PRESCRIPTION DRUG TRAFFICKING & ABUSE TRENDS

May 15, 2013
EU-US Dialogue on Drugs
Brussels, Belgium

Russell Holske, Chief of Pharmaceutical Investigations
Operations Division, Office of Diversion Control,
U.S. Drug Enforcement Administration
Outline

• Scope of the Problem
• The Costs
• Drugs of Abuse
• The Controlled Substances Act
• Sources of Drugs
• Responses to Combat the Problem
SCOPE OF THE PROBLEM
The 1960/70s/80s

Uppers - Dexedrine

Downers - Seconal

Meprobamate

Hydromorphone

“Ts and Blues”

Oxycodone/APAP

“Fours and Doors”
The 1990s

OxyContin

10 mg
20 mg
40 mg
80 mg
160 mg

160 mg Controlled-Release Tablets

(oxycodone HCl)
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)
### 2010 Current Users (Past Month) 2011

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<th>Drug Type</th>
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<td><strong>Heroin:</strong></td>
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Source: 2010 & 2011 NSDUH
Number of Forensic Cases (January 2001 – June 2012)

NFLIS
Estimated U.S. Law Enforcement Encounters

Methadone  Oxycodone  Hydrocodone

Jan-Jun  Jul-Dec  Jan-Jun  Jul-Dec  Jan-Jun  Jul-Dec  Jan-Jun  Jul-Dec  Jan-Jun  Jul-Dec  Jan-Jun  Jul-Dec  Jan-Jun  Jul-Dec

Number of Cases

0  5,000  10,000  15,000  20,000  25,000  30,000

320%  229%  402%
Past Year Initiates 2011 -- Ages 12 and Older

Note: Numbers refer to persons who used a specific drug for the first time in the past year, regardless of whether initiation of other drug use occurred prior to the past year.

Source: 2011 NSDUH
Parents & Their Attitudes

Parents are not discussing the risks of abusing prescription drugs

Source: 2011 Partnership Attitude Tracking Study
Parents & Their Actions

Parents and their abuse of prescription drugs

Source: 2011 Partnership Attitude Tracking Study
Where do kids get their information from?
From websites like erowid.com
What are kids listening to… Eminem?

- Rap star Eminem has a Vicodin® tattoo on his arm and a picture of a Vicodin® tablet on one of his CDs.
One of the mint-filled pill bottles distributed to some fourth graders at Westchase Elementary.

By JOSÉ PATIÑO GIRONA | The Tampa Tribune
Published: February 8, 2010

What two fourth-grade teachers at Westchase Elementary School apparently thought was a creative way to calm students about to take the FCAT made at least one caregiver fear the teachers were sending a different message — that taking drugs while under stress is OK.

Sandy Young walked into her grandson's fourth-grade classroom last Thursday and saw pill bottles on each students' desk. Her mind raced with questions and thoughts of disbelief.

Young said she immediately questioned Westchase Elementary fourth-grade teacher Beth Watson about the pill bottles, which were filled with pieces of small mint candy.

"She said it was nothing but some mints; it was just something special for the kids, for the FCAT to mellow them out," Young said.

Young said she was shocked and speechless and walked out of the room when Watson started the students on a math assignment.

Young said the pill bottles go against the lessons of teaching children to say no to drugs.

"We turn around and we have our teachers giving them drugs," said Young, 60, of Tampa. "I don't care if it's mints or not. ... If it's in a prescription bottle, it's a drug."

Young said the bottle reads 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. (Deborah) Falcon's authorization required."

The school received one complaint since pill bottles were distributed on Thursday, said Linda Cobbe, a school district spokeswoman. It's believed only two fourth-grade teachers at the school distributed the pill bottles.

The principal met with the students on Monday to confirm the pill bottles contained mints that were safe to eat. The students were asked to dump the mints in a separate container and the pill bottles were thrown away, Cobbe said.

She said the bottle idea was tied to the children's book the students recently read, "George's Marvelous Medicine," about a boy who concocts potions to try to change the disposition of his cranky grandmother.

The teachers were just trying to use a creative way to get across to the students not to be stressed with the FCAT writing examination that will be administered to fourth-, eighth- and 10th-graders beginning today, Cobbe said.

"Elementary teachers do creative things to make learning fun," Cobbe said.

The teachers won't be disciplined, and it wasn't their intention to promote drug use, Cobbe said.

