

# The National Pharmaceutical Situation Report

U.S. Department of Education Office of Safe and Drug Free Schools National Harbor, MD – August 2009

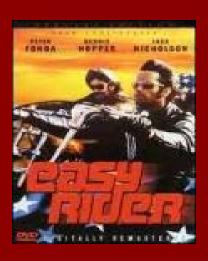
> Joseph T. Rannazzisi Deputy Assistant Administrator Office of Diversion Control

#### **OBJECTIVES**

- History of Prescription Drug Abuse
  - > Where we've been Where we are going?
- Current controlled substance pharmaceuticals of abuse
- Non-controlled drugs of abuse
- > New drugs of abuse



Marijuana



The 1960's



Seconal



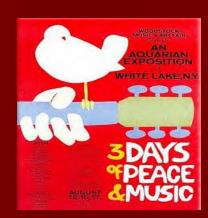
Dexedrine



Meprobamate



LSD



Valley of the Dolls

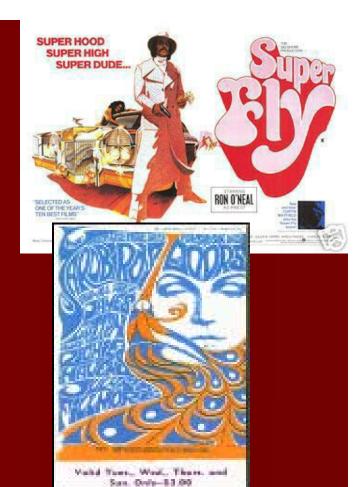


## The 1970's

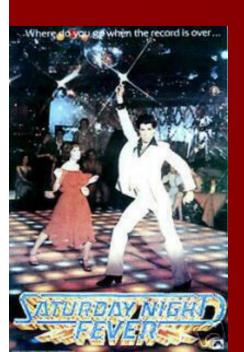












#### T's and Blues

(Talwin and Pyrabenzamine)







Hydromorphone

## The 1980's





#### 4's and Doors

Tylenol w/Codeine and Doriden



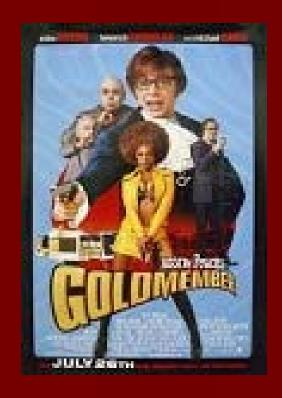


Cocaine

# Oxycodone 10 10 mg 20 10 mg 20 mg 40 mg

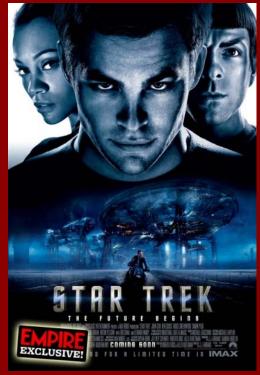
160 mg
Controlled-Release Tablets
(oxycogone HCI)

## The 1990's



Methamphetamine





## **TODAY**





Ketamine

**MDMA** 

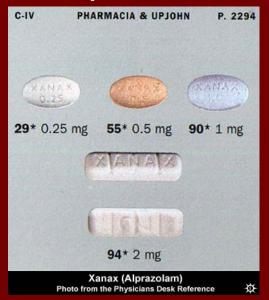


transferrations.

Flunitrazapam (Rohypnol)



#### **Alprazolam**



# THE PERFECT STORM

#### Technology

- Law enforcement struggling to keep up
  - Training
    - Rapidly changing environment
  - Equipment
    - Costly
    - Rapidly changing / outdated
  - Laws
    - Written prior to technological advancements
      - Encryption (Skype)
      - Wi Fi (Coffee shops)
- Jurisdictional issues
  - Drug seeker in one state
  - Web server in another state or offshore
  - Financial component in another location or offshore
  - Source of supply in yet another state or offshore



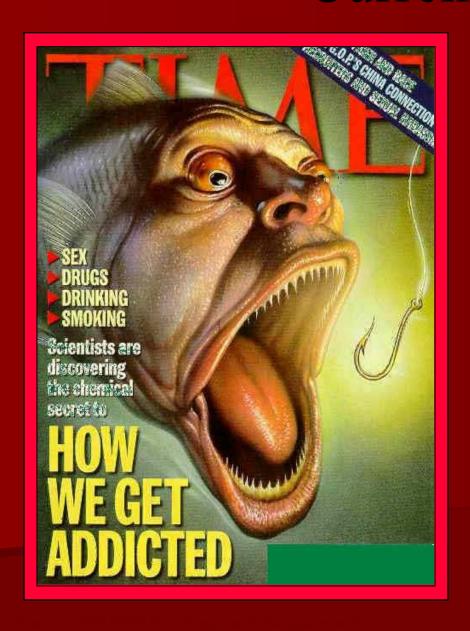




#### The Perfect Storm

- Misperception: When we don't see specific drugs anymore the problem has gone away
- Baby Boomers are retiring in large numbers and will need additional medications more in the medicine cabinet
- Shift in the user / abuser population Getting younger
- Dealing with the Information / Electronic era
  - Web sites such as Erowid
  - Social networking blogging, twitter, MySpace, Facebook, text messaging or chat rooms for instant exchanges of information such as sources of the drugs
  - Anonymity no more face-to-face meetings. Drugs are delivered right to your own home

#### Current Users



**ANY ILLICIT DRUG:** 

19.9 million

(8% of population)

**MARIJUANA: 14.4 million** 

**PSYCHOTHERAPEUTIC** 

**DRUGS: 6.9 million** 

**COCAINE: 2.1 million** 

**METHAMPHETAMINE: 529,000** 

**HEROIN: 153,000** 

## Scope and Extent of Problem



0.3 million

0.35 million

**Sedatives** 

1.2 million

1.1 million

**Stimulants** 

1.6 million

1.8 million

**Anti-Anxiety Medication** 

4.4 million | 5.2 million

**Narcotic Pain Relievers** 

Source: 2004 and 2007 National Survey on Drug Use and Health



#### 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 Seekers
  - Drug rings
  - Doctor-shopping
  - Forged / fraudulent / altered prescriptions
  - The medicine cabinet
- The Internet

