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

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

DoubleTree Hotel
Portland, Maine
September 12/13, 2015

Joseph Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
<table>
<thead>
<tr>
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**Proposed FY-2015 PDACs**
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
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
Questions to Discuss

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
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

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

2012  Current Users (Past Month)  2013

ANY ILLICIT DRUG:
23.9 million

MARIJUANA: 18.9 million

PSYCHOTHERAPEUTIC DRUGS: 6.8 million

COCAIN: 1.6 million

Methamphetamine 440,000

Heroin: 335,000

Source: 2012 & 2013 NSDUH

ANY ILLICIT DRUG:
24.6 million

MARIJUANA: 19.8 million

PSYCHOTHERAPEUTIC DRUGS: 6.5 million

COCAIN: 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, 2003-2011

Source: 2011 National Survey on Drug Use and Health
Number of Forensic Cases 2001-2011

NFLIS
Estimated U.S. Law Enforcement Encounters

U.S. Drug Enforcement Administration
Office of Diversion Control
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

Poisoning Deaths

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<tr>
<td>2013</td>
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U.S. Drug Enforcement Administration
Office of Diversion Control
Drug-Poisoning Deaths Involving Opioid Analgesics or Heroin in the US, 1999-2013

Number of Deaths in Thousands

Year

Heroin

Opioid Analgesics

'99  2.0  4.0
'00  1.8  4.4
'01  1.8  5.5
'02  2.1  7.5
'03  2.1  8.5
'04  1.9  9.9
'05  2.0  10.9
'06  2.1  13.7
'07  2.4  14.4
'08  3.0  14.8
'09  2.4  15.6
'10  3.0  16.7
'11  4.4  16.9
'12  5.9  16.0
'13  8.3  16.2

Date Prepared/ Source: 01/28/15, CDC/NCHS, National Vital Statistics System, Mortality File

U.S. Drug Enforcement Administration
Office of Diversion Control
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
- No 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.
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
- Downers - Barbiturates
- Quaalude
- Hydromorphone
- Meprobamate
- Oxycodone/APAP

“Ts and Blues”

“Fours and Doors”
Inadequate Pain Control
A further discovery, startling and alarming, was that among the better class of people, those outside the underworld, the habit of using narcotic drugs has its origin, to a great degree, in the prescribing by physicians of their use for the relief of pain.

Beatrice Fairfax Writes of the Problems and Pitfalls of the War Workers Especially for Washington Women

Today's Topic

Answers to Correspondents

What's Doing: Where: When

U.S. Drug Enforcement Administration
Office of Diversion 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?
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 the advice of those on the front line of the 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 positions; Edward Connerly, MD, Steven Pawlik, PhD, and Ben A. Rich, JD, 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 patients' 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 Health Care 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 the 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 those who need [controlled substances] for pain receive them while preventing misuse and diversion. Only through dialogue based on 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' 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 Nov. 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 recently passed national law, National All Schedules Prescription Electronic Reporting Act (NAPSER), which institutes a national prescription monitoring program, may offer some steps forward, but it also carries the potential to impede optimal prescribing and could even 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 a 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 striving for such policies is in the best interest of society. The least we can do is to make sure that the casualties of legally deserve 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. American Academy of Pain Medicine commentators 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 "lack of comprehensive enforcement."
Experts call for balance in addressing under treated pain and drug abuse

The chilling effect

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.

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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. AAMP President Scott M. Fishman, MD, presented the case for cooperation on drugs to ease pain and improve patients’ lives.

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About the American Academy of Pain Medicine

Founded in 1983 as the American Academy of Algiology, 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 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 entrusted to help are not acceptable. These relationships can only create confusion and even worse, lead to a loss of faith in the medical profession. We will not stand idly by to allow our patients to continue to suffer or die needlessly from these painkillers."
“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 DAVLEY
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.”
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.

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

- Children/Teens
  - Information from the Internet
  - or their peers
  - Following parents
GET INVOLVED

TEACH
DEA Web-based Resources

www.DEA.gov
Community Coalitions and Advocacy Groups
Community Anti-Drug Coalitions of America

WWW.cadca.org
Pharmaceuticals
Legend Drugs v. Controlled Substances
Legend Pharmaceuticals
Non-Controlled Substances

➤ Muscle Relaxant:
  – Cyclobenzaprine (Flexeril®)
NFLIS Selected Drug Reports, 2010 – 2015
Federal, State, and Local Labs

* 2015 data are NFLIS reports for January – May, only. Data for 2015 are incomplete due to the normal lag time in reporting to NFLIS.

