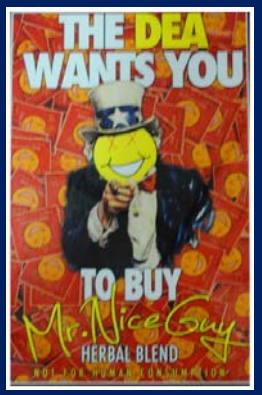
Combat Methamphetamine Enforcement Act (CMEA) Requirements for Retail Distributors & Synthetic Drug Overview



August 3 & 4, 2013
Pharmacy Diversion Awareness Conference (PDAC)
Baton Rouge, LA

Robert J Bell, Staff Coordinator,
Synthetic Drugs and Chemicals Section,
DEA Office of Diversion Control

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.

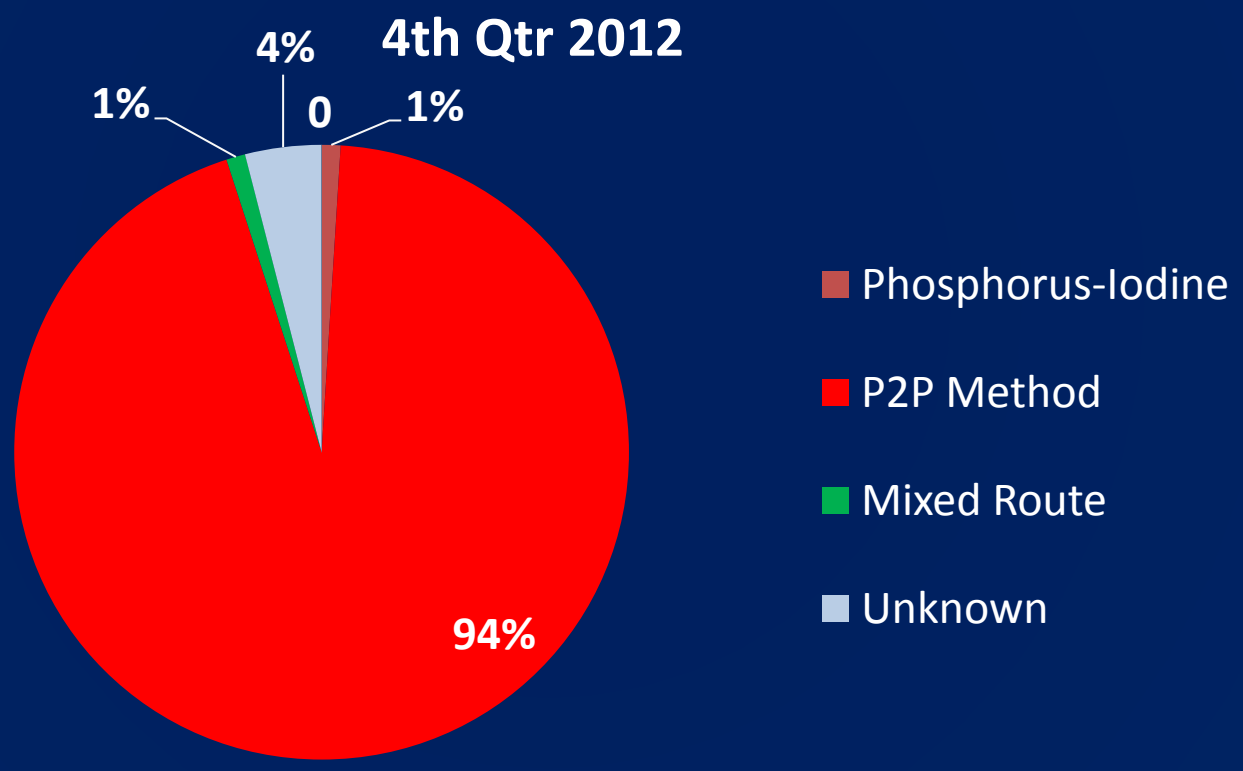
◄ An individual suffering from "crank bugs", a condition sometimes seen in cases of heavy methamphetamine abuse. A similar condition, called "coke bugs" or "snow bugs", is also seen in heavy cocaine users. This is a drug induced hallucination or sensation that bugs are crawling on or under the skin. 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.

U.S. Methamphetamine Problem

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.)

DEA Forensic Sciences
Methamphetamine Profiling Program (MPP)



Domestic Lab Problem: Fueled by Ephedrine & Pseudoephedrine

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

Why Pseudoephedrine or Ephedrine to Make Methamphetamine?

Because it Makes the Best Finished Product!!

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.

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*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

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

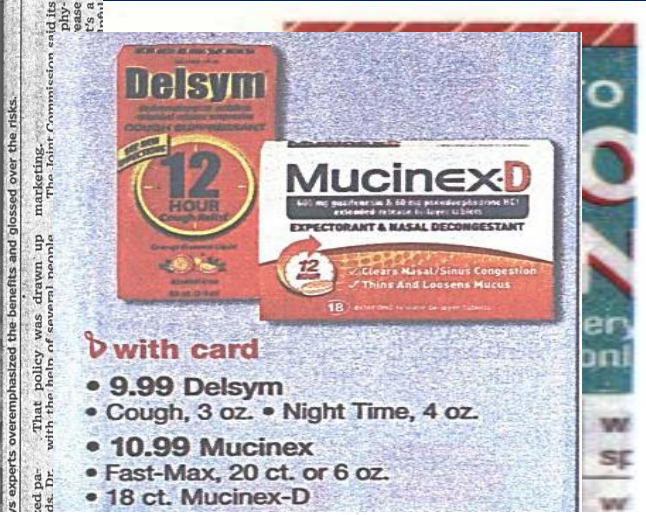
U.S. SCPLs Problem Dominated by Single Container Production Method

- 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

buy 1 get 1 50% off
with card Hot or Cold Therapy



with card
- 9.99 Delsym
- Cough, 3 oz. • Night Time, 4 oz.
- 10.99 Mucinex
- Fast-Max, 20 ct. or 6 oz.
- 18 ct. Mucinex-D

4.99

with card Household Cleaners
Items shown, plus: Liquid-Plumr, 16 or 17 oz. • Pine-Sol All Purpose, 40 oz. • Tilex Mold & Mildew, 32 oz. • Clorox Toilet Bowl, 2 pk., 3.5 oz ea.

