Prescription Drug Abuse

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“Responding to America’s Prescription Drug Abuse Crisis”
or
“When Two Addictions Collide”
Goals and Objectives

• Describe the scope of the prescription drug abuse problem

• Identify methods of pharmaceutical diversion

• Discuss Law Enforcement Efforts

• Identify what “Red Flags” to look for
Disclosure Information

“No Financial Relationships to Disclose”
Mission Statement

• To enforce the controlled substances laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States.

• To recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.
Office of Diversion Control

• Is to Prevent, Detect, and Investigate the Diversion of Pharmaceutical Controlled Substances and Listed Chemicals from Legitimate Channels.

• While Ensuring an Adequate and Uninterrupted Supply of Controlled Substances to Meet Legitimate Medical, Commercial, and Scientific Needs.
Closed System of Distribution

1,523,135 (04/04/2014)
Practitioners: 1,176,272
Retail Pharmacies: 69,860
Hospital/Clinics: 16,045

Law: 21 USC 822 (a) (1) Persons Required to Register:
“Every person who manufactures or distributes any Controlled Substance or List I Chemical or who proposes to engage in ..”

Law: 21 USC 822 (a) (2) Persons Required to Register:
“Every person who dispenses, or who proposes to dispense any controlled substance ...”
# Top 25 Medicines by Dispensed Prescriptions (U.S.)

<table>
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<th>Dispensed Prescriptions Mn</th>
<th>2008</th>
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<td><strong>Total U.S. Market</strong></td>
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<td>1 hydrocodone/paracetamol</td>
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Source: IMS Health, National Prescriptions Audit, Dec 2012

**Notes:**
- Report reflects prescription-bound products including insulins and excluding other products such as OTC.
- Table shows leading active-ingredients or fixed-combinations of ingredients, and includes those produced by both branded and generic manufacturers.
- Active ingredient names use international naming standards (e.g. paracetamol is called acetaminophen in the U.S.). Includes all prescriptions dispensed through retail pharmacies - including independent and chain drug stores, food store pharmacies and mail order as well as long-term care facilities.
- Prescription counts are not adjusted for length of therapy. 90-day and 30-day prescriptions are both counted as one prescription.
- Updated March 22, 2013

May 2013 © Copyright IMS Health, a healthcare information, services and technology company.
Opioid Prescriptions See a Small Drop

In 2013, there were 230 million prescriptions for opioids. This represents about a 5% drop from a year earlier when 241 million were written.

Source: IMS Health; February 26, 2014
Commonly Abused Medications

- **OPIOIDS**: Derived from the opium poppy, or synthetic versions of it, and used for pain relief.

- **BENEZODIAZEPINES**: Central nervous system depressants used as sedatives, to induce sleep, prevent seizures, and relieve anxiety.

- **AMPHETAMINE LIKE DRUGS**: Central nervous system stimulants used to treat attention deficit hyperactivity disorder (ADHD).
Prescription drug epidemic?
How did we get to this point?
The Perfect Storm

• Industry is producing a wider variety of controlled substance pharmaceuticals and practitioners are prescribing more.

• Use of Medicare / Medicaid or insurance to fund drug habits.

• Information / Electronic Era.

• Belief that a pill will solve all of our ailments.
Westchase teachers learn a lesson: Say 'no' to mints in pill bottles

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.
The Fifth New Vital Sign???

• Temperature
• Heart Rate
• Blood Pressure
• Respiration

• PAIN
Pharmaceutical firms paid to attend meetings of panel that advises FDA

By Peter Whoriskey,  E-mail the writer

A scientific panel that shaped the federal government’s policy for testing the safety and effectiveness of painkillers was funded by major pharmaceutical companies that paid hundreds of thousands of dollars for the chance to affect the thinking of the Food and Drug Administration, according to hundreds of e-mails obtained by a public records request.

The e-mails show that the companies paid as much as $25,000 to attend any given meeting of the panel, which had been set up by two academics to provide advice to the FDA on how to weigh the evidence from clinical trials. A leading FDA official later called the group “an essential collaborative effort.”

Patient advocacy groups said the electronic communications suggest that the regulators had become too close to the companies paying to shape the $100 billion-a-year paink

American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics

by Charles Ornstein and Tracy Weber
ProPublica, May 8, 2012, 9:57 p.m.

A version of this story was published in The Washington Post.
Quick Facts

• Prescription Drug Abuse has always been around: “Grand Daddy Of All Drug Abuse”.

• Is the Nation’s fastest growing drug problem and has been classified as an epidemic.

• In 2010, 38,329 unintentional drug overdose deaths occurred in the United States, increase for 11th consecutive year; one person dies every 14 minutes1. 22,134 were prescription drug overdose deaths, of which opioid pain relievers were involved in 16,651 deaths (75.2 %)1.

• Opioid pain relievers were involved in more overdose deaths than cocaine and heroin combined1.

• Enough prescription pain relievers were prescribed in 2010 to medicate every American adult every four hours for a month1.

1SOURCE: CDC, 2010 Drug Overdose Deaths In The United States; October 2012
CDC, Pharmaceutical Overdose Deaths, United States, 2010; February 20, 2013 (Update)
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
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
- Missouri (7): 17 deaths per 100,000*

*Drug Overdose Mortality Rate Tripled From 1999-2010

SOURCE: Trust for America’s Heath-Prescription Drug Abuse: Strategies To Stop The Epidemic; October 2013
Rush Limbaugh

Steven Tyler

Eminem

Brett Farve

Jack T. Camp, Jr.
October 10, 2010
November 18, 2010
March 10, 2011
Rush Limbaugh Arrested On Drug Charges

Rush Limbaugh and prosecutors in the long-running prescription fraud case against him have reached a deal, conservative commentator to be dropped without a guilty plea if he continues treatment, his attorney said Friday.

Limbaugh turned himself in to authorities on a warrant filed Friday charging him with fraud to conceal information, Barbara, a spokeswoman for the Palm Beach County Jail. He and his attorney Roy Black left about an hour later and fingerprinted and he posted $3,000 bail, Barbier said.

Prosecutors' three-year investigation of Limbaugh began after he publicly acknowledged being addicted to a rehabilitation program. They accused Limbaugh of "doctor shopping," or illegally receiving multiple prescriptions for pain medication.

After learning that he received about 2,000 painkillers, prescribed by four doctors in six months, at a pharmacy near his home, Limbaugh, who pleaded not guilty Friday, has steadfastly denied doctor shopping. Black said the charge will comply with court guidelines.

Coheed and Cambria Bassist Arrested Before Gig

Originally posted Jul 10th 2011 5:18 PM PDT by TMZ Staff

Michael Todd, the bassist for the band Coheed and Cambria, was arrested for armed robbery after he allegedly held up a Walgreens by claiming he had a bomb ... and this all went down right before they played a show!

Michael Baze accidentally overdosed

Associated Press

LOUISVILLE, Ky. — Jockey Michael Baze, who won more than 900 horse races in a nine-year career, died from an accidental overdose of cocaine and prescription pain medication at Churchill Downs, the horseman's office said Friday.

The 24-year-old Baze was pronounced dead on May 10. His body was found in his vehicle near the stables at the famed Louisville track.

Jefferson County Deputy Coroner Jim Wesley said the cause of death was multiple substance intoxication. Significant amounts of cocaine and the pain medication oxycodone were found in Baze's system, said Wesley, citing toxicology results.

Baze was facing a drug possession charge at the time of his death. The week he died, he was scheduled to appear at a preliminary hearing on a charge of first-degree possession of cocaine. He also was charged with identity theft.

Baze was arrested last November in connection to the arrest warrant.