"I know that is not the intent of the teachers," Cobbe said. "That is not the outcome they would wish for."

Young said her grandson has been at Westchase Elementary for a year, and she hasn't had any complaints. But this experience has soured her.

It concerns her that now someone might hand her grandson a pill bottle with drugs and he might think it's OK to consume its contents.

"We as parents and grandparents have to drill it into them that this is unacceptable and hope and pray that they don't accept drugs from someone else," Young said.
DEATHS

Marilyn Monroe
August 5, 1962

Elvis Presley
August 16, 1977

Gerald Levert
November 10, 2006

Anna Nicole Smith
February 8, 2007

Heath Ledger
January 22, 2008

Michael Jackson
June 25, 2009

Luna Vachon
August 27, 2010

Michael Baze
May 10, 2011

Whitney Houston
February 11, 2012

Thomas Kinkade
April 6, 2012
The Costs
Economic Costs

• $55.7 billion in costs for *prescription drug abuse* in 2007¹

  ➢ $24.7 billion in direct healthcare costs

• Opioid abusers generate, on average, annual direct health care costs 8.7 times higher than non-abusers²

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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.
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 Center Number of U.S. Poison Exposure Case Mentions 2004 - 2008

Source: American Association of Poison Control Centers (AAPCC) Annual Reports, 2004-2008
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
Emergency Department Visits (2004-2009)

Emergency Department Visits Involving Illicit Drugs or Non-medical Use of Pharmaceuticals, 2004-2009


Source: CDC National Center for Health Statistics (NCHS) Data Brief, December 2011, updated with 2009 and 2010 mortality data
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.

Public Health Impact of Opiate Analgesic Abuse

For every 1 unintentional opioid overdose death in 2009, there were...

- Abuse treatment admissions: 11
- ED visits for misuse or abuse: 41
- People with abuse/dependence: 148
- Nonmedical users: 419

Mortality figure is for unintentional overdose deaths due to opioid analgesics in 2009, from CDC/Wonder.
Treatment admissions are for with a primary cause of synthetic opioid abuse in 2009, from TEDS.
Emergency department (ED) visits related to opioid analgesics in 2009, from DAWN.
Abuse/dependence and nonmedical use of pain relievers in the past month are from the 2009 National Survey on Drug Use and Health.
WHAT PEOPLE ARE ABUSING
Commonly Abused Controlled Pharmaceuticals

Carisoprodol
C-IV as of 1/11/2012

OxyContin 80mg

Oxymorphone

Hydrocodone

Oxycodone 30 mg

Alprazolam
Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen
Total U.S. Retail* Distribution of Selected Drugs
January 1, 2008 – December 31, 2011

*Retail includes pharmacies, hospitals, practitioners, mid-level practitioners, teaching institutions, and narcotic treatment programs.

Source: ARCOS
Date Prepared: 08/28/2012

Drug Enforcement Administration
Office of Diversion Control
Office of the Deputy Assistant Administrator

Source: ARCOS
Total U.S. Retail* Distribution of Selected Drugs
January 1, 2008 – December 31, 2011

*Retail includes pharmacies, hospitals, practitioners, mid-level practitioners, teaching institutions, and narcotic treatment programs.

Source: ARCOS
Date Prepared: 08/28/2012
Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

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

- Brand Names: Vicodin®, Lortab®, Lor cet®

- 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
The Trinity

Hydrocodone

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

Alprazolam
Benzodiazepine

Opiate
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
How to Abuse Oxycodone
Other Oxycodone Products

Percocet

Percodan

Tylox

Roxicodone
Oxycodone 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

Tuesday, April 3, 2012

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.
Opana ER (Oxymorphone) (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming popular and is abused in similar fashion to oxycodone; August 2010 (Los Angeles FD TDS)
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: $10.00 – $80.00
Methadone- 5mg & 10mg

Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg
Methadone History

• Methadone was developed in 1937 in Germany as a field painkiller, in anticipation of the potential loss of the raw opium supply for drugs like morphine in the event of war.

• The Controlled Substances Act and corresponding regulations established strict rules for methadone clinics, or Narcotic Treatment Programs (NTPs).

