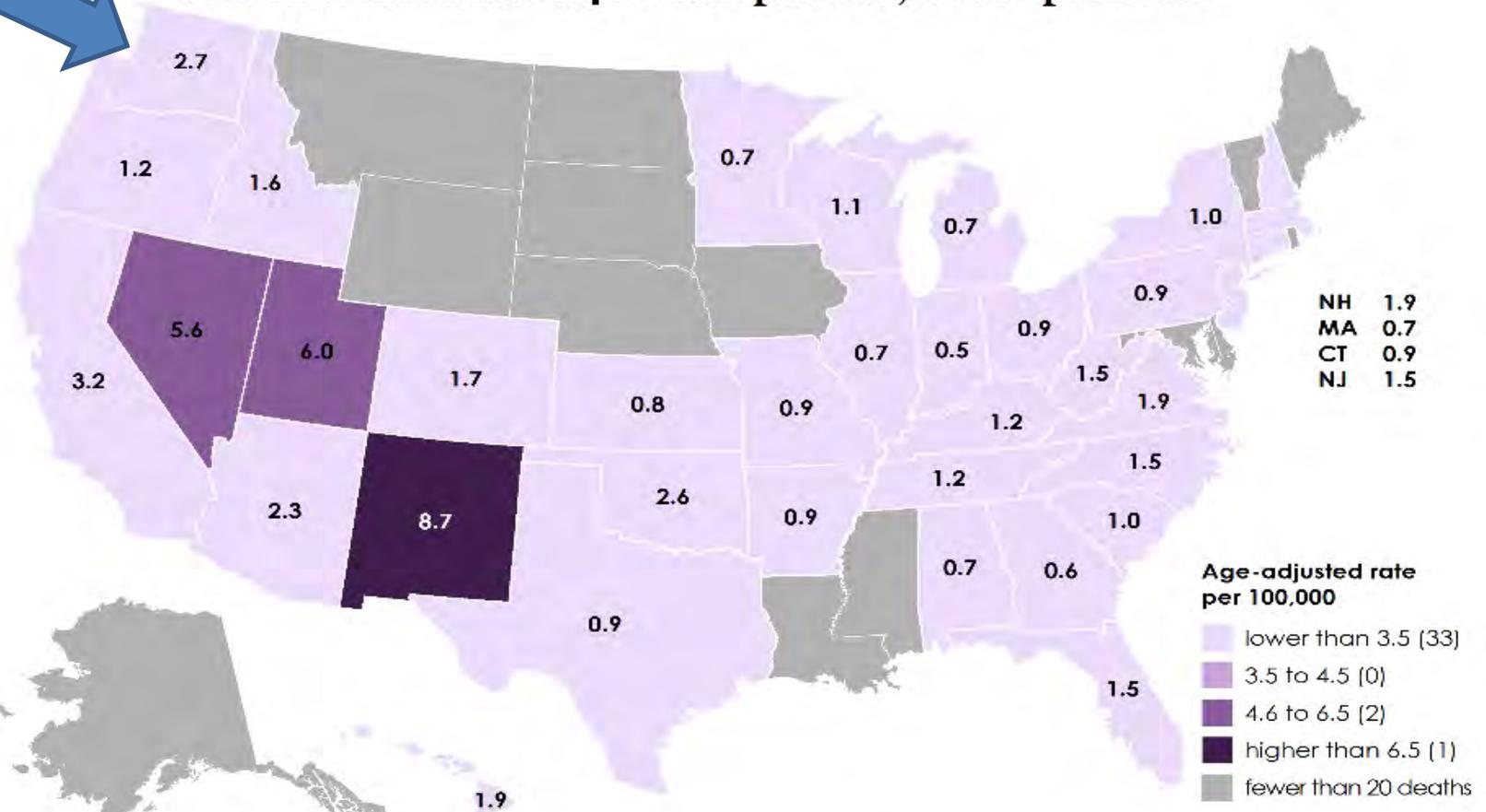
Some states have more painkiller prescriptions per person than others.



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



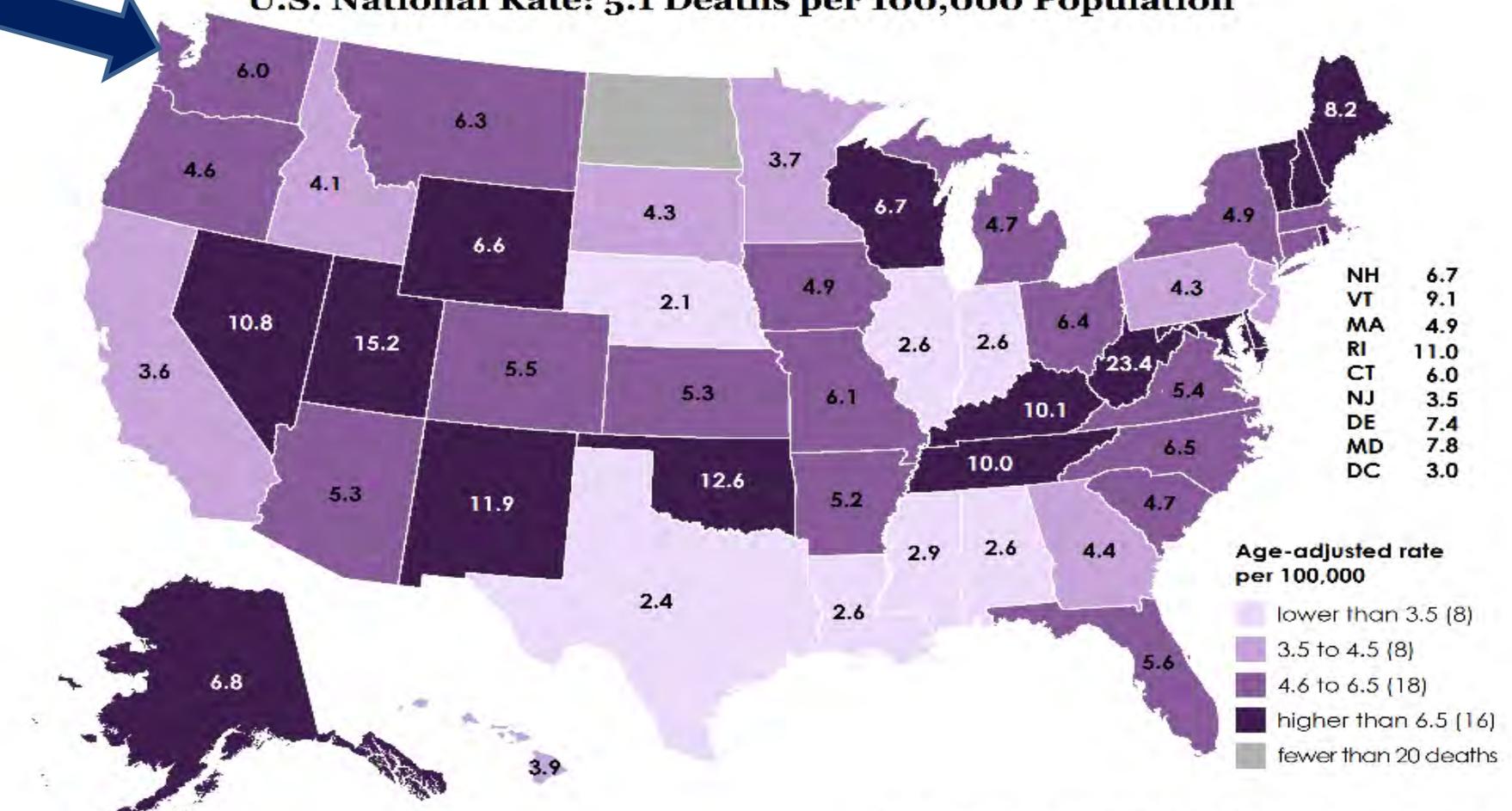
Source: Centers for Disease Control and Prevention, National Center for Health Statistics, Underlying Cause of Death on CDC WONDER Online Database, extracted January 26, 2015.



