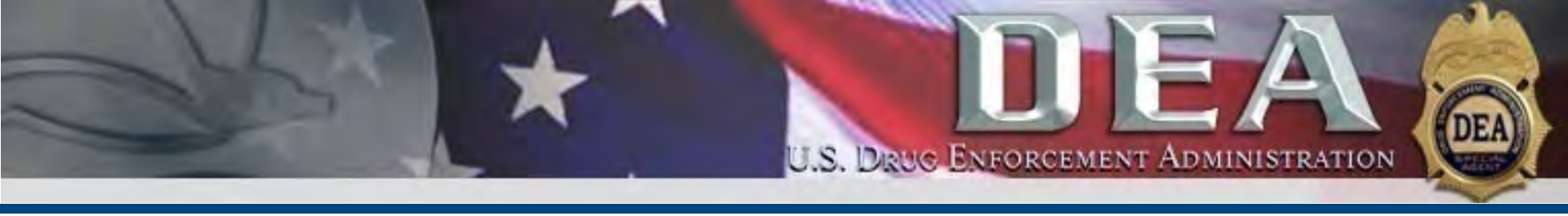


DEA Trends & Update

Wichita, Kansas Pharmacy Diversion Awareness Conference

March 11-12, 2017

The United States Department of Justice
Drug Enforcement Administration

Luis Carrion
Staff Coordinator
Liaison and Policy Section
Diversion Control Division

Goals and Objectives

- Public Health Epidemic
- Drugs of Abuse
- From Pharmaceuticals to Heroin
- Violence
- Indiscriminate Prescribing
- Criminal Activity
- Legal Obligations of DEA Registrants
- DEA’s Mission and Response
- Drug Disposal

Public Health Epidemic

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

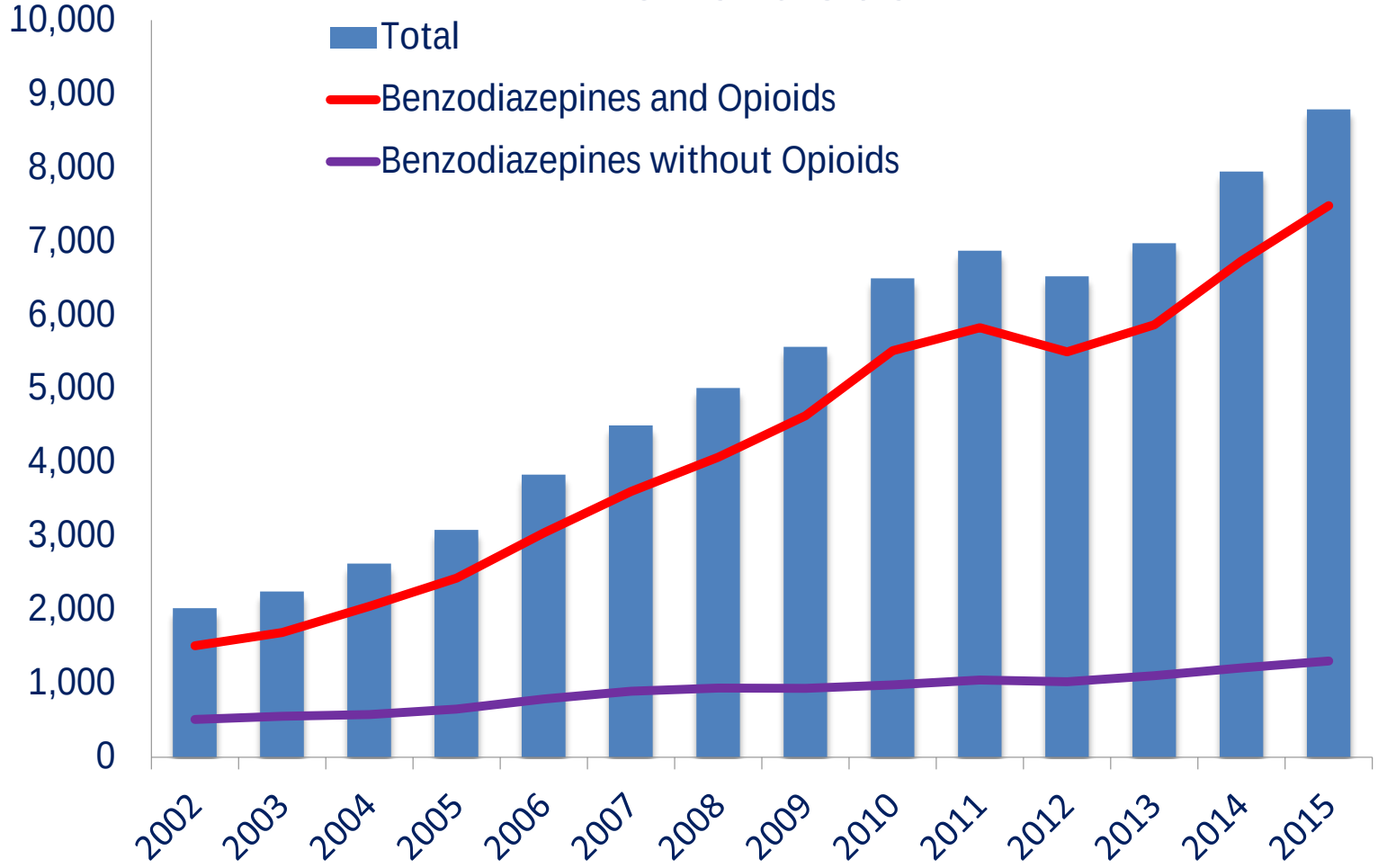
On an average Day in the U.S.:

- 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

National Institute on Drug Abuse

Opioid involvement in benzodiazepine overdose



Source: National Center for Health Statistics, CDC Wonder

How did we get here?

