U.S. Drug Enforcement Administration

Anabolic Steroids, Performance Enhancing Drugs and Dietary Supplements

National Organization of Black Law Enforcement Executives

July 2009

Norfolk, Virginia

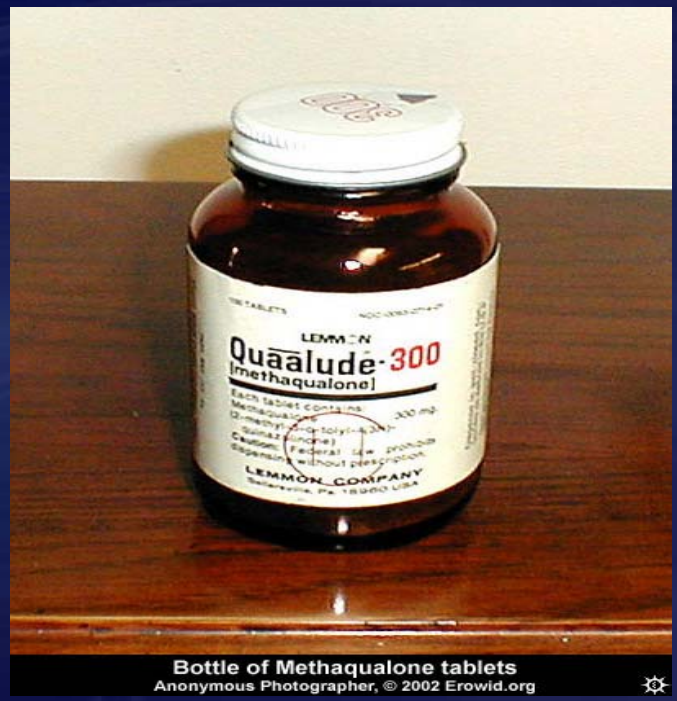
OBJECTIVES

- Current State of Prescription Drug Abuse
- Anabolic Steroids and Dietary Supplements
  - Pharmacology/adverse effects
  - Dosing
  - Legislation
  - Poly drug use/Drugs of abuse
  - Diversion/Trafficking trends
  - Internet
  - hGh
  - Testing
- Current Issues
  - Methadone

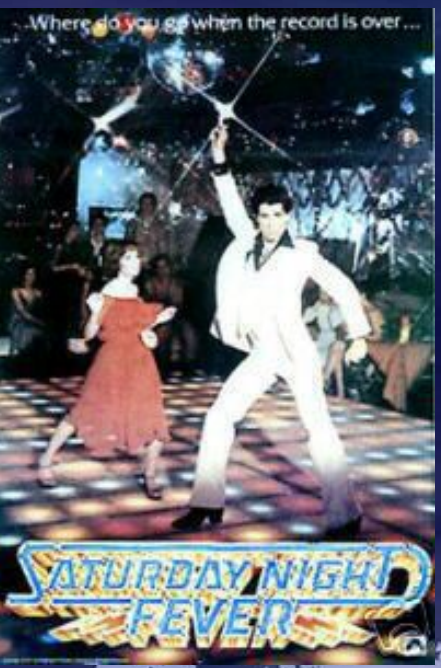
The Perfect Storm

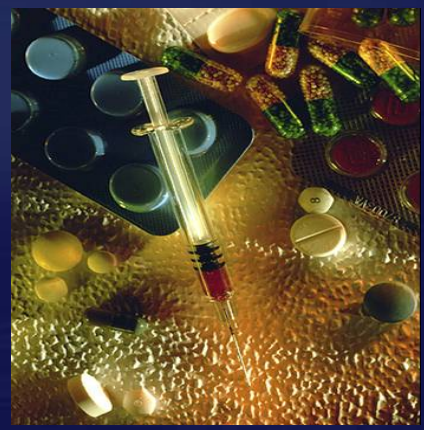
- **Misperception: When we don’t see specific drugs anymore the problem has gone away**

The 1970's



Bottle of Methaqualone tablets
Anonymous Photographer, © 2002 Erowid.org

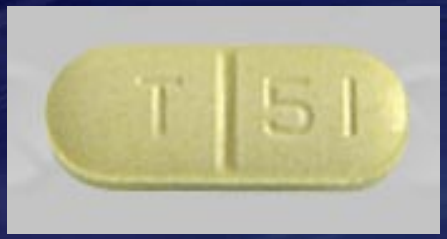




Heroin

The 1980's

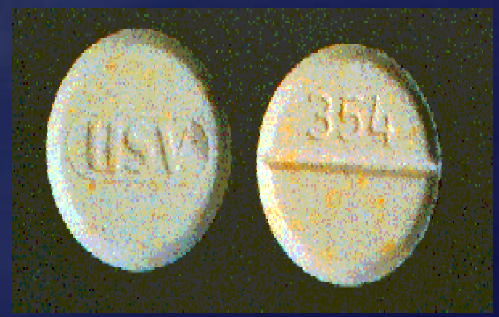
T's and Blues
(Talwin and Pyrabenzamine)



4's and Doors
Tylenol w/Codeine and Doriden

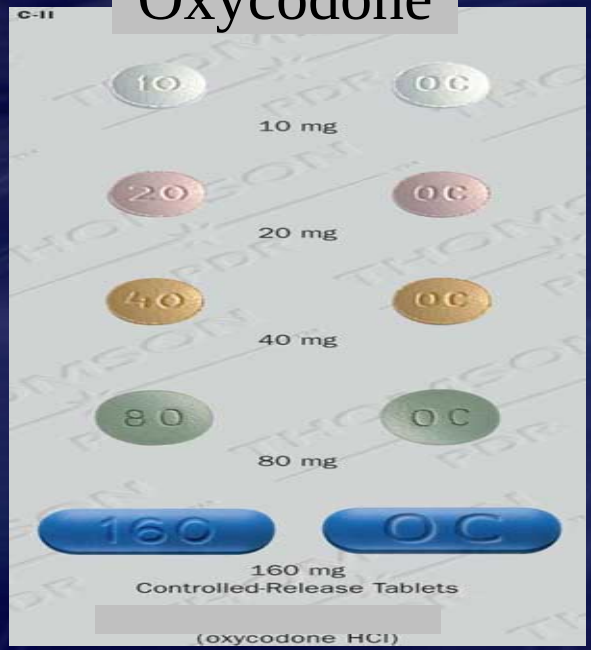
Hydromorphone

Cocaine



The 1990's

Oxycodone



Methamphetamine

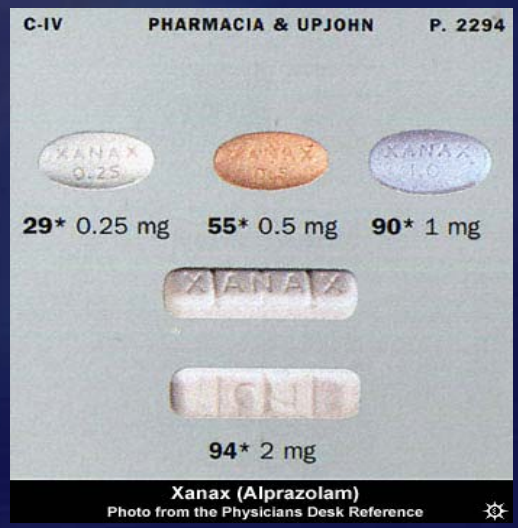
2000 and Beyond

Hydrocodone

Ketamine

Flunitrazapam
(Rohypnol)