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



Our Youth

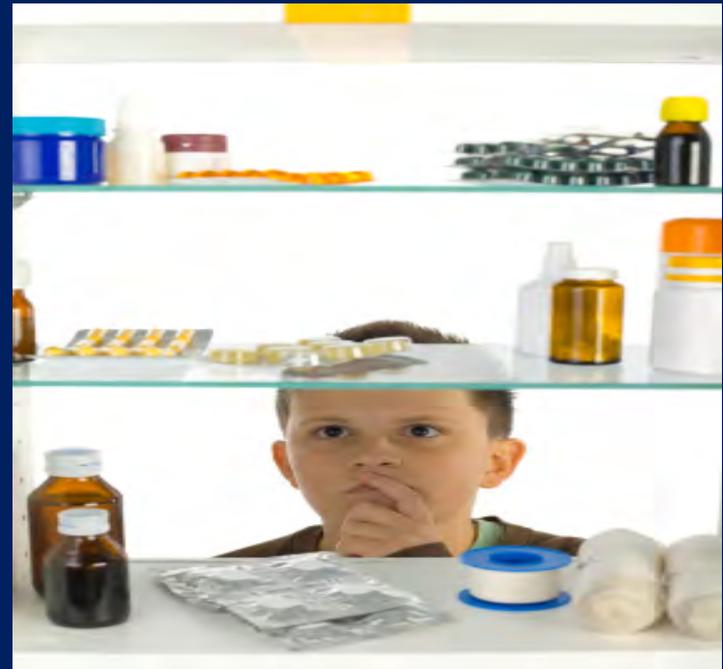
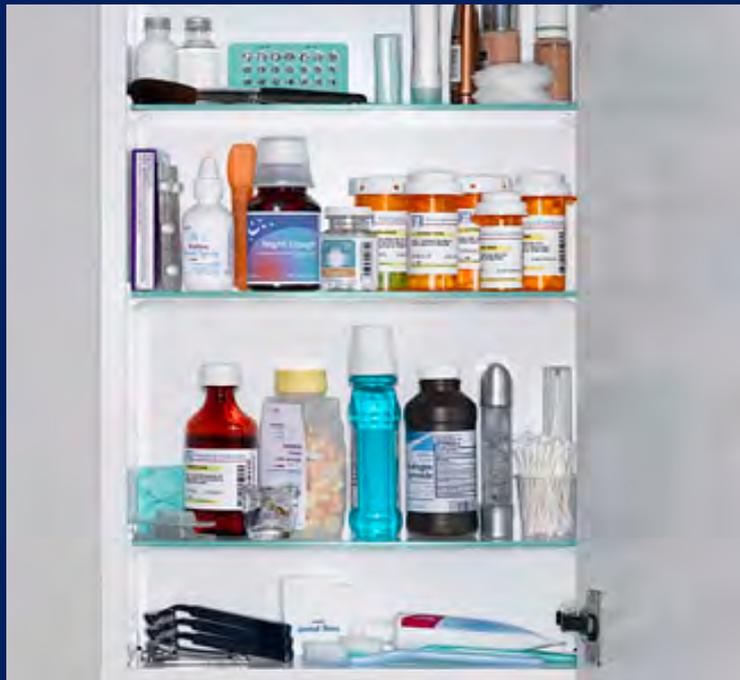


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Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!





Medicine Cabinets: Easy Access

- More than half of teens (**73%**) indicate that it's easy to get prescription drugs from their parent's medicine cabinet
- Half of parents (**55%**) say anyone can access their medicine cabinet
- 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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Violence Related to Controlled Substance Pharmaceuticals

ASSASSIN



Ready for mayhem, the lunatic strolls through the door.



