NASCA - 2014

DEA Update

October 23, 2014

Ruth A. Carter, Chief
Liaison and Policy Section
Office of Diversion Control
Ruth.A.Carter@usdoj.gov
The mission of the Office of Diversion Control is to **prevent**, **detect**, and **investigate** the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

**while** …

ensuring an adequate and uninterrupted supply of controlled substances to meet **legitimate medical**, **commercial**, and **scientific needs**
Closed System of Distribution

1,540,386 (10/17/2014)

- Practitioners: 1,188,575
- Retail Pharmacies: 70,258
- Hospital/Clinics: 16,057
Closed System of Distribution

- Cyclic Investigations
- Established Schedules
- Record Keeping Requirements
- Registration
- Security Requirements
- Established Quotas
- ARCOS
The DEA is responsible for:

– the **oversight** of the system
– the **integrity** of the system
– the **protection** of the public health and safety
2014 Updates
Distributor Initiative Briefings

- Due Diligence Responsibilities
- Suspicious Order Monitoring System
- Review of ARCOS data
- National Rx Abuse Trends

August 2005 – Present:
- Briefings to **83** firms with **276** registrations
Pharmacy Diversion Awareness Conference

- Designed to educate pharmacy staff on ways to address and respond to potential diversion activity
### Completed PDACs

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### Proposed FY-2015 PDACs

- 22-Las Vegas, NV February 7-8, 2015
- 23-Birmingham, AL March 28-29, 2015
- 24-Norfolk, VA May 30-31, 2015
- 25-Oklahoma City, OK June 2015
- 26-Milwaukee, WI July 25-26, 2015
- 27-Bangor, ME July 2015
- 28-Seattle, WA August 2015
- 29-Billings, MT (MT,WY,ND,SD) TBD
The Secure and Responsible Drug Disposal Act of 2010
The Problem: Easy Access
More than half of teens (73%) indicate that it’s easy to get prescription drugs from their parent’s medicine cabinet.

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

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

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

Turn in your unused or expired medication for safe disposal Saturday, Sept. 25th

Click here for a collection site near you.
First Eight DEA Take Back Days (Combined)

Collection of 2,100+ tons

September 27, 2014

Ninth (Final) DEA Take Back Day, approximately 309 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.
October 6, 2014

Hydrocodone combination products placed into schedule II of the CSA

79FR49661 dated August 22, 2014
Most Commonly Prescribed Controlled Substance???

Hydrocodone/acetaminophen
Worldwide Hydrocodone Use

- **67 countries** reported an estimated hydrocodone need to the International Narcotics Control Board

- **20 countries** – 1 kilogram or greater
- **4 countries** – 500-999 grams
- **10 countries** – 100-499 grams
- **6 countries** – 25-99 grams
- **27 countries** – Less than 25 grams

Worldwide Hydrocodone Use

20 Countries (1 kilogram or greater)

- **8 countries** – 1-5 kilograms
- **4 countries** – 5-10 kilograms
- **8 countries** – 10 kilograms or greater

Top 10 List

- 10 Guatemala 10 kilograms
- 09 India 10 kilograms
- 08 Vietnam 20 kilograms
- 07 China 20 kilograms
- 06 Denmark 25.5 kilograms
- 05 Columbia 30 kilograms
- 04 Syrian Republic 50 kilograms
- 03 Canada 115.5 kilograms
- 02 United Kingdom 200 kilograms
- 01 United States 79,700 kilograms 99.3%

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, дехтропроксифен, dihydrocodeine, fentanyl, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and trimeperidine.

