Denver Pharmacy Diversion Awareness Conference

DEA Perspective: Pharmaceutical Use & Abuse

August 2 & 3, 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.
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.
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
Drug-Induced Deaths vs. Other Injury Deaths (1999–2009)

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

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 Health—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
  ➢ $24.7 billion in direct healthcare costs

• Opioid abusers generate, on average, annual direct healthcare costs 8.7 times higher than non-abusers

Addicted Infants Triple in a Decade

3.4 out of 1,000 suffer painkiller withdrawal

By Liz Szabo
USA TODY

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 abused narcotic pain medications, the study says. It's published today in the Journal of the American Medical Association.

Born into addiction
Babies exposed to drugs in the womb have more health problems than other newborns.

- Drug-exposed
  - Other: 9%
  - Other: 31%

- Breathing problems
  - 9%

- Low birthweight
  - 19%

- Feeding problems
  - 7%

- Seizures
  - 2.3% - 0.1% - 1 - under 5 lbs pounds

Source: 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.
<table>
<thead>
<tr>
<th>Year</th>
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<th>Oxycodone</th>
</tr>
</thead>
<tbody>
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<td>15,069</td>
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<td>2008</td>
<td>26,306</td>
<td>17,256</td>
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<td>2009</td>
<td>27,753</td>
<td>18,396</td>
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<td>2010</td>
<td>28,310</td>
<td>19,363</td>
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<tr>
<td>2011</td>
<td>30,792</td>
<td>19,423</td>
</tr>
<tr>
<td>2012</td>
<td>29,391</td>
<td>18,495</td>
</tr>
</tbody>
</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

Violence
Violence Related to Controlled Substance Pharmaceuticals

ASSASSIN

Chilling anatomy of drugstore massacre

DRUGSTORE MASSACRE

Husband and wife busted in Rx-slay horror

PAIN KILLER

He never gave them a chance. The cold-blooded killer who murdered four people in a Long Island pharmacy methodically shot each victim, shooting, step-by-step, methodically through the slaughter revealed yesterday.

PAGES 4-5
Nassau police respond to the scene of a shooting Saturday at Charlie's Family Pharmacy, 3931 Merrick Rd., in Seaford. (Dec. 31, 2011) Photo Credit: Kevin P. Coughlin

Robbery suspect, federal agent killed in Seaford

A robbery suspect and a federal agent who had dropped by to pick up a prescription for his ailing father both died of gunshot wounds Dec. 31, 2011, after police struggled with the suspect in the doorway of a Seaford pharmacy.

Be the first to rate: ★★★★★ Click to rate

Related

Nassau
Cops: Fatal shooting at Seaford drugstore
WHERE PEOPLE ARE GETTING THEIR DRUGS
The Medicine Cabinet: The Problem of Easy Access
More than half of teens (73%) indicate that it’s easy to get prescription drugs from their parent’s medicine cabinet.

Half of parents (55%) say anyone can access their medicine cabinet.

Almost four in 10 teens (38%) who have misused or abused a prescription drug obtained it from their parent’s medicine cabinet.

Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
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 (23%) reports having misused a prescription drug at least once in their lifetime (up from 18% in 2008 to 23% in 2013), which translates to about 5 million teens. That is a 33% increase over a five-year period.

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 2013, published July 2014
Percentage of Past Month Nonmedical Use of Psychotherapeutics by Age, 2003-2012

Source: 2012 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
Teen Misuse & Abuse

Prevalence of Teen Prescription Drug Misuse and Abuse
% Used at Least Once (n=3705)

<table>
<thead>
<tr>
<th>Year</th>
<th>Lifetime</th>
<th>Annual</th>
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<tr>
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<td>20%</td>
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</tr>
<tr>
<td>2011</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>24%</td>
<td>18%</td>
</tr>
<tr>
<td>2013</td>
<td>23%</td>
<td>16%</td>
</tr>
</tbody>
</table>

“(In your lifetime/in the past 12 months), how many times have you tried any prescription drug (when a doctor did not prescribe it for you) in order for you to get high or change your mood?”
Teen Prescription Drug Misuse & Abuse

- 23% report having abused RX medications at least once in their lifetime.

- 31% believe “it’s okay to use prescription drugs that were not prescribed to them to deal with an injury or pain, as long as they are not getting high.”

- 22% 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.
Teen Attitudes

- **31%** believe prescription drugs (Ritalin or Adderall) can be used as study aids.

- **29%** believe taking a larger dose than prescribed to them is okay as long as they are not getting high.

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
Other Controlled Substances

How many times have you used the following substances at least once in your lifetime:

- **17%** have used synthetic marijuana
- **7%** used bath salts
- **8%** used methamphetamine
- **15%** used OTC cough medicine (+3% - 2012)

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
National Study: Teens Report Higher Use of Performance Enhancing Substances

Prevalence of Teen Steroid / Synthetic hGH Abuse
% Used at least once in lifetime (n=3705)

- Synthetic hGH
- Steroids

<table>
<thead>
<tr>
<th>Year</th>
<th>Synthetic hGH</th>
<th>Steroids</th>
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<tbody>
<tr>
<td>2009 (A)</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>2010 (B)</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>2011 (C)</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>2012 (D)</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>2013 (E)</td>
<td>11% ABCD</td>
<td>7% A</td>
</tr>
</tbody>
</table>

“In your lifetime, how many times, if any, have you done each of the following… used (steroids/human growth hormone) for athletic performance or physical appearance when a doctor did not prescribe them for you? A-E indicates a significant difference at the 95% confidence level.