The 1960s/70s/80s

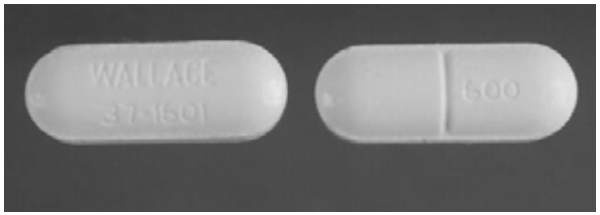
Uppers - Amphetamines

Quaalude

"Ts and Blues"

Downers - Barbiturates

Hydromorphone



Meprobamate

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" or the "Holy Trinity"**
    - **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.

“Primum non nocere”

"First, do no harm”

Drugs of Abuse

U.S. Drug Enforcement Administration
Diversion Control Division

Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

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

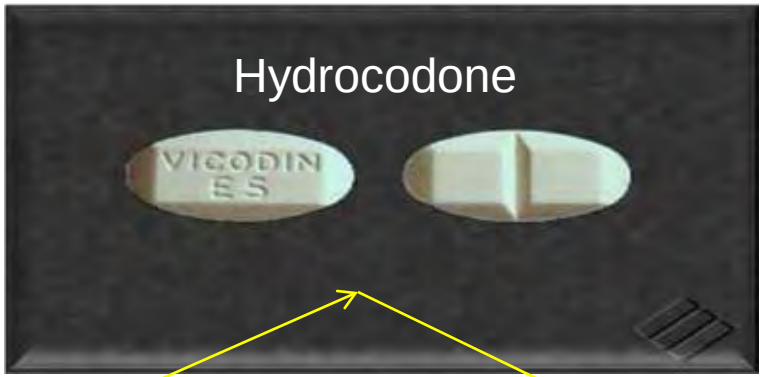
- Brand Names: Vicodin®, Lortab®, Lorcet®

- **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

www.bluelight.org/vb/threads/713412-Zohydro-s-Here-Our-New-Problem-Child-(HOLY-LORD-IN-HEAVEN)?highlight=zohydro

#19

jackie jones

Bluelight Crew

Join Date: Jul 2008

Location: A spoonful of sugar helps the medicine go down.

Posts: 5,589

20-02-2014 15:32

- potent extended release formulation
- straight-up hydrocodone/no acetaminophen
- Opiate: 5-10 times stronger than Vicodin
- Manufactured by Zogenix
- Approved by FDA 10/25/2013
- can last up to 12 hours of pain relief per dose

REPLY QUOTE

#20

Bigfanofthemdrugs

Moderator
Drug Culture
Cannabis Discussion

Join Date: Mar 2012

Location: The Limbic System

20-02-2014 20:20

Idk what you guys are tripping about, I'm stoked to get in on some of that, hydrocodone is one of my favorite opioids. It's just as euphoric as oxy IMO.

Oxymorphone Extended Release
Opana ER® (Schedule II)

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

Hydromorphone

- 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*.**

Methadone- 5mg &10mg

Methadone 40 mg

Other Opiates of Interest

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

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

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

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

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

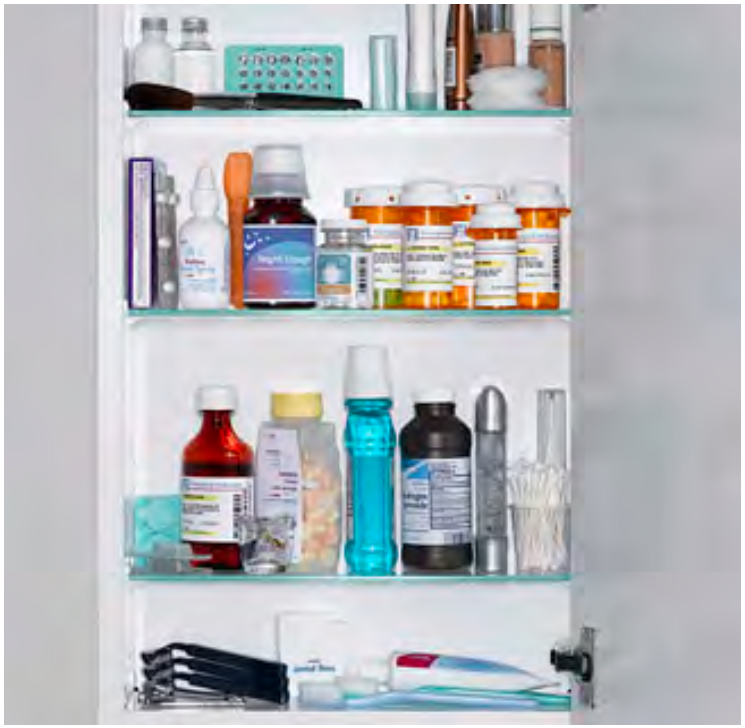
Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 60 mg

Our Youth

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

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PSYCHEDELICSCIENCE2013 APRIL 18TH REGISTER NOW
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Home | Forum | What's New? | Wiki

The Front Page | Advanced Search

The Front Page

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

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

Features

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

Forums

Focus Forums
Drug FAQs
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.