# Juvenile Drug Diversion Sources...

- Obtain through friends or acquaintances
- 70% of youth obtain prescription drugs for free from friends or family
- From the medicine cabinet
- Can result in fatal overdoses when opiate naïve

# What are kids are listening to... Eminem?

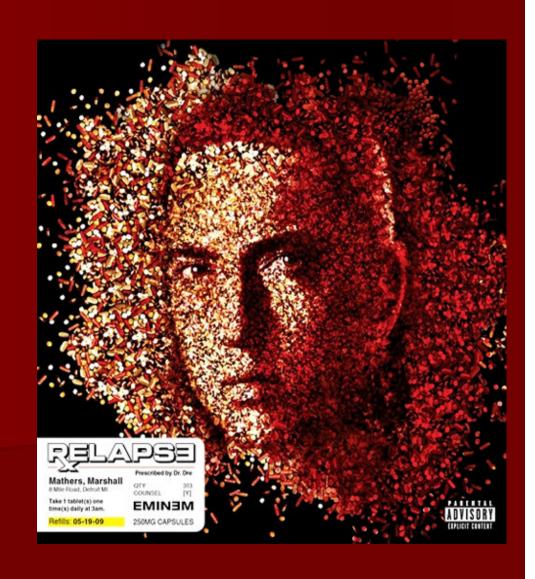


Rap star Eminem has a Vicodin® tattoo on his arm and a picture of a Vicodin® tablet on one of his CDs

"I invented violence, you vile venomous volatile ... vain Vicodin"

#### About Eminem...

- "Relapse" CD released in 2009
- Admits to taking as many as 20 Vicodin, Ambien and Valium a day.
- 2005 almost overdosed on Methadone.



# What are kids are listening to... Lil' Wyte?

Rap song "Oxycotton" (sic) about
 OxyContin and other prescription
 drugs. Can be found on the Internet &
 YouTube



# Commonly Abused Controlled Substance Pharmaceuticals



## Hydrocodone, APAP c-III

- > Hydrocodone / Acetaminophen (toxicity)
- > Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects
- ➤ Brand Names: Vicodin<sup>®</sup>, Lortab<sup>®</sup>, Lorcet<sup>®</sup>
- "Cocktail" or "Holy Trinity"
  - > Hydrocodone
  - Soma ® / carisoprodol
  - ➤ Alprazolam / Xanax®
- ➤ Street prices: \$2 to \$10+ per tablet depending on strength & region





## Hydrocodone

- Vicodin / hydrocodone second only to marijuana as the 'drug of choice' for teens
- From 2005 to 2007, non-medical use of Vicodin® increased\*:
  - ➤ 10th graders increased from 5.9% to 7.2%
  - > 12th graders maintained an average 9.6%
- \*\*In 2004, the U.S. consumed 99% of world's supply of hydrocodone yet the U.S. makes up only 4.5% of the world's population

<sup>\*\*</sup>SOURCE: JAMA, January 17, 2007 - Vol 297, No 3, Opioid Prescriptions Soar



# Vicodin®-5/500mg

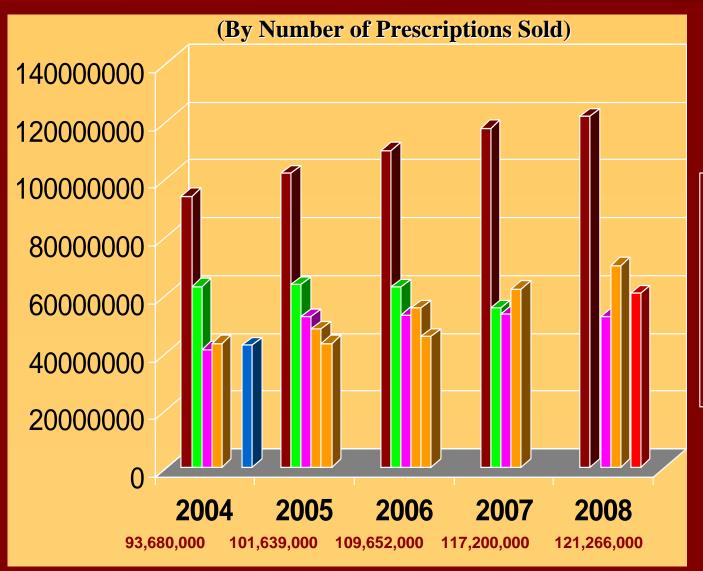




# Norco® 7.5/325mg



# Top Five Prescription Drugs Sold in the U.S. (2004-2008)



Source: Verispan

- □ Hydrocodone
- Lipitor
- Amoxicillin
- Lisinopril
- Hydrochlorothiazide
- Simvastatin
- Atenolol
  - 1. Pain reliever
  - 2. Cholesterol
  - 3. Antibiotic
  - 4. Blood pressure
  - 5. Diuretic
  - 6. Cholesterol
  - 7. Heart disease



# Fentanyl

- Fentanyl Citrate dispensed in a berry flavored lollipop-type unit
- > Fentanyl Patches
- > Fentanyl is 100 times more potent than morphine
- Intended to be used for chronic cancer pain and only for people who are already taking and who are tolerant to prescription opioid (narcotic) pain medicines
- Abused for its intense euphoric effects



**Fentora®** 

Actiq®





## $OxyContin^{\circledR} \ \ (Schedule \ II)$

- Controlled release formulation of Schedule II oxycodone
  - 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
  - Street Slang: "Hillbilly Heroin"
  - 10, 15, 20, 30, 40, 60, 80mg available
- Effects:
  - Similar to morphine in effects and potential for abuse/ dependence
- Street price: Approx. \$80 per 80mg tablet
- Since 2002, use among 12th graders has remained between approximately 4% and 5%\*



# OxyContin®-80mg



# METHADONE



# KidsPeace Teens Overdose on Methadone



#### Girl who OD'd Dies:

She and another girl allegedly took stolen methadone from counselor while at KidsPeace Recovery Institute.