• Used as an analgesic— inexpensive pain reliever covered by insurance companies
Deaths Involving Methadone

Source: NCHS Data Brief #81, December 2011
Other Narcotics

- Fentanyl
- Meperidine
- Codeine
- Hydromorphone
- Morphine
- Propoxyphene
Benzodiazepines

- Alprazolam
- Clonazepam
- Diazepam
- Lorazepam
- Triazolam
- Temazepam
- Flunitrazepam
- Midazolam
Other Controlled Substances

- Phentermine C-IV
- Phendimetrazine C-III
  - Bontril®
- Amphetamines
  - Adderall C-II
  - Methylphenidate C-II
    - Ritalin®
    - Concerta®
Ritalin® / Concerta® / Adderall

• Used legitimately to treat ADHD

• Used non-medically to get high and as an academic “performance-enhancer” to improve memory and improve concentration – gain the edge
  • Higher GPA
  • Higher SAT / ACT score
  • Get that scholarship
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
The CSA: Checks & Balances
The CSA’s Closed System of Distribution

1,417,915 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
        - Wholesalers - Distributors
          - Smaller Distributors
            - Hospitals
              - Physicians (Rx and drugs)
                - NTPs
                  - Patients

- QUOTAS
  - (Thebaine)

- 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)
• **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)

• 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))
What can happen when these checks and balances collapse?
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. (43% of all oxycodone 30mg products were distributed to Florida)
WHERE PEOPLE ARE GETTING THEIR DRUGS
Methods of Diversion

• **The Medicine Cabinet**
  – **Doctor Shopping**
    – Drug rings
    – Forged / fraudulent / altered prescriptions
  – **Practitioners / Pharmacists**
    – Illegal distribution
    – Self abuse
    – Trading drugs for sex
  – **Pharmacy / Other Theft**
    – Armed robbery
    – Burglary (Night Break-ins)
    – In Transit Loss (Hijacking)
    – Smurfing
  – **Employee Pilferage**
    – Hospitals
    – Practitioners’ offices
    – Nursing homes
    – Retail pharmacies
    – Manufacturing / distribution facilities

• **The Internet**

• **Pain Clinics**
Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

• Unreasonable quantities being prescribed

• Insurance rules
Doctor Shopping

Individual “Patients”

- Target Physicians
  - prescriptions from multiple physicians
  - Refills – long periods of treatment - no follow-up

- Target Pharmacies
  - Utilize multiple pharmacies to fill the orders to avoid suspicion
  - Target pharmacies that don’t ask questions
Doctor Shopping

 Trafficking Organizations

— Recruit individuals to obtain narcotics
  • Patients with legitimate medical conditions (elderly/homeless)
  • False identification, obtained from consenting individuals, used to “create” medical records and obtain scripts
  • Pay patients for their narcotics and services (with $$ or narcotics)
  • Bring patients to distant locations
Pharmacy Run Sheets...

Contacts

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<th>Company</th>
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Date: 3-5-07

3:50 AM Back pain - O’Connor 4:50 AM 5:15 AM

Oxycodone ER 30 mg (8) 90
Oxycodone 40 mg (100 mg) 30

Cyclobenzaprine 10 mg (53) 90

Wheaton Franciscan Pharmacy 4:28 PM 7:50 AM

2:38 PM Bhakti Ambulance 10:25 AM 9:30

The Pharmacy Shp 414-384-1042 5:15 AM

3:20 PM 1:10 PM Milwaukee 5225 business

90 Oxycodone ER 80 mg
20 Diazepam 5 mg no Fx
90 Oxycodone 15 mg
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*December 2020*
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Pain Clinics
THE MIGRATION

Mayo Clinic of Jacksonville

(FLA) (MIAMI)
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
Top 100 Practitioner Purchasers of Oxycodone Nationwide
January 1, 2009 – September 30, 2009

97 Practitioners in Florida Purchased 20,760,567 units
1 Practitioner in Ohio Purchased 465,200 units – 2.2%
1 Practitioner in North Carolina Purchased 153,200 units – 0.7%
1 Practitioner in California Purchased 130,000 units – 0.6%

Source: ARCOS
Date Prepared: 01/12/2010
Drugs Prescribed

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

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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)
### Reports of Rx Drugs Detected in Deceased Persons and Cause of Death

