



# Current Trends in DEA Compliance

## National Association Chain Drug Stores

August 24, 2015



The United States Department of Justice  
**Drug Enforcement Administration**

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Liaison and Policy Section  
Office of Diversion Control





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# *What People Are Abusing*

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# Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)
- Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin<sup>®</sup>, Lortab<sup>®</sup>, Lorcet<sup>®</sup>
- Currently, combination products are Schedule III
- **October 6, 2014 moved to SCHEDULE II**
- “Cocktail” or “Trinity”
  - Hydrocodone
  - Soma<sup>®</sup> / carisoprodol
  - Alprazolam / Xanax<sup>®</sup>
- 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%



# The Trinity



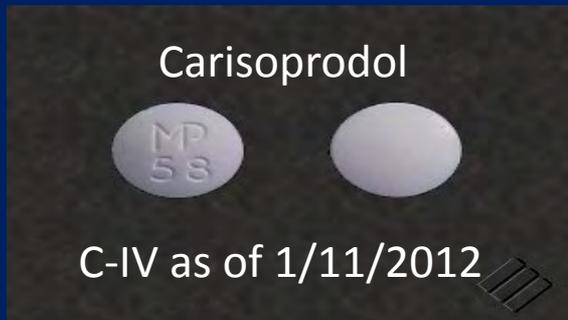
Opiate



Muscle Relaxant



Benzodiazepine



Carisoprodol

C-IV as of 1/11/2012

# Commonly Abused Controlled Substances



Hydrocodone



OxyContin 80mg



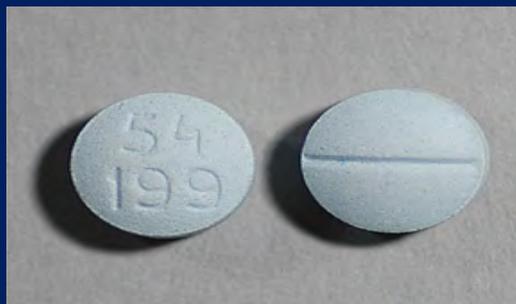
Oxymorphone



Alprazolam



Oxycodone 30 mg



U.S. Drug Enforcement Administration  
Office of Diversion Control



# 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<sup>®</sup> / carisoprodol, Alprazolam / Xanax<sup>®</sup>)
- 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 vs. Heroin*





# The Circle of Addiction & The Next Generation

Oxycodone  
Combinations

Percocet®

\$7-\$10/tab

OxyContin®  
\$80/tab

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

Hydrocodone  
Lorcet®  
\$5-\$7/tab

Heroin  
\$15/bag





# Heroin: No Longer Confined to Urban Areas


**NOW OPEN**  
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 See what it's like to love our brand  
**OF SILVER SPRING**  
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**1-888-589-3065**  
 www.DARCARSvolkswagen.com  
 Call / Email Alex Pedram, General Sales Manager  
 APedram@Darcars.com

washingtonexaminer.com  
  
**The Examiner**  
**WASHINGTON**  
 WEDNESDAY, DECEMBER 5, 2012

**Ship's Hatch**  
 Army, Navy,  
 USAF, USMC & USCG  
 Promotion/Retirement  
 Gifts, Flag Cases,  
 Presentation Clocks  
**703.413.6289**  
 www.shipshatch.com  
 Located in the Shops at Crystal City


**'Liaisons Dangereuses'**  
 New approach to classic P. 19


**Playoff possibilities**  
 Schedule favors Skins P. 35

**Cooling down**  

**60°-34°**  
 DETAILS P. 4

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

**LOCAL**  
**FBI analyst busted**

# Heroin use spikes in area suburbs

## Pill addicts risk deadly drug



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# *The CSA: Checks and 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