#### **EAST COUNTY COURTS**

# Woman is sentenced in teen's death

#### Girl was given methadone pills

By Angelica Martinuz STAFF WRITTR

A Santee mother who gave a reenage friend of her daughter's a deadly dose of methadone and penicillin was sentenced yesterday to six years in , be alive if it weren't for the DESON.

Laura Susan Wion, 45, appeared disorientated and under the influence of medication as she told the court that she meant no harm when she gave Kelses Pheips the pills to treat a sure throat in August 2006, ..

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

But prosecutor Chris Lindbenz characterized the statements read on her behalf by relatives and Iriends as The Laura Wion show."

"The fact is the victim would defendant's actions The said.

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

 Her, defense attorney. Micromis during the visit. chael Malowney, asked Superior Court Judge Charles W. Er :

vio for a four-year orising sentence.

He puntrayed Kelses as a troubled teen who ran from home and used drugs.

Tracy Moe, Kelsea's mother. said Kelsea was a loving dangle-(er who was depicted unfairly.)

"Six years is absolutely nothing to give to this woman who killed my daughter," Moe said. "Krisea was made not to be a person she buly was not ".

Kelsea died Aug. 21. 2006. after visiting Wion's rhaughter. She had complained of a sore throat and other cold symp-

Wion, who had been prescribed methodone and other

medications, gave methodone to the girl.

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

Investigators found 18 moth: adone pills near Kelsca's bed. The drug is commonly grescribed for relief of slevery pain. and used to ease withdrawalsymptoms for those addicted to upiates such as herojn.

Angelica Marijanez: (619) 293-1317; angetica.martinez⊉uniontrid.com



## Report finds trends in child deaths

By ALISHA 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 Tuolumne County, according to a recently-released

the Sonora Police Department, the spokesman Lt. Dan Bressler said. Public Health Department, Child Welfare Services and other agencies, examined 11 deaths of youths through age 25. Most were teens and young adults.

One of the concerning trends was a

The Child Death Review Team, made rise in abuse of prescription drugs, up of officials from the Sheriff's Office, particularly methadone, Shefiff's

> "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 overdose in 2007, two of which

involved a mixture of alcohol and process of identifying the extent of help with withdrawals of harsher problem," he said. drugs such as heroin.

Tuolumne County isn't the only area to see a rise in prescription drug abuse, said Dr. Todd Stolp, county public ed cases in which there wasn't enough héalth officer.

"It's a national issue, but we're in the

methadone, a painkiller also used to the problem and how to address the

There were three suicides in 2007. The number could be higher, however, because there were some drug-relat-

SEF DEATHS/PLANE



#### Methadone (Sch. II)

- "Growing drug problem" (according to toxicology experts)
- Abuse linked to:
  - Increased prescribing by doctors of methadone to treat pain (5 & 10 mg vs 40mg tablets)
  - Inexpensive compared to alternative opioids
  - 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: \$1 per mg (\$10 per 10mg tablet)



# Methadone-10mg





## Other Controlled Substances

- Phentermine C-IV
- Phendimetrazine c-III
  - Bontril®
- Benzodiazepines
  - Alprazolam/Xanax ®
- Amphetamines
  - Adderall c-II
  - Methylphenidate c-11
    - Ritalin®
    - Concerta®

# Ritalin® / Concerta® and Adderall

- Used legitimately to treat ADHD
- ➤ Used non-medically to get high and as an academic "performance-enhancer" to improve memory and improve concentration – gain the edge
  - > Higher GPA
  - > Higher SAT / ACT score
  - Get that scholarship



# Alprazolam Xanax® (Z-bars)

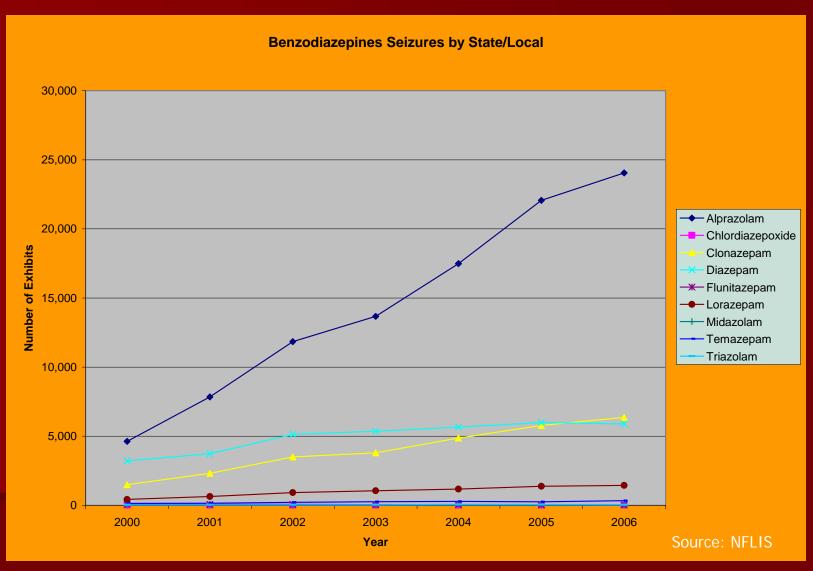
C-IV

- 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 7<sup>th</sup>\*\*
- \* Source IMS Health
- \*\* Source Verispan VONA





