UPDATE FROM THE U.S. DRUG ENFORCEMENT ADMINISTRATION

October 24, 2013
National Association of State Controlled Substance Authorities (NASCA), Kansas City, Missouri

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

- Synthetic (Designer) Drugs
- Heroin (Prescription Drugs)
- Hydrocodone
- Drug Disposal
- Electronic Prescribing of Controlled Substances (ECPS)
- DEA Resources
Synthetic (Designer) Drugs
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 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” are a large family of chemical structures functionally (biologically) similar to THC, the active principle of marijuana.

They may have less, equivalent or more pharmacologic (psychoactive) activity than THC.
## 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>Psychological</th>
<th>Anxiety, aggressive behavior, agitation, confusion, dysphoria, paranoia, agitation, irritation, panic attacks, intense hallucinations</th>
</tr>
</thead>
<tbody>
<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, by State, 2010

Reports per State
- 200 or More
- 100-199
- 50-99
- 1-49
- 0
- No Data

Source: NFLIS
Synthetic Cannabinoids, by State, 2011
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.
Adverse Health Effects

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

<table>
<thead>
<tr>
<th>System</th>
<th>Symptoms</th>
</tr>
</thead>
<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 Cathinones, by State, 2010

Source: NFLIS
Synthetic Cathinones, by State, 2011

Source: NFLIS
Synthetic Cathinones, by State, 2012

DEA Office of Diversion Control

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

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)
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
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.
A total of 251 NPS (including ketamine) were reported to UNODC by 40 countries and territories up to 2012.

Source: data from the MTF Survey 2010-2011
Base: 12th graders %
Question on synthetic cannabinoids was introduced in 2011 for the first time
As of August 6, 2013, U.S. law enforcement has encountered:

- 95 synthetic cannabinoids
- 51 synthetic cathinones
- 87 other compounds (2C compounds, tryptamine, piperazines, etc.)
‘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.
American Association of Poison Control Centers (AAPCC) Reporting

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

Calls to U.S. Poison Control Centers

Synthetic Cannabinoids

- 2010: 2,906
- 2011: 6,968
- 2012: 5,205
- 2013*: 1,593

*As of July 31, 2013

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
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 July 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
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
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. “N-Bomb” 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

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

*DEA Office of Diversion Control*
In the U.S. why are synthetic compounds marketed the way they are (i.e., not for “Human Consumption”)?

- Synthetic cannabinoids are sold as “potpourri” or “incense” products at retail outlets and on the Internet.
- Synthetic cathinones are sold as “bath salts”, “jewelry cleaner,” and “plant food” at retail outlets and on the Internet.
21 USC 813 – A Controlled Substance Analogue, shall, to the extent intended for human consumption, be treated for the purposes for any Federal law as a controlled substance in Schedule I.

21 USC 802(32) – chemical structure is substantially similar to a controlled substance in schedule I or II and has a similar pharmacologic effect.
The U.S. Controlled Substance Analogue Act

- The “intended for human consumption” requirement is often demonstrated by law enforcement investigations.

- Requires proof of substantial similarity both with respect to chemical structure and actual or represented pharmacological effect.

- The substantial similarity standard often results in a battle of the experts, which is resource intensive and highly unpredictable.
Operation “Log Jam” (July 2012)

Goals of Operation

- Target manufacturers, wholesale distributors, and retail distributors
- Develop information about foreign sources of supply
- Raise public awareness
- Develop leads for Phase II initiative

- 70 DEA Investigations
- 15 ICE/HSI Investigations
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)
Heroin (& Prescription Drugs)
Circle of Addiction & the Next Generation

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

Hydrocodone
- Lorcet®
  - $5-$7/tab

OxyContin®
- $80/tab

Roxicodone®
- Oxycodone IR
  - 15mg, 30mg
  - $30-$40/tab

Heroin
- $15/bag
HEROIN: NO LONGER CONFINED TO URBAN AREAS

Heroin use spikes in area suburbs
Pill addicts risk deadly drug
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 per-
cent 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 sub-
urban kids to come into the city, the
dealers have gone out to the sub-
rubs," 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
Suburban Hospital in Bethesda,
Montgomery and Fairfax counties have both reported spikes in heroin use.

"Instead of waiting for the suburban kids to come into the city, the dealers have gone out to the suburbs. 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."

— Mike Gimbel, former heroin addict

"Getting high"

Percentage of Maryland high schoolers who reported using heroin:

<table>
<thead>
<tr>
<th></th>
<th>2011</th>
<th>2009</th>
<th>2007</th>
<th>2005</th>
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</thead>
<tbody>
<tr>
<td>Males</td>
<td>5.7</td>
<td>5.8</td>
<td>3.7</td>
<td>2.8</td>
</tr>
<tr>
<td>Females</td>
<td>1.9</td>
<td>1.7</td>
<td>0.8</td>
<td>2.3</td>
</tr>
<tr>
<td>Total</td>
<td>4.2</td>
<td>4.1</td>
<td>2.4</td>
<td>2.6</td>
</tr>
</tbody>
</table>

SOURCE: MARYLAND YOUTH RISK BEHAVIOR SURVEY

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 con-
nect 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

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)
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.
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
There is a surge in heroin use in Michigan, where the number of people seeking treatment in state-sponsored programs has nearly doubled since 2003.

