Philadelphia Pharmacy Diversion Awareness Conference

DEA Perspective: Pharmaceutical Use & Abuse
July 12 & 13, 2014
Goals and Objectives

• Explain the current prescription drug abuse problem and the impact on society.
• Discuss legal obligations of the DEA registrant
• Identify methods of pharmaceutical diversion and discuss how the pharmacist can prevent diversion in the retail setting
• The “CSA” – Checks and Balances
• DEA’s response
Prescription Drug Abuse & Trafficking Trends

OR

Responding to America’s Prescription Drug Abuse Crisis

“When Two Addictions Collide”
Mayo Clinic Study on Prescription Drugs

- The three most common types of prescriptions are antibiotics, antidepressants, and painkiller opioids.

- 70% of Americans are taking at least one prescription drug.

- More than 50% are on at least two prescriptions.

Source: Mayo Clinic Press Release, 6/19/2013
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.
In Florida two Westchase teachers learn a lesson: Say 'no' to mints in pill bottles

The drug bottles were made more realistic with labels that read in part: “Watson’s Whiz Kid Pharmacy. Take 1 tablet by mouth EVERY 5 MINUTES to cure FCAT jitters. Repeated use may cause craft to spontaneously ooze from pores. No refills. Ms. Falcon’s authorization required.”

The teachers’ unusual calming tactic was discovered by Sandy Young, who was greeted with the sight of a pill bottle on each student’s desk when she visited her grandson’s classroom. The teacher assured her that the pills were fake and just a lighthearted attempt at reducing the stress of the test-taking students.
The 1960/70s/80s

- **Uppers - Dexedrine**
- **Downers - Seconal**
- **Meprobamate**
- **Hydromorphone**
- **Oxycodone/APAP**

- **“Ts and Blues”**
- **“Fours and Doors”**
The 1990s

OxyContin
Consequences

In 2011, approximately 41,340 unintentional drug overdose deaths occurred in the United States, one death every 13 minutes.

16,917 (41%) of these deaths were attributed to opioid overdoses. Equates to 46 deaths every day--almost 2 per hour.

In 31% of these deaths benzodiazepines were cited as a contributing cause.

Prescription drug abuse is the fastest growing drug problem in the United States.

Sources: CDC Vitalsigns: Opioid Painkiller Prescribing (July 2014) and CDC Morbidity and Mortality Weekly Report (July 1, 2014)
U.S. Drug Overdose Deaths by Major Drug Type, 1999-2010

Source: CDC/NCHS, NVSS
Causes of death attributable to drugs include accidental or intentional poisonings by drugs and deaths from medical conditions resulting from chronic drug use. Drug-induced causes exclude accidents, homicides, and other causes indirectly related to drug use. Not all injury cause categories are mutually exclusive.

About 18 women die every day of a prescription painkiller overdose in the United States

Source: CDC VitalSigns July 2013
Drug Overdose Mortality Rates per 100,000 People 1999

Drug Overdose Mortality Rates per 100,000 People 2010

Where Prescription Painkiller Overdose Deaths Are The Highest

- Most severe in Southwest and Appalachian
- In 2010, the top three states were West Virginia, New Mexico, and Kentucky;
  - West Virginia: 28.9 deaths per 100,000
  - New Mexico: 23.8 deaths per 100,000
  - Kentucky: 23.6 deaths per 100,000
- Lowest—North Dakota: 3.4 deaths per 100,000
- Minnesota ranked 47th 7.3 deaths per 100,000

SOURCE: Trust for America’s Heath-Prescription Drug Abuse: Strategies To Stop The Epidemic; October 2013
Public Health Impact of Opiate Analgesic Abuse

For every 1 unintentional opioid overdose death in 2010, there were:

- Abuse treatment admissions: 10
- ED visits for misuse or abuse: 28
- People with abuse/dependence: 108
- Nonmedical users: 733

Mortality figure is for unintentional overdose deaths due to opioid analgesics in 2010, from CDC/Wonder. Treatment admissions are for with a primary cause of synthetic opioid abuse in from TEDS. Emergency department (ED) visits related to opioid analgesics in from DAWN. Abuse/dependence and nonmedical use of pain relievers in the past month are from the National Survey on Drug Use and Health.
Today’s Perfect Storm

- Industry is producing a wider variety of controlled substance pharmaceuticals

- Use of Medicare / Medicaid or insurance to fund drug habits

- The Information / Electronic era (i.e., web sites such as Erowid & Bluelight, social networking, blogging, twitter, text messaging, & chat rooms for instant exchanges of information)
Some states have more painkiller prescriptions per person than others.

More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Methamphetamine & Heroin abusers

COMBINED!!
Burden on the health care delivery system
Economic Costs

• $55.7 billion in costs for prescription drug abuse in 2007\textsuperscript{1}
  • $24.7 billion in direct healthcare costs

• Opioid abusers generate, on average, annual direct healthcare costs 8.7 times higher than non-abusers\textsuperscript{2}


Addicted infants triple in a decade

3.4 out of 1,000 suffer painkiller withdrawal

By Liz Szabo
USA TODAY

The number of babies born addicted to the class of drugs that includes prescription painkillers has nearly tripled in the past decade, according to the first national study of its kind.

