Chemical Control Actions

Liqun L. Wong
Chief
Data Analysis Unit
Drug & Chemical Evaluation Section
Office of Diversion Control
Drug Enforcement Administration

2016 DEA Chemical Industry Conference
Mesa, Arizona
May 4-5, 2016
ODE Section Functions

Activities:

- **Scientific evaluations pertaining to drug control and chemical regulations under CSA**
  - Control status determinations
  - Drug scheduling
  - Exemptions
  - Schedule I Researcher Registration

- **Generate reports regarding drug abuse, chemical diversion and emergent/changing trafficking trends**

- **Provide technical and regulatory control information and trending to federal, state, and local public health and law enforcement officials**
ODE Functions

- Control Status Determinations

- Scheduling actions
  - FDA approvals
  - Petitions
  - DEA initiated actions
  - Chemical controls
  - Legislation

- Exemptions
  - Anabolic steroid products
  - Anabolic steroid veterinary implants
  - Chemical mixtures
  - Chemical preparations

- Schedule I Researcher Registration
Substances are evaluated as to their control status under the CSA

- Is the substance named?
- Is it defined?

A written response is generated as to the control status

If controlled, a drug code is provided
Control Status

► Is the substance named or defined under the CSA?
  - ODE provides drug code
  - ODE establishes new drug codes
  - ODE provides conversion factors

► Letter of No Objection (LONO)
  - ODE provides internal support as to control status
  - ODG generates the LONO
Control Status Inquiry

A control status inquiry can be placed directly with ODE. Include:

- Chemical name
- Chemical structure

Mailing address can be found on the Office of Diversion Control’s website

(http://www.deadiversion.usdoj.gov/21cfr/cfr/1321/1321_01.htm)
Chemical Control

- **Controlled Substances Act (1970)**

  the principal federal law directed at combating the illicit manufacture and distribution of controlled drugs in the United States. Since its passage in 1970, the CSA has been amended on a number of occasions.

- **Chemical Diversion and Trafficking Act (CDTA, 1988)**
  - regulated 12 precursor chemicals, eight essential chemicals, tableting machines, and encapsulating machines
  - resulted in the incorporation of Article 12 into the U.N. Convention Against Illicit Drug Traffic of 1988 (the Vienna Convention)
Chemical Control Background

- Chemical Diversion and Trafficking Act of 1988 (CDTA)
- Domestic Chemical Diversion Control Act (DCDCA, 1993)
  - Eliminated single entity ephedrine tablet loophole
  - No controls on Combination EPH, PSE, PPA
- Comprehensive Methamphetamine Control Act (MCA 1996)
  - Control drug products containing EPH, PSE, PPA
- Methamphetamine Anti–Proliferation Act (MAPA, 2000)
  - Reduce transaction threshold from 24g to 9g of PSE and PPA
  - Blister pack exempted
- Combat Methamphetamine Epidemic Act (CMEA, 2005)
- Methamphetamine Production Prevention Act of 2008 (MPPA)
- Combat Methamphetamine Enhancement Act of 2010 (MEA)
Chemical Control Background

- Total of 41 List I and List II chemicals
- List I chemical handlers (Importers/Exporters/Manufacturers/Distributors) must:
  - registration
  - maintain records
  - report suspicious orders
- Through industry outreach and voluntary compliance measures, DEA strives to control chemical diversion in partnership with industry and the public.
- DEA routinely inspects records and required controls
### Listed Chemicals Regulated Under the Controlled Substances Act

See 21 C.F.R. §§ 1309, 1310, 1313 and 1314 for details.

