SYNTHETIC DRUGS 101: TRAFFICKING & ABUSE TRENDS

February 19, 2013
Synthetic Drugs Symposium, Substance Abuse & Mental Health Services Integrated Task Force, Washington, D.C.

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

• Synthetic Cannabinoids
• Synthetic Cathinones
• Other Synthetic Compounds
• Scope of the Problem
• Control Efforts: State, Federal, & International
Designer Drugs

These drugs are perceived as being ‘legal’ alternatives to marijuana, cocaine, methamphetamine, and MDMA.
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.
Designer Drugs: Novel Psychoactive Substances

- Clandestinely produced to mimic the effects of a controlled substance (a substance with an abuse potential)
- Scientific literature excavated to identify substances
  - No industrial or medical use for these substances
    - Substances rejected due to poor therapeutic potential
    - Characterization as being “research chemicals,” the only research being undertaken is to their abuse liability and toxicity
- Challenge
  - Change public misperception as to legality and hazards
  - Minimize appeal, a result of devious and aggressive marketing
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
### Cannabinoid Timeline

- **1964** – Isolation of THC from Cannabis
- **1967** – Synthesis of synthetic THC
- **1968** – Pfizer starts developing CP cannabinoids for analgesic effects
- **1988** – Isolation of CB1 Receptor
- **1993** – CB1 Receptor discovered
- **2004** – K2 sold on the Internet
- **2008** – U.S. seizes Spice products at border
- **2009** – USAFE bans spice
- **2011** – U.S. temporarily controls five synthetic cannabinoids
- **2009** – European countries begin controlling K2/Spice
- **2012** – Synthetic Drug Abuse & Prevention Act
Abusers are presenting at Emergency Departments and also seeking treatment for dependence and withdrawal. 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

- 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 extracts including: Castanea sativa, Clematis, Vitalba, Nolium boves, and Ledum palustre.

NOT FOR HUMAN CONSUMPTION FOR AROMATHERAPY USE ONLY
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: Cathinones

<table>
<thead>
<tr>
<th></th>
<th>Cardiovascular</th>
</tr>
</thead>
<tbody>
<tr>
<td></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

- Like the cannabinoids, unregulated and unlicensed industry (many manufacturers)
- Full disclosure of ingredients typically not present
- Significant batch to batch variances “Hot Spots”
Other Synthetic Compounds
Categories

- **2C Series**
  - Category of phenethylamines
  - Contain 2,5-dimethyloxy
- **Piperazaines**
  - Used as industrial chemicals
- **Tryptamines**
  - Occur naturally in plant species
  - Produced synthetically
- **Arylcylohexamines**
25I-NBOMe and 25C-NBOMe

- Hallucinogens, abused orally
- Encountered on blotter paper and in dropper bottles
- Possibly mistaken for LSD
- Linked to recent deaths
- “N-BOMB”, “Smiles”
Piperazines

- Stimulant and hallucinogenic properties
- Often referred to as amphetamine-like
- Examples: BZP, TFMPP, mCPP, and MeOPP
- Tableted
- BZP-TFMPP combination abused to mimic the effects of ecstasy

4/10/2013
Tryptamines

• Hallucinogenic
• “reality distorting”
• Powders, tablets, or blotter paper
• Examples: 5-MeO-DALT, 5-MeO-DIPT, AMT and many more…….
Methoxamine (MXE)

- Dissociative (mind altering effects) and depression of pain
- Sold as a “ketamine derivative” (Ketamine- schedule III)
- Effects similar to PCP
- Effects range 5-7 hours
- First reported to NFLIS in 2011
- Deaths attributed to the substance
Methylhexanamine (DMAA)

- Stimulant
- Encountered on designer drug market as a cathinone replacement. Also found on the dietary supplement market
- Deaths attributed to the substance
- April 27th, FDA challenges marketing of DMAA products for lack of safety evidence
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
• 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
Scope of the Problem
As of January 31, 2013, the NFLIS system shows U.S. law enforcement encountering:

- 51 cannabinoids
- 31 cathinones
- 76 “other” compounds (i.e. amphetamines, tryptamines, 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.
“I told the police straight up what we were selling was legal,” the man said. “We had results from a DEA-registered lab.”

A raid in which $10,000 worth of synthetic marijuana was seized from a Newport News hookah bar has not resulted in charges, either. The owner did not return calls, but he told a local newspaper in September that he was selling a new version of spice.

State Sen. Mark R. Herring (D-Loudoun), who wrote Virginia’s spice law, said it has helped educate people about the dangers of the drug and encouraged reputable retailers to stop selling it. But he said that more needs to be done. He said legislation is being written that would add six compounds to the banned list.

Lawmakers on the federal level are also taking a more comprehensive approach by seeking to ban spice compounds, as well as classes of chemical structures on which synthetic marijuana compounds are commonly built.

