Controlled Substance and Legend Drug Diversion: A Law Enforcement and Regulatory Perspective

Wisconsin Pharmacy Diversion Awareness Conference
National Association of Boards of Pharmacy (NABP)
Wisconsin Pharmacy Examining Board
Drug Enforcement Administration
Department of Health and Human Services – Office of Inspector General

Hyatt Regency Hotel
Milwaukee, Wisconsin
July 25/26, 2015

Joseph Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
### Completed PDACs

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### Proposed FY-2015 PDACs

- 25-Oklahoma City, OK June 27-28, 2015
- 26-Milwaukee, WI July 25-26, 2015
- 27-Seattle, WA August 8-9, 2015
- 28-Portland, ME September 12-13, 2015

### Postponed FY-2015 PDAC

- Rapid City, SD
I have no financial relationships to disclose

and

I will not discuss off-label use and/or investigational drug use in my presentation
Goals and Objectives

- Background of prescription drug and opioid use and abuse – scope of the problem and potential solutions

- Identify and discuss the pharmacology of commonly diverted and abused pharmaceuticals

- Identify methods of pharmaceutical diversion and discuss how the pharmacist can prevent diversion in the retail setting

- Discuss the pharmacist and corresponding responsibility

- Discuss disposal regulations
Questions to Discuss

According to the National Survey on Drug Use and Health (NSDUH), in 2013 there were 6.5 million persons aged 12 and older who used prescription-type psychotherapeutic drugs non-medically in the last month. Which class of pharmaceutical had the highest level of non-medical use?

A) Stimulants
B) Sedatives
C) Pain relievers
D) Tranquilizers
According to the National Survey on Drug Use and Health (NSDUH), in 2013, participants identified the most frequent method of obtaining a prescription-type psychotherapeutic drug that they most recently non-medically used as:

A) Internet  
B) From a friend or relative for free  
C) Purchased from a friend or relative  
D) Purchased from stranger/drug dealer
Questions to Discuss

In determining whether a prescription is valid, a pharmacist is only required to 1) call the prescribing practitioner to verify that he/she authorized the prescription and 2) check to see if he/she has a valid and current DEA registration prior to dispensing the controlled substance;

A) True
B) False
Questions to Discuss

True or False...

For a controlled substance prescription to be effective, it must be, “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.”

- A) True
- B) False
Questions to Discuss

- Which of the following statements is false concerning regulations promulgated under the Secure and Responsible Drug Disposal Act of 2010:

A) Regulations do not limit the ways ultimate users may dispose of pharmaceutical controlled substances – they expand them.

B) Any method of pharmaceutical disposal that was valid prior to these regulations continues to be valid.

C) Any DEA registrant may participate as an authorized collector of pharmaceutical controlled substances.

D) DEA may not require any person to establish or operate a disposal program.
Questions to Discuss

What combination of drugs is referred to as the “trinity”?

A) Hydrocodone, alprazolam, and carisoprodol

B) Promethazine with codeine, methylphenidate and carisoprodol

C) Hydromorphone, carisoprodol and buprenorphine

D) Methadone, diazepam and tramadol
Responding to America’s Prescription Drug Abuse Crisis

“When Two Addictions Collide”

Pharmaceuticals

Money - Greed
Primum non nocere
Prescription Drug Abuse is driven by Indiscriminate Prescribing Criminal Activity
What is the Societal Damage of Prescription Controlled Substance and Legend Drug Abuse?
Consequences

In 2011, approximately 41,340 unintentional drug overdose deaths occurred in the United States, one death every 12.45 minutes. (increased for 12\textsuperscript{th} consecutive year)\textsuperscript{1}

Of this number, 22,810 deaths were attributed to Prescription Drugs (16,917 attributed to opioid overdoses/ (74.165%).

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

\textsuperscript{1}SOURCE: CDC National Center for Health Statistics/National Vital Statistics Report; June 2014
CDC Vital Signs: Opioid Painkiller Prescribing; July 2014
2012 Current Users (Past Month) 2013

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

ANY ILLICIT DRUG: 24.6 million
MARIJUANA: 19.8 million
PSYCHOTHERAPEUTIC DRUGS: 6.5 million
COCAINE: 1.5 million
Methamphetamine: 595,000
Heroin: 289,000

Source: 2012 & 2013 NSDUH
More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Heroin, and Inhalant abusers

COMBINED!!!
Scope and Extent of Problem:
Past Month Illicit Drug Use among Persons
Aged 12 or Older

Percentage of Past Month Nonmedical Use of Psychotherapeutics by Age, 2003-2012

Source: 2011 National Survey on Drug Use and Health
Drug Overdose Mortality Rates per 100,000 People 1999

Drug Overdose Mortality Rates per 100,000 People 2010

Poisoning Deaths: Opioid Analgesics

Source: CDC/NCHS, National Vital Statistics System
Naloxone
Naloxone Hydrochloride - Narcan

NARCAN (naloxone) is indicated for the complete or partial reversal of opioid depression, including respiratory depression, induced by natural and synthetic opioids, including propoxyphene, methadone and certain mixed agonist-antagonist analgesics: nalbuphine, pentazocine, butorphanol, and cyclazocine. NARCAN (naloxone) is also indicated for diagnosis of suspected or known acute opioid overdosage.
Woodbridge police officer saves 2 overdose victims in 5 days using Narcan

WOODBRIDGE — A township police officer who had just undergone training in the use of Narcan saved the lives of two overdose victims over five days, according to police. “The timing could not have been better,” said Woodbridge police Capt. Roy Hoppock.

Narcan, also known as nasal naloxone, is an opioid-reversal drug recently approved for use by law enforcement to help save heroin and opioid users from death by overdose.

The first incident in Woodbridge occurred about 8:45 p.m. on Jan. 21 when police received a 911 call about a 25-year-old woman who had overdosed on narcotics in a home in the Colonia section.

“One officer immediately administered Nasal Naloxone (Narcan) to the victim,” Hoppock said in a statement. “Almost immediately the victim showed signs of regaining consciousness.”

Hoppock identified the officer as Patrolman Christopher McClay. Hoppock said McClay had received training in the use of Narcan just two hours before the 911 call.

At 2:43 a.m. on Jan. 25, police received a 911 call about an unconscious person in a business parking lot in the Iselin section. “As officers arrived, they observed the victim, a male age unknown breathing, but unconscious,” Hoppock said.

The same officer who participated in the Jan. 21 call, McClay, administered Narcan to the victim, Hoppock said. “The victim appeared to regain consciousness,” Hoppock said. “At that point EMS arrived and the victim was transported to JFK Hospital.” Hoppock said the Woodbridge Police Department is now in the process of training all patrol officers in the use of Narcan.

The drug has been used by paramedics and emergency room doctors for years. Only recently has it been given to police officers, who are often the first on the scene of drug overdoses.

According to the state Attorney General’s Office, there were 741 heroin-related deaths in New Jersey in 2013, a 160 percent increase since 2010.
Agonist vs. Antagonist

### Agonist

**Agonist** + **Receptor** → **Pharmacological Response**

### Antagonist

**Antagonist** + **Receptor** → **Pharmacological Response**
Opioid Displacement

- Naloxone displaces the opioid from the receptor
- Dependent on mode of administration, onset can be apparent within a few minutes
The U.S. Population Grows at a Rate of Less Than 1% Per Year!

Source: U.S. Census Bureau
Why are these statistics outpacing population growth?

We all want to feel good and prescription drug use/abuse is an accepted method of curing whatever ails you. There is a pill for everything and medication use is encouraged in society.

Our children are following our lead.
Pharmaceutical Abuse
U.S. District Judge Jack Camp said he could not overlook the misconduct.

NEWMAN, 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."
Rush Limbaugh Arrested On Drug Charges

Rush Limbaugh and prosecutors in the long-running prescription fraud case against him have reached a deal. A 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 informants. He and his attorney Roy Black left about an hour and a half ago, he posted $3,000 bail, Black said.

Prosecutors' three-year investigation of Limbaugh began after he publicly acknowledged being addicted to oxycodone.

Limbaugh, who pleaded not guilty Friday, has steadfastly denied doctor shopping. Black said the charge will comply with court guidelines.

Rangers' Boogaard died of alcohol, oxycodone mix

Updated 5/20/2011 11:05 PM

MINNEAPOLIS (AP) — The death of New York Rangers enforcer 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 in his passion for the game, his teammates, and his community work was unstoppable. Experts say mixing alcohol and medicines can cause dangerous reactions. Drinking alcohol while taking strong painkillers like oxycodone can result in breathing problems and increase the risk of an overdose, according to the National Institute on Alcohol Abuse and Alcoholism. The family thanked the Rangers, Minnesota Wild, the NHL and the NHLPA for “supporting Derek’s continued efforts in his battle.”

Regardless of the cause, Derek's passing is a tragedy,” NHL spokesman Frank Brown said in an email. The Rangers and Wild had no comment.

Coeed 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!

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.
DEATHS
Violence
Armed Robbery

- Keep calm – Do as directed
- Do not challenge the bad actor – give him what he wants
- Let him leave the store without any intervention.
- As soon as he clears the store lock the door, call 911 and check on your customers/patients
- Write down any observations (clothing, height, weight, distinguishing features) while it is fresh in your mind
- Armed Robbery is an act of desperation. No amount of drug loss is worth your life or the life of your patients
ASSASSIN

Chilling anatomy of drugstore massacre

DRUGSTORE MASSACRE

Husband and wife busted in Rx-slay horror

PAIN KILLER

He never gave them a chance. The cold-blooded killer who murdered four people in a Long Island pharmacy methodically shot each, the film, shocking, step-by-step surveillance footage of the slaughter revealed yesterday.
Michael Baffour Addo was a well-liked pharmacist at Rite Aid in the Frandor Shopping Center in Lansing. (Courtesy photo)

By Melissa Anders | manders@mlive.com
Follow on Twitter
on May 13, 2014 at 4:14 PM, updated May 14, 2014 at 5:38 PM

LANSING — Michael Addo, known as a friendly Rite Aid pharmacist with a "million dollar smile," had a toddler and wife in Ghana, where he hoped to retire and live.

RIDE AID AND EAST LANSING SHOOTING CASE

Do you know a WWII vet?

Michigan has 39,000 living WWII veterans -- help us find them

Source:
Pharmacist slain in Beach robbery was much beloved

By Stacy Parker
The Virginian-Pilot
© April 15, 2014

VIRGINIA BEACH

When pharmacist David Kilgore left Rite Aid three-plus years ago, customers transferred their prescriptions to his new, small independent business.

They admired the way he connected with them on a personal level.

Monday, they placed flowers at his pharmacy's doorstep after learning the 46-year-old was shot during a morning robbery and later died.

"It was always, 'Hey Pete, how you doing?'" said Peter Carlson, who dropped off a colorful bouquet at Beach Pharmacy on Monday evening.

Related: Suspect identified, charged with murder

The pharmacist was working at Rite Aid on Laskin Road near the Oceanfront when development

Source:
http://hamptonroads.com/2014/04/pharmacist-slain-beach-robbery-was-much-beloved
Burden on the health care delivery system
Opioid overdoses in the ED: Visits by region, inpatient costs

**Note:** Based on data from the 2010 Nationwide Emergency Department Sample.

Prescription drug epidemic?
How did we get to this point?
Laudanum is no more dangerous than many of the preparations sold as soothing syrups; it has the saving grace of the "poison" label. (By courtesy of the Committee on Interstate and Foreign Commerce.)
The 1960s/70s/80s

Uppers - Amphetamines
- Meprobamate

Downers - Barbiturates

Quaalude

Hydromorphone

Oxycodone/APAP

“Ts and Blues”

“Fours and Doors”
OxyContin® Tablets
(oxycodone hydrochloride controlled-release)

The 1990s
Inadequate Pain Control
We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.
The Fifth Vital Sign?