His mother, Terri Gibson, said that her son was a talented jockey who "loved his horse" but that "he was trying to fight his demons just like everyone else has to do every day.

Baze was remembered for his kindness, his quiet nature and his "mantra" to "be the best that I can be.

Churchill Downs spokesman John Motz said Baze also rode only briefly at Churchill Downs in the Hall of Fame rider Mike Smith's stable.

Rangers' Boogaard died of alcohol, oxycodone mix

Updated 5/20/2011 11:09 PM

MINNEAPOLIS (AP) — The death of Minnesota Wild forward Derek Boogaard was an accident, due to a toxic mix of alcohol and the powerful painkiller oxycodone.

The Hennepin County Medical Examiner announced Boogaard's cause of death Friday, saying it was unclear exactly when the 28-year-old died. Boogaard was found dead in his Minneapolis apartment last month after he sustained a concussed.

Boogaard's agent, Ron Salcer, said it has been a very difficult time for his family.

Thomas Kinkade cause of death: alcohol, Valium

Updated 2012-05-08 7:16

An autopsy has concluded that Thomas Kinkade's death was caused by an accidental overdose.

NBC Bay Area News reported late Monday that the Santa Clara County medical examiner's autopsy is complete and reveals that Kinkade died April 6 in his California home from a combination of alcohol and prescription drugs. He was 54.

Jack Camp, Senior Federal Judge, Arrested On Drug, Gun Charges

ATLANTA — A veteran federal judge faces drug and firearms charges after an exotic dancer at an Atlanta strip club told authorities he used cocaine, marijuana and other illegal drugs with her.

Senior U.S. District Judge Jack T. Camp was arrested Friday minutes after he handed an undercover law enforcement agent $160 for cocaine and Roxycodone, a narcotic pain medication, that he intended to use with the exotic dancer, authorities said in a court document released Monday. They said they also found two firearms in the front seat of his vehicle.

Camp, 67, who has presided over some high-profile cases, was released Monday on a $50,000 bond. His attorney, William Morrison, said after a brief hearing that the judge intends to plead not guilty. Morrison said Camp would probably take a leave of absence and would not preside over any more cases until the charges are resolved.
Wrestler Benoit's doctor gets 10 years in prison

Updated 5/12/2009 2:34 PM | Comment | Recommend

NEWNAN, Ga. (AP) — The personal doctor to a professional wrestler who killed himself, his wife and their 7-year-old son was sentenced to 10 years in prison Tuesday for illegally distributing prescription drugs to patients.

Dr. Phil Astin, 54, had pleaded guilty Jan. 29 to a 175-count federal indictment.

Prosecutors said Astin prescribed painkillers and other drugs to known addicts for years. They said at least two of Astin's patients died because of his lax oversight of what medicines they were taking. However, the indictment was unclear about whether Chris Benoit, a wrestler for Stamford, Conn.-based World Wrestling Entertainment, was one of the two.

"I take full responsibility," Astin told the judge Tuesday. "I am sorry I hurt so many lives. I was thinking that I was looking after my patients."

U.S. District Judge Jack Camp said there was no doubt Astin tried to help hundreds of patients at his western Georgia clinic. But the judge said he could not overlook Astin's misconduct.

"The fact that two people did die outweighs other conditions that I must consider," Camp said.

A federal investigation found Astin wrote prescriptions without conducting physical exams and sometimes gave patients as many as four simultaneous prescriptions for Percocet. He also prescribed "cocktails" of drugs like Percocet, Oxycontin, Vicodon and Adderall.

"Medical doctors know that after a period of time, if the prescriptions are not working, you get them off," Assistant U.S. Attorney John Horn said during the hearing.

Investigators cited one case in which an unidentified female patient began receiving a combination of drugs that included Xanox from Astin in 2002. She died in June 2007, the same month authorities found Benoit and his family dead in their suburban Atlanta home.
National Abuse Facts

• In 2012, 23.9 million Americans aged 12 or older were current (past month) users of illicit drugs.

• 6.8 million used prescription-type psychotherapeutic drugs (any pain relievers, tranquilizers, stimulants or sedatives) for non-medical purposes in a one-month period.

• 2011: 6.1 million; 2010: 7.0 million.

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 03, 2013 by the Dept of HHS/Substance Abuse and Mental Health Services Administration (SAMHSA)
National Abuse Facts

• In 2012, there were 2.4 million persons aged 12 or older who used psychotherapeutics nonmedically for the first time within the past year, which averages to around 6,700 initiates per day.

• Non-medical use of prescription-type drugs is second only to marijuana.

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 03, 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)
Figure 2.1 Past Month Illicit Drug Use among Persons Aged 12 or Older: 2012

- Illicit Drugs: 23.9 million
- Marijuana: 18.9 million
- Psychotherapeutics: 6.8 million
- Cocaine: 1.6 million
- Hallucinogens: 1.1 million
- Inhalants: 0.5 million
- Heroin: 0.3 million

Notes:
1 Illicit Drugs include marijuana/hashish, cocaine (including crack), heroin, hallucinogens, inhalants, or prescription-type psychotherapeutics used nonmedically.

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 03, 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)
Figure 5.1 First Specific Drug Associated with Initiation of Illicit Drug Use among Past Year Illicit Drug Initiates Aged 12 or Older: 2012

- Marijuana (65.6%)
- Pain Relievers (17.0%)
- Inhalants (6.3%)
- Tranquilizers (4.1%)
- Stimulants (3.6%)
- Hallucinogens (2.0%)
- Sedatives (1.3%)
- Cocaine (0.1%)
- Heroin (0.1%)

2.9 Million Initiates of Illicit Drugs

Note: The percentages do not add to 100 percent due to rounding or because a small number of respondents initiated multiple drugs on the same day. The first specific drug refers to the one that was used on the occasion of first-time use of any illicit drug.
Figure 2.16 Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2011-2012

Source Where User Obtained

- More than One Doctor (1.8%)
- Free from Friend/Relative (54.0%)
- One Doctor (19.7%)
- Other1 (5.1%)
- Bought on Internet (0.2%)
- Drug Dealer/Stranger (4.3%)
- Bought/Took from Friend/Relative (14.9%)

Source Where Friend/Relative Obtained

- One Doctor (82.2%)
- More than One Doctor (3.6%)
- Free from Friend/Relative (5.4%)
- Bought/Took from Friend/Relative (5.4%)
- Other1 (1.8%)
- Drug Dealer/Stranger (1.4%)
- Bought on Internet (0.2%)

1 The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 3, 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)
2011 Current Users (Past Month) 2012

ANY ILLICIT DRUG: 22.5 million
MARIJUANA: 18.1 million
PSYCHOTHERAPEUTIC DRUGS: 6.1 million
COCAIN: 1.4 million
Methamphetamine: 439,000
Heroin: 281,000

ANY ILLICIT DRUG: 23.9 million
MARIJUANA: 18.9 million
PSYCHOTHERAPEUTIC DRUGS: 6.8 million
COCAIN: 1.6 million
Methamphetamine: 440,000
Heroin: 335,000

Source: 2011 & 2012 NSDUH
Teens and Their Attitudes

• 1 in 4 teens (24 percent) reports having misused or abused a prescription drug at least once in their lifetime (up from 18 percent in 2008 to 24 percent in 2012), which translates to about 5 million teens. 33 percent increase over 5 year period.

• 1 in 5 (20 percent) abused before age 14.

• 27 percent mistakenly believe that using prescription drugs are “safer” than illicit drugs.

• 33 percent believe “it’s okay to use prescription drugs not prescribed to them.”

• 23 percent believe parents don’t care if caught using.