About 3.4 of every 1,000 infants born in a hospital in 2009 suffered from a type of drug withdrawal commonly seen in the babies of pregnant women who abuse narcotic pain medications, the study says. It’s published today in the Journal of the American Medical Association.

By Frank Pompa, USA TODAY
Economic Costs

• Maternal opioid dependence can affect birth costs

• A recent study showed in 2009, the average hospital stay for opioid exposed infants with neonatal abstinence syndrome (NAS) was 16 days\(^1\)

• The hospitalization cost of treating each baby with NAS averaged $53,400\(^2\)

• State Medicaid programs paid for 77.6\% of these births\(^3\)

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2. Ibid.
3. Ibid.
### National Poison Data System (Formerly known as Toxic Exposure Surveillance System) – Total Annual Mentions of Toxic Exposures

<table>
<thead>
<tr>
<th>Year</th>
<th>Hydrocodone</th>
<th>Oxycodone</th>
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<tbody>
<tr>
<td>2001</td>
<td>15,191</td>
<td>9,480</td>
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<td>28,310</td>
<td>19,363</td>
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<tr>
<td>2011</td>
<td>30,792</td>
<td>19,423</td>
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</table>
Emergency Room Visits (2004-2010)

- **Increase of 115%**: ER visits attributable to pharmaceuticals (i.e., with no other type of drug or alcohol) (626,472 to 1,345,645)
  - No Significant Change: ER visits attributable to cocaine, heroin, marijuana, or methamphetamine

- Rx Drugs most frequently implicated: Opiates/Opioids pain relievers
  - Oxycodone products **255%** increase
  - Hydrocodone products **149%** increase

Fatal Links: Investigators put together puzzle to solve Rite Aid manager's murder

Murder victim Jason Scott McClay
WHERE PEOPLE ARE GETTING THEIR DRUGS
Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!
The Medicine Cabinet: The Problem of Easy Access
Medicine Cabinets: Easy Access

• More than half of teens (56%) indicate that it’s easy to get prescription drugs from their parent’s medicine cabinet.

• Half of parents (49%) say anyone can access their medicine cabinet.

• More than four in 10 teens (42%) who have misused or abused a prescription drug obtained it from their parent’s medicine cabinet.

• Almost half (49%) of teens who misuse or abuse prescription medicines obtained them from a friend.


U.S. Drug Enforcement Administration Office of Diversion Control
So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules
National Abuse Facts

• In 2012, there were 2.4 million persons aged 12 or older who used psychotherapeutics non-medically for the first time within the past year, approximately 6,700 new initiates per day.*

• One in four teens (24%) reports having misused a prescription drug at least once in their lifetime (up from 18% in 2008 to 24% in 2012), which translates to about 5 million teens. That is a 33% increase over a five-year period.

• 23.9 million Americans aged 12 or older were current (past month) users of illicit drugs.

SOURCE: * 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)  ** The Partnership at Drugfree.org / MetLife Foundation Partnership Attitude Tracking Studies 2012, published April 2013
Percentage of Past Month Nonmedical Use of Psychotherapeutics by Age, 2003-2011

Source: 2011 National Survey on Drug Use and Health
Past Year Initiates 2012 – Ages 12 and Older

Figure 7.2 Specific Illicit Drug Dependence or Abuse in the Past Year among Persons Aged 12 or Older: 2012

- Marijuana: 4,304
- Pain Relievers: 2,056
- Cocaine: 1,119
- Tranquilizers: 629
- Stimulants: 535
- Heroin: 467
- Hallucinogens: 331
- Inhalants: 164
- Sedatives: 135

Numbers in Thousands

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)

U.S. Drug Enforcement Administration Office of Diversion Control
Teen Prescription Drug Misuse & Abuse

- **1 in 5** teens who have abused RX medications have done so before age **14**.

- **33%** believe “it’s okay to use prescription drugs that were not prescribed to them to deal with an injury, illness or physical pain.”

- **23%** say their parents don’t care as much if they are caught using RX drugs without a prescription, compared to getting caught with illegal drugs.