1. Temperature
2. Heart Rate
3. Blood Pressure
4. Respiration
5. Pain?
Pain Scale

Wong-Baker FACES Pain Rating Scale

0
No Hurt

1
Hurts Little Bit

2
Hurts Little More

3
Hurts Even More

4
Hurts Whole Lot

5
Hurts Worst

No Pain
Sin dolor
Không Đau
Tsis Mob

Mild Pain
Dolor leve
Hơi Đau
Mob Me Ntsis

Moderate Pain
Dolor moderado
Đau Viên Phải
Mob Hauj Sim

Severe Pain
Dolor agudo
Rát Đau
Mob Heev

English
Spanish
Vietnamese
Hmong
Russian

Experts call for balance in addressing under treated pain and drug abuse

Healthcare decisions must remain in the hands of healthcare professionals for the sake of patients

A balance must be struck between physicians’ responsibility to treat chronic pain and the Drug Enforcement Administration’s (DEA) duty to combat drug abuse, according to a series of seven commentaries by national thoughtleaders published today in the February issue of Pain Medicine.

The commentaries explore the current state of the use of pain medicine from a variety of perspectives, with an emphasis on the tension between physicians treating legitimate pain and the DEA. Pain Medicine is the Journal of the American Academy of Pain Medicine (AAPM).

According to the American Pain Foundation, chronic pain affects more than 50 million Americans. People suffering from chronic pain may need pain medicine to lead normal lives, such as being able to work and to participate in family life. Many patients with chronic pain have lost access to appropriate medical care due to tension between regulatory/legislative bodies and the medical community.

The lead commentary describing current DEA policy on pain care with controlled substances was written by Howard A. Heit, MD, a pain and addiction medicine specialist who has collaborated with the DEA. AAPM President Scott M. Fishman, MD, presents a scathing critique of the conflict of war on drugs with efforts to improve pain care. Jennifer Bolen, JD, former Assistant US Attorney with the United States Department of Justice, makes a compelling case that current DEA policies are founded on erroneous and inappropriate assumptions. Edward Covington, MD, Steven Pavalk, PhD, and Ben A. Rich, PhD, add additional dimensions to the current perceived state of imbalance, while Will Rowe, Executive Director of the American Pain Foundation, a patient advocacy organization, provides perspective on patient’s rights.

Victories and Defeats in Pain Care

Dr. Heit and others worked with the DEA to develop the August 2004 Frequently Asked Questions and Answers for Healthcare Professionals and Law Enforcement Personnel, which the DEA subsequently disavowed causing “confusion and consternation” among physicians who treat pain.

"It is now apparent to me that the spirit of cooperation that existed between the DEA and the pain community to achieve the goal of balance has broken down. The DEA seems to have ignored the input and needs of the healthcare professionals and pain patients who actually prescribe, dispense and use controlled substances," Dr. Heit states in his commentary.

"It is essential that we resume dialogue between the DEA and healthcare professionals for the benefit of our patients and society," continues Dr. Heit. "The DEA and the healthcare professionals treating pain both have important jobs to do in ensuring those who need controlled substances for pain receive them while preventing misuse and diversion. Only through dialogue based on open and mutual trust and respect can this balance be restored."

Other government initiatives have challenged the line between health policy and law enforcement. This includes Congress’s empowerment of the DEA allowing the agency authority in reviewing new drugs, a role previously held only by the Food and Drug Administration, according to Dr. Fishman. On November 4, 2005, Congress reversed itself and rescinded the DEA’s new authority.

As healthcare’s regulatory authority shifts from health agencies to law enforcement agencies, the DEA and Federal prosecutors have used the courts to bypass state medical boards when scrutinizing physician practices. Dr. Fishman says that the recent passage of the National All Schedules Prescription Electronic Reporting Act (NAPSER), which institutes a national prescription monitoring program, may offer some forward-looking solutions, but it carries the potential to impede optimal prescribing and could even perpetuate the already harmful prescribing that may facilitate abuse. "While this new law is presented to the public as a clinical tool to improve patient care and safety, ... profound inadequacies suggest this law may be intended less as a clinical tool than an insurance physician mouser," Dr. Fishman states.

"Healthcare decisions, including those involving legitimate use of analgesics, must remain in the hands of healthcare professionals," comments Dr. Fishman. "The DEA should be required to work with health agencies and healthcare professionals in finding common ground and reaching the rational position of balance that is in the public’s best interest. Healthcare oversight must remain within agencies whose primary responsibility is to improve public health and continue to insist that drug abuse can be curbed without undermining patients in pain and for whom such policies is in the best interest of society. The least we can do is to make sure that the casualties of legitimate decease relief.

Freedom to Care for Pain Patients Critical

Reluctance to prescribe powerful pain medicine among the medical community for fear of retribution has led to the needless suffering of countless people in pain.

The Department of Justice must "stop the abuse and diversion of prescription medicines without harming access to these medicines for people affected by pain," states Will Rowe, Executive Director. The commentaries point to a failure on the part of the DEA in not abiding by its commitment to the pain community to pursue a balance between the war on drugs and the rights of pain patients, and also cite the DEA’s "incomprehensible command."

About the American Academy of Pain Medicine

Founded in 1983 as the American Academy of Algology, the American Academy of Pain Medicine (AAPM) has evolved as the primary organization for physicians practicing the specialty of Pain Medicine in grown, a defined body of knowledge and scope of practice have emerged, and today, Pain Medicine is recognized as a discrete specialty by the American Medical Association (AMA). AAPM is the only pain Delegates. The Journal Pain Medicine is published six times a year by Blackwell Science, Inc. For more information, visit www.painmed.org.

About the American Pain Foundation

Founded in 1997, the American Pain Foundation is an independent nonprofit 501(c)(3) organization serving people with pain through information, advocacy, and support. Our mission is to improve the quality of care, providing practical information, promoting research, and advocating to remove barriers and increase access to effective pain management. For more information, visit www.painfoundation.org.
Experts call for balance in addressing under treated pain and drug abuse

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Victors and Saints: Pain Care

Dr. Heit and other authors have signed a petition, dated August 2004, entitled “Pain Care: Facts and Answers for Health Care Professionals and the Law Enforcement Personnel, which the author believes may help to clarify confusion and communications among physicians who treat pain.

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"It is essential that we resume dialogue between the DEA and healthcare professions for the benefit of our patients and society,” continues Dr. Heit. "The DEA and the healthcare professionals treating pain both have an important job to do in ensuring that the patients who need [controlled substances] for pain receive them while preventing misuse and diversion. Only through dialogue based on and mutual trust and respect can this balance be restored."

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As healthcare’s regulatory authority shifts from health agencies to law enforcement agencies, the DEA and Federal prosecutors have used the courts to bypass state medical boards when scrutinizing physician practices. Dr. Fishman says that the recently passed national law, National All Schedules Prescription Electronic Reporting Act (NASPER), which institutes a national prescription monitoring program, may offer some steps forward, but it also carries the potential to impede optimal prescribing and could perpetuate aberrant prescribing that may facilitate abuse. While this new law is presented to the public as a clinical tool to improve patient care and safety, "...profound inadequacies suggest that this law may be intended less as a clinical tool than as a physician mouse trap," Dr. Fishman states.

"Healthcare decisions, including those involving legitimate use of analgesics, must remain in the hands of healthcare professionals,” comments Dr. Fishman. "The DEA should be required to work with health agencies and healthcare professionals in finding the common ground and reaching the rational position of balance that is in the public’s best interest. Healthcare oversight must remain within agencies whose primary responsibility is to improve public health, continue to insist that drug abuse can be curbed without undermining patients in pain and striving for such policies is in the best interest of society. The least we can do is to make sure that the casualties of legitimate relief.

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The Department of Justice must "stop the abuse and diversion of prescription medicines without harming access to these medicines for people affected by pain," states Will Rowe, Executive Director, AAMAP. The commentary points to a failure on the part of the DEA in not abiding by its commitment to the pain community to pursue a balance between the war on drugs and the rights of pain patients, and also cites the need to assert the more comprehensive command.

About the American Academy of Pain Medicine

Founded in 1983 as the American Academy of Allogology, the American Academy of Pain Medicine (AAMAP) has evolved as the primary organization for physicians practicing the specialty of Pain Medicine in grown, a defined body of knowledge and scope of practice have emerged, and today, Pain Medicine is recognized as a discrete specialty by the American Medical Association (AMA). AAMAP is the only pain Delegates. The Journal Pain Medicine is published six times a year by Blackwell Science, Inc. For more information, visit www.painmed.org.

About the American Pain Foundation

Founded in 1997, the American Pain Foundation is an independent nonprofit 501(c)3 organization serving people with pain through information, advocacy, and support. Our mission is to improve the quality of awareness, providing practical information, promoting research, and advocating to remove barriers and increase access to effective pain management. For more information, visit www.painfoundation.org.
American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics
For Immediate Release
May 08, 2012

Contact: Communications Office (Baucus), 202-224-4515
Jill Gerber (Grassley), 202-224-6522

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

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

Washington, DC – Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior Committee member Chuck Grassley (R-Iowa) initiated an investigation today into the connections of drug manufacturers Purdue Pharma, Endo Pharmaceuticals, and Johnson & Johnson with medical groups and physicians who have advocated the increased use of narcotic painkillers, or opioids. The Senators also asked seven other medical groups to produce information about their financial ties and collaborations with opioid manufacturers. In letters sent to each yesterday, Baucus and Grassley requested documents and financial information from the companies and noted that deaths resulting from opioid overdoses have recently skyrocketed, growing nearly 400 percent between 1999 and 2008, the most recent year data was available. They also highlighted news reports suggesting the increase may be driven by misinformation and dubious marketing practices used by the pharmaceutical companies and the medical organizations they fund.

“Overdoses on narcotic painkillers have become an epidemic, and it’s becoming clear that patients aren’t getting a full and clear picture of the risks posed by their medications,” Baucus said. “When it comes to these highly-addictive painkillers, improper relationships between pharmaceutical companies and the people they are trying to help are not sustainable. The public needs authoritative information to make sound decisions about their health care.”
“Recent investigative reporting from the Milwaukee Journal Sentinel/Medpage Today and ProPublica revealed extensive ties between companies that manufacture opioids and non-profit organizations such as the American Pain Foundation....and the Joint Commission.”
Bioethics think tank’s ties to pain pill industry studied

BY ALAN BAVLEY
The Kansas City Star

A U.S. Senate committee is examining a Kansas City-based bioethics think tank’s financial ties to the pain pill industry.

The inquiry is part of a sweeping investigation by the Senate Finance Committee of connections between pain drug manufacturers and organizations and physicians who have advocated for increased use of narcotic — also known as opioid — painkillers.

Abuse of these potentially addictive pain medications has become a national epidemic and accounts for more overdose deaths than heroin and cocaine combined. About 5 million people had used the drugs recently without a prescription, a federal survey found.

