United States Encounters and Efforts against Synthetic Designer Drugs

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22nd National Conference on Pharmaceutical and Chemical Diversion

Antonio R. Guzman, Staff Coordinator
Synthetic Drugs and Chemical Section
U.S. Drug Enforcement Administration
Synthetics Drugs Overview

Looking Forward

Chemical Trafficking Trends (Meth, Cocaine & Heroin)

Questions?
Compounds Encountered in the U.S. since 2009

More than 233 new Synthetic Compounds From 8 Classes of Drugs

U.S. law enforcement has encountered:

- 95 synthetic cannabinoids
- 51 synthetic cathinones
- 87 other compounds (2C compounds, tryptamine, piperazines, etc.)
CHANGE

Change is the only constant in the drug world.
Synthetic Designer Drugs

• These drugs are perceived as being ‘legal’ alternatives to marijuana, cocaine, methamphetamine, MDMA and LSD

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

• Often more dangerous than the traditional illicit drugs they are purported to mimic
Synthetic Cannabinoids
(Spice, K2, legal weed)
What’s in a Name?

- Developer/institution
  - JWH = John W. Huffman
  - AM = Alexandros Makriyannis

- Website
  - RCS-4 (SR-19, BTM-4)
  - RCS-8 (SR-18, BTM-8)

- Pharmaceutical companies
  - A = Abbott Laboratories
  - WIN = Sterling Winthrop

- Pop culture references
  - 2NE1
  - AKB48
  - STS135
  - XLR-11
  - BB-22

- Chemical names
  - QUPIC (PB-22)
  - AB-FUBINACA
  - AB-PINACA
Synthetic Cannabinoid Profit Margin

One Kilogram of Powder

Thirteen Kilograms of Organic Leaf

$20.00 each 1 to 2 Gram Package

Approximately $250,000 Profit per Kilogram
Synthetics

Cannabinoids by Generation*

• **Generation 1**
  – Includes: JWH-018, JWH-019, JWH-073

• **Generation 2**
  – Includes: AM 2201, RCS-4, JWH-122

• **Generation 3**
  – Includes: AKB48, STS-135

• **Generation 4**
  – Includes: UR-144, 5-Fluoro-UR-144

• **Generation 5**
  – Includes: PB-22, 5-fluoro-PB-22, BB-22

• **Generation 6**
  – Includes: AB-PINACA, AB-FUBINACA, ADB-PINACA

• **Generation 7**
  – Includes: THJ-018, FUB-PB-22

* Generations identified by DEA STRL
Synthetic Cannabinoids

- Unregulated and unlicensed industry
- Multiple manufacturers

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

• What does it look like?

• How is transformed/made into a usable form?
SYNTHETIC CANNABINOID

4-methoxynaphthalen-1-yl-
(1-pentylinde-3-yl)methanone
For Research Purposes ONLY
Not for Human Consumption
ACETONE SOLVENT – 5 gallon cans
Bulk Plant Material
Dried Ground Plant Leaves
Mix the product
Add Flavoring
Packaging Center
Packaging can be done by hand or using automated tools. Commercial packages are typically 1g, 3g, 5g, and 10g sizes.
Other Processing Locations
Sold at Gas Stations, Convenience Stores, Head Shops and Online
Why Spice? - 18 year old’s perception

• “Spice vs Marijuana”
  – Doesn’t show up on urinalysis testing
  – More potent
    • “10Xs higher”
  – Less expensive
    • “10Xs cheaper”
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>
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</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>
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<tr>
<td>Metabolic</td>
<td>Hypokalemia, hyperglycemia</td>
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<tr>
<td>Gastrointestinal</td>
<td>Nausea, vomiting</td>
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<tr>
<td>Autonomic</td>
<td>Fever, mydriasis</td>
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<tr>
<td>Other</td>
<td>Organ damage</td>
</tr>
</tbody>
</table>
Cost Comparison – “potpourri”

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

AB-PINACA and nicotine

5F-UR-144
Brand: Magic Juice Watermelon

AB-FUBINACA
Components of disposable E-cigarette

- Material soaked in liquid is wrapped around the heating element
- Battery that supplies power to the heating element
- Body of the e-cig
- Heating element
Dropper bottles used with refillable E-cigs

AB-PINACA and AB-FUBINACA
BATH SALTS, PLANT FOOD, GLASS CLEANER, ETC.
Synthetic Cathinones
(bath salts, plant food, glass cleaner, “Molly”)

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

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

• Synthetic cathinones are sold in retail stores, on the internet, and in “head shops” as “bath salts”, “plant food”, “jewelry cleaner”, “lady bug attractant” and others.
Synthetic Cathinones
(bath salts, plant food, glass cleaner)

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

- Blow – ½ gram = $40
- 453 grams per pound
- 680 grams in above Plant Food
- Equivalent Cost = $54,400
Synthetic cathinone users commonly report cardiac, psychiatric, and neurological signs and symptoms with death.