...

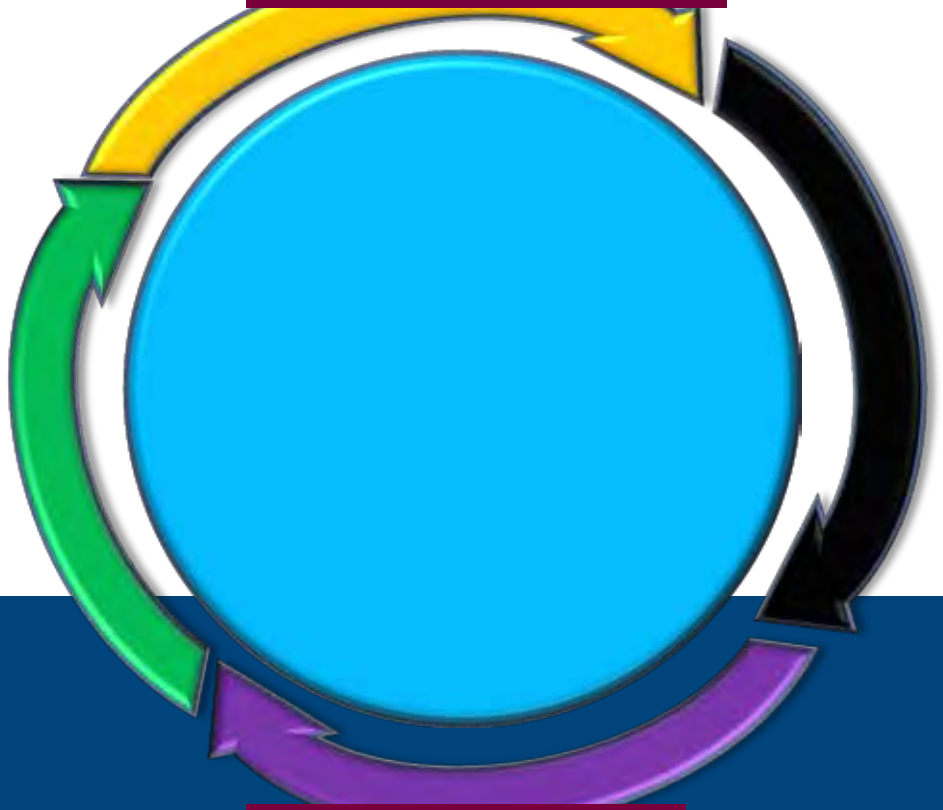
start | Bluelight - The Front ...

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
$8 -$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

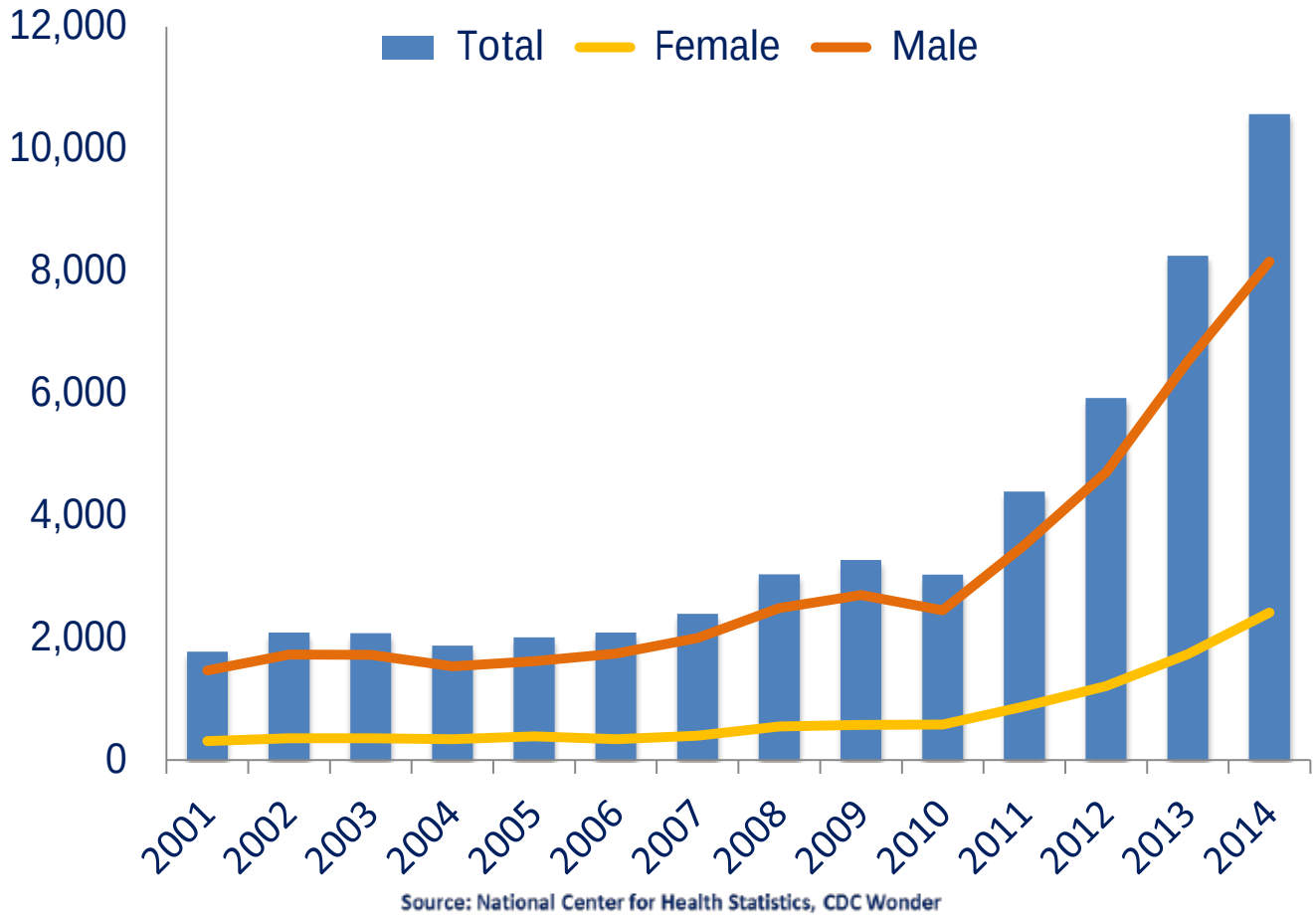
Police in East Liverpool, Ohio released these images they say to illustrate the impact of the heroin and painkiller epidemic. (City of East Liverpool, Ohio/Facebook)