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
Teen Use of Performance Enhancing Substances

- Boys 12%
- Girls 9%
- African American teens 15%
- Hispanic teens 13%

The results of this study further demonstrate the importance of educating young people, their parents and coaches on the risks associated with the use of performance-enhancing drugs, and the need to protect young people from those who would prey on them as easy marketing targets."

Travis T. Tygart, CEO of the U.S. Anti-Doping Agency

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
Reasons for Misuse & Abuse

“What was the one main reason why you last used a prescription drug without a prescription?”

- To help me relax: 15%
- To experiment: 15%
- To have fun: 14%
- Being high feels good: 12%
- To help me forget my troubles: 12%
- To deal with pressures & stress from school: 9%
- My friends are using: 9%
- To relieve boredom: 8%
- To help deal with problems at home: 8%
- It’s a habit, I can’t stop: 8%
- To feel better about myself: 7%
- To look cool: 6%
- Don’t know: 9%

Date Prepared/Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
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 8** indicate it’s okay for their teen to take a prescription drug without a prescription.

✓ **9%** believe it’s okay for their teen to take a prescription drug without a prescription if used for reducing pain.

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
Where our kids learn about drugs!

**Learned About Risk of Drugs From Following Sources by Teen Drug Use**

<table>
<thead>
<tr>
<th>Source</th>
<th>Teens Who Do Not Use Drugs (n=1409)</th>
<th>Teens Who Do Use Drugs (n=2087)</th>
</tr>
</thead>
<tbody>
<tr>
<td>School</td>
<td>57% B</td>
<td>44%</td>
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<tr>
<td>Parents</td>
<td>38% B</td>
<td>31%</td>
</tr>
<tr>
<td>Friends</td>
<td>25%</td>
<td>34% A</td>
</tr>
<tr>
<td>On the Street</td>
<td>14%</td>
<td>21% A</td>
</tr>
</tbody>
</table>

A-B indicates a significant difference at the 95% confidence level.

“*How much have you learned about the risks of drugs from each of the following:*

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
Where else do our 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>
<tr>
<td><strong>Comments</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Unsatisfactory: Stimulants contributing to Ritalin 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)

(By Number of Prescriptions Sold)

Source: IMS Health

- Hydrocodone/Apap
- Lipitor
- Amoxicillin
- Lisinopril
- Simvastatin
- Levothyroxine
- Azithromycin
- Amlodipine besylate
Commonly Abused Controlled Pharmaceuticals

- Carisoprodol
- OxyContin 80mg
- Oxycodone 30 mg
- Oxymorphone
- Hydrocodone
- Alprazolam
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>
<th>Capsule color(s)</th>
<th>Capsule Text</th>
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<td>43376-250-10 100 ct bottles</td>
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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
OXycodone
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
FDA approves **Targiniq ER** - new extended release oxycodone with abuse-deterrent properties

Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride extended-release tablets), an extended-release/long-acting (ER/LA) opioid analgesic to treat severe pain.

10/5mg, 20/10mg, and 40/20mg tablets

FDA News Release 7/23/2014
Prescription Opiates v. Heroin
Circle of Addiction & the Next Generation

Hydrocodone
Lorcet®
$5-$7/tab

Oxycodone Combinations
Percocet®
$7-$10/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

Tuesday, April 3, 2012

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.

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.

Photo by Randy Pench/Sacramento Bee/MCT
HEROIN: NO LONGER CONFINED TO URBAN AREAS
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

Source: SAMSHA Treatment Episode Data Set, 1998-2008 released July 15, 2010
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<td>2013</td>
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<td>114,148</td>
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<tr>
<td>2014: Jan - Mar</td>
<td>26,635</td>
<td>21,324</td>
</tr>
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</table>
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
Methadone
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 also 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 24 in 2007. 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

Meperidine

Morphine

Codeine

Propoxyphene
Benzodiazepines

- Alprazolam
- Clonazepam
- Diazepam
- Lorazepam
- Midazolam
- Triazolam
- Temazepam
- Flunitrazepam
• 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 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
Teen OTC Cough Medicine Misuse and Abuse

Prevalence of Teen OTC Cough Medicine Abuse
% Used at Least Once (n=3705)

- Lifetime
- Annual
- Monthly

2009 (A): 12%
2010 (B): 11% CDE
2011 (C): 12%
2012 (D): 12%
2013 (E): 15% ACD

“(In your lifetime/in the past 12 months/in the past 30 days), how many times have you taken a non-prescription cough or cold medicine to get high?”
A-E indicates a significant difference at the 95% confidence level.

