Abuse

- In 2008, 6.2 million Americans used prescription-type psychotherapeutic drugs for non-medical purposes in a one-month period (2.5% of the U.S. population)
  - More than cocaine, heroin, hallucinogens and inhalants combined
- In 2008, among all illicit drug categories, non-medical use of prescription pain relievers tied with marijuana with the highest rate of new abusers (2.2 million).

- From 2002 to 2008, increase in young adults (age 18-25) rate of non-medical use of prescription pain relievers (4.1 to 4.6%)

- In 2008, 5.9% of young adults (age 18 to 25) used psychotherapeutic drugs for non-medical purposes.

SOURCE: 2008 National Survey on Drug Use and Health (NSDUH) published Sept 2009 by the Dept of HHS/Substance Abuse and Mental Health Services Administration (SAMHSA)
Emergency Room Data

- From 2004 to 2006
  - No Significant Change: ER visits attributable to cocaine, heroin, marijuana, and stimulants (the major illicit drugs)
  - Increase of 44%: ER visits attributable to pharmaceuticals alone (i.e., with no other type of drug)

- Drugs most frequently implicated in non-medical use:
  - Benzodiazepines (Valium®, Xanax®) 36% increase
  - Hydrocodone/combinations (Norco®, Vicodin®) 44% increase
  - Oxycodone/combinations (OxyContin®) 56% increase

SOURCE: 2006 DAWN (Drug Abuse Warning Network) report published August 2008 (most recent data)
Emergency Room Data

- Portland-Vancouver-Beaverton Metro Area
  - 2007 emergency room reporting
  - 161 total reported drug-related accidental deaths
  - 99 (61%) deaths involved prescription opiates/opioids, to include oxycodone, hydrocodone, morphine, codeine
  - Of the 99, 40 deaths involved Methadone (25% of total)

SOURCE: 2006 DAWN (Drug Abuse Warning Network) report published August 2008 (most recent data)
Parents are still not discussing the risks of abusing prescription and over-the-counter medicines despite the increase in parent/teen discussions about the risks of illegal drugs

- Only 24% of teens report that their parents talked with them about the dangers of abusing prescription (Rx) drugs or use of medications outside of a doctor’s supervision
- Just 18% of teens say their parents discuss the risks of abusing over-the-counter (OTC) cough medicine

SOURCE: 2008 Partnership Attitude and Tracking Study (PATS) Released FEB 2009 by The Partnership for a Drug-Free America
Teen Abuse

- The abuse of prescription medicines among teens continues to be a troubling trend\(^1\)
  - Teens mistakenly believe that abuse of prescription drugs is less dangerous than abuse of illegal street drugs
  - Teens report prescription drugs are easier to get than illegal drugs, up significantly from 2005
  - 10% of teens report having abused a Rx pain reliever

- Prescription drugs “used to get high”; more teens reported them as “easier to obtain” than beer\(^2\)
  - 35% said they could obtain within a day
  - 26% said they could obtain within an hour

SOURCES:
1. 2008 Partnership Attitude and Tracking Study (PATS) Released FEB 2009 by The Partnership for a Drug-Free America
Drugs of Concern

- Hydrocodone (Schedule III)
- OxyContin® (Schedule II)
- Fentanyl (Schedule II)
- Methadone (Schedule II)
- Cough Syrup (Schedule V)
Hydrocodone (Schedule III)

- **Trade names:**
  - Vicodin®, Lortab®, Lorcet®, Norco®
- **Street prices:** $1 to $3 per tablet
- **Hydrocodone/Acetaminophen mix-toxicity**
- **Similarities:**
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects
- **From 2005 to 2007, non-medical use of Vicodin® increased³:**
  - 10th graders increased from 5.9% to 7.2%
  - 12th graders maintained an average 9.6%

³SOURCE: 2007 Monitoring the Future study released April 2008. MTF is conducted by the Institute for Social Research at the University of Michigan.
Vicodin-5/500mg
Norco 7.5/325mg
OxyContin® (Schedule II)

- Controlled release formulation of Schedule II Oxycodone
  - Street Slang: “Hillbilly Heroin”
  - 10, 15, 20, 30, 40, 60, 80mg available

