DEA Trends & Update

Wichita, Kansas Pharmacy Diversion Awareness Conference

March 11-12, 2017
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

U.S. Drug Enforcement Administration
Diversion Control Division
On an average Day in the U.S.:

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

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
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
  - Hydromorphone
- Downers - Barbiturates
  - Meprobamate
- "Ts and Blues" - Oxycodone/APAP
The 1990s

OxyContin® Tablets
(Oxycodeone 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

NOTE: 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 went into effect.
“Primum non nocere”
"First, do no harm"
Drugs of Abuse
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

Hydrocodone

Carisoprodol
Aka: Soma
Muscle Relaxant
C-IV as of 1/11/2012

Alprazolam
Benzodiazepine

Opiate
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

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 IMD.
Oxymorphone Extended Release
Opana ER® (Schedule II)

 Vy 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
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
Pills v. Heroin
Circle of Addiction & the Next Generation

- Hydrocodone (Lorcet®) $5-$7/tab
- Oxycodone Combinations
  - Percocet® $7-$10/tab
- Oxycodone IR 15mg, 30mg $30-$40/tab
- Heroin $8-$10/bag
- OxyContin® $80/tab
- Roxicodone®
  - Oxycodone IR 15mg, 30mg $30-$40/tab

U.S. Drug Enforcement Administration
Diversion Control Division
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
Heroin Seizure

Pharmaceutical Oxycodone 30mg

U.S. Drug Enforcement Administration
Diversion Control Division
NEWS

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

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)
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

¹NIDA, June 2015
²SAMHSA, August 2013
³NIDA, February 2015
Violence
Starting the year with a bang

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

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 terrorististic 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
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.


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

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 nonopioid therapies with patient
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

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

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

Criminal Activity
United States V. Alvin Yee, M.D.

Dr. Alvin Yee

U.S. Drug Enforcement Administration
Office of Diversion Control
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.
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
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)
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)
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

U.S. Drug Enforcement Administration
Diversion Control Division
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;
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
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
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

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

1,677,537 (1/18/2017)
Closed System of Distribution

Cyclic Investigations

Record Keeping Requirements

Security Requirements

Established Schedules

Registration

Established Quotas

ARCOS
Drug Enforcement Administration
Office of Diversion Control
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
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

Drug Enforcement Administration

Diversion Control

Law Enforcement

Community Outreach

DEA Special Agent
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.
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
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.
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

- Nevada (NV)
- Utah (UT)
- New Mexico (NM)
- Iowa (IA)
- Ohio (OH)
- Kentucky (KY)
- West Virginia (WV)
- Tennessee (TN)
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)

Got Drugs?

Turn in your unused or expired medication for safe disposal Saturday.

Click here for a collection site near you.

10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration
Diversion Control Division

APRIL 29, 2017

#13
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:

- Disposal in Trash (ONDCCP 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)
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.

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 comingle.
- 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