National Trends and Deterrent Strategies For Prescription and OTC Drug Abuse

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Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
Introduction

- Background and Statistics
- Regulatory Control
- Methods of Diversion
- Internet Diversion
- Commonly Diverted Pharmaceuticals
- Steroids/hGH
- Dietary Supplements
- Salvia Divinorum
The 1960's

Marijuana

Seconal

LSD

Dexedrine

Meprobamate
The 1970’s

Heroin
The 1980’s

T’s and Blues
(Talwin and Pyrabenzamine)

4’s and Doors
(Tylenol w/Codeine and Doriden)

Hydromorphone

Cocaine
The 1990’s

Oxycodone

Methamphetamine
2000

Hydrocodone

Ketamine

MDMA

Flunitrazapam (Rohypnol)

Alprazolam
Scope and Extent of Problem

2004 | 2007
---|---
Sedatives | 0.3 million | 0.35 million
Stimulants | 1.2 million | 1.1 million
Anti-Anxiety Medication | 1.6 million | 1.8 million
Narcotic Pain Relievers | 4.4 million | 5.2 million

Source: 2004 and 2007 National Survey on Drug Use and Health
Teens and Their Attitudes

- 1 in 5 teens report abusing Rx medications to get high
- 2 in 5 teens believe that Rx meds are “much safer” than illegal drugs
- 31% teens believe there's “nothing wrong” with using Rx meds without a prescription “once in a while”
- Nearly 3 in 10 teens believe Rx pain relievers are not addictive

Partnership for a Drug Free America Study
Regulatory Control
Controlled Substances Act of 1970

- Established a “closed system” of distribution
- Five “schedules” of controlled substances
- Created the Compliance Program (1971) to monitor the legitimate manufacture and distribution of controlled substances
- Clearly differentiated controlled substances from other “legend” drugs handled under the FDCA
- Authorized DEA to register dispensers, practitioners and pharmacies
- CSA/Regulations address creation, signature, retention of prescription/records
## Prescription Requirements

<table>
<thead>
<tr>
<th></th>
<th>Schedule II</th>
<th>Schedule III</th>
<th>Schedule IV</th>
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<td>Yes</td>
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<td>Oral</td>
<td>Emergency Only*</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Facsimile</td>
<td>Yes**</td>
<td>Yes</td>
<td>Yes</td>
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<td>Refills</td>
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<td>Yes#</td>
<td>Yes#</td>
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<tr>
<td>Partial Fills</td>
<td>Yes***</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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</table>

* Must be reduced in writing, and followed by sign, hard copy of the prescription.
** A signed, hard copy of the prescription must be presented before the medication is dispensed.
*** 72 hour time limitation.
# With medical authorization, up to 5 in 6 months.
Prescription Drug Monitoring Programs
# 39 States with Legislation Enabling a Prescription Monitoring Program

**29 Operational – 9 Enacted Legislation Only**

*as of June 2008*

<table>
<thead>
<tr>
<th>STATE</th>
<th>PROGRAM TYPE</th>
<th>SCHEDULES COVERED</th>
<th>YEAR ENACTED</th>
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<td>Electronic C II-IV 2008</td>
<td>2006</td>
<td></td>
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<td>KY</td>
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<td>January 1999</td>
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<tr>
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<td>Electronic C II-IV</td>
<td>2008</td>
<td></td>
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<td>14</td>
<td>LA*</td>
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<td>VA</td>
<td>Electronic C II-IV</td>
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<td>June 2006</td>
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</tbody>
</table>
The PDMP database allows investigators to obtain pharmacy data from multiple locations without having to visit each and every pharmacy.

Deter and identify illegal activity such as prescription forgery, indiscriminate prescribing and "doctor shopping."

Patient specific drug information upon request of the patient’s physician or pharmacist.

Notification of physicians when their patients are seeing multiple prescribers for the same class of drugs.

Assists healthcare professionals in managing patient care.
# PMP as an Investigative Tool

<table>
<thead>
<tr>
<th>Date filled</th>
<th>Patient name</th>
<th>Drug name</th>
<th>Patient address</th>
<th>Prescriber Info.</th>
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<td>APAP/Hydrocodone Barbituate</td>
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<td>APAP/Hydrocodone Barbituate</td>
<td>Pompano Beach, FL</td>
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</tbody>
</table>
To be effective, a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner who is acting in the usual course of his professional practice.
Methods of Diversion

- **Practitioners / Pharmacists**
  - Illegal distribution
  - Self abuse
  - Trading drugs for sex

- **Employee pilferage**
  - Hospitals
  - Practitioners’ offices
  - Nursing homes
  - Retail pharmacies
  - Manufacturing / distribution facilities

- **Pharmacy / Other Theft**
  - Armed robbery
  - Burglary (Night Break-ins)
  - In-Transit Loss (Hijacking)
  - Smurfing

- **Patients**
  - Drug rings
  - Doctor-shopping
  - Forged / fraudulent / altered prescriptions

- **Internet availability**
Internet Diversion
Rogue Internet Pharmacy
Checks and Balances

Physician

Pharmacist

Patient
Ordering from a Rogue Site
(Historically)
Google Search: buy hydrocodone - Microsoft Internet Explorer

Web images Groups News Froogle more
Advanced Search Preferences

Results 1 - 10 of about 251,000 for buy hydrocodone. (0.30 seconds)

Order Hydrocodone Online
www.legaldroconline.com $37.04 shipped, huge savings. FDA approved, 100% legal purchase.

Buy Hydrocodone Online. Buy Hydrocodone Online Hydrocodone relieves pain. Acetaminophen is a less potent pain reliever that increases... www.freewebs.com/hydrocodone/ - 22k - Cached - Similar pages

Buy cheap hydrocodone Apap and Watson online - Vicodin - Cheap ...
Pillsnweb.com Buy Hydrocodone and Vicodin Online Hydrocodone relieves pain. Acetaminophen is a less potent pain reliever that increases... www.pillsnweb.com/ - 7k - Cached - Similar pages

Top 10 hydrocodone links: cheapest prices, side effects, info, buy ...
... http://www.e-discount.com/tr=e114/Hydrocodone At PrescriptionAmerica.com
Buy Hydrocodone at PrescriptionAmerica.com ... Buy cheap Hydrocodone online.
... www.drp-ecostar.com/ directory HY-hydrocodone - 20k - Sep 15, 2004 - Cached - Similar pages

Buy hydrocodone from home - purchase hydrocodone online ...
... Click here to order Hydrocodone Online. ... Brand Name: Hydrocodone/APAP. The following product information ...
www.anzwere.org/foodpharmasc - 24k - Cached - Similar pages
Xanax-But Adderall-Alprazolam-Vicodin-Hydrocodone
... More, Xanax, Alprazolam Lorat...-Buy Lorat Hydrocodone-Buy Hydrocodone
Demerol-Buy Demerol codeine buy codeine altavista buy altav.
www.pickyourpharmacy.com/ - 31k - Cached - Similar pages

Buy Hydrocodone APAP Online, Cheap Prices
Buy Hydrocodone APAP Online Cheap, Buy Hydrocodone APAP Online. Order Hydrocodone APAP Online Hydrocodone relieves pain. ... Copyrights. Buy Hydrocodone APAP ...
...www.1035com.com/ - 22k - Cached - Similar pages