The Center for Practical Bioethics is one of seven organizations that received letters this week from the Senate committee asking them for information about their financial ties and collaborations with opioid manufacturers.

The other organizations are the American Pain Foundation, the American Academy of Pain Medicine, the American Pain Society, the Wisconsin Pain and Policy Study Group, the Joint Commission of Accreditation of Healthcare Organizations and the Federation of State Medical Boards.

Recent investigations by news organizations have found that some of these groups, such as the American Pain Foundation, a patient advocacy group, are funded largely by the drug industry.

The Senate committee is seeking to determine whether any of the groups promoted misleading information about the risks and benefits of opioids while receiving financial support from manufacturers of the drugs.

A Senate aide told The Kansas City Star that the investigation may bring into question guidelines for pain management, or the legitimacy of some of the organizations under scrutiny.

One of the organizations, the American Pain Foundation, disbanded last week, citing “irreparable economic circumstances.”
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.”
Commonly Abused Controlled Pharmaceuticals

Carisoprodol
C-IV as of 1/11/2012

Hydrocodone

OxyContin 80mg
Oxycodone HCL ER

Oxycodone 30 mg

Oxymorphone

CYCLOBENZAPRINE
(FLEXERIL)

Alprazolam

Oxymorphone

C-IV PHARMACIA & UPJOHN
P. 2294

Hydrocodone

Oxymorphone

C-IV as of 1/11/2012

Oxycodone 30 mg

Alprazolam

Oxymorphone

C-IV PHARMACIA & UPJOHN
P. 2294

Hydrocodone

Oxymorphone

C-IV PHARMACIA & UPJOHN
P. 2294

Hydrocodone

Oxymorphone

C-IV PHARMACIA & UPJOHN
P. 2294
The Holy Trinity

- Oxycodone
- Alprazolam
- Carisoprodol

Opiate

Muscle Relaxant

C-IV as of 1/11/2012

Benzodiazepine

U.S. Drug Enforcement Administration
Office of Diversion Control
Direct to Consumer Advertising
We will not arrest our way out of this problem!!!!!!

Enforcement is just as important as....

Prevention/Education

Treatment
Drug Education
or not
Teen Prescription Drug Misuse & Abuse

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

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

- **22%** say their parents don’t care as much if they are caught using RX drugs without a prescription, compared to getting caught with illegal drugs.
Education

Children/Teens

Information from the Internet or their peers

Following parents
Where do kids get their information from?

www.EROWID.org
# Psychoactive Plants and Drugs

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Common Psychoactives ▼ Go Chemicals ▼ Go Plants ▼ Go
Smart Drugs ▼ Go Pharmaceuticals ▼ Go Herbs ▼ Go

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www.EROWID.org
If this is your first visit, be sure to check out the FAQ. You may have to register before you can post: click the register link above to proceed. To start viewing messages, select the forum that you want to visit from the selection below.

THE FRONT PAGE

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 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, where we hope to help those struggling with drug addiction.
Ok--- so here is my current experiment status' so far.

1.) Milling / Grinding OP 80 - I have found the best way to crush OP30 with the use of a foot file / nail file. Hoseclamp did not work good. Using the file, I was able to get it to a powder around 20% thicker than the old OC.

2.) Experiment 1: Fail - My first experiment was to mill the OP80 and I left it overnight in a mixture of apple cider vinegar and lemon juice. 8-9 hours later, I drank it and received minimal if any effects except a horrible case of acid stomach. I suspect all the acid may have killed the alkaloids or something, or just failed to extract it completely.

3.) Experiment 2: Fail - Grinding up and parachuting - despite milling those OPs down, they still retain substantial time release. I found this to be a failure and it released the oxy slowly over the course of many hours.

4.) M.L.K - I read that if you put M.L.K drops (a popular, common solvent) in a spoon to saturate some milled OP 80, then let it evaporate, it dissolves the plastic and leaves a snortable powder that does not Gel. Many people report success with this, but I did not. Perhaps I did not use enough M.L.K or let it dissolve for long enough.

I posted this in the other thread, but I find this information useful and suggest you all read it here in case u missed it:

From the Purdue website, here is a summary of the info I found:
http://www.fda.gov/ohrms/dockets/ac/...-05-Purdue.pdf

Besides the obvious Simple, Medium, and Complex solvent thing that has everyone confused--- here is some information you guys should consider in ur investigations:

1.) At room temperature, using commonly found solvents, the best they could do was extracting 50% of the oxycodone for SHORT DURATION Shaking Extractions at room temperature.

2.) At room temperature with some less readily available solvents, extraction was as high as 70% during a "SHORT DURATION" shaking extraction at room temp.

3.) When we are dealing with EXTENDED extraction times at ROOM temperature--- some SIMPLE HOUSEHOLD solvents extracted up to 78% of the oxycodone! That might mean if we leave oxycodone soaked in acetone, M.E.K, or Ether for some time we can get almost 80% of the OC out. How long is an extended duration, I wonder? 1 hour, 2, hour, 4 hours --- shaking and stirring it. In the end, I would assume we would filter out the gunk, evaporate the solvent, and be left with pure oxycodone residue. The 22% or so that wasn't extracted would remain in the gunk we filter and we could eat them or something. There was one simple solvent they listed, however, that only got 2-9% out--- in other words destroying the alkaloid entirely. Not sure which one that is but maybe we can research solvents known to destroy oxycodone molecules. The Medium and Complex solvents all removed most of the oxycodone when leaving them at room temperature for extended periods of time.
5 mg alprazolam has done nothing

#1

looneytong7
Greenlighter

04-04-2014 14:14

Months ago, maybe even a year ago now, a friend introduced me to Xanax because we had been on a meth bender and sleeping had become impossible for me and I needed sleep badly. I took quarter of a 2 mg brick and it knocked me out and I loved it, the refreshing sleep. I’ve taken it around 10 times since then, every now and then when I really need to get to sleep and never more than 1-2 mg. So I definitely don’t have a high tolerance to the stuff or anything.

I haven’t had them for months now though. I had been smoking meth today and wanted to sleep. So well over 5 hours ago now, I took quarter of a 2 mg brick, 45 minutes later it hadn’t done a thing, so I took another quarter. So I’d had 1 mg. Half an hour later, still nothing. Waited a bit then swallowed the other half of the brick, 2 mg still would do anything at all other than make me feel slightly relaxed. Swallowed another half a brick or 1 mg, waited 40 minutes, still nothing. Swallowed another whole brick, bringing the total dose up to 5 mg about half an hour ago and still I am wide awake. They aren’t fake Xanax. So wtf is up with this!? 😯 a few days before this I was taking a couple 25mg seroquel per night for about a week if that make a difference, haven’t had any for a few days though.

Does anybody know wtf is up with this?

#2

deerman
Greenlighter

04-04-2014 22:39

Xanax doesn’t do anything of value for me, except make me pass out if I take too much.

Ativan on the other hand does wonders. Lorazepam is a highly effective benzo for putting one to sleep, in fact I have never heard of a doctor prescribing xanax for sleep, however it is common with lorazepam. Actually Xanax is downright destructive for sleep, do some research.

Perhaps your Xanax is old? Otherwise, join the club. Xanax fucking sucks for me, Ativan is the wonder benzo, not that I have a need for benzos anymore.

Maybe one should lay off the meth if they feel a need to take meds to go to sleep? How about a big hot meal with lots of vegetables and some chelated magnesium and lots of water? Get your body back in balance, meth will wreck your CNS if you aren’t being a careful user.

If you insist on using a prescription medication to help come down off meth and get to sleep, I would use lorazepam or ambien. But you’re just wreaking more havoc to your body by taking all those drugs...
Is there any way to get high off of just 5mg of hydrocodone?

Hydromethoinine  
07-04-2014 22:40

I have only been up to 25mg, and it has worked plenty fine for me. 10 gives me a slightly euphoric feeling. Could I use a certain potentiator, or maybe use a certain method? I only have this one 5/500 pill left. Thanks.

danolaa420  
Greenlighter  
Yesterday 00:38

Crush it into fine powder and grab a pitch at a time and put it in ur rear end or put the powder in a capsule and stick it up should dissolve

Hydromethoinine  
Yesterday 00:45

Would snorting help at all? I know some people have different reactions to snorting it. I know the acetaminophen isn't nice on the nose, but still.
Dr. Deception

Greenlighter

Join Date: Dec 2013
Location: New York
Posts: 24

10-02-2014 02:48

ok so me and my friend have 3 0.25 mg alprazolam tablets now. i've been doing some research about this drug, but i still need to know more before we do them. some info about us im 5'5" and weigh 130lbs has 6'1" i think and around 140-150 i believe. neither of us have any tolerance to this drug, but we're not newbies to drugs. we've both used cannabis, hydrocodone, alcohol, and we've dabbled a little in the methy/phenidate ring but not too much. so getting back to the point, i would like to know how much to take each to feel a "high" feeling or however your supposed to feel when you take it recreationally. i also want to know what's the best way to take it like snorting it, orally take it, parachuting it? plus how long does it take to feel effects, and how long they last, so if you could get back to me on this info it would be greatly appreciated. thank you.

Su77en

Greenlighter

Join Date: Jan 2014
Posts: 1

10-02-2014 03:03

I'm trying to process everything now. Can you come across with more for me? Put a pen in it and get back 2 me. Su77en

Dr. Deception

Greenlighter

Join Date: Dec 2013

10-02-2014 03:13

im sorry, but how do you mean? i just want an answer to my questions.if you don't know them thats ok im sure someone else on this forum does.
Pimp Lazy

Join Date: Jan 2004
Posts: 2,245

07-09-2005 23:58

Flexeril and cannabis has one of the most pleasant body buzzes I've ever had. Smoked opium comes close to that. I imagine the first items might be useful on the come down. Peace.

liquid arcadia

Join Date: Jan 2005
Posts: 379

09-09-2005 01:17

Flexeril works GREAT for me, I ate one 10 mg and it knocked me the fuck out after eating a strong meth infected pill... after I woke up I was very lethargic, as it wore off I could feel the meth take over again and had some trouble sleeping that night... amazing stuff... works great!

Psilocyte

Join Date: Feb 2006
Posts: 454

09-09-2005 05:14

^ really? hmm, I wonder why it does nothing for me. I've taken it in the same situation (meth laced pills). I ended up taking 60 mg that night and nothing worked. As soon as I took 2 temazepam I was finally relaxed though.
Brian242  15-01-2012 00:56

Bluelighter

Ok so we all (or most) know that Soma potentiates opiates very well, but I was wondering about taking 1-2mg Clonazepam with 1-2 350mg Soma's. Has this been done and is it safe?

---

Violenza666  15-01-2012 01:05

Bluelighter

Soma potentiates everything for me. However for the Benzo and Soma non tolerant it's likely a knockout... lol I am prescribed both...

Try half a Soma with 1mg Klonopin... or try a whole Soma with .5 Klonopin... Valium makes me less noddly when I mix it with soma... but sometimes I'll be sitting there relaxing and ill fall asleep for hours... I am a stay at home mom so my rule is I don't take my Soma when I am home alone and that way I don't nod out and fall asleep.

How often do you use Klonopin? How tolerant are you? It is safe for some people... for some they can die... all I can tell you... Be careful!