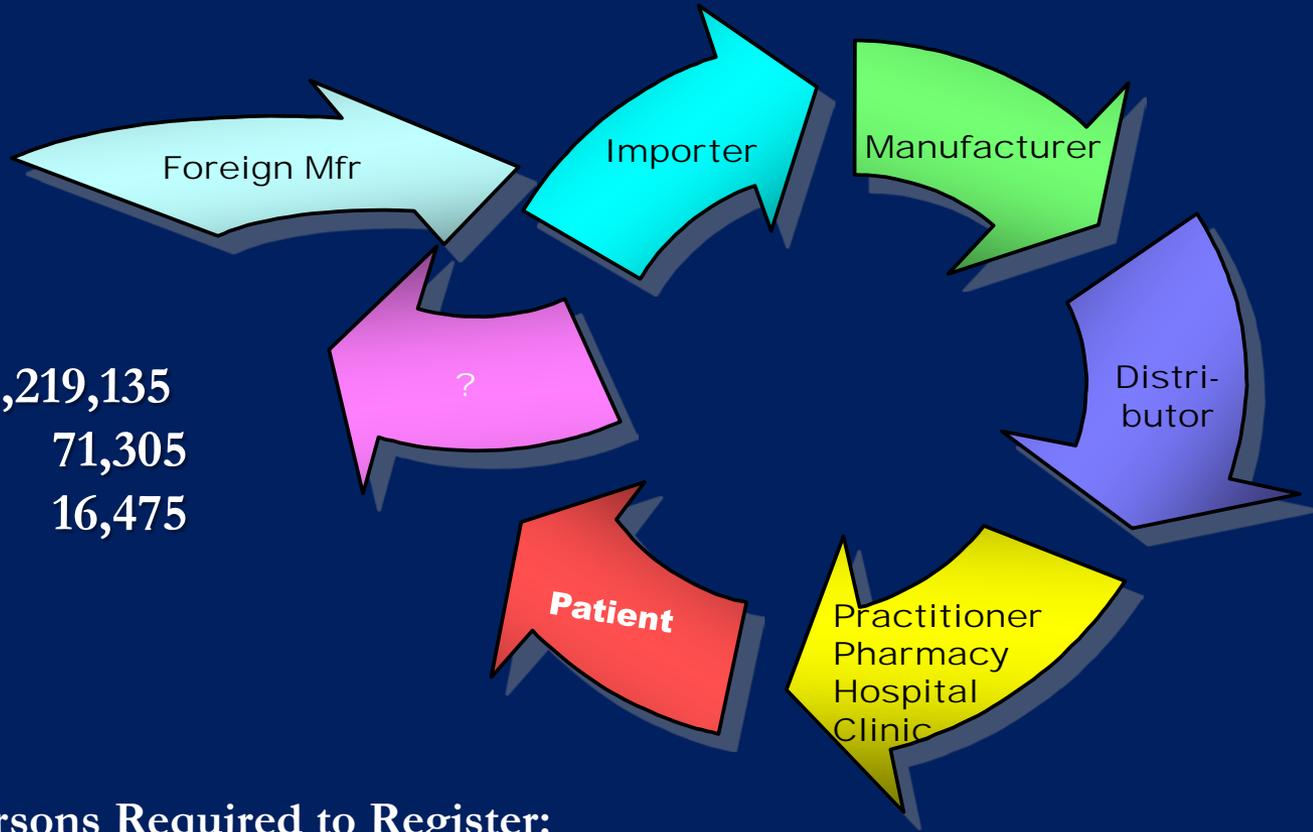


# *Cutting off the Source of Supply*





# Closed System of Distribution



1,599,457 (08/14/15)

Practitioners:	1,219,135
Retail Pharmacies:	71,305
Hospital/Clinics:	16,475

**Law: 21 USC 822 (a) (1) Persons Required to Register:**

“Every person who manufactures or distributes any Controlled Substance or List I Chemical or who proposes to engage in ..”

**Law: 21 USC 822 (a) (2) Persons Required to Register:**

“Every person who dispenses, or who proposes to dispense any controlled substance ...”



# *Closed System of Distribution*





# *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





# *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 – August 21, 2015:** Briefings to **85** firms with **280** registrations