Buy Diazepam Online
... pregnancy vicodin and sex us prescriptions valium Florist Online No Prescription GENERIC FIORICET Tramadol HCI Buy hydrocodone vicodin pills
... www.1035com.com/ - 22k - Cached - Similar pages
Top 10 Hydrocodone Results

Buy Pain Medication From Home
http://www.e-discountrx.com/?r=s114/

Hydrocodone At PrescriptionAmerica.com
http://www.prescriptionamerica.com/

Hydrocodone - COD ONLY - 99% Approval Guaranteed
Buy Hydrocodone (Generic Vicodin) online with No Prescription, Free Consultations, 99% approval, Next Day Shipping with tracking. No Hidden Fee’s, pay only medication and shipping costs. U.S. Pharmacy with U.S. physicians
http://www.hydrocodonecod.com/

Hydrocodone - Watson
http://www.slimmeryou.com/

Order Hydrocodone Online - Online scripts.com
Find real doctors and prescriptions online. It’s fast, secure, and private. Overnight delivery available. Order your consultation now.
http://www.Online-Scripts.com/

Buy Hydrocodone Hassle Free
Order up to 90 days’ supply of Hydrocodone from our exclusive pharmacies. Easy discreet delivery to your home or office. Eliminate
Order hydrocodone online from our U.S. based licensed pharmacy. No prior prescription needed. No consultation fees.

Order hydrocodone online from our U.S. based licensed pharmacy. No prior prescription needed. No consultation fees.

Hydrocodone is habit forming. It is possible become physically and/or psychologically dependent on the hydrocodone drug. Do not take more than the prescribed amount of hydrocodone or take it for longer than is directed by your doctor. Withdrawal effects may occur if hydrocodone and acetaminophen is stopped suddenly after several weeks of continuous use of hydrocodone.
Online Pharmacy Consultations

- Easy to obtain
- Convenient
Problems with Online Consultations

- According to AMA, this method of providing patients with prescription medication falls well below the accepted standard of medical care
  - Forms ask for minimal information
  - No mechanism to determine if questions answered correctly or truthfully
  - No explanation of risk associated with drug
  - No medical assessment at all
  - No follow up

No Prescription Needed & No Questions Asked
- Percodan
- Oxycodone
- Morphine
- Codeine
- Valium
- Darvon
- Hydrocodone
- Vicodin
Components necessary for Domestic Rogue Internet Operation

- Web Broker / Facilitator (optional)
- Practitioner
- Pharmacy
- **All members of scheme are complicit thereby eliminating all checks and balances
- Source of Supply
1. Consumer in Montana orders hydrocodone on the Internet

2. Request goes through Website Server in San Antonio, TX

3. Web Company (located in Miami, FL) adds request to queue for Physician approval

4. Order is approved by Physician in New Jersey and returned to Web Company

5. Approved order then sent by Web Company to an affiliated Pharmacy

6. Pharmacy in Iowa fills order and ships to Consumer via Shipper
How Regulatory/Criminal Enforcement and Legislation Changed the Landscape
Cut off the Supply

Seek administrative action against DEA registrants found to be contributing to the illegal distribution of controlled substances over the Internet

- Orders To Show Cause
- Immediate Suspensions
# The Dirty Dozen

PHARMACIES CLOSED IN 2007 following Baywatch / Lightning Strike

<table>
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<tr>
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<th>Total 2006 Dosage Units</th>
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<tbody>
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<td>1</td>
<td>15,596,380</td>
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<tr>
<td>2</td>
<td>9,082,010</td>
</tr>
<tr>
<td>3</td>
<td>9,081,976</td>
</tr>
<tr>
<td>4</td>
<td>4,733,290</td>
</tr>
<tr>
<td>5</td>
<td>4,220,840</td>
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<td>6</td>
<td>4,564,480</td>
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<tr>
<td>7</td>
<td>1,988,600</td>
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<tr>
<td>8</td>
<td>1,656,450</td>
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<tr>
<td>9</td>
<td>2,731,420</td>
</tr>
<tr>
<td>10</td>
<td>1,962,620</td>
</tr>
<tr>
<td>11</td>
<td>793,350</td>
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<tr>
<td>12</td>
<td>1,051,500</td>
</tr>
</tbody>
</table>

**TOTAL DOSAGE UNITS** 57,462,916
Rogue Internet Pharmacy Scheme

Manufacturers
DEA Registrants who are authorized to produce and distribute controlled substances. (1330 firms including all manufacturers and wholesale distributors)

Wholesale Distributors
DEA Registrants who are authorized to distribute controlled substances.

Brick and Mortar Pharmacies
DEA Registrants who are authorized to dispense controlled substances to individual customers. (64,000 registered pharmacies)

Customers

Practitioners
DEA Registered doctors, nurse practitioners, etc... who are authorized to issue prescriptions for controlled substances. (900,000 Practitioners)

2. RIP sends order to practitioner

Rogue Internet Pharmacies (RIP)
Website Operators who Sell controlled substances over the Internet. These entities are not registered with DEA and do not handle controlled substances.

1. Customer places order over the Internet

3. Practitioner sends prescription to pharmacy directly or through RIP

4. Pharmacy sends controlled substances to customer

Typical Internet Diversion Communications

Flow of Controlled Substances
Actions Taken

- Immediate Suspensions / Order to Show Cause
  - AmerisourceBergen Corp
    - Orlando, FL
  - McKesson Corp
    - Tampa, FL
    - $13,250,000 civil penalty
  - Cardinal Corp
    - Lakeland, FL; Stafford, TX; Swedesboro, NJ; and Auburn, WA
    - $34,000,000 civil penalty
  - Bellco Drug Corp, Long Island, NY
  - Southwood, Lake Forest, CA

- Voluntary Surrender
  - Richie Pharmacal, Glasgow, KY
Current Legislation

- Internet Legislation
  - S-980
  - H.R. 6353

- Ryan Haight Online Consumer Protection Act
  (signed by the President October 15, 2008)
  - Requires online pharmacies to obtain special DEA registration
  - Requires identifying information to be posted on the web site
  - Defines terms such as “online pharmacy” and “telemedicine”
  - Expands the definition of a valid prescription to include at least one in-person medical evaluation of the patient
  - Penalty enhancements
  - Reporting requirements regarding Rx sales
Ryan Haight Online Pharmacy
Consumer Protection Act

- New DEA registration requirements for all Internet pharmacies
- Reporting requirements
  - Number of prescriptions
  - Dosage unit totals
- Disclosure requirement on home page
  - Name, address, phone, & E-mail of all pharmacies
  - Name & license # of pharmacists in charge
  - Name, address, phone, degree of all physicians
- Statutory implementation 180 days from signing
  (April 13, 2009)
Adaptation

- From questionnaires - to asking for medical records
- From the doctor sending the Rx to the rogue pharmacy - to sending it to the “patient”
- From doctors located in other states - to sending “patients” to doctors within the same state
- Selling non-controlled, legend drugs of abuse
Commonly Abused Prescription
Controlled Substances
Hydrocodone, APAP

- Brand Names: Vicodin®, Lortab®, Lorcet®
- “Cocktail” used by drug abusers
  - Hydrocodone
  - Soma / carisoprodol
  - Alprazolam / Xanax®
- Vicodin / hydrocodone second only to marijuana as the ‘drug of choice’ for teens
- *In 2004 U.S. consumed 99% of world’s supply of hydrocodone yet the U.S. makes up only 4.5% of the world’s population

*SOURCE: JAMA, January 17, 2007 – Vol 297, No 3, Opioid Prescriptions Soar*

- Between 1990 and 2007
  - 21% growth in population

- Between 1990 and 2007
  - *280% increase in the distribution of hydrocodone*

*Source: ARCOS (Date Prepared: 04/02/2008)
Top Five Prescription Drugs Sold in the U.S. (2005-2007)

Note: Percentage change from the number of prescriptions sold in the previous years.