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<td>620</td>
<td>716</td>
<td>785</td>
<td>693</td>
<td>720</td>
<td>694</td>
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<tr>
<td>Oxycodone</td>
<td>340</td>
<td>496</td>
<td>705</td>
<td>941</td>
<td>1,185</td>
<td>1,516</td>
<td>1,247</td>
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<tr>
<td>Hydrocodone</td>
<td>221</td>
<td>236</td>
<td>264</td>
<td>270</td>
<td>265</td>
<td>315</td>
<td>307</td>
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<td>Benzodiazepines</td>
<td>574</td>
<td>553</td>
<td>743</td>
<td>929</td>
<td>1,099</td>
<td>1,304</td>
<td>1,950*</td>
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<tr>
<td>Morphine</td>
<td>247</td>
<td>229</td>
<td>255</td>
<td>300</td>
<td>302</td>
<td>262</td>
<td>345</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>2,002</td>
<td>2,230</td>
<td>2,752</td>
<td>3,133</td>
<td>3,571</td>
<td>4,091</td>
<td></td>
</tr>
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</table>

* Many of the deaths were found to have several drugs contributing to the cause of death, thus, the count of specific drugs is greater than the number of cases. In report years 2010 and earlier, drug categories as a whole had included the total number of deaths per category, as well as total deaths per each specific drug. For example, in 2010, benzodiazepines were the cause of death in 1,304 cases. However, benzodiazepines were present 1,726 times in those 1,304 deaths (i.e., a single death could have been caused by multiple benzodiazepines). Report year 2011 does not provide a total per category.

**SOURCE:** Florida Medical Examiner's Commission
**PHYSICIAN NEEDED, START IMMEDIATELY** (WEST PALM BEACH, FLORIDA)

Date: 2010-03-03, 5:22PM EST
Reply to: job-gekbz-1627117891@craigslist.org

**PHYSICIAN NEEDED, START IMMEDIATELY**

M.D. / D.O. FOR CONTINUING CARE / PAIN MANAGEMENT CENTER

- FULL TIME & PART TIME POSITIONS ARE AVAILABLE – START IMMEDIATELY!
- Experience in Pain Management is preferred but NOT necessary. We will train if needed!
- GREAT Compensation ($12,000+ PER WEEK!!!)
- Position may include Medical Director for facility
- Doctor’s need to have their Dispensing License or can obtain one
- Perfect opportunity for a M.D. / D.O. / or Retiree
- Please send resume with salary requirements to: DPerezWPM@Gmail.com
ALL INQUIRES CONTACT: DPerezWPM@Gmail.com OR CALL 561-253-4038

DOCTOR'S NEEDED (MIAMI)

Date: 2010-02-21, 6:50PM EST
Reply to: doctor247@hotmail.com

CAN EARN OVER $500 DOLLARS AN HOUR
FLEXIBLE HOURS
WEEKDAYS, WEEKENDS OR BOTH
YOU MAKE YOUR OWN SCHEDULE
CONTACT ERIC TEL 305 710-0013
CAN SEND US YOUR CV AT doctor247@hotmail.com

- Location: MIAMI
- Compensation: can earn over $500 dollars an hour
- This is a part-time job.
- Principals only. Recruiters, please don't contact this job poster.
- Phone calls about this job are ok.
- Please do not contact job poster about other services, products or commercial interests.
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 trafficking charges.

Feds raid Fla. pill mills; arrest docs, owners

By CURT ANDERSON
The Associated Press
Wednesday, February 23, 2011; 5:23 PM

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.
June 2010 DEA takes action against four wholesale distributors supplying doctors who were dispensing from rogue pain clinics.
Prevention Tips

- Install an alarm system and test it often.
- Install security cameras behind the cash register facing the front counter.
  - Inspect cameras regularly to ensure they are functioning.
  - Properly store recorded data.
- Install hold-up/duress buttons.
- Invite local police to conduct a security assessment. Learn the names of the officers who patrol your neighborhood and encourage them to stop by.
- Ensure there is adequate outside lighting and leave some lights on after closing.
- Change locks, alarm codes, and safe combinations when an employee leaves.
- Have at least two employees open and close the store.
- Try to greet customers as they enter your pharmacy. Your attention can discourage a robber.
- Watch for people hanging around and not buying anything.
- Beware of suspicious activity outside your business.

What to Do During a Robbery

Always be aware of your surroundings. Don’t get caught off guard!