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."



Opiates and Heroin

- 4 out of 5 recent heroin initiates used prescription opioids non-medically.[1]
- The recent heroin abuse rate is 19 times higher among those who reported prior non-medical use of pain relievers than among those who did not report such use.[2]
- Overdose deaths from heroin abuse have more than doubled since 2010.[3]

[1]NIDA, June 2015
[2]SAMHSA, August 2013
[3] NIDA, February 2015

Violence

U.S. Drug Enforcement Administration
Diversion Control Division

Starting the year with a bang

Saranac Hale Spencer, The News Journal 12:36 a.m. EST January 4, 2016

18
3

(Photo: DELAWARE STATE POLICE)

A 26-year-old Lewes man threatened to detonate explosives he said were strapped to his body if a pharmacist at a Walgreens near Magnolia didn't give him prescription drugs, according to state police.

The man, Curtis Kuhn, didn't actually have explosives strapped to his body, according to police.

Kuhn went into the pharmacy at about 9:30 a.m. on Saturday and put a note on the counter demanding Percocet and Xanex – he told the pharmacist that he had explosives strapped to his body and he was being forced to commit the robbery by someone who was sitting in a car in the parking lot, according to police.

When officers arrived shortly after that, they took Kuhn into custody without incident and found that he had no explosives and there was no car fitting his description in the parking lot, according to police.

Kuhn was charged with first-degree attempted robbery, attempted theft of a controlled substance and two counts of terroristic threatening. He was arraigned and sent to Vaughn Correctional Center near Smyrna for lack of $27,000 secured bond and

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

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

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

Potential Red Flags

- Many customers receiving the same combination of prescriptions; ***cocktails***
- Many customers receiving the same strength of controlled substances; no individualized dosing: ***multiple prescriptions for the strongest dose***
- Many customers ***paying cash*** for their prescriptions
- ***Early refills***
- Many customers with ***the same diagnosis codes*** written on their prescriptions;
- Individuals driving ***long distances to visit physicians*** and/or to fill prescriptions;

Potential Red Flags continued

Customers ***coming into the pharmacy*** in groups, each ***with the same prescriptions issued by the same physician***; and

Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.) - **Check Dr. Specialty**

Overwhelming proportion of prescriptions filled by pharmacy are controlled substances

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

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

www.nabp.net

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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 Mission