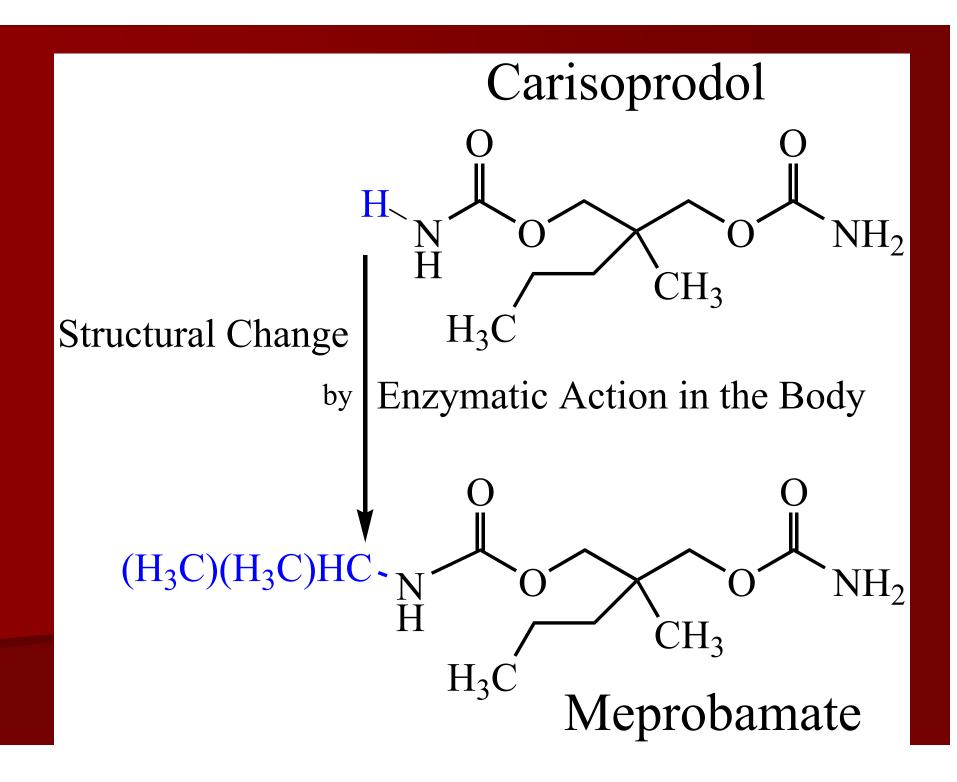
#### State and Local Seizure Data





#### Non-Controlled Substances

- Analgesic:
  - Tramadol (Ultram®, Ultracet®)
    - Arkansas, and Kentucky
- Muscle Relaxant:
  - Carisoprodol (Soma®)
    - Alabama, Arkansas, Arizona, Connecticut, Florida, Georgia, Hawaii, Indiana, Kentucky, Massachusetts, Minnesota, Nevada, New Mexico, Oklahoma, Oregon, and West Virginia.
  - Cyclobenzaprine (Flexeril®)
- Cough Suppressant:
  - Dextromethorphan (DXM)
    - Over-the-Counter (OTC) cold medication, such as: Coricidin HPB
       Cough and Cold Tablets and Robitussin Cough Syrup





#### Methods of Diversion

- Practitioners / Pharmacists
  - Illegal distribution
  - Self abuse
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- Employee pilferage
  - Hospitals
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  - Nursing homes
  - Retail pharmacies
  - Manufacturing / distribution facilities

- Pharmacy / Other Theft
  - Armed robbery
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  - The medicine cabinet
- The Internet

#### Prescription Requirements

	Schedule II	Schedule III	Schedule IV	Schedule V
Written	Yes	Yes	Yes	Yes
Oral	Emergency Only*	Yes	Yes	Yes
Facsimile	Yes**	Yes	Yes	Yes
Refills	No	Yes#	Yes#	Yes#
Partial Fills	Yes***	Yes	Yes	Yes

<sup>\*</sup> Must be reduced in writing, and followed by sign, hard copy of the prescription.

<sup>\*\*</sup> A signed, hard copy of the prescription must be presented before the medication is dispensed.

<sup>\*\*\* 72</sup> hour time limitation.

<sup>#</sup> With medical authorization, up to 5 in 6 months.



### Internet Diversion

### Rogue Internet Pharmacy

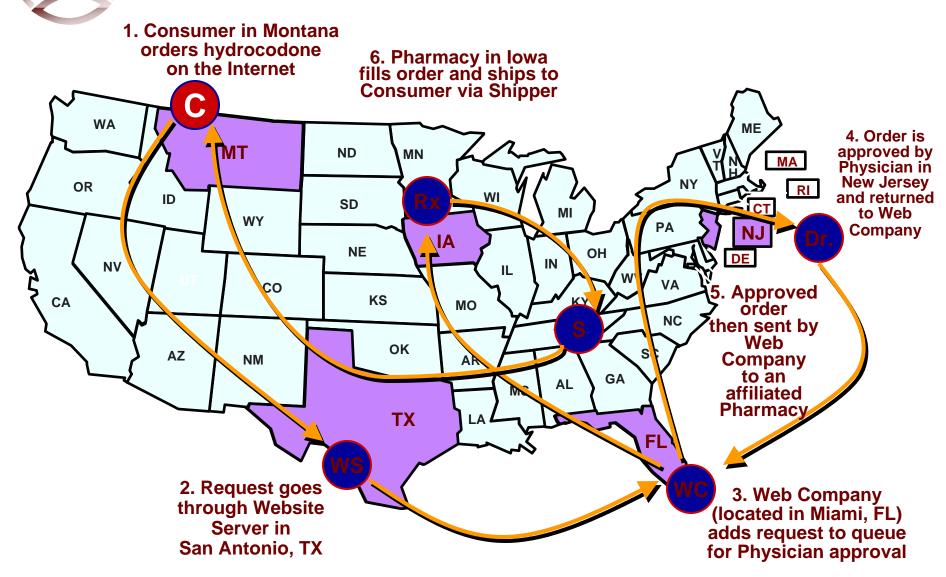




## Components for a Domestic Rogue Internet Operation

- Web Broker / Facilitator (optional)
- > Practitioner
- > Pharmacy
- \*\*All members of scheme are complicit thereby eliminating all checks and balances
- Source of Supply