- Do not resist! Cooperate fully with the robber.
- Remain calm and avoid sudden movements.
- Do exactly what you are told to do, nothing more and nothing less.
- Make mental notes on aspects of the robber (e.g., clothing, hair length and color, size, build, tattoos, scars, and other body features).
- Do not attempt to apprehend the criminal yourself.
Responses to the Problem
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
Education Gaps

Health Care Providers

- **2000 survey**: 56% of residency programs required substance use disorder training, median number of curricular hours ranged from 3 to 12 hours\(^1\)

- **2008 follow-up**: “Although the education of physicians on substance use disorders has gained increased attention, and progress has been made to improve medical school, residency, and post-residency substance abuse education since 2000, these efforts have not been uniformly applied.”\(^2\)

Pharmacists\(^3\)

- 67.5% report receiving two hours or less of addiction or substance abuse education in pharmacy school
- 29.2% reported receiving no addiction education
- Pharmacists with greater amounts of addiction-specific education:
  - Higher likelihood of correctly answering questions relating to the science of addiction and substance abuse counseling
  - Counseled patients more frequently and felt more confident about counseling

---

**Education Goals**

**Needs**

- Knowledge on appropriate prescribing
- Effective identification of patients at risk for abuse
- Screening, intervention, and referral for those misusing or abusing prescription drugs
- PDMP use in everyday clinical practice
- Ensure community leader, parents, and young people understand the dangers of prescription drug misuse.

**Main Actions**

- Legislation requiring mandatory education for all clinicians who prescribe controlled substances
- Increased substance abuse education in health profession schools, residency programs, and continuing education
- Expedited research on the development of abuse deterrent formulations
Disposal

Goals

- Easily accessible, environmentally friendly method of drug disposal that reduces the amount of prescription drugs available for diversion and abuse

Main Actions

- Publish and implement regulations allowing patients and caregivers to easily dispose of controlled substance medications
- Once regulations are in place, partner with stakeholders to promote proper medication disposal programs
Ultimate User Disposal of Medicines

**National Take-Back Events:** Take-back events are a good way to remove expired, unwanted, or unused medicines from the home.

**Law Enforcement Collection Bins:** Collection bins installed by our Law Enforcement Partners are a good way to remove expired, unwanted, or unused medicines from the home.

**Disposal in Household Trash:** Mix medicines (do not crush tablets or capsules) with substances such as kitty litter or used coffee grounds and place the mixture in a container such as a sealed plastic bag and throw the container in your household trash.

**Disposal by Flushing:** Some medicines have specific disposal instructions that indicate they should be flushed down the sink or toilet when they are no longer needed.
On October 12, 2010, President Obama signed the "Secure and Responsible Drug Disposal Act of 2010."

This Act allows DEA to draft new regulations which permits ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.
National Take Back Initiatives

Over 1,200,000 kilograms collected since September 2010

30 September 2010: 110,174 kilograms

30 April 2011: 171,179 kilograms

29 October 2011: 171,402 kilograms

28 April 2012: 250,982 kilograms

29 September 2012: 221,998 kilograms

27 April 2013: 337,499 kilograms
National Take Back Day: Sept 29, 2012
Total Collection Sites: 5,263

Drug Enforcement Administration
Diversion Control Program
Enforcement

Goals

- Increase law enforcement and prosecutor training around prescription drug diversion and abuse
- Assist states in addressing “pill mills” and doctor shopping

Main Actions

- Provide technical assistance to states on model regulations/laws for pain clinics
- Encourage High-Intensity Drug Trafficking Areas (HIDTAs) to work on prescription drug abuse issues
- Support prescription drug abuse-related training programs for law enforcement
Cutting off the Source of Supply
Realignment of DEA’s Diversion Control Efforts

• In October 2008, the DEA 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.

• This approach provides a significant increase in the number of Special Agents and Task Force Officers who possess the requisite law enforcement authorities needed when conducting criminal investigations, i.e., the ability to conduct surveillance, make arrests and execute search warrants.
First Prong: Increased Enforcement Efforts

• Currently 51 operational Tactical Diversion Squads (TDS) throughout the United States. Phase II implementation has begun with additional TDS groups being deployed across the U.S. (58 total approved)

• These TDS enforcement groups incorporate the skill sets of DEA Special Agents, Diversion Investigators, other federal law enforcement, and state and local Task Force Officers.

• During FY 2011, the TDS Groups, collectively, have seized $53,295,081 ($45,128,794 in Assets and $8,166,287 in Frozen, Indicted, Restricted, and Encumbered Assets).
Second Prong: Renewed Focus on Regulatory Oversight

• 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.