2012 Partnership Attitude Tracking Study: April 23, 2013
Teen Attitudes

✓ 1 in 4 teens (25%) say there is little to no risk using pain relievers without a prescription

✓ 1 in 5 (20%) say pain relievers are not addictive

✓ 1 in 5 (22%) say the same about Ritalin or Adderall
Other Controlled Substances

- **12%** of teens have used synthetic marijuana over the past year
- **3%** used bath salts
- **4%** used methamphetamine (since 2008)
- **7%** used OTC cough medicine (since 2008)
- **Lifetime steroid use at 5%** (since 2008)

2012 Partnership Attitude Tracking Study: April 23, 2013
Reasons for Misuse & Abuse

- To help me relax: 18%
- To have fun: 16%
- Being high feels good: 14%
- To help me forget my troubles: 13%
- To deal w/ pressures & stress from school: 11%
- My friends are using: 11%
- To help deal with problems at home: 8%
- To feel better about myself: 8%
- To look cool: 6%
- It’s a habit I can’t stop: 4%
- Don’t know: 70%

*2012 Partnership Attitude Tracking Study: April 23, 2013*
Parents

✓ 1 in 6 (16%) believe using prescription drugs to get high is safer than using street drugs—more than 1 in 4 teens (27% share that same belief)

✓ 1 in 5 indicate they have given their teen a prescription drug that was not prescribed for them.

✓ 14% admitted they themselves have misused or abused prescription drugs within the past year

2012 Partnership Attitude Tracking Study: April 23, 2013
Where do kids get their information from?
Where do kids get their information from?
### MEDICINE ABUSE REPORT CARD

<table>
<thead>
<tr>
<th>Subject</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>During the last conversation they had with their parents regarding substance abuse, only <strong>14 percent of teens</strong> indicated they had discussed the misuse or abuse of any type of prescription drug.</td>
<td>F-</td>
</tr>
<tr>
<td>In comparison, a <strong>majority of teens (81 percent)</strong> say they have discussed the risks of marijuana use with their parents.</td>
<td>B</td>
</tr>
<tr>
<td><strong>80 percent</strong> have discussed alcohol.</td>
<td>B</td>
</tr>
<tr>
<td><strong>Nearly one-third of teens</strong> have discussed crack/cocaine.</td>
<td>D-</td>
</tr>
</tbody>
</table>

**Comments**

- **Unsatisfactory:** Stimulants contributing to Rx epidemic
- **One in four teens** believes that prescription drugs can be used as a study aid.
- **Nearly one-third of parents** say they believe ADHD medication can improve a child’s academic or testing performance, even if the teen does not have ADHD.
WHAT PEOPLE ARE ABUSING
Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen
Top Five Prescription Drugs Sold in the U.S. (2006-2011)

Source: IMS Health

(By Number of Prescriptions Sold)
Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

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

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

- Currently a Schedule III (combination products)
- Notice of Proposed Rulemaking to Schedule II, issued February 27, 2014

- “Cocktail” or “Trinity”
  - Hydrocodone
  - Soma® / carisoprodol
  - Alprazolam / Xanax®

- Street prices: $2 to $10+ per tablet depending on strength & region
Single Entity Extended Release Hydrocodone

Manufactured by Alkermes Gainesville LLC for Zogenix, Inc. (San Diego, CA)

FDA Approval October 2013

Anticipated Launch March 2014
## How Supplied

<table>
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<tr>
<th>Strength</th>
<th>Image</th>
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<th>Capsule Text</th>
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<td>“Zogenix 50 mg” in black ink</td>
<td>43376-250-10 100 ct bottles</td>
</tr>
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</table>
Toxicity

- Zohydro™ ER contains high amounts of hydrocodone
- Use in opioid non-tolerant patients may lead to toxicity, particularly acute and fatal respiratory depression
  - Capsules are to be swallowed whole
  - Capsules can be broken
The Trinity

Benzodiazepine

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

Hydrocodone
Opiate

Alprazolam
Benzodiazepine
Oxycodone

• OxyContin controlled release formulation of Schedule II oxycodone
  – The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
  – Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
  – 10, 15, 20, 30, 40, 60, 80mg available

• Effects:
  – Similar to morphine in effects and potential for abuse/dependence
  – Sold in “Cocktails” or the “Holy Trinity” (Oxycodone, Soma® / carisoprodol, Alprazolam / Xanax®)

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

• NOTE: New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.
OxyContin® Change
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)*

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 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.
Prescription Opiates  v. Heroin
Circle of Addiction & the Next Generation

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

- **Hydrocodone**
  - Lorcet®
  - $5-$7/tab

- **Heroin**
  - $15/bag

- **OxyContin®**
  - $80/tab

- **Roxicodone®**
  - Oxycodone IR 15mg, 30mg
  - $30-$40/tab
More suburban teens turning from pills to heroin, authorities say
By Ed Fletcher
McClatchy Newspapers

Brandon Scott, 19, of Auburn, Calif., leads a workshop at the Auburn Library regarding drugs and how they affect teens. Brandon transitioned from RX to heroin but has since gone through the Full Circle Treatment Center program and has been clean for about two years.

SACRAMENTO, Calif. - Heroin, a drug most often associated with the gritty back alleys of big cities, is making a surprising surge in suburban, affluent places.