<table>
<thead>
<tr>
<th>Drug</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone/APAP (Pain reliever)</td>
<td>101,639,000</td>
<td>109,652,000</td>
<td>117,200,000</td>
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<tr>
<td>Lipitor (Cholesterol)</td>
<td>63,219,000</td>
<td>62,311,000</td>
<td>55,039,000</td>
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<tr>
<td>Lisinopril (Blood pressure)</td>
<td>47,829,000</td>
<td>55,039,000</td>
<td>52,104,000</td>
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<tr>
<td>Amoxicillin (Antibiotic)</td>
<td>42,747,000</td>
<td>45,777,000</td>
<td>52,803,000</td>
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<tr>
<td>Hydrochlorothiazide (Diuretic)</td>
<td>42,747,000</td>
<td>45,124,000</td>
<td>52,987,000</td>
</tr>
</tbody>
</table>

Source: Drug Topics
Revised September 19, 2008

*In 2007 Levothyroxine was #5
Hydrocodone Distribution*
CY2000-2008 U.S. Average

* Includes sales to Retail Registrants, i.e. pharmacies, hospitals, practitioners, teaching institutions, and mid level practitioners

Source: ARCOS
Date Prepared: 09/09/08
## NFLIS National Data – 2006 & 2007  
### Narcotic Analgesics

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<tr>
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<tr>
<td>Oxycodone</td>
<td>19,923</td>
<td>29.75%</td>
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<tr>
<td>Methadone</td>
<td>7,023</td>
<td>10.49%</td>
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<tr>
<td>Methadone</td>
<td>7,023</td>
<td>10.49%</td>
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<tr>
<td>Morphine</td>
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<td>5.81%</td>
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<td>Codeine</td>
<td>2,597</td>
<td>3.88%</td>
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<tr>
<td>Propoxyphene</td>
<td>1,488</td>
<td>2.22%</td>
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<tr>
<td>Hydromorphone</td>
<td>1,303</td>
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<tr>
<td>Dihydrocodeine</td>
<td>1,290</td>
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<td>Fentanyl</td>
<td>1,270</td>
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<tr>
<td>Buprenorphine</td>
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### Narcotic Analgesics (continued)

<table>
<thead>
<tr>
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<th>*Percent</th>
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<tbody>
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<td>Hydrocodone</td>
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<td>39.66%</td>
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<tr>
<td>Oxycodone</td>
<td>24,029</td>
<td>31.24%</td>
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<tr>
<td>Methadone</td>
<td>7,496</td>
<td>9.75%</td>
</tr>
<tr>
<td>Methadone</td>
<td>7,496</td>
<td>9.75%</td>
</tr>
<tr>
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<td>5.46%</td>
</tr>
<tr>
<td>Codeine</td>
<td>2,674</td>
<td>3.48%</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>1,306</td>
<td>1.70%</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>1,559</td>
<td>2.03%</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>957</td>
<td>1.24%</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>732</td>
<td>0.95%</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>2,094</td>
<td>2.72%</td>
</tr>
</tbody>
</table>

*Percentage of all narcotic analgesics exhibits analyzed*
BENZODI AZEPI NES
Benzodiazepines

- First benzodiazepine, chlordiazepoxide was approved for use in the early 1960’s

- Benzodiazepines, as a class, are one of the most widely prescribed drugs in the world

- They are approved in the U.S. to treat anxiety, insomnia, and seizures (Sch IV depressant under the CSA)

- Adverse effects include: amnesia, restlessness, delirium, aggression, depression, hallucinations, and paranoia
### NFLIS National Data – 2006-2007
### Benzodiazepines

<table>
<thead>
<tr>
<th></th>
<th>2006 Number of exhibits</th>
<th>2007 Number of exhibits</th>
<th>Percent</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Alprazolam</strong></td>
<td>25,617</td>
<td><strong>Alprazolam</strong></td>
<td>29,353</td>
<td>62.85%</td>
</tr>
<tr>
<td><strong>Clonazepam</strong></td>
<td>6,755</td>
<td><strong>Clonazepam</strong></td>
<td>7,014</td>
<td>16.56%</td>
</tr>
<tr>
<td><strong>Diazepam</strong></td>
<td>6,314</td>
<td><strong>Diazepam</strong></td>
<td>6,179</td>
<td>15.48%</td>
</tr>
<tr>
<td><strong>Lorazepam</strong></td>
<td>1,574</td>
<td><strong>Lorazepam</strong></td>
<td>1,573</td>
<td>3.86%</td>
</tr>
<tr>
<td><strong>Temazepam</strong></td>
<td>326</td>
<td><strong>Temazepam</strong></td>
<td>295</td>
<td>0.80%</td>
</tr>
<tr>
<td><strong>Chlordiazepoxide</strong></td>
<td>100</td>
<td><strong>Chlordiazepoxide</strong></td>
<td>88</td>
<td>0.25%</td>
</tr>
<tr>
<td><strong>Triazolam</strong></td>
<td>50</td>
<td><strong>Triazolam</strong></td>
<td>57</td>
<td>0.12%</td>
</tr>
<tr>
<td><strong>Flunitrazepam</strong></td>
<td>35</td>
<td><strong>Flunitrazepam</strong></td>
<td>23</td>
<td>0.09%</td>
</tr>
<tr>
<td><strong>Midazolam</strong></td>
<td>12</td>
<td><strong>Midazolam</strong></td>
<td>10</td>
<td>0.03%</td>
</tr>
</tbody>
</table>
Drug abusers often prefer alprazolam due to its rapid onset and longer duration of action.

Alprazolam was ranked third in the number of prescriptions for controlled substances in 2003, 2004, 2005 and 2006*.

For all sales of generic pharmaceuticals, alprazolam was ranked 7th**.

Source IMS Health
** Source Verispan VONA
From 2001 to 2006, the number of seizures for alprazolam increased from 17,926 to 29,143 (62% increase).