5.99

balance rewards
buy 2 get 750 points

with card Energizer Batteries
Advanced Lithium: 4 pk. AA or AAA
- Single 9 volt Max: 8 pk. AA or AAA
- 4 pk. C or D • 2 pk. 9 volt

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

One Pot Gone Wild

"Two men plead guilty in meth lab-lab fire that heavily damaged Kalamazoo apartment building"

Kalamazoo Gazette March 31, 2010

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

Drug & Endangered Children (DEC)

On a daily basis, children are identified in federal, state, local and tribal law enforcement drug investigations

Drug & Endangered Children (DEC)

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

Ingredients	Number of tablets = 3.6 grams
25 mg Ephedrine HCl	175 Tablets
25 mg Ephedrine Sulfate	186 Tablets
30 mg Pseudoephedrine HCl	146 Tablets
60 mg Pseudoephedrine HCl	73 Tablets
120 mg Pseudoephedrine HCl	36 Tablets
30 mg Pseudoephedrine Sulfate	155 Tablets
60 mg Pseudoephedrine Sulfate	77 Tablets
120 mg Pseudoephedrine Sulfate	38 Tablets
240 mg Pseudoephedrine Sulfate	19 Tablets
Phenylpropanolamine (PPA)	FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use is by prescription only.

Liquids - Number of milliliters in 3.6 grams

Ingredients	Number of milliliters (ml) = 3.6 grams
6.25 mg Ephedrine HCl/ 5 ml Liquid	3515 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	468 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	2929 ml
15 mg Pseudoephedrine HCl / 5 ml Liquid	1464 ml
15 mg Pseudoephedrine HCl / 2.5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	732 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	366 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	366 ml
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.

Number of tablets in 9 grams

Ingredient	Number of tablets = 9 grams
25 mg Ephedrine HCl	439 Tablets
25 mg Ephedrine Sulfate	466 Tablets
30 mg Pseudoephedrine HCl	366 Tablets
60 mg Pseudoephedrine HCl	183 Tablets
120 mg Pseudoephedrine HCl	91 Tablets
30 mg Pseudoephedrine Sulfate	389 Tablets
60 mg Pseudoephedrine Sulfate	194 Tablets
120 mg Pseudoephedrine Sulfate	97 Tablets
240 mg Pseudoephedrine Sulfate	48 Tablets
Phenylpropanolamine (PPA)	FDA issued a voluntary recall as being unsafe for human consumption. Veterinary use by prescription only.

Liquids - Number of milliliters in 9 grams

Ingredients	Number of milliliters (ml) = 9 grams
6.25 mg Ephedrine HCl / 5 ml Liquid	8788 ml
15 mg Pseudoephedrine HCl / 1.6 ml Liquid	1171 ml
7.5 mg Pseudoephedrine HCl / 5 ml Liquid	7323 ml
15 mg Pseudoephedrine HCl / 5 ml Liquid	3661 ml
15 mg Pseudoephedrine HCl / 2.5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 5 ml Liquid	1830 ml
30 mg Pseudoephedrine HCl / 2.5 ml Liquid	915 ml
60 mg Pseudoephedrine HCl / 5 ml Liquid	915 ml
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

Tracking

- 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

Congressional Testimony in Support of National Legislation to Schedule Pseudoephedrine and Ephedrine

- 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

From Congressional Quarterly Today's online news (July 24, 2012)

- "We're talking about major declines in meth labs almost instantly after passage of those [state] laws. The policy works and it should be embraced on a nationwide scale."

"perhaps the most compelling (testimony) that I have heard."

- subjects during his years as a legislator, but "yours is perhaps the most compelling that I have heard."

Schedule III Prescription Only

- 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

DISCLOSURE – NEITHER of these Systems will have ANY impact on Methamphetamine Availability in the United States!!!!!!

Question #1

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

Question #3

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: A Tough Problem

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

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

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

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

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

Adverse Health Effects

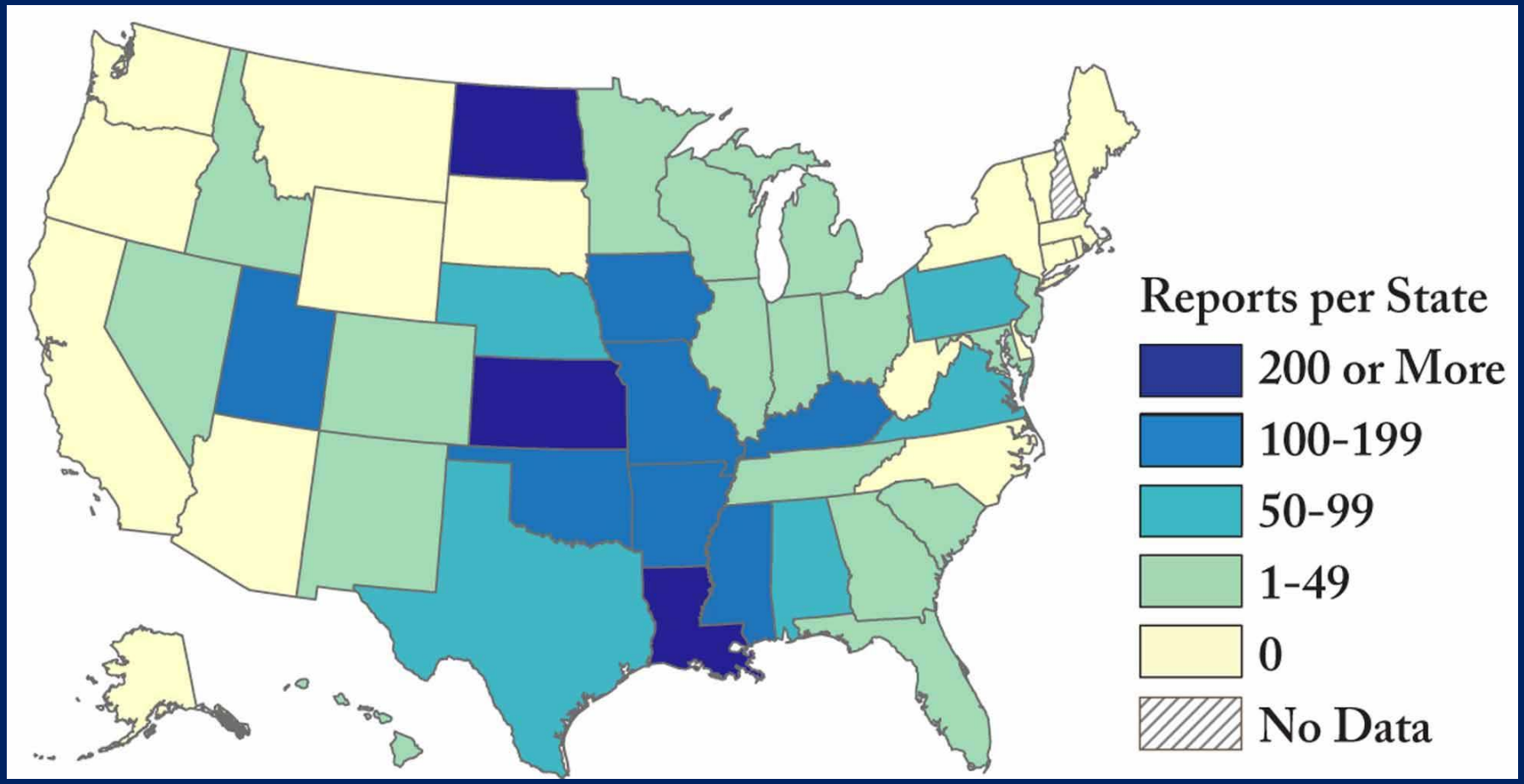
Multiple deaths have been connected to the abuse of these substances alone and with other substances on-board.