Many new heroin addicts started as teens, abusing prescription painkillers they found in their homes, say law enforcement and public health officials.
HEROIN: NO LONGER CONFINED TO URBAN AREAS

Heroin use spikes in area suburbs
Pill addicts risk deadly drug
People Reporting Heroin Use:

2007 – 373,000
2012 – 669,000

• Numbers in the thousands

2012 National Drug Survey on Drug Use and Health
Substance Abuse Treatment Admissions within Specific Age Groups That Reported Any Pain Reliever Abuse: 1998-2008

Up more than fourfold

Source: SAMSHA Treatment Episode Data Set, 1998-2008 released July 15, 2010
## HEROIN CASES and EXHIBITS

### National Forensic Laboratory Information System

<table>
<thead>
<tr>
<th>Year</th>
<th># Exhibits</th>
<th># Cases</th>
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<td>69,467</td>
<td>60,851</td>
</tr>
<tr>
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<td>73,569</td>
<td>64,471</td>
</tr>
<tr>
<td>2006</td>
<td>83,945</td>
<td>72,351</td>
</tr>
<tr>
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<td>82,408</td>
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<td>2008</td>
<td>94,229</td>
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<tr>
<td>2014: Jan - Mar</td>
<td>26,635</td>
<td>21,324</td>
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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
WHY IS IT ALSO USED AS AN ANALGESIC??????

Cheapest narcotic pain reliever – synthetic

Insurance companies

What’s the problem?
Rising methadone deaths

Our view: Baltimore public health officials are trying to find out if treatment for chronic pain sufferers accounts for increase in methadone overdoses

The June letter from the Baltimore Health Department alerted physicians, nurses and other providers to a significant increase in methadone-related overdose deaths. The letter from Dr. Laura Herrera, a deputy city health commissioner, raised the possibility that the overdoses involved prescriptions for pain. It was a cautionary reminder that health care providers should educate their patients about the proper use of methadone and the lethal risks of taking extra doses.

Dr. Herrera was right to be concerned. Methadone overdose deaths of city residents have risen from seven in 1995 to 74 in 2007, the last year for which statistics are available, there was a 23 percent increase in such deaths over the previous year. The city deaths coincide with a similarly disturbing fivefold increase in methadone-related deaths nationally between 1999 and 2005, but proving that the use of methadone as a pain reliever caused these deaths isn’t easy — no one tracks how many physicians prescribe methadone to relieve chronic pain from cancer or arthritis, for example.

Prescribing methadone has been an accepted form of treatment for chronic pain for some time, according to pain specialists at Johns Hopkins Hospital and the University of Maryland Medical Center. They add that they have seen no methadone-related deaths among their patients. Methadone used for pain treatment is prescribed in pill form, its risk stems from the drug’s potency and its lingering presence in the body once its pain-relieving function has ceased. An extra dose could slow down a patient’s breathing, resulting in coma or death.

To identify the extent of the problem and the patients most at risk, the city Health Department has reviewed data from the medical examiner’s office. It also has asked the quasi-public city agency that oversees drug treatment in Baltimore to cross-check methadone overdose victims against its patient rosters. That’s a critical aspect of the review because it could uncover misuse, abuse or diversion of methadone from drug treatment centers. Or it could lend credence to the prevailing view that more training is required for private physicians who prescribe methadone for pain.

At least 29 states have prescription monitoring programs that would identify indiscriminate prescribing, doctor-shopping and other abuses. A task force established this year in Maryland is studying the possibility of establishing a similar tracking system for methadone and other controlled substances.

Until then, Dr. Herrera and her colleagues at the Health Department have moved expeditiously and forthrightly to unravel this mystery. The results of their findings are the key to understanding and reversing this disturbing trend.
Methadone has been used for decades to treat drug addiction, but in recent years it has been increasingly prescribed to relieve pain. As methadone prescriptions for pain have increased so have methadone-related fatal overdoses.

Researchers found that while methadone accounts for only 2% of painkiller prescriptions in the United States, it is involved in more than 30% of prescription painkiller overdose deaths.

Six times as many people died of methadone overdoses in 2009 than a decade before.
Overdose...Why?

- Patients not taking the drug as directed
- Physicians not properly prescribing the drug
- Non-medical users ingesting with other substances
- Opiate naive
Other FDA Approved Drugs for Narcotic Addiction Treatment

Schedule III

- Buprenorphine – similar to other opioids and produces less euphonic effects
- Abused as a replacement for other opioids; general hold over
- Popular in prisons, “prison heroin”
- Prices: $2.00 to $15.00
  - Suboxone (sublingual, buprenorphine/naloxone tablet)
  - Zubsolv (sublingual, buprenorphine/naloxone tablet)
Opana ER (Oxymorphone) (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming more popular and is abused in similar fashion to oxycodone
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: $10.00 – $80.00
Other Narcotics

- Fentanyl
- Hydromorphone
- Meperidene
- Morphine
- Codeine
- Propoxyphene
Benzodiazepines

Alprazolam
Clonazepam
Diazepam
Lorazepam
Midazolam
Triazolam
Temazepam
Flunitrazepam
Ritalin® / Concerta® / Adderall®

