Baton Rouge Pharmacy Diversion Awareness Conference

DEA Perspective: Pharmaceutical Use & Abuse

August 3 & 4, 2013
In 2010, approximately 38,329 unintentional drug overdose deaths occurred in the United States, one death every 14 minutes.

Of this number, 22,134 of these deaths were attributed to Prescription Drugs (16,651 attributed to opioid overdoses / 75.2 %).

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

Source: CDC Drug Overdose Deaths in the United States, 2010   (October 2012)
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.

A growing epidemic among women - Prescription Drug Overdoses

• Nearly **48,000** women died of prescription painkiller* overdoses between 1999 and 2010.

• Deaths from prescription painkiller overdoses among women have increased more than **400%** since 1999, compared to 265% among men.

• For every woman who dies of a prescription painkiller overdose, **30** go to the emergency department for painkiller misuse or abuse.

Source: CDC VitalSigns July 2013
Prescription painkiller overdose deaths are a growing problem among women.

SOURCE: National Vital Statistics System, 1999-2010 (deaths include suicides)
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)
More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Methamphetamine & Heroin abusers

COMBINED!!
The Costs
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

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\(^3\)

2. Ibid.
3. Ibid.
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

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
WHAT PEOPLE ARE ABUSING
Commonly Abused Controlled Pharmaceuticals

Hydrocodone

Carisoprodol
C-IV as of 1/11/2012

Oxycodone 30 mg

OxyContin 80 mg

Oxymorphone

Alprazolam

Oxycodone 30 mg

Hydrocodone
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)

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

- Street prices: $2 to $10+ per tablet depending on strength & region
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.
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
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. 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 1996 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 said 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 even after 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 26 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.
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 – Drug Code 9064
  - Subutex (sublingual, single entity tablet)
  - Suboxone (sublingual, buprenorphine/naloxone tablet)
Suboxone – Schedule III

– Used to treat opiate addiction (new Methadone)
– Contains both Buprenorphine and Naloxone
  • Buprenorphine similar to other opioids and produces less euphonic effects
  • Naloxone blocks the effects of opioids
– Taken: orally
– Abused as a replacement for other opioids; general hold over
– Popular in prisons, “prison heroin”
– Prices: $2.00 to $15.00
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
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
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®)

• **Muscle Relaxant:**
  – Cyclobenzaprine (Flexeril®)
Tramadol Prescriptions

<table>
<thead>
<tr>
<th>Year</th>
<th>Prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>24,500,000</td>
</tr>
<tr>
<td>2008</td>
<td>26,660,000</td>
</tr>
<tr>
<td>2009</td>
<td>28,344,000</td>
</tr>
<tr>
<td>2010</td>
<td>30,570,000</td>
</tr>
<tr>
<td>2011</td>
<td>36,776,000</td>
</tr>
</tbody>
</table>

Source: IMS Health National Prescription Audit Plus downloaded 6/5/2012
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
  - (Thebaine)
  - QUOTAS
  - Importers
    - Manufacturers
      - Dosage Form Manufacturers
        - Wholesalers - Distributors
          - Smaller Distributors
            - Hospitals
            - Pharmacies
            - Physicians (Rx and drugs)
            - NTPs
              - 21 CFR 1306.04
              - 21 CFR 1301.71
              - 21 USC 823(c)(1)
              - 21 USC 823(d)(1)
              - 21 USC 823(b)(1)
              - 21 USC 823(e)(1)
              - 21 CFR 1301.74
(Suspicious Orders)
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)
Check 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?
WHAT’S A ROGUE “PAIN CLINIC” OR “PILL MILL” LOOK LIKE ??

First – Lets go Find your Clinic !!
Large-Scale Diversion

- In 2009, the average purchase for all oxycodone products for all pharmacies in US – 63,294 d.u.

- In 2010, the average was – 69,449 d.u.

- In 2009, the average purchase for all oxycodone products for the top 100 pharmacies in Florida – 1,226,460 d.u.

- In 2010, the average was – 1,261,908 d.u.
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
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)
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
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 doctors, were arrested and charged with fraud and money laundering.

WESTON, Fla. -- U.S. Drug Enforcement Administration agents and local police swept across South Florida on Wednesday making arrests as part of a lengthy undercover operation into illegal pill mills that dispense huge amounts of powerful prescription drugs across the nation.

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
Palm Beach Post Staff Writers
Updated: 11:20 a.m. Thursday, Feb. 24, 2011
Posted: 9:57 a.m. Wednesday, Feb. 23, 2011
Operators of four crooked pain clinics in Palm Beach County made millions of dollars by peddling pills to patients with trumped up injuries, rewarding themselves with boats, exotic cars and real estate while rates of overdose deaths and drug-dealing soared, state prosecutors alleged in court documents made public Wednesday.
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 pharmacies after Florida target

By Donna Leinwand Leber
USA TODAY

Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving 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-prescribing physicians has fallen to 13 from 90 in 2010, DEA Special Agent David Melenevitz says.

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

“Drug dealers are finding ways around new laws that shut down “pill mills” dispensing dangerous painkillers. In Florida, dozens of pill mills have been closed or shut down after doctors were barred from prescribing oxycodone directly to patients. Now pill mills are moving their operations to state police and federal agents.

“Traffickers adapt to situations,” says Mark Trouille
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.
Pharmacy Run Sheets...

