PRESCRIPTION DRUG
TRAFFICKING & ABUSE TRENDS

November 16-17, 2013
Pharmacy Diversion Awareness Conference (PDAC)
Louisville, KY

Alan G. Santos, Associate Deputy Assistant Administrator,
Operations Division, Office of Diversion Control,
U.S. Drug Enforcement Administration
Disclosure Information

I have no financial relationships to disclose !!
Rx Trends Outline

- Scope of the Problem
- The Costs
- What People are Abusing
- The “CSA” – Checks & Balances
- Where People are Getting Their Drugs (Evolution of Problem & Pill Mills)
OBJECTIVES

1. Identify current trends in pharmaceutical controlled substance abuse.

2. Describe the impact pharmacy diversion has on communities.
1. What is the most commonly prescribed controlled substance in the U.S.?
   a. Oxycodone  
   b. Methylphenidate  
   c. Hydrocodone/APAP  
   d. Alprazolam
2. Name four common methods of diversion.
3. 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
Prescription Drug Abuse & Trafficking Trends

OR

Responding to America’s Prescription Drug Abuse Crisis

“When Two Addictions Collide”
SCOPE OF THE PROBLEM
Mayo Clinic Study on Prescription Drugs

- The three most common types of prescriptions are antibiotics, antidepressants, and painkiller opioids.
- 70% of Americans are taking at least one prescription drug.
- More than 50% are on at least two prescriptions.

Source: Mayo Clinic Press Release, 6/19/2013
Not a New Problem ....
The 1960/70s/80s

Uppers - Dexedrine
Downers - Seconal
Meprobamate
Hydromorphone
Oxycodone/APAP

“Ts and Blues”
“Fours and Doors”
The 1990s

OxyContin

10 mg
20 mg
40 mg
80 mg
160 mg

Controlled-Release Tablets

(oxycodone HCl)
In 2010, approximately 38,329 unintentional drug overdose deaths occurred in the United States, one death every 14 minutes.

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

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

Source: CDC Drug Overdose Deaths in the United States, 2010   (October 2012)
U.S. Drug Overdose Deaths by Major Drug Type, 1999-2010

Source: CDC/NCHS, NVSS
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

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
Today’s Perfect Storm

- Industry is producing a wider variety of controlled substance pharmaceuticals

- Use of Medicare / Medicaid or insurance to fund drug habits

- The Information / Electronic era (i.e., web sites such as Erowid & Bluelight, social networking, blogging, twitter, text messaging, & chat rooms for instant exchanges of information)
2010  Current Users (Past Month)  2011

**ANY ILLICIT DRUG:**
- 22.6 million

**MARIJUANA:**
- 17.4 million

**PSYCHOTHERAPEUTIC DRUGS:**
- 7 million

**COCAINENE:**
- 1.5 million

**Methamphetamine:**
- 353,000

**Heroin:**
- 239,000

**ANY ILLICIT DRUG:**
- 22.5 million

**MARIJUANA:**
- 18.1 million

**PSYCHOTHERAPEUTIC DRUGS:**
- 6.1 million

**COCAINENE:**
- 1.4 million

**Methamphetamine:**
- 439,000

**Heroin:**
- 281,000

Source: 2010 & 2011NSDUH
Prescription Drug Abuse

More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Methamphetamine & Heroin abusers

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

Past Year Initiates 2012 – Ages 12 and Older

Figure 7.2 Specific Illicit Drug Dependence or Abuse in the Past Year among Persons Aged 12 or Older: 2012

- Marijuana: 4,304
- Pain Relievers: 2,056
- Cocaine: 1,119
- Tranquilizers: 629
- Stimulants: 535
- Heroin: 467
- Hallucinogens: 331
- Inhalants: 164
- Sedatives: 135

Numbers in Thousands

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)
In 2012, there were 2.4 million persons aged 12 or older who used psychotherapeutics non-medically for the first time within the past year, approximately 6,700 new initiates per day.*

One in four teens (24%) reports having misused a prescription drug at least once in their lifetime (up from 18% in 2008 to 24% in 2012), which translates to about 5 million teens. That is a 33% increase over a five-year period.

SOURCE: * 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)
** The Partnership at Drugfree.org / MetLife Foundation Partnership Attitude Tracking Studies 2012, published April 2013
Parents & Their Attitudes

Parents are not discussing the risks of abusing prescription drugs

Source: 2011 Partnership Attitude Tracking Study
Parents & Their Actions

Parents and their abuse of prescription drugs

Source: 2011 Partnership Attitude Tracking Study
Where do kids get their information from?
Westchase teachers learn a lesson: Say 'no' to mints in pill bottles

One of the mint-filled pill bottles distributed to some fourth graders at Westchase Elementary.

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

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

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

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

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

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

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

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

Young said the bottle reads in part: "Watson's Whiz Kid Pharmacy. Take 1 tablet by mouth EVERY 5 MINUTES to cure FCAT jitters. Repeated use may cause craft to spontaneously ooze from pores. No refills. Ms. (Deborah) Falcon's authorization required."

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

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

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

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

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

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

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

Young said her grandson has been at Westchase Elementary for a year, and she hasn't had any complaints. But this experience has soured her. It concerns her that now someone might hand her grandson a pill bottle with drugs and he might think it's OK to consume its contents.

"We as parents and grandparents have to drill it into them that this is unacceptable and hope and pray that they don't accept drugs from someone else," Young said.
Wrestler Benoit's doctor gets 10 years in prison

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

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

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

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

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

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

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

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

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

Investigators cited one case in which an unidentified female patient began receiving a combination of drugs that included Xanax from Astin in 2002. She died in June 2007, the same month authorities found Benoit and his family dead in their suburban Atlanta home.
Rush Limbaugh Arrested On Drug Charges
Rush Limbaugh and prosecutors in the long-running prescription fraud case against him have reached a deal calling for the only charge against the conservative commentator to be dropped without a guilty plea if he continues treatment.

Limbaugh turned himself in to authorities on a warrant filed Friday charging him with drug offenses. The warrant was obtained by a federal grand jury in New York, where the case against Limbaugh is being prosecuted.

Prosecutors’ three-year investigation of Limbaugh began after he publicly acknowledged he needed help with prescription painkillers. He received about 2,000 pills a month, prescribed by four doctors in six states.

Limbaugh, who pleaded not guilty Friday, has steadfastly denied doing anything wrong.

Rangers’ Boogaard died of alcohol, oxycodone mix

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 dead in his Minneapolis apartment last Monday after he sustained a concussion.

Boogaard’s agent, Ron Saks, said the family was “shocked” and “heartbroken” by the announcement.

“Regardless of the cause, Derek’s passing is a tragedy,” NHL spokesman Frank Brown said in an email.

“Derek was a truly special young man,” Brown said. “We are all devastated by his passing.”

Thomas Kinkade cause of death: alcohol, Valium

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

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

Jack Camp, Senior Federal Judge, Arrested On Drug, Gun Charges
ATLANTA — A veteran federal judge faces drug and firearms charges after an exotic dancer at an Atlanta strip club told authorities he used cocaine, marijuana and other illegal drugs with her.

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

Coheed and Cambria Bassist Arrested Before Gig
Originally posted Jul 10th 2011 5:18 PM PDT by TMZ Staff

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

Michael Baze accidentally overdosed

The 22-year-old jockey was pronounced dead on May 10. His body was found in his vehicle near the stables at the famed Louisville track.

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

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

Baze was arrested last November on the arrest warrant.

His mother, Teri Gibson, said he was a great son and that he did not do drugs.

Thomas Kinkade cause of death: alcohol, Valium

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

NBC Bay Area News reported late Monday that the Santa Clara County medical examiner’s autopsy is complete and reveals that Kinkade died April 6 at his California home from a combination of alcohol and prescription drugs. He was 54.
Russell Jones, aka Ol’ Dirty Bastard  
November 13, 2004

Kenneth Moore, aka Big Moe  
October 14, 2007

Brittany Murphy  
December 20, 2009

Anna Nicole Smith  
February 8, 2007

Heath Ledger  
January 22, 2008

Leslie Carter  
January 31, 2012

Ken Caminiti  
October 10, 2004

Whitney Houston  
February 11, 2012

Derek Boogaard  
May 13, 2011

DEATHS
The toxicology tests also showed therapeutic amounts of painkillers hydrocodone, oxycodone and tramadol, and anti-anxiety drugs alprazolam and diazepam. Mays had suffered hip problems and was scheduled for hip-replacement surgery the day after he was found dead.
The Costs
Economic Costs

• $55.7 billion in costs for prescription drug abuse in 2007\(^1\)
  ➢ $24.7 billion in direct healthcare costs

• Opioid abusers generate, on average, annual direct health care costs 8.7 times higher than non-abusers\(^2\)


Addicted infants triple in a decade

3.4 out of 1,000 suffer painkiller withdrawal

By Liz Szabo
USA TODAY

The number of babies born addicted to the class of drugs that includes prescription painkillers has nearly tripled in the past decade, according to the first national study of its kind.