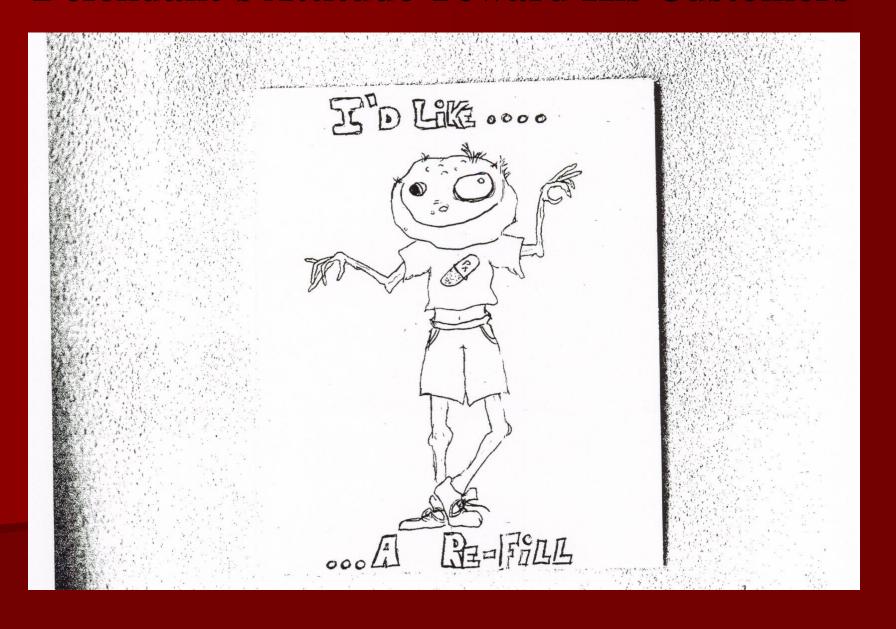
#### Domestic 'Rx' Flow



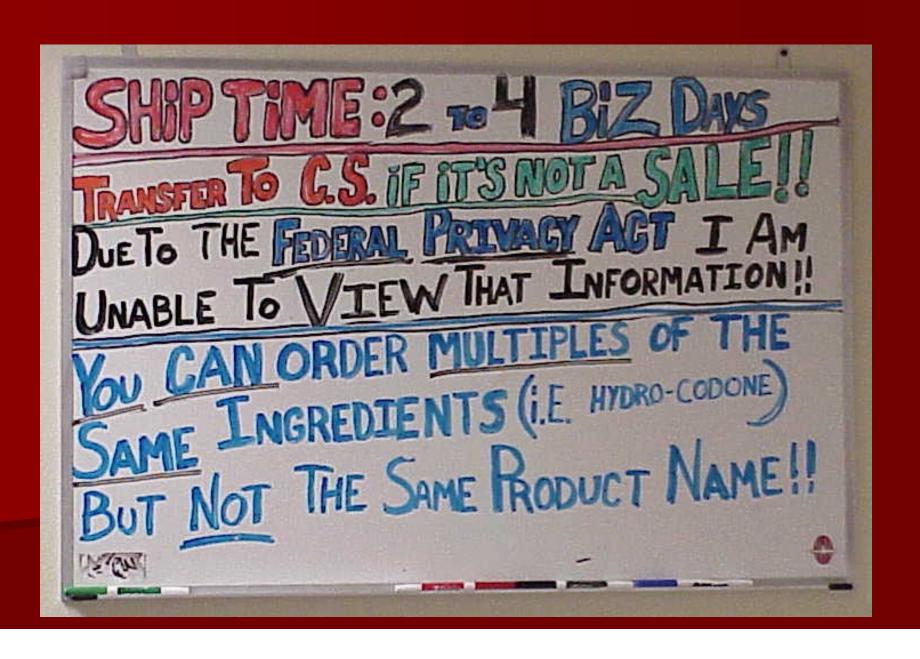


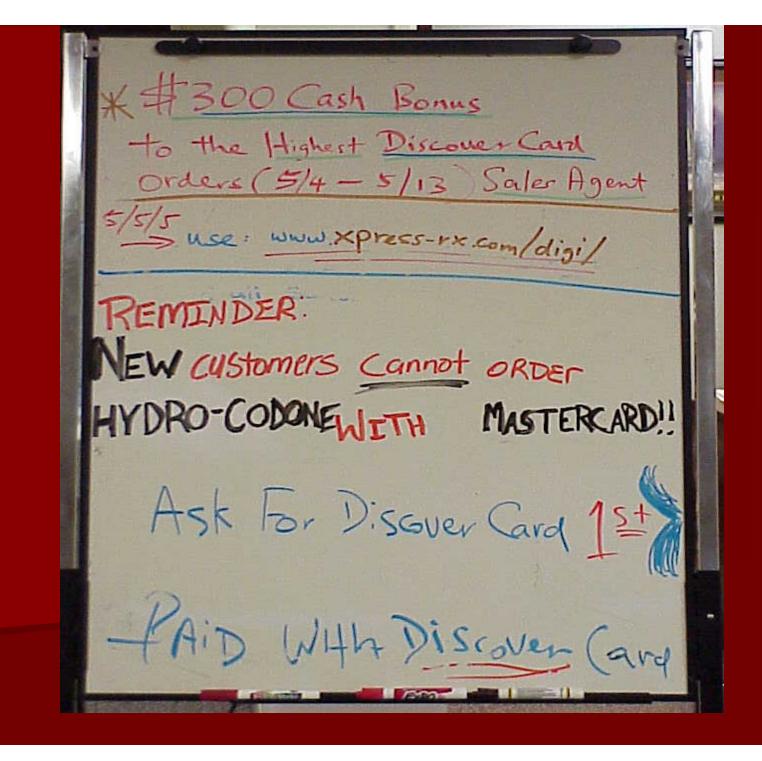
# Case Example Minneapolis, Minnesota

#### **Defendant's Attitude Toward His Customers**



#### **Defendant's Attitude Toward His Business**



























**Total Forfeiture:** 

\$4,370,258.80

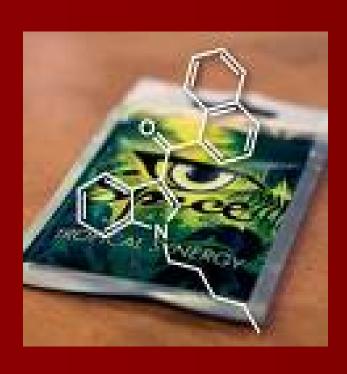
#### THC-like Substances ("Spice")





- An herbal mixture called "Spice" is sold in European countries mainly via Internet shops. It is also encountered in the U.S.
- "Spice" is purported to contain substances with marijuana-like psychoactive effects (e.g., HU-210, HU-211, JWH-018, JWH-073 and CP 47,947 & homologues) and it may be abused via smoking.