---

Brian242  15-01-2012 01:20

Bluelighter

Soma potentiates everything for me. However for the Benzo and Soma non tolerant it's likely a knockout... lol I am prescribed both...
Dear Drugs-Forum readers: We are a small non-profit that runs one of the most read drug information & addiction help websites in the world. We serve over 3 million readers per month, and have costs like all popular websites: servers, hosting, licenses and software. To protect our independence we do not run ads. We take no government funds. We run on donations which average $25. If everyone reading this would donate $5 then this fund raiser would be done in an hour. If Drugs-Forum is useful to you, take one minute to keep it online another year by donating whatever you can today. Donations are currently not sufficient to pay our bills and keep the sites up. Your help is most welcome. Thank you.
Dear Drugs-Forum readers: We are a small non-profit that runs one of the most read drug information & addiction help websites in the world. We serve over 3 million readers per month, and have costs like all popular websites: servers, hosting, licenses and software. To protect our independence we do not run ads. We take no government funds. We run on donations which average $25. If everyone reading this would donate $5 then this fund raiser would be done in an hour. If Drugs-Forum is useful to you, take one minute to keep it online another year by donating whatever you can today. Donations are currently not sufficient to pay our bills and keep the site up. Your help is most welcome. Thank you.

PLEASE HELP

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**Why Drugs-Forum is so addictive...**

Post by Afl from 11 years ago at 09:36 by Afl

Since starting this site 11 years ago DF has evolved so much. In the beginning it was a place for posting crap and having fun. Hell, I remember that I used to ask members to confront them about posting on the site. That all has changed.

What has become clear is that we are just at the start of something great. Something with meaning. Something that will grow big and influential. Back then we already knew that this site was going to make a difference. This has not changed.

The site has already made significant impact. With 35 million readers per year it affects the world. It's one of the main go-to places on the net. It affects what people know about drugs and how people perceive drugs. Drug Policy Organisations attribute a lot to DF.

The site has changed lives and saved lives. Lives we...

---

**Getting addicted to opiates full time...**

Post by Jonny88 on 17-03-2015 at 23:30 by Jonny88

After I received that first packet of Oxy's everything changed pretty rapidly. They were a step up from the other pain killers I had been taking in terms of strength and the euphoria was incredible; it allowed me to be really confident again and go out to clubs even dancing for hours again like if I had been taking ecstasy still. If you crush up Oxycontin, and snort it, you get the effects instantly and it hits you harder. I had started swallowing them one by one carrying others crushed up into a powder in a bag with me, I just snorted in pub toilets like people take cocaine but it was opiates for me. I loved it so much I just didn't care about anything else. I budgeted all my monthly outgoings around ordering a big parcel from Mexico or Serbia or wherever I could get them sent from dodgy online pharmacies.

It was around the initial...

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**Recent Entries**

- Getting addicted to opiates full time. (Jonny88) 17-03-2015
- Jumped (Galahad) 17-03-2015
- University (Galahad) 02-03-2015
- Education system failure, online dropouts, and smartphones. (Schooled) 26-02-2015
- There Are No Lions... (Just Those Who Quit Trying) (The Flying Pan-Things Always Get Hot In Here) 25-02-2015
- Brutalism from the 20th Century. (Schooled) 24-02-2015
- Hypocrisy determining truth behind the Big (Schooled) 22-02-2015
- The Crisis Articles (Our test and determiningfacial thinking) (Schooled) 22-02-2015

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**Recent Comments**

- I'm proud of you, I can see the heart in your eye. (Jonny88) 17-03-2015
- Addiction at once. The pain of poly-drug addiction. (Jonny88) 17-03-2015
- I love the writing style of this blog, it's so witty. (Jonny88) 17-03-2015
GET INVOLVED

TEACH
Community Coalitions and Advocacy Groups
Community Anti-Drug Coalitions of America

WWW.cadca.org
Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non-Medical Use

Friends and Family...For Free!!
The Medicine Cabinet and the Problem of Pharmaceutical Controlled Substance Disposal
The Problem – Easy Access
More than half of teens (73%) indicate that it’s easy to get prescription drugs from their parent’s medicine cabinet.

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

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

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules
National Take Back Initiative
September 26, 2015

Got Drugs?

Turn in your unused or expired medication for safe disposal Saturday

September 26, 2015

10:00 AM – 2:00 PM
Nationwide Take-back Initiative

Over 3.4 million pounds (1,733 tons) collected

- On September 30, 2010, approximately 122 tons
- On April 30, 2011, approximately 188 tons
- On October 29, 2011, approximately 189 tons
- On April 28, 2012, approximately 276 tons
- On September 29, 2012, approximately 244 tons
- On April 27, 2013, approximately 376 tons
- On October 26, 2013, approximately 324 tons
- On April 26, 2014, approximately 390 tons
- On September 27, 2014, approximately 309 tons

U.S. Drug Enforcement Administration
Office of Diversion Control
Secure and Responsible Drug Disposal Act of 2010

• Legislation that provides ultimate users and long-term care facilities (LTCFs) with additional methods to dispose of unused, unwanted, or expired controlled pharmaceuticals in a secure, safe, and responsible manner.

• Authorized DEA to promulgate regulations that allow ultimate users to transfer pharmaceutical controlled substances to authorized entities for disposal.
  o Specific language in the regulation continues to allow Federal, State, tribal, and local law enforcement to maintain collection receptacles at the law enforcement’s physical location; and either independently or in partnership with private entities or community groups, to voluntarily hold take-back events and administer mail-back programs.

• Created an exception for LTCFs to transfer pharmaceutical controlled substances for disposal on behalf of patients who reside or have resided at that facility.
Secure and Responsible Drug Disposal Act of 2010

- Regulations do not limit the ways ultimate users may dispose of pharmaceutical controlled substances – they expand them.
- Any method of pharmaceutical disposal that was valid prior to these regulations continues to be valid.
- Participation is voluntary.
- DEA may not require any person to establish or operate a disposal program.
Disposal of Controlled Substances, Final Rule

✓ Ultimate users will now have more locations where they can securely, safely, responsibly, and conveniently dispose of their unwanted pharmaceutical controlled substances.

✓ Expected benefit to the public by:
  o Decreasing the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
  o Protecting the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users.
Authorized to Collect

• The following persons are authorized to collect from ultimate user and other non-registrants for destruction:

  – Any DEA registrant authorized pursuant to § 1317.40
  – Federal, State, tribal, or local law enforcement when in the course of official duties and pursuant to § 1317.35

Registrants authorized to collect:
  – Manufacturers
  – Distributors
  – Reverse Distributors
  – Narcotic Treatment Programs
  – Hospitals/clinics with an on-site pharmacy
  – Retail Pharmacies

Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.

21 CFR § 1317.40
How does a registrant become a collector?

• Authorized registrant must be registered to handle schedule II controlled substances
• Request a modification in writing to the DEA or on-line at www.DEAdversion.usdoj.gov
• Request must contain:
  – Registrant’s name, address, and DEA number
  – The method(s) of collection:
    o Collection receptacle and/or mail-back program
  – Authorized signature per § 1301.13(j)
• No fee is required for this modification request

21 CFR §§ 1301.51(b) and (c)
New Authorized Methods of Collection

• Collection receptacles
• Mail-back programs
Collection Receptacles

• Only ultimate users shall put the controlled substances directly into the collection receptacle.

• Controlled and non-controlled substances may be comingled.

• Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.

• Registrants shall not dispose of stock/inventory in collection receptacles.

21 CFR § 1317.75(b) and (c)
Design of Collection Receptacle

• Securely fastened to a permanent structure.

• Securely locked, substantially constructed container with permanent outer container and removable inner liner.

• Outer container must have small opening that allows for contents to be added but does not allow for removal of contents.

21 CFR § 1317.75(e)
Collection Receptacle Location

- Must be securely placed and maintained:
  - Inside collector’s registered location
  - Inside law enforcement’s physical location, or
  - Inside an authorized LTCF
Collection Receptacle Location

- **Registered location** – immediate proximity of designated area where controlled substances are stored and at which an employee is present.

- **LTCF** – located in secure area regularly monitored by LTCF employees.

- **Hospital/clinic** – located in an area regularly monitored by employees, **not** in proximity of where emergency or urgent care is provided.

- **NTP** – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

*21 CFR § 1317.75(d)*
Mail-Back Program

Requirements of mail-back program

• Only lawfully possessed schedules II-V controlled substances may be collected

• Controlled and non-controlled substances may be collected together

21 CFR § 1317.70 (b)
Mail-back Program:
Who is Authorized to Operate?

Any authorized collector that has and utilizes at its registered location (on-site) a method of destruction consistent with § 1317.90

21 CFR § 1317.70
Mail-Back Packaging Specifications

- Packages may be made available for sale or free of charge;
- Any person may partner with a collector or law enforcement to make packages available to the public;
- Nondescript and no markings that indicate it contains controlled substances;
- Water- and spill-proof, tamper-evident, tear-resistant, and sealable;
- Pre-addressed with the collector’s registered address;
- Pre-paid postage;
- Unique ID number so package can be tracked; and
- Instructions for mailing.

21 CFR § 1317.70 (c)
PhRMA v. County of Alameda
Cert. denied (5/26/2015)

2012 Ordinance requiring manufacturers and distributors to be responsible for costs of disposal of unused medicines

District court found that the Ordinance serves a legitimate public health and safety interest at a relatively modest cost.
PROZAC® (fluoxetine HCl) FISH (?)

U.S. Drug Enforcement Administration
Office of Diversion Control
**Medicines Recommended for Disposal by Flushing**
**Listed by Medicine and Active Ingredient**

This list from FDA tells you what expired, unwanted, or unused medicines you should flush down the sink or toilet to help prevent danger to **people and pets in the home**.

FDA continually evaluates medicines for safety risks and will update the list as needed. Please visit the **Disposal of Unused Medicines: What You Should Know** page at [www.fda.gov](http://www.fda.gov) for more information.