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



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



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

Chilling anatomy of drugstore massacre

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

PAGES 4-5

DRUGSTORE MASSACRE



Husband and wife busted in Rx-slay horror



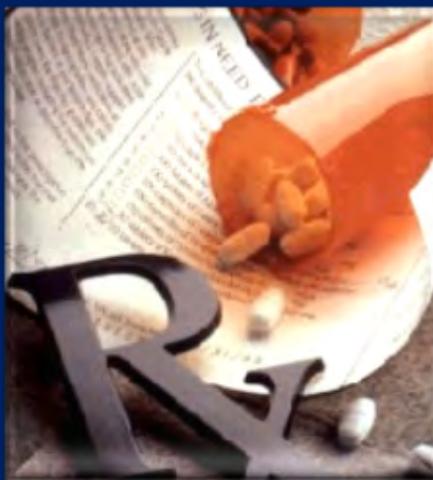
PAIN KILLER

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

PAGES 4-5



Drugs of Abuse

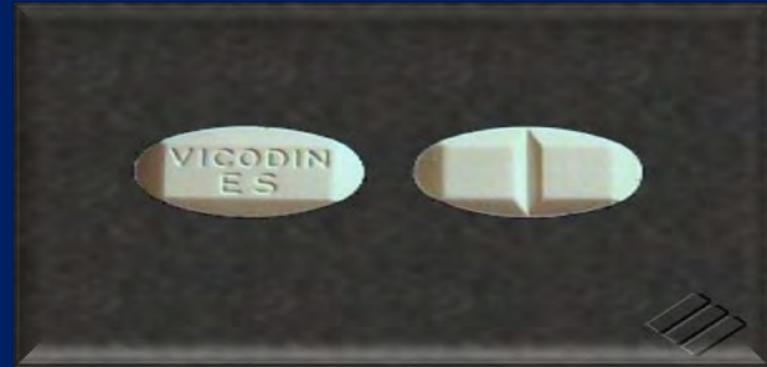


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Carisoprodol
C-IV as of 1/11/2012

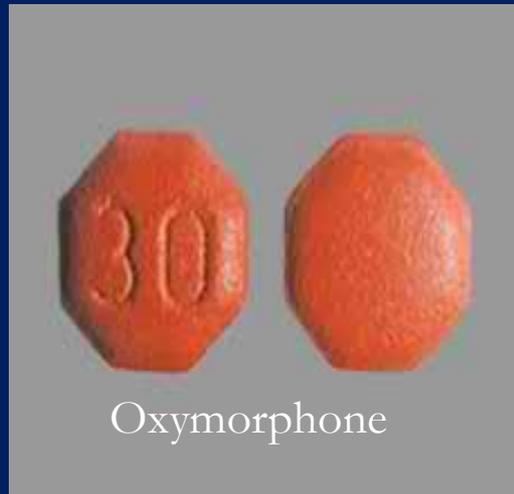
Commonly Abused Controlled Substances



Hydrocodone



OxyContin 80mg



Oxymorphone



Alprazolam

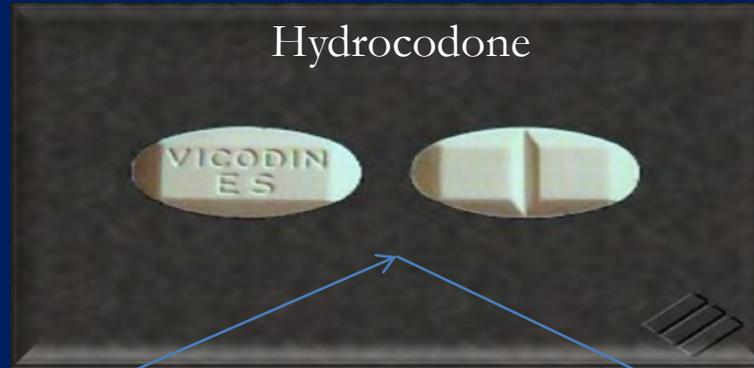


Oxycodone 30 mg





The Trinity



Hydrocodone

Opiate



Carisoprodol

C-IV as of 1/11/2012

Muscle Relaxant



Alprazolam

Benzodiazepine



Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)
- Similarities:
 - Structurally related to codeine
 - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin[®], Lortab[®], Lorcet[®]
- Currently, combination products are Schedule III
- **October 6, 2014 moved to SCHEDULE II**
- “Cocktail” or “Trinity”
 - Hydrocodone
 - Soma[®] / carisoprodol
 - Alprazolam / Xanax[®]
- Street prices: \$2 to \$10+ per tablet depending on strength & region





Worldwide Hydrocodone Use

- 67 Countries reported an estimated need requirement for hydrocodone to the International Narcotics Control Board
- 20 countries reported an estimated need of 1 kilogram or greater.
- 4 countries reported an estimated need between 500 grams and 999 grams
- 10 countries reported an estimated need between 100 grams and 499 grams
- 6 countries reported a need between 25 grams and 99 grams
- 27 countries reported a need of less than 25 grams



Worldwide Hydrocodone Use

- **Of the 20 Countries** that reported an estimated needs requirement for hydrocodone at one kilogram or more
- **8 countries** reported an estimated need of 1 kilogram to 5 kilograms
- **4 countries** reported an estimated need over 5 kilograms to 10 kilograms
- **8 countries** reported an estimated need over 10 kilograms



Top 10 List

- 10 Guatemala 10 kilograms
- 09 India 10 kilograms
- 08 Vietnam 20 kilograms
- 07 China 20 kilograms
- 06 Denmark 25.5 kilograms
- 05 Columbia 30 kilograms
- 04 Syrian Republic 50 kilograms
- 03 Canada 115.5 kilograms
- 02 United Kingdom 200 kilograms
- 01 United States 79,700 kilograms 99.3%

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.



Prescription Opiates v. Heroin



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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