#### THC-like Substances ("Spice")



- HU-210 is both chemically and pharmacologically similar to Δ9-THC, the main active ingredient in marijuana.
- HU-211 is chemically, but not pharmacologically similar to Δ9-THC
- JWH-018, JWH-073 and CP
   47,497 are pharmacologically,
   but not chemically, similar to
   Δ9-THC

#### Salvia Divinorum

- Indigenous to the state of Oaxaca, Mexico.
- One of several "vision-inducing" plants employed by the Mazatec Indians living in the mountains and uplands valleys of northeastern Oaxaca in Mexico.
- Abused primarily by adolescents and young adults for its hallucinogenic effects by
  - smoking (common) or
  - chewing

#### Salvia Divinorum

- A perennial herb in the mint family (Labiatae or Lamiaceae).
- Internet sites advertise Salvia as a legal alternative to other controlled hallucinogens
- "Maria Pastora", "Sage of the Seers", "Diviner's Sage", "Salvia", "Sally-D", "Magic Mint"
- Sold as fresh and dried leaves, whole plants, cuttings & extracts

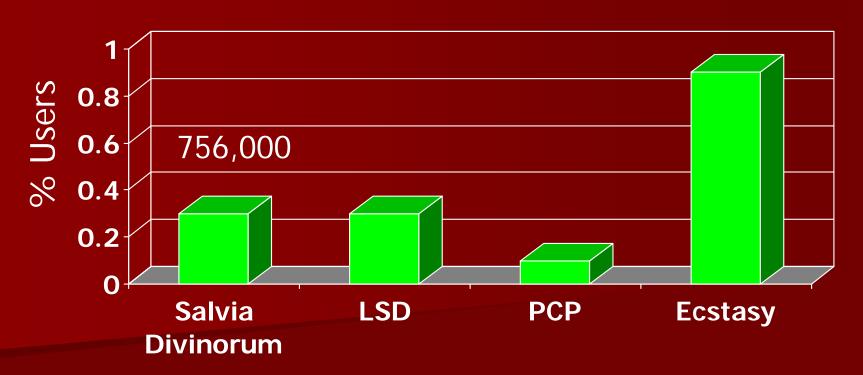






#### Hallucinogens Use

### Percentages of past year hallucinogen use among persons aged 12 or older



Source: NSDUH Report, February 2008



#### Anabolic Steroids

#### What are 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).

# Classification as an Anabolic Steroid

Steroids effect reproductive tissue, muscle, bone, hair follicles, liver, kidneys, immune, and central nervous systems

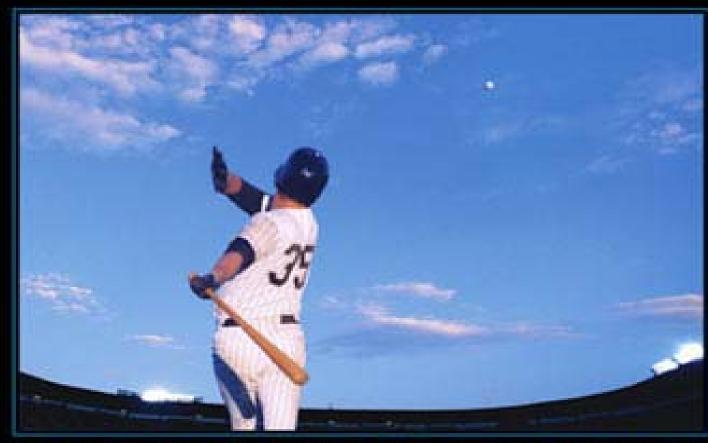
VS.