• Used legitimately to treat ADHD

• Abuse prevalent among college students; can be snorted, injected or smoked; nicknamed “College Crack”

• $5.00 to $10.00 per pill on illicit market

• Adderall® Abusers are 5 times more likely to also abuse prescription pain relievers, 8 times more likely to abuse Benzodiazepines

Source: NSDUH Report; Non-Medical Use of Adderall Among Full-Time College Students, published April 2009
Required Reading

DIAGNOSTIC AND STATISTICAL MANUAL OF MENTAL DISORDERS
FOURTH EDITION
TEXT REVISION

DSM-IV-TR®

AMERICAN PSYCHIATRIC ASSOCIATION
ADHD Medication

- **1 in 8** teens (2.7 million) misuse or abuse

- **29%** parents believe can improve academic or testing performance, even if teen is does not have ADHD

- **1 in 4** teens believes these drugs can be used as a study aid

*2012 Partnership Attitude Tracking Study: April 23, 2013*
Dextromethorphan (DXM)

- Cough suppressant in over 125 OTC medications (e.g., Robitussin and Coricidin)
- Bulk form on the Internet
- At high doses, has Ketamine- and PCP-like effects
- Produces physical and psychological dependence
- Deaths associated with DXM abuse
Cough Syrup Cocktails

- “Syrup and Soda”
- “Seven and Syrup”
- “Purple Drank”
Non-Controlled Substances

- **Analgesic:**
  - Tramadol (Ultram®, Ultracet®)
  - Notice of Proposed Rulemaking to place Tramadol into Schedule IV issued November 4, 2013.
  - Effective August 18, 2014, Schedule IV controlled substance

- **Muscle Relaxant:**
  - Cyclobenzaprine (Flexeril®)
Tramadol Prescriptions

Source: IMS Health National Prescription Audit Plus
Cyclobenzaprine (Amrix®, Flexeril®, Fexmid®)

- A skeletal muscle relaxant prescribed for acute temporary muscle spasms caused by local trauma or strain.

- Marketed in the United States since 1977 (by Merck Com.).

- Currently non-controlled under the CSA.

- Chemical structure related to tricyclic antidepressant drugs (e.g., amitriptyline)

- Cyclobenzaprine, similar to other skeletal muscle relaxants, is being diverted and abused
The CSA: Checks & Balances
The CSA’s Closed System of Distribution

1,469,821 DEA Registrants
The CSA’s
Closed System of Distribution

- Cyclic Investigations
- Established Schedules
- Record Keeping Requirements
- Security Requirements
- Registration
- Established Quotas
- ARCOS
The Flow of Pharmaceuticals

- Raw Material
  - Importers
    - Manufacturers
      - Dosage Form Manufacturers
        - Smaller Distributors
          - Wholesalers - Distributors
            - Physicians (Rx and drugs)
              - NTPs
                - PATIENTS
  - Imp - Manufacturers
    - Dosage Form Manufacturers
      - Manufacture Dosage Form
        - Manufacturers
          - Dosage Form Manufacturers
            - Pharmacies
              - Hospitals
                - PATIENTS

- QUOTAS
  - (Thebaine)
  - Raw Material
    - 21 USC 823(c)(1)
    - 21 USC 823(d)(1)
    - 21 CFR 1301.71
    - 21 USC 823(b)(1)
    - 21 USC 823(e)(1)
    - 21 CFR 1301.71
    - (Suspicious Orders)
  - 21 CFR 1306.04
Checks and Balances of the CSA and the Regulatory Scheme

• **Distributors** 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)
Checks and Balances
Under the CSA

• Practitioners

“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)
Checks and Balances
Under the CSA

- Pharmacists – The Last Line of Defense

“The responsibility for the proper prescribing and dispensing of controlled substances is upon the practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” (21 CFR §1306.04(a))
System of Checks and Balances

The Last Line of Defense
What can happen when these checks and balances collapse?
## Drugs Prescribed

- A ‘cocktail’ of oxycodone and alprazolam (Xanax®)
- An average ‘patient’ receives prescriptions or medications in combination

<table>
<thead>
<tr>
<th>Schedule II</th>
<th>Schedule III</th>
<th>Schedule IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone 15mg, 30mg</td>
<td>Vicodin (Hydrocodone)</td>
<td>Xanax (Alprazolam)</td>
</tr>
<tr>
<td>Roxicodone 15mg, 30mg</td>
<td>Lorcet</td>
<td>Valium (Diazepam)</td>
</tr>
<tr>
<td>Percocet</td>
<td>Lortab</td>
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</tr>
<tr>
<td>Percodan</td>
<td>Tylenol #3 (codeine)</td>
<td></td>
</tr>
<tr>
<td>Demerol</td>
<td>Tylenol #4 (codeine)</td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Average Charges for a Clinic Visit