Contacts

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
<th>Address</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auco</td>
<td></td>
<td>2060 E. Layton St.</td>
<td></td>
</tr>
<tr>
<td>Aurora</td>
<td></td>
<td>899 W. Washington</td>
<td>384-4030</td>
</tr>
<tr>
<td>Walmart</td>
<td></td>
<td>4701 S. 27th St.</td>
<td></td>
</tr>
<tr>
<td>Walgreens</td>
<td></td>
<td>3152 S. 27th St.</td>
<td></td>
</tr>
<tr>
<td>CVS</td>
<td></td>
<td>9220 W. Greenfield A</td>
<td></td>
</tr>
<tr>
<td>Lab603</td>
<td></td>
<td>10401 W. Bluemound</td>
<td></td>
</tr>
<tr>
<td>Osco</td>
<td></td>
<td>5740 W. Washington</td>
<td></td>
</tr>
<tr>
<td>Osco</td>
<td></td>
<td>9705 W. Layton</td>
<td></td>
</tr>
<tr>
<td>Walmart</td>
<td></td>
<td>S. 2800 Greenfield</td>
<td></td>
</tr>
<tr>
<td>Walmart</td>
<td></td>
<td>S. 1060 Greenfield</td>
<td></td>
</tr>
<tr>
<td>K-Mart</td>
<td></td>
<td>5600 S. 106th St.</td>
<td></td>
</tr>
<tr>
<td>K-Mart</td>
<td></td>
<td>5141 Douglas Ave.</td>
<td></td>
</tr>
<tr>
<td>K-Mart</td>
<td></td>
<td>9601 S. 27th St.</td>
<td></td>
</tr>
<tr>
<td>Target</td>
<td></td>
<td>4321 W. Greenfield</td>
<td></td>
</tr>
<tr>
<td>Target</td>
<td></td>
<td>5430 W. Howell</td>
<td></td>
</tr>
<tr>
<td>Jerome Drugs</td>
<td></td>
<td>575 W. 17301</td>
<td></td>
</tr>
<tr>
<td>Community</td>
<td></td>
<td>Pharmacy 3801</td>
<td></td>
</tr>
<tr>
<td>Shopko</td>
<td></td>
<td>8801 W. Washington</td>
<td></td>
</tr>
<tr>
<td>Sanny</td>
<td></td>
<td>17500 W. Oklahoma</td>
<td></td>
</tr>
<tr>
<td>Swans</td>
<td></td>
<td>550 W. Warner</td>
<td></td>
</tr>
<tr>
<td>PC</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date: 3-5-07

Diagnosis: 4-5-07

- Back pain - 4-5-07
  - OxyCodone 30mg (60) 90
  - OxyContin 40mg (100) 91
  - Vicodin 10mg (32) 40
  - Benadryl 10mg (200) 50
  - Wheaton Franciscan Pharmacy 444-101-7500
  2560 W. Layton, Milwaukee 53214 281-7500

3-13 5-07

- Bactrim - 500/500 MG

The Pharmacy Shoppe 444-584-1064
- 3001 S. 157th St. Milwaukee 53215 (6121)

- 90 OxyCodone 10mg 557
- 20 Diazepam 5mg 40
- 90 OxyCodone 15mg 35
<table>
<thead>
<tr>
<th></th>
<th>DX</th>
<th>ROX</th>
<th>LOR</th>
<th>X's</th>
<th>Sommas</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Cooper</td>
<td></td>
<td>90</td>
<td></td>
<td>150</td>
<td>90</td>
</tr>
<tr>
<td>World Wide</td>
<td>500</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. Pretto</td>
<td></td>
<td>120</td>
<td>180</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jerry's</td>
<td>820</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. Farrell</td>
<td></td>
<td>170</td>
<td>120</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pill Store</td>
<td>240</td>
<td>270</td>
<td>150</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>Dr. Weed</td>
<td></td>
<td></td>
<td>240</td>
<td>150</td>
<td>90</td>
</tr>
<tr>
<td>Generic Depot</td>
<td>1110</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. Osorio</td>
<td></td>
<td></td>
<td></td>
<td>120</td>
<td>60</td>
</tr>
<tr>
<td>Off Phar</td>
<td>240</td>
<td></td>
<td></td>
<td></td>
<td>100</td>
</tr>
<tr>
<td>Dr. Cosby</td>
<td></td>
<td>40</td>
<td>90</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Town</td>
<td>540</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. Mendez</td>
<td></td>
<td>110</td>
<td>90</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>Off Phar.</td>
<td>228</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. Sulkin</td>
<td></td>
<td></td>
<td>90</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>Hand</td>
<td>180</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. Mellon</td>
<td></td>
<td>240</td>
<td>270</td>
<td>150</td>
<td>120</td>
</tr>
<tr>
<td>Alpha</td>
<td>1200</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. Smith</td>
<td></td>
<td></td>
<td></td>
<td>120</td>
<td></td>
</tr>
<tr>
<td>Garden Drug</td>
<td>772</td>
<td>120 (2/5)</td>
<td>120</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr. Lazzerini</td>
<td></td>
<td></td>
<td>120</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pro Script</td>
<td>315</td>
<td></td>
<td></td>
<td>60</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td>120</td>
</tr>
</tbody>
</table>
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

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
Cutting off the Source of Supply
DEA Legal Recourse

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

- Civil
  - Fines

- Criminal
  - Arrests & Forfeiture of Assets
National Take Back Initiatives

Over 2.8 million pounds (1,409 tons) collected

September 30, 2010: 242,383 pounds (121 tons)

April 30, 2011: 376,593 pounds (188 tons)

October 29, 2011: 377,086 pounds (189 tons)

April 28, 2012: 552,161 pounds (276 tons)

September 29, 2012: 488,395 pounds (244 tons)

April 27, 2013: 742,497 pounds (371 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
Thank You / Questions