Date Prepared/ Source: 4/14/14,
## State Ranking* - Hydrocodone
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*Business Activity - Practitioners*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of April 1, 2014
# State Ranking* - Hydrocodone
## January – December 2013

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*Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of April 1, 2014
Drugs of Concern
## State Ranking* - Oxycodone
### January – December 2013

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*Business Activity - Practitioners*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of March 18, 2014
State Ranking* - Oxycodone
January – December 2013

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* Business Activity – Retail Pharmacies

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of March 18, 2014
Oxymorphone Extended Release
Opana ER® (Schedule II)

- Opana ER® - (Schedule II)
  - Treats constant, around the clock, moderate-severe pain
  - Becoming popular
  - Abused in similar fashion to oxycodone; August 2010 (Los Angeles FD TDS)
  - Slang: Blues, Mrs. O, Octagons, Stop Signs, Panda Bears
  - Street: $10.00 – $80.00
# State Ranking* - Oxymorphine

**January – December 2013**

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*Business Activity - Practitioners*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of March 18, 2014
## State Ranking* - Oxymorphone
### January – December 2013

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*Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of March 18, 2014
Hydromorphone

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

**January – December 2013**

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*Business Activity - Practitioners*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of March 18, 2014
### State Ranking* - Hydromorphone
#### January – December 2013

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*Business Activity – Retail Pharmacies*

Source: Drug Enforcement Administration, Office of Diversion Control, Pharmaceutical Investigations Section, Targeting and Analysis Unit
Most current ARCOS information as of March 18, 2014

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

Alprazolam
Clonazepam
Diazepam
Lorazepam
Midazolam
Triazolam
Temazepam
Flunitrazepam
Stimulants

Amphetamine Salts C-II

➢ Adderall® C-II

Methylphenidate C-II

➢ Ritalin®
 ➢ Concerta®
1 in 8 teens (2.7 million) misuse or abuse

1 in 4 teens believe these drugs can be used as a study aid

2012 Partnership Attitude Tracking Study: April 23, 2013
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
Teen OTC Cough Medicine Misuse and Abuse

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

- Lifetime
- Annual
- Monthly

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

17% ACD
11% CDE
8%
5%

12%
12%
12%

7%
7%
7%
5%

15% ACD

“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”
The Holy Trinity

Oxycodone

Carisoprodol
Muscle Relaxant
C-IV as of 1/11/2012

Alprazolam
Benzodiazepine

U.S. Drug Enforcement Administration
Office of Diversion Control
Scheduling Actions
Completed Scheduling Actions
2009 – 2014

- 2014
  - Hydrocodone CP
  - Suvorexant
  - Tramadol
  - Alfaxalone
  - 4 synthetic cannabinoids
  - 10 synthetic cathinones

- 2013
  - 3 synthetic phenylethamines
  - Perampanel
  - Lorcaserin
  - Methylone

- 2012
  - Methasterone
  - Prostanozol
  - 26 NPS

- 2011
  - Carisoprodol
  - Ezogabine

- 2010
  - ANPP
  - 5-MeO-DMT

- 2009
  - Tapentadol
  - Lacosamide
  - Fospropofol
  - Boldione
  - Desoxymethyltestosterone
  - 19-Nor-4,9(10)-androstadienedione
Types of Scheduling Actions

• Formal
  – HHS scheduling recommendation required
  – 8-factor analysis

• Administrative
  – Anabolic Steroids
  – Synthetic Cannabinoids

• Temporary (emergency)
  – 3 of 8 factors
  – Finding “imminent hazard to public safety”
  – 2 years in Schedule I

• Congressional action (legislative)
  – Anabolic Steroid Control Acts of 1990 and 2004
  – Synthetic Drug Abuse and Prevention Act of 2012 (SDAPA)

• Compliance with international treaties
Formal Scheduling Process

- DHHS recommendation
- DEA requirements:
  - 8-factor analysis
  - Regulatory analysis
  - Publish a notice of proposed rulemaking
  - Consider public comments
  - Publish a final rule
- Schedule is established
Components of 8 Factor Analysis

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
Data

- Scientifically accurate and legally defensible
- Active process – seek out this information
- Dependent on the type of substance
- Purchase or contract for necessary data
- Substantial portion of budget
Data Sources

- Scientific / medical literature
- NIDA abuse liability testing
- National and other databases for data on:
  - Abuse/dependence/death/injury
  - Trafficking/Diversion
  - Assessment of legitimate use
Data Sources