2013 Partnership Attitude Tracking Study: July 23, 2014
Cough Syrup Cocktails

- “Syrup and Soda”
- “Seven and Syrup”
- “Purple Drank”

PURPLE DRANK
ima grip and sip
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
- Registration
- Security Requirements
- Established Quotas
- ARCOS
The Flow of Pharmaceuticals

Raw Material

Importers

Manufacturers

Dosage Form Manufacturers

Imp - Manufacturers

Dosage Form Manufacturers

Raw Material

(Thebaine)

QUOTAS

Smaller Distributors

Wholesalers - Distributors

Hospitals

Pharmacies

Physicians

(Rx and drugs)

NTPs

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
21 CFR 1301.74
(Suspicious Orders)

21 CFR 1306.04

PATIENTS
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?
The Florida “Migration”: Was this Normal??

Vast majority of the “patients” visiting Florida “pain clinics” came from out-of-state:

- Georgia
- Kentucky
- Tennessee
- Ohio
- Massachusetts
- New Jersey
- North and South Carolina
- Virginia
- West Virginia
Explosion of South Florida Pain Clinics

As of June 4, 2010, Florida has received 1,118 applications and has approved 1,026

*As of May 14, 2010, Broward 142; Miami-Dade 79; Palm Beach 111
Why is this happening?
One case in Florida owner/operator of pain clinic allegedly generated $40 million in drug proceeds

Houston investigation $41.5 million in assets
• Another case in Florida - pain clinic operation paid his doctors (in 2009):
  – $861,550
  – $989,975
  – $1,031,975
  – $1,049,032
  – $1,225,775
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.
Agents Raid Florida Clinics in Drug Crackdown

By DON VAN NATTA Jr.

MIAMI — Drug Enforcement Administration agents and other law enforcement officials on Wednesday raided six South Florida pain clinics accused of illegally dispensing potent prescription drugs across the United States. Twenty-two people, including owners, were arrested on trafficking charges.

11 arrested in Palm Beach County as part of multi-agency pill mill raid

In Palm Beach County, the raids focused on five doctors in four pain clinics.

By CYNTHIA ROLDAN AND MICHAEL LAFORGIA
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.”
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: 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
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

Continued from LA

to the four pharmacies "tragically high," and says Cardinal ignored red flags raised within its system to detect suspicious orders.

"Our system did raise questions with these four pharmacies," said Cardinal spokeswoman Debbie Mitchell. "We took action to stop the flow of prescriptions from the pharmacies to the customers.

"Cardinal argues that volume alone is not enough to determine whether a pharmacy is diverting drugs, but because it doesn't account for a pharmacy's location, the age and health of the population, and the proximity to hospitals, we can't agree.

"The problem was that Cardinal simply declared that its system was adequate by itself and didn't take any action to stop the prescriptions from going to the people identified larger wholesalers.

"In 2009, the DEA cited Cardinal in a complaint that it had failed to properly report suspicious orders.

CPS, in a statement Feb. 17, in response to a Reuters report that it has been issuing subpoenas for documents related to its inspections of pharmacies that have received bulk orders for oxycodone, said the company is "interested in working with the DEA to ensure that its system is robust and effective in preventing the diversion of controlled substances into the wrong hands.

"The DEA has taken an active role in ensuring that Cardinal's system is robust and effective in preventing the diversion of controlled substances into the wrong hands. We are committed to working closely with the DEA to ensure that this system is robust and effective in preventing the diversion of controlled substances into the wrong hands.

CPS has also been taking action to improve its system, including implementing new protocols and increasing the number of investigators.

In a separate statement, Cardinal said that it has "always been proactive in implementing new protocols and increasing the number of investigators to prevent the diversion of controlled substances into the wrong hands."
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

The $80 million settlement is the largest fine paid by a pharmacy chain as related to D.E.A.'s strategy of cracking down on rampant prescription drug abuse.
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 recently skyrocketed, growing nearly 450 percent between 1999 and 2003, 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 to 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 Opied Investigation Letter to Purdue Pharma (286.2 KB)
- Baucus Grassley Opied Investigation Letter to Federation of State Medical Boards (279.9 KB)
- Baucus Grassley Opied Investigation Letter to the Joint Commission (27.2 KB)
- Baucus Grassley Opied Investigation Letter to Wisconsin Pain And Policy Studies Group (27.7 KB)
- Baucus Grassley Opied Investigation Letter to American Academy of Pain Medicine (27.7 KB)
- Baucus Grassley Opied Investigation Letter to American Pain Foundation (27.4 KB)
- Baucus Grassley Opied Investigation Letter to American Pain Society (27.4 KB)
- Baucus Grassley Opied Investigation Letter to Center for Practical Ethics (27.2 KB)
- Baucus Grassley Opied 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

SEARCH

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About this Data
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
EDITORIAL CARTOON By Nate Beeler/Examiner

JACKPOT!

Prescription Drugs Found In Tap Water
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; or

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

www.DEA.gov
DEA Web-based Resources

www.JustThinkTwice.com
DEA Web-based Resources

www.GetSmartAboutDrugs.com
Thank You / Questions