Teens and Their Attitudes
Bluelight Remembers Ryan Haight, Launch of the Recovery forums

by Sebastians_ghost Published on 12-02-2013 06:45

Dear Bluelighters,

As some of you may remember, February 12th is the twelfth anniversary of the passing of one of our own. To most it will be remembered as the first day "Bluelight went black." To those of us who knew Ryan Haight (a.k.a Quicksilver) it is also the day we lost a friend.

The impact of Ryan's life and untimely death have echoed forward in the passage of the Ryan Haight Internet Pharmacy Consumer Protection Act of 2008, signed into law by President G.W. Bush in October of the same year. In honor of Ryan, Bluelight is proud to announce the launch of a new collection of forums designed to support sober living, and provide help to those struggling with drug...
Opiophile depends on community contributions to run. Unfortunately our sole payment processor Google Wallet is closing November 19th.

This means the contributions we receive this coming week will need to keep us online until a new provider can be found.
Source of Concerns

• 1 in 5 parents (20 percent) report that they have given their teen a prescription drug that was not prescribed to them.

• 17 percent of parents do not throw away expired medications.

• 14 percent of parents say they themselves have misused or abused prescription drugs within the past year.

• 49 percent of parents say anyone can access their medicine cabinet.

Source of Concerns

• Prescription Painkiller Overdoses are an under-recognized and growing epidemic among women. About 18 deaths every day; more than 6,600 in 2010.

• Nearly 48,000 women died between 1999 and 2010.

• 400 percent increase since 1999, compared to 265 percent among men.

• For every woman that dies, 30 go to the emergency department for misuse or abuse.

To Address This Issue, National Framework: Four Prong Approach

• Education
• Enforcement
• Monitoring
• Proper Medication Disposal

SOURCE: ONDCP’s 2011 Prescription Drug Abuse Prevention Plan released on Tuesday, April 19, 2011
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)
**Drugs of Concern**

- Hydrocodone (Schedule III)
- Oxycodone/OxyContin® (Schedule II)
- Oxymorphone/Opana® (Schedule II)
- Xanax®/Alprazolam (Schedule IV)
- Methadone (Schedule II)
- Fentanyl (Schedule II)
- Adderall® (Schedule II)
- Cough Syrup (Schedule V)
- Carisoprodol/Soma® (Schedule IV)
- Hydromorphone (Schedule II)
## Prescription Requirements

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</table>

* Must be reduced in writing, and followed by sign, hard copy of the prescription.

* Must be reduced in writing, and followed by sign, hard copy of the prescription. A signed, hard copy of the prescription must be presented before the medication is dispensed.

*** 72 hour time limitation.

# With medical authorization, up to 5 in 6 months.
Hydrocodone (Schedule III)

• Hydrocodone / Acetaminophen (toxicity)

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

• Brand Names: Vicodin®, Lortab®, Lorcet®, Norco®

• Street prices: $2 to $10+ per tablet depending on strength, region & availability

• Most prescribed drug in the United States
Hydrocodone (Schedule III)

- CSA defines hydrocodone substance as Schedule II, while its combination products as Schedule III.

- DEA has received a petition to reschedule CIII hydrocodone combination products to CII.

- In 2004, DEA completed an initial review forwarded the data to DHHS with a request for scientific and medical evaluation and scheduling recommendation.

- In 2008, HHS provided a scientific and medical evaluation.

- In 2009, DEA sent additional data to FDA/HHS and requested a scientific and medical evaluation.
Factors determinative of control or removal from schedules (21 USC 811(c))

(1) Its actual or relative potential for abuse
(2) Scientific evidence of its pharmacologic effect, if known
(3) The state of current scientific knowledge regarding the drug or other substance
(4) Its history and current pattern of abuse
(5) The scope, duration and significance of abuse
(6) What, if any, risk there is to public health
(7) Its psychic or physiological dependence liability
(8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter
Hydrocodone (Schedule III)

• January 24-25, 2013: Food and Drug Administration (FDA) held a Drug Safety and Risk Management Advisory Committee Meeting on the reclassification from Schedule III to Schedule II.

• Committee recommended the up scheduling by 19-10 vote.

• October 24, 2013: FDA recommends reclassification to Schedule II.

• February 27, 2014: DEA publishes NPRM to reschedule from III to II.
Zohydro™ ER Pharmacology

• Zohydro™ ER, extended release capsules contain a higher amount of pure hydrocodone dosages compared to other hydrocodone-containing products as immediate release tablets (e.g., 50 mg vs. 10 mg)

• Zohydro™ ER is a Schedule II opioid
  • Other Schedule II opioids include Fentanyl, Oxycodone, Methadone, Morphine

• Hydrocodone is approximately:
  • 1 times as potent as oxycodone
  • 1.5 times as potent as morphine
  • 10 times as potent as codeine

• The principal therapeutic action of hydrocodone is analgesia. As with other opioids, hydrocodone causes respiratory depression.
Manufactured by Alkermes Gainesville LLC for Zogenix, Inc. (San Diego, CA)

FDA Approval October 2013

Anticipated Launch March/April 2014
## How Supplied

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<th>Strength</th>
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Toxicity

• Zohydro™ ER contains high amounts of hydrocodone

• Use in opioid non-tolerant patients may lead to overdose, particularly acute and fatal respiratory depression
  • Capsules are indicated to be swallowed whole
  • Breaking of capsules and crushing beads

• Co-ingestion of alcoholic beverages may result in fatal plasma hydrocodone levels
OxyContin® (Schedule II)

- Controlled release formulation of Schedule II Oxycodone
  - Street Slang: “Hillbilly Heroin”, “OC”, “Oxy”
  - Strengths*: 10, 15, 20, 30, 40, 60, 80mg

- Effects
  - Similar to morphine in effects and potential for abuse/dependence
- Street prices: $25 to $80 per 80mg tablet
- Addiction, crime and fatal overdoses have all been reported as a result of OxyContin® abuse*
  - The controlled release method of delivery (12 hours) allows for a long duration of drug action so it contains much larger doses of Oxycodone – abusers crush tablets for a powerful morphine-like high

*New OP formula developed to prevent the medication from being tampered (August 2010). Several ways to defeat have been listed on internet.
New OxyContin® OP

08-27-2010, 01:11 AM

mz.mary420
Member

well just got ours and they suck! when snorted the pill balls up in your nose and gets stuck, so i tried sucking on one and it did ok, but tastes nasty. No way you can shoot them as mentioned in a previous post. havent tried smoking it yet, kinda in a hole money wise, it cost me over $700.00 to get my 80s filled and i probably wont even get half my money back 😞

* if anyone has tried to smoke this new formulated shit, please post! thanks

08-27-2010, 06:09 AM

mephist00
Member

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

so far the only way ive been able to beat the time release, is use a hose clamp to grind it very fine, and snort it.. it doesn't gel up like you would think (doesn't gel up like the football shaped generic 40's do anyways) it just kinda turns snotty.. but if you can get it down fast it seems to work ok

---

Originally Posted by stalk
I've come to the conclusion it's because these psychedelic visions are simply vibrating on a higher, or different, spectrum of frequencies that normally the monkey does not perceive.
**Opana ER (Schedule II)**

- **Opana ER** - (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)
  - “New King of the Street”; Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
  - Street: $10.00 – $80.00
Xanax® (Schedule IV)

• Brand name formulation of alprazolam

• Anti-anxiety agent used primarily for short-term relief of mild to moderate anxiety and nervous tension; rapid onset and long duration

• Part of the class of drugs called benzodiazepines, more commonly referred to as ‘benzos’