MDMA

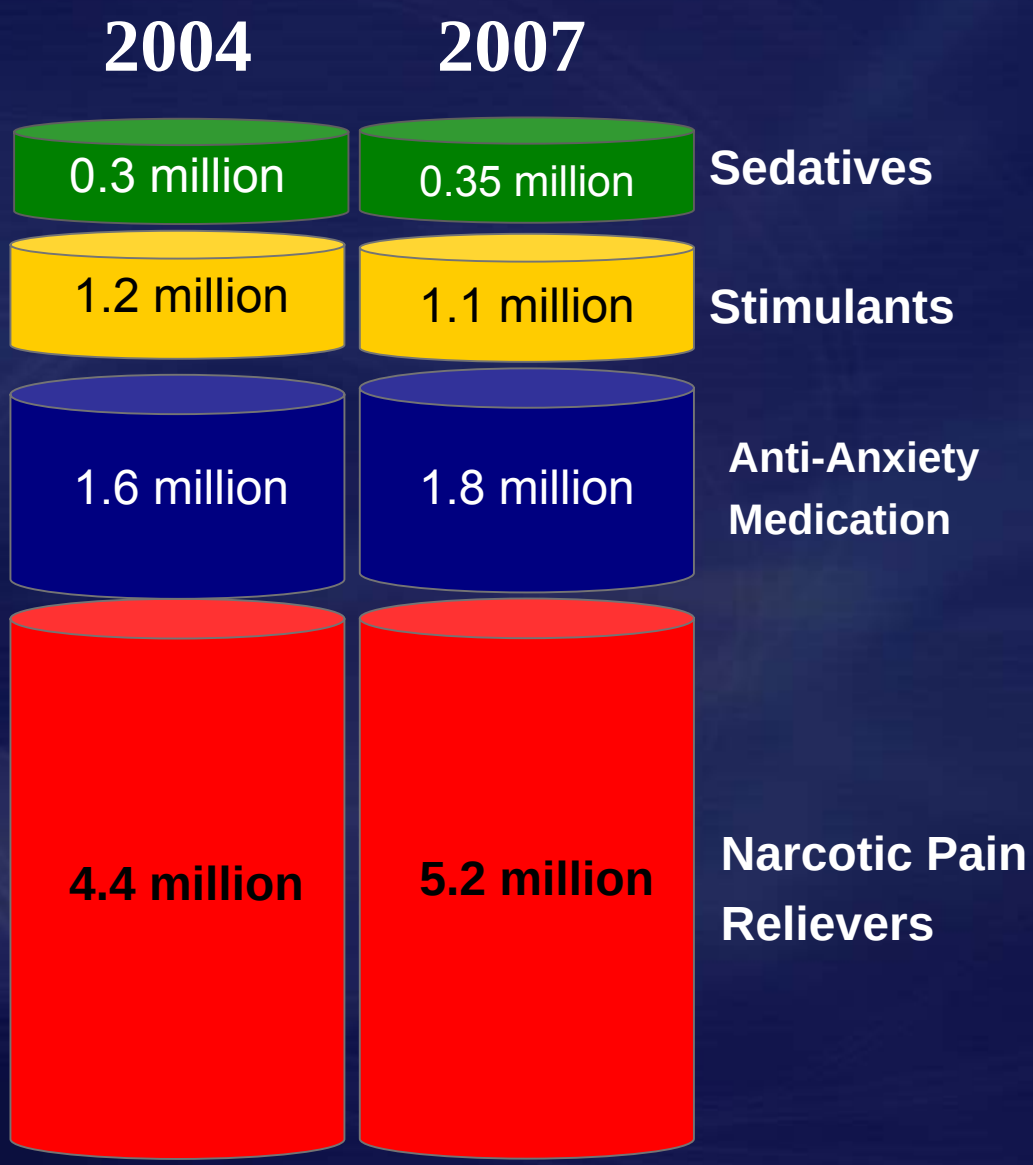


Alprazolam

The Perfect Storm

- Misperception: When we don't see specific drugs anymore the problem has gone away
- Baby Boomers are retiring in record numbers and will need additional medications
- Federal, State and local labs are reporting higher numbers of exhibits and cases related to pharmaceuticals
- Shift in the user / abuser population
- Use of Medicare / Medicaid or insurance to fund drug habits
- Information / Electronic era
  - Web sites such as Erowid
  - Social networking – blogging, twitter, or chat rooms for instant exchanges of information
  - Anonymity – no more face-to-face meetings

Scope and Extent of Problem



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

Trends in Prescription Drug Abuse

- **Non-medical use of prescription pain relievers was the category with the largest number of new initiates (2.1 million)[1]**
- **Non-medical use of prescription drugs ranks second only to marijuana as the most prevalent category of drug abuse**
- **Non-medical use of prescription drugs is higher than abuse of cocaine, heroin and hallucinogens combined**

[1]SOURCE: 2007 National Survey on Drug Use and Health

Abuse

- In 2007, 6.9 million Americans used prescription-type psychotherapeutic drugs for non-medical purposes in a one-month period (2.8% of the U.S. population)
  - More than cocaine, heroin, hallucinogens and inhalants combined
- 4.6 million young adults (18 to 25) used prescription pain relievers for non-medical purposes

SOURCE: 2007 National Survey on Drug Use and Health (NSDUH) published Sept 2008 by the Dept of HHS/ Substance Abuse and Mental Health Services Administration (SAMHSA)

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

Source: Partnership for Drug Free America

Teens and Their Attitudes

- **The abuse of prescription and over-the-counter medicines among teens continues to be a troubling trend**
  - **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**
  - **Majority of teens report abusing a prescription medication at least once in their lives**
  - **10% of teens report having abused a Rx pain reliever**
  - **7% of teens have abused OTC cough medicine**

SOURCE: 2008 Partnership Attitude and Tracking Study (PATS) Released FEB 2009

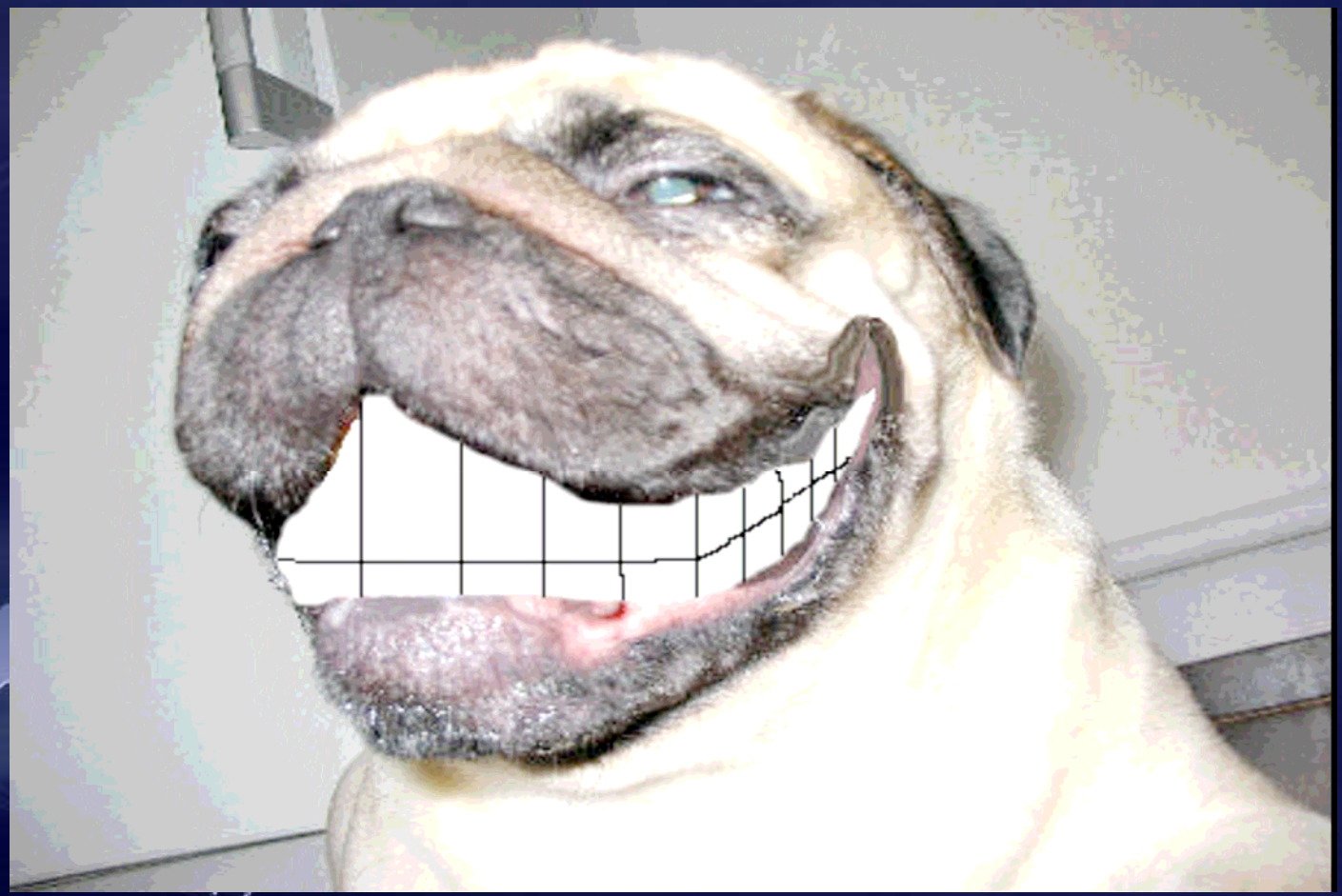
Teen Attitudes

- 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

Steroids and Dietary Supplements

Steroid Use is all about appearance, not performance



WHY????

- To Gain an Edge on the Competition….

Timeline

- 1935 – Testosterone synthesized
- 1939 – Boje suggests exogenous testosterone admin may enhance athletic performance
- 1940s – Use by bodybuilders
- 1954, first reports of athletes using AAS for an increase in strength and power
- 1974, ban by IOC
- By 1980, 1 in 5 NCAA Div I athletes had used AAS

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).

Pharmacology/Indications

- **Promote growth of skeletal and cardiac muscle; Increase bone density; Increase red blood cells**
- **Minimize catabolic effects associated with HIV-AIDs (wasting)**
- **Age related wasting**
- **Testicular failure (hypogonadism)**
- **Certain Cancers**
- **Anemias**
- **Trauma**