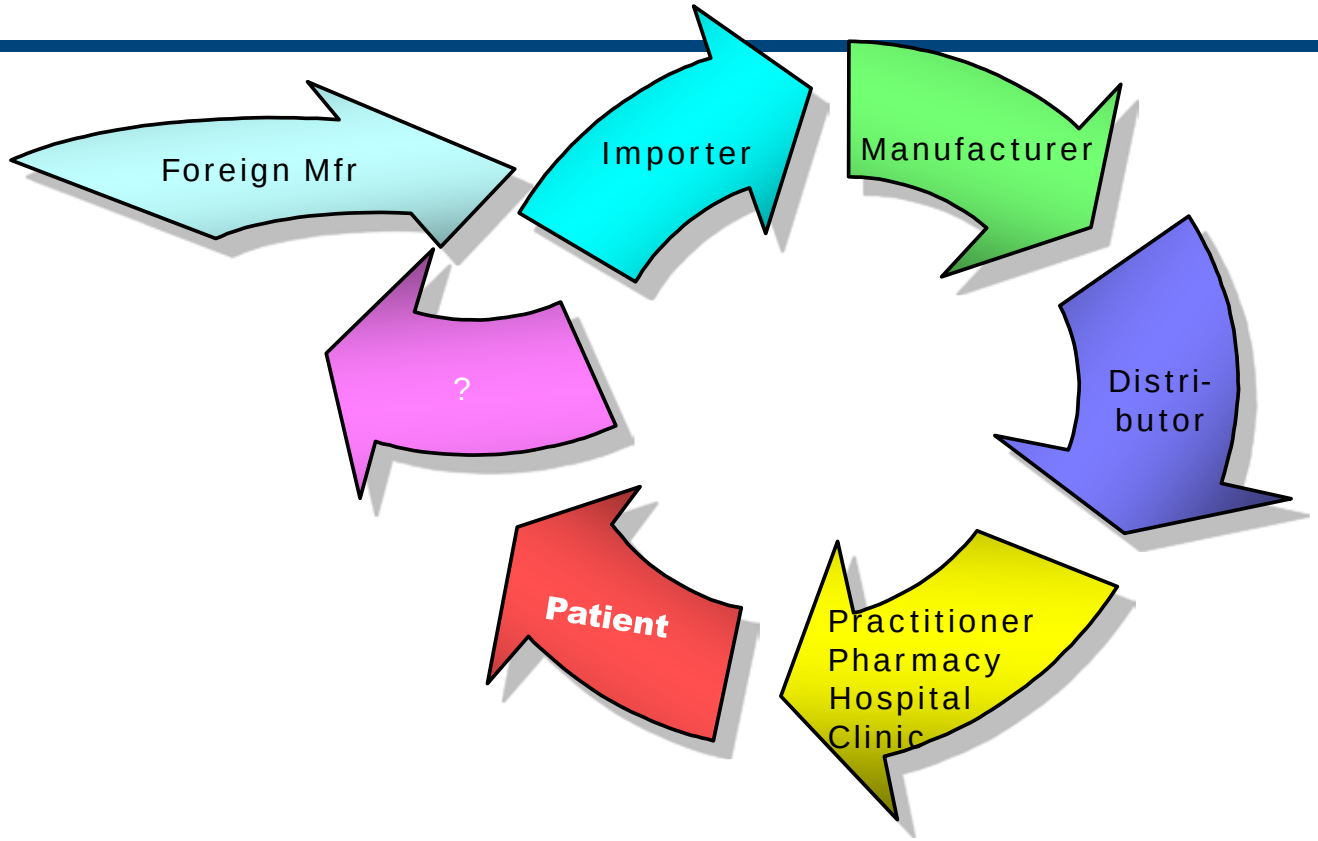
Mission

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.