**Androgenic Effects** 

**Mascularization** 

**Anabolic Effects** 

Protein building in skeletal muscle and bone

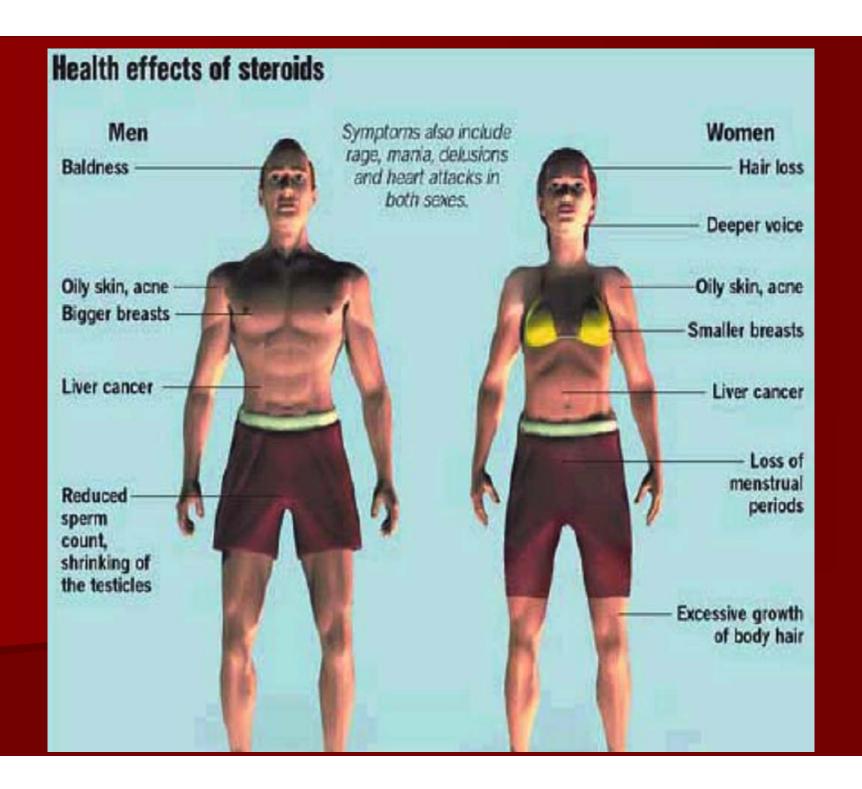


### POSSIBILITIES

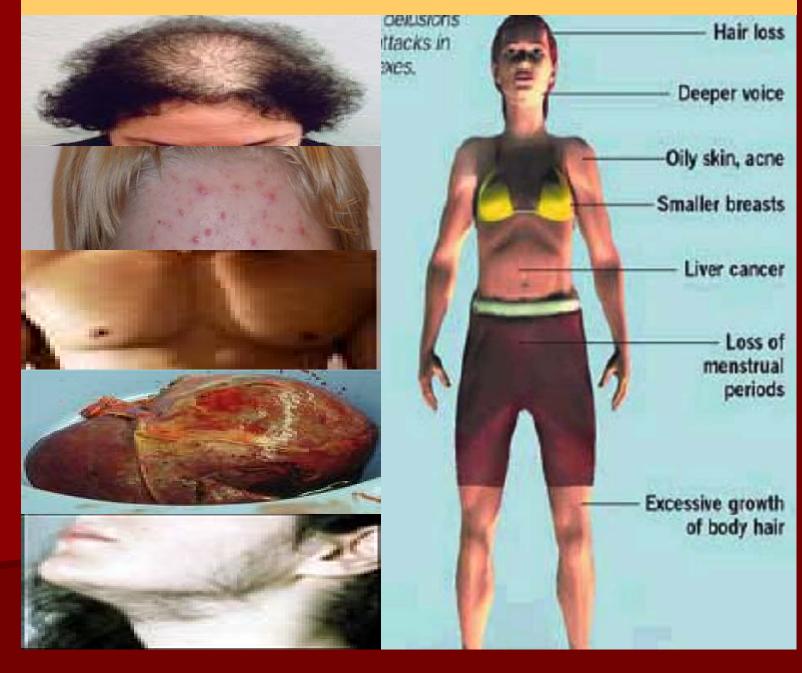
WITH FOCUS, DEDICATION AND STEROIDS, MEN CAN ACHIEVE IMPOSSIBLE DREAMS.

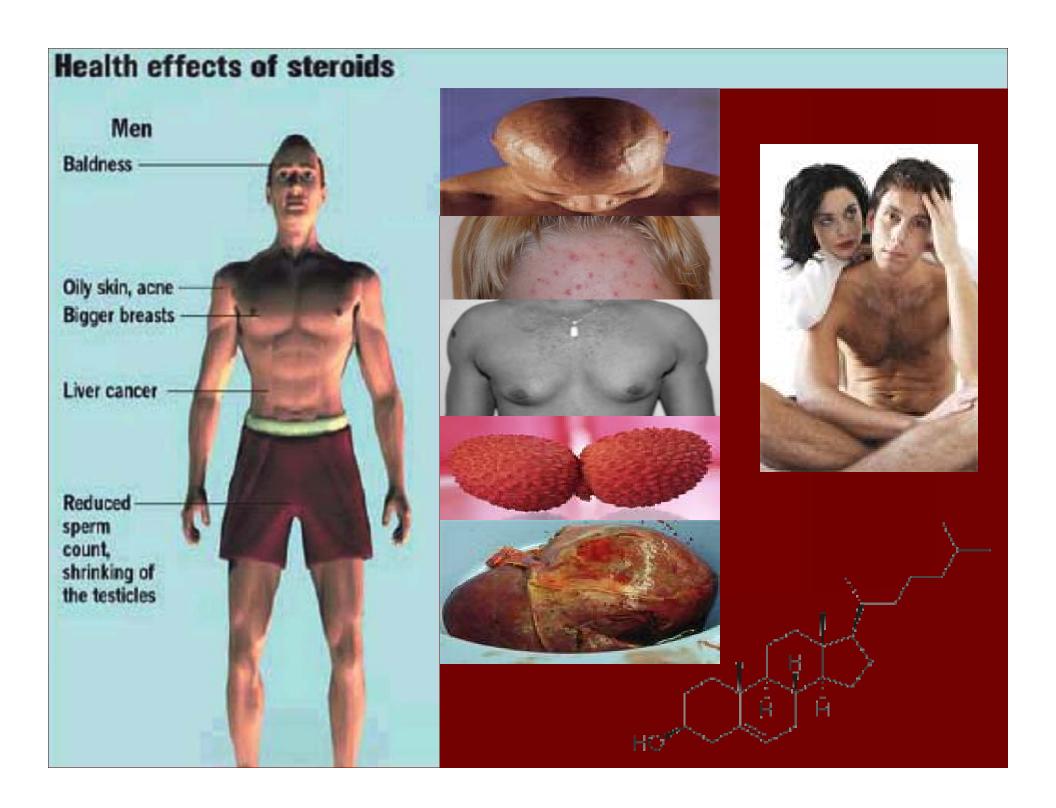
LIKE BREAKING A WORLD RECORD. OR GROWING THEIR OWN BREASTS.