- Effects:
  - Similar to morphine in effects and potential for abuse/dependence

- Street prices: $25 to $80 per 80mg tablet

- Addiction, crime and fatal overdoses have all been reported as a result of OxyContin® abuse
  - The controlled release method of delivery allows for a longer duration of drug action so it contains much larger doses of Oxycodone
  - Abusers easily compromise the controlled release formulation by crushing the tablets for a powerful morphine-like high
  - Since 2002, use among 12th graders has remained between approximately 4% and 5%³

³SOURCE: 2007 Monitoring the Future study released April 2008
Oxycontin- 80mg
Fentanyl (Schedule II)

- **Trade-Names:**
  - Actiq®: dispensed in a berry flavored lollipop-type unit
  - Duragesic®: trans-dermal patch for chronic pain
  - Fentora™: effervescent tablet formulation
    - Approved by the FDA September 2006
    - Compared to same dose as Actiq®, the effervescent tablet allows a larger amount of Fentanyl to be absorbed rapidly through the oral membranes

- **Street prices:** $25 to $40 per patch/lollipop
Fentanyl - Abuse

- Fentanyl is 100x more potent than morphine
- Numerous reports of overdose deaths resulting from mixing Fentanyl with heroin or cocaine, or ingesting patch
- While most illegal use of Fentanyl is from diverted products
  - Recent epidemic is linked mainly to illicitly manufactured Fentanyl
    - Previously, Fentanyl could only be made by expert chemists
    - New, easier synthetic method now available on the Internet
    - Inexpensive to manufacture with very high profit margin
Fentanyl-Actiq 1600mcg
“Growing drug problem” (according to toxicology experts)

Abuse linked to:
- Increased prescribing by doctors of methadone to treat pain
- High level of diversion to illicit market

Increasing chances of an overdose
- Remains in the body much longer than other similar substances
- Overdoses and deaths have quadrupled since 1999

Street Prices: $2 to $10 per 10mg tablet

SOURCE: UPI, Inc. articles published February 2007
Methadone-10mg

Mallinckrodt Pharmaceuticals 10mg
Cough Syrup (Schedule V)

- Promethazine with Codeine
  - Hycotuss® syrup with hydrocodone (Schedule III)
- Commonly sold in pint bottles
- Preferred abuse by mixing with Sprite®, Vodka/Rum, “Jolly Rancher,” and crushed Vicodin®
- Street Prices: $250 to $600 per pint
Promethazine with Codeine
Trends in Pharmaceutical Diversion

- Doctor Shopping
- Prescription Fraud
- Theft
- Internet Pharmacies
Doctor Shopping

- **Individual Patients**
  - **Target Physicians**
    - Obtain prescriptions from multiple physicians
    - Physicians willing to prescribe controlled substances over an extended period of time with little or no follow-up
  - **Target Pharmacies**
    - Utilize multiple pharmacies to fill the orders to avoid suspicion
    - Pharmacies known to dispense controlled substances without asking questions
Doctor Shopping

- Trafficking Organizations
  - Recruit individuals to obtain narcotics
    - Patients often have legitimate medical conditions (favorite targets: seniors, nursing homes, homeless shelters)
    - With cooperating physician or staff, patients never see physician
      - False identification, obtained from consenting individuals, used to “create” medical records and obtain scripts
    - Pay patients for their narcotics and services
  - Target physicians
    - Those known to prescribe with little or no follow-up
    - Sympathetic to patients’ medical situation
    - Commonly long distance from patients’ residence
  - Utilize Medicaid (or state public health)
    - Reduces cost of office visits and controlled substances at pharmacy
    - Increases profit margin
Doctor Shopping

- **Trafficking Organizations (continued)**
  - Well Organized
    - Often provide transportation of patients to/from physicians and pharmacies, or delivery of medication (maintains legitimate cover)
    - Maintain distribution outlets (sells both prescriptions and controlled substances)
  - Supported by “Pill-Mill” physicians and pharmacies
    - Physicians and pharmacies that “sell” scripts and narcotics to large numbers of drug seekers
    - Characteristics of pill-mill physicians
Prescription Fraud

