DEA Trends & Update

Missoula, Montana Pharmacy Diversion Awareness Conference

August 5, 2017

The United States Department of Justice
Drug Enforcement Administration

Luis Carrion
Staff Coordinator
Liaison and Policy Section
Diversion Control Division

Housekeeping

Welcome to the Pharmacy Diversion Awareness Conference (PDAC)

- (Omaha, Nebraska)
- 90th PDAC (Sunday, June 4, 2017)
- Please silence **cell phones**
- **NO VIDEO/AUDIO RECORDING**
- **RESTROOMS**
- **CPE Codes**
  - Codes will be provided at the end of each presentation block
  - Due by **Thursday August 3rd, 2017 by *11:59pm CDT***
  - Don't forget to complete your evaluations
  - Please wait to register until Monday
  - In about 3 weeks, presentations will be available
- **PARKING**
- **LUNCH:** On-site restaurants / Other options within walking distance
- **COFFEE:** On-site options

Goals and Objectives

- DEA's Mission
- Public Health Epidemic
- Looking at the Past
- Drugs of Abuse
- Impact on the youth
- From Pharmaceuticals to Heroin
- Indiscriminate Prescribing
- Criminal Activity
- Legal Obligations of DEA Registrants
- DEA's Response
- Drug Disposal

DEA's Mission

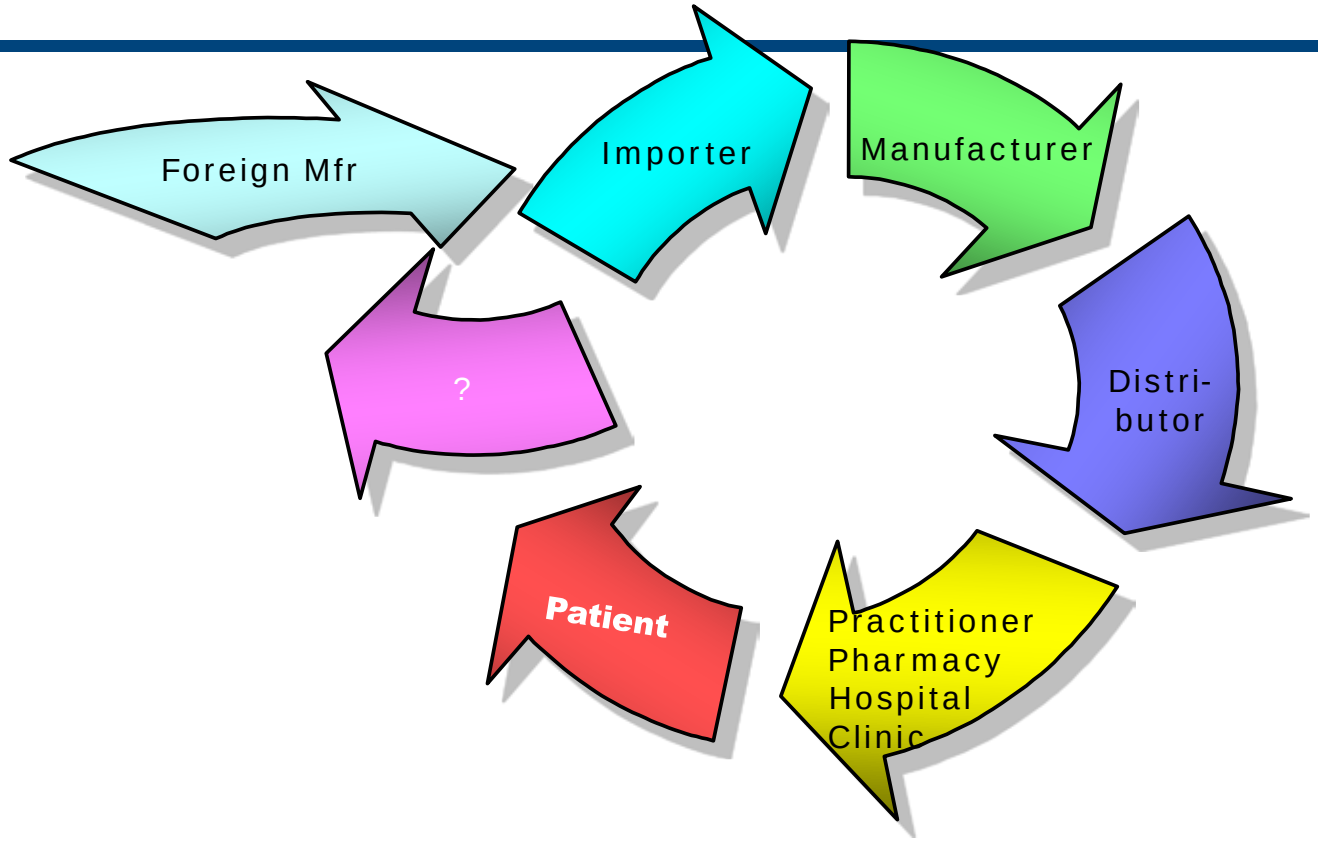
Mission

The mission of the Diversion Control Division 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.

