Goals and Objectives

- Background of prescription drug and opioid use and abuse – Scope of the problem
- Identify and discuss the pharmacology of commonly diverted and abused pharmaceuticals
- Identify methods of pharmaceutical diversion
- Discuss law enforcement role in preventing abuse and trafficking
Prescription Drug Abuse & Trafficking Trends

OR

Responding to America’s Prescription Drug Abuse Crisis

“When Two Addictions Collide”
DRUG-FREE AMERICA

AGE 0-4
AMOXICILLIN

AGE 4-12
RITALIN

AGE 12-18
APPETITE SUPPRESSANTS

AGE 18-24
HISTORY OF SOMEONE I KNEW WHEN I WAS

AGE 24-38
PROZAC

AGE 38-65
ZANTAC

AGE 65+
EVERYTHING ELSE
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
Rx Drug Ads on TV – Educational or Influential?

Overweight? Suffering from anxiety or erectile dysfunction? Well, relief is just a prescription pill away according to the endless television ads promoting prescription drugs.
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)
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.

1SOURCE: CDC National Center for Health Statistics/National Vital Statistics Report; June 2014
CDC Vital Signs: Opioid Painkiller Prescribing; July 2014
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.


U.S. Drug Enforcement Administration Office of Diversion Control
<table>
<thead>
<tr>
<th>Drug Type</th>
<th>2011 Users</th>
<th>2012 Users</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Any Ilicit Drug</strong></td>
<td>22.5 million</td>
<td>23.9 million</td>
</tr>
<tr>
<td>Marijuana</td>
<td>18.1 million</td>
<td>18.9 million</td>
</tr>
<tr>
<td>Psychotherapeutic Drugs</td>
<td>6.1 million</td>
<td>6.8 million</td>
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<tr>
<td>Cocaine</td>
<td>1.4 million</td>
<td>1.6 million</td>
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<tr>
<td>Methamphetamine</td>
<td>439,000</td>
<td>440,000</td>
</tr>
<tr>
<td>Heroin</td>
<td>281,000</td>
<td>335,000</td>
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</tbody>
</table>

Source: 2011 & 2012 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


U.S. Drug Enforcement Administration
Office of Diversion Control
Percentage of Past Month Nonmedical Use of Psychotherapeutics by Age, 2003-2011

Source: 2011 National Survey on Drug Use and Health
Emergency Room Data 2004-2011

- **Increase of 148%**: ER visits attributable to pharmaceutical(s) alone (i.e., with no other type of illicit drug or alcohol) (336,753 to 835,275)
  - No Statistically Significant Change: ER visits attributable to cocaine, heroin, or methamphetamine;
  - 62% increase in marijuana (281,619 to 455,668)

- **Increase of 128%**: ER visits attributable to pharmaceuticals alone, plus pharmaceutical(s) in combination with illicit drug(s) and/or alcohol (628,474 to 1,430,156)

- **Rx Drugs most frequently implicated**: Opiates/Opioids pain relievers (+183%)
  - Oxycodone products 262% increase
  - Hydrocodone products 107% increase
  - Fentanyl products 104% increase
  - Zolpidem 136% increase
  - Alprazolam 166% increase
  - Clonazepam 117% increase
  - Carisoprodol no statistically significant change

- For patients aged 20 and younger misuse/abuse of pharmaceuticals increased 45.4%
- For patients aged 20 and older the increase was 111%

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

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

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

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)
Where Painkiller Prescriptions Are The Highest

• In 2012, Southern states had the most per person.

• The top three states were Alabama, Tennessee, and West Virginia;
  Alabama: 143 per 100 people
  Tennessee: 143 per 100 people
  West Virginia: 138 per 100 people

• Lowest-Hawaii: 52 per 100 people

SOURCE: CDC Vital Signs: Opioid Painkiller Prescribing; July 2014
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 2010

Poisoning Deaths: Opioid Analgesics

Source: CDC/NCHS, National Vital Statistics System
The U.S. Population Grows at a Rate of Less Than 1% Per Year!

Source: U.S. Census Bureau
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.

Why are these statistics outpacing population growth?
Wrestler Benoit's doctor gets 10 years in prison

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."
Drug Overdose Mortality Rates per 100,000 People 1999

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

The Fifth Vital Sign?