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	Conjunctivitis

Synthetic Cannabinoids

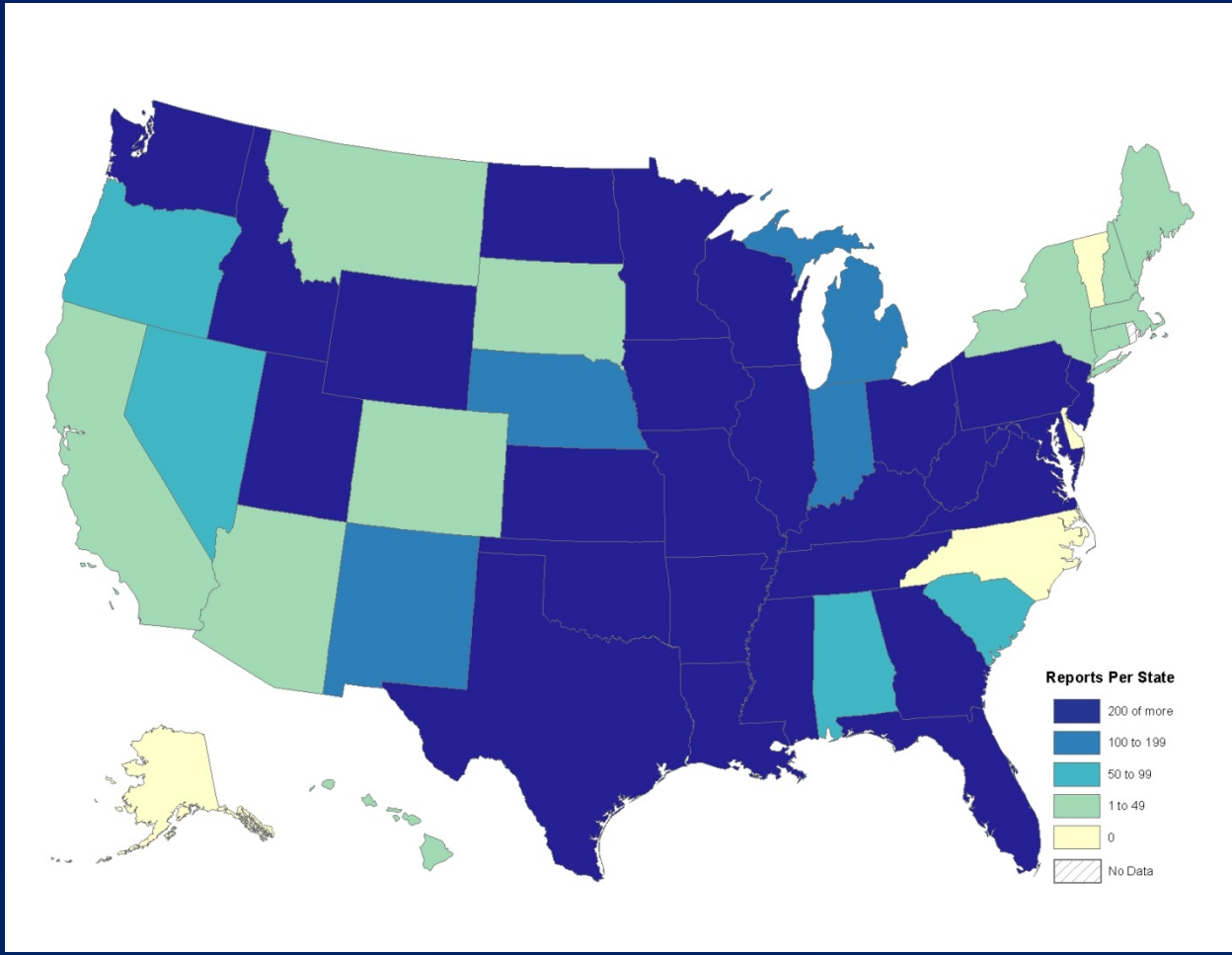
- Unregulated and unlicensed industry (many manufacturers)
- Full disclosure of ingredients typically not present
- Batch to batch variance (i.e., "Hot Spots")