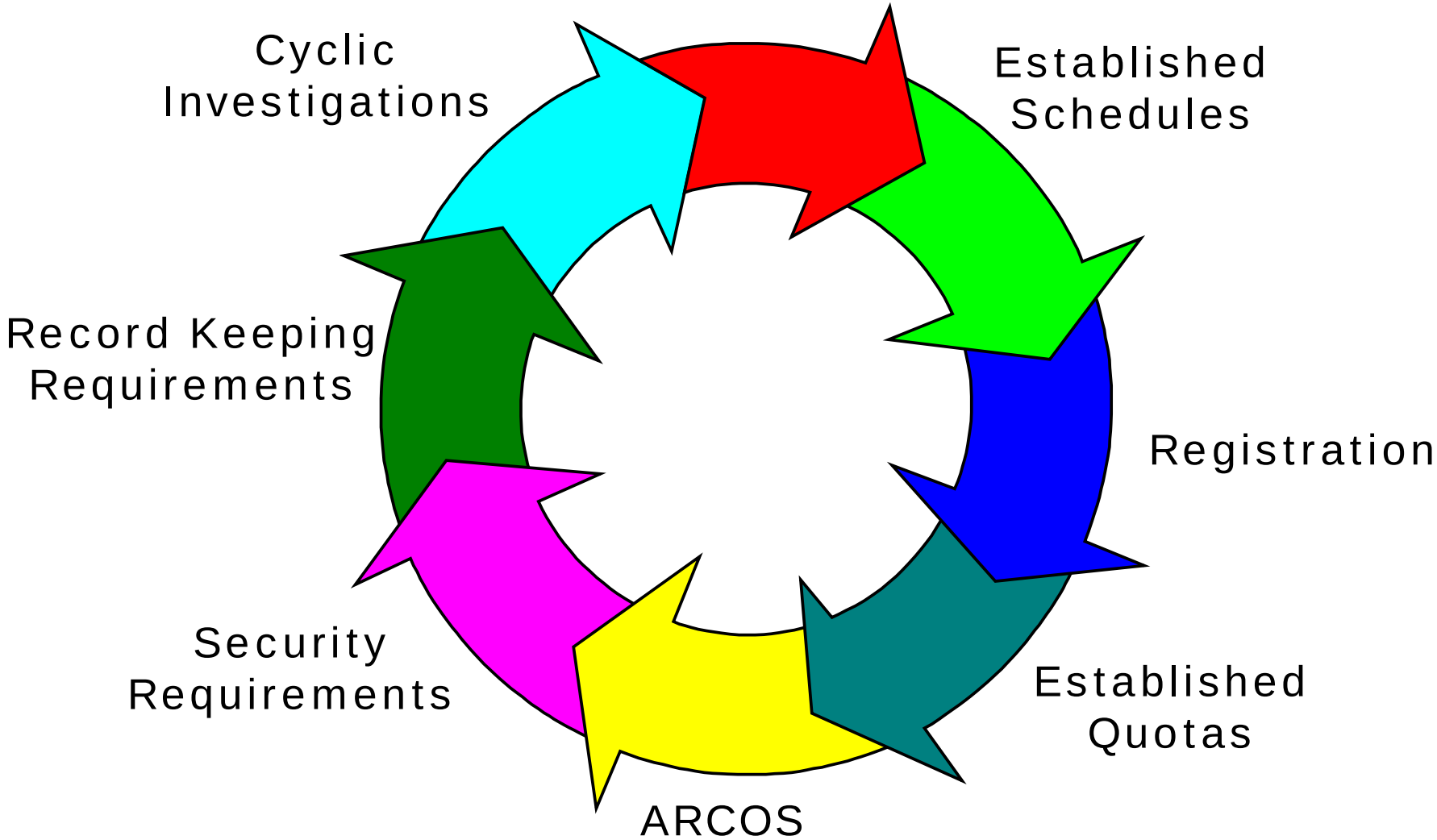
Closed System of Distribution



1,707,111 (7/31/2017)

- **Practitioners: 1,267,267**
- **Mid Level Practitioner: 333,579**
- **Retail Pharmacies: 71,851**
- **Hospital/Clinics: 17,756**

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 doesn't regulate the practice of medicine.

Public Health Epidemic

U.S. Drug Enforcement Administration
Diversion Control Division

Public Health Epidemic

2000-2015

Over **550,000** unintentional **drug overdose deaths** in the US

2015

52,404 drug-related overdose deaths

143 deaths every 24 hours (129 in ’14)
1 death every 10.07 minutes (11.16 minutes ‘14)

33,091 deaths involved opioids, including heroin (91)
*17,536 deaths involved opioid pain relievers (48)

*Opioid Pain relievers (other than synthetic opioids) ICD-10 codes (T40.2, T40.3, & T40.6) excluding the category predominated by illicit fentanyl

CDC National Center for Health Statistics/Morbidity and Morality Weekly Report (MMWR); December 30, 2016

On an average Day in the U.S.:

- More than **650,000 opioid prescriptions** dispensed[1]
- **3,900 people** initiate nonmedical use of prescription opioids[2]
- **580 people** initiate heroin use[2]

1. **Source:** IMS Health National Prescription Audit
2. SAMHSA National Survey on Drug Use and Health
3. Center for Disease Control (CDC) National Vital Statistics System

Data Brief 273: Drug Overdose Deaths in the United States, 1999–2015

Data table for Figure 5. Percentage of drug overdose deaths involving selected drug categories: United States, 2010, 2014, and 2015