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

Classification as an Anabolic Steroid

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

Androgenic Effects

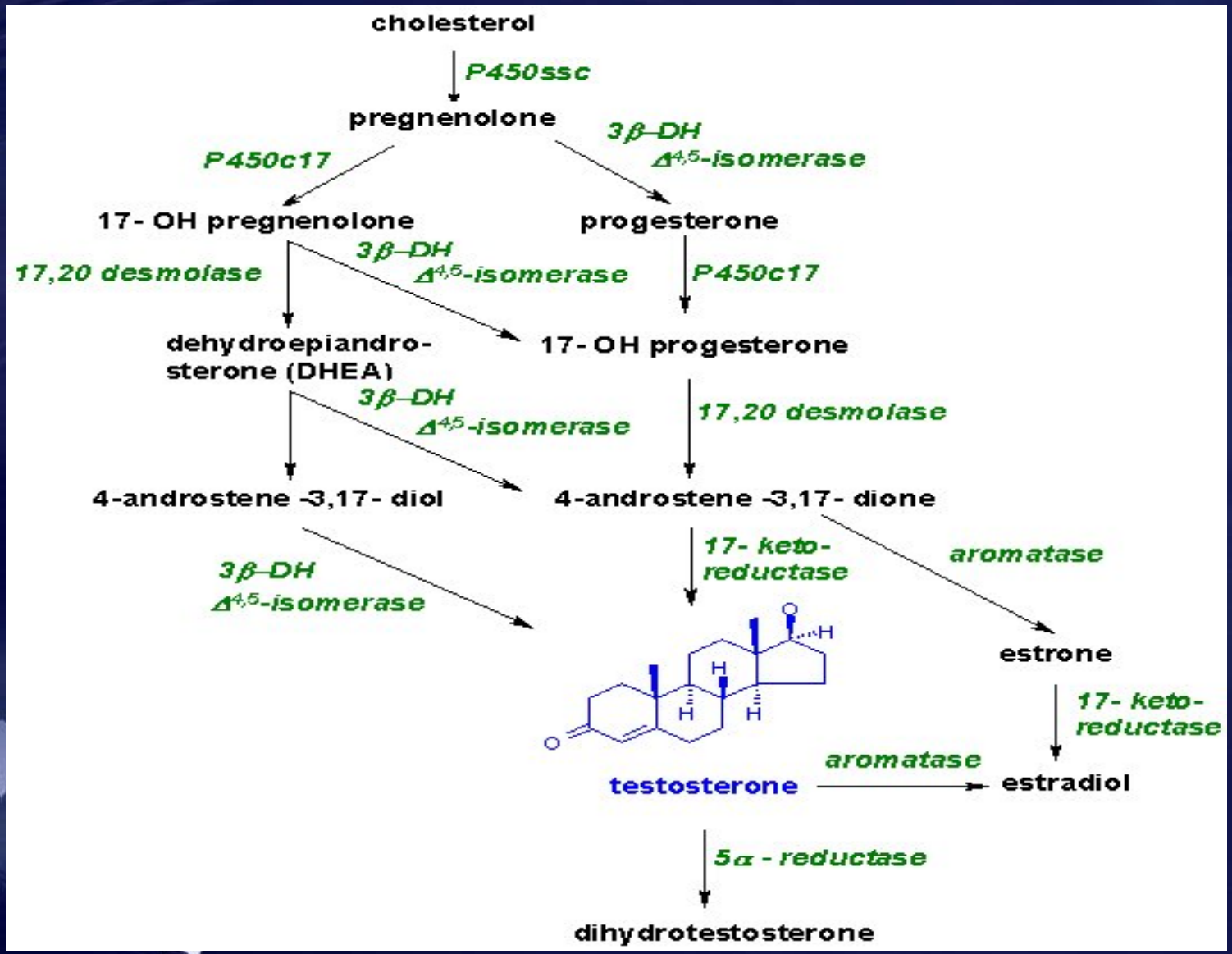
Mascularization

vs.

Anabolic Effects

Protein building in skeletal muscle and bone

Synthesis of Testosterone



Testosterone

- Testosterone levels decline between the ages of 35 and 75. The decline is associated with:
  - Loss of muscle mass
  - Loss of muscle fibers
  - Doubling of fat mass
  - Decrease in bone mineral density
- Short half-life due to rapid metabolism

Ergogenic Effects of AAS[#]

- Increase in lean body mass
- Increase in muscle cross-sectional area
- Decrease in body fat
- Enhance recovery between workouts
- Enhance recovery from injury
- Increase protein synthesis
- Increase in muscle endurance
- Increase in erythropoiesis, hemoglobin, and hematocrit
- Increase in bone mineral density
- Increase in glycogen storage
- Increase in lipolysis
- Increase in neural transmission
- Reduced muscle damage
- Increase in pain tolerance
- Behavior modification

[#]From: Hoffman and Ratamess, *J Sports Sci Med* 2006, 5, 182-193

Commonly Abused Steroids

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

- Injectable Steroids
  - Deca-Durabolin (nandrolone decanoate)
  - Durabolin (nandrolone phenproionate)
  - Depo-Testosterone (testosterone cypionate)
  - Equipoise (boldenone undecylenate)
  - Tetrahydrogestrinone (THG)

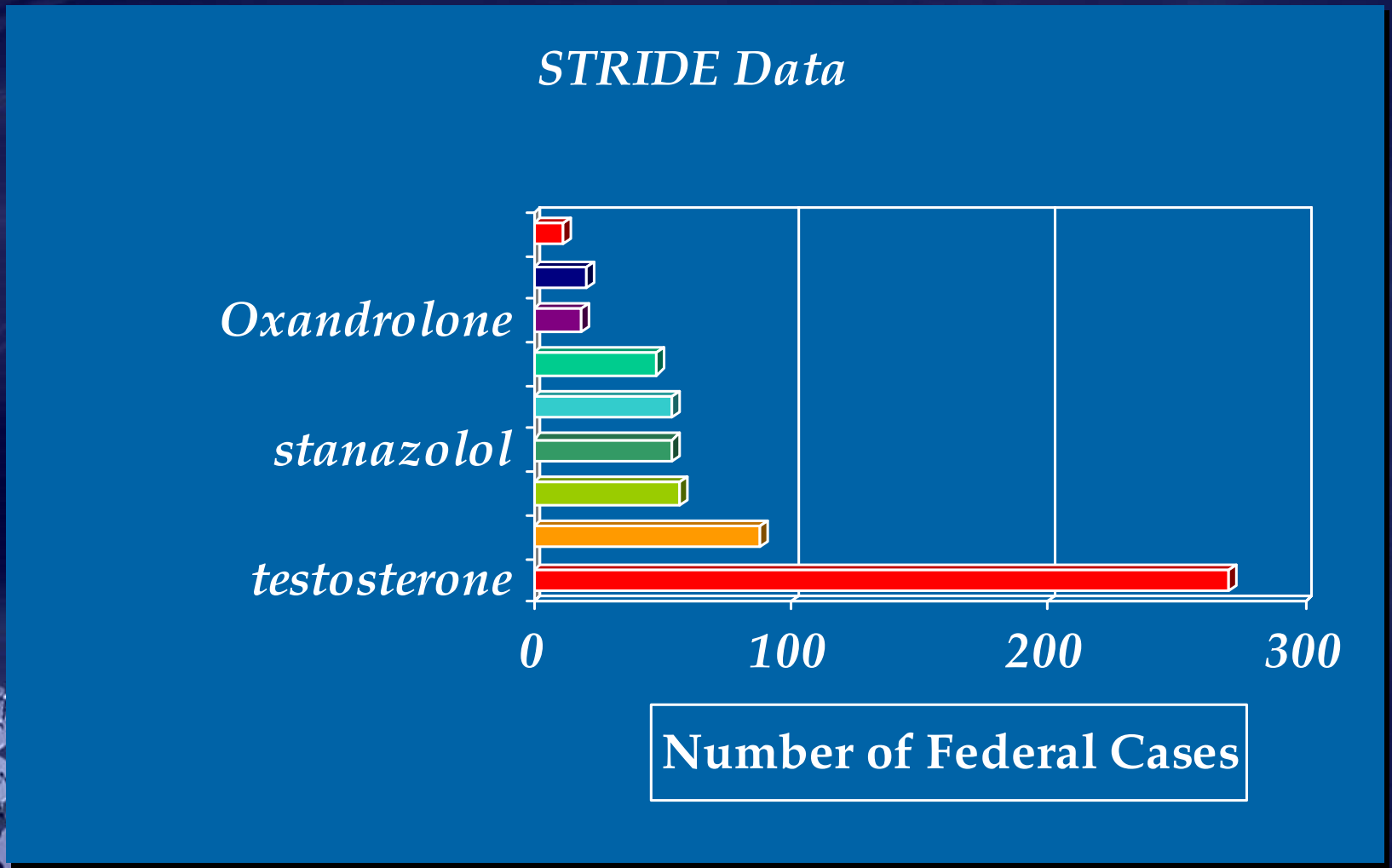
Commonly Abused Steroids

DECA
DURABOLIN

DIANABOL Tabs.

SUSTANON

Steroid Abuse

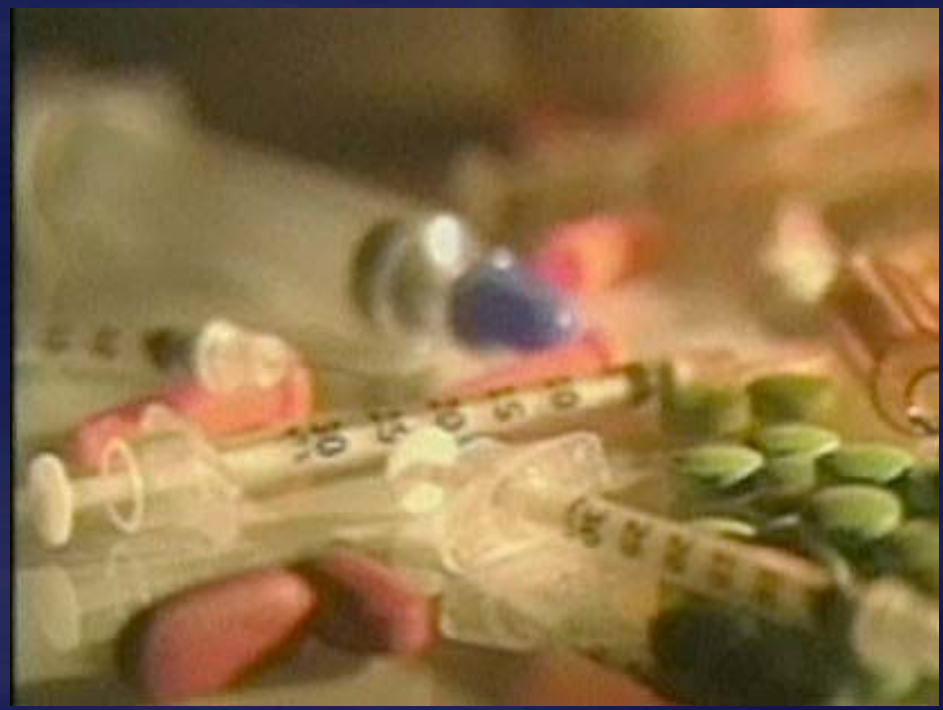


Number of Federal Cases Involving the most frequently encountered steroids. *2007 STRIDE Data.*

Legislation

Anabolic Steroids in the USA

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



Timeline of Regulatory Control

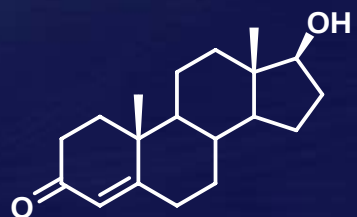
- Anti-Drug Abuse Act of 1988

  - Made the distribution or possession of anabolic steroids for non-medical reasons a Federal offense.