From 1995 to 2002, Emergency Department visits involving benzodiazepines increased 41% and from 2004 to 2005 they increased 19.4%.
State and Local Seizure Data

Benzodiazepines Seizures by State/Local

Year
  2000 2001 2002 2003 2004 2005 2006

Number of Exhibits
  0 5,000 10,000 15,000 20,000 25,000 30,000

- Alprazolam
- Chlordiazepoxide
- Clonazepam
- Diazepam
- Flunitrazepam
- Lorazepam
- Midazolam
- Temazepam
- Triazolam
Dispensed Prescriptions by Year from IMS Health

- ALPRAZOLAM
- LORAZEPAM
- CLONAZEPAM
- DIAZEPAM
- TEMAZEPAM
- CHLORDIAZEPOXIDE
- TRIAZOLAM
- MIDAZOLAM

Years:
- 2002
- 2003
- 2004
- 2005
- 2006
OXYCODONE PRODUCTS

- OxyContin
- Tylox
- Percocet
- Percodan
### NFLIS National Data – 2006 & 2007

**Narcotic Analgesics**

<table>
<thead>
<tr>
<th>Narcotic Analgesic</th>
<th>Number</th>
<th><em>Percent</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>26,017</td>
<td>38.85%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>19,923</td>
<td>29.75%</td>
</tr>
<tr>
<td>Methadone</td>
<td>7,023</td>
<td>10.49%</td>
</tr>
<tr>
<td>Morphine</td>
<td>3,887</td>
<td>5.81%</td>
</tr>
<tr>
<td>Codeine</td>
<td>2,597</td>
<td>3.88%</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>1,488</td>
<td>2.22%</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>1,303</td>
<td>1.95%</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>1,290</td>
<td>1.93%</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>1,270</td>
<td>1.90%</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>1,113</td>
<td>1.66%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Narcotic Analgesic</th>
<th>Number</th>
<th><em>Percent</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>30,504</td>
<td>39.66%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>24,029</td>
<td>31.24%</td>
</tr>
<tr>
<td>Methadone</td>
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</table>

*Percentage of all narcotic analgesics exhibits analyzed*
Total prescriptions (expressed in thousands) and average number of dosage units per prescription (shown in parentheses) for oxycodone products. (NPA Plus™, from 2002 thru 2007, data extracted March 2008)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Product Type</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone</td>
<td>All Products</td>
<td>29,387</td>
<td>32,523</td>
<td>34,790</td>
<td>37,895</td>
<td>42,292</td>
<td>45,878</td>
</tr>
<tr>
<td></td>
<td>Combination oral solid products</td>
<td>19,873</td>
<td>22,022</td>
<td>24,011</td>
<td>26,547</td>
<td>29,366</td>
<td>31,404</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(45.9)</td>
<td>(48.5)</td>
<td>(50.9)</td>
<td>(53)</td>
<td>(54.5)</td>
<td>(56.6)</td>
</tr>
<tr>
<td></td>
<td>Single entity extended-release oral solid products</td>
<td>7,112</td>
<td>7,561</td>
<td>7,294</td>
<td>7,153</td>
<td>7,599</td>
<td>8,078</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(69.8)</td>
<td>(70.64)</td>
<td>(72)</td>
<td>(72.77)</td>
<td>(73)</td>
<td>(73.5)</td>
</tr>
<tr>
<td></td>
<td>Single entity immediate-release oral solid products (exclude liquids)</td>
<td>2,114</td>
<td>2,642</td>
<td>3,165</td>
<td>3,841</td>
<td>4,948</td>
<td>5,997</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(96)</td>
<td>(97.90)</td>
<td>(100.3)</td>
<td>(100.1)</td>
<td>(99.4)</td>
<td>(102.6)</td>
</tr>
</tbody>
</table>
Oxycodone Distribution*  
CY2000-2008 U.S. Average

* Includes sales to Retail Registrants, i.e. pharmacies, hospitals, practitioners, teaching institutions, and mid level practitioners

Source: ARCOS  
Date Prepared: 09/09/08
NFLIS Cases by Drug

Number of Cases

- Tramadol
- Hydromorphone
- Carisoprodol
- Oxycodone
- Alprazolam
- Hydrocodone

*January- September 2008
METHADONE
One Pill can Kill

THE METHADONE POISONING “Epidemic”

Increasing use of Methadone as a pain killer may be fueling a disturbing increase in deaths related to this potent drug.

Death and morbidity associated with methadone treatment has increased dramatically in recent years, largely in the population prescribed this drug for pain control rather than addiction maintenance. Inadvertent overdose is becoming increasingly common, likely in part because the drug’s acute pain-relieving effect lasts only 4 to 6 hours, yet it has a very long and variable plasma half-life of 24 to 56. In some studies 15 to 35 hours, is stored in body tissues, and toxic accumulation occurs with too-frequent consumption. Adverse effects are most common in patients treated with methadone in combination with other drugs. Both cardiac and respiratory systems are vulnerable targets for the drug’s toxic actions, and other co-administered drugs can inaccurately increase the risk of death through a variety of mechanisms including direct central nervous system depression of respiration, idiosyncratic respiratory vulnerability, and lethal cardiac arrhythmia. Idiosyncratic factors also play a part in methadone’s cardiac toxicity, and risk factors are well characterized, though perhaps not sufficiently widely known and understood by key stakeholders. The recent change in FDA labeling requirements for the drug—and the November 2006 posting of a government warning regarding its use in pain treatment—has not yet reduced morbidity and mortality associated with methadone as reported in the MedWatch database for the first quarter of 2007.
“Death and morbidity associated with methadone treatment has increased dramatically in recent years, largely in the population prescribed this drug for pain control rather than addiction maintenance.”
Rising methadone deaths

Our view: Baltimore public health officials are trying to find out if treatment for chronic pain sufferers accounts for increase in methadone overdoses

The June letter from the Baltimore Health Department alerted physicians, nurses and other providers to a significant increase in methadone-related overdose deaths. The letter from Dr. Laura Herrera, a deputy city health commissioner, raised the possibility that the overdoses involved prescriptions for pain. It was a cautionary reminder that health care providers should educate their patients about the proper use of methadone and the lethal risks of taking extra doses.

Dr. Herrera was right to be concerned. Methadone overdose deaths of city residents have risen from seven in 1995 to 14 in 2007. In 2007, the last year for which statistics are available, there was a 23 percent increase in such deaths over the previous year. The city deaths coincide with a similarly disturbing fivefold increase in methadone-related deaths nationally between 1998 and 2005. But proving that the use of methadone as a pain reliever caused these deaths isn't easy — no one tracks how many physicians prescribe methadone to relieve chronic pain from cancer or arthritis, for example.

Prescribing methadone has been an accepted form of treatment for chronic pain for some time, according to pain specialists at Johns Hopkins Hospital and the University of Maryland Medical Center. They add that they have seen no methadone-related deaths among their patients. Methadone used for pain treatment is prescribed in pill form; its risk stems from the drug's potency and its lingering presence in the body once its pain-relieving function has ceased. An extra dose could slow down a patient's breathing, resulting in coma or death.

To identify the extent of the problem and the patients most at risk, the city Health Department has reviewed data from the medical examiner's office. It also has asked the quasi-public city agency that oversees drug treatment in Baltimore to cross-check methadone overdose victims against its patient rosters. That's a critical aspect of the review because it could uncover misuse, abuse or diversion of methadone from drug treatment centers. Or it could lend credence to the prevailing view that more training is required for private physicians who prescribe methadone for pain.