• Extremely addictive
  • Once dependence has occurred, Xanax makes it markedly more difficult for individuals to successfully self-detox than other benzodiazepines

$2.00-$2.50 for 2mg dosage unit.
Fentanyl (Schedule II)

• Fentanyl is 100x more potent than morphine

• Trade-Names:
  • Actiq®: dispensed in a berry flavored lollipop-type unit
  • Duragesic®: trans-dermal patch for chronic pain
  • Fentora™: effervescent tablet formulation
    • Approved by the FDA September 2006
    • Compared to same dose as Actiq®, the effervescent tablet allows a larger amount of Fentanyl to be absorbed rapidly through the oral membranes

• Street prices: $25 to $40 per patch/lollipop
Fentanyl
Methadone (Schedule II)

- “Growing drug problem”
- Abuse linked to:
  - Increased prescribing by doctors to treat pain; 4 million prescriptions written in 2009
  
  - High level of diversion to illicit market
- Inexpensive
  - Insurance companies prefer Methadone because of price
- Increasing chances of an overdose
  - Remains in the body much longer than other similar substances – effects can last up to 24 hours
  - Although chemically unlike morphine or heroin, produces many of the same effects
  - 6x as many people died in 2009 than a decade before; 5,000 deaths per year; 1 in 3 prescription painkiller deaths
- Street Prices: $2 to $10 tablet

1SOURCE: Center for Disease Control and Prevention (CDC), Prescription Painkiller Overdoses, published July 2012
One Pill Can Kill

THE METHADONE POISONING "Epidemic"

Increasing use of Methadone as a pain killer may be fueling a disturbing increase in deaths related to this potent drug.

Death and morbidity associated with methadone treatment has increased dramatically in recent years, largely in the population prescribed this drug for pain control rather than addiction maintenance. Accidental overdose is becoming increasingly common, likely in part because the drug's acute pain-relieving effect lasts only 4 to 6 hours, yet it has a very long and variable plasma half-life of 24 to 36 (in some studies 15 to 55) hours, is stored in body tissues, and toxic accumulation occurs with too-frequent consumption. Adverse effects are most common in patients treated with methadone in combination with other drugs. Both cardiac and respiratory systems are vulnerable targets for the drug’s toxic actions, and other co-administered drugs can interactively increase the risk of death through a variety of mechanisms including direct central nervous system depression of respiration, idiosyncratic respiratory vulnerabilities, and lethal cardiac arrhythmias. Idiosyncratic factors also play a part in methadone’s cardiac toxicity, and risk factors are well characterized, though perhaps not sufficiently widely known and understood by key stakeholders. The recent change in FDA labeling requirements for the drug—and the November 2006 posting of a government warning regarding its use in pain treatment—has not yet reduced morbidity and mortality associated with methadone as reported in the MedWatch database for the first quarter of 2007.
Adderall® (Schedule II)

- Amphetamine used to treat ADHD
- Abuse prevalent among college students; can be snorted, injected or smoked; nicknamed “College Crack”
- Used to enhance/lengthen academic performance
- $5.00 to $30.00 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; Also seeing abuse by athletes

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
Some hyperactive-impulsive or inattentive symptoms that cause impairment must have been present before age 7 years, although many individuals are diagnosed after the symptoms have been present for a number of years, especially in the case of individuals with the Predominantly Inattentive Type (Criterion B).

- Fails to give close attention to details...makes careless mistakes in schoolwork, work
- Difficulty sustaining attention in tasks
- Does not seem to listen when spoken to
- Does not follow through on instructions
- Difficulty organizing tasks
- Often loses things necessary for tasks
- Easily distracted
- Forgetful

- Fidgets
- Can’t remain seated
- Restlessness
- Difficulty awaiting turn
- Often interrupts or intrudes
There are no laboratory tests, neurologocal assessments, or attentional assessments that have been established as diagnostic in the clinical assessment of Attention-Deficit/Hyperactivity Disorder.
Adderall® (Schedule II)

• One in eight teens (about 2.7 million) now reports having misused or abused the Rx stimulants Ritalin or Adderall at least once in their lifetime.

• 9 percent of teens (about 1.9 million) report having misused or abused in the past year (up from 6 percent in 2008) and 6 percent of teens (1.3 million) report abuse in the past month (up from 4 percent in 2008).

Adderall® (Schedule II)

• One in four teens (26 percent) believes that prescription drugs can be used as a study aid.

• Almost one-third of parents (29 percent) say they believe ADHD medication can improve a child’s academic or testing performance, even if the teen does not have ADHD.

Suboxone (Schedule III)

- Treat opiate addiction (New Methadone)
  - Contains 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

September 18, 2012: Reckitt Benckiser Pharmaceuticals-discontinuing distribution within 6 months; pediatric exposure; SUBLINGUAL FILM
Cough Syrup (Schedule V)

- Promethazine with Codeine (Purple Drank, Lean, Sizzurp)
  - Hycotuss® syrup with hydrocodone (Schedule III)
  - Less popular because of atropine to deter abuse

- Commonly sold in pint bottles

- Preferred abuse by mixing with Sprite®, Vodka/Rum, “Jolly Rancher,” and crushed Vicodin®

- Street Prices: $200 to $600 per pint depending on region

- Large profit margin
  - Diverted wholesale/retail price ($8 to $12/pint) vs. street price.
OTC Cough Syrup

- Dextromethorphan (DXM)
  - Over-the-counter (OTC) cough suppressant found in more than 120 cold medications, either alone or in some sort of combination.
  - Street Names: Triple C, Skittling, Robo-tripping
  - Effects: Euphoria; Auditory hallucinations similar to PCP or Ketamine
  - Abuse: Orally

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<th>Plateau</th>
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<td>100-200</td>
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<td>2nd</td>
<td>200-400</td>
<td>Euphoria and hallucinations</td>
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<td>3rd</td>
<td>300-600</td>
<td>Distorted visual perceptions</td>
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<td></td>
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<td>Loss of motor coordination</td>
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<tr>
<td>4th</td>
<td>500-1500</td>
<td>Dissociative sedation</td>
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*DEA is attempted to control this substance*
Recent CVS Receipt

Preventing Teen Cough Medicine Abuse

You must be 18 years of age or older to purchase medicine containing dextromethorphan
Cocktails

• Common identification of pattern of abuse by physicians and users: “Pill Mills”

• Maximizes effect of narcotic abuse-Opiate

• Preferred Prescriptions- “Holy Trinity” or “Trinity”
  • Schedule II and III narcotics (OxyContin®, Vicodin®)
  • Schedule IV Benzodiazepines (Xanax®, Valium®)
  • Scheduled IV Muscle Relaxant/Sedative (Soma®)
  • Non-Controlled Opioid Analgesic-Tramadol (Ultram®) substituted for Schedule II/III narcotic
  • Non-Controlled Muscle Relaxant- Flexeril substituted for Schedule IV
Heroin vs. OxyContin®/Oxycodone

- Heroin – Schedule I
  - Synthesized from morphine (constituent of opium)
  - High potential for abuse
  - Has no accepted medical use in treatment
- OxyContin® / Oxycodone - Schedule II
  - Synthesized from Thebaine (constituent of opium)
  - High potential for abuse
  - Has an accepted medical use with severe restrictions

- WARNING: (Purdue website)
  - OxyContin contains oxycodone which is an Opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine
  - OxyContin can be abused in a manner similar to other Opioid agonists, legal or illicit.
Circle of Addiction

Oxycodone
(Percocet®, Percodan®, Roxicodone®)

Hydrocodone
(Vicodin®, Lortab®, Lorcet®)

OxyContin®
Replacing it with
(OPANA)

Heroin
Heroin a Growing Problem in St. George

St. George, Utah is known as a good place to raise a family or to retire, but aside from the wholesome image, it's fighting a newfound heroin problem.

