Combat Methamphetamine Enforcement Act (CMEA) Requirements for Retail Distributors & Synthetic Drug Overview

December 8-9, 2012
Pharmacy Diversion Awareness Conference (PDAC)
Indianapolis, Indiana

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

• Scope of the Methamphetamine Problem

• The Combat Methamphetamine Epidemic Act of 2005

• The Debate Over Tracking v. Scheduling
DEA’s MISSION

To disrupt the illicit clandestine manufacturing of controlled substances by preventing the diversion of chemicals to drug trafficking organizations.
Scope of the Methamphetamine Problem
**Methamphetamine Facts**

Methamphetamine is the **most widely abused**, domestically produced **synthetic drug** in the United States.

It is used across all genders, ages, and socio-economic levels.

Has a **high rate of addiction**, a **low rate of sustained recovery**, and is relatively **inexpensive** to manufacture.
An individual suffering from "crank bugs", a condition sometimes seen in cases of heavy methamphetamine abuse. A similar condition, called "coke bugs" or "snow bugs", is also seen in heavy cocaine users. This is a drug induced hallucination or sensation that bugs are crawling on or under the skin. The abuser picks at the skin in an attempt to remove the bugs. The individual pictured had similar marks on his legs, face, chest and back.
The U.S. methamphetamine threat is a two prong problem:

- Methamphetamine manufactured by Mexican Trafficking Organizations (large “Super Labs” in Mexico & the U.S.)
- Small Capacity Production Labs (SCPLs) (based in the U.S.)
Why Pseudoephedrine or Ephedrine to Make Methamphetamine?
The vast majority of the methamphetamine small capacity production laboratory (SCPL) operators in the U.S. acquire the ephedrine and/or pseudoephedrine they utilize from local pharmacies and other retail outlets.
Total Costs: $23.4 BILLION

And it all begins with Smurfing!!

*2009 Rand Study
TOP 5 STATES FOR CLAN LAB SEIZURES

1. MISSOURI – 8,918
2. TENNESSEE – 8,123
3. INDIANA – 5,751
4. KENTUCKY – 5,186
5. OKLAHOMA – 3,422

NATIONAL SEIZURE SYSTEM 2008-2012 (As of 11/28/12)
Pseudoephedrine & Ephedrine Smurfing
Smurfing

During seven-month period in 2008 a defendant:

• made 2,591 PSE purchases from 101 retail pharmacies
• on multiple occasions, he visited up to 25 different stores in one day
• made 412 purchases in excess of the 3.6 gram CMEA limit in a single day from the same store
High quality methamphetamine utilizing pseudoephedrine & ephedrine (very small capacity per lab / 1-3 grams)

Simple to manufacturer by combining into a single container:
- PSE tablets – whole or ground up
- Solvent – ether, camp fuel
- Lithium (batteries)
- Sodium Hydroxide
- Ammonium Nitrate (cold packs)
- Water

Exothermic Reaction
- Filter off liquid
- Use HCl generator to “crash” out Meth
One Pot Gone Wild
Anatomy of a Meth Lab

Investigation: Team of investigators – salary/overtime/equipment

Search Warrant: LE x 6-10 – salary/overtime/equipment/clan lab truck
   Fire Dept/EMS personnel – salary/overtime/equipment
   Assault/injuries/exposure Hospital care/Workers Comp

Children: Decon/Hospital eval & treatment / Social services/Foster care/Future?

Processing Lab Site: LE x 2 – salary/overtime / Chemist – salary/equipment

Cleanup: LE x2 – salary/overtime / Contractor – personnel/equipment/EPA approved disposal site

Real Estate: Remediation/lower property value (including surrounding homes)

Collateral Damage: Possible explosions/fires to include surrounding area

Defendants/Lab Operator: Hospital/Decontamination / Addiction treatment / Judicial costs
   Incarceration costs

Abusers: Addiction/violence & other criminal acts/unemployment/treatment/judicial costs/incarceration

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

- 1 lb of Meth Produces/Yields 5-6 Pounds of Toxic Waste

- U.S. Clean Up Costs
  2009 – $13.2 million
  2010 - $16.9 million
  2011 - $8.3 million
Why Is this Training Important?

• Because federal law, the Combat Methamphetamine Epidemic Act of 2005, says you cannot sell Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, or phenylpropanolamine until you have completed some form of training.