- Price varies if medication is dispensed or if customers receive prescriptions.
- Some clinics advertise in alternative newspapers citing discounts for new patients such as 'buy one get one free' or “50% off with this ad”.
- Typically, initial office visit is $250; each subsequent visit is $150 to $200.
- Average 120-180 30mg oxycodone tablets per visit.
Cost of Drugs

- The ‘cocktail’ prescriptions go for $650 to $1,000
- According to medical experts, most clinics do not require sufficient medical history and tests for proper prescribing of Schedule II substances
- Each oxycodone 30mg tablet costs $1.75 to $2.50 at the clinics
  - On the street in Florida, that pill can be re-sold for $7 to $15
  - Outside of Florida, it can be re-sold for $25 to $30 ($1 per mg)
Why is this happening?
Its All About Profit

- One case in Florida owner/operator of pain clinic allegedly generated $40 million in drug proceeds
- Houston investigation $41.5 million in assets
State of Florida Legislative Actions

- **Effective October 1, 2010**
  - Pain clinics are banned from advertising that they sell narcotics
  - They can only dispense 72-hour supply of narcotics
  - Prohibits the registration of pain clinics unless they are owned by physicians or licensed by non-physicians as a health care clinic

- **Effective July 1, 2011**
  - Clinics must turn over their supply of C-II and C-III controlled substances
  - Clinics are no longer able to dispense these drugs
  - Clinics cannot have ANY affiliation with a doctor that has lost a DEA number
June 2010 DEA takes action against four wholesale distributors supplying doctors who were dispensing from rogue pain clinics.
Clinic response to Enforcement Actions & the Florida legislation prohibiting the sale of CS from pain clinics?

Buy Pharmacies or Move to Other States!
Traffickers adapt to situations,” says Mark Trouville, Special Agent in charge of the Drug Enforcement Administration’s field offices in Florida. “We knew once we put pressure on the pill mills, the wrong people would start opening pharmacies.

Dealers creative in oxycodone bid

They try to open pharmaacies before Florida target.

By Donna Leinwand Leger
USA TODAY

Drug dealers are finding creative ways around new laws to sellable painkillers such as oxycodone.

In Florida, hundreds of people have opened pharmacies after barred doctors from dispensing narcotics directly to patients. The hospital forced patients to fill prescriptions at pharmacies. Now, they moved their operations to state police and federal agents.

“Traffickers adapt to situations,” says Mark Trouville, special agent in charge of the Drug Enforcement Administration’s field offices in Florida. “We knew once we put pressure on the pill mills, the wrong people would start opening pharmacies.

Florida was the nation’s center of prescription painkiller distribution until the state enacted laws last year aimed at pill mills — clinics where doctors perform cursory examinations on people with dubious injuries and dispense addictive painkillers.

Since then, the number of Florida doctors among the nation’s top 100 oxycodone-purchasing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenkevitz says.

Applications for non-chain pharmacies jumped about 80% in 2011 to 381 from a typical year before the crackdown, Trouville says.

‘Traffickers adapt to situations,” says Mark Trouville, Special Agent in charge of the Drug Enforcement Administration’s field offices in Florida. “We knew once we put pressure on the pill mills, the wrong people would start opening pharmacies.

The DEA is working with the state to inspect pharmacies, says Barbara Heath of the DEA’s Atlanta field division. She expects problems pharmacies in North Carolina and Tennessee as they are pushed out of Georgia.

The DEA has already identified pharmacies in North Carolina and Tennessee as they are pushed out of Georgia.

Dotcom’s flamboyant life of riches and creating one of the Web’s most popular and controversial sites — a site that came into the government’s cross-hairs two years ago after a complaint from the Motion Picture Association of America.

In the days after Dotcom’s arrest, the case has triggered an angry response from the hacker
MIGRATION OF PAIN CLINICS
Methods of Diversion

- Practitioners / Pharmacists
  - Illegal distribution
  - Self abuse
  - Trading drugs for sex

- Employee pilferage
  - Hospitals
  - Practitioners’ offices
  - Nursing homes
  - Retail pharmacies
  - Manufacturing / distribution facilities

- Pharmacy / Other Theft
  - Armed robbery
  - Burglary (Night Break-ins)
  - In Transit Loss (Hijacking)
  - Smurfing

- Patients
  - Drug rings
  - Doctor-shopping
  - Forged / fraudulent / altered prescriptions

- Internet availability
Doctor Shopping
Doctor Shopping: What is it?

Practiced by both Individual “Patients Drug Seekers” & Trafficking Organizations

− Target Physicians
  • Obtain prescriptions from multiple physicians
  • Physicians who are willing to prescribe controlled substances over an extended period of time with little or no follow-up

− Target Pharmacies
  • Utilize multiple pharmacies to fill the orders to avoid suspicion
  • Pharmacies known to dispense controlled substances without asking questions are targeted
* The operation of Nebraska’s PDMP is currently being facilitated through the state’s Health Information Initiative. Participation by patients, physicians, and other health care providers is voluntary.
Dr. Paul H. Volkman was sentenced in the Southern District of Ohio on February 14, 2012 to four consecutive life sentences and ordered to forfeit $1.2 million. Volkman was convicted on 12 counts of illegal distribution of controlled substances, four of which resulted in a death; one count of conspiracy to distribute controlled substances; four counts of maintaining a drug premise; and one count of possession of a firearm in furtherance of a drug trafficking crime.