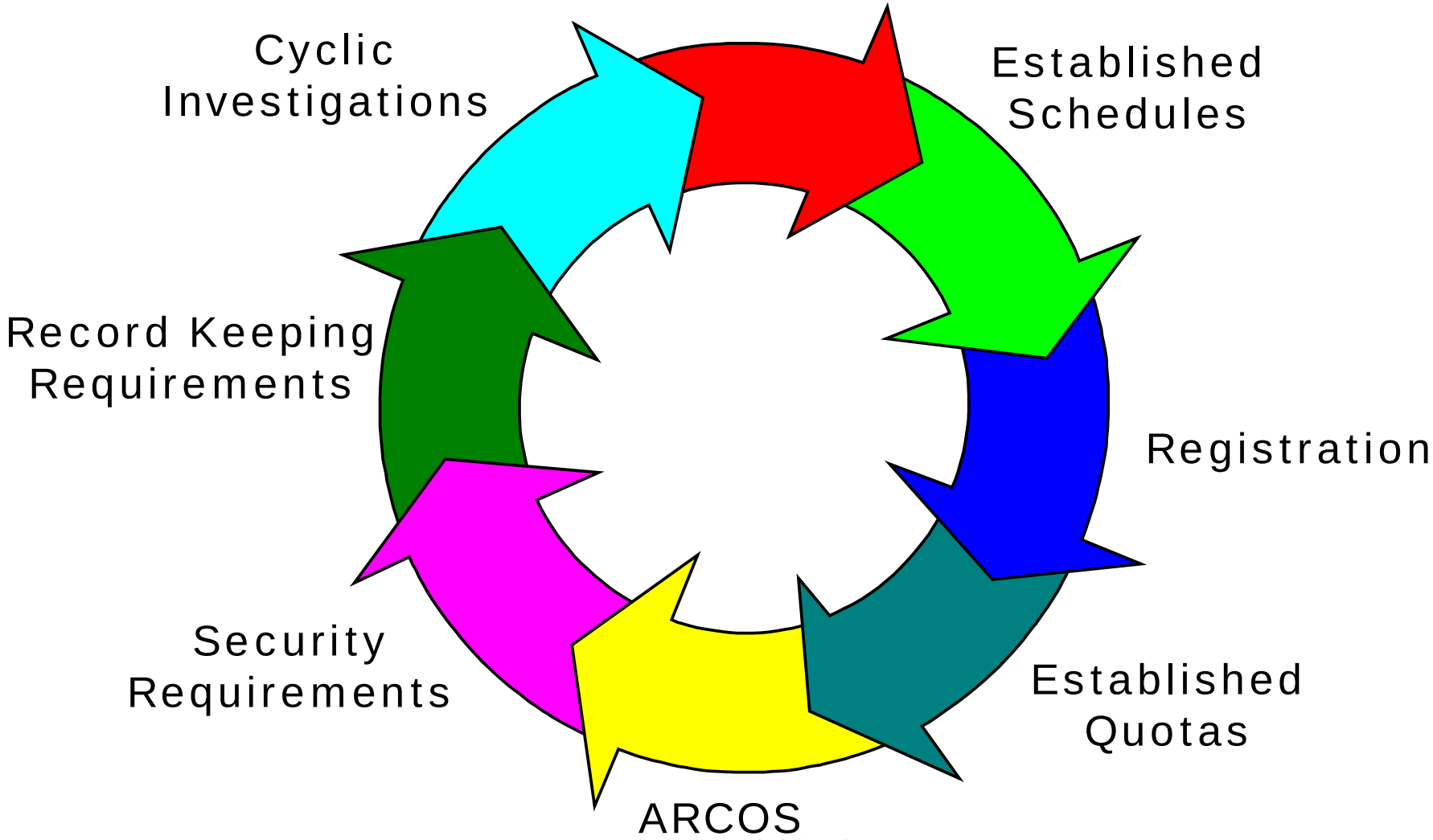
Closed System of Distribution



1,677,537 (1/18/2017)

- **Practitioners: 1,253,249**
- **Mid Level Practitioner: 319,280**
- **Retail Pharmacies: 72,126**
- **Hospital/Clinics: 17,674**

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's Response

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

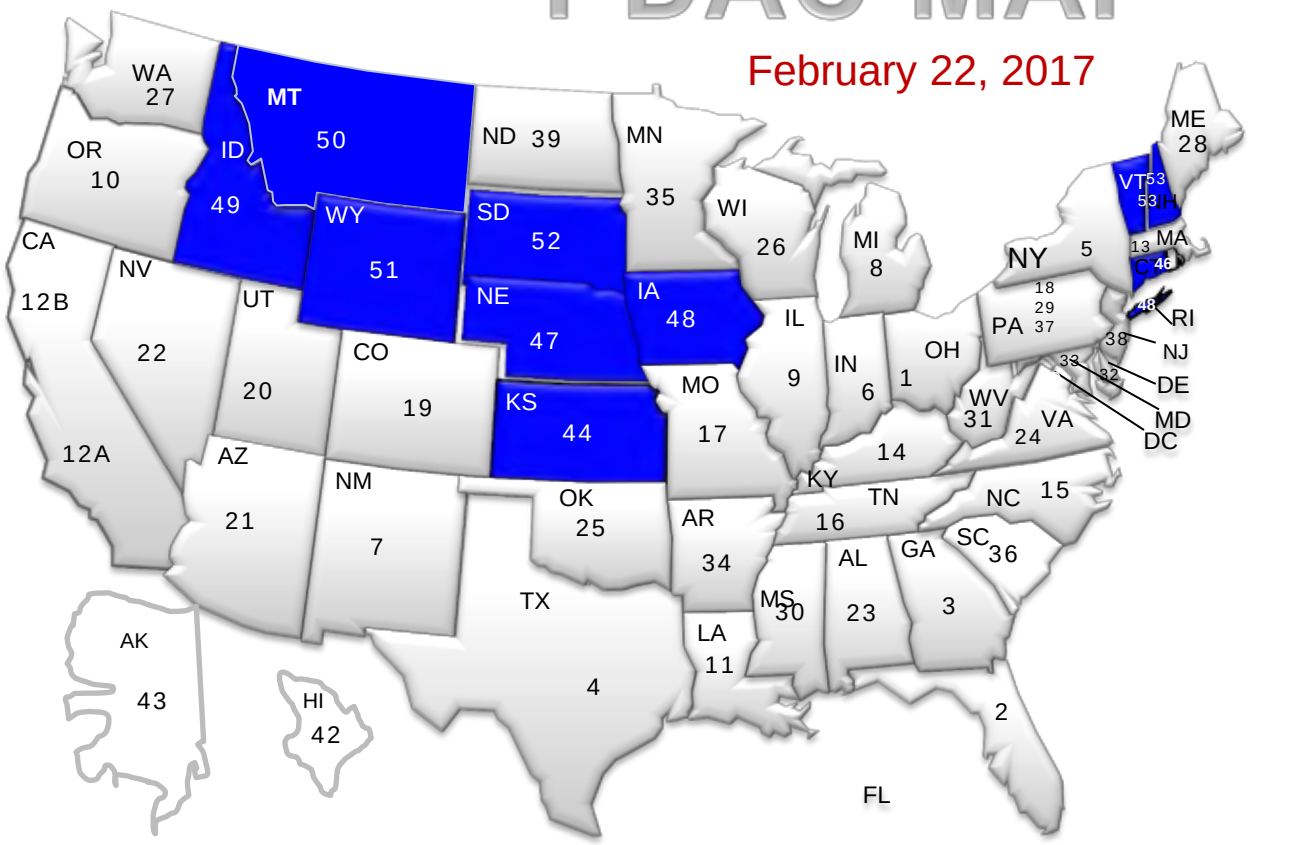
Pharmacy Diversion Awareness Conferences