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

**Wong-Baker FACES Pain Rating Scale**

- No Pain
- Little Bit
- Hurts Little More
- Hurts Even More
- Whole Lot
- Worst

- No Pain
- Sin dolor
- Khong Đau
- Tsis Mob
- Отсутствие боли

- Mild Pain
- Dolor leve
- Hơ Đau
- Mob Me Ntsis
- Слабая боль

- Moderate Pain
- Dolor moderado
- Đau Vira Phai
- Mob Hauj Sim
- Умеренная боль

- Severe Pain
- Dolor agudo
- Rát Đau
- Mob Heev
- Сильная боль

---

Pharmaceutical Controlled Substances
Opiates
Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen
Worldwide Hydrocodone Use

- **67 countries** reported an estimated need requirement for hydrocodone to the International Narcotics Control Board.
- **20 countries** reported an estimated need of 1 kilogram or greater.
- **4 countries** reported an estimated need between 500 grams and 999 grams.
- **10 countries** reported an estimated need between 100 grams and 499 grams.
- **6 countries** reported a need between 25 grams and 99 grams.
- **27 countries** reported a need of less than 25 grams.


U.S. Drug Enforcement Administration
Office of Diversion Control
Worldwide Hydrocodone Use

- Of the 20 Countries that reported an estimated needs requirement for hydrocodone at one kilogram or more

- 8 countries reported an estimated need of 1 kilogram to 5 kilograms

- 4 countries reported an estimated need over 5 kilograms to 10 kilograms

- 8 countries reported an estimated need over 10 kilograms


U.S. Drug Enforcement Administration Office of Diversion Control
# Top 10 List

<table>
<thead>
<tr>
<th>Rank</th>
<th>Country</th>
<th>Quantity</th>
</tr>
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<tbody>
<tr>
<td>10</td>
<td>Guatemala</td>
<td>10 kg</td>
</tr>
<tr>
<td>9</td>
<td>India</td>
<td>10 kg</td>
</tr>
<tr>
<td>8</td>
<td>Vietnam</td>
<td>20 kg</td>
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<tr>
<td>7</td>
<td>China</td>
<td>20 kg</td>
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<tr>
<td>6</td>
<td>Denmark</td>
<td>25.5 kg</td>
</tr>
<tr>
<td>5</td>
<td>Columbia</td>
<td>30 kg</td>
</tr>
<tr>
<td>4</td>
<td>Syrian Republic</td>
<td>50 kg</td>
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<tr>
<td>3</td>
<td>Canada</td>
<td>115.5 kg</td>
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<tr>
<td>2</td>
<td>United Kingdom</td>
<td>200 kg</td>
</tr>
<tr>
<td>1</td>
<td>United States</td>
<td>79,700 kg</td>
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</table>

INCB: Availability of opioids* for pain management (2010-2012 average)

(Consumption in defined daily doses for statistical purposes (S-DDD) per million inhabitants per day)

*Codeine, дектропрогрувфене, dihydrocodeine, fentanyl, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimiperidine.
Top Five Prescription Drugs Sold in the U.S. (2008-2011)

- Hydrocodone/Paracetamol
- Levothyroxine
- Sodium
- Lisinopril
- Simvastatin
- Metoprolol

Source: IMS Health
Hydrocodone / Acetaminophen (toxicity)

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

Brand Names: Vicodin®, Lortab®, Lorcet®

“Cocktail” or “Holy Trinity”
Hydrocodone
Soma ® / carisoprodol
Alprazolam / Xanax®

Street prices: $2 to $10+ per tablet depending on strength & region
October 6, 2014

Hydrocodone combination products placed into schedule II of the CSA

79FR49661 dated August 22, 2014
# State Ranking* - Oxycodone

January – December 2013

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<th>STATE</th>
<th>TOTAL</th>
<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
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<th>RANK</th>
<th>STATE</th>
<th>TOTAL</th>
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<td>PA</td>
<td>297,341,980</td>
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<td>MD</td>
<td>128,027,280</td>
<td>23</td>
<td>CT</td>
<td>72,412,470</td>
<td>34</td>
<td>KS</td>
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<td>291,383,620</td>
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<td>VA</td>
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<td>72,203,730</td>
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<td>NM</td>
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<td>ME</td>
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<td>97,740,170</td>
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<td>NC</td>
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<td>OR</td>
<td>95,608,810</td>
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<td>NV</td>
<td>58,577,300</td>
<td>39</td>
<td>DE</td>
<td>26,926,890</td>
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<td>NJ</td>
<td>177,267,830</td>
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<td>IN</td>
<td>92,666,390</td>
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<td>LA</td>
<td>54,777,500</td>
<td>40</td>
<td>IA</td>
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<td>AZ</td>
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<td>CO</td>
<td>89,415,210</td>
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<td>UT</td>
<td>52,478,120</td>
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<td>TN</td>
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<td>MI</td>
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<td>WV</td>
<td>44,705,160</td>
<td>42</td>
<td>RI</td>
<td>17,868,720</td>
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<td>MA</td>
<td>137,178,760</td>
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<td>SC</td>
<td>79,444,900</td>
<td>32</td>
<td>IL</td>
<td>44,362,470</td>
<td>43</td>
<td>HI</td>
<td>16,361,480</td>
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<td>11</td>
<td>WA</td>
<td>129,721,790</td>
<td>22</td>
<td>KY</td>
<td>74,443,010</td>
<td>33</td>
<td>AR</td>
<td>39,813,350</td>
<td>44</td>
<td>NE</td>
<td>15,564,300</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 March 18, 2014
Oxycodone HCL CR
(OxyContin®) Reformulation
Hydromorphone
Other Opiates of Interest

Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 100 mg

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

Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 30 mg

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

Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 100 mg

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

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

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

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

Fentora®

Actiq®

U.S. Drug Enforcement Administration
Office of Diversion Control
Opiates v. Heroin
Papaver Somniferum

Poppy

Codeine

Morphine

Thebaine

Hydrocodone

Hydromorphone

Oxycodone
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
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
Treatment of Narcotic Addiction
Methadone- 5mg & 10mg

Mallinckrodt Pharmaceuticals 5 mg & 10mg

Methadone 40 mg
Overdose...Why?

- Patients not taking the drug as directed
- Physicians not properly prescribing the drug
- Non medical users ingesting with other substances
- Opiate naive
One Pill can Kill

The Methadone Poisoning by Jonathan J. Lipman, Ph.D.
Other FDA Approved Drugs for Narcotic Addiction Treatment

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

Alprazolam
Clonazepam
Diazepam
Lorazepam
Midazolam
Triazolam
Temazepam
Flunitrazepam
Stimulants

Amphetamine Salts C-II

- Adderall® C-II

Methylphenidate C-II

- Ritalin®
- Concerta®
Ritalin® / Concerta® / Adderall®

- 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 Medication

✓ **1 in 8** teens (2.7 million) misuse or abuse

✓ **29%** parents believe can improve academic or testing performance, even if teen is does not have ADHD

✓ **1 in 4** teens believes these drugs can be used as a study aid

2012 Partnership Attitude Tracking Study: April 23, 2013
Parents’ Lax 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.

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.

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

- 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
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**
- **Annual**
- **Monthly**

<table>
<thead>
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<th>Year</th>
<th>Lifetime</th>
<th>Annual</th>
<th>Monthly</th>
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<tr>
<td>2009</td>
<td>12%</td>
<td>8%</td>
<td>5%</td>
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<td>2010</td>
<td>11%</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>2011</td>
<td>12%</td>
<td>7%</td>
<td>5%</td>
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<tr>
<td>2012</td>
<td>12%</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>2013</td>
<td>15%</td>
<td>7%</td>
<td>5%</td>
</tr>
</tbody>
</table>

"(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.

2013 Partnership Attitude Tracking Study: July 23, 2014
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”
Non-Controlled Substances

• **Analgesic:**
  – Tramadol (Ultram®, Ultracet®)
  – Notice of Proposed Rulemaking to place Tramadol into Schedule IV issued November 4, 2013.
  – Effective August 18, 2014, Schedule IV controlled substance

• **Muscle Relaxant:**
  – Cyclobenzaprine (Flexeril®)
Tramadol Prescriptions

2007: 24,500,000
2008: 26,660,000
2009: 28,344,000
2010: 30,570,000
2011: 36,776,000
2012: 39,800,000

Source: IMS Health National Prescription Audit Plus
Cyclobenzaprine
(*Amrix®, Flexeril®, Fexmid®*)

- A skeletal muscle relaxant prescribed for acute temporary muscle spasms caused by local trauma or strain.

- Marketed in the United States since 1977 (by Merck Com.).

- Currently non-controlled under the CSA.

- Chemical structure related to tricyclic antidepressant drugs (e.g., amitriptyline)

- Cyclobenzaprine, similar to other skeletal muscle relaxants, is being diverted and abused
Pharmaceutical Diversion
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

U.S. Drug Enforcement Administration
Office of Diversion Control
Doctor Shopping
Commonly Abused Controlled Pharmaceuticals

Carisoprodol
C-IV as of 1/11/2012

CYCLOBENZAPRINE
(FLEXERIL)

Hydrocodone

OxyContin 80mg
Oxycodone HCL ER

Oxymorphone

Alprazolam
The Holy Trinity

- Oxycodone
- Carisoprodol
- Alprazolam

Opiate

Muscle Relaxant

Benzodiazepine

C-IV as of 1/11/2012

U.S. Drug Enforcement Administration
Office of Diversion Control
The Controlled Substances Act