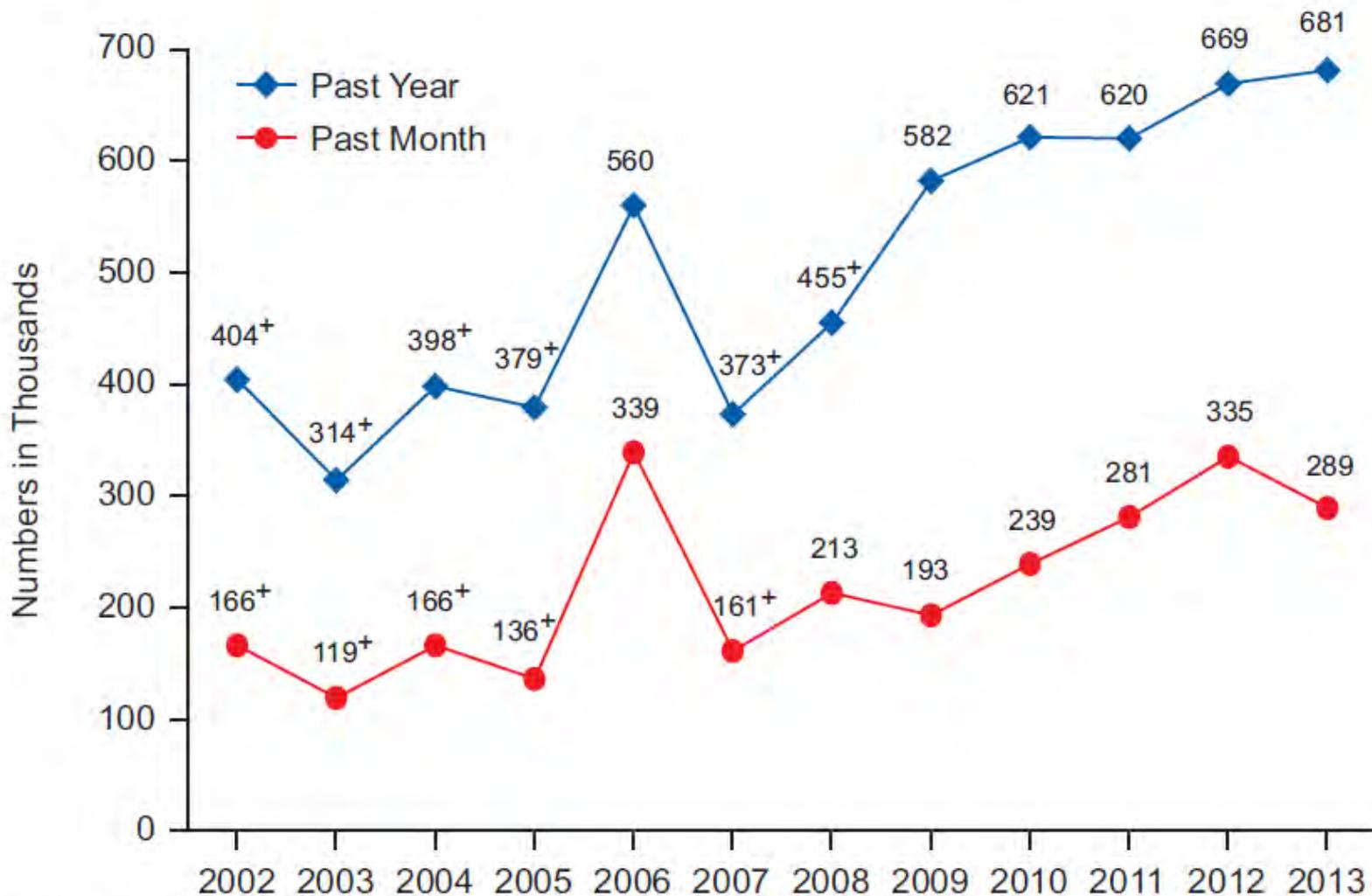
Lorcet®

\$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

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New approach to classic P. 19

Playoff possibilities
Schedule favors Skins P. 35

Cooling down

60°-34°
DETAILS P. 4

POLITICS

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

LOCAL

FBI analyst busted

Heroin use spikes in area suburbs

Pill addicts risk deadly drug

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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. Lankenau 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



The Controlled Substances Act: Checks & Balances



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Mission

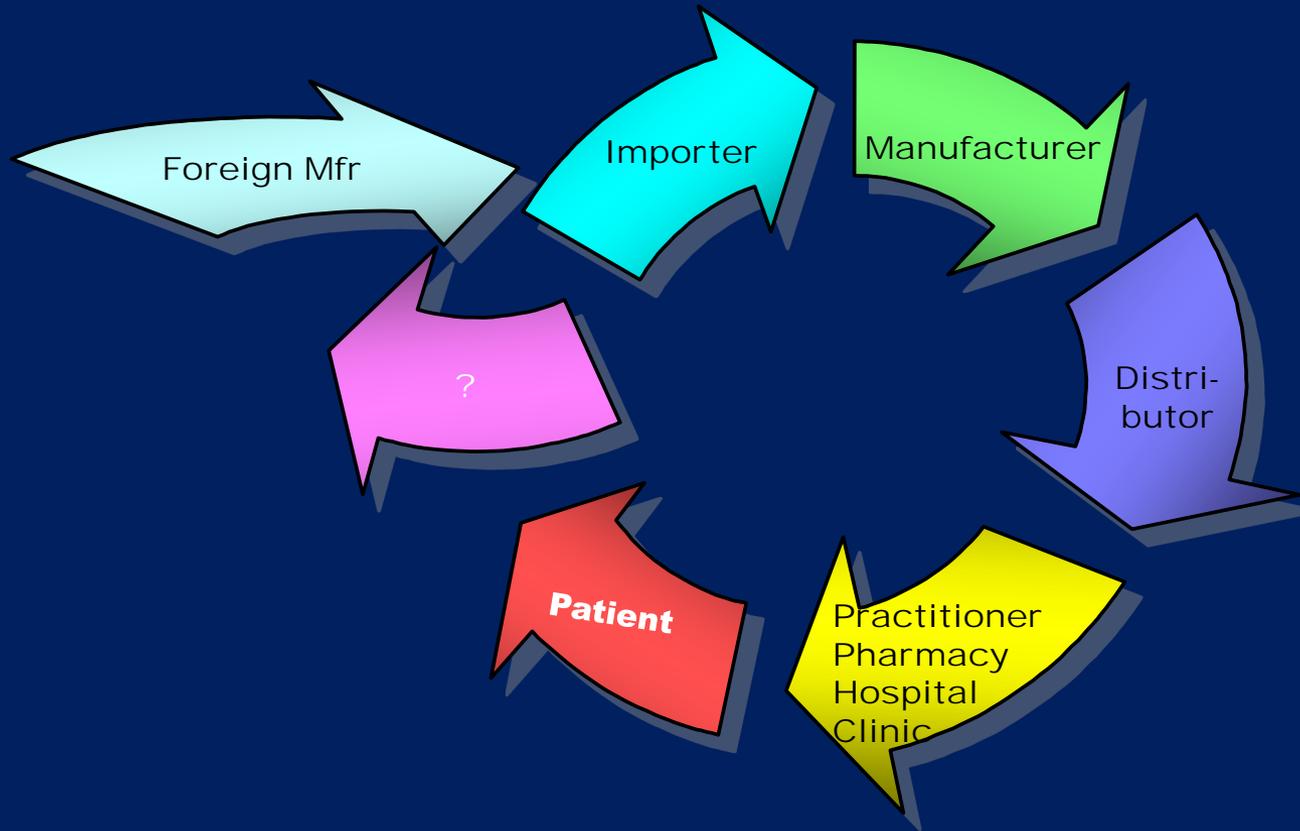
The mission of the Office of Diversion Control is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

while ...