About 3.4 of every 1,000 infants born in a hospital in 2009 suffered from a type of drug withdrawal commonly seen in the babies of pregnant women who abuse narcotic pain medications, the study says. It's published today in The Journal of the American Medical Association.

Source: Journal of the American Medical Association

By Frank Pompa, USA TODAY
Economic Costs

• Maternal opioid dependence can affect birth costs

• A recent study showed in 2009, the average hospital stay for opioid exposed infants with neonatal abstinence syndrome (NAS) was 16 days\(^1\)

• The hospitalization cost of treating each baby with NAS averaged $53,400\(^2\)

• State Medicaid programs paid for 77.6% of these births\(^3\)

---

2. Ibid.
3. Ibid.
### National Poison Data System (Formerly known as Toxic Exposure Surveillance System) – Total Annual Mentions of Toxic Exposures

<table>
<thead>
<tr>
<th>Year</th>
<th>Hydrocodone</th>
<th>Oxycodone</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>15,191</td>
<td>9,480</td>
</tr>
<tr>
<td>2002</td>
<td>17,429</td>
<td>10,515</td>
</tr>
<tr>
<td>2003</td>
<td>19,578</td>
<td>11,254</td>
</tr>
<tr>
<td>2004</td>
<td>22,654</td>
<td>12,603</td>
</tr>
<tr>
<td>2005</td>
<td>22,229</td>
<td>13,191</td>
</tr>
<tr>
<td>2006</td>
<td>22,319</td>
<td>13,473</td>
</tr>
<tr>
<td>2007</td>
<td>24,558</td>
<td>15,069</td>
</tr>
<tr>
<td>2008</td>
<td>26,306</td>
<td>17,256</td>
</tr>
<tr>
<td>2009</td>
<td>27,753</td>
<td>18,396</td>
</tr>
<tr>
<td>2010</td>
<td>28,310</td>
<td>19,363</td>
</tr>
<tr>
<td>2011</td>
<td>30,792</td>
<td>19,423</td>
</tr>
</tbody>
</table>
• **Increase of 115%**: ER visits attributable to pharmaceuticals *(i.e., with no other type of drug or alcohol)* (626,472 to 1,345,645)

• No Significant Change: ER visits attributable to cocaine, heroin, marijuana, or methamphetamine

Source: CDC National Center for Health Statistics (NCHS) Data Brief, December 2011, updated with 2009 and 2010 mortality data
Drug-Induced Deaths vs. Other Injury Deaths (1999–2009)

Causes of death attributable to drugs include accidental or intentional poisonings by drugs and deaths from medical conditions resulting from chronic drug use. Drug-induced causes exclude accidents, homicides, and other causes indirectly related to drug use. Not all injury cause categories are mutually exclusive.

For every 1 unintentional opioid overdose death in 2010, there were...

- Abuse treatment admissions: 10
- ED visits for misuse or abuse: 28
- People with abuse/dependence: 108
- Nonmedical users: 733

Mortality figure is for unintentional overdose deaths due to opioid analgesics in 2010, from CDC/Wonder. Treatment admissions are for with a primary cause of synthetic opioid abuse in from TEDS. Emergency department (ED) visits related to opioid analgesics in from DAWN. Abuse/dependence and nonmedical use of pain relievers in the past month are from the National Survey on Drug Use and Health.
For Immediate Release
May 08, 2012.

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 450 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.

"Opioid overdoses 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 organizations that promote their drugs can put lives at risk. These painkillers have an important role in health care when prescribed and used properly, but pushing misleading information on consumers to boost profits is not only wrong, it's dangerous."

"The problem of opioid abuse is bad and getting worse," Grassley said. "Something has to change. A greater understanding of the extent to which drug makers underwater literature on opioids is a good start. Doctors and patients should know about the medical literature and groups that guide the drugs' use are paid for by the drug's manufacturers and if so, how much. Education on the proper use of pain medication is a key step in preventing abuse and misuse, so it's important to understand what medical information is out there."

The Centers for Disease Control and Prevention have declared overdoses from opioid painkillers to be a public health epidemic. Deaths from painkiller overdoses have tripled over the last decade and led to the deaths of 4,000 Americans in 2009, exceeding those caused by heroin and cocaine combined.
Now, Dr. Portenoy and other pain doctors who promoted the drugs say they erred by overstating the drugs’ benefits and glossing over risks. “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did,” Dr. Portenoy said in an interview with the Wall Street Journal. “We didn’t know then what we know now.”
WHAT PEOPLE ARE ABUSING
Commonly Abused Controlled Pharmaceuticals

- Hydrocodone
- OxyContin 80mg
- Oxymorphone
- Oxycodone 30 mg
- Alprazolam
- Carisoprodol
- Oxycodone 30 mg
- OxyContin 80mg
- Oxymorphone
- Hydrocodone
- Alprazolam

C-IV as of 1/11/2012
HYDROCODONE
Hydrocodone

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

- **Brand Names:** Vicodin®, Lortab®, Lorcet®

- **Street prices:** $2 to $10+ per tablet depending on strength & region
Top Five Prescription Drugs Sold in the U.S. (2006-2011)

(By Number of Prescriptions Sold)

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

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

Source: ARCOS
Date Prepared: 08/28/2012

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

Source: ARCOS
Date Prepared: 08/28/2012
The Trinity

Hydrocodone

Opiate

Carisoprodol

Muscle Relaxant

C-IV as of 1/11/2012

Alprazolam

Benzodiazepine

Alprazolam

Opiate
FDA Advisory Committee Votes in Favor of Hydrocodone Rescheduling

On January 25, 2013, the FDA’s Drug Safety and Risk Management Advisory Committee voted yes (19-10) to recommend rescheduling of hydrocodone from Schedule III to Schedule II.

4. (VOTING) Based on the background materials, presentations and the discussion above, do you recommend that hydrocodone combination products be rescheduled from schedule III to schedule II of the Controlled Substances Act (CSA)? Please explain the basis for your vote.

Yes: 19  No: 10  Abstain: 0  No Voting: 0

The committee members that voted yes stated that the pharmacology and epidemiology data shows no difference between the abusability of hydrocodone combination products and other schedule II products. They believed that current controls of these products are inadequate with regard to drug abuse; and that rescheduling is a first step in ushering in a new thought process, by prescribers and patients, about the use of hydrocodone combination products. Members also thought rescheduling would reduce the amount of drug product in circulation.

The committee members that voted no stated that the pharmacology and epidemiology data shows no difference between the abusability of hydrocodone combination products and other schedule II products. They believed that current controls of these products are inadequate with regard to drug abuse; and that rescheduling is a first step in ushering in a new thought process, by prescribers and patients, about the use of hydrocodone combination products. Members also thought rescheduling would reduce the amount of drug product in circulation.

Please see the transcript for details of the committee discussion.
FDA recommends stricter painkiller rules

FDA Recommends Hydrocodone Up-Scheduling

Source: www.newsday.com, October 24, 2013

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
FDA Approves Pure Hydrocodone Pain Killer

New narcotic pain pill Zohydro: Pure hydrocodone pain-killer approved by FDA

Zohydro, a pure hydrocodone pain pill, has just been approved for sale in the U.S. by the FDA. This pure hydrocodone pill will be classified as a Schedule II drug, much like Oxycontin and oxycodone, according to "Fox and Friends Weekend" on Sunday Oct. 27.

According to Bloomberg on Oct. 25, Hydrocodone is the narcotic pain medication found in pain pills like Vicodin.
Oxycodone

- OxyContin controlled release formulation of Schedule II oxycodone
  - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
  - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
  - 10, 15, 20, 30, 40, 60, 80mg available

- Effects:
  - Similar to morphine in effects and potential for abuse/dependence
  - Sold in “Cocktails” or the “Holy Trinity” (Oxycodone, Soma® / carisoprodol, Alprazolam / Xanax®)

- Street price: Approx. $80 per 80mg tablet

**NOTE:** New formulation introduced into the marketplace in 2010 that is more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.
Heroin (& Prescription Drugs)
Circle of Addiction & the Next Generation

- Hydrocodone (Lorcet®)
  - $5-$7/tab

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

- OxyContin®
  - $80/tab

- Heroin
  - $15/bag

- Roxicodone®
  - Oxycodone IR
  - 15mg, 30mg
  - $30-$40/tab
HEROIN: NO LONGER CONFINED TO URBAN AREAS

Heroin use spikes in area suburbs
Pill addicts risk deadly drug

Cooling down
60° - 34°
DETAILS P. 4

POLITICS
Stalemate on ‘cliff’
Sides stop talking;
Obama’s rate hikes
may be flexible. P. 13

LOCAL
FBI analyst busted
SACRAMENTO, Calif. - Heroin, a drug most often associated with the gritty back alleys of big cities, is making a surprising surge in suburban, affluent places.