At least 20 states have prescription monitoring programs that would identify indiscriminate prescribing, doctor-shopping and other abuses. A task force established this year in Maryland is studying the possibility of establishing a similar tracking system for methadone and other controlled substances.

Until then, Dr. Herrera and her colleagues at the Health Department have moved expeditiously and forthrightly to unravel this mystery. The results of their findings are the key to understanding and reversing this disturbing trend.
3 more arrests in OD case

Incident involved liquid methadone

By Mike Karr

NORTH

Father gets 4-year term in son's methadone death

A Lehigh County man who
pleaded guilty last month in
the methadone overdose of his
2-year-old son was sentenced
in a four-year term today.

Denis Marzur, 34, of New-
ark, N.J., pleaded guilty to
voluntary manslaughter and
child endangering in the death
of his son, Benjamin Scott.

Masters.

Benjamin died March 12.

A toxicology test showed
the boy died from ingesting
methadone. Masters, who admitted
at the trial that he bought
the drug for his son and
his 17-year-old daughter,
pleaded guilty to
possession of the drug.

The trial lasted about
three weeks was held Oct.
22 through Oct. 22.

Masters is a 17-year-old
student at the school where
Benjamin died.

Masters told police in March
he didn't know what had hap-
pened, but his son had been
found at the scene.

He was sentenced in May.

— Boba Barrett

NORTHWEST
Alarmed officials point to methadone

New Hampshire drug deaths soaring

Alarmed officials point to methadone

By MARY CLAIRE MAY

AUGUST 17, 2006

A10

NH. drug deaths soaring

Alarmed officials point to methadone

New Hampshire drug deaths soaring

DRUGS: Continuing from A1

An addict who gets methadone at a clinic for heroin withdrawal typically gets only one dose per visit. The supply and the amount dispensed are closely monitored, making it almost impossible to abuse or sell.

That’s not so methadone, according to state officials. In its crisis, patients are given many days’ supply when they are in for a period of treatment.

Lamarre knows firsthand about the issue. At one clinic in the state’s treatment program, he suffers from heroin addiction. As part of his recovery, he relies on methadone.

Last year, more than 120 heroin deaths were reported in New Hampshire, according to state police. Twenty of those cases involved methadone, the state said.

Lamarre said the clinic is careful about dosage. Methadone is dispensed on a daily basis.

Two ways to drug

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Two ways to drug
Man faces charges in woman's overdose death

COLUMBUS — An East Franklin Street man faces multiple charges for allegedly providing the drugs and needle used last year in the overdose death of a 45-year-old woman, according to police.

Joseph Laboleta, 27, allegedly provided Stephanie Armes, 31, with the methadone, and naloxone that led to her death on April 19. Police also said Laboleta failed to seek medical attention for Armes, who complained of a headache and was slurred.

The charges include gross a controlled substance offense, possession of a Schedule I drug, possession of a Schedule II drug, possession of a Schedule III drug, possession of a Schedule IV drug, possession of a Schedule V drug, and possession of drug paraphernalia.

Laboleta was charged with misdemeanor possession of drug paraphernalia and released on a $3,500 bond.

Teen dies of suspected overdose

BY RICK HALL

The teenager who died July 29 in the 1220 block of Jefferson Avenue was identified as William "Timmy" Littlejohn, 15. The Jefferson Avenue Youth Center was the scene of the incident, according to authorities.

Littlejohn was pronounced dead at University Medical Center on June 1. Authorities said they are investigating the death as a drug overdose.

The Family Violence Prevention Center is working with local authorities on the case. The organization said it is providing support to the family and friends of the victim.

A fund has been established to help cover medical expenses. Donations can be made to the Bill Littlejohn Fund at the First National Bank of Columbus.
EAST COUNTY COURTS

Woman is sentenced in teen's death

Girl was given methadone pills

By Angelica Martinez
Staff Writer

A Santee mother who gave a teenage friend of her daughter's a deadly dose of methadone and penicillin was sentenced yesterday to six years in prison.

Laura Susan Wion, 45, appeared disoriented and under the influence of medication as she told the court that she meant no harm when she gave Kelsea Phelps the pills to treat a sore throat in August 2006.

Friends and relatives who spoke on Wion's behalf called her a "wonderful" person who wouldn't intentionally harm anyone.

But prosecutor Chris Lindberg characterized the statements read on her behalf by relatives and friends as "the Laura Wion show."

"The fact is the victim would be alive if it weren't for the defendant's actions," he said.

Wion pleaded guilty June 11 to charges of involuntary manslaughter and felony child abuse.

Her defense attorney, Michael Madoney, asked Superior Court Judge Charles W. Ervin for a four-year prison sentence.

He portrayed Kelsea as a troubled teen who ran from home and used drugs.

Tracy Morgan, Kelsea's mother, said Kelsea was a loving daughter who was depicted unfairly.

"Six years is absolutely nothing to give to this woman who killed my daughter," Morgan said. "Kelsea was made out to be a person she truly was not."

Kelsea died Aug. 21, 2006, after visiting Wion's daughter. She had complained of a sore throat and other cold symptoms during the visit.

Wion, who had been prescribed methadone and other medications, gave methadone to the girl.

Kelsea then went to her Santee home and briefly spoke with relatives before she went to bed. Her mother discovered her dead in her bed the next morning when she went to wake Kelsea for school.

Investigators found 18 methadone pills near Kelsea's bed. The drug is commonly prescribed for relief of severe pain and used to ease withdrawal symptoms for those addicted to opioids such as heroin.

Angelica Martinez;
(619) 293-1317;
angelica.martinez@uninc.org
Overdose deaths
Prescription drugs take deadly toll in WV

An alarming new study has found that prescription drugs killed more people in West Virginia in 2017 than illegal drugs. According to the report, nine out of ten accidental overdose deaths reported in the Mountain State involved prescription drugs. Researchers in a joint state-federal study came to the troubling conclusion after studying 432 accidental overdose autopsy reports, excluding suicides and overdoses, the Associated Press reported.

The report found that one-third of the prescription drugs taken during the fatal incidents were being used as a result of prescriptions issued by a doctor within the last 30 days. The report found fewer than one in four of the deaths involved illegal narcotics.

Aran Hall, a Centers for Disease Control and Prevention Intelligence Service Officer for the West Virginia Department of Health and Human Resources, said there is a perception among some citizens that just because narcotics are legal and prescribed drugs, they are somehow safer.

The report found that methadone contributed to one of three deaths, or more than any other prescription drug. However, the report found that only 10 of the overdose victims were enrolled in a methadone clinic for drug abuse treatment.

The report found that other opioid drugs frequently linked to accidental overdose deaths included hydrocodone and oxycodone. The two narcotics contributed to one in five deaths. Morphine contributed to about one in seven deaths, the report found. Anti-anxiety drugs were found in 42 percent of the deaths.

While law enforcement officials have been fighting the illegal drug scourge in our region for years, accidental overdose deaths associated with the misuse of prescription narcotics now represents an emerging epidemic for the Mountain State.

The alarming new study from the West Virginia Department of Health and Human Resources should be viewed as a call to action for our community. We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.