• This training will help you to understand the laws and what you must know before you can sell these drug products.
What is the Purpose of the Law?

- The law establishes requirements for selling Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, and phenylpropanolamine because these ingredients can be used illegally to make methamphetamine or amphetamine.

- In all states every seller of these drug products must follow the law.

- Some states have tougher laws than the current federal law. If your state has tougher laws, those laws must be followed in addition to the federal law.
What are ephedrine, pseudoephedrine, and phenylpropanolamine used for?

- Ephedrine and pseudoephedrine are used to make cough, cold and allergy drug products.
- Ephedrine is used to treat breathing problems.
- Pseudoephedrine is used to treat colds, allergies, and runny noses.
- Phenylpropanolamine is only sold by prescription for animal use.
What am I going to learn from this training?

This training will teach you that:

• You must keep a logbook of sales;

• The name on the identification your customer shows you matches the name your customer wrote in the logbook;

• Scheduled Listed Chemical Products must be kept either behind the counter or in a locked cabinet;

• You can sell only a limited amount (3.6 grams) of these drug products to each customer per day;

• Your customer can only buy a limited amount (9 grams) of these drug products in a 30-day period.
What Information is Required in the Logbook?

- You must keep a logbook which contains a written or electronic list of sales of drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine.

- You must write or enter in the logbook the name of the drug product and the quantity sold.

- Your customer must write or enter in the logbook their name and address, and the date and time of the sale.

- Your customer must also sign the logbook (signature).
Identification and Verification

• Your customer must show you a photo identification issued by a State or the federal government.

• You cannot sell Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, or phenylpropanolamine to customers unless they present appropriate identification.

• You must verify that your customer’s name on the photo identification matches the name your customer wrote in the logbook.

• You must verify that the date and time of the sale that your customer wrote in the logbook are correct.
When is my Customer NOT Required to Sign the Logbook?

- If your customer buys a single package containing not more than 60 milligrams of pseudoephedrine* (one 60 mg tablet or two 30 mg tablets)
  - Your customer does not have to sign the logbook.
  - Your customer does not have to show identification.

* Note: does not apply to ephedrine or phenylpropanolamine
Who Is Allowed Access to the Logbook Information?

- You may share information in the logbook:
  - To comply with the law; and
  - For a product recall.

- Logbook information may **only** be shown to local, state and federal law enforcement.

- Information in the logbook may be copied, inspected only, or turned over entirely.

- You must keep the logbook secure.
How do I store these drug products?

• You must store drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine either behind the counter or in a locked cabinet.

• You must give the drug product directly to the customer who signed the logbook.
How much of these drug products can I sell to each customer per day?

• You cannot sell more than **3.6 grams per day to each customer** of Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine or phenylpropanolamine.

• No matter how many sales you make to a customer, you cannot legally sell more than 3.6 grams per day of these drug products to the same person.
## Number of tablets in 3.6 grams

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Number of tablets = 3.6 grams</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mg Ephedrine HCl</td>
<td>175 Tablets</td>
</tr>
<tr>
<td>25 mg Ephedrine Sulfate</td>
<td>186 Tablets</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine HCl</td>
<td>146 Tablets</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine HCl</td>
<td>73 Tablets</td>
</tr>
<tr>
<td>120 mg Pseudoephedrine HCl</td>
<td>36 Tablets</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine Sulfate</td>
<td>155 Tablets</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine Sulfate</td>
<td>77 Tablets</td>
</tr>
<tr>
<td>120 mg Pseudoephedrine Sulfate</td>
<td>38 Tablets</td>
</tr>
<tr>
<td>240 mg Pseudoephedrine Sulfate</td>
<td>19 Tablets</td>
</tr>
<tr>
<td>Phenylpropanolamine (PPA)</td>
<td>FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use is by prescription only.</td>
</tr>
</tbody>
</table>
### Liquids - Number of milliliters in 3.6 grams

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Number of milliliters (ml) = 3.6 grams</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.25 mg Ephedrine HCl / 5 ml Liquid</td>
<td>3515 ml</td>
</tr>
<tr>
<td>15 mg Pseudoephedrine HCl / 1.6 ml Liquid</td>
<td>468 ml</td>
</tr>
<tr>
<td>7.5 mg Pseudoephedrine HCl / 5 ml Liquid</td>
<td>2929 ml</td>
</tr>
<tr>
<td>15 mg Pseudoephedrine HCl / 5 ml Liquid</td>
<td>1464 ml</td>
</tr>
<tr>
<td>15 mg Pseudoephedrine HCl / 2.5 ml Liquid</td>
<td>732 ml</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine HCl / 5 ml Liquid</td>
<td>732 ml</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine HCl / 2.5 ml Liquid</td>
<td>366 ml</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine HCl / 5 ml Liquid</td>
<td>366 ml</td>
</tr>
</tbody>
</table>

Phenylpropanolamine: FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use is by prescription only.
How much of these drug products can my customer buy in a 30-day period?