Police point to users like Karli Chambers: 27 year-old mother of two had been addicted to prescription drugs, then made an economic decision.

"I couldn't afford the pills," Chambers said in an interview at the Southwest Behavioral Health Center in St. George, where she is getting counseling. "It was too much. The only thing I could find was heroin."

1SOURCE: Rick Egan, Salt Lake Tribune, October 8, 2010
Heroin use by Young Adults Devastates Outer Suburbs

• *There is a surge in heroin use in Michigan*, where the number of people seeking treatment in state-sponsored programs has nearly doubled since 2003.

• *More youths have turned to heroin after abusing "gateway" prescription drugs*, said Dr. Mark Menestrina, an addiction medicine physician at St. John Providence Health System's Brighton Hospital in Livingston County.

• *It may come down to economics*: It's a quick, easy high at $10-$20 a hit.

¹SOURCE: Mark Hicks and Valerie Olander, The Detroit News, April 27, 2011
More suburban teens turning from pills to heroin, authorities say Seattle Times

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

In Placer County, Calif., for example, over the fiscal year that ended in July 2011, 171 people, or nearly 14 percent of patients in the county’s drug treatment clinics, said they were addicted to heroin, up from 8.5 percent the previous year. Many of these new heroin addicts started as teens, abusing prescription painkillers they found in their homes, say law enforcement and public health officials.

The transition from getting high on mom's leftover meds to being a strung-out heroin addict is easier, faster and more common than parents might believe, say addiction experts, drug officers and recovering addicts.

Auburn, Calif., native Brandon Scott was 15 when he started using prescription meds, mostly OxyContin — a brand name of the opioid painkiller oxycodone. In a matter of months he went from enjoying the prolonged buzz of ingesting the pills to boosting the high by crushing the pills and smoking them. Once addicted, and willing to do anything to keep the painful withdrawal symptoms at bay, it was a short leap to heroin, said Scott, who is now 19 and in recovery. "I would have never guessed that I would be putting a needle in my vein to get high. I just thought I was trying to ease the pain," he said.

The painkiller problem is particularly bad in the well-to-do suburbs where there is plenty of "prescribed heroin" to swipe from parents or grandparents, Kool said. He said kids see it as a safe, clean drug since it came from a doctor, as opposed to street drugs such as meth or heroin.

Law enforcement, addiction treatment providers and health officials say the spike in heroin use is alarming.

More suburban teens turning from pills to heroin, authorities say Seattle Times (cont’d.)

When Jeff Kool began his stint as a Roseville, Calif., police drug officer five years ago, methamphetamine was the scourge. Since then he's observed a spike in the use of OxyContin and other prescription drugs.

Now a surge in heroin. "Heroin is off the hook right now," offered Kool.

Ryan Booth, 31, observed the same thing — from a user's perspective. He started with marijuana at 16; by 18 he was on to meth. Four years ago, he began abusing OxyContin, eventually finding his way to heroin. "You start doing one thing and it leads to another," said Booth, who lives in an Auburn, Calif., transitional house. "I see all these young kids getting addicted to pills and then they move on to heroin. That is the epidemic these days."

While many make the switch from painkillers to heroin because heroin is cheaper, others may have been unwittingly pushed in that direction after OxyContin's manufacturer, Connecticut-based Purdue Pharma, discontinued it in 2010, replacing it with MC Contin, a more tamper-resistant product, said Kool.

Kool said that in addition to being on the lookout for obvious signs, such as pipes or needles, parents need to watch for lesser-known signs: bits of foil crumpled up or lying about. The foil is used to burn the crushed painkillers, which leave a black stain.

Heroin use spikes in area suburbs
Pill addicts risk deadly drug
Figure 2.4 Past Month and Past Year Heroin Use among Persons Aged 12 or Older: 2002-2012

- Past Month
- Past Year

Numbers in Thousands


166+ 119+ 166+ 136+ 339 373+ 455+ 582 621 620 669

161+ 193+ 213 239 281 335

*Difference between this estimate and the 2012 estimate is statistically significant at the .05 level.

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 03, 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)
Methods of Diversion

• Customers/Drug Seekers
  • Drug rings
  • Doctor-shopping
  • Forged / fraudulent /altered prescriptions
  • The medicine cabinet

• Employee pilferage
  • Hospitals
  • Practitioners’ offices
  • Nursing homes

• The Internet
• Pain Clinics

• Practitioners/Pharmacists
  • Illegal distribution
  • Self abuse
  • Trading drugs for sex
  • Retail pharmacies
  • Manufacturing / distribution facilities

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

• Ryan Haight Online Pharmacy Consumer Protection Act of 2008
  • Enacted October 15, 2008
  • Effective April 13, 2009
  • Amended 21 USC §841 – Making it illegal under federal law to:
    • Deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized*
    • Aid or abet any activity described [above] that is not authorized
  • Amended 21 USC §843 – Making it illegal under federal law to:
    • Use the Internet to advertise the sale of, or to offer to sell, distribute, or dispense, a controlled substance where such sale, distribution, or dispensing is not authorized

*Exceptions: Mail-order pharmacies; pharmacies filling or refilling prescriptions for controlled substances in Schedule III, IV or V
Internet Pharmacies (continued)

• Amended Controlled Substance Act (CSA) – Requiring:
  • One in-person medical evaluation by prescribing practitioner
  • Legitimate medical purpose
  • “Valid prescription”
    • Schedule II drugs require original signed, written prescription
    • Schedule III, IV and V drugs may be filled if the patient provides the pharmacy with an original, copy or an oral prescription
  • Internet Pharmacies (US) must:
    • Have approved modified DEA Registration*
    • Register physical location where it purchases, stores and dispenses the prescription drugs
    • Comply with special website requirements

*Currently there are 13 applications pending Internet Pharmacy Registrations (no applications have been approved, as of March 18, 2014).
Per Se 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
Doctor Shopping

• A “Doctor Shopper” visits multiple doctors within a specific time frame in order to obtain a specific drug from more than one doctor.

• Can be Individual “Customers” or Trafficking Organizations.

• Their illicit activities are usually facilitated by “Pill Mill” Physicians and their affiliated Pharmacies.
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Theft

• Target Specific
  • Certain type of drugs

• Pharmacy and Delivery Vehicles
  • Burglary/Robbery (Armed or Unarmed)
  • Individuals or Organizations
## Pharmacy Armed Robberies Rankings by State

### January 1 thru December 31, 2013 (700)

<table>
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<tr>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
<th>RANK</th>
<th>STATE</th>
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Source: DEA Drug Theft & Loss Database as of 03/27/2014
Pharmacy Armed Robberies
Rankings by State
January 1 thru December 31, 2013
(700)

* U.S. (Nationwide) – 700
* State of Missouri – 9

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<tr>
<th>Missouri Counties</th>
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<td>CLAY</td>
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<td>TANEY</td>
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No Reported Armed Robberies in remaining counties

Source: DEA Drug Theft & Loss Database as of April 1, 2014
Pain Management Clinics

• Rogue Pain Clinics are opening and operating throughout all regions of the United States.
• Operating under the guise of providing “pain management.”
• Real activities are outside the scope of professional practice and for no legitimate medical purposes.
• “Currently, The Main Source of Diversion”.
• Over recent years, South Florida became the “pill mill” capital of the United States, being the chief supplier of oxycodone that hastened an epidemic of illegal use throughout the United States.
• DEA had identified three major hubs across the United States:
  • Houston, Texas area
  • Los Angeles, California area
  • Tri-county area of South Florida: Broward, Miami-Dade and Palm Beach Counties
How To Sell Drugs

1. Hire a doctor on Craigslist
2. Order opioids, but not too many
3. Rake it in
**PHYSICIAN NEEDED, START IMMEDIATELY** (WEST PALM BEACH, FLORIDA)

Date: 2010-03-03, 5:22PM EST
Reply to: job-gkbz-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 necessary
- 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.
Why the Risk??