We must act now to educate our community. If we fail to act, the number of accidental overdose deaths in the state and the region could continue to rise. It will take a combined effort of public education and law enforcement cooperation to reduce these alarming statistics.
Charge is filed in drug death

MADISON — A Madison man was charged Thursday with first-degree reckless homicide in a January drug death, according to a criminal complaint filed in Dane County Circuit Court.

James C. Swenby supplied methadone, a controlled substance, to Nicholas A. Pristoe, of Madison, who died from an overdose of the drug, prosecutors allege.

According to the complaint:

Pristoe visited Swenby’s Northridge Terrace apartment on Jan. 25, where another resident, Sarah Boyd, saw Swenby hand something to Pristoe and say something to the effect of, “Take a few of these, you’ll feel good.” Pristoe’s girlfriend, Sally Bolser, told police Pristoe had asthma and sometimes had trouble breathing.

Jan Dieter-Fox, another resident of the apartment, told police that Pristoe told him that “Jamie” had given him some pills, but he hadn’t taken them yet.

Boles said that when Pristoe returned home he was having trouble breathing. When she awoke the next day, she said, Pristoe was not breathing. Pristoe, who had a history of drug problems, according to Bolser, was declared dead after attempts to revive him failed. Pristoe’s toxicology tests showed the presence of cocaine and marijuana metabolites as well as the methadone.

Swenby consented to a police search of his bedroom, where police found a prescription bottle of methadone.

Swenby faces up to 25 years in prison and a fine of up to $100,000.
Report finds trends in child deaths

By MISHA WYMAN
The Union Democrat

Prescription drug abuse, suicide and vehicle accidents were the most prevalent causes of death last year among children and young adults in Jackson County, according to a newly-released report.

The Child Death Review Team, made up of officials from the Sheriff’s Office, the Senora Police Department, the Public Health Department, Child Welfare Services and other agencies, examined 11 deaths of youth through age 25. Most were teens and young adults.

One of the concerning trends was a rise in abuse of prescription drugs, particularly methadone, Sheriff’s spokesman Lt. Dan Breckeller said.

“What we’re finding is even small amounts of methadone mixed with alcohol can cause death,” he said. “It doesn’t take much.”

Three young people died of accidental overdoses in 2007, two of which involved a mixture of alcohol and methadone, a painkiller also used to help with withdrawals of harsher drugs such as heroin.

Jackson County isn’t the only area to see a rise in prescription drug abuse, said Dr. Todd Stolp, county public health officer.

“It’s a national issue, but we’re in the process of identifying the extent of the problem and how to address the problem,” he said.

There were three suicides in 2007. The number could be higher, however, because there were some drug-related cases in which there wasn’t enough information.
INDICATIONS

- Pain Treatment
- Narcotic Addiction Treatment/Maintenance
Dosage Forms

- Tablets 5 mg/ 10 mg
- Diskettes 40 mg
- Liquid
Methadone - Pharmacology

- Methadone belongs to pharmacological class called “Opioids”

- Opioids (e.g., hydrocodone, oxycodone, morphine, hydromorphone, fentanyl) are among the most potent analgesic drugs and are widely used.

- Opioids are used in the management of acute and cancer-related pain, and chronic non-cancer pain.

- Opioid analgesics affect number of systems – CNS, cardiovascular, GI tract, Immunological etc.
Methadone – Analgesia

- Actions on CNS – Relieves pain
- Equivalent to morphine in effectiveness
- Its elimination is slower than its duration (4-8 hours) of action
- Patient may feel the need to repeat dose at intervals shorter than body can handle
- Repeated dosing leads to accumulation in the body that may cause serious toxicity
Methadone Use in Pain Management

- 5 and 10 mg methadone tablets - approved for use in pain management
- 40 mg diskettes - not approved for analgesic use
  - FDA alert – Physicians should avoid prescribing 40 mg diskette for pain
  - ARCOS data indicates that 40 mg diskettes are being increasingly prescribed for pain management
  - This is a cause for concern because a 40 to 50 mg methadone can be lethal in opioid-naïve individual
Methadone - Toxicity

- Respiratory depression
  - Major hazard (Similar to other opioid analgesics)
  - Respiratory depression typically occurs later and persist longer than its peak analgesic effects

- Drug Interactions
  - CNS depressants (Alcohol, other opioids or CNS depressants)
  - CYP3A4 inhibitors (some antifungal agents, macrolide antibiotics, and SSRI s)
Methadone Deaths- Two Major Mechanisms

- **Toxicity on heart**
  - QT Interval prolongation and Torsades de Pointes (TdP) – Shared by LAAM, but not by other opioids
  - May lead to ventricular fibrillation and death
Methadone Single Dose Kinetics

Source: Resource Manual for CME course entitled “Prescribing Opioids for Chronic Pain” – Offered by the New England Chapters of the American Society of Addiction Medicine with support form CSAT, SAMHSA
**Fixed Methadone Dose Interval**


**Source:** Resource Manual for CME course entitled “Prescribing Opioids for Chronic Pain” – Offered by the New England Chapters of the American Society of Addiction Medicine with support form CSAT, SAMHSA
SAMHSA convened two meetings (2003 and 2007) to assess the factors behind increase in methadone related deaths. Accumulation to toxic levels of methadone during the start of opioid treatment or pain management due to overestimation of tolerance and methadone’s long, often variable, half-life. Misuse of diverted methadone by individuals with little or no opioid tolerance. Synergistic effects of methadone combined with other CNS depressants (i.e., alcohol, benzodiazepines or other opioids). Increasing use of methadone in pain management may be an important contributing factor.
Who is Prescribing Methadone?

<table>
<thead>
<tr>
<th>5 and 10 mg tablets</th>
<th>40 mg diskettes Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rx</td>
<td>Top Prescribers:</td>
</tr>
<tr>
<td><strong>Top Prescribers:</strong></td>
<td></td>
</tr>
<tr>
<td>• Anesthesiologists</td>
<td>• Family Practitioners</td>
</tr>
<tr>
<td>• Family Practitioners</td>
<td>• Anesthesiologists</td>
</tr>
<tr>
<td>• Internists</td>
<td>• Internists</td>
</tr>
<tr>
<td>• Osteopaths</td>
<td>• Osteopaths</td>
</tr>
<tr>
<td>• Physical Med. &amp;</td>
<td>• Physical Med. &amp; Rehab</td>
</tr>
<tr>
<td>Rehab</td>
<td>• Nurse Practitioners</td>
</tr>
<tr>
<td>• Neurologists</td>
<td>• General Practitioners</td>
</tr>
<tr>
<td>• Nurse Practitioners</td>
<td></td>
</tr>
</tbody>
</table>

Source: IMS Health, National Prescription Audit, November 2006
METHADONE POISONING/DEATH DATA
NFLIS National Data – 2006 & 2007
Narcotic Analgesics