The initial appeal of spice was as a legal high, but it remains popular because most drug tests will not pick it up and it is readily available from dozens of Web sites.

“We had guys with Pentagon security clearance badges coming in to buy it,” said Alan Amsterdam, co-owner of Capitol Hemp in Adams Morgan. Although he stopped selling spice, he is dubious about efforts to control it.

“The government is one step behind science,” Amsterdam said. “It’s here to stay.”
Synthetic Cannabinoids, by State, 2010

Map showing the number of reports per state with different colors indicating the range of reports. The source is NFLIS.
AM-2201 Public Health and Safety Concern

- Many products encountered found to be laced with AM-2201
- These products are being abused by adolescents
- Emergency department presentations:
  - Agitation
  - Anxiety
  - Intense hallucinations
  - Psychosis
  - Seizures
  - Unresponsive
- Toxic effects are a medical concern
Synthetic Cathinones

- 3,4-DMMC
- 3-MEC
- 4-FLUOROISOCATHINONE
- 4-MEC
- 4-MePPP
- 4-METHYLBUPHEDRONE
- alpha-PBP
- alpha-PVP
- BUPHEDRONE
- BUTYLONE
- DIBUTYLONE
- DIMETHYLONE
- ETHYLCATHINONE
- ETHYLONE
- FLUOROMETHCATHINONE
- ISOPENTEDRONE
- MABP
- MDPBP
- MDPPP
- MDPV
- MEPHEDRONE
- METHEDRONE
- METHYLONE
- MOPPP
- MPHPP
- NAPYRONE
- N-ETHYLBUPHEDRONE
- PENTEDRONE
- PENTYLONE
Synthetic Cathinones, by State, 2010

Reports per State
- 50 or More
- 20-49
- 10-19
- 1-9
- 0
- No Data

Source: NFLIS
Synthetic Cathinones, by State, 2011

Source: NFLIS
### 2C/25 Series

<table>
<thead>
<tr>
<th>2C-B</th>
<th>2C-T-4</th>
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<tbody>
<tr>
<td>2C-B-Fly</td>
<td>2C-T-7</td>
</tr>
<tr>
<td>2C-C</td>
<td>2C-T-21</td>
</tr>
<tr>
<td>2C-D</td>
<td>25B-NBOMe</td>
</tr>
<tr>
<td>2C-E</td>
<td>25C-NBOMe</td>
</tr>
<tr>
<td>2C-G</td>
<td>25D-NBOMe</td>
</tr>
<tr>
<td>2C-H</td>
<td>25E-NBOMe</td>
</tr>
<tr>
<td>2C-I</td>
<td>25G-NBOMe</td>
</tr>
<tr>
<td>2C-N</td>
<td>25H-NBOMe</td>
</tr>
<tr>
<td>2C-P</td>
<td>25I-NBOMe</td>
</tr>
</tbody>
</table>
2C-Phenethylamine Reports, by State, 2010

Reports per State

- Dark Blue: 6-26
- Blue: 4-5
- Light Blue: 2-3
- Green: 1
- Light Green: 0
- White: No Data

Source: NFLIS
American Association of Poison Control Centers (AAPCC) Reporting

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

 Calls to U.S. Poison Control Centers

<table>
<thead>
<tr>
<th>Year</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calls</td>
<td>2,906</td>
<td>6,968</td>
<td>5,200</td>
</tr>
</tbody>
</table>

AAPCC as of December 31, 2012.
American Association of Poison Control Centers (AAPCC) Reporting

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

Calls to U.S. Poison Control Centers

AAPCC as of December 31, 2012.
WE DO NOT SHIP BATH SALTS TO LOUISIANA OR FLORIDA!!
ORDERS FROM LOUISIANA AND FLORIDA WILL BE CANCELLED!!

If you like IVORY WAVE, VANILLA SKY, RECHARGE etc.. you are going to LOVE PURE IVORY !!!

It has taken over a month but we finally received our shipment of Bath Salts. We will be adding "PURE IVORY" and "BOLIVIAN BATH" to our line. We were originally going to add "IVORY WAVE" but experienced major inconsistencies in quality from that product not to mention the fact that it is being heavily counterfeited in the UK and here in the USA...

PLEASE NOTE: Due to the concentrated nature of this product we strongly recommend that you purchase the 250mg size if you have never purchased this product before and that for the first few hours you only use one application (10-12mg). You will be surprised by how long it lasts -- there really is no need for a second application for hours. Once you have experienced PURE IVORY bath salts you will know how to apply in future.

It is also strongly recommend that you do not mix these bath salts with other similar products and for health and safety reasons its always best to stay away from alcohol and prescription medication. or be intoxicated when bathing using PURE IVORY or any other bath salts products.
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
Warning!

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.