Many new heroin addicts started as teens, abusing prescription painkillers they found in their homes, say law enforcement and public health officials.
HEROIN: NO LONGER CONFINED TO URBAN AREAS

Traffic in heroin, cocaine and other drugs in the District and Montgomery and Prince George’s counties.

About 4.2 percent of Maryland high school students reported trying heroin at least once in a 2011 statewide survey, up from 2.4 percent in 2007.

Former heroin addict Mike Gimbel has spent the past three decades working on substance abuse education and treatment in Maryland. He called the suburban heroin shift a “big-time trend” in the Washington area and elsewhere.

“Instead of waiting for the suburban kids to come into the city, the dealers have gone out to the suburbs,” he said. “It just blows away these parents in the middle-class communities — the last drug in the world they think their kids are going to use is heroin.”

The resurgence is tied to the booming market for prescription painkillers like OxyContin and Vicodin — experts say painkiller abusers often move on to heroin due to its availability and their craving for a stronger high.

Beth Kane Davidson, director of the Addiction Treatment Center at Suburban Hospital in Bethesda, said. “And then there were times when I thought I was living in hell.”

Dan Torsch died of a heroin overdose at age 24 in December 2010. Since then, his mother set up GRASP, an organization for grieving family members to connect after losing a loved one to substance abuse, along with a foundation in Dan’s name to help families pay for addiction treat-
Past Month & Year Heroin Use – Ages 12 or Older (2002 – 2012)

Figure 2.4 Past Month and Past Year Heroin Use among Persons Aged 12 or Older: 2002-2012

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

SOURCE: 2012 National Survey on Drug Use and Health (NSDUH) published September 2013 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)
Example: “Heroin a Growing Problem in St. George”

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

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

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

1SOURCE: Rick Egan, Salt Lake Tribune, October 8, 2010
METHADONE
Methadone History

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

- The Controlled Substances Act and corresponding regulations established strict rules for methadone clinics, or Narcotic Treatment Programs (NTPs).
Methadone- 5mg & 10mg

Methadone 40 mg

Mallinckrodt Pharmaceuticals 5 mg & 10mg
WHY IS IT ALSO USED AS AN ANALGESIC??????

Cheapest narcotic pain reliever – synthetic

Insurance companies

What’s the problem?
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 the 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 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.
Overdose...Why?

• Patients not taking the drug as directed
• Physicians not properly prescribing the drug
• Non-medical users ingesting with other substances
• Opiate naive
Overdose deaths
Prescription drugs take deadly toll in WV

An alarming new study has found that prescription drugs killed more people in West Virginia in 2017 than illegal drugs. According to the report, nine out of the 10 accidental overdose deaths reported in the Mountain State involved prescription drugs. Researchers in a joint state-federal study came to the troubling conclusion after studying 1,672 accidental overdose autopsies, excluding suicides and overdoses, the Associated Press reported.

The report found that one-third of the prescription drugs taken during the fatal incidents were being used as a result of a prescription issued by a doctor within the last 30 days. The report found fewer than one in four of the deaths involved illegal narcotics.

Arin Hall, a Centers for Disease Control Epidemic Intelligence Service Officer for the West Virginia Department of Health and Human Resources, said there is a perception among some citizens that just because narcotics are legal and prescribed drugs, they are somehow safer.

The report found that methadone contributed to one of three deaths, or more than any other prescription drug. However, the report found that only 10 of the overdose victims were enrolled in an opioid clinic for drug-abuse treatment.

The report found that other opioid drugs frequently linked to accidental overdose deaths included hydrocodone and oxycodone. The two narcotics contributed to one of five deaths. Morphine contributed to about one in seven deaths, the report found. Anti-anxiety drugs were found in 43 percent of the deaths.

While law enforcement officials have been fighting the illegal drug scourge in our region for years, accidental overdose deaths associated with the misuse of prescription narcotics now represents an emerging epidemic for the Mountain State.

The alarming new study from the West Virginia Department of Health and Human Resources should be viewed as a call to action for our community. We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.

We must act now to educate our community. If we fail to act, the number of accidental overdose deaths in the state and the region could continue to rise. It will take a combined effort of public education and law enforcement cooperation to reduce these alarming statistics.
editorials

Rising methadone deaths

Our view: Baltimore public health officials are trying to find out if treatment for chronic pain sufferers accounts for increase in methadone overdoses

The June letter from the Baltimore Health Department alerted physicians, nurses and other providers to a significant increase in methadone-related overdose deaths. The letter from Dr. Laura Herrera, a deputy city health commissioner, raised the possibility that the overdoses involved prescriptions for pain. It was a cautionary reminder that health care providers should educate their patients about the proper use of methadone and the lethal risks of taking extra doses.

Dr. Herrera was right to be concerned: Methadone overdose deaths of city residents have risen from seven in 1995 to 24 in 2007. In 2007, the last year for which statistics are available, there was a 23 percent increase in such deaths over the previous year. The city deaths coincide with a similarly disturbing fivefold increase in methadone-related deaths nationally between 1999 and 2005. But proving that the use of methadone as a pain reliever caused these deaths isn’t easy — no one tracks how many physicians prescribe methadone to relieve chronic pain from cancer or arthritis, for example.

Prescribing methadone has been an accepted form of treatment for chronic pain for some time, according to pain specialists at Johns Hopkins Hospital and the University of Maryland Medical Center. They add that they have seen no methadone-related deaths among their patients. Methadone used for pain treatment is prescribed in pill form; its risk stems from the drug’s potency and its lingering presence in the body once its pain-relieving function has ceased. An extra dose could slow down a patient’s breathing, resulting in coma or death.

To identify the extent of the problem and the patients most at risk, the city Health Department has reviewed data from the medical examiner’s office. It also has asked the quasi-public city agency that oversees drug treatment in Baltimore to cross-check methadone overdose victims against its patient rosters. That’s a critical aspect of the review because it could uncover misuse, abuse or diversion of methadone from drug treatment centers. Or it could lend credence to the prevailing view that more training is required for private physicians who prescribe methadone for pain.

At least 29 states have prescription monitoring programs that would identify indiscriminate prescribing, doctor-shopping and other abuses. A task force established this year in Maryland is studying the possibility of establishing a similar tracking system for methadone and other controlled substances.

Until then, Dr. Herrera and her colleagues at the Health Department have moved expeditiously and forthrightly to unravel this mystery. The results of their findings are the key to understanding and reversing this disturbing trend.
Opana ER (Oxymorphone)  
(Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming more popular and is abused in similar fashion to oxycodone
- Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
- Street: $10.00 – $80.00
Other Narcotics

Fentanyl

Hydromorphone

Meperidine

Morphine

Codeine

Propoxyphene
Benzodiazepines

- Alprazolam
- Clonazepam
- Diazepam
- Lorazepam
- Midazolam
- Triazolam
- Temazepam
- Flunitrazepam
ADHD Drugs: Ritalin® / Concerta® / Adderall®
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
ADHD Drugs

- 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.


Drug Enforcement Administration
Operations Division
Office of Diversion Control
Required Reading
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...make 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

(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:

Hyperactivity
(a) often fidgets with hands or feet or squirms in seat
(b) often leaves seat in classroom or in other situations in which remaining

Fidgets
Can’t remain seated
Restlessness
Difficulty awaiting turn
Often interrupts or intrudes

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.
Dextromethorphan (DXM)

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

- “Syrup and Soda”
- “Seven and Syrup”
- “Purple Drank”
On November 4, 2013, the U.S. Drug Enforcement Administration prepared a “Notice of Proposed Rulemaking” to schedule Tramadol into schedule IV. The notice was open for 60 days of public comment.

The proposed rule action is based on a recommendation from the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule IV controlled substance abuse (including distribution, dispensing, import, export, engendering or prescribing) activities, or permit or propose to handle controlled substances.