Synthetic Cannabinoids, by State, 2010



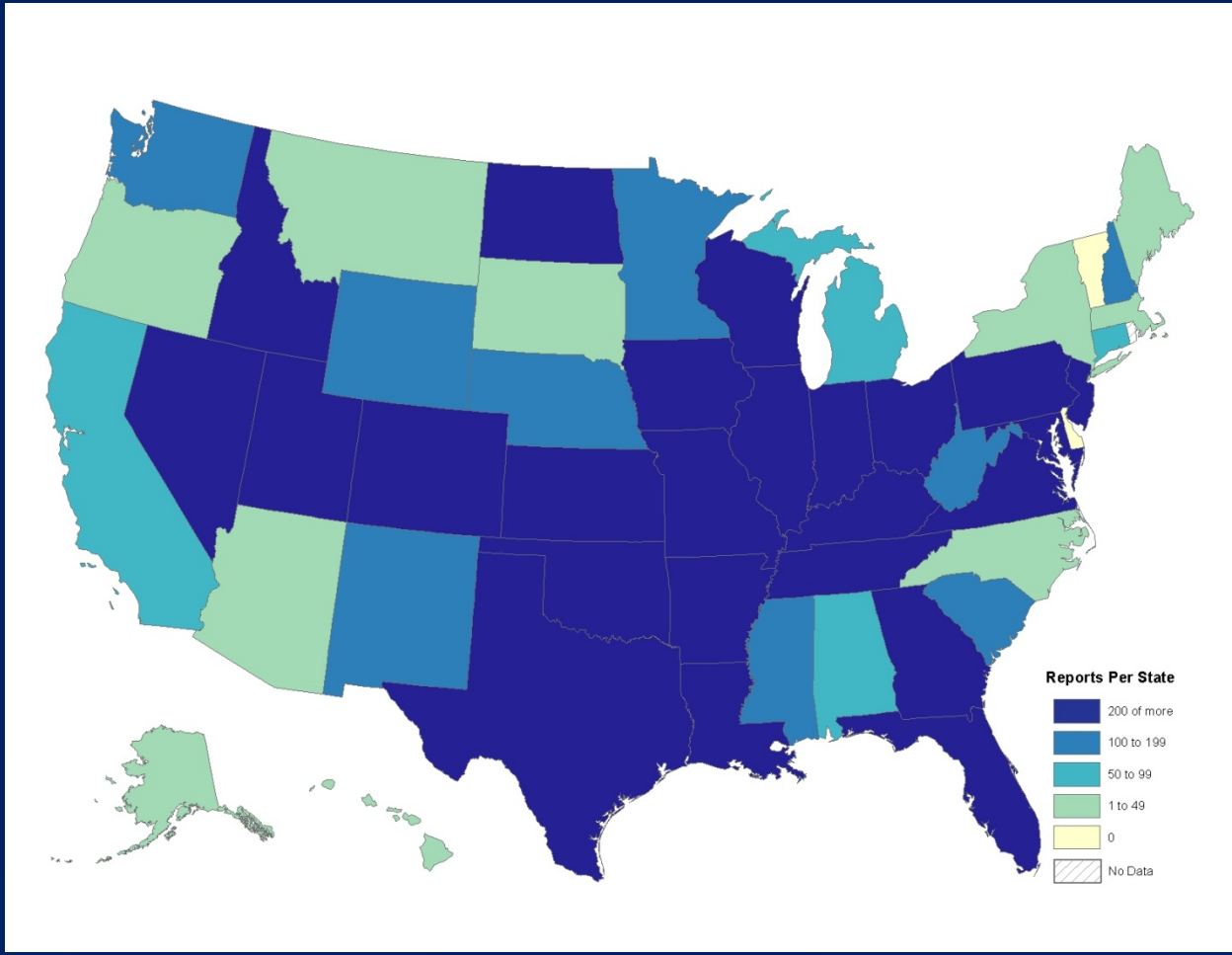
Source: NFLIS

Synthetic Cannabinoids, by State, 2011



Source: NFLIS

Synthetic Cannabinoids, by State, 2012



Source: NFLIS

Synthetic Cathinones

Synthetic Cathinones

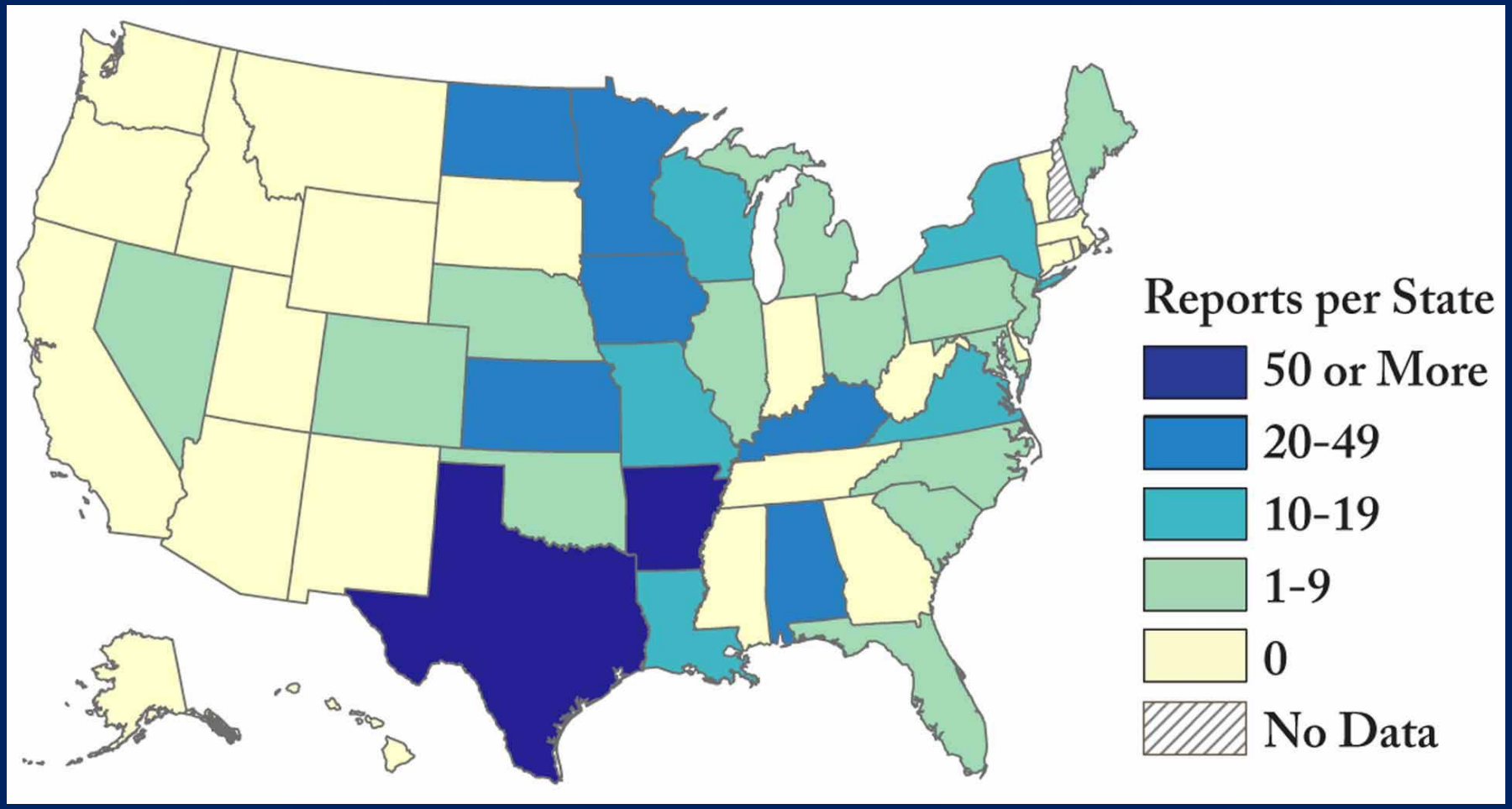
- Structurally and pharmacologically similar to amphetamine, Ecstasy (MDMA), cathinone, and other related substances.
- Are central nervous system (CNS) stimulants and have stimulant and psychoactive properties similar to schedule I and II amphetamine type stimulants.
- Synthetic cathinones are sold 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.