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

Completed PDACs	Attendance
FY-2011	
FY-2016	
29-Pittsburgh, PA 12/10-11/15	196
30-Jackson, MS 1/9-10/16	185
31-Charleston, WV 2/27-28/16	245
32-Wilmington, DE 3/19-20/16	111
33-Towson, MD 4/17-4/18/16	442
34-Little Rock, AR 6/11-12-/16	216
35-Minneapolis/St. Paul, MN 7/8-9/16	151
36-Hilton Head, SC 8/15-16/16	157
37-Camp Hill, PA 8/27/16	84
38-New Brunswick, NJ 9/18-19/16	304
FY-2016 Total Attendance	**2,091**
FY-2017	
39-Fargo, ND 10/2/16	68
40-Washington, DC 11-19-20/16	414
41-Buffalo, NY 12/9-10/16	239
42-Honolulu, HI 1/22-23/17	114
43-Anchorage, AK 2/10/2017	61
Total Attendance To Date	**12,205**

PDAC MAP

February 22, 2017



FY-2017 PDACs

44-Kansas – March 11 & 12, 2017
45-Puerto Rico – March 26 & 27, 2017
46-Connecticut/Rhode Island – April 2017 (Date TBD)
47-Nebraska – June 2017 (Date TBD)
48-Iowa – July 2017 (Date TBD)
49- Idaho – August 2017 (Date TBD)
50-Montana – August 2017 (Date TBD)
51-Wyoming – August 2017 (Date TBD)
52-South Dakota – September 2017 (Date TBD)
53-Vermont/New Hampshire – September 2017 (Date TBD)

39 STATES (incl. the D.C.) 85 PDAC CONFERENCES

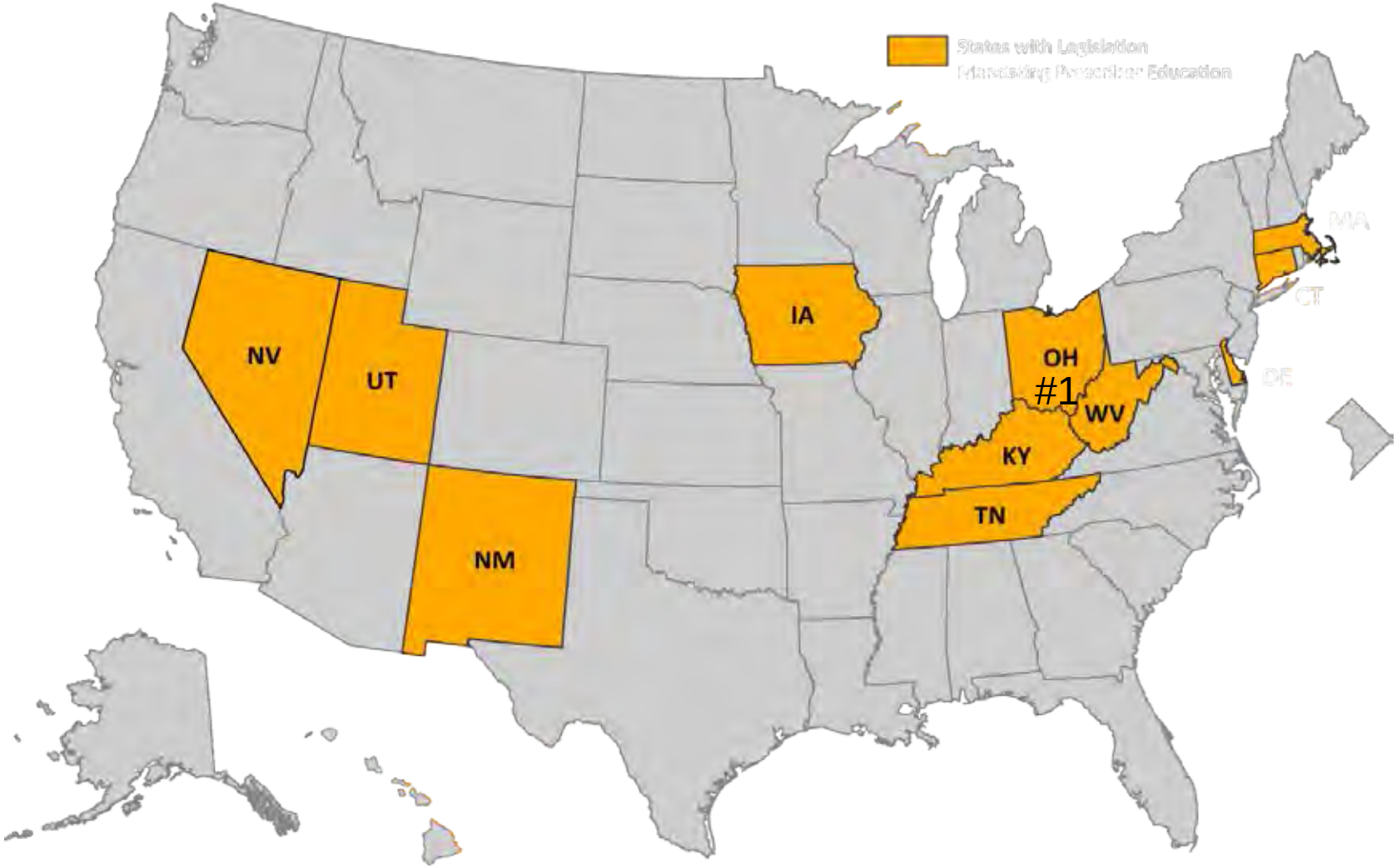
Completed PDACs
Proposed PDACs
* Repeated State