• Your customer cannot buy more than 9 grams in a 30-day period of Scheduled Listed Chemical Products containing ephedrine, pseudoephedrine, or phenylpropanolamine.
<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Number of tablets = 9 grams</th>
</tr>
</thead>
<tbody>
<tr>
<td>25 mg Ephedrine HCl</td>
<td>439 Tablets</td>
</tr>
<tr>
<td>25 mg Ephedrine Sulfate</td>
<td>466 Tablets</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine HCl</td>
<td>366 Tablets</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine HCl</td>
<td>183 Tablets</td>
</tr>
<tr>
<td>120 mg Pseudoephedrine HCl</td>
<td>91 Tablets</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine Sulfate</td>
<td>389 Tablets</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine Sulfate</td>
<td>194 Tablets</td>
</tr>
<tr>
<td>120 mg Pseudoephedrine Sulfate</td>
<td>97 Tablets</td>
</tr>
<tr>
<td>240 mg Pseudoephedrine Sulfate</td>
<td>48 Tablets</td>
</tr>
<tr>
<td>Phenylpropanolamine (PPA)</td>
<td>FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use by prescription only.</td>
</tr>
</tbody>
</table>
Liquids - Number of milliliters in 9 grams

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Number of milliliters (ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.25 mg Ephedrine HCl / 5 ml Liquid</td>
<td>8788 ml</td>
</tr>
<tr>
<td>15 mg Pseudoephedrine HCl / 1.6 ml Liquid</td>
<td>1171 ml</td>
</tr>
<tr>
<td>7.5 mg Pseudoephedrine HCl / 5 ml Liquid</td>
<td>7323 ml</td>
</tr>
<tr>
<td>15 mg Pseudoephedrine HCl / 5 ml Liquid</td>
<td>3661 ml</td>
</tr>
<tr>
<td>15 mg Pseudoephedrine HCl / 2.5 ml Liquid</td>
<td>1830 ml</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine HCl / 5 ml Liquid</td>
<td>1830 ml</td>
</tr>
<tr>
<td>30 mg Pseudoephedrine HCl / 2.5 ml Liquid</td>
<td>915 ml</td>
</tr>
<tr>
<td>60 mg Pseudoephedrine HCl / 5 ml Liquid</td>
<td>915 ml</td>
</tr>
</tbody>
</table>

Phenylpropanolamine | FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use is by prescription only. |
What I have learned from this training?

Now I know:

• how to keep a logbook of sales;
• how to verify information my customer provides me;
• these drug products must be stored either behind the counter or in a locked cabinet;
• I cannot sell more than 3.6 grams of these drug products per day to each customer; and
• my customer cannot buy more than 9 grams of these drug products in a 30-day period.
Additional information

• The Combat Methamphetamine Epidemic Act of 2005 can be found as Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Public Law 109-177)

• The Combat Methamphetamine Epidemic Act of 2005 was implemented into the Controlled Substances Act: 21 U.S.C. §§ 801-971

• For additional information see http://www.DEAdiversion.usdoj.gov
The Debate Over Tracking v. Scheduling
Logbooks electronically connected to database
- Database determines if individual can make purchase
- Permanent electronic record of purchase
- Stop sale ability
- Helps LE identify “smurfers”
- Leads to identification of lab operators and labs
- More arrests and seizures…maybe
- Great tool for LE ….. If all retail outlets are involved and the database is not corrupted by false IDs
Schedule III Prescription Only

- PSE and EPH can only be obtained pursuant to prescription from a physician or practitioner.

- Cannot freely purchase from retail outlets - ends unrestricted availability and smurfing.

- If a CS, PDMP may be utilized for tracking purposes (if authorized by state law or regulation).