### Adverse Health Effects: Cathinones

<table>
<thead>
<tr>
<th>System</th>
<th>Symptoms</th>
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<tr>
<td>Cardiovascular</td>
<td>palpitations, tachycardia, chest pain, vasoconstriction, myocardial infarction</td>
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<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>
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<tr>
<td>Neurological</td>
<td>Seizures, tremor, dizziness, memory loss, cerebral edema, headache, lightheadedness</td>
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<tr>
<td>Musculoskeletal</td>
<td>Arthralgia, extremity changes (coldness, discoloration, numbness, tingling), muscular tension, cramping</td>
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<tr>
<td>Gastrointestinal</td>
<td>Abdominal pain, anorexia, nausea, vomiting</td>
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<tr>
<td>Pulmonary</td>
<td>Shortness of breath</td>
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<tr>
<td>Ear Nose Throat</td>
<td>Dry mouth, nasal pain, tinnitus</td>
</tr>
</tbody>
</table>
Synthetic Cathinones

• Also sold in pill form
• Popular at Clubs
• Available at Parties
• Mimics MDMA
  – Ecstasy/XTC
• Street name “Molly”
The Story of “Molly”

- Ecstasy tablets in the 1980’s – early 2000’s typically contained MDMA
- In approximately 2006, ecstasy tablets featured mostly BZP/TFMPP combinations
  - Users disliked the hangover with this combination
- Rise in crystal or powder MDMA
  - Called “Molly”
- Many current “Molly” investigations have been found to be methylone or other substituted cathinones
  - Cost and easy to obtain
Molly

- Some of the Drugs found in “Molly" (Scheduled)
  - MDMA (1985)
  - Methylone (October 2011)
  - A-PVP (March 2014)
  - 4-MEC (March 2014)
  - Pentadrone (March 2014)
  - Butylone (March 2014)
  - Ethylone
  - others
Using Molly

• Users report that the drug takes effect approximately 15 to 30 minutes after ingestion and that the effects last approximately 2 to 4 hours.

• Molly can be ingested by sniffing or snorting, taken orally, smoked, or liquefied and injected.

• Others report swallowing molly-filled capsules, or dissolving it into a fluid and then drinking it.

• Some say Molly has a bitter taste and is better consumed by “parachuting”
  ○ A method whereby the molly powder is wrapped in a facial tissue and then swallowed.
  ○ The tissue then slowly dissolves and introduces molly into the stomach.
Effects of “Molly”

• The interest in taking these substances is a perception that it enhances visual, audio, and tactile senses.

• Synthetic cathinones act as CNS stimulants, which can cause rapid heart rate, chest pains, insomnia, sweating, and vomiting.

• People using these substances have reported paranoia, delusions, agitation, seizures, suicidal thoughts, and panic attacks. *Body temperature rising is a side effect.

• It is also believed that molly and other synthetic cathinones lower inhibitions and increase sociability.
Other Synthetic Drugs of Abuse
Other Synthetic Drugs of Abuse
MXE - Methoxamine

- 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
Acetylfentanyl

- Chemically-modified derivative of the powerful prescription painkiller Fentanyl
- is reportedly “50 times more potent than heroin and 100 times stronger than morphine
- May 2013 - 10,000 pills of “Desmethyl Fentanyl” intercepted in Montreal— hidden inside a microwave oven and a toaster destined for Colorado
  - Additional 1,500 kilograms of various raw materials; enough to make an additional 3 million pills seized
Acetylfentanyl

• RI Medical Examiner's Office regarding twelve (12) overdose deaths in March/April 2013
• Preliminary Lab/Toxicology reports attribute OD deaths to Acetylfentanyl
  – 5 of 12 overdose deaths occurred in Woonsocket, RI
  – May 16, 2013 two individuals arrested in Woonsocket, RI in possession of 28 grams of suspected Acetyl fentanyl
• Attempts will be made to confirm link to OD deaths
Phenethylamines

25I-NBOMe and 25C-NBOMe

“N-BOMB”, “2-5-I”, “Eye” and “Smiles”