- Anabolic Steroid Control Act of 1990

  - Placed 24 steroids under the CSA

- Anabolic Steroid Control Act of 2004
  - Prohormones added
  - 59 steroids controlled under the CSA
  - Provided DEA with a mechanism to schedule new steroids by administrative process
- DEA NPRM (May 2008) for placement of 3 steroids recently introduced in dietary supplements



Testosterone

Legislation

- 1990- The *Anabolic Steroids Control Act of 1990*, placed 27 (24) steroids into schedule III of the CSA. Increased penalties for steroid trafficking and imposed strict production and record keeping regulations on pharmaceutical firms.

  - Defined Anabolic Steroid as, “ Any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestin's, and corticosteroids), that promotes muscle growth...”

Anabolic Steroid Control Act of 2004

- Added 36 new steroids and formerly over-the counter “prohormone” dietary supplements to the Controlled Substances Act.
- *Does* include androstenedione, androstenediol, and many others, such as THG.
- Does *not* include DHEA.
- Took effect on January 20, 2005.
- Took away the “promotes muscle growth” requirement.

Abuse and Dependence Findings

Steroid Dependence

- AAS share brain sites of action and neurotransmitter systems common with drugs of abuse
- Long term large doses of AAS have been shown to result in dependence associated with an acute withdrawal syndrome

Brower's Model of AAS Dependence

Two Stages:

1. **High dose AAS are used in conjunction with a strict diet and intense training**
2. **Chronic high dose activates brain reward mechanisms**

Withdrawal Syndrome

- Duration from weeks to months
- Consisting of:
  - Depressed mood
  - Fatigue
  - Craving for AAS
  - Restlessness
  - Anorexia
  - Insomnia
  - Decreased libido

Complications of Adolescence Use of AAS

- Adolescence is a critical period in the etiology of psychopathogies:
  - Depression
  - Reward
  - Anxiety
  - Behavioral conduct
- Virilization

Internet Survey of 500 AAS Users

- **26% of respondents started use during teenage years**
- **Dosage range from 70 to 6000 mg/w**
- **Cycle 4 to 20 wks**
- **96% reported self administering additional medications to alleviate unwanted side effects rather than discontinue AAS use**
- **11% obtained AAS with physician's script**
- **95% reported polydrug use**

Parkinson and Evans, *Med Sci Sport* 2006, 644-641

Adolescent Findings

- In 1993, Yesalis et al. reported that 80% of 12- to 17-year olds who had used steroids at once in their lives had committed acts of violence or crimes against property within the past year, a rate more than twice that of those not having taken anabolic steroids
- AAS have the potential to alter both the timing and levels of androgens in adolescent males
- Suppressing endogenous testosterone production and metabolism to estradiol may have a negative result on normal maturation

DOSING

Testosterone

- Plasma half life after oral administration is 30 min
- 90% of an oral dose is metabolized before it reaches systemic circulation
- Transdermal and intramuscular routes of administration improve bioavailability

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.

Result of Modifications

- C17 esterfication permits intramuscular dosing every to 2 to 12 weeks, depending on modification. Natural testosterone would have to be injected multiple times per week to achieve the same levels
- C17 alkylation allows for oral ingestion, retarding hepatic degradation
- Liver toxicity associated with modification

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.

General Comments

- **Multiple forms of AAS (five different is the average) to take advantage of different pharmacokinetic properties**
- **Stackers take supraphysiological doses of AAS for 4-18 weeks, then a drug-free holiday**

Illegal Use of Anabolic Steroids

Dosage and duration are two major differences between the medical and illicit use of anabolic steroids

- **General therapeutic dosage, 42 to 70 mg/wk on a continual basis**
- **Non-medical dosage, 200 to 1500 mg/wk for a cycle with potential stacking**
- **Numerous adverse health effects are attributed to high dosages**

Complex 20-week Cycle Reported in the 2006 Survey

Methandroststenolone (switch to) oxymetholone	50 mg/d p.o. (weeks 1-5) 100 mg/d p.o. (weeks 6-10
Testosterone cypionate	1500 mg/w i.m. (weeks 1-20)
Boldenone undecylenate (switch to) nandrolone decanoate	800 mg/w i.m. (weeks 1-10) 800 mg/w i.m. (weeks 11-20)
Stanozolol (switch to) trenbolone acetate	700 mg/w i.m. (weeks 1-10) 700 mg/w i.m. (weeks 11-20)
Growth Hormone Insulin (Humalog)	6 IU/d (weeks 1-20) 15 U/d (post workout)