For more information, please refer to the Federal Register Vol. 78, No. 213, Monday, November 4, 2013 / Proposed Rules.
Tramadol Prescriptions

Source: IMS Health National Prescription Audit Plus downloaded 6/5/2012
THE CSA: CHECKS & BALANCES

U.S. Drug Enforcement Administration / Operations
Division / Office of Diversion Control
The CSA’s Closed System of Distribution

1,469,821 DEA Registrants
The CSA’s Closed System of Distribution

- Cyclic Investigations
- Established Schedules
- Record Keeping Requirements
- Registration
- Security Requirements
- Established Quotas
- ARCOS
• **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)
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))
What can happen when these checks and balances collapse?
Large-Scale Diversion

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

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

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

- In 2010, the average was – 1,261,908 d.u.
Large-Scale Diversion

➢ In 2011, the average purchase for all oxycodone products for all pharmacies in US – 74,706 d.u.

➢ In 2012, the average was – 73,434 d.u.

➢ In 2011, the average purchase for all oxycodone products for the top 100 pharmacies in Tennessee – 490,781 d.u.

➢ In 2012, the average was – 466,061 d.u.
WHERE PEOPLE ARE GETTING THEIR DRUGS
Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family...For Free!!
The Medicine Cabinet: The Problem of Easy Access
So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules
National Take Back Initiatives

Over 3.4 million pounds (1,733 tons) collected

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

Boxed, Sealed, Counted, Weighed, Consolidated, Secured, and Incinerated
Looking to the Future: The Secure and Responsible Drug Disposal Act of 2010

- On October 12, 2010, the President signed the “Secure and Responsible Drug Disposal Act of 2010.”

- This Act allows DEA to draft new regulations which permits ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion.
The Secure and Responsible Drug Disposal Act of 2010

As DEA worked to promulgate regulations to implement the Act, we have been required to consider:

- Public health and safety
- Ease and cost of program implementation
- Participation by various communities
- Diversion Control
Notice of Proposed Rulemaking for the Disposal of Controlled Substances

The NPRM on disposal was published in the Federal Register on December 21, 2012.

Open for a 60-day public comment period / Closed February 19, 2013.

The Final Rule will be published in the Federal Register upon completion.
Doctor Shopping
Doctor Shopping: What is it?

Practiced by both Individual “Patients Drug Seekers” & Trafficking Organizations

— Target Physicians
  • Obtain prescriptions from multiple physicians
  • Physicians who are willing to prescribe controlled substances over an extended period of time with little or no follow-up

— Target Pharmacies
  • Utilize multiple pharmacies to fill the orders to avoid suspicion
  • Pharmacies known to dispense controlled substances without asking questions are targeted
Doctor Shopping: What is it?

Prescriptions like candy

The story of a Duarte doctor makes it clear a lot can go wrong between the handcuffs and the prison time.

SANDY BANKS

We’re getting tough on drug dealers in Los Angeles these days, sweeping crack sellers off skid row streets, shutting down marijuana dispensaries, prosecuting doctors who peddle prescriptions like candy to patient addicts.

But the story of Dr. Daniel Healy makes it clear that a lot can go wrong between the handcuffs and the prison time.

Healy, according to prosecutors, is a most prolific drug dealer. In 2008 alone, he illegally distributed enough prescription drugs to constitute the federal government’s equivalent of more than 50 kilos of cocaine or 37,000 pounds of marijuana.

The Duarte physician ordered more Vicodin than any doctor in the nation – 1 million pills in 2008. That’s 10 times the stockpile of an average pharmacy; more than his local CVS, Wal-Mart, Target, and City of Hope pharmacies combined.

According to federal legal briefs, Healy made so many over-the-counter sales from his “Kind Care” medical clinic, the office had its own money-counting machine and Healy pocketed $5,000 to $6,000 a day. On the day he was arrested, police pulled over a ghetto street dealer with a wad of cash and pocketful of crack cocaine.

That guy would have received years in little as a sentence.

Healy, a physician, future convicted of his future.

According to prosecutors, Healy is a dealer.

The Duarte physician ordered more Vicodin than any doctor in the nation – 1 million pills in 2008. That’s 10 times the stockpile of an average pharmacy; more than his local CVS, Wal-Mart, Target, and City of Hope pharmacies combined.

Nearly 7 million Americans are abusing pharmaceutical drugs — up from 3.8 million 10 years ago, and more than the number addicted to cocaine, heroin and hallucinogens. Opioid painkillers — the kind Healy dispensed — cause more overdose deaths than cocaine and heroin combined.

Bilatent drug-dealing by doctors is rare. More common is doctor-shopping by patients, thefts from pharmacies, trading muscle relaxers, antidepressants and illicit street sales by drug dealers.

That’s why Healy’s sentence is so disappointing.

Here’s a chance to send a message to “well-meaning” doctors like Healy who might be tempted by easy money and to suffering patients who might not realize that the mild-mannered guy with the stethoscope might have more than their well-being in mind.

The Duarte physician ordered more Vicodin than any doctor in the nation – 1 million pills in 2008. That’s 10 times the stockpile of an average pharmacy; more than his local CVS, Wal-Mart, Target, and City of Hope pharmacies combined.
Dr. Paul H. Volkman was sentenced in the Southern District of Ohio on February 14, 2012 to four consecutive life sentences and ordered to forfeit $1.2 million. Volkman was convicted on 12 counts of illegal distribution of controlled substances, four of which resulted in a death; one count of conspiracy to distribute controlled substances; four counts of maintaining a drug premise; and one count of possession of a firearm in furtherance of a drug trafficking crime.

From 2003 to 2005, Volkman illegally distributed over 2.5 million dosage units of Schedule II drugs, primarily oxycodone, outside the course of professional practice which resulted in the death of four people. Of the approximate one million practitioner registrants in the United States in 2004, Volkman ranked first in purchases of oxycodone.
The operation of Nebraska's PDMP is currently being facilitated through the state’s Health Information Initiative. Participation by patients, physicians, and other health care providers is voluntary.

Potential Red Flags

many customers receiving the same combination of prescriptions

many customers receiving the same strength of controlled substances;

many customers paying cash for their prescriptions;

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.).
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

Domestic ‘Rx’ Flow
### Purchases of Hydrocodone by Known and Suspected Rogue Internet Pharmacies
#### January 1, 2006 – December 31, 2006