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



Closed System of Distribution

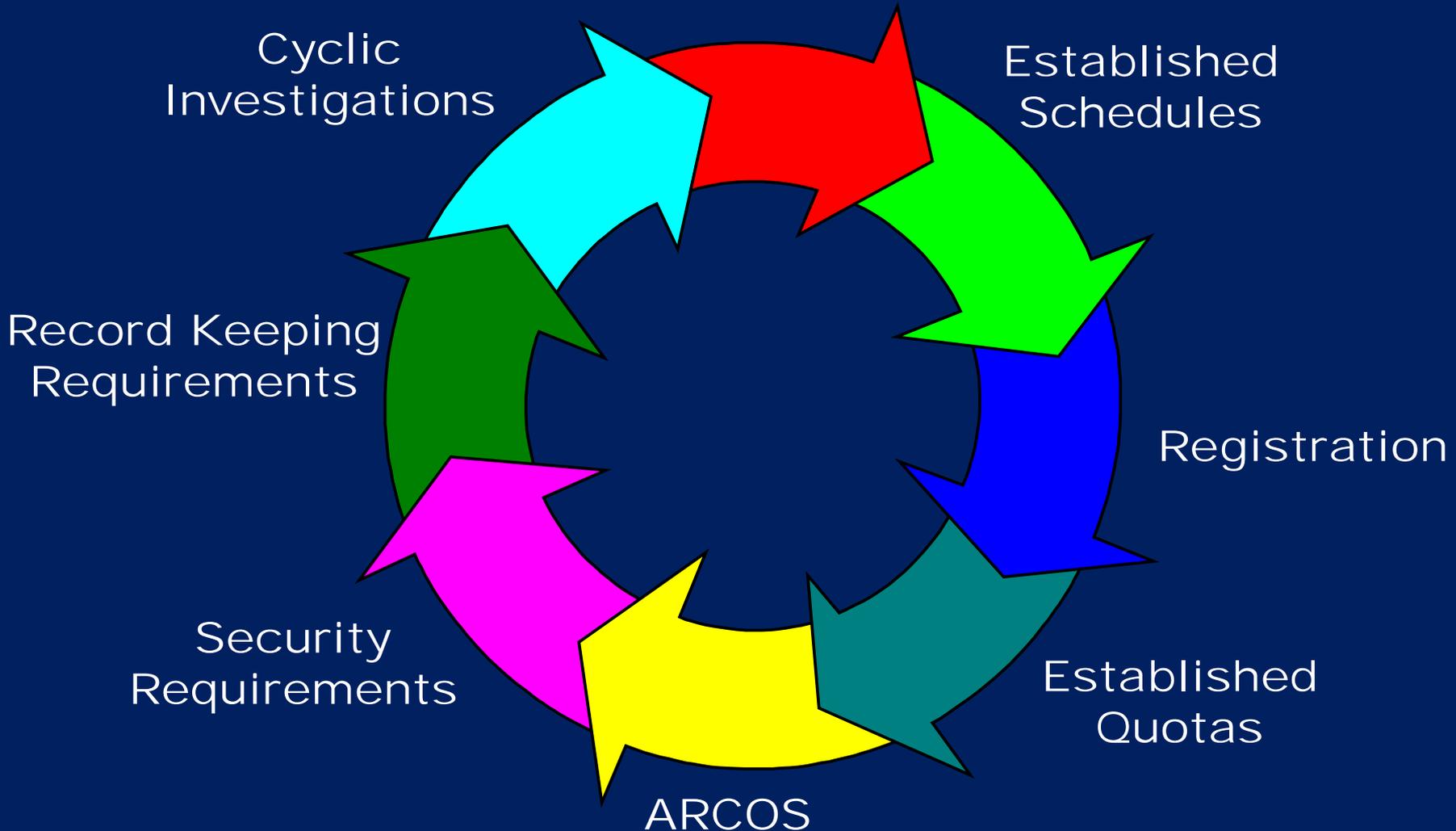


1,604,158 (09/04/2015)

- **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



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Legal Obligations: DEA Registrant



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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)

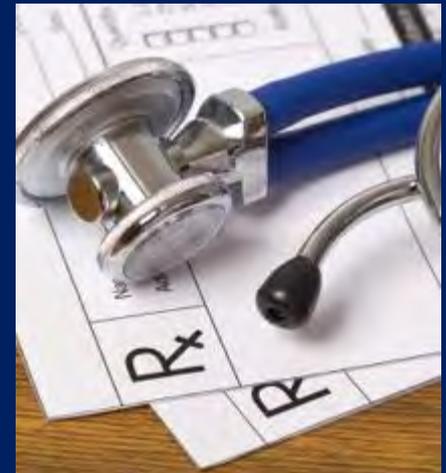


Prescriptions

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.

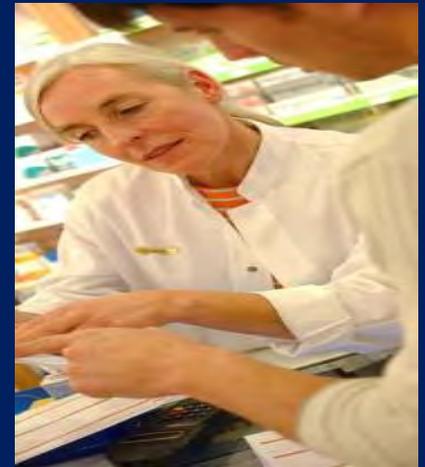
21 CFR § 1306.04(a)





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!!!