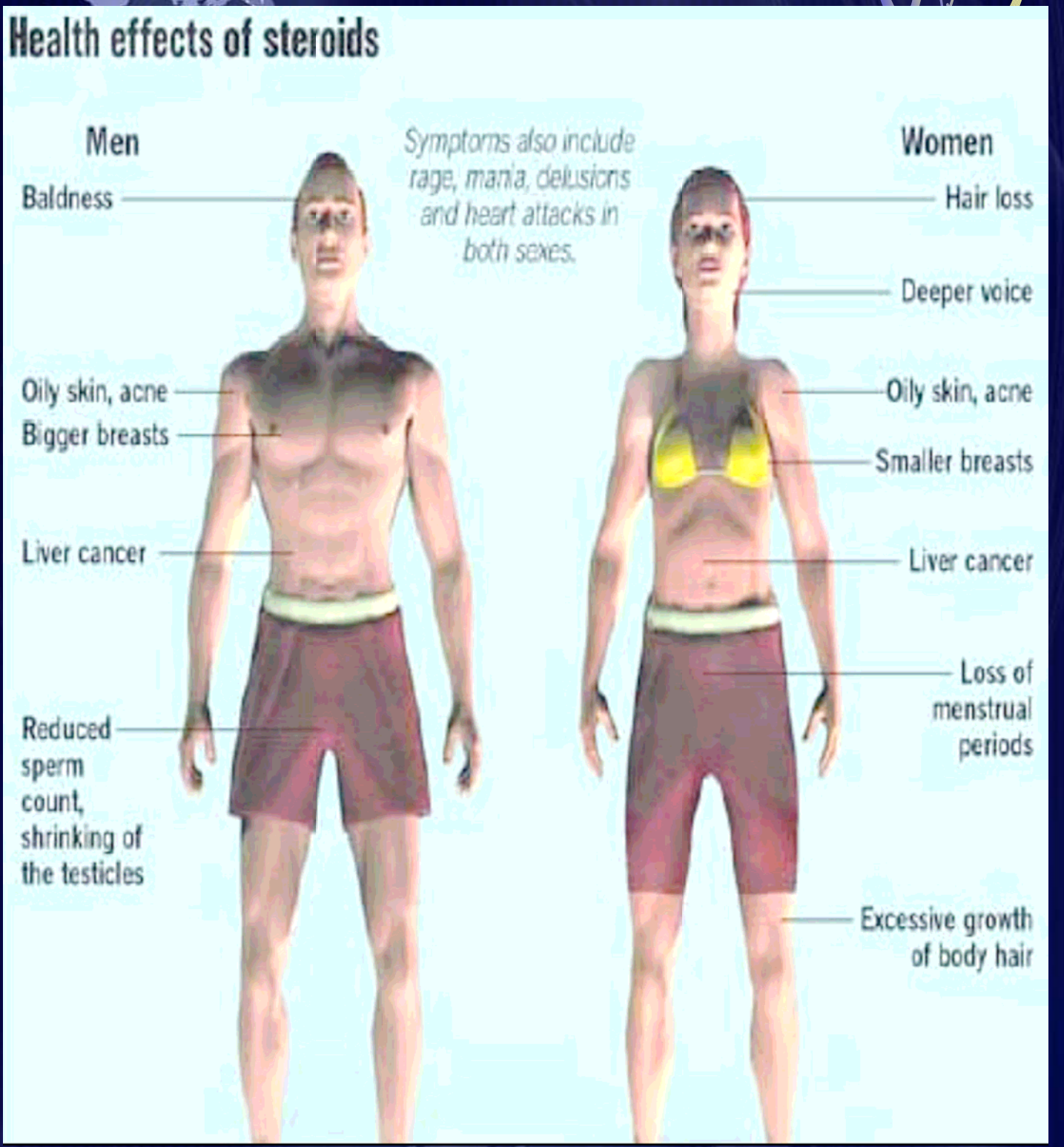
ADVERSE EFFECTS

POSSIBILITIES

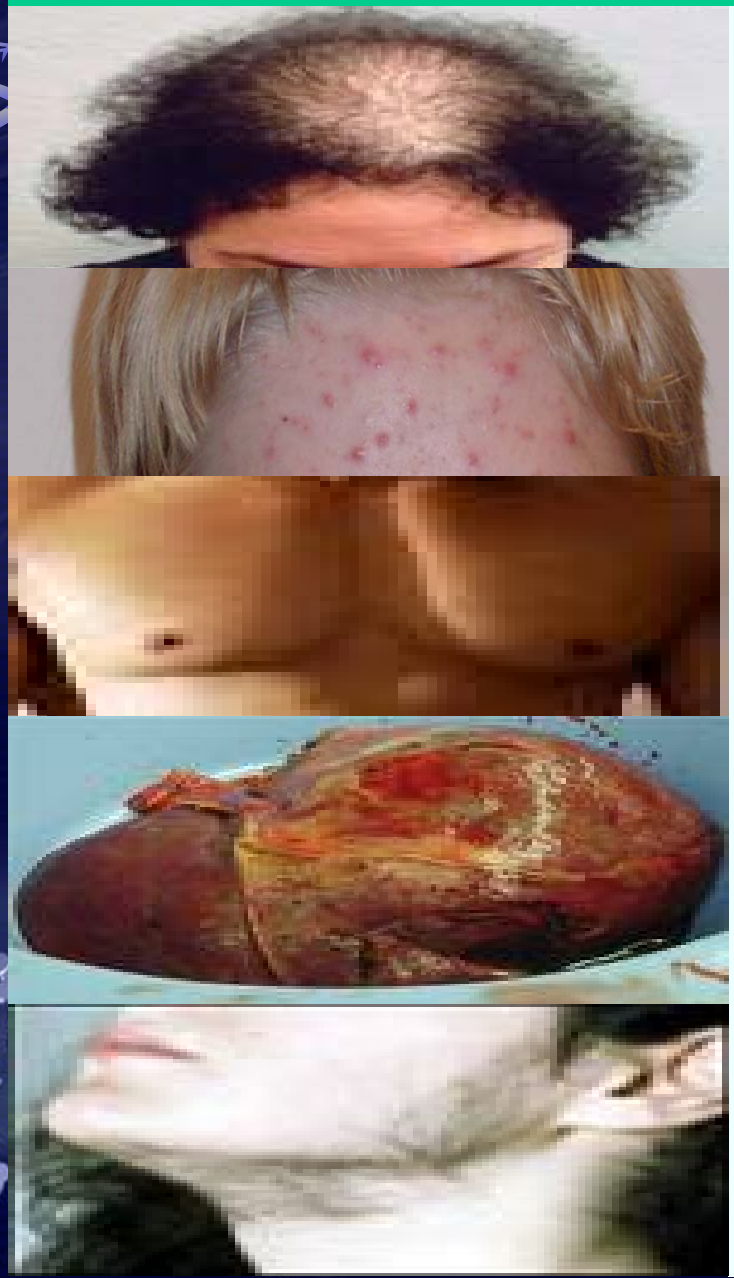
With Focus, Dedication and Steroids, Men Can Achieve Impossible Dreams.
Like Breaking a World Record. Or Growing Their Own Breasts.