From 2003 to 2005, Volkman illegally distributed over 2.5 million dosage units of Schedule II drugs, primarily oxycodone, outside the course of professional practice which resulted in the death of four people. Of the approximate one million practitioner registrants in the United States in 2004, Volkman ranked first in purchases of oxycodone.
Healthcare Professionals in a Hospital setting
Methods of Diversion

- Theft (embezzlement) from automated dispensing systems – PYXIS, Lionville
- Substitution or adulteration of medications
- Theft of sample medications
- Theft of patient medications through charting manipulations
- Self-medication
Embezzlement

- When drugs are administered to the patient, the nurse must manually document in the patient’s MAR (Medication Administration Record).

- Diversion can be discovered only through documentation review:
  - PYXIS reports
  - Physician’s orders
  - Medication Administration Record (MAR)
  - Work Schedule
Embezzlement

- Shortages on PYXIS report
- Nurse withdraws drug for a patient not assigned to her or removes drug when not assigned to work
- Nurse withdraws drug that is not ordered by physician or after order was cancelled
- Nurse withdraws drug more frequently than what is prescribed by physician
- Nurse fails to document wastage when required or wastes entire vials of drug
- Administration of drug not documented on MAR
Lessons Learned
We will not arrest our way out of this problem!!!!!!

- Enforcement is just as important as....
- Prevention/Education
- Treatment
Prescription Drug Abuse Prevention Plan

• Coordinated effort across the Federal government

• Four focus areas
  1) Education
  2) Prescription Drug Monitoring Programs
  3) Proper Medication Disposal
  4) Enforcement
Realignment of DEA’s Diversion Control Efforts

• In October 2008, the then Acting Administrator authorized a two-pronged reorganization of the DEA Diversion Control Program.

• The first prong involved a substantial expansion in the number of Tactical Diversion Squads (TDS) and their deployment throughout the United States.

• The second prong of the reorganization plan called for a renewed focus on DEA’s regulatory oversight of more than 1.4 million DEA registrants.
Cutting off the Source of Supply
DEA snips licenses of pharmaceutical giant's customers

Cardinal Health says it didn't look the other way

By Dennis Leinwand Leget
USA TODAY

Vincent Mottaier, head of a local pharmacy in April 2009 that a local pharmacy was losing the powerful and addictive painkiller oxycodone by the pill or per diem. So Mottaier, an investigator for Cardinal Health, one of the nation's largest distributors of pharmaceuticals, visited Gulf Coast Medical Pharmacy in Fort Myers, Fla. Over the next two years, Mottaier and other Cardinal employees visited that pharmacy at least four times. Each time, they noted disturbing signs: Customers paid cash, oxycodone was the No. 1 salve, and groups of people came in groups to have their prescriptions filled.

DEA's special agent Vincent Mottaier told the owner he wanted more oxycodone. The store had dispensed 462,776 pills over two months. Nearly seven times what the average pharmacy dispenses in a year. Concerned something was off, Mottaier asked Cardinal's permission to contact the Drug Enforcement Administration, which filed complaints in federal court.

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DEA Legal Recourse

- Administrative
  - Immediate Suspension Order (ISO)
  - Memorandum of Agreement (MOA)
  - Order to Show Cause (OTSC)

- Civil
  - Fines

- Criminal
  - Arrests & Forfeiture of Assets
Pharmacy Chain to Pay $80 Million Fine in D.E.A. Inquiry

By BARRY MEIER

The Walgreen Company, the nation's biggest pharmacy operator, agreed on Tuesday to pay $80 million to resolve federal charges that it failed to properly control the sales of narcotic painkillers at some of its outlets.

Officials at the Drug Enforcement Administration described the fine as the biggest ever paid by a pharmacy chain. As part of the settlement, the license of a Florida facility used by Walgreen to distribute controlled drugs was revoked for two years.

D.E.A. officials said that many of the drugs dispensed at the facility made their way to the black market, including oxycodone, a strong narcotic that is also the active ingredient in OxyContin.

Under the agreement, Walgreen committed to establish better internal controls. It acknowledged that practices at a distribution facility and some of its pharmacies in Florida did not meet standards.

Over the last year, federal officials have acted against several major wholesalers of prescription painkillers, like Cardinal Health, as well as drugstores. Such drugs are involved in some 16,000 overdose deaths annually.