<table>
<thead>
<tr>
<th>Rank</th>
<th>County</th>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
<th>Total Purchases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33614</td>
<td>15,596,380</td>
</tr>
<tr>
<td>2</td>
<td>Pinellas</td>
<td>CLEARWATER</td>
<td>FLORIDA</td>
<td>33765</td>
<td>9,077,810</td>
</tr>
<tr>
<td>3</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33614</td>
<td>8,760,876</td>
</tr>
<tr>
<td>4</td>
<td>Baltimore City</td>
<td>BALTIMORE</td>
<td>MARYLAND</td>
<td>21213</td>
<td>5,876,300</td>
</tr>
<tr>
<td>5</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33619</td>
<td>5,718,200</td>
</tr>
<tr>
<td>6</td>
<td>Jefferson</td>
<td>RIVER RIDGE</td>
<td>LOUISIANA</td>
<td>70123</td>
<td>4,892,900</td>
</tr>
<tr>
<td>7</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33634</td>
<td>4,733,290</td>
</tr>
<tr>
<td>8</td>
<td>Polk</td>
<td>LAKELAND</td>
<td>FLORIDA</td>
<td>33813</td>
<td>4,564,480</td>
</tr>
<tr>
<td>9</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33612</td>
<td>4,220,840</td>
</tr>
<tr>
<td>10</td>
<td>Pinellas</td>
<td>CLEARWATER</td>
<td>FLORIDA</td>
<td>33759</td>
<td>3,819,320</td>
</tr>
<tr>
<td>11</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33610</td>
<td>3,044,160</td>
</tr>
<tr>
<td>12</td>
<td>Polk</td>
<td>LAKELAND</td>
<td>FLORIDA</td>
<td>33809</td>
<td>3,039,490</td>
</tr>
<tr>
<td>13</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33612</td>
<td>2,750,000</td>
</tr>
<tr>
<td>14</td>
<td>Polk</td>
<td>LAKELAND</td>
<td>FLORIDA</td>
<td>33813</td>
<td>2,664,120</td>
</tr>
<tr>
<td>15</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33612</td>
<td>1,902,900</td>
</tr>
<tr>
<td>16</td>
<td>Polk</td>
<td>LAKELAND</td>
<td>FLORIDA</td>
<td>33801</td>
<td>1,726,020</td>
</tr>
<tr>
<td>17</td>
<td>Pinellas</td>
<td>CLEARWATER</td>
<td>FLORIDA</td>
<td>33759</td>
<td>1,619,765</td>
</tr>
<tr>
<td>18</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33604</td>
<td>1,570,350</td>
</tr>
<tr>
<td>19</td>
<td>Pinellas</td>
<td>TARPON SPRINGS</td>
<td>FLORIDA</td>
<td>33689</td>
<td>1,464,900</td>
</tr>
<tr>
<td>20</td>
<td>Lincoln</td>
<td>DENVER</td>
<td>NORTH CAROLINA</td>
<td>80037</td>
<td>1,402,450</td>
</tr>
<tr>
<td>21</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33617</td>
<td>1,282,800</td>
</tr>
<tr>
<td>22</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33619</td>
<td>1,272,860</td>
</tr>
<tr>
<td>23</td>
<td>Polk</td>
<td>LAKELAND</td>
<td>FLORIDA</td>
<td>33813</td>
<td>1,039,400</td>
</tr>
<tr>
<td>24</td>
<td>Pasco</td>
<td>WESLEY CHAPEL</td>
<td>FLORIDA</td>
<td>33543</td>
<td>1,030,050</td>
</tr>
<tr>
<td>25</td>
<td>Iredell</td>
<td>MOORESVILLE</td>
<td>NORTH CAROLINA</td>
<td>28117</td>
<td>902,500</td>
</tr>
<tr>
<td>26</td>
<td>Polk</td>
<td>LAKELAND</td>
<td>FLORIDA</td>
<td>33815</td>
<td>867,800</td>
</tr>
<tr>
<td>27</td>
<td>Broward</td>
<td>HOLLYWOOD</td>
<td>FLORIDA</td>
<td>33021</td>
<td>865,700</td>
</tr>
<tr>
<td>28</td>
<td>Los Angeles</td>
<td>ENCINO</td>
<td>CALIFORNIA</td>
<td>91436</td>
<td>798,100</td>
</tr>
<tr>
<td>29</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33604</td>
<td>793,350</td>
</tr>
<tr>
<td>30</td>
<td>Pasco</td>
<td>NEW PORT RICHEY</td>
<td>FLORIDA</td>
<td>34652</td>
<td>583,400</td>
</tr>
<tr>
<td>31</td>
<td>Ravalli</td>
<td>FLORENCE</td>
<td>MONTANA</td>
<td>59833</td>
<td>362,000</td>
</tr>
<tr>
<td>32</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33619</td>
<td>162,000</td>
</tr>
<tr>
<td>33</td>
<td>Broward</td>
<td>DEERFIELD BEACH</td>
<td>FLORIDA</td>
<td>33441</td>
<td>112,600</td>
</tr>
<tr>
<td>34</td>
<td>Hillsborough</td>
<td>TAMPA</td>
<td>FLORIDA</td>
<td>33614</td>
<td>49,600</td>
</tr>
</tbody>
</table>

**Total Purchases:** 98,566,711

**Date Prepared:** 03/07/2007 **Source:** ARCOS
One Internet Case Example
Minneapolis, Minnesota
Total Forfeiture:

$4,370,258.80
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)
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

## Total Population: 1,500,245

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Practitioner</td>
<td>1,168,919</td>
</tr>
<tr>
<td>Mid-Level Practitioner</td>
<td>232,136</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>68,907</td>
</tr>
<tr>
<td>Hospital/Clinic</td>
<td>15,921</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>545</td>
</tr>
<tr>
<td>Distributor</td>
<td>959</td>
</tr>
<tr>
<td>Researcher</td>
<td>7,164</td>
</tr>
<tr>
<td>Analytical Labs</td>
<td>1,525</td>
</tr>
<tr>
<td>NTP</td>
<td>1,319</td>
</tr>
<tr>
<td>ADS Machine</td>
<td>564</td>
</tr>
</tbody>
</table>

as of 07/31/2013
What took the place of internet controlled substance distribution?

Where did it all go?
Normal Practitioner / Patient Relationship

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)
The Florida “Migration”: Was this Normal??

Vast majority of the “patients” visiting Florida “pain clinics” came from out-of-state:

- Georgia
- Kentucky
- Tennessee
- Ohio
- Massachusetts
- New Jersey
- North and South Carolina
- Virginia
- West Virginia
THE MIGRATION

Mayo Clinic of Jacksonville

(FLA) (MIAMI)
“short waits or we will pay you”

“earn $$$ for patient referrals” (sic)
When you get in, make sure you follow the Instructions!!
All the Instructions

PLEASE HAVE EXACT CHANGE

CASH ONLY

NO CREDIT CARDS OR CHECKS ALLOWED.

SORRY FOR THE INCONVIENCE
All of your weapons！！！！！！
Including the knives !!!!
Finally, get your script (s) !!
Make sure you pack them properly for the trip home (which is often out of state)!
**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>
</tbody>
</table>
Average Charges for a Clinic Visit

• Price varies if medication is dispensed or if customers receive prescriptions

• Some clinics advertise in alternative newspapers citing discounts for new patients such as 'buy one get one free' or “50% off with this ad”

• Typically, initial office visit is $250; each subsequent visit is $150 to $200

• Average 120-180 30mg oxycodone tablets per visit
Cost of Drugs

- The ‘cocktail’ prescriptions go for $650 to $1,000
- According to medical experts, most clinics do not require sufficient medical history and tests for proper prescribing of Schedule II substances
- Each oxycodone 30mg tablet costs $1.75 to $2.50 at the clinics
  - On the street in Florida, that pill can be re-sold for $7 to $15
  - Outside of Florida, it can be re-sold for $25 to $30 ($1 per mg)
Explosion of South Florida Pain Clinics

![Bar chart showing the estimated number of pain clinics in Broward County from 2007 to 2009.](#)

As of June 4, 2010, Florida has received 1,118 applications and has approved 1,026.

*As of May 14, 2010, Broward 142; Miami-Dade 79; Palm Beach 111*
Explosion of South Florida Pain Clinics – All Providers (Current and Closed)

- All/State of Florida: 1,501
- Broward County: 236
- Miami-Dade County: 156
- Palm Beach County: 161
- Hillsborough County (Tampa area): 214

As of February 12, 2013.
**PHYSICIAN NEEDED, START IMMEDIATELY**
(WEST PALM BEACH, FLORIDA)

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

**PHYSICIAN NEEDED, START IMMEDIATELY**
M.D. / D.O. FOR CONTINUING CARE / PAIN MANAGEMENT CENTER

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

---

DOCTOR'S NEEDED (MIAMI)

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

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

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

- One case in Florida owner/operator of pain clinic allegedly generated $40 million in drug proceeds
- Houston investigation $41.5 million in assets
Another case in Florida - pain clinic operation paid his doctors:

- $861,550
- $989,975
- $1,031,975
- $1,049,032
- $1,225,775
State of Florida Legislative Actions

• Effective October 1, 2010
  – Pain clinics are banned from advertising that they sell narcotics
  – They can only dispense 72-hour supply of narcotics
  – Prohibits the registration of pain clinics unless they are owned by physicians or licensed by non-physicians as a health care clinic

• Effective July 1, 2011
  – Clinics must turn over their supply of C-II and C-III controlled substances
  – Clinics are no longer able to dispense these drugs
  – Clinics cannot have ANY affiliation with a doctor that has lost a DEA number
Agents Raid Florida Clinics in Drug Crackdown
By DON VAN NATTA Jr.
MIAMI — Drug Enforcement Administration agents and other law enforcement officials on Wednesday raided six South Florida pain clinics accused of illegally dispensing potent prescription drugs across the United States. Twenty-two people, including doctors, were arrested on charges of racketeering and trafficking charges.

11 arrested in Palm Beach County as part of multi-agency pill mill raid
In Palm Beach County, the raids focused on five doctors in four pain clinics.
By CYNTHIA ROLDAN AND MICHAEL LAFORGIA
Palm Beach Post Staff Writers
Updated: 11:20 a.m. Thursday, Feb. 24, 2011
Posted: 9:57 a.m. Wednesday, Feb. 23, 2011
Operators of four crooked pain clinics in Palm Beach County made millions of dollars by peddling pills to patients with trumped up injuries, rewarding themselves with boats, exotic cars and real estate while rates of overdose deaths and drug-dealing soared, state prosecutors alleged in court documents made public Wednesday.
Clinic response to Enforcement Actions & the Florida legislation prohibiting the sale of CS from pain clinics?

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

"Traffickers adapt to situations," says Mark Trouville, Special Agent in charge of the Drug Enforcement Administration’s field offices in Florida. "We knew once we put pressure on the pill mills, the wrong people would start opening pharmacies.