- Hallucinogen, abused orally or through nasal passages
- Encountered on blotter paper and in dropper bottles
- Taken as a substitute for LSD
- Linked to several overdose deaths
- 11/2013 controlled 25I-NBOMe, 25B-NBOMe & 25C-NBOMe
Addressing through Legislation
<table>
<thead>
<tr>
<th>Cannabinoids</th>
<th>Cathinones</th>
<th>Phenethylamines</th>
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</thead>
<tbody>
<tr>
<td>1) AM2201</td>
<td>1) Mephedrone</td>
<td>1) 2C–E</td>
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<tr>
<td>2) AM694</td>
<td>2) MDPV</td>
<td>2) 2C–D</td>
</tr>
<tr>
<td>3) CP-47,497</td>
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<td>3) 2C–C</td>
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<tr>
<td></td>
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<td>4) 2C–I</td>
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<td>5) 2C–T–2</td>
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<td>6) 2C–T–4</td>
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<td>7) 2C–H</td>
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<td>8) 2C–N</td>
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<td>9) 2C–P</td>
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<td>4) CP-47,497 – C8</td>
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<td>homologue</td>
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<td>5) JWH-018</td>
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<td>15) SR-18</td>
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Why is it hard for law enforcement to keep up?
Designer Drug Market Encounters

Mar 2010
State controls initiated

Oct 2010
DEA notice to schedule published

Mar 2011
Final Order placing 5 synthetic cannabinoids in Schedule I

Jun 2012
Federal legislation signed, placing 15 synthetic cannabinoids in Schedule I

Jun 2012
GA Pharmacy Board bans UR-144 & XLR-11

Jul 2012
KS Board of Pharmacy bans UR-144

Dec 2012
State controls UR-144 XLR-11
Synthetics

Cannabinoids by Generation*

- **Generation 1**
  - Includes: JWH-018, JWH-019, JWH-073
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- **Generation 7**
  - Includes: THJ-018, FUB-PB-22

*Generations identified by DEA STRL*
PUBLIC SAFETY CONCERNS

- Overdoses
- Violent Behavior
- Assaults/Attacks
- Homicides
- Suicides
- DUIs with Fatalities and Severe Injuries
- Media Reports – bizarre behavior
  - MS - Self Mutilation
  - IA – Man Eats Dirt
  - NJ – Priest Stabbed
  - PA – Stabbing of Friend
  - ME – Man sees people coming out of mattress, arrested with rifle
  - TN – Couple hallucinates burglary and shoots up house
  - CO – Naked car chaser high on bath salts
  - LA - Suicide
Addressing through Legislation
Synthetic Drugs: U.S. State Controls

- Legislation
- Department of Health
- Pharmacy Board
- Consumer Affairs Dept.
## 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
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### Cathinones
1. Mephedrone
2. MDPV
3. (Methylone)

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

DEA Office of Diversion Control
Why is it hard for law enforcement to keep up?
In the U.S., why are synthetic compounds marketed the way they are (i.e., not for “Human Consumption”)?

- Synthetic cannabinoids are sold as “potpourri” or “incense” products at retail outlets and on the Internet
- Synthetic cathinones are sold as “bath salts”, “jewelry cleaner,” and “plant food” at retail outlets and on the Internet
The U.S. 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.
Assessment of U.S. Analogue Act

• Many successful prosecutions

• 1986 – 2011: ~ 62 prosecutions

• 2011 – Present: ~ 400 prosecutions
Jury Conviction

• “Last Place on Earth” – October 8, 2013
  – Guilty on 51/55 counts
  – jury found drugs to be “controlled substance analogues”
  – AM2201, UR-144, XLR11, 5-MeO-DALT, 4-fluoroamphetamine, and 4-MePPP
Recent Sentencing

  (WDVA – Harrisonburg)

  – Three defendants sentenced in the distribution of synthetic
cathinone drug a-PVP
  • Defendant 1 – 108 months in prison
  • Defendant 2 – 72 months in prison
  • Defendant 3 – 84 months in prison
Perceived Risk and Availability
2012 Monitoring the Future Survey

1 in 9 (11%) High School Seniors (synthetic cannabinoids)
Hospital Emergency Room Admissions

SYNTHETIC CANNABINOID ABUSE
(Spice, K2, legal weed, synthetic marijuana)

- 2010: > 11,000
- 2011: > 28,000

SYNTHETIC CATHINONE ABUSE

- 2010: No Data
- 2011: > 22,000

Source: SAMHSA/DAWN (2011 is the most current report)
8 Teenagers in GA Hospitalized - 8/22/13

Symptoms: Nausea, Vomiting, Weakness, Dry Mouth, Cardiac Problems, Paralysis

Suspected Substance: ADB-PINACA
Denver, CO

* Reports of 3 overdose deaths
* Smoking synthetic drug under the name of “Black Mamba”
* CDC Reports that up to 221 people have been hospitalized

3 Dead, Cause Believed to be Synthetic Marijuana
by KREX News Room

DENVER, Colo. Officials believe synthetic marijuana has taken the lives of three people on the Front Range, and now experts from the Centers for Disease Control and Prevention are investigating.