# *DEA Registrant Initiatives*

## **Pharmacy Diversion Awareness Conference**

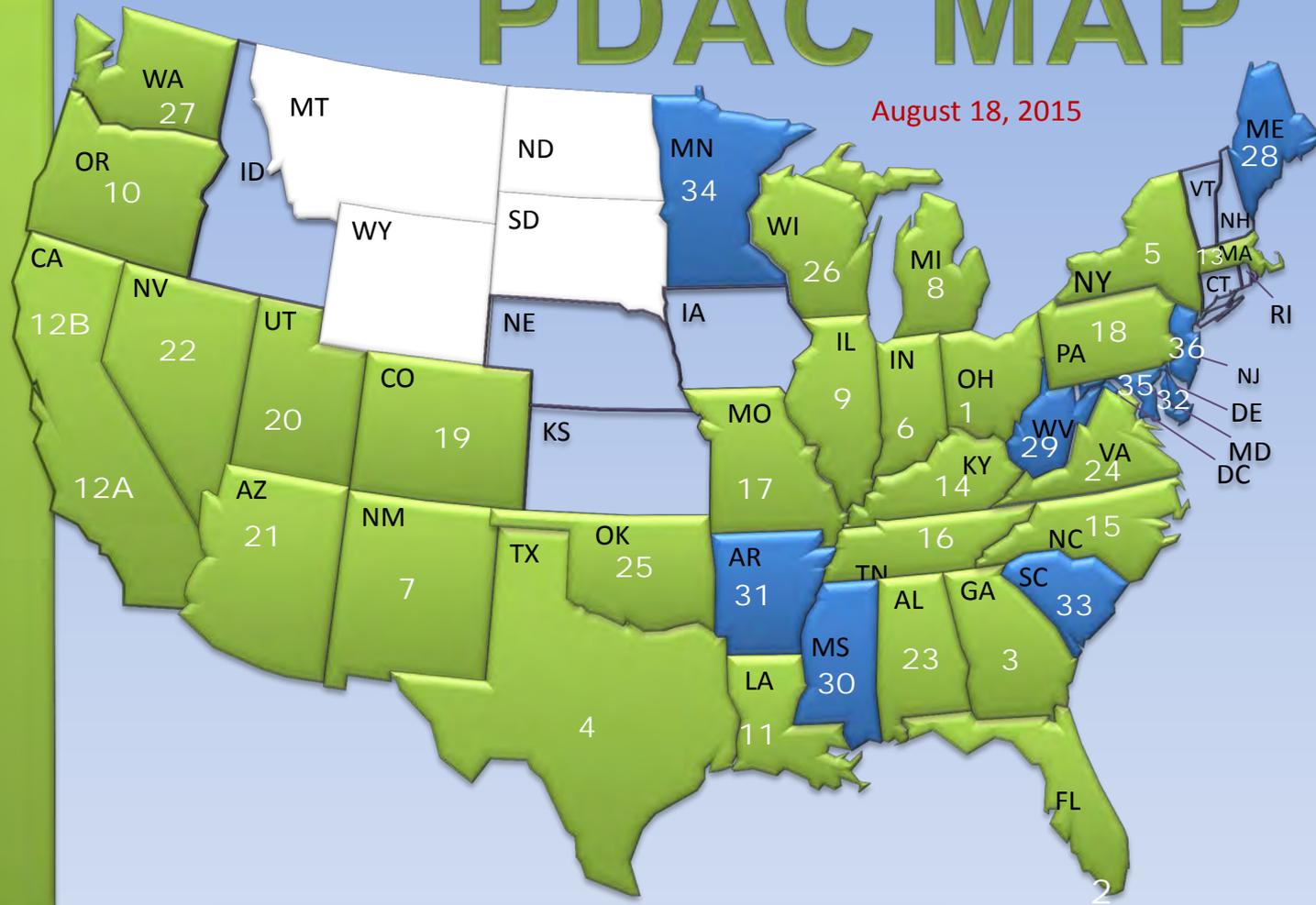
This conference is designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity

# PDAC MAP

August 18, 2015

## Completed PDACs Attendance

Completed PDACs	Attendance
<b>FY-2011</b>	
1-Cincinnati, OH 9/17-18/11	75
<b>FY-2011 Total Attendance</b>	<b>75</b>
<b>FY-2012</b>	
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
<b>FY-2012 Total Attendance</b>	<b>2,429</b>
<b>FY-2013</b>	
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
<b>FY-2013 Total Attendance</b>	<b>2,948</b>
<b>FY-2014</b>	
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
<b>FY-2014 Total Attendance</b>	<b>2,196</b>
<b>FY-2015</b>	
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
<b>Total Attendance To Date</b>	<b>9,124</b>



Approved FY 2015 PDACs  
 28-Portland, ME September 12-13, 2015

Proposed FY-2016 PDACs  
 29-Little Rock, Arkansas November 2015  
 30-Jackson, MS January 2016  
 31-Charleston, WV February 2016  
 32-Wilmington, Delaware March 2016  
 33-Charleston, South Carolina April 2016  
 34-Minneapolis/St. Paul, Minnesota July 2016  
 35-Towson, Maryland August 2016  
 36-New Brunswick, New Jersey September 2016

Completed PDACs

Proposed PDACs



# *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.



# *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



# *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



# *Effective Controls*

21 CFR § 1301.71(a)

*“All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”*



# *Effective Controls*

## 21 CFR § 1301.71(a)

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**



# *Suspicious Orders*

21 CFR § 1301.74(b)

*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.”*



# Prescriptions

21 CFR § 1306.04(a)

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.