#### January 2016

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Precursor</th>
<th>Solvent</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Amphetamine</th>
<th>Cocaine</th>
<th>Mescaline</th>
<th>Methylamphetamine</th>
<th>Methamphetamine</th>
<th>Methadone</th>
<th>Methaqualone</th>
<th>Methcathinone</th>
<th>Methcathinone</th>
<th>Methylenedioxymethamphetamine</th>
<th>Mephedrone</th>
<th>Phencyclidine (PCP)</th>
<th>Phenyl-2-propanone</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. N-Acetylantranilic acid</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>46</td>
<td>40</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Anthranilic acid</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>30</td>
<td>30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Benzaldehyde</td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td>4</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Benzyl cyanide</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Ephedrine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Ergocristine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0.010</td>
<td>0.010</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Ergonovine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0.020</td>
<td>0.020</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Ergotamine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Ethylamine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Gamma-Butyrolactone (GBL)</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Hydriodic acid</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1.7</td>
<td>1.7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Hypophosphorous acid</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Iodine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Isosafrole</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Methylamine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. 3,4-Methylenedioxyphenyl-2-propanone</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. N-Methylphenylephrine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. N-Methylephedrine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. N-Phenyl-4-piperidone (NPP)</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Nitroethane</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>2.5</td>
<td>2.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. Norpseudoephedrine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>2.5</td>
<td>2.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Phenylacetic acid</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>23. Phenylpropanolamine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24. Phosphorus (red)</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25. Phosphorus (white or yellow)</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>26. Piperidine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0.500</td>
<td>0.500</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>27. Piperonal (heliotropin)</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>4</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28. Propionic anhydride</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0.001</td>
<td>0.001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>29. Pseudoephedrine</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30. Safrole</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1.02</td>
<td>1.02</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31. Acetic anhydride</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>150</td>
<td>1,500</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>32. Acetone</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>1</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>33. Benzyl chloride</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>135.8</td>
<td>1,364</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34. Ethyl ether</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>222.3</td>
<td>N/C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35. Hydrochloric acid</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>0</td>
<td>27</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35a. Hydrogen chloride gas</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>145</td>
<td>1,455</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>36. Methyl ethyl ketone (2-Butanone)</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>N/C</td>
<td>1,523</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>37. Methyl isobutyl ketone</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>55</td>
<td>500</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>38. Potassium permanganate</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>55</td>
<td>500</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>39. Sodium permanganate</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>N/C</td>
<td>347</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40. Sulfuric acid</td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıps" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td><img src="1.0" alt="ıp" /></td>
<td>159</td>
<td>1,591</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1 and its salts
2 and its salts and esters
3 and its salts, optical isomers, and salts of optical isomers
4 Exports only, to all Western Hemisphere except Canada
5 Exports only to all South American countries & Panama - Domestic for HCl gas
6 Threshold for HC1 acid and sulfuric acid is 50 gallons, the equivalent weight in kilograms is shown
7 For pseudoephedrine, phenylpropanolamine and ephedrine drug products, see 21 USC § 802(45)(A) and 21 C.F.R. Part 1314
N/C = Not Controlled
Laws Amending Chemical Control Provisions of the CSA

• Chemical Diversion and Trafficking Act of 1988 (CDTA)

• Domestic Chemical Diversion Control Act of 1993 (DCDCA)

• Comprehensive Methamphetamine Control Act of 1996 (CMCA)

• Children’s Health Act of 2000/Methamphetamine Anti-Proliferation Act of 2000 (MAPA)

• Combat Methamphetamine Epidemic Act of 2005 (CMEA)

• Methamphetamine Production Prevention Act of 2008 (MPPA)

• Combat Methamphetamine Enhancement Act of 2010 (MEA)
Chemical Diversion and Trafficking Act of 1988 (CDTA)

- First Chemical Legislation
- Controlled 20 Chemicals and certain equipment
  - 12 Precursor and 8 Essential Chemicals
  - Tableting and Encapsulating Machines
- Imposed recordkeeping and Import/Export reporting Requirement
- Controlled Only Bulk Material
- Tablet Exemption Loophole
• Eliminated the Tablet Exemption Loophole for Single-entity Ephedrine OTC’s
• Eliminated Terms Precursor and Essential Chemicals and Replaced with List I and List II
• Imposed Registration Requirement on Handlers of List I Chemicals
• Established Annual reporting requirements for Manufacturers of List I and II Chemicals
Controlled Ephedrine Combo, Pseudo and PPA OTC Products

Created Exemption for Blister Packs

Placed a 24 gram limit on retail Sales of Non–blister pack products

Created the Special Surveillance List

Created Reporting requirements for Mail Order Transactions

Controlled Iodine and HCl gas as List II chemicals
• Reduced Retail Threshold for Single Transactions of Pseudo and PPA to 9 gram (from 24 grams) for Non-blister pack products
• Package size may not exceed 3 grams
• Enhanced Penalties for Methamphetamine production and Trafficking in List I Chemicals*
Ephedrine/ Pseudoephedrine Exemptions

Final Rulemaking [68 FR 23195] published on May 1, 2003-

- created an exemption for all chemical mixtures containing five percent or less total ephedrine/pseudoephedrine.