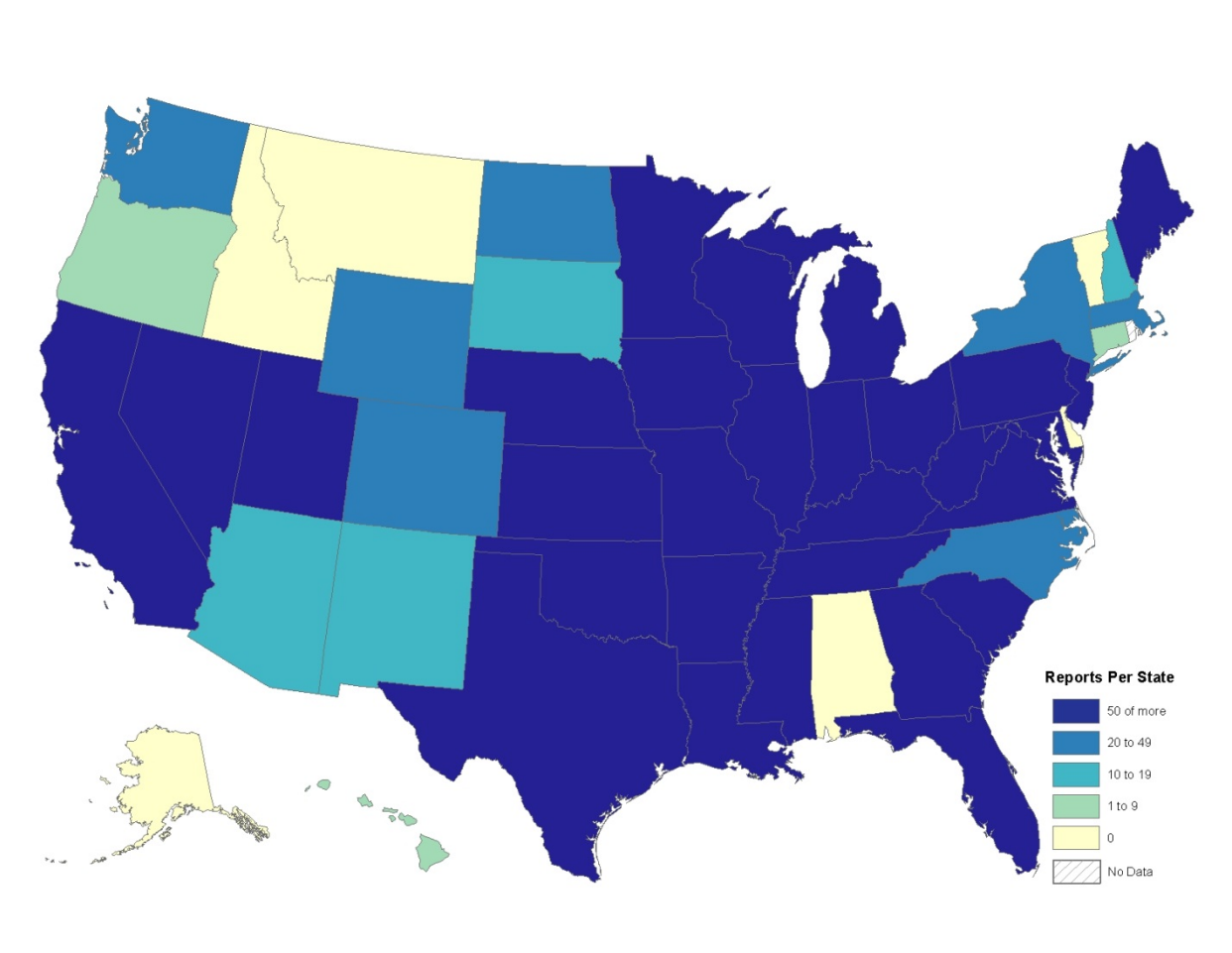
Cardiovascular	palpitations, tachycardia, chest pain, vasoconstriction, myocardial infarction
Psychological	Aggressive behavior, anger, anxiety, agitation, auditory and visual hallucinations, depression, dysphoria, empathy, euphoria, fatigue, formication, increased energy, concentration, panic attacks, paranoia, perceptual disorders, restlessness, self-mutilation, suicidal ideation
Neurological	Seizures, tremor, dizziness, memory loss, cerebral edema, headache, lightheadedness
Musculoskeletal	Arthralgia, extremity changes (coldness, discoloration, numbness, tingling), muscular tension, cramping
Gastrointestinal	Abdominal pain, anorexia, nausea, vomiting
Pulmonary	Shortness of breath
Ear Nose Throat	Dry mouth, nasal pain, tinnitus