Case in Florida, Pain Clinic Owner paid his 5 doctors (in 2009):

- $861,550
- $989,975
- $1,031,975
- $1,049,032
- $1,225,775
Why the Risk??

May 20, 2010: Tampa, Florida owner/operator of pain clinic dispensing oxycodone $5,822,604.00 cash seized
Florida Pain Clinic Ads
“short waits or we will pay you”

“earn $$$ for patient referrals”
Pain Clinic "Customers"
!ATTENTION!

DUE TO THE COST OF OUR INCREASING AND ONGOING LEGAL PROCEEDINGS THE FEE FOR PAIN MANAGEMENT VISTS WILL BE $400 STARTING ON APRIL 1, 2011.

!ATTENTION!
PAIN CLINIC
HEALTH 1 WELLNESS
700 IVES DAIRY ROAD
NORTH MIAMI, FL 33179
$49.00/VISIT
WE ARE THE BEST!
NO MRI REQUIRED
NO MEDICAL RECORDS
NO PHYSICALS
WE DISPENSE NARCOTICS ON SITE
305-690-9784
**Operation Pill Nation**

**Miami Field Division**

- February 14, 2010

- DEA, working with other federal, state and local partners, identifying, targeting and investigating rogue pain clinics.

- Eleven (11) Tactical Diversion Squads (TDS) from across the United States provided assistance, 340 Undercover Buys.

- February 23, 2011: 500 law enforcement officials participated in the takedown.
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.

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.
Pill Mill Clinic Proceeds
Operation Pill Nation

• Enforcement Results:
  • Surrender of 59 DEA Registrations (47 physicians, 8 pharmacies and 4 wholesale distributors)
  • Immediate Suspension Orders issued against 63 DEA Registrations (63 physicians and 1 distributor)
  • Orders to Show Cause issued against 11 DEA Registrations
  • 41 Closed Clinics
  • 58 Arrests (34 physicians, 8 clinic owners and 16 clinic employees)
  • 11 Indictment (11 physician)
  • 2 Information Filed (2 physicians)
  • Assets Seized: $19,022,669.28 (US Currency, Vehicles, Jewelry and Real Estate)
NEWS RELEASE

Davie Pill Mill Owner Pleads Guilty

Defendant Owned and Operated Six Area Pain Management Clinics that Dispensed Oxycodone, Profited More than $22 Million

At sentencing, Colangelo faces a maximum penalty of twenty years in federal prison on the drug conspiracy charge. He also faces maximum penalties of twenty years on the money laundering charge and three years on the tax charge. According to the terms of the plea agreement, Colangelo has agreed to forfeit five (5) properties valued at more than $5 million, approximately $911,951 in cash seized by the IRS from seven bank accounts and a safety deposit box, 52 vehicles and vessels worth more than $6 million and jewelry valued at approximately $20,000, all representing the amount of proceeds he had obtained and laundered as a result of his participation in the drug conspiracy.

Mr. Ferrer thanked the DEA, IRS-CID, and the Broward Sheriff’s Office, as well as the many other state and local agencies for their investigative work.
IN TOUGH TIMES, FLORIDA'S TOURISM INDUSTRY GETS CREATIVE...

HOW ABOUT THAT... COMPLIMENTARY PAIN PILLS ON THE PILLOW!
With money and weapons seized from the residence of the pharmacist Ihsanullah "Sean" Maaf,

On August 10, 2011, agents from the DEA Philadelphia Division Office, along with various federal and local law enforcement officers, arrested William Stukes, Dr. Norman Werther, pharmacist Ihsahullah “Sean” Maaf, and 41 other individuals. The arrests, which resulted in the dismantlement of the Stukes pharmaceutical drug trafficking organization, occurred pursuant to an indictment in the Eastern District of Pennsylvania charging the individuals with drug possession, drug distribution, and health care fraud. Stukes recruited, organized, and transported individuals to Werther’s medical office, where Werther would write them prescriptions for controlled substances such as oxycodone without establishing a legitimate doctor/patient relationship and outside the usual course of professional medical practice. The individuals paid $150 for the office visit and then filled their prescriptions at various pharmacies, including Northeast Pharmacy, where Maaf worked as a pharmacist. Maaf knowingly filled the prescriptions written by Werther and then laundered the money received for his services by structuring cash bank deposits to avoid federal reporting requirements. The drugs were then turned over to Stukes or his drivers and then sold on the streets.

Between September 2009 and July 2011, the Stukes organization earned more than $5 million in illegal drug proceeds and distributed over 200,000 oxycodone pills also resulted in the seizure of nine firearms, $2.3 million in U.S. currency and bank accounts, and the possible forfeiture of real property valued at $3.75 million dollars.
Ill. doc who dispensed more oxycodone from 2003-05 than any other physician gets 4 life terms

By Associated Press, Tuesday, February 14, 1:43 PM

COLUMBUS, Ohio — A Chicago doctor who prosecutors say dispensed more of the powerful painkiller oxycodone from 2003 to 2005 than any other physician in the country was sentenced Tuesday to four life terms in the overdose deaths of four patients.

Dr. Paul Volkman made weekly trips from Chicago to three locations in Portsmouth in southern Ohio and one in Chillicothe in central Ohio before federal investigators shut down the operations in 2006, prosecutors said. He was sentenced in federal court in Cincinnati.

“This criminal conduct had devastating consequences to the community Volkman was supposed to serve,” Assistant U.S. Attorneys Adam Wright and Tim Oakley said in a court filing ahead of Tuesday’s hearing.
Status of Prescription Drug Monitoring Programs (PDMPs)

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

Maps showing the status of PDMPs in each state.

Legend:
- Operational PDMPs
- Enacted PDMP legislation, but program not yet operational
- Legislation Pending
- No Legislation

Research is current as of December 23, 2013
Scheduled Investigations

- Increase in the number of DEA registrants who are required to be investigated to ensure compliance to the CSA and regulations.
- Increase in the frequency of the regulatory investigations.
- Verification investigations of customers and suppliers.
How Do You Lose Your Registration?

The Order to Show Cause Process

21 USC § 824

a) Grounds –
1. Falsification of Application
2. Felony Conviction
3. State License or Registration suspended, revoked or denied, or no longer authorized by State law
4. Inconsistent with Public Interest

b) AG discretion, may suspend any registration simultaneously with Order to Show Cause upon a finding of Imminent Danger to Public Health and Safety (ISO)
DEA Legal Recourse

• Administrative
  Letter of Admonition (LOA)
  Memorandum of Agreement (MOA)
  Order to Show Cause (OTSC)
  Immediate Suspension Order (ISO)

• Civil
  Fines

• Criminal
  Arrested and Charged With CSA Violations or Other State Violations
We Are Not Going To Arrest Our Way Out Of This Problem!!!!

- Enforcement is just as important as……...
- Education/Prevention
- Treatment
Cutting off the Source of Supply
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)
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 83 corporations with 276 distribution centers
- 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
  - Cardinal Health-Lakeland; loss of DEA registration
“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))
Potential Red Flags???