- Fake prescriptions
  - Highly organized
  - Use real physician name and DEA Registrant Number
    - Contact Information false or “fake office”
    - Organizations set-up actual offices with contact information and staff (change locations often to avoid detection)
  - Prescription printing services utilized
    - Not required to ask questions or verify information printed
    - Use of out of state internet based printing services
    - Licensing of printing services in some states to reduce fraud

- Stolen prescriptions
  - Forged
  - “Smurfed” to large number of different pharmacies
Theft

- Common “behind the counter” thefts
  - Lack of adequate background checks of pharmacy staff
  - Systematic
    - Use computer ordering system
    - Take possession at time of delivery (prior to inventory)

- Target Schedule III thru V
  - Inventory requirements vary by State
  - Schedule II security more stringent

- Pharmacy and delivery vehicles
  - Burglary/robbery
  - Known distribution organizations
Internet Pharmacies

- **Ryan Haight Act**
  - Legislation to document/register internet pharmacies
  - Separate identification of
    - Brick and mortar pharmacies
    - Physicians
    - Web-site facilities

- **Prosecution Issues**
  - “Valid prescription,” one in-person visit; legitimate medical purpose
  - Amends 21 USC 841; Internet-related violations
  - Increases statutory sentencing ranges for Schedules III thru V
  - State civil action in federal court
  - “Off-shore” pharmacies and facilitators; Import violations
Additional Facts...

- Cocktails
- Schedule V Cough Syrup
- Street Gangs
- Places of Interest
- Prescription Drug Monitoring
- Outside the Scope
Cocktails

- Common identification of pattern of abuse by physicians and users
- Maximizes effect of narcotic abuse-Opiate Potentiators
- Preferred Prescriptions- “Holy Trinity”
  - Schedule II and III narcotics (Oxycontin®, Vicodin®)
  - Schedule IV Benzodiazapines (Xanax®, Valium®)
  - Non-Controlled Muscle Relaxants/Sedative (Soma®)
  - Non-Controlled Opioid Analgesic-Tramadol (Ultram®) substituted for schedule II/III narcotic
- Pre-written prescriptions and medical records
  - Sponsored by “Pill-Mill” physicians
Cough Syrup

- **Schedule V (Promethazine with Codeine)**
  - Hydrocodone based syrup (Hycotuss®), Schedule III

- **Sophisticated trafficking organizations**
  - Control diversion, storage, transportation, distribution, money laundering

- **Closed-door pharmacies facilitating**
  - Use of DEA registration number utilizing small distributors
  - Owners/pharmacists being paid for services/use
  - Federal/State reporting and inventory requirements are relaxed based on drug schedule
**Cough Syrup**

- **Large profit margin**
  - Diverted wholesale/retail price ($8 to $12/pint) vs. street price ($250 to $600/pint)

- **Remedies**
  - Target money laundering prosecution and asset forfeiture
  - Schedule V, federal misdemeanor offense (state felony)
  - Ryan Haight increased guidelines for Schedule V (second offenders)
Street Gangs

- Pharmaceutical trafficking by traditional street gangs
  - No reliance on outside SOS’s (e.g. illicit narcotics)
  - Non-dependence maintains control
  - Prescription-fraud prevalent
  - Established distribution channels, poly-drug
  - Personnel to support pharmacy smurfing activities
East Coast: Florida Pain Clinics

- Heavy concentrations in Miami-Dade, Broward and West Palm Beach counties
- MD visit and dispense from same location
- Primarily Cash; $200 for initial MD visit, $150 for follow-up visit
- $825 to $950 for cocktail (Soma®, Valium® & Oxycodone®)
- $1.50 to $2.00 per pill from non-affiliated Pharmacy
- $3.00 to $4.00 per pill from pain clinic’s in-house Pharmacy
- Average 120 to 180 pills per prescription
- Out of state patients
  - Distribution to identified states of Maryland, Virginia, Kentucky, Tennessee, Ohio for $30 to $40 per pill
  - DTOs transport patients to clinics every two weeks to meet with as many doctors as possible during a 2-3 day timeframe
Places of Interest