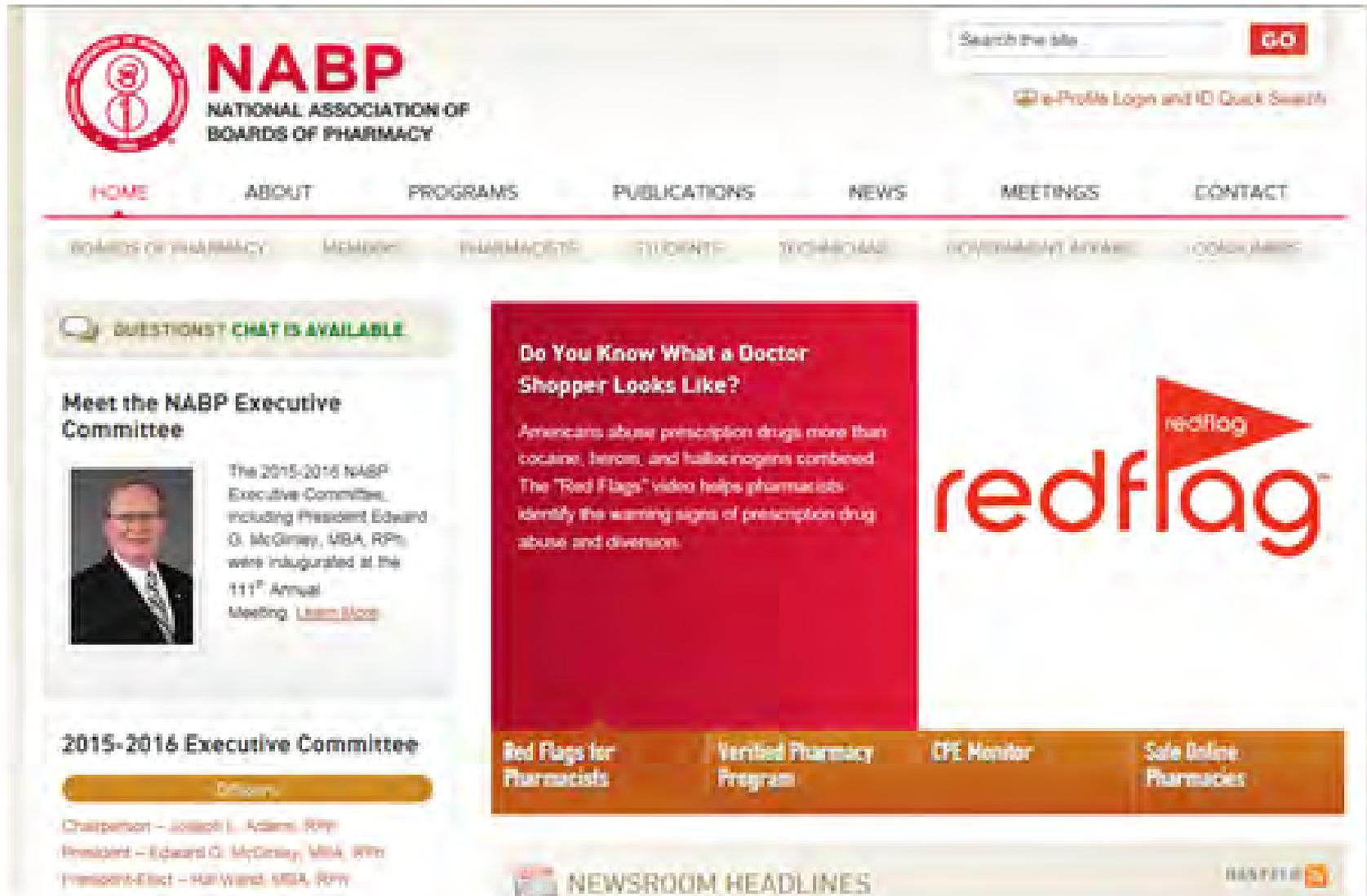


The Last Line of Defense



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www.nabp.net



The screenshot shows the NABP website homepage. At the top left is the NABP logo, a red circle containing a caduceus. 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, WORKBOARDS, GOVERNMENT AFFAIRS, and LOCAL AFFAIRS. A green banner on the left side of the page reads "QUESTIONIST CHAT IS AVAILABLE". Below this is a section titled "Meet the NABP Executive Committee" featuring a portrait of Edward G. McKinley and text about the 2015-2016 Executive Committee. To the right of this section is a large red banner with the text "Do You Know What a Doctor Shopper Looks Like?" and a "redflag" logo. Below the red banner is a navigation bar with four orange buttons: "Red Flags for Pharmacists", "Verified Pharmacy Program", "CPE Monitor", and "Safe Retail Pharmacies". At the bottom of the page, there is a "NEWSROOM HEADLINES" section with a play button icon and a "BANNER" section with a play button icon.

NABP
NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Search the site **GO**

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QUESTIONIST CHAT IS AVAILABLE

Meet the NABP Executive Committee



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

2015-2016 Executive Committee

[Officers](#)

Chairman – Joseph L. Adams, RPh
President – Edward G. McKinley, 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](#) [CPE Monitor](#) [Safe Retail Pharmacies](#)

NEWSROOM HEADLINES [BANNER](#)



The DEA Response



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

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







Community Partnerships

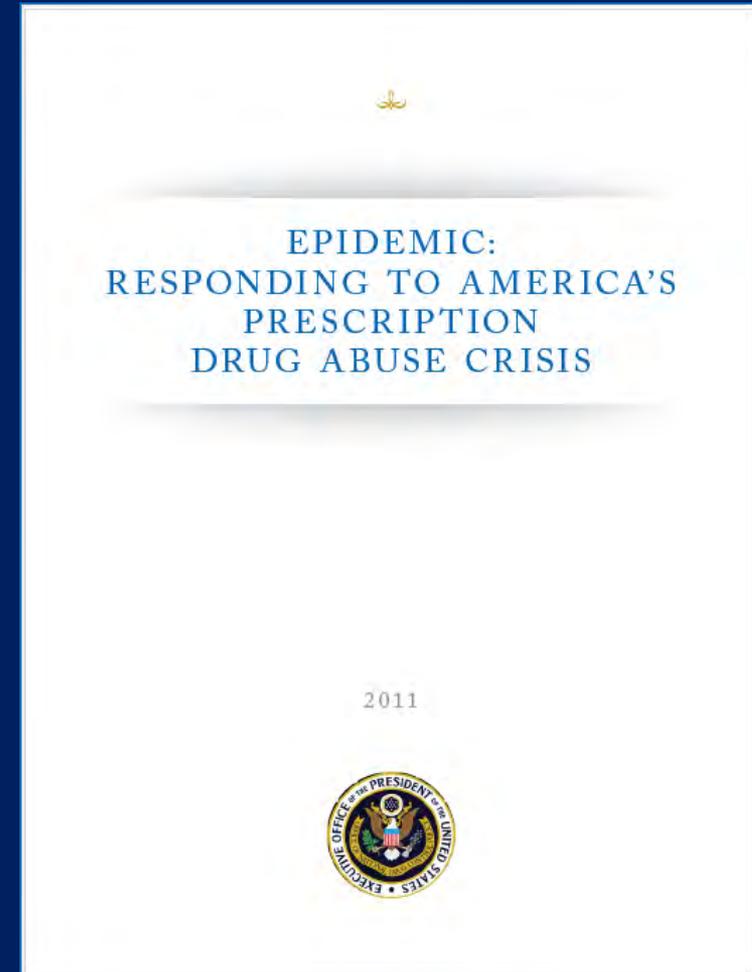


- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education 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 – May 15, 2015: Briefings to **84** firms with **279** registrations