More youths have turned to heroin after abusing "gateway" prescription drugs, said Dr. Mark Menestrina, an addiction medicine physician at St. John Providence Health System's Brighton Hospital in Livingston County.

It may come down to economics: It's a quick, easy high at $10-$20 a hit.

1SOURCE: Mark Hicks and Valerie Olander, The Detroit News, April 27, 2011
Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)

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

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

- Currently a Schedule III (combination products)

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

- Street prices: $2 to $10+ per tablet depending on strength & region
The Trinity

Benzodiazepine

Hydrocodone

Opiate

Carisoprodol

Muscle Relaxant

Alprazolam

Benzodiazepine

C-IV as of 1/11/2012
Top Five Prescription Drugs Sold in the U.S. (2006-2011)

(By Number of Prescriptions Sold)

Source: IMS Health
Drug Disposal
Prescription Drugs at Home: Potential Loaded Weapon
Under Existing Regulations: Ultimate User Disposal of Medicines

**National Take-Back Events:** Take-back events are a good way to remove expired, unwanted, or unused medicines from the home.

**Law Enforcement Collection Bins:** Collection bins installed by our Law Enforcement Partners are a good way to remove expired, unwanted, or unused medicines from the home.

**Disposal in Household Trash:** Mix medicines (do not crush tablets or capsules) with substances such as kitty litter or used coffee grounds and place the mixture in a container such as a sealed plastic bag and throw the container in your household trash.

**Disposal by Flushing:** Some medicines have specific disposal instructions that indicate they should be flushed down the sink or toilet when they are no longer needed.
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.
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.

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
National Take Back Initiatives

*Over 2.8 million pounds (1,409 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)

Next One: **Saturday, October 26, 2013**
National Take Back Day: April 27, 2013
Total Law Enforcement Participation: 4312

Drug Enforcement Administration
Diversion Control Program

Drug Enforcement Administration Diversion Control Program
National Take Back Day: April 27, 2013
Total Collection Sites: 5829

Drug Enforcement Administration
Diversion Control Program
National Take Back Day: April 27, 2013
Total Weight Collected (pounds): 742,497

Drug Enforcement Administration
Diversion Control Program
Take-Back Events

Boxed, Sealed, Counted, Weighed, Consolidated, Secured, and Incinerated
Electronic Prescribing of Controlled Substances (ECPS)
DEA is revising its regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically.

The NPRM on EPCS was published in the Federal Register on March 31, 2010.

Open for a 60-day public comment period / Closed June 1, 2010.

The Final Rule will be published in the Federal Register upon completion.
ECPS Interim Final Rule with Request for Comment

- Provides practitioners with the option of writing Rxs electronically.
- Permits pharmacies to receive, dispense and archive these Rxs.
- Was effective as of June 1, 2010.
- Still many of Questions from stakeholders ??
What does the ECPS Interim Final Rule Allow?

- Practitioners have the option of signing and transmitting prescriptions for controlled substances electronically.
- Permits pharmacies to receive, dispense, and archive electronic prescriptions.
- CII-V prescriptions permissible.
What does the ECPS Interim Final Rule Allow?

- Electronic prescriptions for controlled substances are voluntary from DEA’s perspective.

- Written, manually signed, and oral prescriptions for controlled substances, where applicable, still permitted.
How Many Practitioners Are Using EPCS?

- We do not know!!

- DEA does not track this information.
How Many States Have EPCS Regulations?

All but the following:

- Hawaii
- Maine
- Missouri
- Nebraska
- Vermont
Approved Certification Processes for EPCS

- As set forth in the regulations, before any electronic prescription or pharmacy application may be used to transmit prescriptions, a third party must audit the application for compliance with the requirements of 21 CFR 1311.

- Or a certifying organization whose certification process has been approved by DEA must verify and certify that the application meets the requirements of 21 CFR 1311.
Approved Certification Processes for EPCS

To date, the certifying organizations whose certification processes have been approved by DEA are listed as follows:

- **InfoGard Laboratories Inc.** -- 709 Fiero Lane, San Luis Obispo, CA 93401 Phone: 805-783-0810 Email: epcs@infogard.com Web: www.infogard.com

- **Drummond Group Inc.** -- 3359 North Hwy 183, Suite B-406-238, Austin, TX 78750 Phone: 817-294-7339 Email: info2@drummondgroup.com Website: www.drummondgroup.com

- **iBeta, LLC** -- 2675 South Abilene Street Suite 300, Aurora, CO 80014 Phone: 303-627-1110 Email: epcs@iBeta.com Web: www.iBeta.com

- **Global Sage Group, LLC** -- PO Box 1431, Salem, NH 03079 Email: htheberge@globalsagegroup.com Web: www.globalsagegroup.com
Will DEA Post A List of Software That Has Been Certified Compliant?

Short Answer, NO.

Because, …..
DEA Web-based Resources
Office of Diversion Control
www.deadiversion.usdoj.gov
DEA Web-based Resources

www.JustThinkTwice.com
DEA Web-based Resources

www.GetSmartAboutDrugs.com