• DEA used added manpower resources to increase the frequency of compliance inspections of manufacturers (including bulk manufacturers); distributors; importers; exporters; narcotic treatment programs; DATA-waived practitioners; researchers; and chemical handlers.

• This renewed focus on oversight has enabled DEA to take a more proactive approach to educate registrants and ensure that DEA registrants understand and comply with the Controlled Substances Act and implementing regulations.
Second Prong: Renewed Focus on Regulatory Oversight

- Increased regulatory efforts throughout the U.S.
- Investigating/inspecting all new and renewal pharmacy applications submitted in Florida
- Investigating/Inspecting existing pharmacies registrations
- Results:
  - Withdrawal of applications
  - Orders To Show Cause (OTSC) issued against applications
  - Immediate Suspension Orders (ISO) issued as appropriate
DEA aims big to stem painkiller black market
Cardinal Health says it didn't look the other way

By Donna Lenwand Legg
USA TODAY

Vincent Melofer, former DEA agent, heard a rumor in April 2009 that a local pharmacy was selling the powerful and addictive opioid oxycodone by the pound or less. So Melofer, 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, Melofer and other Cardinal employees visited that pharmacy at least 10 times. Each time, they noted disturbing signs: Customers paid cash, oxycodone was sold by the No. 1 seller, and group purchases were common.

COVER STORY

On Oct. 5, 2010, Melofer's fourth visit, pharmacy owner Teddy Green told him he wanted more oxycodone. The store had dispensed 6,276 pills over the past six weeks, nearly 2,000 more than the average pharmacy, which dispenses in a year. Concerned something was off, Melofer asked Cardinal's permission to conduct a Drug Enforcement Administration inspection. His paperwork was denied.

Cardinal Health's policies require that it conduct inspections of pharmacies that dispense large quantities of controlled substances. The company has a conflict of interest because it also sells those drugs.

Oxycodone purchases

The DEA suspended the licenses of four Florida pharmacies for buying and selling large quantities of oxycodone pills.

The DEA, in a letter released to The Associated Press, accused Cardinal Health of failing to take adequate steps to stop the sale of controlled substances.

The company has made changes to its system, the DEA said, but it has not been enough to stop the illegal sales.

Cardinal Health's response: "We take our responsibilities as a distributor very seriously. We have implemented new policies and procedures to prevent the sale of controlled substances in excess of the legitimate need of the public."
DEA Distributor Initiative

Purpose and format:

- Educate and inform distributors/manufacturers of their due diligence responsibilities under the CSA by discussing their Suspicious Order Monitoring System, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances

August 2005 – Present:

- Briefings to 81 firms with 233 locations

- Examples of civil action against distributors:
  - Cardinal Health, $34 million civil fine
  - McKesson, $13.25 million civil fine
  - Harvard, $6 million civil fine

- Examples of suspension, surrender or revocation of DEA registration
  - Keysource, loss of DEA registration
  - Sunrise, loss of DEA registration
DEA Web-based Resources

www.DEA.gov
DEA Web-based Resources

www.GetSmartAboutDrugs.com
Pharmacy Robbery & Burglary
Tips to Protect Your Customers, Your Business, and Yourself

After a robbery:
- Immediately get treatment for anyone who may be injured.
- Sound the alarm as soon as possible.
- Call police first, then your supervisor.
- Lock doors immediately to prevent re-entry and keep them closed until police arrive.
- Request customers to remain in the store to give a statement to police.
- Protect the crime scene. Stop others from touching anything touched by the suspect(s).
- Do not trust your memory. The quicker you write down what you observed, the better.

After a burglary:
- Notify the local police department.
- Avoid touching or disturbing anything.
- After the police arrive, prepare a detailed list of what was stolen.
- Take the appropriate steps to improve security.

If controlled drugs were taken, report it to your local DEA Field Office, in writing, within one business day and submit a completed DEA Form 106, Report of Theft or Loss of Controlled Substances, as soon as possible. A report should also be filed with the State Board of Pharmacy.