<table>
<thead>
<tr>
<th>Narcotic Analgesics</th>
<th>Number</th>
<th>*Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>26,017</td>
<td>38.85%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>19,923</td>
<td>29.75%</td>
</tr>
<tr>
<td>Methadone</td>
<td>7,023</td>
<td>10.49%</td>
</tr>
<tr>
<td>Morphine</td>
<td>3,887</td>
<td>5.81%</td>
</tr>
<tr>
<td>Codeine</td>
<td>2,597</td>
<td>3.88%</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>1,488</td>
<td>2.22%</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>1,303</td>
<td>1.95%</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>1,290</td>
<td>1.93%</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>1,270</td>
<td>1.90%</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>1,113</td>
<td>1.66%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Narcotic Analgesics</th>
<th>Number</th>
<th>*Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone</td>
<td>30,504</td>
<td>39.66%</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>24,029</td>
<td>31.24%</td>
</tr>
<tr>
<td>Methadone</td>
<td>7,496</td>
<td>9.75%</td>
</tr>
<tr>
<td>Morphine</td>
<td>4,202</td>
<td>5.46%</td>
</tr>
<tr>
<td>Codeine</td>
<td>2,674</td>
<td>3.48%</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>1,306</td>
<td>1.70%</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>1,559</td>
<td>2.03%</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>957</td>
<td>1.24%</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>732</td>
<td>0.95%</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>2,094</td>
<td>2.72%</td>
</tr>
</tbody>
</table>

*Percentage of all narcotic analgesics exhibits analyzed
% Increase in Poisoning Deaths in the U.S. Since 1999

Source: CDC

- All poisoning deaths
- Methadone
- Other opioid
- Other synthetic narcotics
- Cocaine

% Increase in Poisoning Deaths in the U.S. Since 1999

Source: CDC
Note: In 2006, there were about 33-fold more hydrocodone prescriptions, 11-fold more oxycodone prescriptions compared to methadone prescriptions.
Deaths/100,000 Prescriptions in Florida

Source: FDLE and NPA Plus™
Methadone
Distribution
Data
Methadone Distribution by Business Activity

Source: DEA ARCOS

Source: DEA ARCOS
Distribution of 5 and 10 mg Tablets - TOP 5 STATES (2006)

Source: DEA ARCOS

Includes NTP’s

Excludes NTP’s
Purchases* of 40 mg Diskettes by Business Activity - 2006

- **19,275 Pharmacies**
  - 1,676,225 grams

- **810 Hospitals**
  - 45,329 grams (1.40%)

- **58 Practitioners**
  - 44,285 grams (1.37%)

- **424 NTP’s**
  - 1,470,566 grams (45.4%)

*Based on total gram amount

Source: DEA ARCOS

First Half 2007 (01/01/07 - 06/30/07)

- **56.3%**
- **41.2%**
As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution.

The 5mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies.
Other Controlled Substances

Stimulants

- Phentermine
- Phendimetrazine
- Methylphenidate (CII)
- Amphetamine ALKS (CII)
Non-Controlled Substances

- **Analgesic:**
  - Tramadol (Ultram®, Ultracet®)
  - Controlled Substance in OK, AR, KY

- **Muscle Relaxant:**
  - Carisoprodol (Soma®)
  - Controlled in 18 States
Enzymatic Action in the Body

Structural Change by Meprobamate
Anabolic Steroids, Dietary Supplements and hGH
Steroid Use is all about appearance, not performance
WHY????

- To Gain an Edge on the Competition...
Anabolic Steroids in the USA

- Schedule III of the Controlled Substances Act
- 59 Steroids under control in U.S.
Anabolic Steroids

- “Performance enhancing” drugs
- Synthetic testosterone
- Available as injectables, tablets, capsules, gels, and creams
Anabolic Steroids

- Build tissue up ("anabolic") by increasing protein synthesis and nitrogen retention (e.g., stimulate healing in burn victims). Treat some forms of anemia.

- Synthetic variations on the testosterone molecule, these are "androgens" and thus have masculinizing effects ("androgenic") as well as anabolic.

- More properly called "anabolic-androgenic steroids" (or AAS).
Promote growth of skeletal and cardiac muscle; Increase bone density; Increase red blood cells

Indicated for treating specific types of anemia, some breast cancers, osteoporosis, endometriosis

Endocrine dysfunction/hypogonadism/growth retardation
Illicit Use

- Only a small number of anabolic steroids are approved for human or veterinary use.
- Illicit steroids are sold at gyms, competitions and through mail order/Internet operations.
- Steroids are also diverted from pharmacies, physicians or synthesized in clandestine laboratories.
Synthesis of Testosterone

cholesterol \( \xrightarrow{P450ssc} \) pregnenolone

\( \xrightarrow{P450c17} \) 17-OH pregnenolone

\( 17,20 \text{ desmolase} \) 17-OH progesterone

\( \xrightarrow{3\beta-DH, \Delta^{4,5}-\text{isomerase}} \) dehydroepiandrosterone (DHEA)

\( \xrightarrow{17,20 \text{ desmolase}} \) 4-androstene-3,17-diol

\( \xrightarrow{3\beta-DH, \Delta^{4,5}-\text{isomerase}} \) 4-androstene-3,17-dione

\( \xrightarrow{17-\text{keto-reductase}} \) testosterone

\( \xrightarrow{17-\text{keto-reductase}} \) estradiol

\( \xrightarrow{5\alpha-\text{reductase}} \) dihydrotestosterone

\( \xrightarrow{\text{aromatase}} \) estradiol
Injectable Steroids

- Absorbed directly into the blood stream, avoiding a first pass through the liver.
- Intramuscular, not intravenous.
- Most injectable steroids undergo a process called *esterification* to slow their release into circulation.
One Cycle – Approximately 12 Weeks

Esquire Magazine, April 2008 – “Look at Me! I’m a Big Strong Boy” by Craig Davidson

35 Pound Increase in Body Weight

Single Workout Bench Press Increase of 30 Pounds
Health effects of steroids

**Men**
- Baldness
- Oily skin, acne
- Bigger breasts
- Liver cancer
- Reduced sperm count, shrinking of the testicles

**Women**
- Hair loss
- Deeper voice
- Oily skin, acne
- Smaller breasts
- Liver cancer
- Loss of menstrual periods
- Excessive growth of body hair

Symptoms also include rage, mania, delusions and heart attacks in both sexes.
Side Effects of Steroid Use: Women
Men

Baldness

Oily skin, acne

Bigger breasts

Liver cancer

Symptoms:
Rage, manic
and heart
both

Reduced sperm
count,
shrinking of
the testicles
Steroid Abuse

Common Steroids Abused

DECA DURABOLIN
DIANABOL Tabs.
SUSTANON
Commonly Abused Steroids

- **Oral Steroids**
  - Anadrol (oxymetholone)
  - Oxandrin (oxandrolone)
  - Dianabol (methandrostenolone)
  - Winstrol (stanozolol)

- **Injectable Steroids**
  - Deca-Durabolin (nandrolone decanoate)
  - Durabolin (nandrolone phenpropionate)
  - Depo-Testosterone (testosterone cypionate)
  - Equipoise (boldenone undecylenate)
  - Tetrahydrogestrinone (THG)
Patterns of Steroid Abuse

- **Cycling**: alternating periods of anabolic steroid use (on cycle) with periods of either no use or the use of low doses of anabolic steroids.

- **Stacking**: concurrent use of two or more steroids together.

- **Stacking the Pyramid or Pyramiding**: increase in the dose/type early in the cycle and tapering the dose in the latter part of the cycle.
Number of Federal Cases Involving the most frequently encountered steroids.