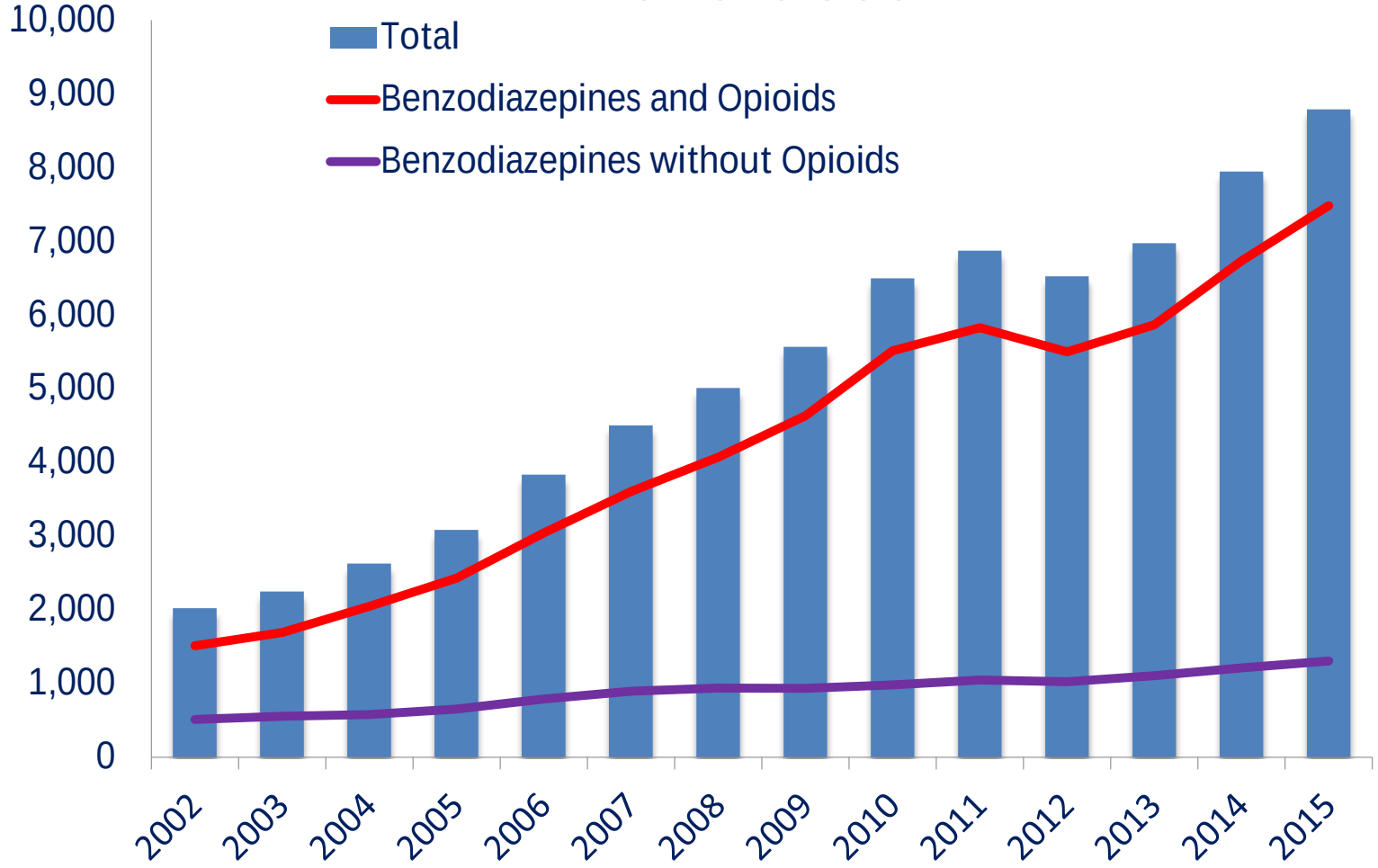
	All drug overdose deaths		Heroin		Natural and semisynthetic opioids		Methadone		Syntheticopioids excluding methadone		Cocaine		Psychostimulants with abuse potential	
Year	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
2010	38,329	100	3,036	7.9	10,943	28.6	4,577	11.9	3,007	7.8	4,183	10.9	1,854	4.8
2014	47,055	100	10,574	22.5	12,159	25.8	3,400	7.2	5,544	11.8	5,415	11.5	4,298	9.1
2015	52,404	100	12,989	24.8	12,727	24.3	3,301	6.3	9,580	18.3	6,784	12.9	5,716	10.9

NOTES: Deaths are classified using the *International Classification of Diseases, Tenth Revision*. Drug overdose deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. Drug overdose deaths involving selected drug categories are identified by specific multiple-cause-of-death codes: for heroin, T40.1; natural and semisynthetic opioids, T40.2; methadone, T40.3; synthetic opioids excluding methadone, T40.4; cocaine, T40.5; and psychostimulants with abuse potential, T43.6. Categories are not mutually exclusive because deaths may involve more than one drug. The percentage of drug overdose deaths lacking information on the specific drugs involved varied by year: 25% in 2010, 19% in 2014, and 17% in 2015.

SOURCE: NCHS, National Vital Statistics System, Mortality.

National Institute on Drug Abuse

Opioid involvement in benzodiazepine overdose



Source: National Center for Health Statistics, CDC Wonder

DRAWINGBOARD / SIGNE

How did we get here?

Rx Drug Ads on TV –

Educational or Influential ?

Overweight? Suffering from anxiety or erectile dysfunction? Well, relief is just a prescription pill away according to the endless television ads promoting prescription drugs.