### Medicines and Active Ingredients

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</tr>
<tr>
<td>Actiq, oral transmucosal lozenge</td>
<td>Fentanyl Citrate</td>
</tr>
<tr>
<td>Avinza, capsules</td>
<td>Morphine Sulfate</td>
</tr>
<tr>
<td>Buprenorphine Hydrochloride, tablets</td>
<td>Buprenorphine Hydrochloride</td>
</tr>
<tr>
<td>Buprenorphine Hydrochloride: Naloxone Hydrochloride, tablets (sublingual)</td>
<td>Buprenorphine Hydrochloride, Naloxone Hydrochloride</td>
</tr>
<tr>
<td>Butrans, transdermal patch system</td>
<td>Buprenorphine</td>
</tr>
<tr>
<td>Daytrana, transdermal patch system</td>
<td>Methyldiphenidate</td>
</tr>
<tr>
<td>Demerol, tablets</td>
<td>Meperidine Hydrochloride</td>
</tr>
<tr>
<td>Demerol, oral solution</td>
<td>Meperidine Hydrochloride</td>
</tr>
<tr>
<td>Diastat/Diastat AcuDial, rectal gel</td>
<td>Diazepam</td>
</tr>
<tr>
<td>Dilaudid, tablets</td>
<td>Hydromorphone Hydrochloride</td>
</tr>
<tr>
<td>Dilaudid, oral liquid</td>
<td>Hydromorphone Hydrochloride</td>
</tr>
<tr>
<td>Dolophine Hydrochloride, tablets</td>
<td>Methadone Hydrochloride</td>
</tr>
<tr>
<td>Duragesic, patch (extended-release)</td>
<td>Fentanyl</td>
</tr>
<tr>
<td>Embeda, capsules (extended release)</td>
<td>Morphine Sulfate: Naltrexone Hydrochloride</td>
</tr>
<tr>
<td>Exalgo, tablets (extended release)</td>
<td>Hydromorphone Hydrochloride</td>
</tr>
<tr>
<td>Fentora, tablets (buccal)</td>
<td>Fentanyl Citrate</td>
</tr>
<tr>
<td>Kadian, capsules (extended release)</td>
<td>Morphine Sulfate</td>
</tr>
<tr>
<td>Methadone Hydrochloride, oral solution</td>
<td>Methadone Hydrochloride</td>
</tr>
<tr>
<td>Methodone, tablets</td>
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</tr>
<tr>
<td>Morphine Sulfate, tablets (immediate release)</td>
<td>Morphine Sulfate</td>
</tr>
<tr>
<td>Morphine Sulfate, oral solution</td>
<td>Morphine Sulfate</td>
</tr>
<tr>
<td>MS Contin, tablets (extended release)</td>
<td>Morphine Sulfate</td>
</tr>
<tr>
<td>Nucynta ER, tablets (extended release)</td>
<td>Tapentadol</td>
</tr>
<tr>
<td>OxyContin, tablets (immediate release)</td>
<td>Oxycodone Hydrochloride</td>
</tr>
<tr>
<td>OxyContin, tablets (extended release)</td>
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</tr>
<tr>
<td>OxyContin, extended release</td>
<td>Oxycodone Hydrochloride</td>
</tr>
<tr>
<td>Percocet, tablets</td>
<td>Acetaminophen: Oxycodone Hydrochloride</td>
</tr>
<tr>
<td>Suboxone, film (sublingual)</td>
<td>Buprenorphine Hydrochloride; Naloxone Hydrochloride</td>
</tr>
<tr>
<td>Xyrem, oral solution</td>
<td>Sodium Oxybate</td>
</tr>
<tr>
<td>Zubzolv, tablets (sublingual)</td>
<td>Buprenorphine Hydrochloride; Naloxone Hydrochloride</td>
</tr>
</tbody>
</table>

### Active Ingredients and Medicines

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Medicine</th>
</tr>
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<tbody>
<tr>
<td>Acetaminophen: Oxycodone Hydrochloride</td>
<td>Percoled, tablets *</td>
</tr>
<tr>
<td>Aspirin: Oxycodone Hydrochloride</td>
<td>Percodan, tablets</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Butrans, transdermal patch (extended release)</td>
</tr>
<tr>
<td>Buprenorphine Hydrochloride</td>
<td>Buprenorphine Hydrochloride, tablets (sublingual) *</td>
</tr>
<tr>
<td>Buprenorphine Hydrochloride: Naloxone Hydrochloride</td>
<td>Buprenorphine Hydrochloride, Naloxone Hydrochloride</td>
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<td>Zubzolv, tablets (sublingual)</td>
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</tbody>
</table>

November 2013
Pharmaceuticals
Legend Drugs v. Controlled Substances
Legend Pharmaceuticals
Non-Controlled Substances

➢ Muscle Relaxant:
  – Cyclobenzaprine (Flexeril®)
Gabapentin

- Structurally related to γ-aminobutyric acid (GABA), an inhibitor of neurotransmission
- Precise mechanism of action producing analgesic and anti-epileptic actions is unknown
- Approved for clinical and veterinary use as a prescription only medication
- Gabapentin is not named or defined under the CSA
- Anecdotal reports of misuse and abuse
Gabapentin Therapeutic Use

- FDA-approved treatment with multiple off-label uses
  - Approved for the treatment of seizures and various pain states
  - Believed to have many advantages over other available medications and a first-line agent in the treatment of neuropathic pain
- Therapeutic category: anticonvulsant; analgesic
- Products: GABAPENTIN, GRALISE, HORIZANT, NEUROTIN
- Effective dose for the treatment of neuropathic pain varies but is similar to the doses effective for seizure treatment ranging from 300 mg/day to over 3600 mg/day
Gabapentin Abuse and Misuse

• Effects vary with user, dosage, past experience, psychiatric history, and expectations

• Abused alone or used as a cutting agent

• Range of experiences have been reported in relation to abuse: euphoria, sociability, marijuana-like high, zombie-like effects, sedation, and hallucinations

• Withdrawal symptoms reported:
  – Per Kruszewski et al.(2009), dependence and abuse involved toxic delirium, intense cravings, and prolonged post-withdrawal confusional state reminiscent of benzodiazepine withdrawal

• Two studies reporting concomitant abuse:
  – Used with cannabis, alcohol, SSRIs, LSD, amphetamine, and GHB (Psychother Psychosom, 2011)
  – Misuse to potentiate the ‘high’ obtain from methadone (Eur Addict Res, 2014)
Controlled Pharmaceuticals
<table>
<thead>
<tr>
<th></th>
<th>Schedule II</th>
<th>Schedule III</th>
<th>Schedule IV</th>
<th>Schedule V</th>
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<tbody>
<tr>
<td>Written</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Oral</td>
<td>Emergency Only*</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Facsimile</td>
<td>Yes**</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Refills</td>
<td>No</td>
<td>Yes#</td>
<td>Yes#</td>
<td>Yes#</td>
</tr>
<tr>
<td>Partial Fills</td>
<td>Yes***</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

* 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.
Marijuana

Question?

Drug or Not

Controlled Substance or Not

Harmful or Not

“Medicinal” or Not

Answer: It’s a Drug, it’s Controlled Federally, It’s Harmful and the “Medicinal” value is not determined by science yet.
Regulatory Controls

• Marijuana is Federally controlled as a Schedule I controlled substance under the Controlled Substances Act (CSA).

• Marijuana has no approved use under the Food, Drug, and Cosmetic Act (FDCA).

  1. Marijuana has a high potential for abuse and no accepted medical use in treatment in the United States
  2. It lacks accepted safety for use under medical supervision
  3. There is sound evidence that smoked marijuana is harmful
Research with Marijuana

Applicants submitting an application and protocol for legitimate research are approved by the Drug Enforcement Administration and the Food and Drug Administration. Currently there are over 265 researchers registered with DEA conducting scientific studies with marijuana, THC or its cannabinoids.

Substances are not approved for medical use through hysteria, rhetoric or public opinion. Substances are approved for medical use through sound science and analysis!

According to established case law, marijuana has no “currently accepted medical use” because: The drug’s chemistry is not known and reproducible; there are no adequate safety studies; there are no adequate and well-controlled studies proving efficacy; the drug is not accepted by qualified experts; and the scientific evidence is not widely available.
Schedule I Researchers

399 Total Schedule I Researcher Registrations

- 265 registered to perform bona fide research with marijuana, marijuana extracts, and THC
- 194 of 265 registered for research with marijuana extracts and derivatives including CBD
- Clinical studies:
  - 17 Researchers are conducting research with smoked marijuana
  - 41 Researchers are conducting research with CBD

Data from June 4, 2015
8-Factor Analysis

1. Actual or relative potential for abuse
2. Scientific evidence of pharmacological effects
3. State of the current scientific knowledge
4. History and current pattern of abuse
5. Scope duration and significance of abuse
6. What, if any, risk to public health
7. Psychic or physiological dependence liability
8. Whether an immediate precursor of a substance already controlled
Petitions to Reclassify
Petitions Filed with DEA

- NORMAL petition - denied
- Gettman petition – denied
- Olsen petition - denied
- Coalition petition – denied
- Krumm petition - pending
- Governor’s petition - pending
New Controlled Substances (Recently Scheduled)

- **Analgesic:**
  - Tramadol (Ultram®, Ultracet®)
  - Schedule IV in CSA as of August 18, 2014
Opiates
Papaver

Poppy

Codeine

Morphine

Thebaine

Hydrocodone

Hydromorphone

Oxycodone

U.S. Drug Enforcement Administration
Office of Diversion Control
• INCB Annual Report
  Narcotic Drugs

• Estimated World Requirements for 2015

• Statistics for 2013
The United States was the country with the highest consumption of the following drugs:

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>DRUG</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>99%</td>
<td>Hydrocodone</td>
<td>99%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>78%</td>
<td>Oxycodone</td>
<td>82%</td>
</tr>
<tr>
<td>Morphine</td>
<td>57%</td>
<td>Morphine</td>
<td>57%</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>51%</td>
<td>Hydromorphone</td>
<td>42%</td>
</tr>
<tr>
<td>Methadone</td>
<td>51%</td>
<td>Methadone</td>
<td>49%</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>31.5%</td>
<td>Fentanyl</td>
<td>37%</td>
</tr>
</tbody>
</table>
Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen
Hydrocodone Top 10 List

- Guatemala: 10 kilograms
- Mexico: 10 kilograms
- Vietnam: 20 kilograms
- China: 20 kilograms
- Denmark: 25 kilograms
- Columbia: 50 kilograms
- Syrian Republic: 50 kilograms
- Germany: 60 kilograms
- Canada: 100 kilograms
- United States: 79,700 kilograms (99.5%)


U.S. Drug Enforcement Administration Office of Diversion Control
Currently, the CSA defines hydrocodone substance as Schedule II, while its combination products as Schedule III.

On October 6, 2014, all hydrocodone products were placed in schedule II.

(see 79FR49661 dated August 22, 2014)
Schedule II

- The drug or other substance has a high potential for abuse
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions
- Abuse of the drug or other substance may lead to severe psychological or physical dependence

Schedule III

- The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I or II
- The drug or other substance has a currently accepted medical use in treatment in the United States
- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence
# Dosing Data for Clinically Employed Opioid Analgesics