2007 STRIDE Data.
Source Areas/Countries: Mexico, Eastern Europe, China (Precursors), and Australia.

Mexico was the most significant manufacturer of steroids seized in the United States.

U.S. customers were purchasing from Mexican pharmacies.

Purchasers then smuggle back across border, or mail from Mexico.

“Operation Gear Grinder” targeted 8 Mexican veterinary steroid manufacturers whose products were illegally via the Internet.
TRENDS (Cont.)

- Shift to bulk purchase - Illegal clandestine steroid manufacturing laboratories have become more abundant than they have in the past.

- Operation Raw Deal

- Online auction sites (e.g. eBay, Yahoo and similar sites) are cooperating with law enforcement, but distributors have altered the methods of describing their products to avoid the filters these companies use to find illegal/illicit products.

- Internet sales from foreign-based web sites to include Prohormones and Steroid precursors

- Prescription Mills
Operation Raw Deal

11.4 million steroid dosage units were seized
Operation Raw Deal

- Raw material obtained from China and other countries
- Internet message boards and chat rooms provided info on how to convert raw material
- Promote and sell conversion kits
Operation Raw Deal

- Two-year international investigation
- U.S., Mexico, Canada, China, Belgium, Australia, Germany, Denmark, Sweden, and Thailand
- Anabolic steroids, HGH, insulin growth factor
- 124 arrests, and 56 U.S. steroid labs seized
COUNTERFEITS OR “BUNK” STEROIDS

- Significant quantities of counterfeit steroids available on the black market. Based on seizure statistics, this number could be 15% or higher.

- Some of the injectable bunk steroids analyzed have contained olive oil and sesame oil.
Human Growth Hormone (hGH)

- Also known as somatotropin
- It is synthesized and secreted by cells of the anterior pituitary.
- Gigantism, acromegaly, hypothyroidism, cardiac disease, myopathies, arthritis, diabetes, impotence, osteoporosis.
- Most Illicit hGH obtained from foreign sources/Internet-Jintropin
- Injection***
hGH

- Considered a Partitioning Agent
- Not Anabolic
- Regulates body composition, glucose and lipid metabolism, skeletal muscle and bone growth.

Indicated in adults for Aids Wasting, Short Bowel Syndrome and hGH deficiency (1 in 10,000).

Technically, not a controlled substance (federal). But, … federal law criminalizes whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition. 21 USC 333(e)

DEA has authority to investigate.
Human Growth Hormone
U.S. Products

- Genotropin
- Humatrope
- Norditropin
- Nutropin
- Saizen
Growth Hormone Releasers

- Also called “hGH Releasers,” “hGH Precursors,” “hGH Secretagogues”
- They do not contain hGH, they will read “hGHR” – a compilation of amino acids.
Dietary Supplements
DRUGS

Must be proven **safe before approved** for market

SUPPLEMENTS

Must be proven **harmful before removed** from market
Dietary Supplements

Definition of products that can be sold as dietary supplements:

- A product (other than tobacco) intended to supplement the diet. The product contains one or more of the following: vitamin; mineral; herb or other botanic; amino acid; dietary substance for use by humans; or a concentrate, metabolite, constituent, extract or combination of these ingredients.

- The product must also be intended for ingestion and cannot be advertised for use as a food.
Designer Steroids
Anabolic Steroid Control Act of 2004

On April 25, 2008, DEA Published a Notice of Proposed Rulemaking to place in Schedule III the following substances:

- Androsta-1,4-diene-3,17-dione (Boldione)
- Desoxymethyltestosterone
- 19-nor-4,9(10)-androstadienedione

These drugs are chemically and pharmacologically similar to testosterone; are not progestins, estrogens or corticosteroids and are not DHEA
Salvia Divinorum
And
Salvinorin A
Salvia Divinorum

- Related to the mint family (*Labiatae* or *Lamiaceae*).
- Hundreds of species.
- Perennial herb.
- Indigenous to the State of Oaxaca in Mexico.
- One of several "vision-inducing" plants employed by the Mazatec Indians living in the mountains and uplands valleys of northeastern Oaxaca in Mexico.
Other Names

- Salvia
- Mexican Mint
- Magic Mint
- Diviner's Sage
- Ska Pastora
- Ska Maria Pastora
- Sage of the Seers
- Leaves of the Shepherdess
Characteristic Features of Salvia Divinorum Plant

- Grows to well over one meter in height.
- Has large (6 inches) ovate green leaves finely dentated along the margin.
- Has hollow square stems.
- Has blossoms with white corollas and purple calyces.
Internet sites advertise Salvia as a legal alternative to other controlled hallucinogens.

Sold as:
- Seeds
- Fresh Leaves
- Dried Leaves
- Whole Plants
- Cuttings
- Extracts (5x, 10x, 15x, 20x)
Exhibits of Salvia Found to Contain Salvinorin A

Salvia from Rochester, Minnesota.

Salvia from Dade County, Florida

Images were obtained from Microgram
Salvia Divinorum Use in the U.S.

Quid method - chewing fresh leave and retaining the leaf mass and juice in the cheek (like chewing tobacco).

Smoking of dried leaves. (Preferred mode of administration by users in the U.S.)

There are anecdotal reports of abuse, but no data from standard drug abuse databases (e.g., DAWN and Poison Control) within the U.S. to accurately estimate the extent of abuse.
Effects

- **Psychoactive effects** (when they occur) start in about 15 to 30 seconds after smoking, 4-10 minutes after chewing and holding in cheek of mouth and 20-30 minutes after oral ingestion. These effects may include:
  - Visual hallucinations with bright lights, vivid colors with distortion of real images and seeing images that are not there.
  - Out of body experience like that of ketamine (CIII).

- **Physical Effects** include lack of coordination, dizziness and slurred speech.
Salvinorin A

- Substance thought to be responsible for the psychoactive effects of salvia.
- Has a unique chemical structure unlike other hallucinogens.
- Only recently have analytical techniques been developed to evaluate this chemical in humans.
- Present in dry leaves at concentrations of about 1-4 mg per gram of dry leaf

In human studies -
- Smoking of dried leaves or up to 2.6 mg Salvinorin A, produced psychoactive effects in about 30 seconds, peaking at about 10 minutes and lasting 15-30 minutes
Salvinorin A

*How may it exert psychoactive effects?*

- Does not bind at receptors normally associated with the psychoactive effects of currently controlled substances including dopamine, serotonin, benzodiazepine, or cannabinoid receptors.

- Does bind with high affinity to opioid kappa receptors.

- Kappa receptor activation is known to be associated with hallucinations and other dysphoric (unpleasant) effects.
Salvinorin A is not currently controlled under the Controlled Substances Act in the United States.

Bill in 2002 - "Hallucinogen Control Act of 2002" - Proposed to place Salvinorin A and *Salvia Divinorum* into Schedule I. It was not reintroduced in 2003.

A number of U.S. states have taken legal action

Salvinorin Divinorum is controlled in Finland, Denmark, Australia and Italy. In Norway it is not controlled but listed as a psychoactive drug.
DEA Web sites

www.DEAdiversion.usdoj.gov or
www.dea.gov
Thank You!

U.S. Department of Justice
Drug Enforcement Administration