Drug dealers are finding ways around new laws that have put restrictions on "pill mills" dispensing painkillers such as oxycodone. In Florida, hundreds of patients and doctors connected to pill mills have been arrested. Many turned to the aviation industry to get their supplies, Trouville says. The DEA can't connect a drug-related death to a pharmacy but can to a health and safety issue, Trouville says.

"They're not selling it as aspirin," Trouville says. "They're not selling it without airtight label and prescription."

"We knew once we put pressure on the pill mills, the wrong people would start opening pharmacies," Trouville says.
Georgia Example: Traditional Pain Management Clinics

Years prior to 2009-2010: 15-20 legitimate clinics

- Almost all owned by Physicians
- Accept insurance, Medicaid, Medicare, etc.
- Patients need appointments
- Follow pain management guidelines
- Patients get a complete physical workup & exam
- Use physical therapy, other treatment methods
- Prescribed drugs usually include non-narcotics
Now approximately 125 rogue clinics

~110-115

~10-15
Georgia Pain Pill Clinics

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

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

Manufacturers
DEA Registrants who are authorized to produce and distribute controlled substances.
(1330 firms including all manufacturers and wholesale distributors)

Wholesale Distributors
DEA Registrants who are authorized to distribute controlled substances.

Drug Seekers

Re-packagers/Re-labelers
DEA Registrants who are authorized to package bulk dosage units into consumer-use size packagers and distribute to pharmacies.

Brick and Mortar Pharmacies
DEA Registrants who are authorized to dispense controlled substances to individual customers.
(66,000 registered pharmacies)

Drugs Dispensed.

Practitioners
DEA Registered doctors, nurse practitioners, PAs etc., who are authorized to issue prescriptions for controlled substances

Prescription Issued to Drug Seeker
Cutting off the Source of Supply
First Prong: Increased Enforcement Efforts

- Currently 58 operational Tactical Diversion Squads (TDS) throughout the United States (66 total approved).

- These TDS enforcement groups incorporate the skill sets of DEA Special Agents, Diversion Investigators, other federal law enforcement, and state and local Task Force Officers.
Second Prong: Renewed Focus on Regulatory Oversight

- Increased regulatory efforts throughout the U.S. (to include increases in frequency of inspections)
- Investigating/Inspecting all new and renewal pharmacy applications submitted in Florida.
- Investigating/Inspecting existing pharmacies registrations
We will not arrest our way out of this problem!!!!!!

• Enforcement is just as important as....
• Prevention/Education
• Treatment
Prescription Drug Abuse
Prevention Plan

• Coordinated effort across the Federal government

• Four focus areas
  1) Education
  2) Prescription Drug Monitoring Programs
  3) Proper Medication Disposal
  4) Enforcement
DEA Web-based Resources

www.JustThinkTwice.com
Thank You / Questions
Synthetic Drug Trafficking & Abuse Trends

November 16-17, 2013
Pharmacy Diversion Awareness Conference (PDAC)
Louisville, KY

Alan G. Santos, Associate Deputy Assistant Administrator,
Operations Division, Office of Diversion Control,
U.S. Drug Enforcement Administration
Outline

Designer Synthetic Drugs: Defining What They Are
- Synthetic Cannabinoids
- Synthetic Cathinones
- Other Synthetic Compounds

Scope of the Problem
- Global Overview of Threat
- U.S. Overview & Experience

Control Efforts: Using All the “Tools Available
- State
- Federal
- International
Designer Drugs: A Tough Problem

Targeting emerging psychoactive designer synthetic drugs [i.e. synthetic cannabinoids (the synthetic marijuana compounds), synthetic cathinones (the synthetic stimulants), and other emerging synthetic compounds] is a priority for DEA.

But it’s a tough public health & safety challenge!
Designer Synthetic Drugs: Defining What They Are
Designer Drugs have rapidly emerged as “legal” alternatives to internationally controlled drugs (such as marijuana, cocaine, methamphetamine, & MDMA) causing similar effects, with the potential to pose serious risks to public health and safety.
Where did they come from?

A highly regarded Medicinal Chemist Dr. F. Ivy Carroll and colleagues stated in a recent publication:

*Throughout the drug discovery process, pharmaceutical companies, academic institutions, research institutions, and other organizations publish their studies in scientific journals, books, and patents. This information exchange, which is essential to the legitimate scientific enterprise, can be, and is, used by clandestine chemists who duplicate the technical sophistication used by the research community to manufacture and market a seemingly endless variety of analogs of so-called designer drugs.*
Where did they come from?

- Substances rejected due to poor therapeutic potential
- Scientific literature excavated to identify substances
- No industrial or medical use for these substances
- Often characterized as being “research compounds” (the only research being undertaken is to determine their abuse potential for sale to consumer market)
Proliferation of Designer Drugs

- Increasingly popular among recreational drug users
- Internet sales
- Head shops/Smoke shops
- Promoted by discussion boards – self studies

Armed with medical research and fueled by Chinese factories and YouTube, a band of outlaws has created a dangerous multibillion-dollar industry.
Synthetic Cannabinoids
Synthetic Cannabinoids

- A “cannabinoid” is a class of chemical compounds in the marijuana plant that are structurally related.

- “Synthetic cannabinoids” are a large family of chemically unrelated structures functionally (biologically) similar to THC, the active principle of marijuana.

- They may have less, equivalent or more pharmacologic (psychoactive) activity than THC.
Synthetic Cannabinoids

- Synthetic Cannabinoids are sold in retail stores, on the internet, and in "head shops" as "Herbal Incense" or "Potpourri"

- Smoked alone or as a component of herbal products

- Abusers report a potent cannabis-like effect
## Adverse Health Effects

Multiple deaths have been connected to the abuse of these substances alone and with other substances on-board.

<table>
<thead>
<tr>
<th>Category</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological</td>
<td>Anxiety, aggressive behavior, agitation, confusion, dysphoria, paranoia, agitation, irritation, panic attacks, intense hallucinations</td>
</tr>
<tr>
<td>Neurological</td>
<td>Seizures, loss of consciousness</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Tachycardia, hypertension, chest pain, cardiac ischemia</td>
</tr>
<tr>
<td>Metabolic</td>
<td>Hypokalemia, hyperglycemia</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Nausea, vomiting</td>
</tr>
<tr>
<td>Autonomic</td>
<td>Fever, mydriasis</td>
</tr>
<tr>
<td>Other</td>
<td>Conjunctivitis</td>
</tr>
</tbody>
</table>
Synthetic Cannabinoids

- Unregulated and unlicensed industry (many manufacturers)
- Full disclosure of ingredients typically not present
- Batch to batch variance (i.e., “Hot Spots”)

Contains a proprietary blend of herbs and extract including:
Cannabis sativa leaves, Cannabis sativa stems, and Pteris spinulosa
Synthetic Cannabinoids, by State, 2012

Source: NFLIS
Synthetic Cathinones
Synthetic Cathinones

- Structurally and pharmacologically similar to amphetamine, Ecstasy (MDMA), cathinone, and other related substances.

- Are central nervous system (CNS) stimulants and have stimulant and psychoactive properties similar to schedule I and II amphetamine type stimulants.

- Synthetic cathinones are sold in retail stores, on the internet, and in “head shops” as “bath salts”, “plant food”, or “jewelry cleaner”
### Adverse Health Effects

**Synthetic cathinone** users commonly report cardiac, psychiatric, and neurological signs and symptoms with death.

<table>
<thead>
<tr>
<th>Cardiovascular</th>
<th>palpitations, tachycardia, chest pain, vasoconstriction, myocardial infarction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychological</td>
<td>Aggressive behavior, anger, anxiety, agitation, auditory and visual hallucinations, depression, dysphoria, empathy, euphoria, fatigue, formication, increased energy, concentration, panic attacks, paranoia, perceptual disorders, restlessness, self-mutilation, suicidal ideation</td>
</tr>
<tr>
<td>Neurological</td>
<td>Seizures, tremor, dizziness, memory loss, cerebral edema, headache, lightheadedness</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>Arthralgia, extremity changes (coldness, discoloration, numbness, tingling), muscular tension, cramping</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>Abdominal pain, anorexia, nausea, vomiting</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Shortness of breath</td>
</tr>
<tr>
<td>Ear Nose Throat</td>
<td>Dry mouth, nasal pain, tinnitus</td>
</tr>
</tbody>
</table>
Synthetic Cathinones

- Like the cannabinoids, unregulated and unlicensed industry (many manufacturers)
- Full disclosure of ingredients typically not present
- Significant batch to batch variances (i.e., “Hot Spots”)
Synthetic Cathinones, by State, 2010

Source: NFLIS
Synthetic Cathinones, by State, 2011
Synthetic Cathinones, by State, 2012

Source: NFLIS
Dance drug molly now linked to FOURTH overdose as police fear killer tainted batch has spread throughout East Coast

- Mary 'Shelley' Goldsmith, 19, died August 31 at one of Washington, DC's largest nightclubs
- While toxicology results are pending, the honors student's father admits Shelley was likely on 'molly,' a term for MDMA or ecstasy
- Olivia Rotondo, 20, and Jeffrey Russ, 23, died at New York City's Electric Zoo dance party after taking the drug
- Brittany Flannigan, 19, from New Hampshire, died August 28 after apparently overdosing on MDMA at a Boston concert
What is “Molly”?