- West Coast: Los Angeles
  - Large number of DEA registrants (physicians, pharmacies, distributors)
  - Distribution networks north along the west coast to Seattle
  - United States (Las Vegas); Houston, Louisiana, Memphis, Atlanta; U-Hauls and express mail services
  - Similar to Florida pain clinics; however, most clinics issue prescriptions which are filled at “approved” pharmacies (partnered with physicians)
  - Patients travel from all over California and out of state to visit “Pill Mill” clinics; regularly transported in by bus/van by distribution organizations
Places of Interest

- Houston:
  - Large number of DEA registrants (physicians, pharmacies, distributors)
  - Distribution networks to neighboring states: Louisiana, Arkansas, and Mississippi
  - Prescriptions are being filled in Texas, drugs then carried to state of origin
  - Medical visits range from $85 to $100
  - Average $55 to fill prescription at quantities of 120 pills
  - Drug most commonly written is hydrocodone
Places of Interest

- Houston (continued)
  - Try to keep as closed system (i.e. script is faxed to partnering pharmacy)
  - Partnering pharmacy sells narcotics at a reduced rate to avoid extra scrutiny
  - Owner’s of pain clinics are usually non-DEA registrants
  - Pain clinics will hire a medical director who is a DEA registrant
    - Sign blank prescription pads
    - Show up a clinic once every few days
    - Non-licensed PA’s and foreign MD’s will examine patients (customers) and fill-out signed prescriptions
  - Legislation pending in Texas to correct deficiencies
Prescription Drug Monitoring

- Tool for physicians/pharmacies to prevent abuse
- Tool for law enforcement in investigating diversion
- Drug Schedules reported vary by state
- Sort by practitioner, pharmacy, patient
- As of January 2009:
  - 32 States with operational Prescription Drug Monitoring Programs
  - 6 States with enacted programs not yet operational
  - 12 States with no program
  - Funded by federal grants
Outside the Scope

- Indicators/Probable Cause Factors
  - Inordinately large quantities of controlled substances
  - Inordinately large quantities of prescriptions
  - Large numbers of young patients with chronic pain
  - No medical history/no physical exam or cursory exam
  - Referred pharmacies
  - Prescription intervals inconsistent with legitimate treatment
  - Physician/staff use street slang
  - No logical connection between drug and diagnosis/condition
Outside the Scope

- Indicators/Probable Cause Factors (continued)
  - Patients receive same drugs, or combination, regardless of diagnosis/condition
  - Physician writes scripts in 3rd party patient names
  - Physician will not write refills
  - Patients travel long distances
  - Large amounts of cash patients
  - Large amount of narcotic prescribing by non-pain specialists
Adderall abuse
- Schedule II Amphetamine
- Used to treat ADHD, effective in weight loss
- Abuse prevalent among college students
- Used to enhance/lengthen academic performance
- Replace coffee and “Red Bull” type stimulants
- $5.00 per pill on illicit market
- Tablet can be snorted, injected or smoked
- Highly addictive
- Sold on internet sites, such as Craigslist.com
Emerging Trends, Etc

- Steroids in Dietary Supplements
  - Professional sports controversy; athletes testing positive for banned substances blaming supplements
  - Dietary Supplements not regulated by FDA
    - FDA can only investigate if supplement found to cause harm following marketing
  - Anabolic Steroid: Any drug or hormonal substance chemically related to testosterone (see 21 CFR 1300.01 for prohibited list)
  - Schedule III Controlled Substance
  - New supplements containing synthetic steroids on market
  - Significant press interest, congressional review
Counterfeit pharmaceuticals

- Often obtained through internet sources, both domestic and foreign
- Internet sources advertise on B2B sites, such as Alibaba.com, Tradeboss.com, etc.
- Substances usually obtained through foreign wholesalers
- Substances contain wide variety of ingredients, some toxic, or active ingredients in insufficient levels
Emerging Trends, Etc

- **Fentanyl laced Heroin**
  - DEA investigations have found both imported and domestically modified heroin containing Fentanyl.
  - Antidotal information includes duralgesic patches dried and then added to heroin.