<table>
<thead>
<tr>
<th>DRUG</th>
<th>APPROXIMATE EQUI-ANALGESIC</th>
<th>APPROXIMATE EQUI-ANALGESIC PARENTERAL DOSE</th>
<th>RECOMMENDED STARTING DOSE (adults &gt; 50 kg)</th>
<th>RECOMMENDED STARTING DOSE (children and adults ≤ 50 kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ORAL DOSE</td>
<td>PARENTERAL DOSE</td>
<td>ORAL</td>
<td>PARENTERAL</td>
</tr>
<tr>
<td>Opioid Agonists</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morphine</td>
<td>30 mg q3–4h (around-the-clock dosing)</td>
<td>10 mg q3–4h</td>
<td>15 mg q3–4h</td>
<td>0.3 mg/kg q3–4h</td>
</tr>
<tr>
<td>Codeine</td>
<td>130 mg q3–4h</td>
<td>75 mg q3–4h</td>
<td>30 mg q3–4h</td>
<td>1 mg/kg q3–4h</td>
</tr>
<tr>
<td>Hydromorphone (DILAUDID)</td>
<td>7.5 mg q3–4h</td>
<td>1.5 mg q3–4h</td>
<td>4 mg q3–4h</td>
<td>0.06 mg/kg q3–4h</td>
</tr>
<tr>
<td>Hydrocodone (in LORCET, LORTAB, VICODIN, others, typically with acetaminophen)</td>
<td>30 mg q3–4h</td>
<td>Not available</td>
<td>5 mg q3–4h</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Levorphanol</td>
<td>4 mg q6–8h</td>
<td>2 mg q6–8h</td>
<td>2 mg q6–8h</td>
<td>0.04 mg/kg q6–8h</td>
</tr>
<tr>
<td>Meperidine (DEMEROL)</td>
<td>300 mg q2–3h</td>
<td>100 mg q3h</td>
<td>Not recommended</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Methadone (DOLOPHINE, others)</td>
<td>20 mg q6–8h</td>
<td>10 mg q6–8h</td>
<td>2.5 mg q12h</td>
<td>0.2 mg/kg q12h</td>
</tr>
<tr>
<td>Oxycodone (REXICODONE, OXYCONTIN, also in PERCOCET, PERCODAN, TYLOX, others)</td>
<td>30 mg q3–4h</td>
<td>Not available</td>
<td>5 mg q3–4h</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Oxyximorphine (NUMORPHAN)</td>
<td>Not available</td>
<td>1 mg q3–4h</td>
<td>Not available</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Propoxyphene (DARVON)</td>
<td>130 mg</td>
<td>Not available</td>
<td>65 mg q4–6h</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Tramadol (ULTRAM)</td>
<td>100 mg</td>
<td>100 mg</td>
<td>50–100 mg q6h</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Opioid Agonist–Antagonists or Partial Agonists</td>
<td>Not available</td>
<td>0.3–0.4 mg q6–8h</td>
<td>0.4 mg q6–8h</td>
<td>Not available</td>
</tr>
<tr>
<td>Buprenorphine (BUPRENEX)</td>
<td>Not available</td>
<td>2 mg q3–4h</td>
<td>2 mg q3–4h</td>
<td>Not available</td>
</tr>
<tr>
<td>Butorphanol (STADOL)</td>
<td>Not available</td>
<td>10 mg q3–4h</td>
<td>Not available</td>
<td>0.1 mg/kg q3–4h</td>
</tr>
</tbody>
</table>

Source: Goodman and Gilman’s *The Pharmacological Basis of Therapeutics*, 12th edition
Approval of Single Entity Extended Release Hydrocodone
Manufactured by Alkermes Gainesville LLC for Zogenix, Inc. (San Diego, CA)

FDA Approval October 2013

Anticipated Launch March 2014
Thread: Zohydro's Here: Our New Problem Child? (HOLY LORD IN HEAVEN)

Results 1 to 25 of 63

18-02-2014 01:19

bigzip44

Zohydro ER (hydrocodone bitartrate), created by Zogenix, which also makes needle-free sumatriptan injections, is to be released next month (March). They will be releasing this drug in 10, 15, 20, 30, 40, and 50 milligram CAPSULES, which I assume will be filled with a pure hydrocodone powder, despite the 11-2 panel of experts the FDA created to vote on the approval of the drug. This drug is now in production, obviously.

I was badly addicted to OxyContin for many years and I remain on buprenorphine to this day. This "new" drug, made from the same compound that first triggered my addiction to opioids (which I found in vicodin, of course) is to be released in EXACTLY the same way careless way that OXYCONTIN was released by Purdue Pharma except in a presumably even more abusable form, a powder within a capsule. Zogenix and Zohydro's proponents have even gone so far as to reject claims that the new Tylenol-free formulation should be required to have a similar abuse preventative formulation that Purdue Pharma was finally forced into creating so as to continue selling their pure-formulation OxyCodone which is now, of course, the new, very unsexy OP.

Ah, now down to business. This drug is making my scrotum stir with anticipation; I cannot see a future where Zohydro exists where I also do not get high on it. What the fuck do you guys think about this new thing? Could this be the gnariest opiate "epidemic" since, well, morphine? I want thoughts, information, experience, opinion, conjecture or speculation any of you professionals have on this new drug.

In my opinion, this is going to change history.

(FYI, this thread was moved from Other Drugs)

18-02-2014 03:06

miscbrahh
I like hydrocodone but it always took too long for me to really enjoy vicodin. Not really a huge fan of the capsule approach either but people also produce fake oxycodone pills so it always comes down to where you're getting them from. I'm just interested to see how hard these are pushed onto current pain patients vs how many people just stick with their regular hydro pills. Still though, any drug in an ER version that isn't abuse proof is cool in my book.

The good news (for us) is that it uses Spheroidal Oral Drug Absorption System. Similar to Adderall XR, you can mash up the little beads and release the goodness 😊

I think the consensus is that more people are using opioids nowadays, especially in the last 5 years, which is why it's starting to be recognized as a problem again. Everything I've read says that all markers of opioid use are up, and anecdotally people are seeing a lot more problems than they used to as well.

- Treatment centers/prisons are seeing more upper-middle-class white males using heroin and strong opiates than they ever have before (and more of that population on MMT or bupe as well)
- Opiate OD has become a major COD for middle-aged women
- Heroin is stronger (in 😊 than it's ever been since the passage of the CSA (and cheaper)

are more people using opiates now on average or are there just more people period and more ways to get in trouble for it?

rhetorical question really, but I tend to think a lot of famous "eccentric" people back in the day were really just huge drug addicts
StealYourFace

18-02-2014 16:40

Looking at the product sheet on the mfg website, it looks as if the time release system is similar to Adderal XR/Dex Spansules with the little time release balls inside. If this is true, these would be awesome. I've never sniffed hydrocodone before for obvious reasons, but this would make it very easy.

"Crosses fingers"

Whosajiggawaaa

18-02-2014 18:09

I have never tried hydrocodone only oxy and almost every other opioid. Sort of amped.
Zohydro ER
(hydrocodone bitartrate)

Oral, Extended Release Hydrocodone without Acetaminophen for Treating Chronic Pain

1st

FDA Approval: March 1, 2013

Bigfanofthemdrugs

20-02-2014 20:20

I'dk what you guys are tripping about, I'm stoked to get in on some of that, hydrocodone is one of my favorite opioids. It's just as euphoric as oxy IMD.
OXYCODONE
Oxycodone HCL CR (OxyContin®) Reformulation
<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>User</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>08-27-2010</td>
<td>01:11</td>
<td>mz.mary420</td>
<td>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</td>
</tr>
<tr>
<td>08-27-2010</td>
<td>06:09</td>
<td>mephist00</td>
<td>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 doesnt gel up like you would think (doesnt gel up like the football shaped generic 40's do anyways) it just kinda turns snotty.. but if you can get it down fast it seems to work ok</td>
</tr>
</tbody>
</table>

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.
Oxycodone 15mg/30mg
Immediate Release
Other Oxycodone Products

Percodan

Tylox

Percocet
Oxymorphone Extended Release
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)
  - Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
  - Street: $10.00 – $80.00
Hydromorphone
Other Opiates of Interest

- Trade Name: MS Contin
  Controlled Ingredient: morphine sulfate, 160 mg

- Trade Name: MS Contin
  Controlled Ingredient: morphine sulfate, 15 mg

- Trade Name: MS Contin
  Controlled Ingredient: morphine sulfate, 10 mg

- Trade Name: Oramorph SR
  Controlled Ingredient: morphine sulfate, 30 mg

- Trade Name: Oramorph SR
  Controlled Ingredient: morphine sulfate, 160 mg

- Trade Name: Oramorph SR
  Controlled Ingredient: morphine sulfate, 60 mg

- Trade Name: Dilaudid
  Controlled Ingredient: hydromorphone hydrochloride, 2 mg

- Trade Name: Dilaudid
  Controlled Ingredient: hydromorphone hydrochloride, 4 mg
Fentanyl

- Fentanyl Patches
- Fentanyl Citrate dispensed in a berry flavored lollipop-type unit
- Fentanyl is 100 times more potent than morphine
- Intended to be used for chronic cancer pain & only for people who are tolerant to prescription opioid (narcotic) pain medicines
- Abused for its intense euphoric effects

Fentora®

Actiq®
Cough suppressant in over 125 OTC medications (e.g. Robitussin and Coricidin)

Bulk form on the Internet

At high doses, has Ketamine - and PCP-like effects

Produces physical and psychological dependence

Deaths associated with DXM abuse
Teen OTC Cough Medicine Misuse and Abuse

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

- Lifetime
- Annual
- Monthly

17% ACD
11% CDE
8%

5%

2009 (A) 2010 (B) 2011 (C) 2012 (D) 2013 (E)

"(In your lifetime/in the past 12 months/in the past 30 days), how many times have you taken a non-prescription cough or cold medicine to get high?"

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

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

U.S. Drug Enforcement Administration
Office of Diversion Control
Cough Syrup Cocktails

- “Syrup and Soda”
- “Seven and Syrup”
- “Purple Drank”
Opioids v. Heroin
U.S. Rates of Opioid Overdose Deaths, Sales, and Treatment Admissions, 1999-2010

Source: National Vital Statistics System (NVSS), DEA’s Automation of Reports and Consolidated Orders System, SAMHSA’s Treatment Episode Data Set
Circle of Addiction & the Next Generation

**Hydrocodone**
Lorcet®
$5-$7/tab

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

**Heroin**
$10/bag

**OxyContin®**
$80/tab

**Roxicodone®**
Oxycodone IR
15mg, 30mg
$30-$40/tab
Heroin use spikes in area suburbs
Pill addicts risk deadly drug
Heroin trafficking organizations relocating to areas where prescription drug abuse is on the rise

Heroin traffickers pave the way for increasing crime and violence

Law enforcement and prosecutors eventually fighting the problem on two fronts (prescription opiate diversion and heroin distribution) further depleting resources

Communities suffer
Clandestinely Produced Synthetic Opioids
What is a synthetic designer drug and why is law enforcement struggling to keep up with these compounds?
Acetylfentanyl

• Chemically-modified derivative of the powerful prescription painkiller Fentanyl
• is reportedly “50 times more potent than heroin and 100 times stronger than morphine
• May 2013 - 10,000 pills of “Desmethyl Fentanyl” intercepted in Montreal— hidden inside a microwave oven and a toaster destined for Colorado
  – Additional 1,500 kilograms of various raw materials; enough to make an additional 3 million pills seized
• RI Medical Examiner's Office regarding twelve (12) overdose deaths in March/April 2013
• Preliminary Lab/Toxicology reports attribute OD deaths to Acetylfentanyl
  – 5 of 12 overdose deaths occurred in Woonsocket, RI
  – May 16, 2013 two individuals arrested in Woonsocket, RI in possession of 28 grams of suspected Acetyl fentanyl
    • Attempts will be made to confirm link to OD deaths
Acetylfentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)

Introduction:

Acetylfentanyl, similar to the Schedule II opioid fentanyl, is a potent opioid analgesic. Recently, it has been linked to a number of overdose deaths in the northeastern part of the U.S. Acetylfentanyl is not a part of most illicit drug screens and remained undetected in many of these cases. Upon being identified in one death, secondary analyses were performed to confirm the presence of acetylfentanyl in numerous jurisdictions.

Chemistry:

The chemical structure of acetylfentanyl and the Schedule II substance fentanyl are shown below.

![Chemical structures of acetylfentanyl and fentanyl](image)

Acetylfentanyl and fentanyl are both synthetic opioids and have similar structures. With one less methyl group attached to the amide group, acetylfentanyl is the N-acetyl version of fentanyl.