- created an exemption for chemical mixtures consisting of unaltered harvested plant material containing ephedrine alkaloids (e.g. ephedra).
Ephedrine/ Pseudoephedrine Concerns

- Ephedra and dietary supplements containing ephedra used as the source of the precursor material for the illicit production of methamphetamine.
- FDA has taken action to eliminate ephedra dietary supplements from the U.S. market.
- Increase in importation of below 5% ephedra chemical mixtures from China to circumvent regulations.
Implement the CMEA, Interim Final Rule effective August 24, 2007:

- originally set at 5% to capture bulk ephedra (ma huang) that historically at concentration of 6-8% ephedrine
- Chemical Mixtures containing <5% total ephedrine/pseudoephedrine become regulated
Examples of List I and List II Chemicals

- Acetic anhydride → heroin synthesis
- Benzaldehyde → amphetamine synthesis
- Ergotamine → LSD synthesis
- Phenylacetic acid → P2P synthesis
- Hypophosphorus acid → am/meth synthesis
- Safrole → MDA/MDMA synthesis
- Potassium permanganate → cocaine purification
Recent Chemical Controls Actions

- **Removal of Ephedrine/Pseudoephedrine Mixture Exemptions**

- **Recent Controls Fentanyl Precursors**
  - NPP (List I, April 23, 2007)
  - ANPP (proposed Schedule II, comment period ended June 9, 2008)

- **Iodine and Mixture Regulations**

- **Under consideration:**
  - L-Phenylacetylcarbinol
  - alpha-Phenylacetoacetonitrile (APAAN)
  - Ephedrine
  - P2P
Illicitly Manufactured Fentanyl–Related Deaths

Illicit Fentanyl Death Database

n=1013

Number of Deaths vs. Time (Months)
Fentanyl Lab in Toluca, Mexico
November 2005, law enforcement seized a lab in the LA area suspected to be Fentanyl lab.

Chemists analyzed the samples submitted and confirmed fentanyl and MDA present.

A 5 kilogram bag of “NPP” (1-phenethyl-4 piperidone) precursor was seized.
Fentanyl Synthesis - Siegfried Method

N-Phenethyl-Piperidone (NPP)
4-Anilino-N-Phenethyl-4-Piperidine (ANPP)
N-Phenethyl-4-piperidone (NPP)

77 FR20039 effective April 23, 2007

- NPP becomes List I chemical
- Chemical mixtures containing NPP are not exempt from regulatory requirements at any concentration
- All transactions (domestic & International) involving NPP, regardless of size, shall be regulated
ANPP Control

- Designates 4-anilino-N-phenethyl-4-piperidine (ANPP) as an immediate precursor to a schedule II controlled substance
- ANPP controlled as schedule II substance, subject to quota requirement
Hundreds of Herbal Incense Products
Designer Drug Phenomenon

- Unprecedented introduction of new substances on the designer drug market

- Devastating consequences
  - Short and long term adverse health effects
  - Abuser presenting at Emergency Department to an unknown drug
  - Significant impact to others connected to the pattern of abuse

![NFLIS Federal, State, and Local Forensic Laboratory Drug Reports Selected Drug Categories, 2006 - 2014](chart.png)
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.
Abuse of designer drugs:

- New abuser population
- Evade regulatory controls and detection
  - Drug screen
- Lack of safety information, acute toxicity and lethality

Drug’s negative effects felt beyond the abuser:

- Communities
- Health providers
- Law enforcement
Since 2011, DEA has temporarily controlled 35+ NPS

July 2012
Congressional Control

March 2011
JWH-018; JWH-073; JWH-200; CP-47,497; cannabicyclohexanol

May 2013
UR-144, XLR-11, AKB-48

February 2014
PB-22; 5F-PB-22; AB-FUBINACA; ADB-PINACA

January 2015
AB-CHMINACA; AB-PINACA; THJ-2201

October 2011
MDPV; methylene; mephedrone

November 2013
25I-NBOMe; 25C-NBOMe; 25B-NBOMe

March 2014
4-MEC; 4-MePPP; α-PVP; butylone; pentedrone; pentylone; flephedrone, 3-FMC; naphyrone; α-PBP

June 2015
Acetyl fentanyl
Synthetic Cannabinoids Containing Products

PB-22

ADB-PINACA

AB-FUBINACCA

AB-CHMINACCA
20 Liter Drums of Acetone

Cement Mixer w/ Veg. Material

Containers of Veg. Material

Tins Containing Mixed Product
Flavoring
Contact Us

Drug Enforcement Administration
Office of Diversion Control
Drug & Chemical Evaluation Section
(202) 307-7183
ODE@usdoj.gov

Terrence L. Boos, PhD, Chief