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

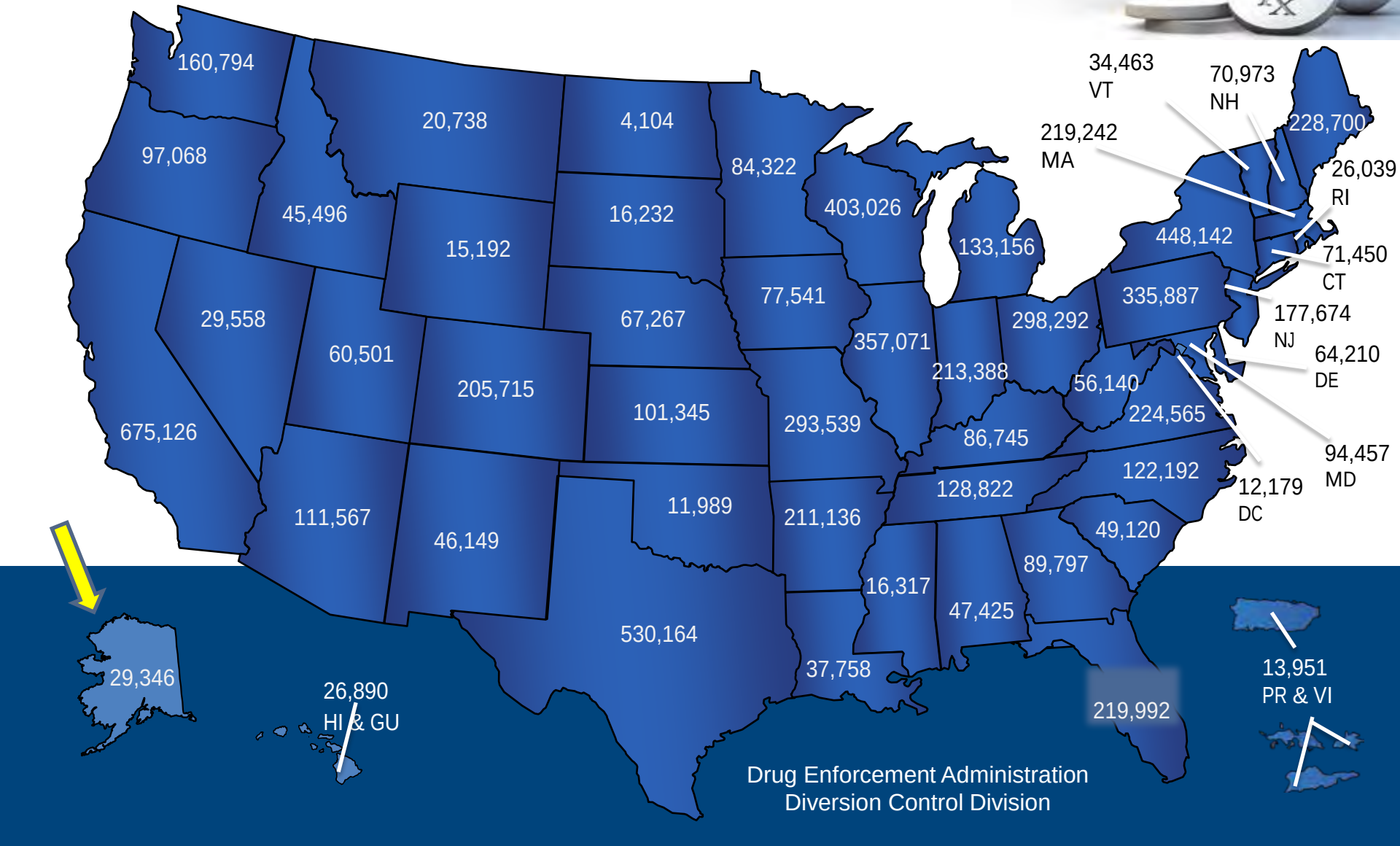
- Second State to Mandate Electronic Prescribing
- Prescribers are required to undergo addiction training every 2 years
- Set cap on daily strength for opioid prescribing:
  - Acute pain – 7 days
  - Chronic pain – 30 days
- **Began: *January 2017***

National Take Back Initiative (NTBI)

10:00 AM – 2:00 PM

National Take Back I-XII Totals:

Total Weight Collected (pounds): 7,202,977 pounds (3601 Tons)



Disposal

Retail Pharmacies' Disposal - Inventory

For disposals of Retail Pharmacy CS inventory:

- **Incineration – DEA's acceptable method 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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U.S. Drug Enforcement Administration
Diversion Control Division