A downstairs neighbor who identified herself as 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, went into the man’s Walter Street apartment, police searched the street a few minutes later. “When questioned, he stated that he did not tell police why he removed the gun.” He did not tell police why he removed 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)
Incidents Involving Synthetic Cathinones and Cannabinoids

Oct-10 Missouri  29-yr old man commits suicide by gun shot to head

Nov-10 Louisiana  21-yr old man cuts throat then shoots himself

Dec-10 Louisiana  Man gets lost in attic; tries to shoot his way out with .38 revolver

Dec-10 Louisiana  Woman in tub thinks she trapped in cage; young child unattended

Dec-10 Mississippi Deputy Sheriff shot and killed

Dec-10 Mississippi Man repeatedly stabs his face and stomach; survives

Dec-10 New Jersey Marine falls from 2nd story window with sword; Woman about to jump holding child

Dec-10 Kansas University student killed after running into head-on traffic
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Incident Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan-11</td>
<td>Florida</td>
<td>Daughter attacks sleeping 71-yr old mother with machete in attempt to behead her</td>
</tr>
<tr>
<td>Jan-11</td>
<td>Florida</td>
<td><strong>Man tears radar unit out of police cruiser with his teeth</strong></td>
</tr>
<tr>
<td>Feb-11</td>
<td>Florida</td>
<td>Man arrested for battering girlfriend</td>
</tr>
<tr>
<td>Feb-11</td>
<td>Louisiana</td>
<td>Overdose death of 47-yr old woman</td>
</tr>
<tr>
<td>Feb-11</td>
<td>Pennsylvania</td>
<td>Two overdose deaths including former State Trooper</td>
</tr>
<tr>
<td>Feb-11</td>
<td>West VA</td>
<td>Man violates domestic violence protective order</td>
</tr>
<tr>
<td>Mar-11</td>
<td>Kentucky</td>
<td>Mother leaves 2-yr old on busy interstate; found wandering in median carrying 5-yr old</td>
</tr>
<tr>
<td>Mar-11</td>
<td>Kansas</td>
<td>50-yr old man found in pajamas out of gas along interstate threatening to harm girlfriend</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>Event Description</td>
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<tr>
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<tr>
<td>Mar-11</td>
<td>Texas</td>
<td>Man enters police station, believes someone hiding under car</td>
</tr>
<tr>
<td>Mar-11</td>
<td>NJ</td>
<td>Rutgers student murdered by longtime boyfriend</td>
</tr>
<tr>
<td>Mar-11</td>
<td>PA</td>
<td>25-yr old man breaks into monastery and stabs priest</td>
</tr>
<tr>
<td></td>
<td>PA</td>
<td>Man jumps from 3rd story window fleeing from nonexistent person</td>
</tr>
<tr>
<td></td>
<td>PA</td>
<td>Couple destroy home walls trying to stab imaginary people; Arrested for endangering 5-yr old child</td>
</tr>
<tr>
<td></td>
<td>PA</td>
<td>Man arrested 3 times in 3 days; chased and entered cars</td>
</tr>
<tr>
<td></td>
<td>PA</td>
<td>Man flees car, believes it was melting and that he was being chased by electricity</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>Incident Description</td>
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</tr>
<tr>
<td>Mar-11</td>
<td>Pennsylvania</td>
<td>2 women arrested after reckless driving with 1 and 3 yr old children in vehicle</td>
</tr>
<tr>
<td>Mar-11</td>
<td>West VA</td>
<td>19-yr man arrested for pointing 3 rifles at family members</td>
</tr>
<tr>
<td>Apr-11</td>
<td>Pennsylvania</td>
<td>Two men found dead in Allegheny National Forest</td>
</tr>
<tr>
<td>Apr-11</td>
<td>Pennsylvania</td>
<td><strong>Man arrested carrying machete in public</strong></td>
</tr>
<tr>
<td>Apr-11</td>
<td>Pennsylvania</td>
<td>Woman driving with toddler arrested for traffic violations after driving erratically and repeatedly banging head against steering wheel</td>
</tr>
<tr>
<td>Apr-11</td>
<td>Pennsylvania</td>
<td>Man arrested in knifepoint robbery</td>
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<tr>
<td>Apr-11</td>
<td>Pennsylvania</td>
<td>Man who believed he was riding a train arrested after breaking into a community college</td>
</tr>
<tr>
<td>Date</td>
<td>Location</td>
<td>Event Description</td>
</tr>
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<tr>
<td>Apr-11</td>
<td>Pennsylvania</td>
<td>45-yr old man subdued by taser arrested, believed demons were after him</td>
</tr>
<tr>
<td>Apr-11</td>
<td>Pennsylvania</td>
<td>Man arrested on burglary charges after breaking into a house during early morning hours while the family was there</td>
</tr>
<tr>
<td>Apr-11</td>
<td>Illinois</td>
<td>Overdose death of woman</td>
</tr>
<tr>
<td>Apr-11</td>
<td>Illinois</td>
<td>Man arrested for disorderly conduct eats dirt while handcuffed</td>
</tr>
<tr>
<td>Apr-11</td>
<td>Ohio</td>
<td>3 arrested after shot is fired with infant and 3-yr old in house</td>
</tr>
<tr>
<td>Apr-11</td>
<td>Washington</td>
<td>Man shoots and kills wife then self during high speed car chase; 5-yr old son later found dead with plastic bag over head at their home</td>
</tr>
</tbody>
</table>
May-11 West VA
Teenager sexually assaults and kills neighbor’s goat with knife