"Spice," "K2" or "Black Mamba" are names for the drug, which is distributed in little packets.

Police believe that a bad batch is being spread around and has left more than 75 people in area emergency rooms, several of those are on life support.

The dangerous drug can be 800 times more potent than THC, the chemical in marijuana that makes you high.

Investigators are currently looking into where people are getting the drugs.
We will not arrest our way out of this problem!

- Enforcement is just as important as....
- Prevention/Education
- Treatment
2013 Monitoring the Future Survey

1 in 13 (7.9 %) High School Seniors (synthetic cannabinoids)
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”.

U.S. Drug Enforcement Administration / Operations Division / Office of Diversion Control
On July 9, 2012, the President signed the Synthetic Drug Abuse Prevention Act of 2012 (Public Law 112-144)

- The law controlled 26 compounds into schedule I
Defined the term “Cannabimimetic Agent” [any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist].

Extends the maximum time that DEA may temporarily control a substance.

Initial time period for temporary scheduling increased from 12 to 24 months / Extension period increased from 6 months to 12 months.

# U.S. Synthetic Drug Abuse and Prevention Act 2012

**Cannabinoids**

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

**Cathinones**

1. Mephedrone
2. MDPV

**Phenethylamines**

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The U.S. Controlled Substance Analogue Act

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

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

- The substantial similarity standard often results in a battle of the experts, which is resource intensive and highly unpredictable.
The Way Forward on the International Front

- Working to identify major foreign based sources
- Working to sensitize partner nations regarding the threat and the need for international controls
- Continue to work bilaterally and with international partners to look at coordinating global outreach and cooperation
Enhancing International Cooperation in the Identification & Reporting of NPS

*(E/CN.7/2013/L.2/ March 2013)*
New Drugs, New Approaches  
The New Zealand Experience  
Enacted 7/18/13

- Ban all NPS not currently regulated

- Create pathway to the market for substances that can be shown to pose no more than a low risk of harm

- Those wishing to sell a NPS will first have to provide clinical data showing that product does not pose undue risk to user or society
New Drugs, New Approaches
The New Zealand Experience

- Strict advertising control
- Can only be sold by licensed party pill shops
- Packaging must be approved and Ingredients must be listed
- Manufacturing practice standard Ingredients
DEA Web-based Resources

www.GetSmartAboutDrugs.com
DEA Web-based Resources

www.JustThinkTwice.com
Methamphetamine Seizures Along the U.S. SW Border (Kilograms)

Source: NSS-EPIC
Query Date: July 1, 2014

Statistics are for Texas, New Mexico, Arizona and California.
P2P Production Area
Jalisco, Mexico
Yearly Purity Results

Number of samples analyzed above each data point
P2P vs. PSE/EPH

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<th>Percentage of Samples</th>
<th>1Q to 3Q-2007</th>
<th>1Q-2008</th>
<th>3Q-2008</th>
<th>1Q-2009</th>
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<td>P2P Method</td>
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<td>Phosphorus-Iodine</td>
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Precursors in Mexico

- Phenylacetic Acid (PAA) regulated
- Esters of PAA now being used
  - Ethylphenyl Acetate (EtPAA)
  - Methylphenyl Acetate (MePAA)
  - MePAA $\rightarrow$ PAA $\rightarrow$ P2P $\rightarrow$ Methamphetamine

- Recent Seizures of EtPAA
  - Guatemala
  - El Salvador
  - Nicaragua

- Potential to manufacture many metric tons per shipment
d-Methamphetamine Trends

**d-isomer only**

- U.S. Combat Meth Act signed into law
- Gradual Comeback of d-meth

Percent of samples

LEVAMISOLE – (Ergamisol)- an old drug once used to treat parasitic worm infections

*Over 80 % of cocaine seized in US is laced w/ levamisole (avg concentration approx 10 %)

*Can lead to severe reduction of white blood cells, a problem called agranulocytosis.

*Cutting agent or modifies pharmacological properties of cocaine

*ID of synergism for cocaine/levamisole interaction (Neuropharmacology, 1/2014, Temple Univ Sch of Med)
WITHDRAWAL FROM OPIATES

"One patient said to me, 'Imagine the worst flu when you’re shivering, you’re vomiting, you can’t eat, you have diarrhea, every atom in your body hurts, you can’t sleep, you lie on the floor just shivering ... and multiply that times a million,'" Fallieras recounted. "And you know if you can just take the pill or inject yourself with heroin, that it just all goes away."
Thank You for your Attention

Antonio R. Guzman
Staff Coordinator
Synthetic Drugs and Chemicals Section
antonio.r.guzman@usdoj.gov