DEA’s collaboration with NABP in producing this pamphlet does not constitute an endorsement by DEA of NABP or its services.
Its All About Profit

- May 20, 2010, Tampa, Florida
- owner/operator of pain clinic dispensing oxycodone
- $5,822,604.00 cash seized
• 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
• 21 USC 841(h)(1): It shall be unlawful for any person to knowingly or intentionally:

  (A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this title; or

  (B) aid or abet any violation in (A)
Violations

Automatic Violation of the CSA if any of the following occurs:

• No in-person medical evaluation by prescribing practitioner

• Online pharmacy not properly registered with *modified* registration.

• Website fails to display required information
Prescription Drug Monitoring Programs
Status of Prescription Drug Monitoring Programs (PDMPs)

*To view PDMP Contact information, hover the mouse pointer over the state abbreviation.

- **Operational PDMPs**
- **Enacted PDMP legislation, but program not yet operational**

Research is current as of December 19, 2012.
Epilogue
Clinic response to the Florida legislation prohibiting the sale of CS from pain clinics?

Buy Pharmacies or Move to Other States!
Beef prices on the way up
Low cattle supplies, strong foreign demand for U.S. beef help fuel price boost. 1B.

Preserving pets after death growing popular as an option
Taxidermist Daniel Ross acknowledges it's a controversial topic, but says the owners "aren't weird, they just really love their pets." 3A.

See news photos of the day on your smartphone
Scan with any QR reader or download the code scanner at scan.mobi. (Available on nearly every U.S. smartphone.)

Dealers creative in oxycodone bid

They try to open pharmacies after Florida targets 'pill mills'

By Donna Leinwand Leger
USA TODAY

Drug dealers are finding creative ways around new laws that crack down on "pill mills" dispensing powerful painkillers such as oxycodone.

In Florida, hundreds of people tried to open pharmacies after the state barred doctors from dispensing the narcotics directly from their clinics and forced patients to fill their prescriptions at pharmacies. Others moved their operations to Georgia, state police and federal agents say.

"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-purchasers fell from 160 in 2010 to 100 in 2011, according to a DEA report.

A pharmacy must register with the DEA and be licensed by the state to dispense controlled substances, which include many drugs that require a doctor's prescription. The DEA can deny a registration if an applicant has been convicted of a drug-related crime or agents find a connection to a pill mill or other activity that poses a threat to public health and safety.

At least 37 pharmacy applicants withdrew their applications in 2011, Trouville says. "They feel the squeeze and move on," he says.

Still, questionable pharmacies are selling thousands of oxycodone and hydrocodone pills to people recruited by drug dealers to get prescriptions from pain clinics. "They're not selling Band-Aids and aspirin," Trouville says. "There's nothing but an empty room with a bulletproof window.

Pharmacy applicants turned down in Florida often try their luck in Georgia, says Rick Allen, director of the Georgia Drugs and Narcotics Agency. Of new non-chain drugstore applications, about 95% have some connection to Florida, he says.

"The people come completely out of left field without any pharmacy background and open a pharmacy in a sleazy strip mall right down the road from a pain clinic," Allen says. "You do a cursory background on them, and they're living in a doublewide in Pembroke Pines, Fla."

The DEA has cancelled 46 registration renewals for non-chain pharmacies this year, mostly for non-serious offenses.
Who is Applying?

- An individual who is tied to Organized Crime
- An individual who works at Boston Market
- An individual whose father owns a pain clinic
- An individual whose mother works at a pain clinic
- An individual whose father is a doctor at a pain clinic
- An individual who is a bartender/exotic dancer
- An individual who is a truck driver
- An individual who is retired from the dry wall business
- An individual who is a secretary at a pain clinic
- An individual who runs a lawn care business
MIGRATION OF PAIN CLINICS
Georgia Example: Traditional Pain Management Clinics

Years prior to 2009-2010:
15-20 legitimate clinics
- Almost all owned by Physicians
- Accept insurance, Medicaid, Medicare, etc.
- Patients need appointments
- Follow pain management guidelines
- Patients get a complete physical workup & exam
- Use physical therapy, other treatment methods
- Prescribed drugs usually include non-narcotics
Now approximately 125 rogue clinics
Georgia Pain Pill Clinics

Now in 2012 – approximately 125 rogue clinics owned by non-physicians, and the owners:

• Are from another state
• Many are convicted felons
• Usually owned or operated a pain clinic in another state.
• Have ties to some type of organized crime
• If from Florida, left not because of the Florida PMP, but due to new Pain Clinic restrictions and no dispensing
Thank You / Questions