*United States v Moore* 423 US 122 (1975)



# ***Checks and Balances Under the CSA***

## **Pharmacists – The Last Line of Defense**

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

**(21 CFR § 1306.04(a))**

*U.S. v. Hayes* 595 F. 2d 258 (5<sup>th</sup> Cir 1979)

*U.S. v. Leal* 75 F. 3d 219 (6<sup>th</sup> Cir 1996)

*U.S. v. Birbragher* 603 F. 3d 478 (8<sup>th</sup> Cir 2010)

*East Main Street Pharmacy* 75 Fed. Reg. 66149 (Oct. 27, 2010)



# Checks and Balances Under the CSA

## Pharmacists – The Last Line of Defense

***“An order purporting to be a prescription issued not in the course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the act (21 USC 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” (21 CFR § 1306.04(a))***

*U.S v. Hayes 595 F. 2d 258 (5<sup>th</sup> Cir 1979)*

*U.S. v. Leal 75 F. 3d 219 (6<sup>th</sup> Cir 1996)*

*U.S. v. Birbragher 603 F. 3d 478 (8<sup>th</sup> Cir 2010)*

*East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)*



# *The Last Line of Defense*





# Corresponding Responsibility

21 CFR § 1306.04(a)

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.





# *Corresponding Responsibility*

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate
- Just because 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!!!



# *DEA Legal Resources*

## ➤ Administrative

Immediate Suspension Order (ISO)

Memorandum of Agreement (MOA)

Order to Show Cause (OTSC)