Synthetic Cathinones, by State, 2010



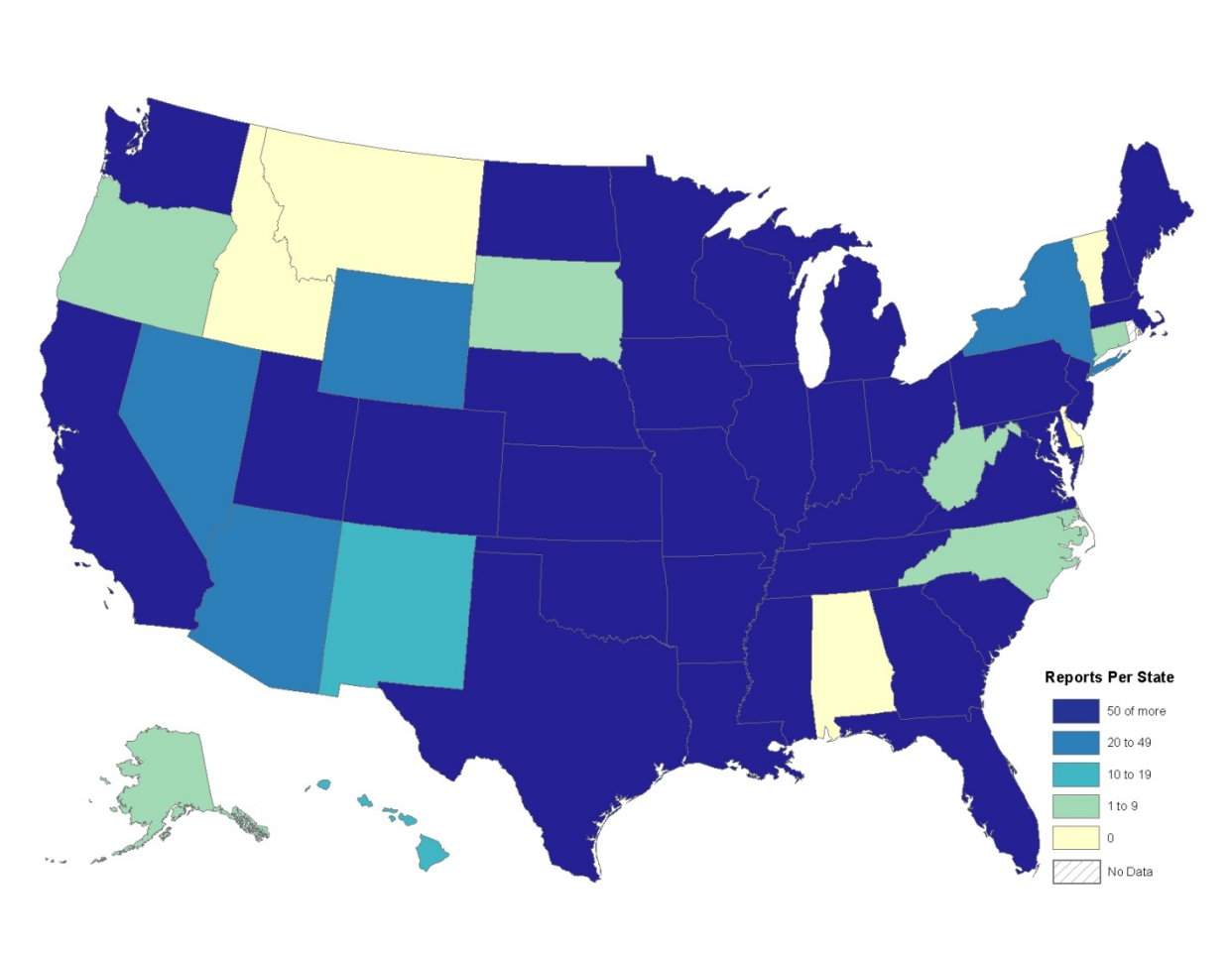
Source: NFLIS

Synthetic Cathinones, by State, 2011



Source: NFLIS

Synthetic Cathinones, by State, 2012



Source: NFLIS

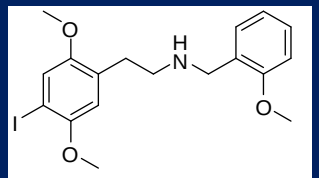
Synthetic Cathinones

- Like the cannabinoids, unregulated and unlicensed industry (many manufacturers)
- Full disclosure of ingredients typically not present
- Significant batch to batch variances (i.e., "Hot Spots")