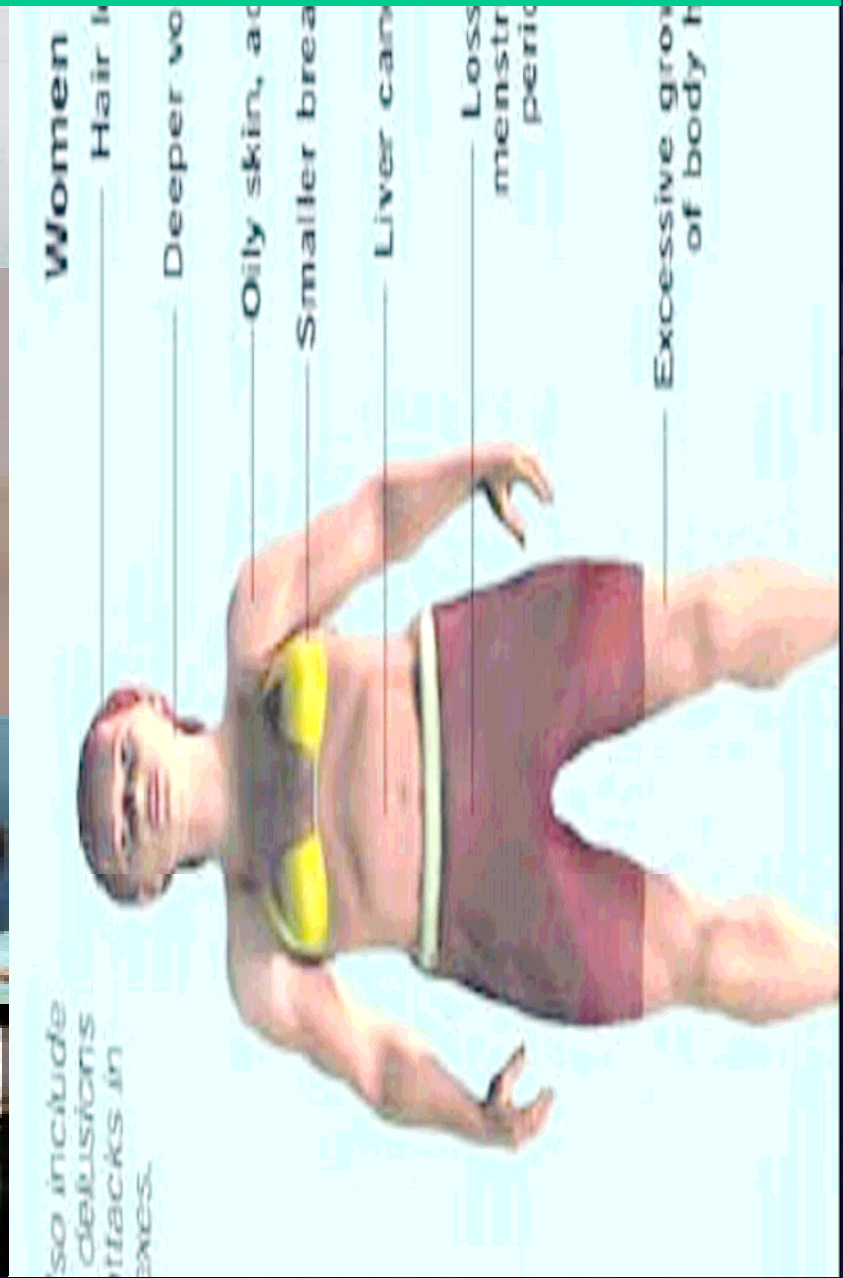
www.despair.com

Health effects of steroids



Side Effects of Steroid Use: Women





Men

Baldness

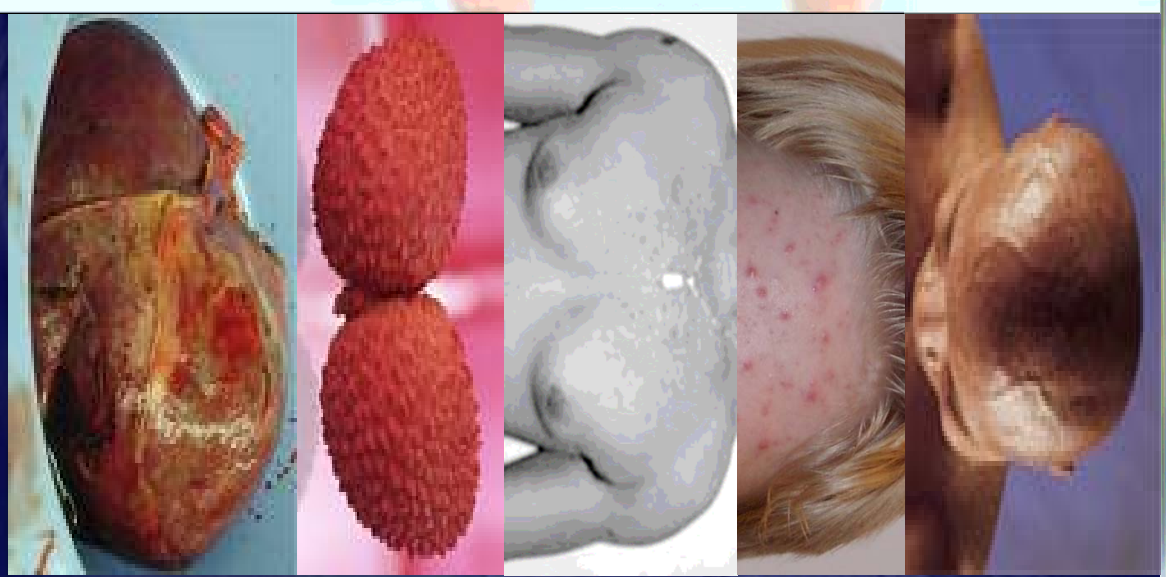
Oily skin, acne

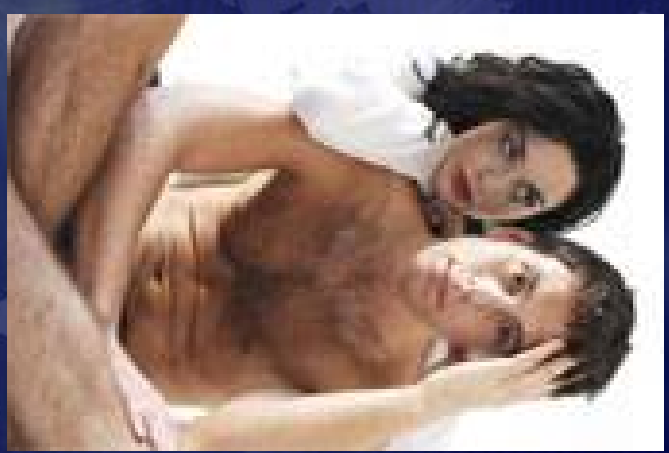
Bigger breasts

Liver cancer

Reduced sperm count, shrinking of the testicles

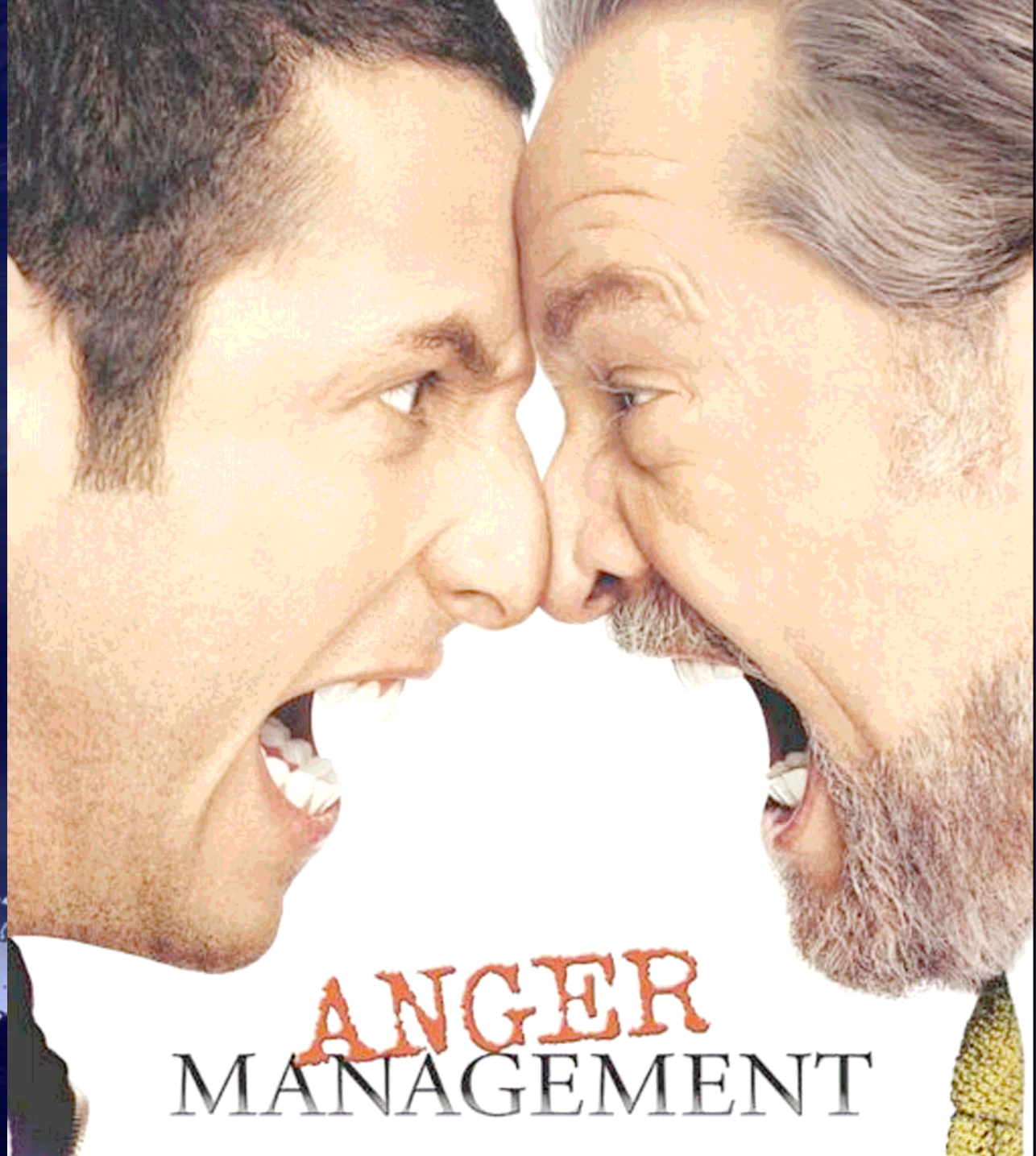
Symptoms ... rage, mani... and heart ... both ...





Side Effects – Both Sexes

- Jaundice
- Trembling
- Swelling of feet or ankles
- Bad breath
- Reduction in HDL, “good” cholesterol
- High blood pressure
- Aching joints
- Increased chance of injury to tendons, ligaments, and muscles

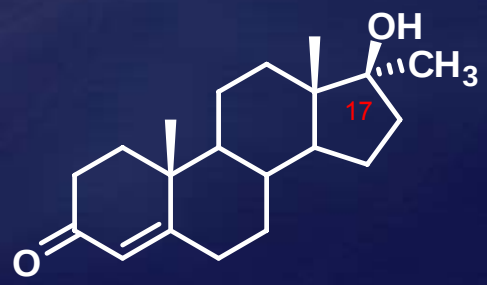

ANGER
MANAGEMENT

Psychiatric Symptoms Associated with AAS

- Extreme variability due to dose, agent, duration and personality of abuser.
- Most common manic-like presentations:
  - Irritability
  - Aggressiveness
  - Euphoria
  - Grandiose beliefs
  - Hyperactivity
  - Reckless and dangerous behavior
- Other presentations:
  - Development of acute psychosis
  - Exacerbation of ticks and depression
  - Development of acute confusion and delirious states

Liver Dysfunction

- 17-alkylated anabolic steroids are know to have liver toxicity
- Alkylation enables the AAS to be given orally and prevents first pass metabolism
- Products:
  - Android (methyltestosterone)
  - Anavar (oxandrolone)
  - Dianabol (methandienone)
  - Proviron (mesterolone)



Methyltestosterone

One Cycle – Approximately 12 Weeks

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

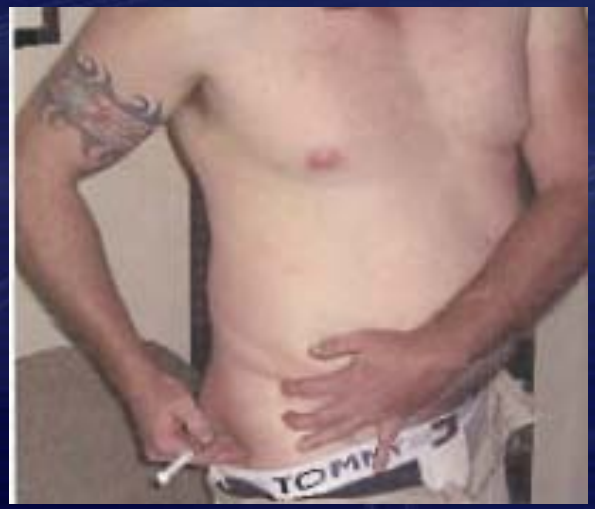
35 Pound Increase in Body Weight

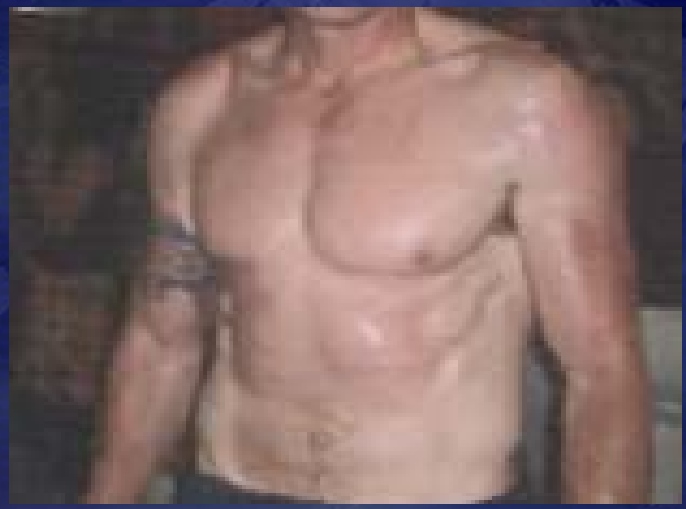
Single Workout Bench Press Increase of 30 Pounds

Before

After

One Cycle – Approximately 12 Weeks





35 Pound Increase in Body Weight

Single Workout Bench Press Increase of 30 Pounds

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Abuse of AAS

- **Polydrug dependence is common (Skarberg et. *al*, 2009). For example:**
  - **Cannabis use to improve sleep**
  - **Narcotic use to decrease pain**
  - **Amphetamine use to increase endurance and burn fat**
- **Characterized as a gateway drug?**

Multisubstance Use as a Feature of Addiction to Anabolic-Androgenic Steroids. Skarberg, K.; Nyberg, F.; Engstrom, I. *Eur Addict Res* **2009**, 15(2), 99-106

Substances Used in Conjunction with Anabolic Steroids

Treatment of Adverse Effects	Enhancement of Effect	Masking Agents
Estrogen antagonists	Aromatase inhibitors	Diuretics
Human chorionic gonadotrophin (hCG)	LH & FSH promotors	Probenecid
Analgesics	hGH	Epitestosterone
Ketoconazole shampoo	Amino acids	Etacrynic acid
Oral hypoglycaemics	Stimulants	
	Diuretics	
	Dehydrating agents	
	Insulin	

Modified from: Trenton and Currier, *CNS Drugs* 2005, 19(7), 571-595

Concomitant Drug Use with AAS

Stimulants			**Antidepressants**	48.3%	Paroxetine
Sympathomimetics	93.5%	Ephedrine			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/ephedrine	**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 Dextropropoxiphene	**Miscellaneous** Muscle Oil Dopamine inhibitors	 9.7% 3.2%	 Synthol Levodopa

N=32 subjects, Sweden

Polysubstance Use

Drug	Purported Use	Significance
Amphetamines	Increase endurance, burn fat	Stimulant
Caffeine	Increase endurance	Stimulant
Ephedrine	Increase endurance, burn fat	Stimulant
Clenbuterol	Increases muscle mass; burn fat	B2-Agonist
Creatine	Increase mass and strength	Phosphorus shuttle
hCG	Increases testosterone levels	Recombinant hormone
hGH	Increase protein and lipid metabolism	Decreases catabolic
Bromcriptine	Burn fat	Dopamine agonist
Insulin	Glucose metabolism, increase protein synthesis	Neuroendocrine enhancement
Opioids	Minimize pain	Obtained illegally
IGF-I	Increase protein and lipid metabolism	hGH promotes IGF-I production
Tamoxifen	Prevent gynecomastia	Aromatase inhibitor
Clomiphen	Prevent gynecomastia	Aromatase inhibitor
Levothyroxine	Increases endurance	Thyroid hormone
Probenicid	Masking agent	Decreases renal excretion