May-11 N. Carolina
Man rams stolen car through front door of convenience store; Steals packets of bath salts

May-11 Pennsylvania
Over 50 rounds fired during shootout by 3 high on bath salts and a man who came to steal their bath salts

May-11 Kentucky
Man arrested at grocery store after damaging merchandise and drinking hand sanitizer

Jun-11 West VA
Man breaks into house at 1:30 a.m.; Breaks police vehicle window on way to jail

Jun-11 Indiana
36-year old commits suicide; Lost 50 pounds in 2 months
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun-11</td>
<td>Pennsylvania</td>
<td>3 arrested after robbing taxi driver and restaurant for money to buy bath salts</td>
</tr>
<tr>
<td>Jul-11</td>
<td>West VA</td>
<td>Woman scratches herself “to pieces”</td>
</tr>
<tr>
<td>Jul-11</td>
<td>Maine</td>
<td>Woman breaks into house and locks herself in bathroom</td>
</tr>
<tr>
<td>Jul-11</td>
<td>Maine</td>
<td>Man makes series of 911 calls; thought he was being chased by people with rifles</td>
</tr>
<tr>
<td>Jul-11</td>
<td>Maine</td>
<td>Man attempts “suicide by cop” wanting police to shoot him</td>
</tr>
</tbody>
</table>
Synthetic Drug “Manufacturing Facility”?

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
Control Efforts
Synthetic Drugs: State Controls

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

Placement of a substance into one of the 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 Office of Diversion Control
Federal Temporary Scheduling
Actions to Date Relative to Synthetic Drugs

- 5 Synthetic Cannabinoid Compounds
  Notice of Intent – November 24, 2010

- 3 Synthetic Cathinone Compounds
  Notice of Intent – September 8, 2011
Synthetic Drug Abuse Prevention Act of 2012

• On July 9, 2012, the President signed the Synthetic Drug Abuse Prevention Act of 2012 (Public Law 112-144), into effect

The law controlled 26 compounds into schedule I

• Provides language which defined the term “Cannabimimetic Agent” [the term means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the five structural classes named in the statute]
The legislation also extends the maximum time that DEA may temporarily control a substance pursuant to 21 U.S.C. 811(h), which is often referred to as the "emergency scheduling" provision.

Under the new law, the initial time period for temporary scheduling has been increased from 12 months to 24 months, and the extension period has been increased from 6 months to 12 months.

The maximum total amount of time a substance may remain temporarily scheduled is now three years.
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
Why are these 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
To Try to Defeat the Controlled Substance Analogue Act!!

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.
Proving Substantial Similarity

• Requires proof of substantial similarity both with respect to chemical structure and actual or represented pharmacological effect. The “intended for human consumption” requirement is often demonstrated by law enforcement investigations.

• The substantial similarity standard often results in a battle of the experts, which is resource intensive and highly unpredictable.

• Constitutional issues (e.g., vagueness) also often come into play.
OPERATION LOG JAM

Results of Operation

- 97 Arrests
- 265 Search warrants
- 73 Consent/Knock-talk contacts
- 1,085 Pounds raw synthetic cathinones
- 167,712 Packets of synthetic cathinones
- 5.3 million Packets of synthetic cannabinoids
- 1,909 Pounds Raw synthetic cannabinoids
- 10,487 Pounds of treated plant material
- 48,253 Pounds of untreated plant material
- More than $40,000,000 US Currency/bank accounts
- Vehicles/value 57/$1,973,500
- Other Assets $5,688,500
- Firearms 47
- 1096 gallons of acetone seized

U.S. Drug Enforcement Administration / Operations
Division / Office of Diversion Control
The Way Forward on the International Front

- Working to identify major foreign based sources (*Obscure middlemen, trading companies, & exporters*)

- Working to sensitize source countries regarding the threat and the need for international controls (*Insufficient regulations & legislation*)

- Working through the UN process to look at coordinated global outreach and cooperation (expanding upon UN CND Resolution 55/1 “Promoting international cooperation in responding to the challenges posed by new psychoactive substances”)