DEA Registrant Initiatives

Pharmacy Diversion Awareness Conference

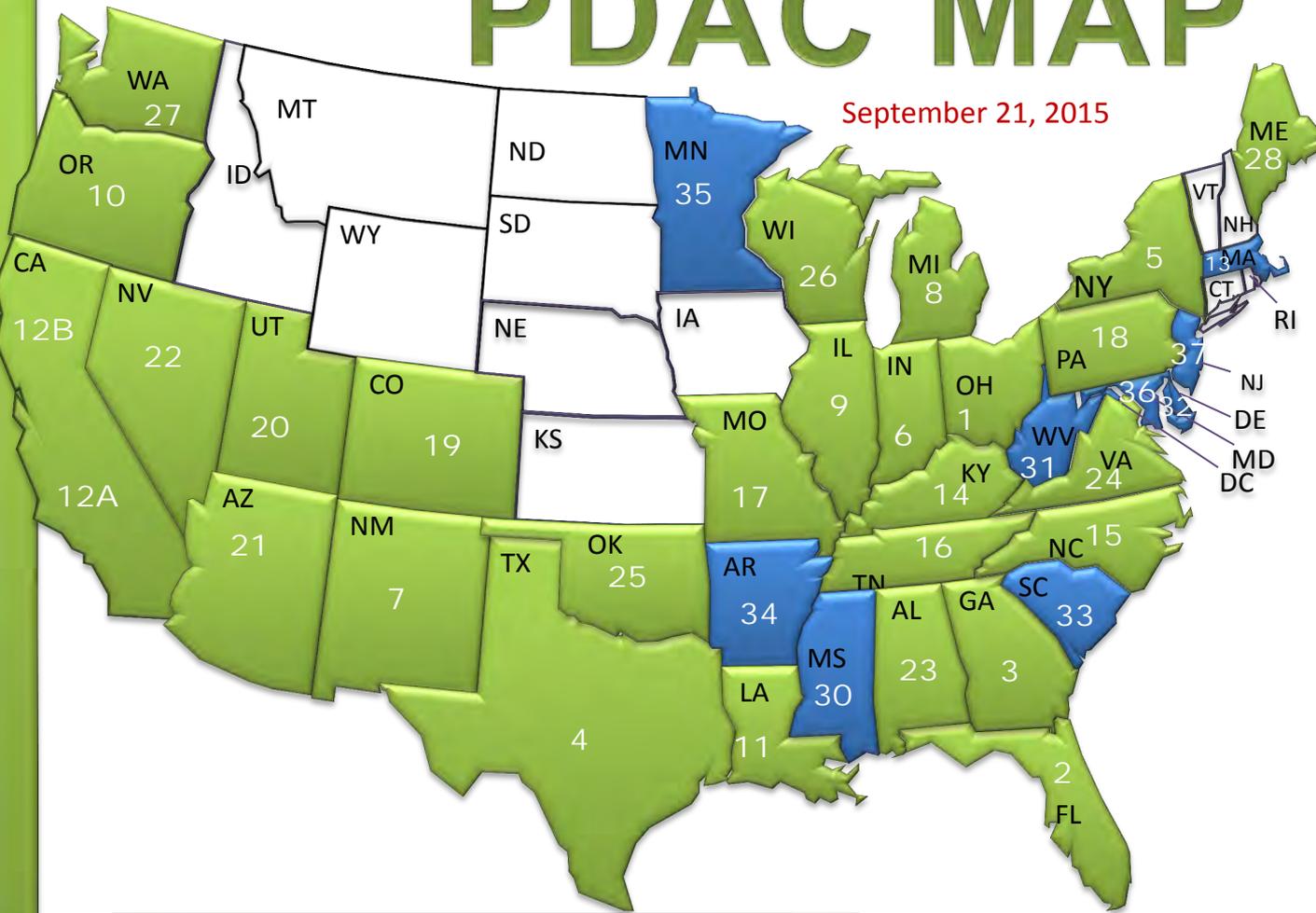
This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity

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

- 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.