- “Molly” – a synthetic designer drug
  - Originally - a street name for pure MDMA (Ecstasy)
  - Currently - a street name for a drug, that has the same effects as MDMA
Phenethylamines

- Are a class of substances with documented psychoactive and stimulant effects / Includes the ‘2C series’ compounds / Abused orally and encountered on “blotter paper” and in “dropper bottles” / Possibly mistaken for LSD / Linked to deaths
2C-Phenethylamine Reports, by State, 2010

Source: NFLIS
2C-Phenethylamine Reports, by State, 2011

Source: NFLIS
2C-Phenethylamine Reports, by State, 2012

Source: NFLIS
Piperizines

- Have hallucinogenic properties as well as often being referred to as amphetamine-like / Tableted and frequently sold as ‘ecstasy’ (BZP-TFMPP combination abused to mimic the effects)
Methoxamine (MXE)

- Dissociative (mind altering effects) and depression of pain
- Effects similar to PCP
- Encountered on designer drug market
- International increase in ketamine abuse
- Deaths attributed to the substance
Problems with All Synthetic / Designer Drugs

- Marketed to teens and young adults
- Easily attainable in retail environments and via the internet
- Unknown ingredient(s)
- No consistency in manufacturing process
- Not tested for human consumption / Unknown short & long term effects!!
- No known dosage – not FDA approved
- Synergistic effects likely when mixed with other drugs or alcohol

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
Scope of the Problem
A global problem that constitutes a significant public health threat to many nations !!!
Of the nations surveyed, 87 % (70 out of 80) indicate that NPS are available in their respective drug markets.

Source: UNODC questionnaire on NPS, 2012
Global Synthetic Drug Use
A total of 251 NPS (including ketamine) were reported to UNODC by 40 countries and territories up to 2012.
At the global level, most reports pertaining to NPS concern synthetic cathinones, with 684 reports, followed by synthetic cannabinoids with 665 reports.
### Trend of NPS Seizures (2009 – 2012)

<table>
<thead>
<tr>
<th>NPS group</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synthetic cannabinoids</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
</tr>
<tr>
<td>Synthetic cathinones</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
<td>⇔</td>
</tr>
<tr>
<td>Ketamine</td>
<td>⇔</td>
<td>⇔</td>
<td>⇔</td>
<td>⇔</td>
</tr>
<tr>
<td>Phenethylamines</td>
<td>⇔</td>
<td>↑</td>
<td>⇔</td>
<td>⇔</td>
</tr>
<tr>
<td>Piperazines</td>
<td>↑</td>
<td>⇔</td>
<td>⇔</td>
<td>⇔</td>
</tr>
<tr>
<td>Plant-based substances</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
<td>⇔</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>-</td>
<td>↑</td>
<td>↑</td>
<td>↑</td>
</tr>
</tbody>
</table>

↑: Increasing, ↓: Decreasing, ⇔: Stable, -: unknown

Source: UNODC questionnaire on NPS, 2012 and ARQ

**Trends for the seven NPS groups fluctuate.**

Seizures of ketamine, phenethylamines and piperazines stable

Rising trends for synthetic cannabinoids, cathinones, and plant-based substances
NPS Trafficking Modes

The mode of trafficking named by most respondents was trafficking by air (30 countries) followed by trafficking by mail (24 countries), without any regional variations.
U. S. Overview & Experience

Source: data from the MTF Survey 2010-2011
Base: 12th graders %
Question on synthetic cannabinoids was introduced in 2011 for the first time
Identified Synthetic Compounds in the U.S.

As of October 15, 2013, the U.S. has encountered:

- 99 synthetic cannabinoids
- 52 synthetic cathinones
- 89 other compounds (2C compounds, tryptamines, piperazines, etc.)

240 Compounds and Counting !!!!!
‘Spice’ makers alter recipes to sidestep state laws banning synthetic marijuana

Rob Ostermaier/Daily Press - Police show what they suspect is “spice,” confiscated during a raid on Outer Edge Gifts in Hampton, Va., on April 5.
Calls to U.S. Poison Control Centers

American Association of Poison Control Centers (AAPCC) Reporting

Calls to poison control centers for exposures to synthetic marijuana (synthetic cannabinoids)

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control

*As of August 31, 2013
Calls to U.S. Poison Control Centers

American Association of Poison Control Centers (AAPCC) Reporting

Calls to poison control centers for exposures to bath salts (synthetic cathinones)

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control

*As of August 31, 2013
Public Safety Concerns

- Driving Under the Influence of Drugs (DUIDs) with fatalities
- Suicides
- Homicide-Suicide
- Overdoses
  - Emergency Department visits
  - First Responders
- Drugs abused to evade drug screens
  - 30-35% of juveniles in drug court tested positive
  - Individuals subjected to routine drug screens
    - Probationer / parolees
Bangor Daily News

Bangor man on bath salts carried assault-style rifle through city, police say

By Nok-Noi Ricker, BDN Staff
Posted July 27, 2011, at 12:50 p.m.

BANGOR, Maine — Police said they were called to Walter Street on Tuesday night to deal with a man acting erratically who reportedly had consumed the synthetic drug bath salts and took off carrying an assault-style rifle.

The man later was picked up carrying ammunition and showed police where he had stashed an M4 rifle wrapped in a blanket. Police, who did not identify the 31-year-old man or arrest him after questioning, said he may face charges.

The man’s ex-girlfriend told police at about 7:30 p.m. Tuesday that he had used bath salts and was “stating that people were coming out of his mattress,”

when Bangor police, who had been called to Walter Street at about 7 p.m. on Tuesday, went into the man’s apartment, Police searched the Walter Street apartment and surrounding areas.

Police found the man on Buck Street a few minutes later. “When questioned about the rifle, the suspect gave up a location on Buck Street where he stated that the rifle was hidden in a shack,” Edwards said. Officers quickly found the location and did in fact find an M4 rifle in two pieces wrapped in a blanket. A subsequent search of the suspect’s backpack netted a full magazine and 18 separate rounds of .223 [caliber] ammunition.

He did not tell police why he removed the gun from his apartment or what his plan was, the sergeant said, adding, “we did confiscate the gun.”

A local agent of the federal Bureau of Alcohol, Tobacco, Firearms and Explosives was called and, along with Bangor police, interviewed the suspect.

The man was released Tuesday evening. The case is being reviewed for possible state and-or federal charges, Edwards said.
First Responder Encounters

➢ Altered mental status presents as severe panic attacks, agitation, paranoia, hallucinations, and violent behavior (e.g., self-mutilation, suicide attempts, and homicidal activity). (Spiller et al., Clinical Toxicology 2011)

  – climbing into the attic of the home with a gun to kill demons that were hiding
  – breaking all the windows in a house and wandering barefoot through the broken glass
  – jumping out of a window to flee from non-existent pursuers; requiring electrical shock (Taser) and eight responders to initially subdue the patient
  – repeatedly firing guns out of the house windows at “strangers” who were not there

➢ Bath salts use tied to three Bangor (Maine) deaths. (Richter, JEMS 2012)

➢ Bath salt abuse: new designer drug keeps EMS crews busy nationwide. (Nevin, JEMS 2011)
First Responders (Cont.)

Drug Endangered Children:

- Leaving a **2-year-old daughter** in the middle of a highway because she had demons (Spiller et al., *Clinical Toxicology* 2011)

- A drug-intoxicated couple hallucinated they were being burglarized, began shooting into walls. Officers found weapons in every room, and a paranoid parent huddled inside the bathroom with **two young children** and a loaded .357 Magnum (Macher, *American Jails* 2011)

- Northeast PA, couple charged with multiple offenses for stabbing at “90-people living in their walls” with **5-year old present** (*Times-Leader.com*, Mar 21, 2011)
Synthetic Drug “Manufacturing Facility”?
Ready to Ship...
Control Efforts: Using all the “Tools” Available
Synthetic Drugs: U.S. State Controls

- Legislation
- Department of Health
- Pharmacy Board
- Consumer Affairs Dept.
U.S. Federal Scheduling & Rescheduling Procedures

Placement of a substance into one of the U.S. Federal Controlled Substance Act (CSA) schedules can be done by statute or through the administrative process.