- In place in Oregon – 96% lab seizure reduction.

- In place in Mississippi – 67% lab seizure reduction.
On July 24, 2012, the House Committee on Oversight and Government Reform held a hearing to examine the resurgence of methamphetamine production in the United States.

The committee specifically wanted to examine state-led efforts to address the clan lab problem through the scheduling of pseudoephedrine and ephedrine.
Decrease in labs leads to a decrease in resources expended – LE and local/city/state funds (OT, lab cleanups, environmental issues, children, defendants, citizens, & cops health care, foster care, etc.)

LE can restructure resources to handle other LE issues instead of providing cleanup service and chasing “smurfers”

Prevents labs – is not a reactive tool, but a preventative measure
As a DEA registered pharmacy, we are not required to maintain a ephedrine/pseudoephedrine logbook.

True or False
Question #2

Pseudoephedrine or ephedrine is the primary ingredient used in the domestic manufacture of:

a) Hydrocodone
b) Methamphetamine
c) Oxycodone
d) Soma
Federal law/regulations limit the retail sale of ephedrine or pseudoephedrine to 3.6 grams of these drug products to each customer per day, and the customer can only buy a limited amount (9 grams) of these drug products in a 90 day period.

True or False
SYNTHETIC DRUG
TRAFFICKING & ABUSE TRENDS
Outline

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

These drugs are perceived as being ‘legal’ alternatives to marijuana, cocaine, methamphetamine, and MDMA.
Designer Drugs: 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._
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
Synthetic Cannabinoids
Synthetic Cannabinoids:

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

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

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

• Synthetic Cannabinoids are sold in retail stores, on the internet, and in “head shops” as “Herbal Incense” or “Potpourri”

• Smoked alone or as a component of herbal products

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

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

<table>
<thead>
<tr>
<th>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”)
Synthetic Cathinones
Synthetic Cathinones

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

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

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

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

<table>
<thead>
<tr>
<th>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

- 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
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”
Methoxamine (MXE)

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

- Marketed to teens and young adults
- Easily attainable in retail environments and via the internet
- Unknown ingredient(s)
- No consistency in manufacturing process
- Not tested for human consumption / Unknown short & long term effects!!
- No known dosage – not FDA approved
- Synergistic effects likely when mixed with other drugs or alcohol
Scope of the Problem
‘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.
4-Methylnaphthalamethcathinone
Non-Controlled Until Very Recently
American Association of Poison Control Centers (AAPCC) Reporting

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

Updated as of July 6, 2012

Calls to U.S. Poison Control Centers

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
American Association of Poison Control Centers (AAPCC) Reporting

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

Updated as of July 6, 2012

Calls to U.S. Poison Control Centers

Calls to U.S. Poison Control Centers

<table>
<thead>
<tr>
<th>Year</th>
<th>Calls</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>304</td>
</tr>
<tr>
<td>2011</td>
<td>6,138</td>
</tr>
</tbody>
</table>

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
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
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)
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)
Control Efforts
Why are these synthetic compounds marketed the way they are?

- Synthetic cannabinoids are sold as incense products at retail outlets and on the Internet
- Synthetic cathinones are sold as bath salts and plant food at retail outlets and on the Internet

WHY?
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.
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
Actions to Date Relative to Synthetic Drugs

- 5 Synthetic Cannabinoid Compounds
- 3 Synthetic Cathinone Compounds
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 Prevention Act of 2012

Cannabimimetic agents (Cannabinoids)

5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497).
5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog).
1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678).
1-butyl-3-(1-naphthoyl)indole (JWH–073).
1-hexyl-3-(1-naphthoyl)indole (JWH–019).
1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200).
1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250).
1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081).
1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122).
1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398).
1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201).
1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694).
1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4).
1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR–18 and RCS–8).
1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203).
Cathinones
4-methylmethcathinone (Mephedrone).
3,4-methylenedioxypyrovalerone (MDPV).

Phenethylamines (2C Compounds)
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E).
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D).
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C).
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I).
2-(2,5-Dimethoxyphenyl)ethanamine (2C–H).
2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C–N).
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P).
International Control

- Vast majority of these compounds are research chemicals not under international control

- Often sourced from Asian nations and Eastern Europe
The Way Forward on the International Front

- Working to identify major foreign based sources

- Working to sensitize source countries regarding the threat and the need for international controls

- 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”)

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