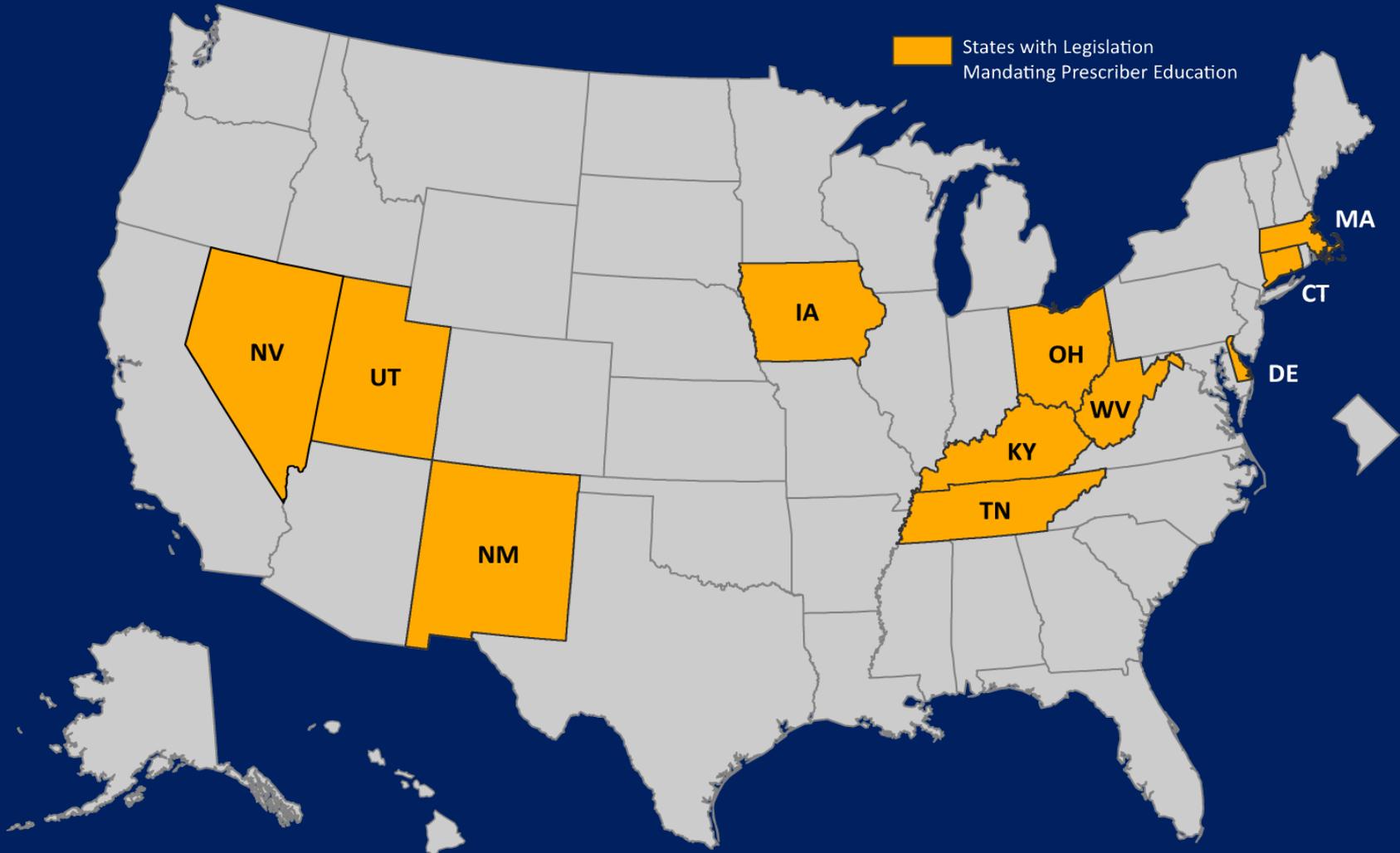


Scheduled Investigations

- 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





Secure and Responsible Drug Disposal Act of 2010



The Problem: Easy Access





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

- 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 Pharmacies

21 CFR § 1317.40

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



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)



National Take Back Initiative

September 26, 2015

Got **Drugs?**

Turn in your
unused or expired
medication for safe disposal
Saturday **September 26, 2015**

Click here
for a collection
site near you.



10:00 AM – 2:00 PM

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



Miscellaneous Pharmacy Topics



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



Pre-Populated Prescription

A pharmacy may not act as an agent of the physician

- A practitioner may authorize an agent to prepare the prescription, instructing agent as to required elements of the prescription

21 CFR § 1306.05(f)

- An agent cannot legally perform duties that must be personally performed by the individual practitioner

21 CFR § 1306.04(a)



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 court 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



Registrant Disposal



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



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)



Pharmaceutical Wastage

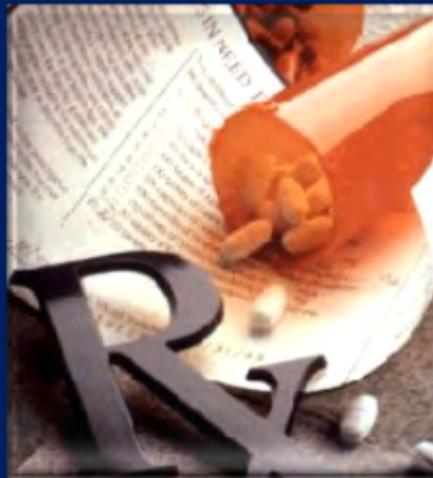


Pharmaceutical Wastage

- 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

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

- Header:** "DEA" in large gold letters, "UNITED STATES Drug Enforcement Administration" in white, and the slogan "TOUGH WORK, VITAL MISSION".
- Navigation Menu:** HOME, ABOUT, CAREERS, OPERATIONS, DRUG INFO, PREVENTION, PRESS ROOM.
- Main Content Area:**
 - Left: "Tough Work, Vital Mission The Facts About DEA" with a blue background and a white arrow graphic.
 - Center: A large gold DEA badge.
 - Right: Three blue and gold boxes for "Drug Facts for Today's Teens", "A DEA Resource for Parents", and "Wall of Honor".
- Footer/Bottom Section:** Three columns: "TOP STORY" (Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy), "TOPICS OF INTEREST" (DEA Fact Sheet, Drugs of Abuse: A DEA Resource Guide, etc.), and "RESOURCE CENTER" (Controlled Substances Act, DEA Museum and Visitors Center, etc.).



DEA Web-based Resources

www.JustThinkTwice.com

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

Parents & Educators | Drug Glossary

SEARCH

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

THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF?

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

[GET THE FACTS ABOUT METHAMPHETAMINE »](#)

MARIJUANA | COCAINE | METH

IT'S TIME TO 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.



DEA Web-based Resources

www.GetSmartAboutDrugs.com

The screenshot shows the homepage of the GetSmartAboutDrugs.com website. At the top left is the DEA logo and the text "GetSmartAboutDrugs A DEA Resource for Parents". A navigation bar contains links for Home, Identify, Prevent, Help, Hot Topics, DEA in the Community, and Communities of Practice. A search bar is located on the right side of the navigation bar. The main content area features a "COMMUNITIES of PRACTICE" section with a sub-header "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." Below this text is a "Learn more" button with a right-pointing arrow. To the right of the text is a small image of a computer monitor displaying the "TRAIN the TRAINER" module. Further right are two promotional boxes: "DEA Publications" with a "READ MORE" button and "Watch the Videos" with a "VIEW" button. At the bottom of the page, there are three columns: "Latest News" with two articles, "Voices" with a story titled "Irma Perez's Story", and "Inside DEA" with a paragraph about the agency's role.

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

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](#)

BACK STOP NEXT

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...



thomas.w.prevoznik@usdoj.gov

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