Federal officials have said that

Continued on Page 2
For Immediate Release
May 8, 2012

Baucus, Grassley Seek Answers about Opioid Manufacturers’ Ties to Medical Groups

Finance Leaders Investigate Whether Pharmaceutical Companies Encouraged Non-Profit Beneficiaries to Promote Misleading Information about Narcotic Painkillers

Washington, DC – Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior Committee member Chuck Grassley (R-Iowa) initiated an investigation today into the connections of drug manufacturers Purdue Pharma, Endo Pharmaceuticals, and Johnson & Johnson with medical groups and physicians who have advocated the increased use of narcotic painkillers, or opioids. The Senators also asked seven other medical groups to produce information about their financial ties and collaborations with opioid manufacturers. In letters sent to each yesterday, Baucus and Grassley requested documents and financial information from the companies and noted that deaths resulting from opioid overdoes have skyrocketed, growing nearly 450 percent between 1999 and 2000, the most recent year data was available. They also highlighted news reports suggesting the increase may be driven by misinformation and dubious marketing practices used by the pharmaceutical companies and the medical organizations they fund.

“Overdoses on narcotic painkillers have become an epidemic, and it’s becoming clear that patients aren’t getting a full and clear picture of the risks posed by their medications,” Baucus said. “When it comes to these highly-addictive painkillers, improper relationships between pharmaceutical companies and the organizations that promote their drugs can put lives at risk. These painkillers have an important role in health care when prescribed and used properly, but pushing misleading information on consumers to boost profits is not only wrong, it’s dangerous.”

“The problem of opioid abuse is bad and getting worse,” Grassley said. “Something has to change. A greater understanding of the extent to which drug makers underwrite literature on opioids is a good start. Doctors and patients should know if the medical literature and groups that guide the drugs’ use are paid for by the drugs’ manufacturers and if so, how much. Education on the proper use of pain medication is a key step in preventing abuse and misuse, so it’s important to understand what material is out there.”

The Centers for Disease Control and Prevention have declared overdoses from opioid painkillers to be a public health epidemic. Deaths from painkiller overdoses have tripled over the last decade and led to the deaths of 16,000 Americans in 2010, exceeding those caused by heroin and cocaine combined.

Related Files

- Baucus Grassley Opioid Investigation Letter to Purdue Pharma
- Baucus Grassley Opioid Investigation Letter to Federal of State Medical Boards
- Baucus Grassley Opioid Investigation Letter to the Joint Commission
- Baucus Grassley Opioid Investigation Letter to Wisconsin Pain and Policy Studies Group
- Baucus Grassley Opioid Investigation Letter to American Academy of Pain Medicine
- Baucus Grassley Opioid Investigation Letter to American Pain Foundation
- Baucus Grassley Opioid Investigation Letter to American Pain Society
- Baucus Grassley Opioid Investigation Letter to Center for Practical Bioethics
- Baucus Grassley Opioid Investigation Letter to Johnson and
Dollars for Doctors
How Industry Money Reaches Physicians

The Story So Far

Feature Stories

- News App: Dollars for Docs
- Dollars for Docs Mints a Millionaire
- Med Schools Flunk at Keeping Faculty Off Pharma Speaking Circuit
- Financial Ties Bind Medical Societies to Drug and Device Makers

Dollars for Docs

Has Your Health Professional Received Drug Company Money?
Updated March 11, 2013

SEARCH

Name, institution or city:
Examples: Klein, Duke/University, Miami

State
All States

Advanced search

SEARCH

Embed on your site

About this Data

Heart of Nevada Dealers: Who Is Lending Dollars for Docs?

46 updates since last visit
Nationwide Take-back Initiative
Over 4.1 million pounds (2,123 tons) collected

- On September 30, 2010, approximately 122 tons
- On April 30, 2011, approximately 188 tons
- On October 29, 2011, approximately 189 tons
- On April 28, 2012, approximately 276 tons
- On September 29, 2012, approximately 244 tons
- On April 27, 2013, approximately 376 tons
- On October 26, 2013, approximately 324 tons
- On April 26, 2014, approximately 390 tons
Take-Back Event

Boxed, Sealed, Counted, Weighed, Consolidated, Secured, and Incinerated
Secure and Responsible Drug Disposal Act of 2010

- 12/21/2012 – Proposed Drug Disposal Regulations are published in Federal Register

- 2/19/2013 – Comment period on proposed regulations

- Review of comments, and hearings if requested

- Finalization of rules
What to Do?

✓ Take the time and talk to your patients about abuse and dependence potential for medications that have been prescribed;

✓ Securing their medications in their homes;

✓ Discuss how to properly dispose of expired or unused medications; and
What to Do?

- If you suspect or know of diversion of pharmaceuticals by a healthcare profession report it to your state Professional Licensing Board (Dental, Medical, Nursing or Pharmacy Board);

- Contact your local law enforcement authority;

- Contact local DEA Office and ask for the TDS or Diversion Group.
DEA Web-based Resources

www.JustThinkTwice.com
DEA Web-based Resources

www.GetSmartAboutDrugs.com
Thank You / Questions