Drugs of Abuse

U.S. Drug Enforcement Administration
Diversion Control Division

Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen

Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

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

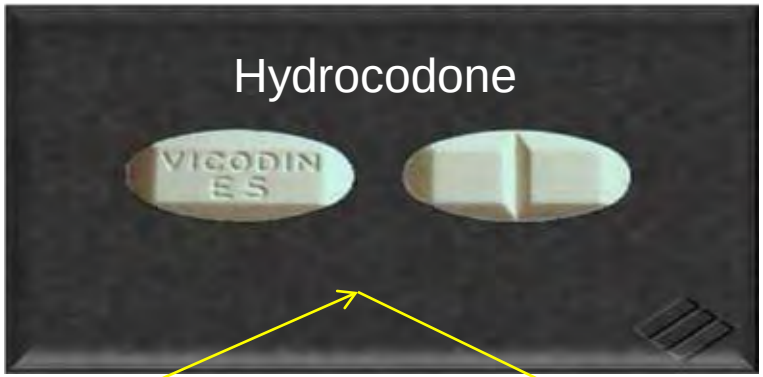
- Brand Names: Vicodin®, Lortab®, Lorcet®

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

- **"Cocktail" or "Trinity"**
  Hydrocodone (opioid)
  Soma ® / carisoprodol (Schedule 4 muscle relaxant)
  Alprazolam / Xanax® (Benzo)

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

The Trinity Cocktail



Opiate

Muscle Relaxant

Benzodiazepine

The 1990s

OxyContin® Tablets
(oxycodone hydrochloride controlled-release)

Oxycontin

- 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, 20, 40, 80mg available

- Effects:
  - Similar to morphine in effects and potential for abuse/ dependence
  - Sold in **"Cocktails" such as:**

  Oxycodone, Soma ® and Xanax®

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

*

Oxycodone HCL CR (OxyContin®) Reformulation

<u>NOTE:</u> **New formulation** introduced **in 2010** made it more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.

Caused large drops in sales when the reformulation when into effect.

Hydromorphone

- Opioid
- Used for moderate to severe pain
- 8 times stronger than morphine
- Recreationally used as heroin
- Best consumed intravenously

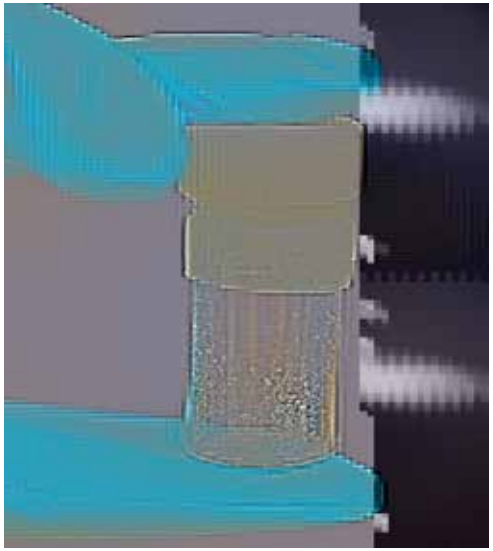
***In 2008, there were over 14,000 hydromorphone overdose deaths in the US*.**

Fentanyl

Legitimate

VS.

Clandestine



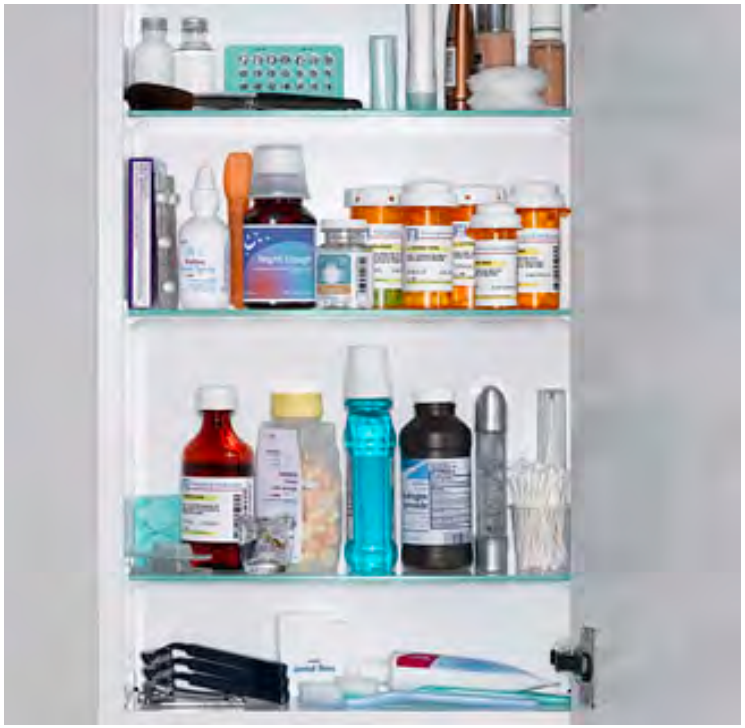
Impact on our youth

Skittles Party

Generation RX

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

Friends and Family…For Free!!



Where else do our kids get their information from?

www.erowid.org

Where do kids get their information from?

www.bluelight.org

www.bluelight.ru/vb/

Google Bluelight

User Name | Password | Log in | Remember Me? | Help | Register

BLUELIGHT

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PSYCHEDELICSCIENCE2013 APRIL 18TH REGISTER NOW
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The Front Page | Advanced Search

The Front Page

If this is your first visit, be sure to check out the FAQ.

You may have to register before you can post: click the register link above to proceed. To start viewing messages, select the forum that you want to visit from the selection below.