Pharmacology:

Acetylfentanyl ($EC_{50} = 676 \text{ nM}$), similar to morphine ($EC_{50} = 23.6 \text{ nM}$), has been shown to bind to $\mu$-opioid receptors in rat cerebrum membrane preparations. Acetylfentanyl, similar to morphine, has been shown to inhibit the twitch response in electrically stimulated vas deferens preparation. A pharmacology study using acetic acid writhing test showed that acetylfentanyl produces analgesic response in mice 15.7-fold more potent than that of morphine. Potency of acetylfentanyl was about 3-fold less than that of fentanyl in this assay. The $ED_{50}$ (the dose at which 50% of test animals had met the criterion for analgesic response) dose for acetylfentanyl, fentanyl and morphine were 0.021, 0.0061, and 0.33 mg/kg, respectively. Similarly, in another study using tail flick and phenylquinone writhing tests, acetylfentanyl produced analgesic response in mice. Acetylfentanyl has been shown to completely suppress the signs of withdrawal in morphine-dependent monkeys.

Besides analgesia, fentanyl-like substances, similar to other opioid analgesics, produce a variety of pharmacological effects including alteration in mood, euphoria, drowsiness, respiratory depression, suppression of cough reflex, constriction of pupils (miosis), and impaired gastrointestinal motility. Clinical studies evaluating pharmacological effects of acetylfentanyl in humans have not been reported in the scientific literature.

In acute toxicity studies in mice, the LD$_{50}$ (the dose causing death of 50% of test animals) of acetylfentanyl and fentanyl are 9.3 mg/kg and 82 mg/kg, respectively. Significant bleeding in the small intestines of mice was observed in acetylfentanyl-administered mice.

Licit Uses:

There are no published studies as to the safety of acetylfentanyl for human use. There are no commercial or medical uses for this substance.

Illicit Uses:

As a $\mu$-opioid receptor agonist, acetylfentanyl may serve as a direct substitute for heroin or other $\mu$-opioid receptor agonist substances in opioid dependent individuals.

Recently, the Centers for Disease Control and Prevention (CDC) issued a health alert to report that between March 2013 and May 2013, 14 overdose deaths related to injected acetylfentanyl had occurred among intravenous drug users (ages between 19 and 57 years) in Rhode Island.

After confirming five overdoses in one county, including a fatality, Pennsylvania asked coroners and medical examiners across the state to screen for acetylfentanyl. This request led to 50 confirmed fatalities and five non-fatality overdoses statewide in 2013.

Control Status

Acetylfentanyl is not currently scheduled under the Controlled Substance Act (CSA). However, if intended for human consumption, acetylfentanyl may be treated as a “controlled substance analogue” under the CSA pursuant to 21 U.S.C §§802(32)(A) and 813.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 202-353-1263, telephone 202-307-7183, or E-mail ODE@usdoj.gov.
Acetyl Fentanyl Deaths

- Most recent: September 2014, Bend, OR, confirmed by M.E. toxicology
- **14** overdose deaths in RI; March-May 2013, reported by CDC
- Approximately **50** overdose deaths in PA; 2013, (caused by fentanyl or acetyl fentanyl) reported by PA Dept. of Drug and Alcohol Programs
- **3** overdose deaths in NC; February 2014, Reported by NC Dept. of Health and Human Services
- **5** overdose deaths in LA; October 2013, reported by the media

Likely that the prevalence of acetyl fentanyl in opioid-related emergency room admissions and deaths are under-reported. Since standard radioimmunoassays (e.g. ELISA) detect presence of fentanyl and its analogues. **Confirmatory GC/MS is necessary.**

- DEA monitoring Acetyl fentanyl deaths for possible scheduling
- Total number of fentanyl and acetyl fentanyl deaths unknown without old DAWN system.
CrystalRows.com is a Chinese web store which provides a large number of chemicals for students, researchers, and anyone else who might be interested. CrystalRows.com is a newly founded (2014) dropshipping company of research chemicals. We cooperate with a high standards laboratory in China which is able to manufacture up to 500kg weekly of research chemicals. Read More.
Acetyl fentanyl / China White

**Synonyms**: NIH 10485, Desmethyl fentanyl, MCV 4848, China White

**Formal Name**: N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide, monohydrochloride

**CAS Number**: 117332-89-5

**Molecular Formula**: C21H26N2O • HCl

**Formula Weight**: 358.9

**Formulation**: A crystalline solid

**Purity**: ≥98%

**Stability**: 2 years

*Acetyl fentanyl* (acetyl fentanyl) is an **opioid** analgesic medication that is certainly a great analog associated with **fentanyl**. Numerous studies projected *acetyl fentanyl* is actually around 5 to 15 times stronger compared to heroin. It is additionally documented to be eighty times stronger compared to morphine, as well as fifteen times less strong when compared with fentanyl.

It hasn't ever been approved for healthcare usage and also has just recently been marketed illegitimately as a developer drug. *Acetyl fentanyl* was found simultaneously with fentanyl itself and had almost never been found within the illegitimate industry during the late eighties, and yet never was.
drug-addicted people. Undesirable side effects can include itching, nausea, and respiratory depression, and this can be really dangerous.

Legality in United States

The substance is now operating inside a legal grey area. As being an analog of fentanyl, offering acetylfentanyl on purpose for human consumption is prosecutable by the United States Department of Justice as a DEA Schedule I controlled substance. Then again, since the substance isn't classified on the DEA's schedule record if the substance is tagged “not for human consumption” it might be allowed to circulate, just like bath salts have been in past times.

10g Acetyl fentanyl / China White
360.00$  Add to cart

25g Acetyl fentanyl / China White
720.00$  Add to cart

50g Acetyl fentanyl / China White
1,450.00$  Add to cart

100g Acetyl fentanyl / China White
2,300.00$  Add to cart

Date Prepared/ Source: www.crystalrows.com, retrieved 01/23/2015
As a legit and serious vendor, we provide small sample packages to any client who would like to try our services, delivery time, and the quality of our products.

Our sample package cost 150 USD + 50 USD Shipping.

Inside the package you can include:

5g of any cannabinoid or 5 different x 1g.

OR

3g of any opioid or 3 items x 1 g

OR

2g of any benzodiazepine or 2 items x 1g.

OR

5g of any stimulant or 5 items x 1g.

OR

2g of any hallucinogen or 2 items x 1g.

If you like our product and services, then the next order must be 10g of each kind.

DO NOT CONTACT US FOR FREE SAMPLES.

DO NOT ASK TO RECEIVE AND PAY AFTER.
### Other Fentanyl-Related Compounds Include:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Temporary Scheduling under 21 USC 811(h)</th>
<th>Extension of Temporary Scheduling</th>
<th>Permanent Scheduling</th>
<th>Rescheduling from CI to CII</th>
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*Note: The table above lists other fentanyl-related compounds along with their temporary and permanent scheduling dates, federal register citations, and the date of their classification. The entries show how these substances were scheduled under temporary and permanent federal regulations.*
Synthetic Opioid
AH-7921

• Synthetic Opioid
• Mimics heroin
• 21 overdose deaths associated in Europe
• Relatively new in US market
  Seized in Reno, NV
• Dealer attempting to get a substance that is “not an analogue”
• This is marketed as “badger repellant”
W-15 (Synthetic Opioid)

Noticed a few vendors stocking W-15 recently. Seriously little info available on it, but I thought there might be a few people here interested. Apparently it's about 5x more potent than morphine. That's all I've really found out, so here's some pics!

Looks like this:

```
\[
\text{\includegraphics{w-15.png}}
\]
```

Hopefully a few knowledgeable people will have some insight.

UPDATE: Found an experience report whilst searching. It's on reddit: http://www.reddit.com/r/opiates/comments/wt_rc_opiate/

According to that, doesn't look very promising :/
W-18 (Synthetic Opioid)

- (4-Nitrophenylethyl)piperidylidene-2-(4-chlorophenyl)sulfonamide (W-18) is a potent \( \mu \)-opioid agonist with a distinctive chemical structure which is not closely related to other established families of opioid drugs.

- This compound was found to be around 10,000x more potent than morphine in animal studies, however due to its structural differences from other opioid drugs it would be difficult to represent as being "substantially similar in chemical structure" to any controlled drugs. This makes it likely that it would not be illegalized under drug analog laws.
METHADONE
Methadone - 5mg & 10mg

Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg

METHADOSE™ Dispersible Tablets (Methadone Hydrochloride Tablets for Oral Suspension USP)

Each tablet contains:
Methadone Hydrochloride USP ........ 40 mg
Rx only

Usual Dosage:
See accompanying literature for dosage.

Keep tightly closed.
Dispense in a tight container (USP) with a child-resistant closure.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.
Hazelwood, MO 63042 USA.

U.S. Drug Enforcement Administration
Office of Diversion Control
Treatment of Narcotic Addiction
WHY IS IT ALSO USED AS AN ANALGESIC?

Cheapest narcotic pain reliever – synthetic

Insurance companies

What’s the problem?
Overdose...Why?

- Patients not taking the drug as directed
- Physicians not properly prescribing the drug
- Non medical users ingesting with other substances
- Opiate naive
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. Inadvertent 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, respiratory depression, 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.

The Methadone Poisoning by Jonathan J. Lipman, Ph.D.
Prescription Opioid Trafficking Trends
DATA-2000 Physicians
Other FDA Approved Drugs for Narcotic Addiction Treatment

- **Schedule III**
  - Buprenorphine – Drug Code 9064
    - Subutex (sublingual, single entity tablet)
    - Suboxone (sublingual, buprenorphine/naloxone tablet)
Benzodiazepines

Trade Name: Valium
Controlled Ingredient: diazepam, 10 mg

Trade Name: Valium
Controlled Ingredient: diazepam, 5 mg

Trade Name: Valium
Controlled Ingredient: diazepam, 2 mg

U.S. Drug Enforcement Administration
Office of Diversion Control
Alprazolam (Schedule IV)

- Brand name formulation of Xanax®

- Anti-anxiety agent used primarily for short-term relief of mild to moderate anxiety

- 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.

U.S. Drug Enforcement Administration
Office of Diversion Control
Drug abusers often prefer alprazolam due to its rapid onset and longer duration of action.

Alprazolam was ranked third in the number of prescriptions for controlled substances in 2003, 2004, 2005 and 2006.*

For all sales of generic pharmaceuticals, alprazolam was ranked 7th**

* Source IMS Health
** Source Verispan VONA
Non-Controlled Benzodiazepines under the CSA

“Diverted”

Non-Controlled Benzodiazepines
approved for medical use abroad

Phenazepam:
approved for medical use in Russia and some Commonwealth of Independent States

Etizolam:
approved for medical use in Japan, India and Italy

Brotizolam:
approved for medical use in Netherlands, Germany, Spain, Belgium, Austria, Portugal, Israel, Italy, Japan

“Designer”

Non-Controlled Benzodiazepines
not approved for medical use internationally

Deschloroetizolam

Flubromazepam

Pyrazolam

Deschloroetizolam

Flubromazolam

Diclazepam

Clonazolam

Deschloroetizolam

Flubromazolam

Diclazepam

Clonazolam
Stimulants

Amphetamine Salts C-II
- 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
Parents’ Relaxed Attitudes and Permissiveness

Approximately 29% of parents surveyed say they believe ADHD medication can improve a child’s academic or testing performance, even if the teen does not have ADHD.