Other Synthetic Compounds

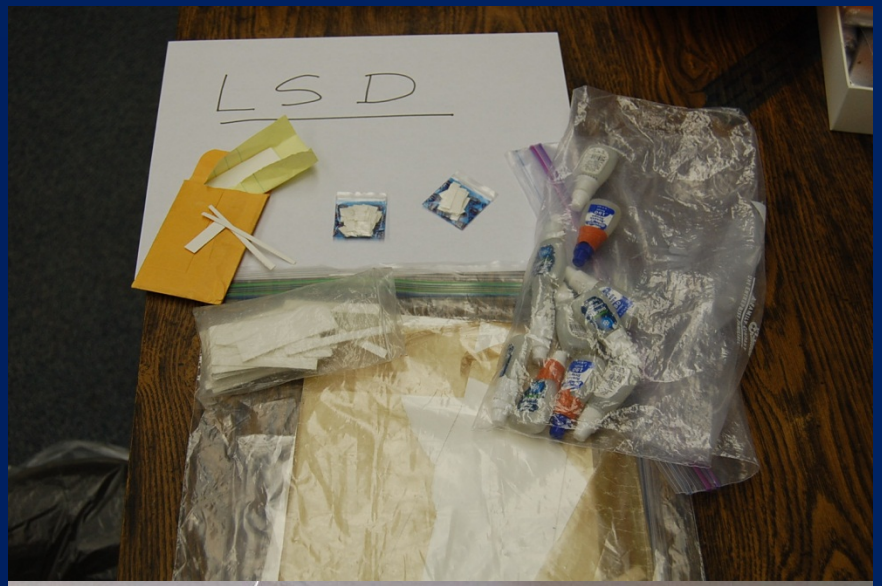
25I-NBOMe and 25C-NBOMe

- Hallucinogens, abused orally



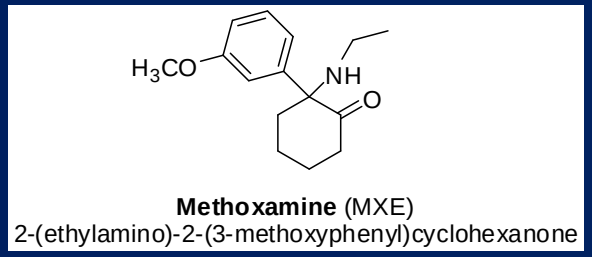
2C-I-NBOMe or 25I-NBOMe

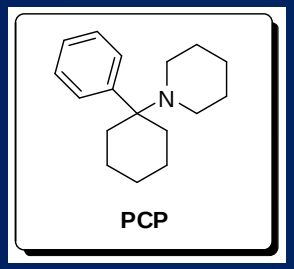
- Encountered on blotter paper and in dropper bottles
- Possibly mistaken for LSD
- Linked to recent deaths
- "N-BOMB", "Smiles"



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





CBP Photo

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

National Forensic Laboratory Information System (NFLIS) Participating Laboratories

DEA Office of Diversion Control

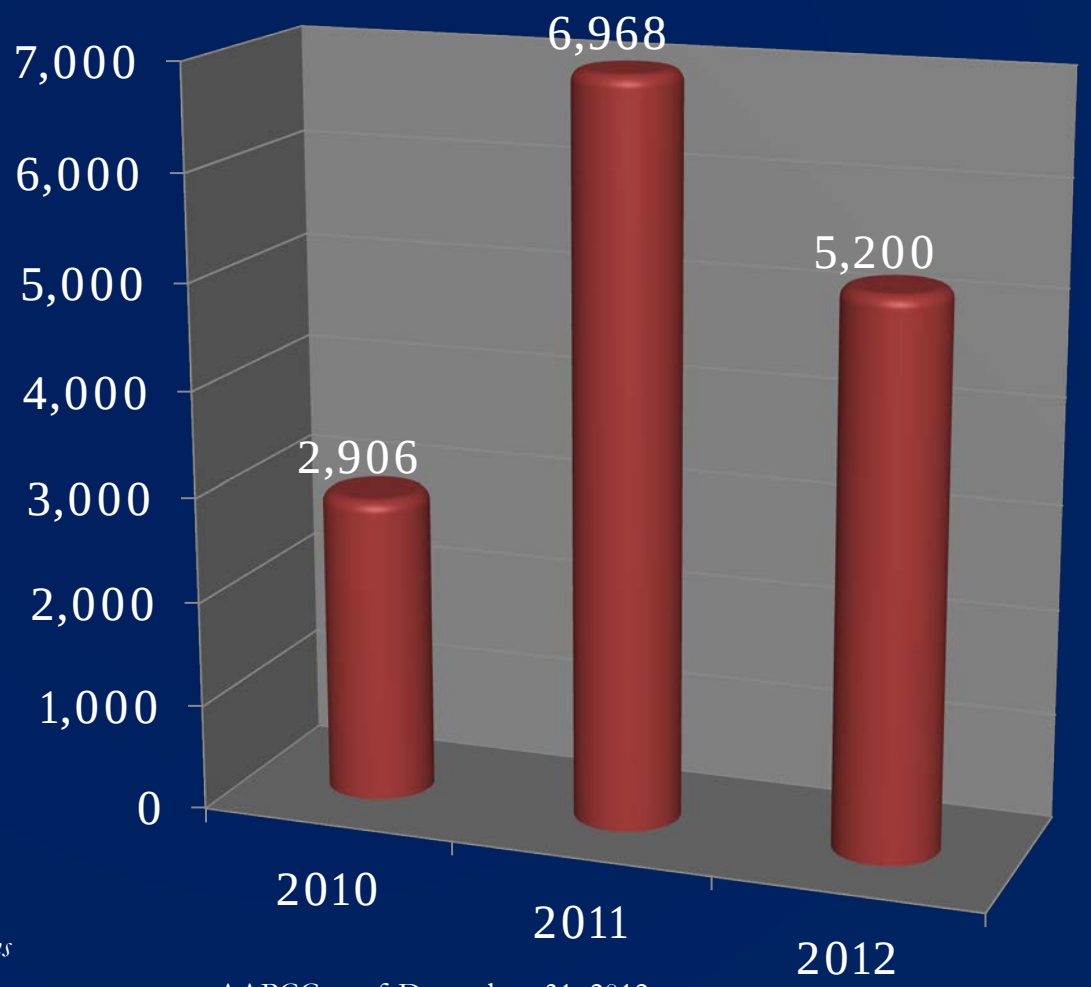
‘Spice’ makers alter recipes to sidestep state laws banning synthetic marijuana

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.