- National Survey on Drug Use and Health (NSDUH)
  - A SAMHSA sponsored database, formerly known as National Household Survey on Drug Abuse
- Treatment Episode Data Set (TEDS)
  - A SAMHSA sponsored database
- Monitoring the Future (MTF)
  - A NIDA sponsored database
- American Association of Poison Control Centers (AAPCC)
Data Sources – Trafficking & Diversion

- DEA data – National Forensic Laboratory Information System (NFLIS), System to Retrieve Information from Drug Evidence (STRIDE), drug theft data, enforcement and diversion investigative case files
- U.S. Customs Border Protection (CBP) seizure data, international trafficking data (Ex. Interpol)
- El Paso Intelligence Center’s (EPIC) Clandestine laboratory data
Synthetic Designer Drugs
These drugs are perceived as being ‘legal’ alternatives to marijuana, cocaine, methamphetamine, MDMA and LSD.

These drugs are being marketed and sold as:
- incense and potpourri
- bath salts
- glass cleaner
- shoe deodorizer
- plant food
- “Molly”
- Research chemicals
- And many other names

Often more dangerous than the traditional illicit drugs they are purported to mimic.
Synthetic Cannabinoids
(Spice, K2, legal weed)
Synthetic Cannabinoids

- Unregulated and unlicensed industry
- Multiple manufacturers

- Sold in convenience stores, gas stations (often behind the counter), smoke and head shops and online
- Significant batch to batch variance (i.e. “hot spots”, multiple or different drugs)
- Labeled “Not for Human Consumption”
Synthetic Cannabinoids

- What does it look like?

- How is transformed/made into a usable form?
Synthetic Cannabinoids

RCS JWH-081
4-methoxynaphthalene-1-yl-(1-pentyllindol-3-yl)methanone
For Research Purposes ONLY
Not for Human Consumption

1000g
Bulk Plant Material
Dried Ground Plant Leaves
Mix the product
Add Flavoring
Cannabinoid Drying
Packaging Center
Other Processing Locations
CANNABINOID PROCESSING

May 2010 near Richmond, VA
Sold at Gas Stations, Convenience Stores, Head Shops and Online
Cost Comparison – “potpourri”

- Scooby Snax 4 gram = $25
- 453 grams per pound
- 336 grams real potpourri above
- Equivalent Cost = $2,100
Liquid Cannabinoid Delivery Method
E-cigarettes

AB-PINACA and nicotine

5F-UR-144
Brand: Magic Juice Watermelon

AB-FUBINACA

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
Why Spice? - 18 year old’s perception

- “Spice vs Marijuana”
  - Doesn’t show up on urinalysis testing
  - More potent
    - “10Xs higher”
- Less expensive
  - “10Xs cheaper”
# Adverse Health Effects: Cannabinoids

- **Psychological**
  - Anxiety, aggressive behavior, agitation, confusion, dysphoria, paranoia, agitation, irritation, panic attacks, intense hallucinations

- **Neurological**
  - Seizures, loss of consciousness

- **Cardiovascular**
  - Tachycardia, hypertension, chest pain, cardiac ischemia

- **Metabolic**
  - Hypokalemia, hyperglycemia

- **Gastrointestinal**
  - Nausea, vomiting

- **Autonomic**
  - Fever, mydriasis

- **Other**
  - Organ damage

- **Abusers at ED/ER**
- **Withdrawal Symptoms**
- **Seeking Treatment**
- **Multiple deaths**
Synthetic Cathinones
(bath salts, plant food, glass cleaner, “Molly”)

• Structurally and pharmacologically similar to amphetamine, Ecstasy (MDMA) 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”, “jewelry cleaner”, “lady bug attractant” and others.
BATH SALTS, PLANT FOOD, GLASS CLEANER, ETC.
Synthetic Cathinones
(bath salts, plant food, glass cleaner)

- Like the cannabinoids, unregulated and unlicensed industry
- Full disclosure of ingredients typically not present
- Significant batch to batch variances “Hot Spots”
- Sold in convenience stores, gas stations and online
Cost Comparison – plant food & “plant food”