Checks and Balances
The Flow of Pharmaceuticals

Raw Material

Importers

Manufacturers

Dosage Form Manufacturers

Imp - Manufacturers

Dosage Form Manufacturers

Wholesalers Distributors

Smaller Distributors

Hospitals

Pharmacies

Physicians (Rx and drugs)

NTPs

21 CFR 1306.04

PATIENTS

21 USC 823(c)(1)
21 USC 823(d)(1)
21 CFR 1301.71

21 USC 823(b)(1)
21 USC 823(e)(1)
21 CFR 1301.71
21 CFR 1301.74
(Suspicious Orders)
Closed System of Distribution

1,532,161 (06/04/2014)
Practitioners: 1,182,465
Retail Pharmacies: 70,115
Hospital/Clinics: 16,047

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
Recordkeeping Requirements
Security Requirements
ARCOS Reporting

Established Schedules
Registration
Established Quotas

U.S. Drug Enforcement Administration
Office of Diversion Control
Cutting off the Source of Supply
Checks and Balances of the CSA and the Regulatory Scheme

➢ Distributors of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” (21 CFR § 1301.74)
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)
US v. Rosen 582 F.2d 1032 (5th Cir. 1978)

Rosen was a 68 yo physician who had a practice that was focused on obesity. He dispensed large quantities of stimulants to undercover officers outside the scope and not for a legitimate purpose.

The 5th circuit had to address whether the medication was dispensed “for a legitimate medical purpose and in the course of the doctors professional practice.” In its analysis, the court stated, “We are however, able to glean from reported cases, certain recurring concomitance of condemned behavior, examples of which include the following:

An inordinately large quantity of controlled substances prescribed

Large numbers of prescription were issued

No physical exam given

The physician warned the patient to fill prescriptions at different drug stores
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;
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
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))
System of Checks and Balances

The Last Line of Defense
DEA Legal Recourse

➢ Administrative
  - Immediate Suspension Order (ISO)
  - Memorandum of Agreement (MOA)
  - Order to Show Cause (OTSC)

➢ Civil
  - Fines

➢ Criminal
  - Tactical Diversion Squads
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
ONDCP Strategy

“Epidemic: Responding To America’s Prescription Drug Abuse Crisis” (Released in April 2011)

- **Education**
  - Healthcare Provider Education
  - Parent, Youth, and Patient Education

- **Tracking and Monitoring**
  - Work with states to establish effective PDMPs
  - Support NASPER
  - Explore reimbursements to prescribers who check PDMPs before writing a prescription

- **Proper Medicine Disposal**

- **Enforcement**
  - Assist states address doctor shopping and pill mills
  - Increase HIDTA intelligence-gathering and investigation of prescription drug trafficking
  - Expand the use of PDMPs to identify criminal prescribers and clinics
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

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

➢ Children/Teens
Information from the Internet or their peers
Following parents
Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non-Medical Use

Friends and Family...For Free!!
The Medicine Cabinet and the Problem of Pharmaceutical Controlled Substance Disposal
The Problem – Easy Access
Medicine Cabinets: Easy Access

- More than half of teens (73%) indicate that it’s easy to get prescription drugs from their parent’s medicine cabinet.

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

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

Date Prepared/ Source: 2013 Partnership Attitude Tracking Study, published 7/23/14
National Take Back Initiative

Got Drugs?

Turn in your unused or expired medication for safe disposal Saturday, September 27, 2014.

Click here for a collection site near you.

10:00 AM – 2:00 PM
Nationwide Take-Back Initiative
Over 4.1 million pounds (2,123 tons) collected

- On September 30, 2010, approximately 122 tons
- On April 30, 2011, approximately 188 tons
- On October 29, 2011, approximately 189 tons
- On April 28, 2012, approximately 276 tons
- On September 29, 2012, approximately 244 tons
- On April 27, 2013, approximately 376 tons
- On October 26, 2013, approximately 324 tons
- On April 26, 2014, approximately 390 tons
Secure and Responsible Drug Disposal Act of 2010

• Disposal rule eliminated existing 21 CFR 1307.12 and 1307.21

• New part 1317 contains the requirements on:
  – disposal procedures;
  – collection of pharmaceutical controlled substances from ultimate users;
  – return and recall; and
  – destruction of controlled substances
Secure and Responsible Drug Disposal Act of 2010

• Regulations do not limit the ways that ultimate users may dispose of pharmaceutical controlled substances—they expand them.

• Any method of pharmaceutical disposal that was valid prior to these regulations continues to be valid.
DEA Web-based Resources
Office of Diversion Control
www.deadiversion.usdoj.gov
DEA Web-based Resources

www.JustThink Twice.com
DEA Web-based Resources

www.GetSmartAboutDrugs.com
Thank You / Questions

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