Calls to U.S. Poison Control Centers

American Association of Poison Control Centers (AAPCC) Reporting

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

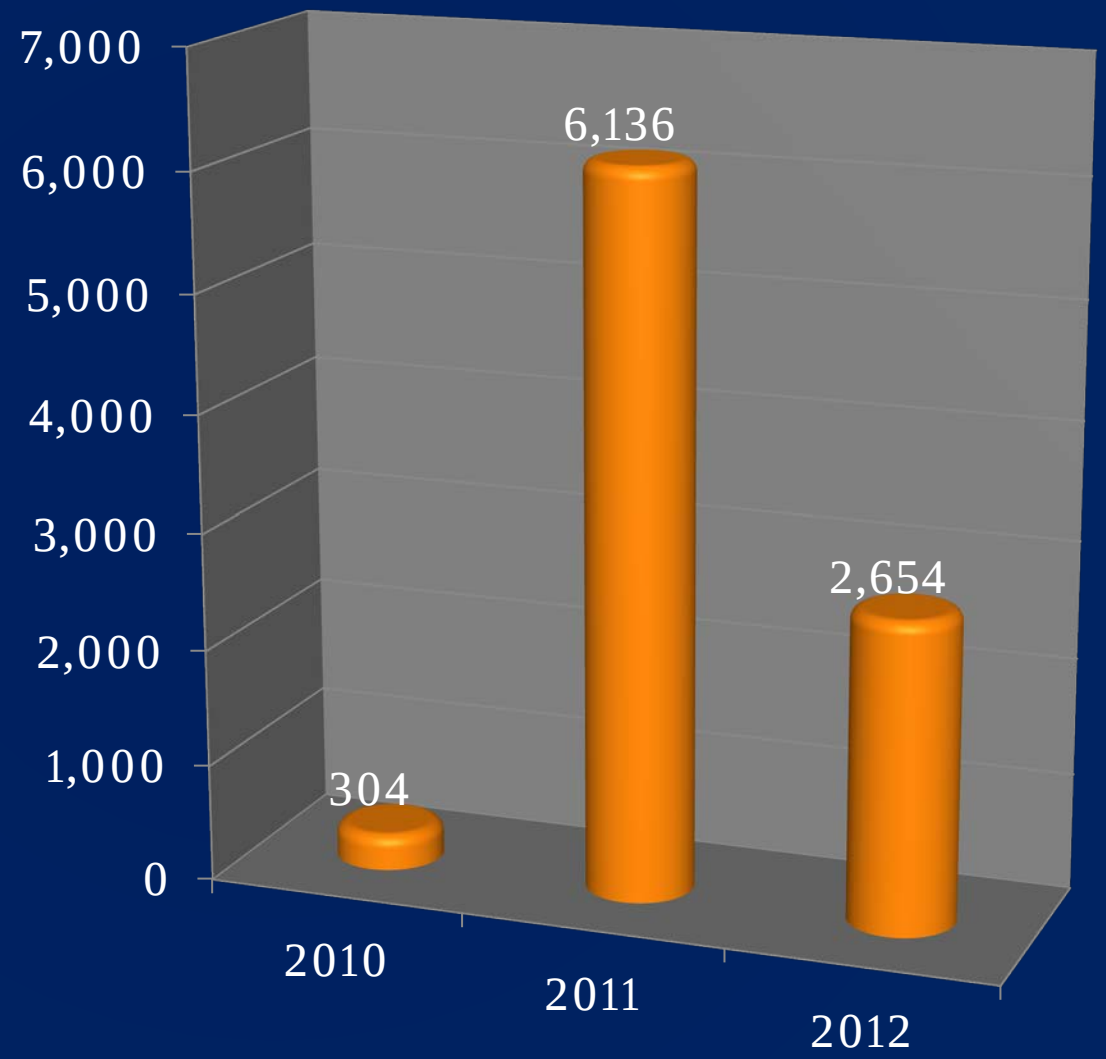


AAPCC as of December 31, 2012.

Calls to U.S. Poison Control Centers

American Association of Poison Control Centers (AAPCC) Reporting

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



AAPCC as of December 31, 2012.

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

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.

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,"

lice,

ath

When Bangor po illard, went into the man's Walter Street apar

Police searched th orn found the man on Buck Street a few minu

"When questione

he stated that the did in fact find an M4 rifle in two pieces wrappe e and 18 separate rounds of .223 [caliber] amm

He did not tell po said, adding, "we did confiscate the gun."

A local agent of t ng 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)

Synthetic Drug "Manufacturing Facility"?

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

Foreign Sourced Research Chemical

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

Synthetic Drug "Manufacturing Facility"?

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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

Federal Temporary Scheduling Process

- DEA collects information from law enforcement and public health officials regarding encounters and evaluates this information relative to the three factors required for temporary scheduling.

- Once sufficient information has been collected, a letter is transmitted from DEA to the U.S. Department of Health & Human Services (DHHS) to communicate intention to temporary schedule [and to verify no active new drug applications (NDAs) or investigations drug applications (INDs) for the proposed substances filed].

Federal Temporary Scheduling Process

- DEA letter of intent to DHHS, solicits a comment to control these substances within 30 days. Based on the DHHS response, a "Notice of Intent" can be published in the U.S. Federal Register with a "Final Order" published at minimum 30-days after the "Notice of Intent".

- As there is no "comment period" provided for temporary scheduling, civil and criminal sanctions applicable to the manufacture, possession, importation, and exportation are effective upon publication of the "Final Order".

Federal Temporary Scheduling Actions to Date Relative to Synthetic Drugs

- 5 Synthetic Cannabinoid Compounds
- 3 Synthetic Cathinone Compounds

Recent Federal Temporary Scheduling Actions

- On April 12, 2013 a *Federal Register Notice of Intent* to Temporarily Control three synthetic cannabinoids (UR-144, XLR11, and AKB48) was published.
- Controlling them will enable law enforcement to prosecute more importers, distributors and retailers for trading in dangerous drugs that cause Americans serious harm and death.
- After no fewer than 30 days, DEA will publish a Final Rule to Temporarily Control these chemicals as Schedule I substances for up to two years, with the possibility of a one-year extension.

U.S. 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]

U.S. Synthetic Drug Abuse Prevention Act of 2012

- 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

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

The Controlled Substance Analogue Act

- 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
- One reason for this marketing strategy is that traffickers think they are overcoming one of the major prongs of the Act

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.

The Controlled Substance Analogue Act: 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" (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

- 66 DEA Investigations
- 15 ICE/HSI Investigations

Operation "Log Jam"

Results of Operation

- 97 Arrests
- 265 Search warrants
- 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
- 47 Firearms
- 1096 gallons of acetone seized

The Way Forward on the International Front

- Working to identify major foreign based sources (*Obscure middlemen, trading companies, & exporters, sharing leads from "Operation Log Jam" and other investigations)*

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

- Continue to work bilaterally and with international partners to look at coordinating global outreach and cooperation (expanding upon UN CND Resolution 55/1 "*Promoting international cooperation in responding to the challenges posed by new psychoactive substances*")

Thank You / Questions