- Blow – $40
- 453 grams per pound
- 680 grams in above Plant Food
- Equivalent Cost = $54,400

U.S. Drug Enforcement Administration / Operations
Division / Office of Diversion Control
Adverse Health Effects: Cathinones

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<tr>
<th>System</th>
<th>Effects</th>
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<tbody>
<tr>
<td>Cardiovascular</td>
<td>palpitations, tachycardia, chest pain, vasoconstriction, myocardial infarction</td>
</tr>
<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 cathinone users commonly report cardiac, psychiatric, and neurological signs and symptoms with death.
Synthetic Cathinones

- Also sold in pill form
- Popular at Clubs
- Available at Parties
- Mimics MDMA
  - Ecstasy/XTC
- Street name “Molly”
What is Molly?
Where did the term come from?

• Molly – derived from the word “molecule”
  – Rogue chemists would often alter one molecule to
    defeat the controlled substance laws

• 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
Molly

• Some of the Drugs found in “Molly" (Scheduled)
  – MDMA (1985)
  – Methylone (October 2011)
  – A-PVP (March 2014)
  – 4-MEC (March 2014)
  – Pentadrone (March 2014)
  – Butylone (March 2014)
  – Ethylone
  – others
Phenethylamines
25I-NBOMe and 25C-NBOMe
“N-BOMB”, “2-5-I”, “Eye” and “Smiles”

- Hallucinogen, abused orally or through nasal passages
- Encountered on blotter paper and in dropper bottles
- Taken as a substitute for LSD
- Linked to several overdose deaths
- 11/2013 controlled 25I-NBOMe, 25B-NBOMe & 25C-NBOMe
Designer Drug Market Encounters

- **JWH-018**: Nov 2009
- **AM2201**: Apr 2011
- **XLR-11**: Feb 2012
- **UR-144**: Mar 2012
- **AKB-48**: Feb 2013
- **PB-22**: Feb 2013

**Timeline**
- **Mar 2010**: State controls initiated
- **Oct 2010**: DEA notice to schedule published
- **Mar 2011**: Final Order placing 5 synthetic cannabinoids in Schedule I
- **Jun 2012**: Federal legislation signed, placing 15 synthetic cannabinoids in Schedule I
- **Dec 2012**: State controls UR-144 XLR-11
- **Jun 2012**: GA Pharmacy Board bans UR-144 & XLR-11
- **KS Board of Pharmacy bans UR-144**
Temporary Scheduling Synthetic Drugs

3 of the 8 Factors:

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

Substance remains in Schedule I for two years at which time must be placed into Schedule I by DEA.
Synthetic Drug Abuse Prevention Act of 2012

- Synthetic Drug Abuse Prevention Act of 2012 (Public Law 112-144)
- Effective July 9, 2012
- Placed 26 substances under Schedule I
  - 15 synthetic cannabinoids
  - 2 cathinones
  - 9 phenethylamines
- Extended temporary control status from 1 year to 2 years
- Provided a mechanism for future placement of synthetic cannabinoids
# Synthetic Drug Abuse Prevention Act of 2012

## Cannabinoids

1. AM2201
2. AM694
3. CP-47,497
4. CP-47,497 – C8 homologue
5. JWH-018
6. JWH-073
7. JWH-081
8. JWH-200
9. JWH-019
10. JWH-250
11. JWH-122
12. JWH-203
13. JWH-398
14. SR-19
15. SR-18

## Cathinones

1. Mephedrone
2. MDPV

## Phenethylamines

1. 2C–E
2. 2C–D
3. 2C–C
4. 2C–I
5. 2C–T–2
6. 2C–T–4
7. 2C–H
8. 2C–N
9. 2C–P

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**DEA Office of Diversion Control**
DEA Web-Based Resources

Office of Diversion Control
www.deadiversion.usdoj.gov
DEA Web-Based Resources

www.DEA.gov
DEA Web-Based Resources

www.JustThinkTwice.com
DEA Web-Based Resources

www.GetSmartAboutDrugs.com
Thank you