U.S. Drug Enforcement Administration Office of Diversion Control
Teen Attitudes

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

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

- Used legitimately to treat ADHD

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

- $5.00 to $10.00 per pill on illicit market

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

Source: NSDUH Report; Non-Medical Use of Adderall Among Full-Time College Students, published April 2009
Trends in Abuse of Ritalin/Adderall

- One in eight teens (about 2.7 million) now reports having misused or abused these prescription stimulants at least once in their lifetime.
- 9% of teens (about 1.9 million) report having misused or abused these prescription stimulants in the past year (up from 6% in 2008).
- 6% of teens (about 1.3 million) report abuse of these prescription stimulants in the past month (up from 4% in 2008).
- One in four teens (26%) believes that prescription drugs can be used as a study aid.
- More than one in five teens (22%) says there is little or no risk in using Ritalin/Adderall without a prescription.


U.S. Drug Enforcement Administration
Office of Diversion Control
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

(g) often loses things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools)
(h) is often easily distracted by extraneous stimuli
(i) is often forgetful in daily activities

(2) six (or more) of the following symptoms of hyperactivity-impulsivity have persisted for at least 6 months to a degree that is maladaptive and inconsistent with developmental level:
There are no laboratory tests, neurological assessments, or attentional assessments that have been established as diagnostic in the clinical assessment of Attention-Deficit/Hyperactivity Disorder.
Methods of Diversion

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

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

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

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

- The medicine cabinet / obituaries
- The Internet
- Pain Clinics
Where are the Pharmaceuticals Coming From?

- Friends and Family for Free
- Medicine Cabinet
- Doctor Shopping
- Internet
- Pain Clinics
Prescription Fraud

➢ **Fake prescriptions**
  - Highly organized
  - Use real physician name and DEA Registrant Number
    • Contact Information false or “fake office”
      - (change locations often to avoid detection)
  - Prescription printing services utilized
    • Not required to ask questions or verify information printed

➢ **Stolen prescriptions**
  - Forged
  - “Smurfed” to a large number of different pharmacies
Criminal Activity
Egregious Activity
(Not on the fringes)
Doctor Shopping
Prescription Drug Monitoring Programs
Mandatory PDMP review before prescribing CS?
Pharmacist access to PDMP
Standard of Care
National Association of Boards of Pharmacy
Diversion via the Internet
1. Consumer in Montana orders hydrocodone on the Internet.

2. Request goes through Website Server in San Antonio, TX.

3. Web Company (located in Miami, FL) adds request to queue for Physician approval.

4. Order is approved by Physician in New Jersey and returned to Web Company.

5. Approved order then sent by Web Company to an affiliated Pharmacy.

6. Pharmacy in Iowa fills order and ships to Consumer via Shipper.
New Felony Offense Internet Trafficking - 10/15/2008

- 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)

What has been the reaction????
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.
# Current CSA Registrant Population

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<td>Chemicals</td>
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As of 06/25/15
SOOOO... How many have applied for registration for Internet Pharmacy Operations?????

53 applications filed
40 withdrawn
9 applications filed in error
4 pending
NONE APPROVED

As of June 11, 2015
What took the place of Internet Medical Care and Internet CS pharmaceutical Distribution?
Pain Clinics
Explosion of South Florida Pain Clinics

As of June 4, 2010, Florida has received 1,118 applications and has approved 1026

*As of May 14, 2010, Broward 142; Miami-Dade 79; Palm Beach 111
Medical Care?

- Many of these clinics are prescription/dispensing mills
- Minimal practitioner/patient interaction
Increased Law Enforcement Pressure

- Clinics migrating north and west
- Funded by owners in Florida
MRI DONE TODAY
SAME DAY REPORTS GUARANTEED!
ALL WALK-INS WELCOME!!
NO APPOINTMENT NEEDED
All Reports Are Read With A Board Certified Radiologist For The Best Diagnostic Results.
$240 CASH OR CREDIT ONLY
No Insurance Accepted
“short waits or we will pay you”

“earn $$$ for patient referrals” (sic)
Chronic Pain?
Stop Hurting & Start Living!

Established • Professional • Dedicated

Utilizing FDA Approved Medications
Outpatient Detox Available

ACCEPTING NEW PATIENTS
DON'T DELAY! CALL TODAY!
Drugs Prescribed

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

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<th>Schedule II</th>
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<td>Xanax (Alprazolam)</td>
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<td>Roxicodone 15mg, 30mg</td>
<td>Lorcet</td>
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<td>Methadone</td>
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</table>
The Controlled Substances Act

21 United States Code
CSA Registrant Population

Current Number of DEA Registrants: 1,582,633

Provisional registrations in effect at the time CSA was passed (relative to the Harrison Narcotics Act of 1914): 480,000

June 12, 2015

1973

U.S. Drug Enforcement Administration
Office of Diversion Control
Closed System of Distribution

1,582,633 (06/12/15)
Practitioners: 1,207,876
Retail Pharmacies: 71,110
Hospital/Clinics: 16,411

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 ...”
Cutting off the Source of Supply
The Controlled Substances Act

Checks and Balances
The Flow of Pharmaceuticals

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

**QUOTAS**
- 21 USC 823(c)(1)
- 21 USC 823(d)(1)
- 21 CFR 1301.71

- 21 USC 823(b)(1)
- 21 USC 823(e)(1)
- 21 CFR 1301.71
- 21 CFR 1301.74
  (Suspicious Orders)

**21 CFR 1306.04**

U.S. Drug Enforcement Administration
Office of Diversion Control
Diversion via the Internet
1. Consumer in Montana orders hydrocodone on the Internet

2. Request goes through Website Server in San Antonio, TX

3. Web Company (located in Miami, FL) adds request to queue for Physician approval

4. Order is approved by Physician in New Jersey and returned to Web Company

5. Approved order then sent by Web Company to an affiliated Pharmacy

6. Pharmacy in Iowa fills order and ships to Consumer via Shipper
# Purchases of hydrocodone by Known and Suspected Rogue Internet Pharmacies

**January 1, 2006 – December 31, 2006**

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**Total:** 98,566,711

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Date Prepared: 03/07/2007 Source: ARCOS
Checks and Balances of the CSA and the Regulatory Scheme

➢ **Distributors** of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” (21 CFR § 1301.74)
Checks and Balances
Under the CSA

• Practitioners

“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.” (21 CFR § 1306.04(a))

United States v Moore  423 US 122 (1975)
Perfunctory initial physical exam...return visits no exam

Physical exam included needle mark checks...some were simulated

Patient received quantity of drugs requested...were charged based on quantity

Unsupervised urinalysis – results did not matter

Accurate records not kept – quantity dispensed not recorded

Practitioner not authorized to conduct methadone maintenance;

Patient directed prescribing;
The Controlled Substances Act
Illegal Distribution

21 U.S.C. § 841 (a) Unlawful acts:

Except as authorized by this subchapter, it shall be unlawful for any person to knowingly or intentionally

(1) to manufacture, distribute or dispense, or possess with intent to manufacture, distribute or dispense, a controlled substance; or
Pharmacists have a responsibility to protect patients, as well as the public, from the abuse, misuse and diversion of prescription drugs.

2014 AACP Program Material
Checks and Balances
Under the CSA

Pharmacists – The Last Line of Defense

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

U.S v. Hayes 595 F. 2d 258 (5th Cir 1979)
U.S. v. Leal 75 F. 3d 219 (6th Cir 1996)
U.S. v. Birbragher 603 F. 3d 478 (8th Cir 2010)
East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)
Pharmacists – The Last Line of Defense

“An order purporting to be a prescription issued not in the course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the act (21 USC 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” (21 CFR § 1306.04(a))

U.S. v. Hayes 595 F. 2d 258 (5th Cir 1979)
U.S. v. Leal 75 F. 3d 219 (6th Cir 1996)
U.S. v. Birbragher 603 F. 3d 478 (8th Cir 2010)
East Main Street Pharmacy 75 Fed. Reg. 66149 (Oct. 27, 2010)
The Last Line of Defense

U.S. Drug Enforcement Administration
Office of Diversion Control
Corresponding Responsibility

When prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real purpose of the prescriptions.

(Ralph J. Bertolino, 55 FR 4729, 4730 (1990)),
Corresponding Responsibility Cases

East Main Street Pharmacy; Affirmance of Suspension Order
[Federal Register (Volume 75, Number 207) October 27, 2010
pages 66149-66165] ; see also Paul H. Volkman 73 FR 30630, 30642 (2008)

Holiday CVS, L.L.C, d/b/a CVS/Pharmacy Nos. 219 and 5195; Decision
and order
[Federal Register Volume 77, Number 198 (Friday October 12, 2012) pages 62315-62346]
Potential Red Flags

Many customers receiving the same combination of prescriptions; cocktail

Many customers receiving the same strength of controlled substances; no individualized dosing: multiple prescriptions for the strongest dose

Many customers paying cash for their prescriptions

Early refills

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.).

Overwhelming proportion of prescriptions filled by pharmacy are controlled substances

Pharmacist did not reach out to other pharmacists to determine why they were not filling a particular doctor’s prescription

Verification of legitimacy not satisfied by a call to the doctors office
Red Flag?

What happens next?

You attempt to resolve...
Resolution is comprised of many factors

- Verification of a valid practitioner DEA number! It is not, however, the end of the pharmacist’s duty. Invalid DEA number = Invalid RX
- Resolution cannot be based solely on patient ID and prescriber verification.
- You must use your professional judgment, training and experience...we all make mistakes
- Knowledge and history with the patient
- Circumstances of prescription presentation
- Experience with the prescribing practitioner
- It does not require a call to the practitioner for every CS RX
- This is not an all-inclusive list...
Who do I call to report a practitioner?

- State Board of Pharmacy/Medicine/Nursing/Dental
- State/County/Local Police
- DEA local office and Tactical Diversion Squad
- Health department
- HHS OIG if Medicare/Medicaid fraud
Practical Application of the Controlled Substances Act to the Current Rogue Pain Clinic Situation
What can happen when these checks and balances collapse and diversion occurs?
Purchases of Oxycodone 30mg

- In 2009, 44% of all oxycodone 30mg products were distributed to Florida
- In 2010, 43% of all oxycodone 30mg products were distributed to Florida
Paul Volkman, Chicago Doctor, Gets 4 Life Terms In Drug Overdose Case

ANDREW WELSH-HUGGINS  02/14/12 06:45 PM ET Associated Press
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.

"Volkman's actions created and prolonged debilitating addictions; distributed countless drugs to be sold on the street; and took the lives of numerous individuals who died just days after visiting him," they said.

The 64-year-old Volkman fired his attorneys earlier this month and said he acted at all times as a doctor, not a drug dealer. "The typical drug dealer does not care how much drugs a client buys, how often he buys, or what he does with his drugs," Volkman said in a 28-page handwritten court filing Monday, maintaining that he did all those things and more for his patients.
Why is this happening?
What’s the Profit?

- May 20, 2010, Tampa, Florida
- Owner/operator of pain clinic dispensing oxycodone
- $5,822,604.00 cash seized

U.S. Drug Enforcement Administration
Office of Diversion Control
What’s the Profit?

- One case in Florida owner/operator of pain clinic allegedly generated $40 million in drug proceeds
- Houston investigation $41.5 million in assets
What’s the Profit?

Another case in Florida - pain clinic operation paid his doctors (in 2009):
  – $861,550
  – $989,975
  – $1,031,975
  – $1,049,032
  – $1,225,775
Florida Pain Clinic Raid
A group of 19 manatees was freed after being trapped in a 36-inch storm drain, officials said early Tuesday.
Questions
Thank You!