Features

Bluelight Wiki	Our own Wiki project
Blogs	Blogs from our members
Bluelight Mobile	Use Bluelight on the go!
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Twitter	Follow us on Twitter

Forums

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Ecstasy Discussion
Cannabis Discussion
Steroid Discussion
Psychedelic Drugs
Other Drugs

Drug Discussion
Drug Studies
Drugs in the Media
Basic Drug Discussion
Advanced Drug

Australia & Asia
Australian Drug Discussion
Australian Social & Events

Europe & Africa
European Drug Discussion
European Events

North America & South America
North & South American Social & Drug Discussion
North & South American Events

THE FRONT PAGE

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

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

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

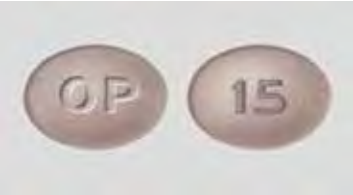
Through the efforts of Brad Burge, MAPS' Director of Communications, Rick Doblin, MAPS' Founder and Executive Director, Sebastians_Ghost and The_Love_Bandit of Bluelight.ru, we will soon undertake an exciting partnership to reinvigorate the MAPS forum and increase opportunities for public education about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

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

...

start | Bluelight - The Front ...

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

Quote

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:

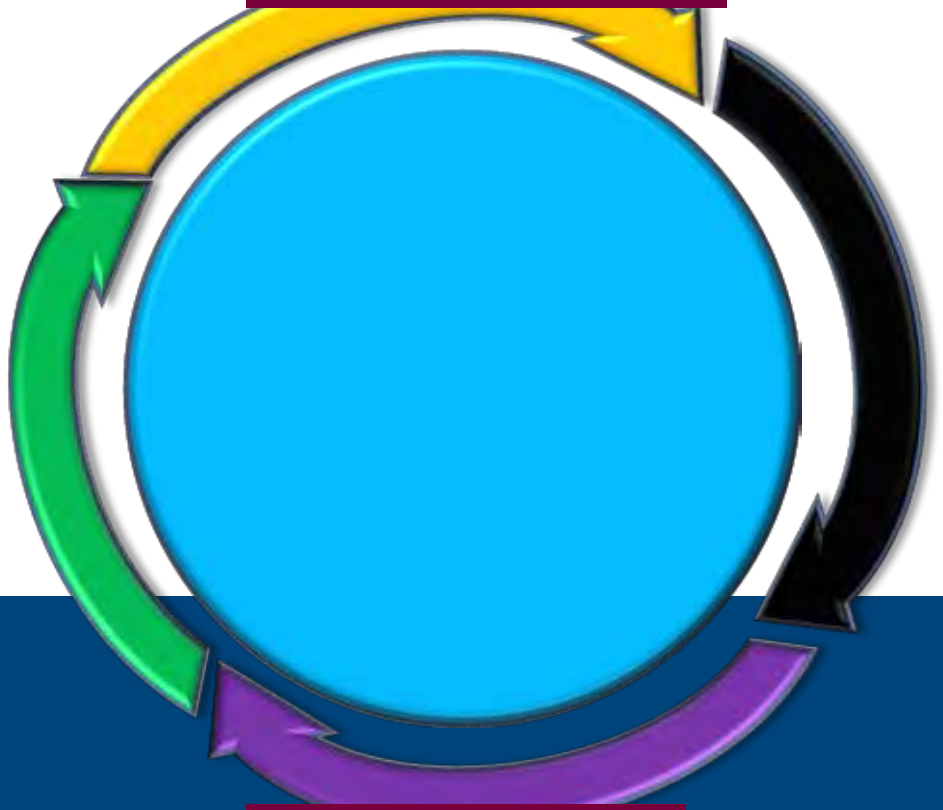
Originally Posted by **stalk**
I've come to the conclusion it's because these psychedelic visions are simply vibrating on a higher, or different, spectrum of frequencies that normally the monkey does not perceive.

Pills v. Heroin

U.S. Drug Enforcement Administration
Diversion Control Division

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
$5 -$10/bag

U.S. Drug Enforcement Administration
Diversion Control Division

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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

Community Impact?

Heroin trafficking organizations relocating to areas where prescription drug abuse is on the rise

Heroin traffickers pave the way for increasing crime and violence

Law enforcement and prosecutors eventually fighting the problem on two fronts (prescription opiate diversion and heroin distribution) further depleting resources