Adapted from Brower, Curr Psych Rep 2002, 4, 377-387

Specific Pharmaceuticals taken in Combination with AAS for Treatment of Adverse Effects

Hydrocodone, APAP C-III

- 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*

Hydrocodone (Schedule III)

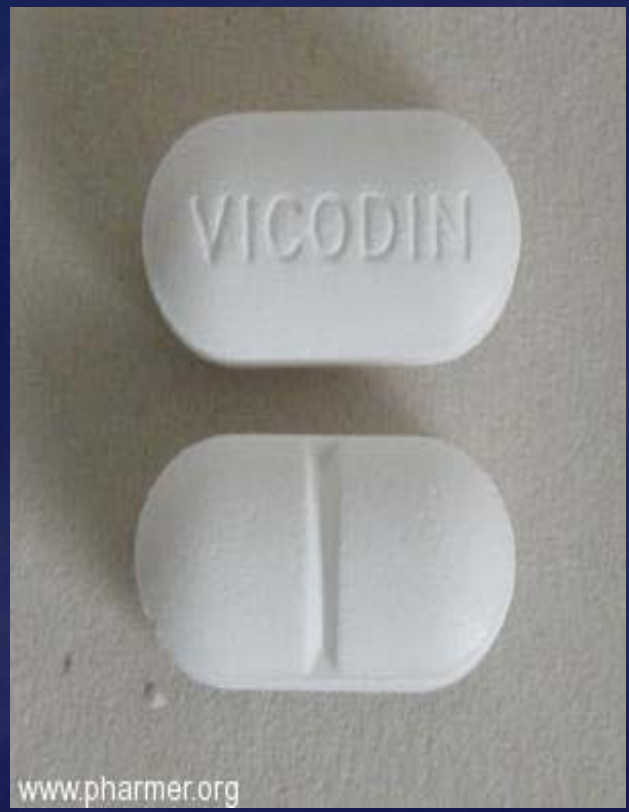
- Street prices: $1 to $3 per tablet
- Hydrocodone/Acetaminophen mix-toxicity
- Similarities:
  - Structurally related to codeine
  - Equal to morphine in producing opiate-like effects
- From 2005 to 2007, non-medical use of Vicodin® increased[3]:
  - 10th graders increased from 5.9% to 7.2%
  - 12th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

[3]SOURCE: 2007 Monitoring the Future study released April 2008. MTF is conducted by the Institute for Social Research at the University of Michigan.

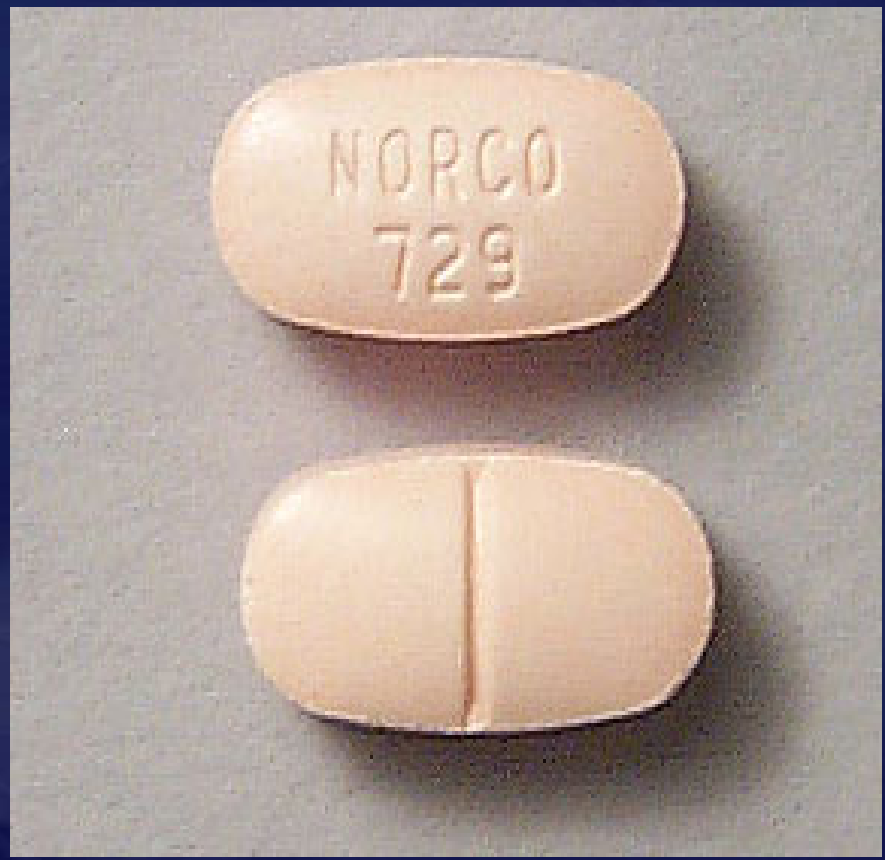
NFLIS National Data - 2006
Narcotic Analgesics

	Number	Percent
Hydrocodone	26,017	38.85%
Oxycodone	19,923	29.75%
Methadone	7,023	10.49%
Morphine	3,887	5.81%
Codeine	2,597	3.88%
Propoxyphene	1,488	2.22%
Hydromorphone	1,303	1.95%
Dihydrocodeine	1,290	1.93%
Fentanyl	1,270	1.90%
Buprenorphine	1,113	1.66%