Many customers receiving the same combination of prescriptions;

Many customers receiving the same strength of controlled substances;

Many customers paying cash for their prescriptions;

Prescriptions that results in therapeutic conflicts;

Many customers with the same diagnosis codes written on their prescriptions;

Individuals driving long distances to visit physicians and/or to fill prescriptions;

Customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and

Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).
DEA suspends Walgreens Distribution Center in Jupiter from dispensing controlled substances, including oxycodone

By Alexandra Stemler
Palm Beach Post Staff Writer

JUPITER — A suspension order has been placed on the Walgreens Distribution Center by the DEA for distributing controlled substances, including oxycodone, a Drug Enforcement Administration spokeswoman said.

The Walgreens Corp. has an opportunity to engage in a hearing to determine whether

USA TODAY

Drug wholesaler, 2 pharmacies charged in DEA crackdown

By Donna Leinwand Leifer, USA TODAY

Federal authorities have expanded their crackdown on painkiller abuse, charging a major health care company and two CVS pharmacies in Florida with violating their licenses to sell powerful pain pills and other drugs.

The DEA has suspended the controlled substance license of two CVS pharmacies in Sanford, Florida.

DEA moves against two Florida pharmacies, distributor over pill sales

February 06, 2012 | From John Douglas, CNN

Agents from the Drug Enforcement Administration raided two CVS pharmacies in central Florida over the weekend, removing controlled substances and suspending the stores’ ability to handle or distribute drugs such as painkillers oxycodone and hydrocodone.

The DEA said that during one year, the two pharmacies — both in Sanford, Florida — ordered over 3 million oxycodone units from a pharmaceutical wholesaler, while a typical pharmacy orders 69,000.

"Each registrant (pharmacy) was filing prescriptions far in excess of legitimate needs of its customers," said DEA Special Agent in Charge Mark Trouville during a press conference Monday in central Florida.
NEWS RELEASE

WALGREENS AGREES TO PAY A RECORD SETTLEMENT OF $80 MILLION FOR CIVIL PENALTIES UNDER THE CONTROLLED SUBSTANCES ACT

Largest Fine Paid by a DEA Registrant

JUN 11 – (MIAMI, FL) – Mark R. Trouville, Special Agent in Charge, Drug Enforcement Administration (DEA), Miami Field Division, and Wifredo A. Ferrer, United States Attorney for the Southern District of Florida, announced that Walgreens Corporation (Walgreens), the nation’s largest drug store chain, has agreed to pay $80 million in civil penalties, resolving the DEA’s administrative actions and the United States Attorney’s Office’s civil penalty investigation regarding the Walgreens Jupiter Distribution Center and six Walgreens retail pharmacies (collectively “Registrants”) in Florida. The settlement further resolves similar open civil investigations in the District of Colorado, Eastern District of Michigan, and Eastern District of New York, as well as civil investigations by DEA field offices nationwide, pursuant to the Controlled Substances Act (the Act).
Costco says cooperating with DEA probe on controlled substances

Oct 16 (Reuters) - Costco Wholesale Corp said on Wednesday that it will cooperate with the U.S. Drug Enforcement Administration in its ongoing investigation of prescriptions for controlled substances, after receiving subpoenas and warrants from the DEA.

The DEA has targeted large pharmacy chains and distributors to stem the flow of prescription drugs where abuse is suspected.

The DEA revoked the controlled substance licenses of two CVS Caremark Corp drugstores in Florida in 2012, and earlier this year Walgreen Co reached a record $80 million settlement with the agency to resolve allegations that its negligence in record-keeping and dispensing allowed highly addictive drugs to reach abusers and be sold illegally.

Costco announced its plans to cooperate with the DEA's subpoenas and administrative inspection warrants in a filing with the U.S. Securities and Exchange Commission on Wednesday. It said the matter concerned its "fulfillment of prescriptions related to controlled substances and related practices."

Additional details were not provided, and company representatives could not be immediately reached for comment.
Neonatal Abstinence Syndrome (NAS) Diagnosis Triples between 2000 and 2009

- In 2009, NAS was diagnosed in newborns at a rate of 3.39 per 1000 hospital births per year.

- In 2009, the estimated number of newborns with NAS was 13,539 or approximately 1 infant born per hour in the United States with signs of drug withdrawal.

- Between 2000 and 2009, the annual rate of NAS diagnosis among newborns in the United States increased almost 3-fold.

Source: Journal of the American Medical Association, Published online April 30, 2012
Neonatal Abstinence Syndrome (NAS) Diagnosis Triples between 2000 and 2009 (Continued)

• The study also finds that the rate of maternal opiate use increased nearly 5-fold (from 2000 to 2009).

• Between 2000 and 2009, total hospital charges for NAS are estimated to have increased from $190 million to $720 million*.

* Adjusted for inflation

Source: Journal of the American Medical Association, Published online April 30, 2012
Addicted Infants Triple in a Decade

Prescription abuse

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.

Born into addiction

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug-exposed Other</td>
<td>9%</td>
</tr>
<tr>
<td>Breathing problems</td>
<td>31%</td>
</tr>
<tr>
<td>Low birthweight</td>
<td>19%</td>
</tr>
<tr>
<td>Feeding problems</td>
<td>7%</td>
</tr>
<tr>
<td>Seizures</td>
<td>18%</td>
</tr>
<tr>
<td>1 – under 5½ pounds</td>
<td>3%</td>
</tr>
</tbody>
</table>

Source: Journal of the American Medical Association

By Frank Pompe, USA TODAY
Substances for Which Most Recent Treatment Was Received in the Past Year among Persons Aged 12 or Older: 2012

Figure 7.8 Substances for Which Most Recent Treatment Was Received in the Past Year among Persons Aged 12 or Older: 2012

- Alcohol: 2,395
- Pain Relievers: 973
- Marijuana: 957
- Cocaine: 658
- Tranquilizers: 458
- Heroin: 450
- Hallucinogens: 366
- Stimulants: 357

Numbers in Thousands

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)
Received Most Recent Treatment in the Past Year for the Use of Pain Relievers among Persons Aged 12 or Older: 2002 - 2012

Figure 7.9 Received Most Recent Treatment in the Past Year for the Use of Pain Relievers among Persons Aged 12 or Older: 2002-2012

*Difference between this estimate and the 2012 estimate is statistically significant at the .05 level.*
National Take Back Day
April 26, 2014

4,114 Agencies; 5,683 Sites
647,211 Pounds Collected (324 Tons)
National Take Back Initiative

• On September 30, 2010: 242,383 pounds (121 tons)
• On April 30, 2011: 376,593 pounds (188 tons)
• On October 29, 2011: 377,086 pounds (189 tons)
• On April 28, 2012: 552,161 pounds (276 tons)
• On September 29, 2012: 488,395 pounds (244 tons)
• On April 27, 2013: 742,497 pounds (371 tons)
• On October 26, 2013: 647,211 pounds (324 tons)

• Over 3.4 million pounds (1,733 tons) collected/turned in
Secure and Responsible Drug Disposal Act of 2010

• Enacted in October 2010 (Pub. L. 111-273, codified at 21 U.S.C. 822(g) and 823(b)(3))

• Act allows an ultimate user to “deliver” a controlled substance “to another person for the purpose of disposal” in accordance with regulations issued by DEA

• If the ultimate user dies while in lawful possession of the controlled substance, then any person lawfully entitled to dispose of the decedent’s property may deliver the controlled substance to another person for the purpose of disposal.

• DEA may also, by regulation, authorize long term care facilities (LTCFs) to dispose of controlled substances on behalf of ultimate users who reside or have resided at the LTCF.