Communities suffer

Pharmaceutical Oxycodone 30mg

Heroin Seizure

NEWS

COPS: PHOTOS OF BOY WITH PASSED-OUT ADULTS SHOW DRUG SCOURGE

Share Email

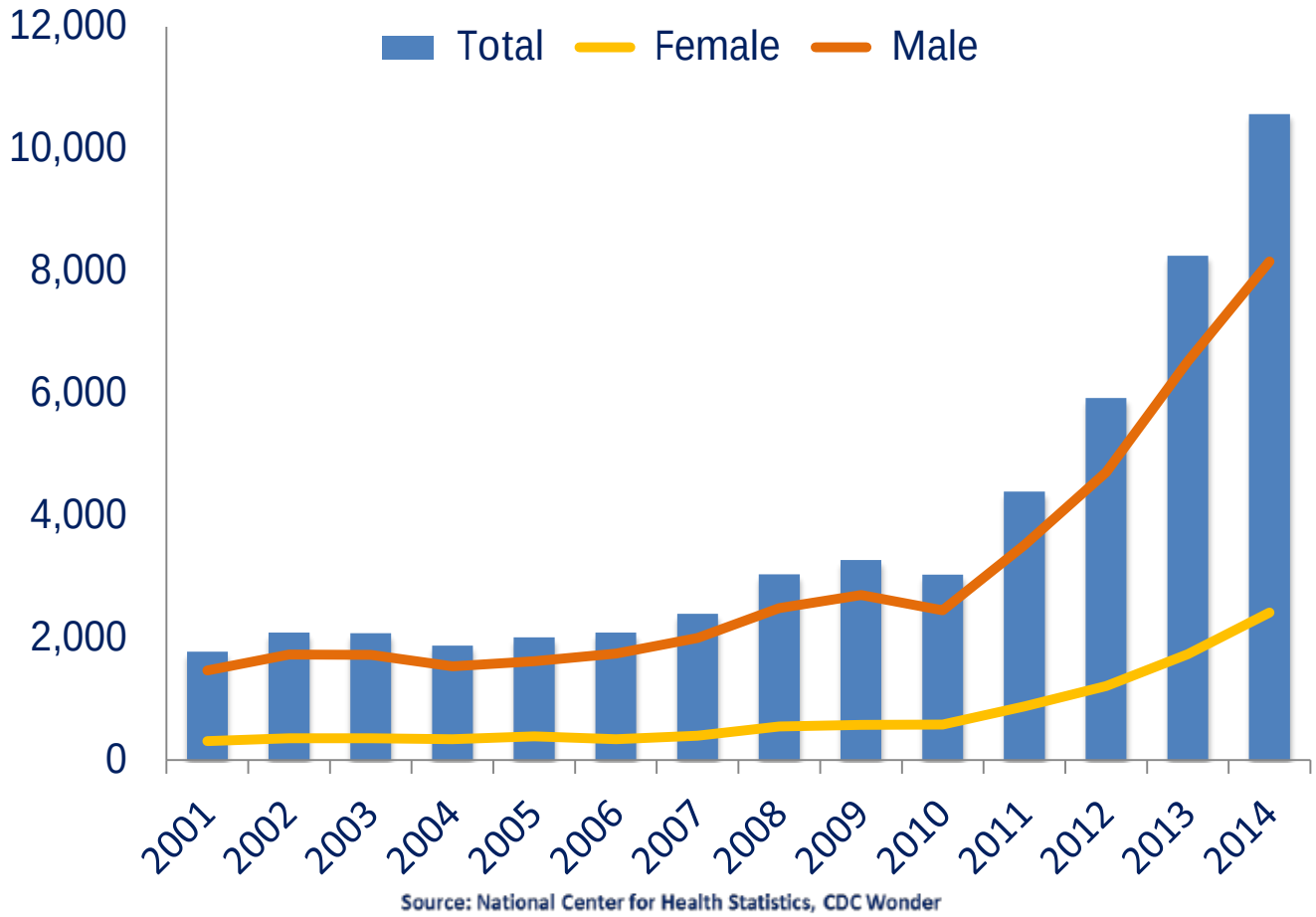
Police in East Liverpool, Ohio released these images they say to illustrate the impact of the heroin and painkiller epidemic. (City of East Liverpool, Ohio/Facebook)

Scope of the Problem

CDC (2016):

Heroin deaths **more than triple** between 2010-2014

"This increase . . . has been shown to be closely tied to opioid pain reliever misuse and dependence."



Violence

U.S. Drug Enforcement Administration
Diversion Control Division

Violence Related to Controlled Substance Pharmaceuticals

NEW YORK POST Page Six

METRO EDITION www.nypost.com $1.00

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

NEW YORK POST Page Six

METRO EDITION www.nypost.com $1.00

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 Melissa's addiction, cops said yesterday.

PAGES 4-5

Prescription Drug Abuse is driven by

Indiscriminate Prescribing

Criminal Activity

“Primum non nocere”
"First, do no harm”

This is the basic principle to practice medicine.
Doctors take an oath to do no harm and provide the best care for their patients.
Doctors are realizing the potential for addiction when they first prescribe opioids for chronic pain, even if it is in small quantities. Indiscriminate prescribing can endanger patients’ lives. Patients have gotten addicted and have overdosed.
Doctors are realizing that freely prescribing opioids is dangerous, causing them to use other remedies and implement opioids as the last option.

Many Patients Share Medication prescribed

Two new U.S. studies shed light on opioid epidemic

- **1. University of Pennsylvania Dental School Study:**

***More than half of the narcotics prescribed for wisdom teeth removal go unused…findings suggest that more than 100 million pills prescribed go unused…leaving the door open for possible misuse or abuse.**

Source: https://www.pennmedicine.org/news/news-releases/2016/september/100-million-prescription-opioid

- **2. John Hopkins Study:**

+60% had leftover opioids they hung on for **"future use"**

20% **shared** their medications

8% likely will share w/ **friend**

14% likely will share w/ **relative**

-10% **securely lock their medication**

https://www.nlm.nih.gov/medlineplus/news/fullstory_159336.html

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Clinical Reminders:
  - **Opioids are not first-line or routine therapy for chronic pain**
  - Establish and measure goals for pain and function
  - Discuss benefits and risks and availability of non opioid therapies with patient

Source: CDC Morbidity & Mortality Weekly Report **CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, March 15, 2016** www.cdc.gov/drugoverdose/prescribing/guideline.html