- **Statute:** Congress may designate a substance a controlled substance or reschedule a drug within the scheduling hierarchy by passing legislation. This, by far, is the easiest method in which to add, remove or transfer a substance between schedules.

- **Administrative Process:** The Attorney General, by rule, (using his administrative authority) to add, remove or transfer a substance between schedules. *The legal definition of control, “…means to add a drug or other substance, or immediate precursor, to a schedule…whether by transfer of another schedule or otherwise”*. 21 USC 802(5)
Federal Temporary Scheduling

- Because of the lack of effective legislative controls to combat the synthetic problem early on, federally we looked to temporary scheduling as a solution.

- Requires an AG finding (delegated down to DEA) that the scheduling of a substance in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety.

- ...and the substance is not listed in any other schedule in Section 21 USC 812 or no exemption or approval is in effect under the FDCA.
Federal Temporary Scheduling
(Comprehensive Crime Control Act of 1984)

As set forth under 21 U.S.C 811(h), three factors (4, 5 & 6) under the CSA (21 U.S.C. 811(c)) are to be considered in the evaluation:

1. Its actual or relative potential for abuse
2. Scientific evidence of its pharmacological effects
3. The state of current scientific knowledge regarding the substance
4. Its history and current pattern of abuse
5. The scope, duration, and significance of abuse
6. What, if any, risk there is to the public health
7. Its psychic or physiological dependence liability
8. Whether the substance is an immediate precursor of a substance already controlled
DEA collects information from law enforcement and public health officials regarding encounters and evaluates this information relative to the three factors required for temporary scheduling.

Once sufficient information has been collected, a letter is transmitted from DEA to the U.S. Department of Health & Human Services (DHHS) to communicate intention to temporary schedule [and to verify no active new drug applications (NDAs) or investigations drug applications (INDs) for the proposed substances filed].
Federal Temporary Scheduling Process

- DEA letter of intent to DHHS, solicits a comment to control these substances within 30 days. Based on the DHHS response, a “Notice of Intent” can be published in the U.S. Federal Register with a “Final Order” published at minimum 30-days after the “Notice of Intent”.

- As there is no “comment period” provided for temporary scheduling, civil and criminal sanctions applicable to the manufacture, possession, importation, and exportation are effective upon publication of the “Final Order”.

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
U.S. Federal Temporary Scheduling

Actions to Date Relative to Synthetic Drugs

---

**Background Information and Evaluation of Three Factor Analysis (Factors 4, 5 and 6) for Temporary Scheduling**

**Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20552**

**April 2005**

**Introduction**

Since 2008, there has been a marked increase in the law enforcement encounters of various synthetic stimulants of the United States. Both law enforcement and public health reports suggest the sustained popularity of these substances in the designer drug market, most commonly abused as plant material adulterants. These associated products are often being sold as incense and labeled “not for human consumption.” Additionally, these products are marketed as a “legal high” or “legal alternative to marijuana” and are readily available over the internet, in head shops, or sold in convenience stores.

These substances have no accepted medical use in the United States and have been reported to produce adverse effects in humans. Chronic abuse of synthetic cathinones in general has been linked to adverse health effects, including signs of addiction and withdrawal (Zimmermann et al., 2009; Muller et al., 2010), as well as numerous reports of emergency room admissions resulting from their abuse (Forrester et al., 2011; Perrens-Clausen et al., 2012; SAVINSA, 2012).

---

**Table 1**

<table>
<thead>
<tr>
<th>Compound</th>
<th>CAS Registry Number</th>
<th>Formula</th>
<th>Molecular Weight</th>
<th>Synthetic Cathinones</th>
</tr>
</thead>
<tbody>
<tr>
<td>M-PPP</td>
<td>90249-27-6</td>
<td>C15H11NO2</td>
<td>241.23</td>
<td>Yes</td>
</tr>
<tr>
<td>2,3-MPPP</td>
<td>90249-28-7</td>
<td>C15H11NO2</td>
<td>241.23</td>
<td>Yes</td>
</tr>
<tr>
<td>2,3,3-MPPP</td>
<td>90249-29-8</td>
<td>C15H11NO2</td>
<td>241.23</td>
<td>Yes</td>
</tr>
</tbody>
</table>

---

**Suggested Readings**

For a more detailed analysis of the synthetic cathinones and their effects, refer to the following sources:

U.S. Federal Temporary Scheduling Actions Relative to Synthetic Drugs

To date, 8 Synthetic Cannabinoids, 3 Synthetic Cathinone, and 3 Phenethylamine Compounds have been controlled or in the process of being controlled:

- 5 Cannabinoid Compounds (March 2011 Final Order)
- 3 Cathinone Compounds (October 2011 Final Order)
- 3 Cannabinoid Compounds (May 2013 Final Order)
- 3 Phenethylamine Compounds [i.e. “NBOMe” products (October 2013 Notice of Intent)]
On July 9, 2012, the President signed the Synthetic Drug Abuse Prevention Act of 2012 (Public Law 112-144)

- The law controlled 26 compounds into schedule I
Defined the term “Cannabimimetic Agent” [any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist].

Extends the maximum time that DEA may temporarily control a substance.

Initial time period for temporary scheduling increased from 12 to 24 months / Extension period increased from 6 months to 12 months.
### U.S. Synthetic Drug Abuse and Prevention Act 2012

#### Cannabinoids

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AM2201</td>
</tr>
<tr>
<td>2</td>
<td>AM694</td>
</tr>
<tr>
<td>3</td>
<td>CP-47,497</td>
</tr>
<tr>
<td>4</td>
<td>CP-47,497 – C8 homologue</td>
</tr>
<tr>
<td>5</td>
<td>JWH-018</td>
</tr>
<tr>
<td>6</td>
<td>JWH-073</td>
</tr>
<tr>
<td>7</td>
<td>JWH-081</td>
</tr>
<tr>
<td>8</td>
<td>JWH-200</td>
</tr>
<tr>
<td>9</td>
<td>JWH-019</td>
</tr>
<tr>
<td>10</td>
<td>JWH-250</td>
</tr>
<tr>
<td>11</td>
<td>JWH-122</td>
</tr>
<tr>
<td>12</td>
<td>JWH-203</td>
</tr>
<tr>
<td>13</td>
<td>JWH-398</td>
</tr>
<tr>
<td>14</td>
<td>SR-19</td>
</tr>
<tr>
<td>15</td>
<td>SR-18</td>
</tr>
</tbody>
</table>

#### Cathinones

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mephedrone</td>
</tr>
<tr>
<td>2</td>
<td>MDPV</td>
</tr>
</tbody>
</table>

#### Phenethylamines

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2C–E</td>
</tr>
<tr>
<td>2</td>
<td>2C–D</td>
</tr>
<tr>
<td>3</td>
<td>2C–C</td>
</tr>
<tr>
<td>4</td>
<td>2C–I</td>
</tr>
<tr>
<td>5</td>
<td>2C–T–2</td>
</tr>
<tr>
<td>6</td>
<td>2C–T–4</td>
</tr>
<tr>
<td>7</td>
<td>2C–H</td>
</tr>
<tr>
<td>8</td>
<td>2C–N</td>
</tr>
<tr>
<td>9</td>
<td>2C–P</td>
</tr>
</tbody>
</table>
The Way Forward on the International Front

- Working to identify major foreign based sources

- Working to sensitize partner nations regarding the threat and the need for international controls

- Continue to work bilaterally and with international partners to look at coordinating global outreach and cooperation
Enhancing International Cooperation in the Identification & Reporting of NPS

(E/CN.7/2013/L.2/ March 2013)
The Way Forward on the International Front / CND Resolutions

Major Tenants of Resolution:

- Encourages nations to take a comprehensive and coordinated approach to the detection, analysis, and identification of NPS

- Urges nations to share with one another information on the identification of NPS using, where appropriate, existing national and regional early warning systems and networks

- Urges nations to include information on the potential adverse impacts and risks to public health and safety of new psychoactive substances through prevention & awareness to counter public perceptions on NPS
The Way Forward on the International Front / CND Resolutions

Major Tenants of Resolution (Continued):

- Encourages nations, and relevant international institutions, to share and exchange ideas, best practices, and experiences regarding new laws, regulations and restrictions, to attack the NPS issue

- Urges the UNODC to continue to develop a voluntary electronic portal for national forensic and/or drug testing laboratories to enable timely and comprehensive sharing of information on NPS (an early warning system)
Thank You