• DEA is working to promulgate regulations to implement this Act. DEA must consider:
  • Public health and safety
  • Ease and cost of program implementation
  • Participation by various communities
  • Diversion Control

• Participation is voluntary. DEA may not require any person to establish or operate a delivery or disposal program.
Costs Associated with Prescription Drug Abuse

• To insurers for prescription painkiller abuse and misuse was $72.5 billion.

• The abuse of prescription painkillers resulted in $42 billion in lost productivity and $8.2 billion in criminal justice costs.

Source: Coalition Against Insurance Fraud (2007 Study); Clinical Journal of Pain (March/April 2011-Volume 27,Issue 3)
Fine agreed with Superior Court Judge Robert Perry that the 1,500 pills cited were "a lot of drugs," but said it was "antiquated thinking" to equate the number of pills with addiction. The pills included various opiates, muscle relaxants and other drugs.
A Pain-Drug Champion Has Second Thoughts

By Thomas Catan and Evan Perez

It has been his life’s work. Now, Russell Portenoy appears to be having second thoughts.

Two decades ago, the prominent New York pain-care specialist drove a movement to help people with chronic pain. He campaigned to rehabilitate a group of painkillers derived from the opium poppy that were long shunned by physicians because of their addictiveness.

Dr. Portenoy’s message was wildly successful. Today, drugs containing opioids like Vicodin, OxyContin and Percocet are among the most widely prescribed pharmaceuticals in America.

Opioids are also behind the country’s deadliest drug epidemic. More than 16,500 people die of overdoses annually, more than all illegal drugs combined.

Now, Dr. Portenoy and other pain doctors who promoted the drugs say they erred by overstating the drugs’ benefits and glossing over risks. “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did,” Dr. Portenoy said in an interview with The Wall Street Journal. “We didn’t know then what we know now.”

Recent research suggests a significantly higher risk of addiction than previously thought, and questions whether opioids are effective against long-term chronic pain.

The change of heart among former champions of opioid use has happened quietly, largely beyond the notice of many doctors. New York psychiatrist Joseph Carmody said he was “shocked” after attending a recent lecture outlining the latest findings on opioid risk.

“It goes in the face of everything you’ve learned,” he said. “You saw other doctors come around to it and saying, ‘Oh my God, what are we doing?’”

Because doctors feared they were dangerous and addictive, opioids were long reserved mainly for cancer patients. But Dr. Portenoy argued that they could be also safely be taken for months or years by people suffering from chronic pain. Among the assertions he and his followers made in the 1990s: Less than 1% of opioid users became addicted, the drugs

Please turn to page A12
AMA Tells Pharmacists: “Don’t Call Us We’ll Call You”

By Larry K. Houck –

Pharmacists are under increasing pressure to take extraordinary steps to verify prescriptions for controlled substances, especially in light of the fact that the Drug Enforcement Administration (“DEA”) has asserted that pharmacists are the gatekeepers or the “last line of defense” in the fight against prescription drug abuse. Alan G. Santos, DEA, Combatting Pharmaceutical Diversion: Targeting “Rogue Pain Clinics” & “Pill Mills,” Prescription Drug Awareness Conference, May 4-5, 2013, unnumbered slides. However, if the American Medical Association (“AMA”) adopts either of two committee resolutions at its 2013 meeting, pharmacists who serve that gatekeeper role should not expect cooperation from prescribing physicians.
September 24, 2013: Nationwide Release of CVS Caremark’s proposed solutions to combat prescription drug abuse:

• Require electronic prescribing
• Create uniform national monitoring (PDMPs)
• Ensure proper drug disposal
• Identify extreme prescribing
Public Awareness

Cases Against Doctors

- DEA maintains a list on the Diversion website of all doctors (MD and DO) who were federally convicted for the diversion of controlled pharmaceuticals since January 2003 (570).

- The intent is to convey to the public and our registrant population that DEA does not target physicians who legitimately and properly treat pain and that the doctors who are listed were arrested for truly egregious behavior.

- Entries are normally published following sentencing. High-profile cases are sometimes published immediately following conviction. March 27, 2014: 262 cases have been posted.

- Website address: www.deadiversion.usdoj.gov
I. Criminal Cases Against Doctors (PDF)
   * This is a listing of investigations of physician registrants in which DEA was involved that resulted in the arrest and prosecution of the registrant. DEA is in the process of adding to this site cases against DEA physician registrants since 2003 which have resulted in arrests and prosecutions.

II. Administrative Actions Against Doctors
Reporting Suspicious Activity

Contact Local DEA Office

- Ask for TDS Group or Diversion Group
- **877 RxAbuse Hotline**
- The Rx Abuse Hotline is a toll free number that the public can use to report what they believe may be illegal activity concerning controlled pharmaceuticals.
- FY 2012: 438 calls; FY 2013: 725 calls; FY 2014: 456 calls

UMPIRE

- UMPIRE (Unlawful Medical Products Internet Reporting Effort) is a Diversion Internet web-based system that was established in 2002. The UMPIRE system provides the public with an avenue to report what they believe may be illegal activity concerning controlled pharmaceuticals.
- FY 2012: 460 submissions; FY 2013: 503 submissions; FY 2014: 334 submissions
Public Awareness
Extortion Scam

- Ongoing international phone scam, based in Dominican Republic
- Contact individuals who have ordered on-line meds
- Represent that they are DEA agents
- Demand payment in lieu of arrest
- Payment sent to DR via Western Union/Money Gram
- Hotline available on internet
- DEA contacting callers and documenting all calls
- 11 indicted in January 2011, pending extradition process
- FY 2011: 2,085 calls; $1,564,866.00; $362,479.00
- FY 2012: 3,156 calls; $1,697,015.00; $421,843.00
- FY 2013: 3,910 calls; $1,394,300.00; $459,280.00
- FY 2014 (03/27/2014): 1,693 calls; $2,404,831; $757,384.00

Website address: www.dea.gov or www.deadiversion.usdoj.gov
DEA Warns Public of Extortion Scams

ALERT

Extortion SCAM
Press Releases

ALERT - EXTORTION SCAM - ALERT
DEA Warns Public of Extortion Scam by DEA Special Agent Impersonators

The Drug Enforcement Administration is warning the public about criminals posing as DEA special agents or other law enforcement personnel as part of an international extortion scheme.

The criminals call the victims (who in most cases previously purchased drugs over the Internet or by telephone) and identify themselves as DEA agents or law enforcement officials from other agencies. The impersonators inform their victims that purchasing drugs over the Internet or by telephone is illegal, and that enforcement action will be taken against them unless they pay a fine. In most cases, the impersonators instruct their victims to pay the “fine” via wire transfer to a designated location, usually overseas. If victims refuse to send money, the impersonators often threaten to arrest them or search their property. Some victims who purchased their drugs using a credit card also reported fraudulent use of their credit cards.

Impersonating a federal agent is a violation of federal law. The public should be aware that no DEA agent will ever contact members of the public by telephone to demand money or any other form of payment.

The DEA reminds the public to use caution when purchasing controlled substance pharmaceuticals by telephone or through the Internet. It is illegal to purchase controlled substance pharmaceuticals online or by telephone unless very stringent requirements are met. And, all pharmacies that dispense controlled substance pharmaceuticals by means of the Internet must be registered with DEA. By ordering any pharmaceutical medications online or by telephone from unknown entities, members of the public risk receiving unsafe, counterfeit, and/or ineffective drugs from criminals who operate outside the law. In addition, personal and financial information could be compromised.

Anyone receiving a telephone call from a person purporting to be a DEA special agent or other law enforcement official seeking money should refuse the demand and report the threat.

Report Extortion Scam: 1-877-792-2873