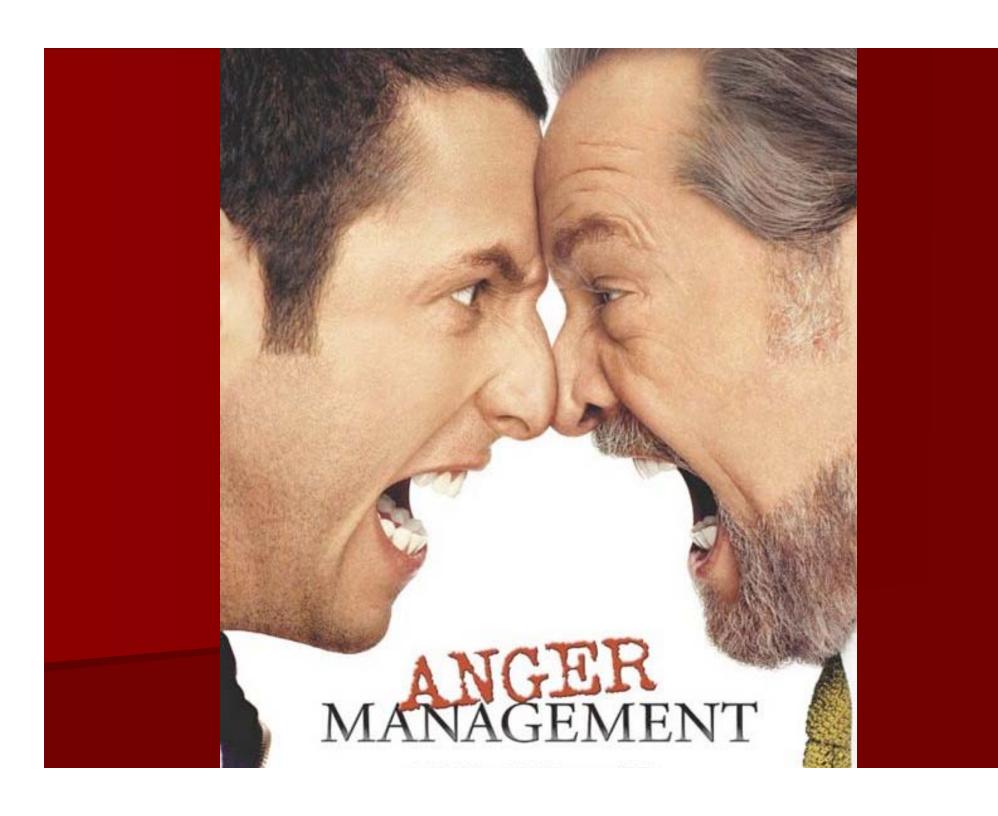
www.despair.com



#### Side Effects of Steroid Use: Women







#### One Cycle – Approximately 12 Weeks



Before



After

35 Pound Increase in Body Weight

Single Workout Bench Press Increase of 30 Pounds

#### **Concomitant Drug Use with AAS**

Stimulants Sympathomimetics	93.5%	Ephedrine	Antidepressants	48.3%	Paroxetine Citalopram Venlafaxine
Sedatives			Anti-oestrogens	38.7%	Proviron
Benzodiazepine derivatives	64.5%	Diazepam Oxazepam			Tamoxifen Clomiphene
Phenothiazine derivatives	22.6%	Promomethazine Fentiazin	Anti-inflammatories, NSAIDs	12.9%	Naproxen Ketoprofen
Azaspirone derivatives	6.4%	Buspirone	Diuretics	12.9%	Spironolactone Furosemide
Andrenergic drugs	58.3%	Clenbuterol Salbutamol Ethylmorphine/eph edrine	Anti-acne preparations	9.7%	Roaccutane
Testosterone Releasers	51.6%	hCG Menotrophin	Antihypertensive drugs	6.4%	Clonidine hydrochloride
Analgesics	48.3%	Acetylsalicylic acid Codeine Morphine Dextropropoxiphen	Miscellaneous  Muscle Oil  Dopamine inhibitors	9.7% 3.2%	Synthol Levodopa

### Dietary Supplements



"These now regulations will fundamentally change the way we get around them."

"These new regulations will fundamentally Change the way we get around them"



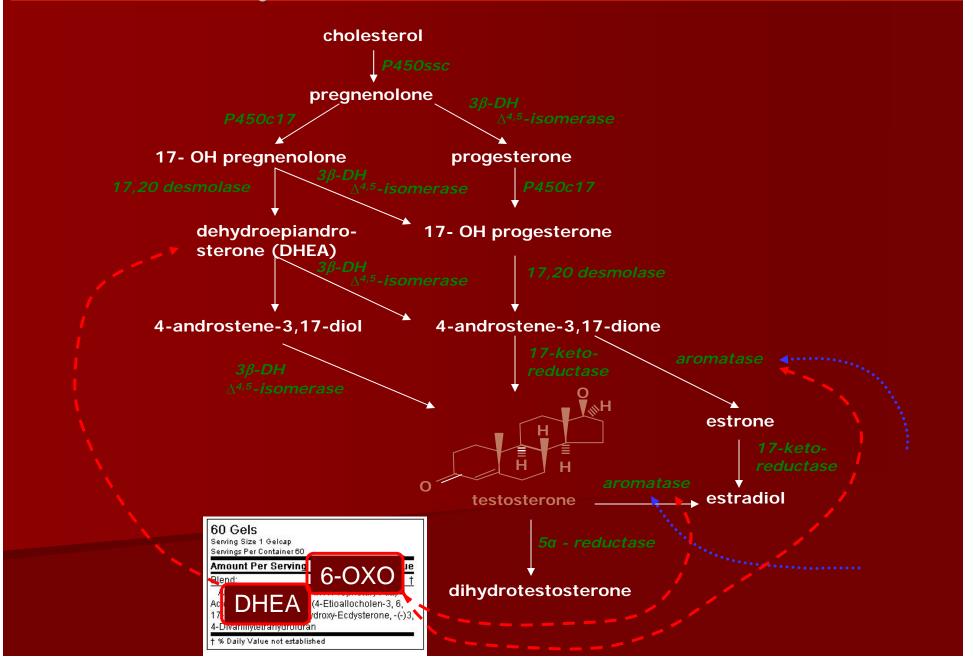
#### **DRUGS**

Must be proven safe before approved for market

#### **SUPPLEMENTS**

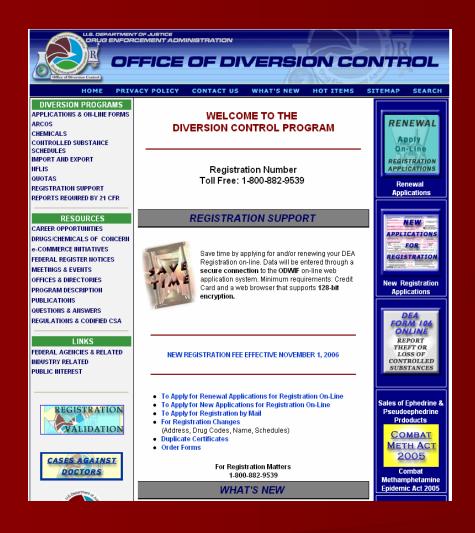
Must be proven harmful before removed from market

#### **Synthesis of Testosterone**



# Three Steroids to be added to the CSA

- DEA in process to control three anabolic steroids in schedule III of the CSA
  - Boldione (Madol)
  - Desoxymethyltestosterone
  - 19-nor-4,9(10)-androstadienedione
- As of August 2008, 58 dietary supplements were purported to contain one or more of these three steroids



#### www.DEAdiversion.usdoj.gov or www.dea.gov



### Questions?