<table>
<thead>
<tr>
<th>Drug</th>
<th>2015*</th>
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</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>3,380</td>
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<tr>
<td>Tramadol</td>
<td>1,067</td>
</tr>
<tr>
<td>Gabapentin</td>
<td>308</td>
</tr>
</tbody>
</table>

Drug: BUPRENORPHINE, TRAMADOL, GABAPENTIN
Gabapentin

• Structurally related to γ-amino-butyric 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, NEURONTIN

• 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)
NFLIS Drug Reports – Federal, State & Local Laboratories

*2014 data still being reported

Date Prepared/ Source: 01/28/15, NFLIS
Controlled Pharmaceuticals
## Prescription Requirements

<table>
<thead>
<tr>
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<th>Schedule II</th>
<th>Schedule III</th>
<th>Schedule IV</th>
<th>Schedule V</th>
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</thead>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Oral</td>
<td>Emergency Only*</td>
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<td>Yes</td>
<td>Yes</td>
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<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.

U.S. Drug Enforcement Administration
Office of Diversion Control
Marijuana

Question?

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

Alzheimer's Disease
Anorexia
AIDS
Arthritis
Cachexia
Cancer
Epilepsy
Glaucoma
HIV
Migraine
Multiple Sclerosis
Nausea
Pain
Wasting Syndrome
Neuropathic pain
Post-amputation pain
Neuropathy
Trigeminal neuralgia
rheumatoid arthritis
Nausea of cancer chemotherapy
AIDS wasting
Motion sickness
Menstrual cramps
Rheumatoid arthritis
Alzheimer's disease
Hypertension
Brain injury/stroke
Crohn's/colitis
Depression/mental illness
Eating disorders
Nail Patella Syndrome
Spinal cord injury
Tourette's syndrome
Pain
Fibromyalgia
Spasticity
Asthma
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.

Substances are not approved for medical use through hysteria, rhetoric or public opinion.

Substances are approved for medical use through sound science and analysis.

Currently there are over 265 researchers registered with DEA conducting scientific studies with marijuana, THC or its cannabinoids.

Throughout the drug discovery process, pharmaceutical companies, academic institutions, research institutions, and other organizations publish their studies in scientific journals, books, and patents.

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
New Controlled Substances (Recently Scheduled)

- Analgesic:
  - Tramadol (Ultram®, Ultracet®)
  - Schedule IV in CSA as of August 18, 2014
Opiates/Opioids
INCB Annual Report
Narcotic Drugs

Estimated World Requirements for 2015

Statistics for 2013

U.S. Drug Enforcement Administration
Office of Diversion Control
The United States was the country with the highest consumption of the following drugs:

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

Hydrocodone/acetaminophen
### Estimated World Requirements of Narcotic Drugs 2015

#### Hydrocodone Top 10 List

<table>
<thead>
<tr>
<th></th>
<th>Country</th>
<th>Kilograms</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Guatemala</td>
<td>10 kilograms</td>
</tr>
<tr>
<td>09</td>
<td>Mexico</td>
<td>10 kilograms</td>
</tr>
<tr>
<td>08</td>
<td>Vietnam</td>
<td>20 kilograms</td>
</tr>
<tr>
<td>07</td>
<td>China</td>
<td>20 kilograms</td>
</tr>
<tr>
<td>06</td>
<td>Denmark</td>
<td>25 kilograms</td>
</tr>
<tr>
<td>05</td>
<td>Columbia</td>
<td>50 kilograms</td>
</tr>
<tr>
<td>04</td>
<td>Syrian Republic</td>
<td>50 kilograms</td>
</tr>
<tr>
<td>03</td>
<td>Germany</td>
<td>60 kilograms</td>
</tr>
<tr>
<td>02</td>
<td>Canada</td>
<td>100 kilograms</td>
</tr>
<tr>
<td>01</td>
<td>United States</td>
<td>79,700 kilograms</td>
</tr>
</tbody>
</table>

Top Five Dispensed Prescriptions CY2009 - 2013
IMS National Prescription Audit
(In Millions of Prescriptions)

- Acetaminophen/hydrocodone
- Levothyroxine (Levothroid)
- Lisinopril (Prinivil)
- Metoprolol (Lopressor)
- Simvastatin (Zocor)
<table>
<thead>
<tr>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
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<td>982,753,220</td>
<td>12</td>
<td>NC</td>
<td>220,543,770</td>
<td>23</td>
<td>AR</td>
<td>125,187,020</td>
<td>34</td>
<td>NJ</td>
<td>54,941,330</td>
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<td>NY</td>
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<td>MA</td>
<td>56,870,370</td>
<td>44</td>
<td>SD</td>
<td>16,805,590</td>
</tr>
</tbody>
</table>

* Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015
## State Ranking* - Hydrocodone
### January – December 2014

<table>
<thead>
<tr>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
<th>RANK</th>
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<th>STATE</th>
<th>TOTAL</th>
<th>RANK</th>
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</table>

* Business Activity – Retail Pharmacies

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015
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
NFLIS Cases
(Federal, State, and Local)

Number of Cases

2006 2007 2008 2009 2010 2011 2012 2013

MEPERIDINE
OXYMORPHONE
CODEINE
HYDROMORPHONE
METHADONE
MORPHINE
HYDROCODONE
OXYCODONE

U.S. Drug Enforcement Administration
Office of Diversion Control
Approval of Single Entity Extended Release Hydrocodone
## State Ranking* - Oxycodone
### January – December 2013

<table>
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<tr>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
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*Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015
# State Ranking* - Oxycodone
January – December 2014

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* Business Activity – Retail Pharmacies

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
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* Business Activity – Retail Pharmacies

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

U.S. Drug Enforcement Administration
Office of Diversion Control
## State Ranking* - Oxymorphone

### January – December 2014

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*Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015
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*Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015
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*Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/08/2015

U.S. Drug Enforcement Administration
Office of Diversion Control
## State Ranking* - Fentanyl
### January – December 2013

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* Business Activity – Retail Pharmacies

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 01/29/2015

U.S. Drug Enforcement Administration
Office of Diversion Control
State Ranking* - Fentanyl
January – September 2014

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* Business Activity – Retail Pharmacies

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 01/29/2015
Dextromethorphan (DXM)

- Cough suppressant in over 125 OTC medications (e.g. Robitussin and Coricidin)
- Bulk form on the Internet
- At high doses, has Ketamine - and PCP-like effects
- Produces physical and psychological dependence
- Deaths associated with DXM abuse
Teen OTC Cough Medicine Misuse and Abuse

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

- **Lifetime**: 17% ACD
- **Annual**: 11% CDE
- **Monthly**: 5%

```
2009 (A) | 2010 (B) | 2011 (C) | 2012 (D) | 2013 (E)
5%       | 6%       | 5%       | 4%       | 5%
```

“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.
Cough Syrup Cocktails

- “Syrup and Soda”
- “Seven and Syrup”
- “Purple Drank”
Opioids v. Heroin
**Papaver**

- Poppy
- Codeine
- Morphine
- Thebaine
- Hydrocodone
- Hydromorphone
- Oxycodone

**Somniferum**

U.S. Drug Enforcement Administration
Office of Diversion Control
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

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

Hydrocodone
- Lorcet®
- $5-$7/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
Community Impact?

Heroin trafficking organizations relocating to areas where prescription drug abuse is on the rise

Heroin traffickers pave the way for increasing crime and violence

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

Communities suffer
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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
Acetylfentanyl

- 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 ($EC_{50} = 676$ nM), similar to morphine ($EC_{50} = 23.8$ nM), has been shown to bind to μ-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 62 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 μ-opioid receptor agonist, acetylfentanyl may serve as a direct substitute for heroin or other μ-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-fatal 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.
## Other Fentanyl-Related Compounds Include:

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DEA History Fentanyl-Related Events

- April 2005 - March 2007: Spike in fentanyl seizures and over 1013 documented non-pharmaceutical overdose deaths
  - Synthetic route identified as Siegfried method
  - DEA Controlled Precursor N-phenethyl-4-piperidone (NPP) in 2007 as List 1 Chemical and 4-anilino-N-phenethyl-4-piperidine (ANPP) as a Schedule II immediate precursor in 2010.
- Recent Spike in Fentanyl seizures 2013-14
  - Identification of acetyl fentanyl

NFLIS Reports: Fentanyl
(State/Local Labs Jan 2003-Sept 2014) ** Through Sept 2014

*
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:

![W-15 chemical structure](image)

Hopefully a few knowledgeable people will have some insight. 😊


According to that, doesn't look very promising :/

Last edited by xool; 04-08-2013 at 09:15 PM.
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.
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*Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 09/10/2014
# State Ranking* - Methadone
## January – September 2014

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*Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of 01/29/2015
Methadone- 5mg & 10mg

Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg
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
Florida Deaths Per 100,000 Prescriptions
2008-2011

Sources:
- Death Data: Florida Department of Law Enforcement, “Drugs Identified in Deceased Persons by Florida Medical Examiners”
- Prescription Data: IMS Exponent, State Level: Florida Retail Prescription Data

U.S. Drug Enforcement Administration
Office of Diversion Control
One Pill can Kill

The Methadone Poisoning by Jonathan J. Lipman, Ph.D.

