DEA Trends & Update
Boise, Idaho
Pharmacy Diversion Awareness Conference
October 22-23, 2017

Luis Carrion
Staff Coordinator
Liaison and Policy Section
Diversion Control Division
I have no relevant personal/professional/financial relationship(s) to disclose
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
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

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

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

U.S. Drug Enforcement Administration
Diversion Control Division
Closed System of Distribution

Cyclic Investigations

Established Schedules

Record Keeping Requirements

Registration

Security Requirements

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 doesn’t regulate the practice of medicine.*
Public Health Epidemic
Present Epidemic Drug Crisis

- U.S. faces epidemic: addiction to opioids
  A. Prescription pain relievers
  B. Heroin

Problem stems from:
  a. pain from injuries, accidents, surgeries, etc…
  b. the increased availability of these drugs
  c. Teenagers who are bored and curious

- According to SAMHSA, in 2015, 2.6 million people were addicted to these opioids
- Nationwide, there has been over 50,000 overdose deaths
- According to the US Surgeon General, around 250 million prescriptions are written every year, enough for each American to have one bottle
- U.S. has 5% of the world’s population and we acquire over 80% of prescription drugs – pills are taken regularly
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
- 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

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

<table>
<thead>
<tr>
<th>Year</th>
<th>All drug overdose deaths</th>
<th>Natural and semisynthetic opioids</th>
<th>Methadone</th>
<th>Synthetic opioids excluding methadone</th>
<th>Cocaine</th>
<th>Psychostimulants with abuse potential</th>
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<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Percent</td>
<td>Number</td>
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<td>2010</td>
<td>38,329</td>
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<td>3,036</td>
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<td>2015</td>
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<td>100</td>
<td>12,989</td>
<td>24.8</td>
<td>12,727</td>
<td>24.3</td>
</tr>
</tbody>
</table>

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.


*CDC’s estimate for 2016—62,497 total drug overdose deaths*
Opioid involvement in benzodiazepine overdose

Source: National Center for Health Statistics, CDC Wonder
DRUG-FREE AMERICA

AGE 0-4
AMOXICILLIN

4-12
RITALIN

12-18
APPETITE SUPPRESSANTS

18-24
NO-DOZ

24-38
PROZAC

38-65
ZANTAC

65 - EVERYTHING ELSE
How did we get here?

U.S. Drug Enforcement Administration
Diversion Control Division
Before the 1990’s

Doctors – mindful of patients’ addiction potential

They prescribed opioids for:
- Acute pain patients
- Hospice patients
- Bone fractures
- After surgeries

Doctors did not prescribe opioids for chronic pain such as back pains, headaches, etc....

No long term opioid treatment

Doctors considered the prescribing of opioids to be unsafe and dangerous
Before the 1990’s

During chronic pain:

a. Non controlled drugs were prescribed
b. Muscle relaxants
c. Therapeutic remedies
d. Acupuncture
e. Use opioids as the last resort

NO “EASY FIX” CONCEPT
Around mid 90’s – Change takes place

Pain Advocates encouraged a shift of how the medical field was practicing medicine
• Opiates started to get used more frequently
• Two campaigns: Marketing & Education

Convinced the medical community:
• Opioids were under prescribed
• Patients suffered from unnecessary pain
• Opioids were not addictive
• Opioids were safe

Result: Doctors started to freely prescribe opioids
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**

- 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 (Opiate)
Carisoprodol (Muscle Relaxant) Aka: Soma
Alprazolam (Benzodiazepine)

C-IV as of 1/11/2012
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” such as: 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.
Happy Prometh Day!

Happy 32nd Birthday Brandon
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

Versus

Clandestine
INCONSISTENT BLENDING
CLANDESTINE FENTANYL - OVERDOSE

- Bulk clandestinely manufactured Fentanyl of unknown concentration is imported into the US
- Fentanyl is then “cut” blended then repackaged is powder/pills
- Inconsistent blending combined with unknown purity results in powders and pills of various concentration. Which may lead to overdoses.
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

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.ru 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.
New OxyContin® OP

**mz.mary420**
Member

Join Date: May 2010
Location: down south
Posts: 6

08-27-2010, 01:11 AM

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 mentioned 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

**mephist00**
Member

Join Date: Apr 2008
Location: NY
Age: 25
Posts: 628

08-27-2010, 06:09 AM

ya my friend has tried to smoke the new ones... said its very harsh on the lungs and throat..

so far the only way i've been able to beat the time release, is use a hose clamp to grind it very fine, and snort it. it doesn't 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

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
Circle of Addiction & the Next Generation

Oxycodone Combinations
- Percocet®
  - $7-$10/tab

Hydrocodone
- Lorcet®
  - $5-$7/tab

Heroin
  - $5 -$10/bag

OxyContin®
  - $80/tab

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

U.S. Drug Enforcement Administration
Diversion Control Division
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
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.”

Source: National Center for Health Statistics, CDC Wonder
Violence
Violence Related to Controlled Substance Pharmaceuticals

NEW YORK POST
Page Six

ASSASSIN

Chilling anatomy of drugstore massacre

DRUGSTORE MASSACRE
Husband and wife busted in Rx-slay horror

PAIN KILLER
**Judge’s Sentence**

**Wife** (driver of get away car): 25 years in prison

**Husband** (shooter):

- Five (5) consecutive life terms in person
- Solitary Confinement

“I promised you when you plead guilty that you hoped for mercy. I will not disappoint you. You merit the scorn of this community, your victims’ families and this court. Each one of your victims was unique. They had one thing in common: they were all very good people. They were the kind of people who tended to help others. Ironically, if you would have asked for their help, they would have come to your aid. They were the kind of people our community rightly treasures. I want the record to show in light of your murderous character, you are to be placed in the most restrictive conditions possible, solitary confinement and be denied all privileges for the rest of your life.”
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 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 non-opioid 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

Evaluation of 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

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
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

U.S. Drug Enforcement Administration
Diversion Control Division
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!!!
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)
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 conducts inspections to ensure compliance with the Controlled Substances Act and its implementing regulations.

DEA increased the frequency of pharmacy regulatory inspections.

Verifications of customers and suppliers.
Drug Enforcement Administration

360 Degree Strategy

360 Strategy

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.
National Take Back Initiative (NTBI)

10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration
Diversion Control Division

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

#14

OCTOBER 28, 2017
National Take Back I-XIII Totals:
Total Weight Collected (pounds): 8,103,363 (4,052 Tons)

Drug Enforcement Administration
Diversion Control Division
Overseas: 25
Questions?

Luis.A.Carrion@usdoj.gov

U.S. Drug Enforcement Administration
Diversion Control Division