## ➤ Civil

Fines

## ➤ Criminal

Arrests

Criminal fines





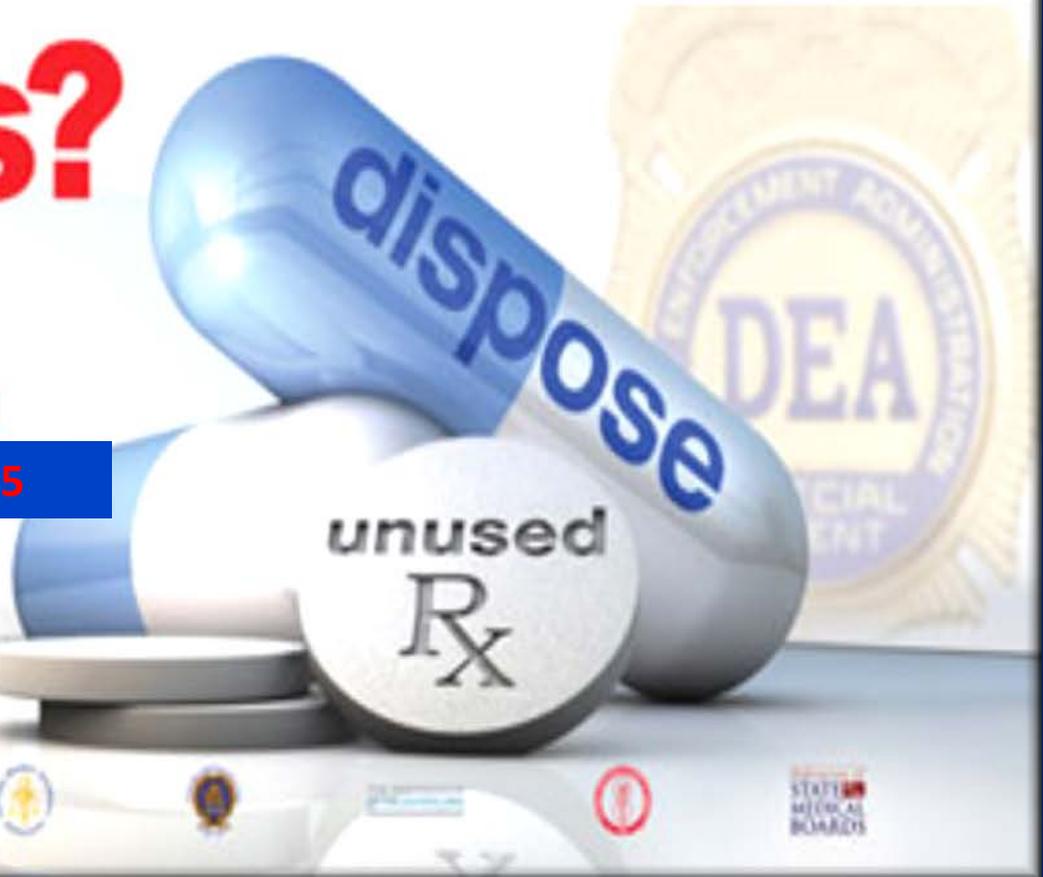
# *National Take Back Initiative*

## *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





# DEA Web-Based Resources

[www.DEA.gov](http://www.DEA.gov)

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

- Header:** "DEA" in large gold letters, "UNITED STATES Drug Enforcement Administration" in white, and the slogan "TOUGH WORK, VITAL MISSION".
- Navigation Menu:** HOME, ABOUT, CAREERS, OPERATIONS, DRUG INFO, PREVENTION, PRESS ROOM.
- Main Content Area:**
  - Left: "Tough Work, Vital Mission The Facts About DEA" with a blue graphic of a hand holding a torch.
  - Center: A large gold DEA badge.
  - Right: Three resource boxes:
    - "Drug Facts for Today's Teens" with link [JustThinkTwice.com](http://JustThinkTwice.com)
    - "A DEA Resource for Parents" with link [GetSmartAboutDrugs.com](http://GetSmartAboutDrugs.com)
    - "Wall of Honor" with link [DEA Remembers](#)
- Footer/Content Columns:**
  - TOP STORY:** "Couple Handed Lengthy Sentences in International Cocaine Trafficking Conspiracy" dated JAN 29 (BROWNSVILLE, TEXAS). Below the headline is a partial line of text: "Norma Alicia Gallegos, 30, and her husband Jose Carlos..."
  - TOPICS OF INTEREST:** DEA Fact Sheet; Drugs of Abuse: A DEA Resource Guide; Extension of Temporary Placement of Five Synthetic Cannabinoids; The DEA Position on Marijuana.
  - RESOURCE CENTER:** Controlled Substances Act; DEA Museum and Visitors Center; Doing Business with DEA; Drug Disposal; Employee Assistance Program.



# DEA Web-Based Resources

[www.JustThinkTwice.com](http://www.JustThinkTwice.com)

The screenshot shows the homepage of the Just Think Twice website. The browser address bar displays "http://www.justthinktwice.com". The website header includes the title "JUST THINK TWICE" and the tagline "YOU'VE HEARD THE FICTION. NOW LEARN THE FACTS." A navigation menu contains links for HOME, DRUG FACTS, FACTS & FICTION, CONSEQUENCES, TEENS TO TEENS, and INSIDE DEA. The main content area features a large banner for "THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF" with a photo of a young woman. Below the banner are three buttons for "MARIJUANA", "COCAINE", and "METH". To the right, there are two smaller promotional boxes: "IT'S TIME TO SMATTER THE MYTHS ABOUT DRUGS AND DRUG ABUSE" and "FACTS & FICTION Get the Facts". At the bottom, a "Did You Know?" section discusses "meth mouth".

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

Parents & Educators | Drug Glossary

SEARCH

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

**THINK YOU KNOW WHAT METHAMPHETAMINE IS MADE OF**

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

[GET THE FACTS ABOUT METHAMPHETAMINE »](#)

MARIJUANA | COCAINE | METH

**IT'S TIME TO 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 a web browser window displaying the homepage of [www.getsmartaboutdrugs.com](http://www.getsmartaboutdrugs.com). The page features a navigation menu with 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 menu. The main content area includes a featured article about the Communities of Practice section, a 'Learn more' button, and a 'BACK STOP NEXT' navigation bar. Below this, there are three main sections: 'Communities of Practice' with a 'READ MORE' button, 'DEA Publications' with a 'READ MORE' button, and 'Watch the Videos' with a 'VIEW' button. At the bottom, there are three columns: 'Latest News' with a link to 'See All News Stories', 'Voices' featuring 'Irma Perez's Story', and 'Inside DEA' with a brief introduction to the organization's members.

### 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...



***Thank You***