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 13 to 55) hours, is stored in body tissues, and toxic accumulation occurs with too-frequent consumption. Adverse effects are most common in patients treated with methadone in combination with other drugs. Both cardiac and respiratory systems are vulnerable targets for the drug's toxic actions, and other co-administered drugs can interactively increase the risk of death through a variety of mechanisms including direct central nervous system depression of respiration, idiosyncratic respiratory vulnerabilities, and lethal cardiac arrhythmias. Idiosyncratic factors also play a part in methadone's cardiac toxicity, and risk factors are well characterized, though perhaps not sufficiently widely known and understood by key stakeholders. The recent change in FDA labeling requirements for the drug—and the November 2006 posting of a government warning regarding its use in pain treatment—has not yet reduced morbidity and mortality associated with methadone as reported in the MedWatch database for the first quarter of 2007.
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)
Dispensed Total U.S. Prescriptions 2009-2014 (In thousands of Prescriptions)

Source: IMS Health National Prescription Audit
Buprenorphine Rx
Calendar Years 2004 – 2013

Thousands

Source: IMS, National Prescription Audit, retrieved 08-22-2014
Number of NFLIS Buprenorphine Reports, 2009 - 2014
Federal, State, and Local Labs

<table>
<thead>
<tr>
<th>Year</th>
<th>Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>7,464</td>
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<tr>
<td>2010</td>
<td>10,157</td>
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<td>2011</td>
<td>10,558</td>
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<td>2012</td>
<td>11,182</td>
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<td>2013</td>
<td>12,122</td>
</tr>
<tr>
<td>2014</td>
<td>13,236</td>
</tr>
<tr>
<td>Year</td>
<td>Cases</td>
</tr>
<tr>
<td>------</td>
<td>-------</td>
</tr>
<tr>
<td>2009</td>
<td>6,909</td>
</tr>
<tr>
<td>2010</td>
<td>9,403</td>
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<td>2011</td>
<td>9,560</td>
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<td>2012</td>
<td>10,074</td>
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<tr>
<td>2013</td>
<td>10,976</td>
</tr>
<tr>
<td>2014</td>
<td>11,947</td>
</tr>
</tbody>
</table>

Number of NFLIS Buprenorphine Cases, 2009 - 2014
Federal, State, and Local Labs
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
Stimulants

Amphetamine Salts C-II

- Adderall ® C-II

Methylphenidate C-II

- Ritalin®
- Concerta®
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.

*Source: 2013 Partnership Attitude Tracking Study, published 7/23/14*
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.

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:

B. Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7 years.
C. Some impairment from the symptoms is present in two or more settings (e.g., at school [or work] and at home).
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
Domestic ‘Rx’ Flow

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

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Population</td>
<td>1,582,633</td>
</tr>
<tr>
<td>Practitioner</td>
<td>1,207,876</td>
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<tr>
<td>Mid-Level Practitioner</td>
<td>272,586</td>
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<tr>
<td>Pharmacy</td>
<td>71,110</td>
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<tr>
<td>Hospital-Clinic</td>
<td>16,411</td>
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<tr>
<td>Teaching Institution</td>
<td>299</td>
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<tr>
<td>Manufacturer</td>
<td>538</td>
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<tr>
<td>Distributor</td>
<td>816</td>
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<tr>
<td>Researcher</td>
<td>7,748</td>
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<tr>
<td>Analytical Labs</td>
<td>1,512</td>
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<tr>
<td>NTP</td>
<td>1,413</td>
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<tr>
<td>Importer/Exporter</td>
<td>493</td>
</tr>
<tr>
<td>ADS Machine</td>
<td>1,636</td>
</tr>
<tr>
<td>Chemicals</td>
<td>989</td>
</tr>
</tbody>
</table>