CDC Guidelines for Prescribing Opioids for Chronic Pain

- **Use immediate-release opioids when starting**
- ***Start low and go slow***
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- ***Follow-up and re-evaluate risk of harm***; reduce dose or taper and discontinue if needed

Source: CDC Morbidity & Mortality Weekly Report **CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, March 15, 2016** www.cdc.gov/drugoverdose/prescribing/guideline.html

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Evaluate risk factors for opioid-related harms
- ***Check PDMP*** for higher dosages and prescriptions from other providers
- ***Use urine drug testing to identify prescribed substances and undisclosed use***
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

Source: CDC Morbidity & Mortality Weekly Report **CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016, March 15, 2016** www.cdc.gov/drugoverdose/prescribing/guideline.html

Survey of Long-Term Painkiller Users

- Majority say their doctor talked about possibility of addiction or dependence – **61% say there was no discussion about plan to get them off.**

- Majority say they used the drugs to relieve pain. Other major reasons for taking them:
  - 20% - ‘for fun or get high”
  - 14% - “to deal with day-to-day stress”
  - 10% - “to relax or relieve tension”

- Other Findings:
  - 34% admit being dependent or addicted
  - 17% have taken painkillers that were not specifically prescribed for them
  - 14% have given their painkillers to a family member or friend
  - 20% know or suspect someone was using, taking or selling their painkillers

Source: Washington Post/Kaiser Family Foundation Survey of Long-Term Prescription Painkiller Users and Their Household Members December 2016

Criminal Activity

United States V. Alvin Yee, M.D.

Dr. Alvin Yee

U.S. Drug Enforcement Administration
Diversion Control Division

United States V. Alvin Yee, M.D.

MEDICAL OFFICE
Various Locations, Orange County, California

United States V. Alvin Yee, M.D.

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.

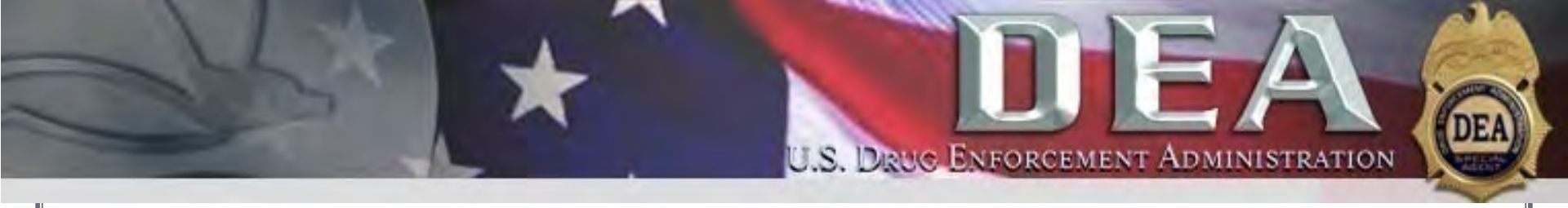
CURES Data (PMP)

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 (92%-30mg) during the one-year period.

96% - oxycodone, hydrocodone, alprazolam, hydromorphone, and oxymorphone.

Almost half of **Yee's patients were 25 and under**.



Legal Obligations of DEA Registrants

U.S. Drug Enforcement Administration
Diversion Control Division

Effective Controls

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

- 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 professional practice.

21 CFR § 1306.04(a)

United States v Moore 423 US 122 (1975)

Corresponding Responsibility by Pharmacist

- 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!!!

Corresponding Responsibility by Pharmacist

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)

The Last Line of Defense

www.nabp.net

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CPE Monitor
Safe Online Pharmacies
NEWSROOM HEADLINES

Who do I call to report a practitioner?

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

DEA's Response

U.S. Drug Enforcement Administration
Diversion Control Division

Scheduled Investigations

- DEA has increased the number of registrants to be inspected to ensure compliance with the Controlled Substances Act and its implementing regulations
- DEA has also increased in the frequency of the regulatory investigations
- Verifications of customers and suppliers

360 Degree Strategy

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.