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
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
<table>
<thead>
<tr>
<th>Year</th>
<th>Hydrocodone</th>
<th>Oxycodone</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>9,376</td>
<td>8,288</td>
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<td>2003</td>
<td>12,130</td>
<td>9,715</td>
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<td>2004</td>
<td>16,401</td>
<td>13,492</td>
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<tr>
<td>2005</td>
<td>21,190</td>
<td>14,643</td>
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<tr>
<td>2006</td>
<td>24,984</td>
<td>17,927</td>
</tr>
<tr>
<td>2007</td>
<td>30,637</td>
<td>22,425</td>
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<tr>
<td>2008</td>
<td>33,731</td>
<td>28,756</td>
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<tr>
<td>2009</td>
<td>38,084</td>
<td>38,332</td>
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<td>2010</td>
<td>39,444</td>
<td>48,210</td>
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<tr>
<td>2011</td>
<td>37,483</td>
<td>46,906</td>
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<tr>
<td>2012</td>
<td>35,140</td>
<td>42,869</td>
</tr>
<tr>
<td>2013*</td>
<td>26,844</td>
<td>31,897</td>
</tr>
</tbody>
</table>

NFLIS – Federal, State, and local cases reported.

Ryan-Haight

U.S. Drug Enforcement Administration
Office of Diversion Control
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
MIGRATION OF PAIN CLINICS

U.S. Drug Enforcement Administration
Office of Diversion Control
MIGRATION OF PAIN CLINICS

U.S. Drug Enforcement Administration
Office of Diversion Control
MIGRATION OF PAIN CLINICS
MIGRATION OF PAIN CLINICS

U.S. Drug Enforcement Administration
Office of Diversion Control
Drugs Prescribed

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

<table>
<thead>
<tr>
<th>Schedule II</th>
<th>Schedule III</th>
<th>Schedule IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone 15mg, 30mg</td>
<td>Vicodin (Hydrocodone)</td>
<td>Xanax (Alprazolam)</td>
</tr>
<tr>
<td>Roxicodone 15mg, 30mg</td>
<td>Lorcet</td>
<td>Valium (Diazepam)</td>
</tr>
<tr>
<td>Percocet</td>
<td>Lortab</td>
<td></td>
</tr>
<tr>
<td>Percodan</td>
<td>Tylenol #3 (codeine)</td>
<td></td>
</tr>
<tr>
<td>Demerol</td>
<td>Tylenol #4 (codeine)</td>
<td></td>
</tr>
<tr>
<td>Methadone</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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):

1973 - 480,000

June 12, 2015
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 ...”
Closed System of Distribution

- Cyclic Investigations
- Established Schedules
- Recordkeeping Requirements
- Registration
- Security Requirements
- Established Quotas
- ARCOS Reporting

U.S. Drug Enforcement Administration
Office of Diversion Control
Cutting off the Source of Supply
The Controlled Substances Act

Checks and Balances
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
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
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
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]
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;
Potential Red Flags continued

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
Nationwide Distribution of Oxycodone
30mg
January – December, 2012

Remaining States
593,625,290 dosage units

Florida
94,923,484 dosage units

Source: ARCOS
Date Prepared: 01/30/2014
Nationwide Distribution of Oxycodone 30mg
January – December, 2012

Remaining States 486,977,390 dosage units

Florida 94,923,484 dosage units

California 55,989,800 dosage units

New York 50,658,100 dosage units

Source: ARCOS
Date Prepared: 01/30/2014

U.S. Drug Enforcement Administration
Office of Diversion Control
Drug Dealers Masquerading as Doctors

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
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
## Deaths Associated with Rx Drugs in Florida

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

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<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Methadone</td>
<td>620</td>
<td>716</td>
<td>785</td>
<td>693</td>
<td>720</td>
<td>694</td>
<td>691</td>
<td>512</td>
<td>389</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>340</td>
<td>496</td>
<td>705</td>
<td>941</td>
<td>1,185</td>
<td>1,516</td>
<td>1,247</td>
<td>735</td>
<td>534</td>
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<tr>
<td>Hydrocodone</td>
<td>221</td>
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<td>264</td>
<td>270</td>
<td>265</td>
<td>315</td>
<td>307</td>
<td>244</td>
<td>291</td>
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<tr>
<td>Benzodiazepines</td>
<td>574</td>
<td>553</td>
<td>743</td>
<td>929</td>
<td>1,099</td>
<td>1,304</td>
<td>1,950</td>
<td>1,337*</td>
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<td>302</td>
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<td>3,571</td>
<td>4,091</td>
<td>6,551</td>
<td>5,255</td>
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</tbody>
</table>

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

SOURCE: Florida Medical Examiner’s Commission
19 Manatees Rescued From Storm Drain in Satellite Beach, Florida

Crews Battle to Free Manatees From Drainage Pipe

A group of 19 manatees was freed after being trapped in a 36-inch storm drain, officials said early Tuesday.
Questions
Thank You!