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

Briefings to **99** firms with **309** registrations

DEA Registrant Initiatives

Pharmacy Diversion Awareness Conferences

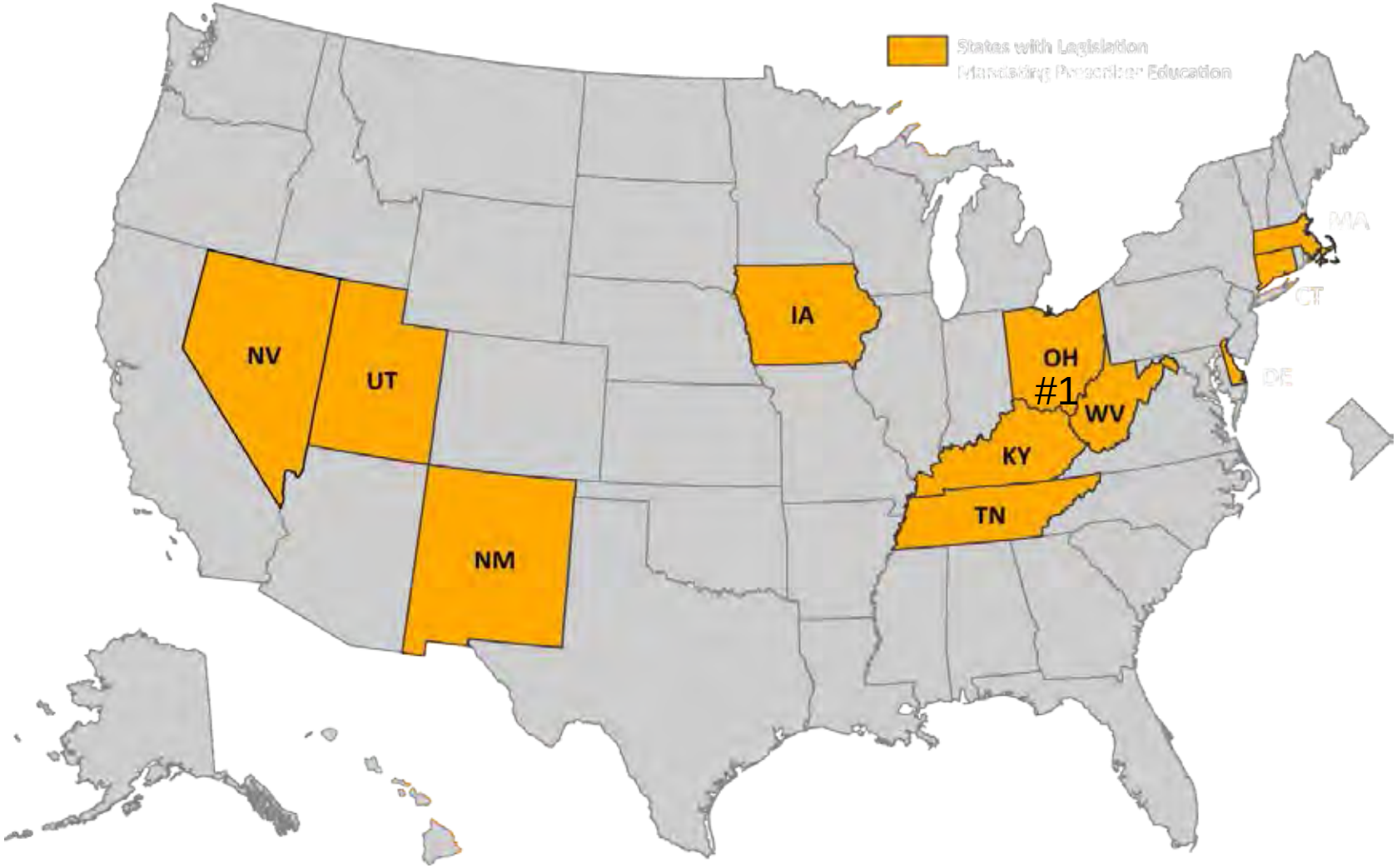
These conferences are designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity.

DEA working jointly with FSMB

- 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

Since 2011, Eleven States have Passed Legislation Mandating Prescriber Education



Maine

- Second State to Mandate Electronic Prescribing
- Prescribers are required to undergo addiction training every 2 years
- Set cap on daily strength for opioid prescribing:
  - Acute pain – 7 days
  - Chronic pain – 30 days
- **Began: *January 2017***

National Take Back Initiative (NTBI)

#14

OCTOBER 28, 2017

10:00 AM – 2:00 PM

Disposal of Controlled Substances

U.S. Drug Enforcement Administration
Diversion Control Division

Retail Pharmacies' Disposal - Inventory

For disposals of Retail Pharmacy CS inventory:

- **Incineration and Chemical Ingestion – DEA's acceptable methods of destruction that renders all controlled substances non retrievable**
- **Retail Pharmacies – Use reverse distributors**
- **Use 222s for transfer of Schedule 2 CS**
- **Reverse Distributors will complete the DEA-41: copy may be requested**
- **Present this to Investigators during onsite inspections**

Ultimate User

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

21 USC § 802(27)

Ultimate user methods of destruction prior to Disposal rule:

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

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)

- Participation is voluntary

  21 USC § 822(g)(2)

- 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.

How a registrant becomes a collector?

- Must be registered to handle Schedule 2 CS
- Must request a modification from DEA (can be in writing or online)
- Request contains:

1. Registrant's name, address and DEA #
2. Method of collection: (receptacle or mail back)
3. Authorized signature

*No fee for modification

21 CFR 1301.51(b) and (c)

Collection Receptacle

Collection means to receive a controlled substance for the purpose of destruction.

§ Places where they can be located:

1. Inside a collector's registered location
2. Inside law enforcement location
3. Inside an authorized LTCF

Collection Receptacles

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

21 CFR § 1317.75(b) and (c)

Design of Collection Receptacles

- Securely fastened to a **permanent structure.**
- **Securely locked**, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have **small opening** that **allows for contents to be added**, but **does not allow for removal of contents**.
- Outer **container must display** a sign **stating only Schedule II-V** and non-controlled substances are acceptable substances.
- **Schedule I** controlled substances **are not permitted to be collected**

21 CFR § 1317.75(e)

Collection Receptacle Inner Liner

- Waterproof, tamper evident and tear resistant
- Removable and sealable without touching content
- Content shall not be viewable from the outside
- Size of liner shall be clearly marked on the outside
- Outside of liner shall have a unique id number

21 CFR 1317.60(a)

Collection Receptacle Location

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

21 CFR § 1317.75(d)

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
- **Registrant must have method of on-site destruction**

21 CFR § 1317.70 (b)

DEA Registrant who sells mail-back packages for another registrant is **NOT** required to modify registration as a collector

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

Questions?

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