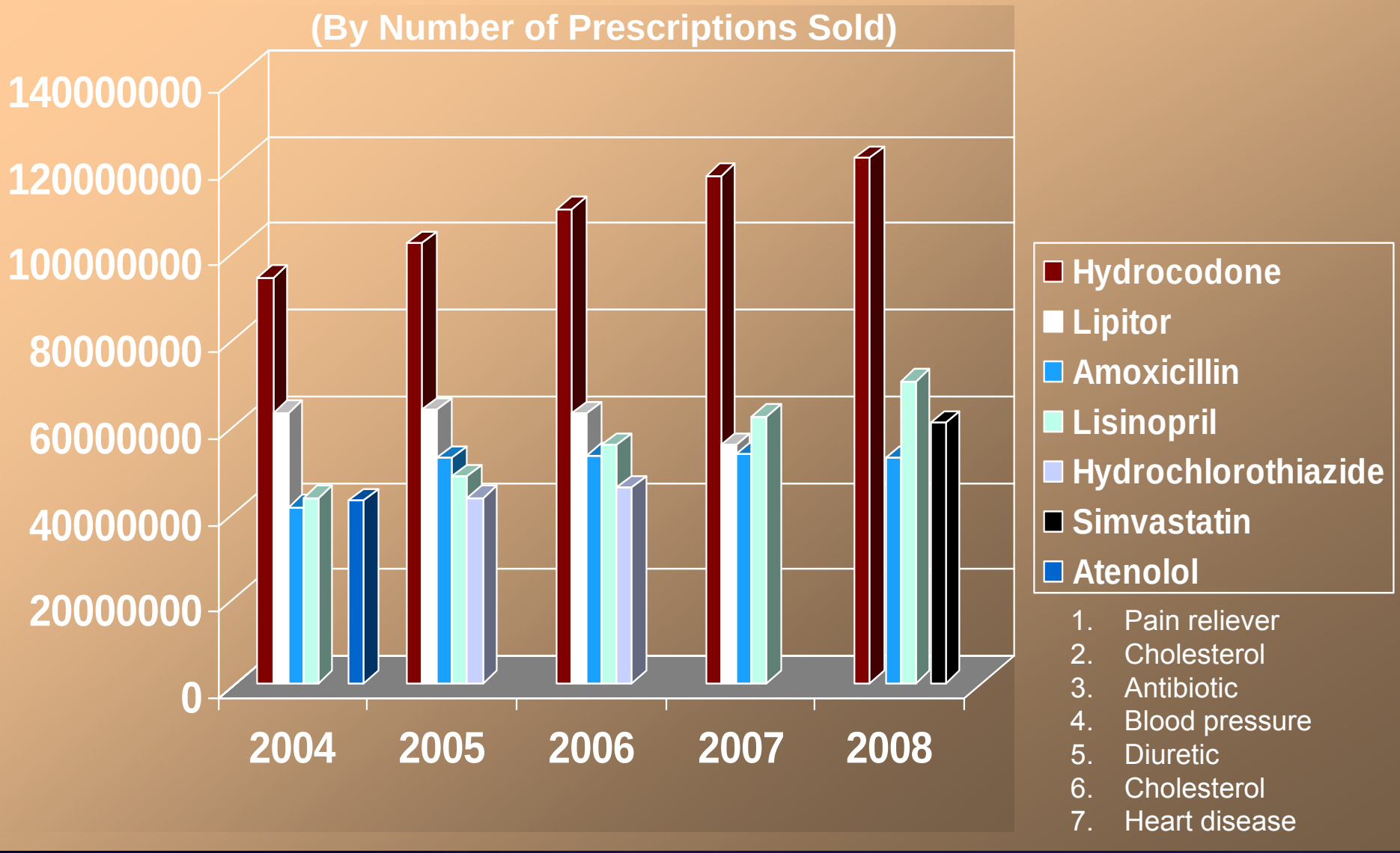
Vicodin-5/500mg



Norco 7.5/325mg

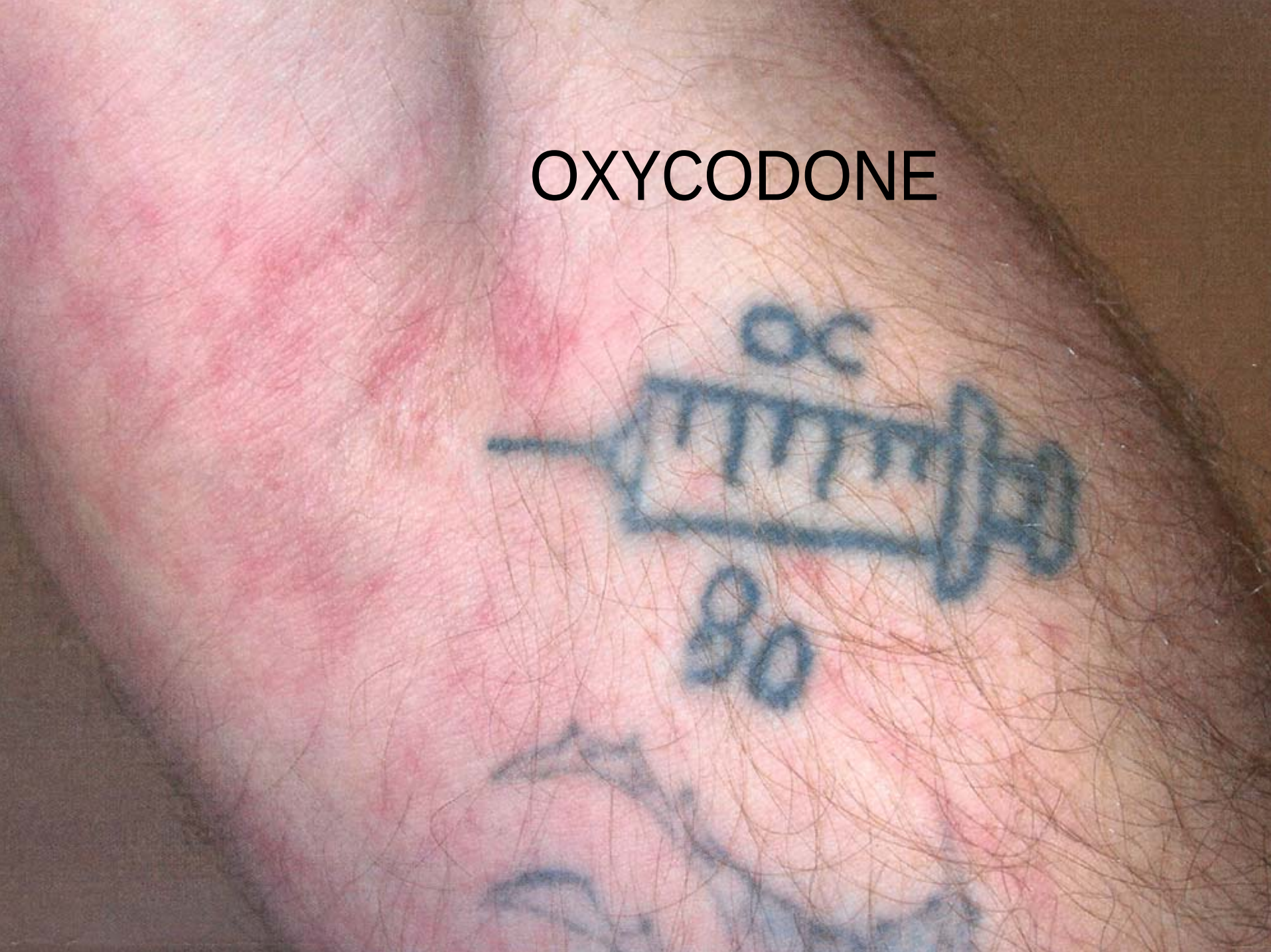


Top Five Prescription Drugs Sold in the U.S. (2004-2008)



1. Pain reliever
2. Cholesterol
3. Antibiotic
4. Blood pressure
5. Diuretic
6. Cholesterol
7. Heart disease

OXYCODONE



OxyContin® (Schedule II)

- Controlled release formulation of Schedule II Oxycodone
  - Street Slang: “Hillbilly Heroin”
  - 10, 15, 20, 30, 40, 60, 80mg available
- Street prices: $25 to $80 per 80mg tablet

OxyContin- 80mg

Other Oxycodone Products

- Percocet
- Percodan
- Tylox

NFLIS National Data - 2006
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	Number	Percent
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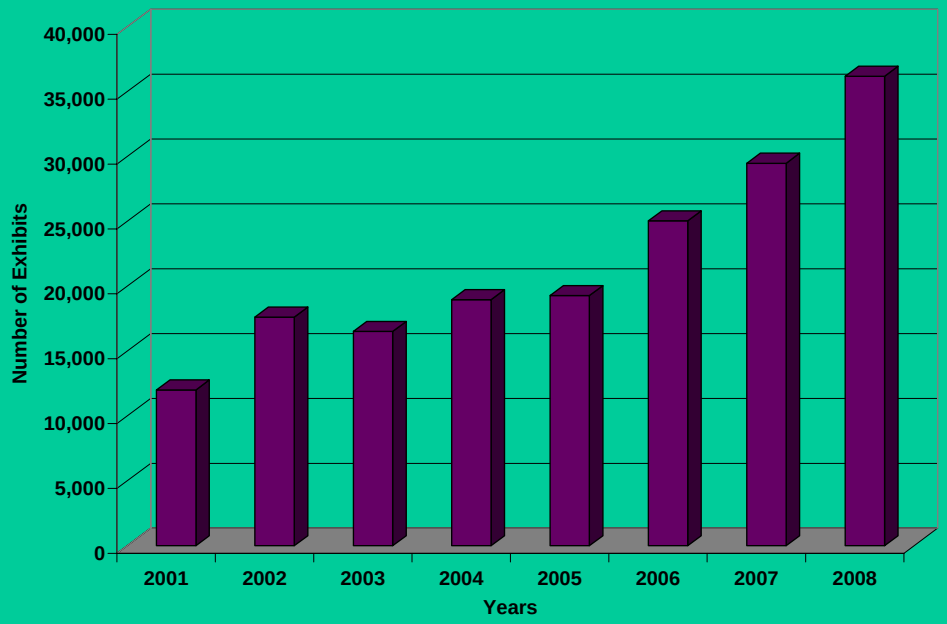
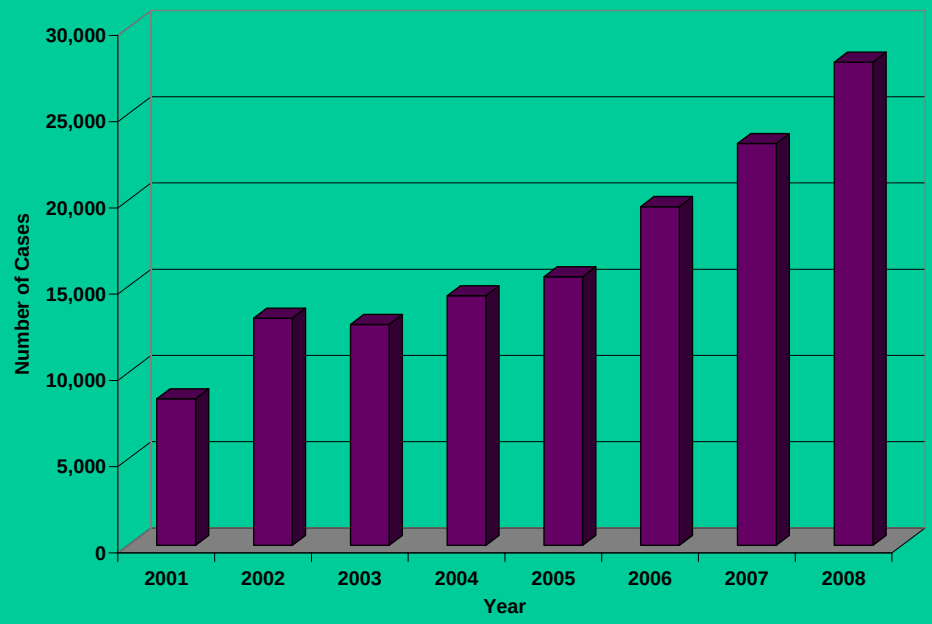
Hydromorphone	1,303	1.95%
Dihydrocodeine	1,290	1.93%
Fentanyl	1,270	1.90%
Buprenorphine	1,113	1.66%

NFLIS National Estimates Oxycodone

Exhibits



Cases

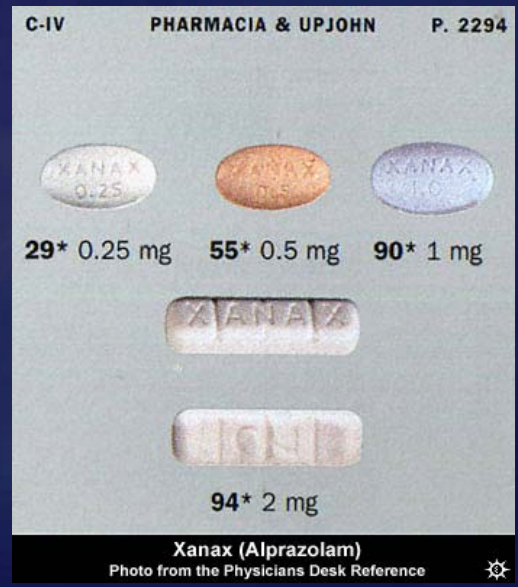


Alprazolam Xanax® (Z-bars)

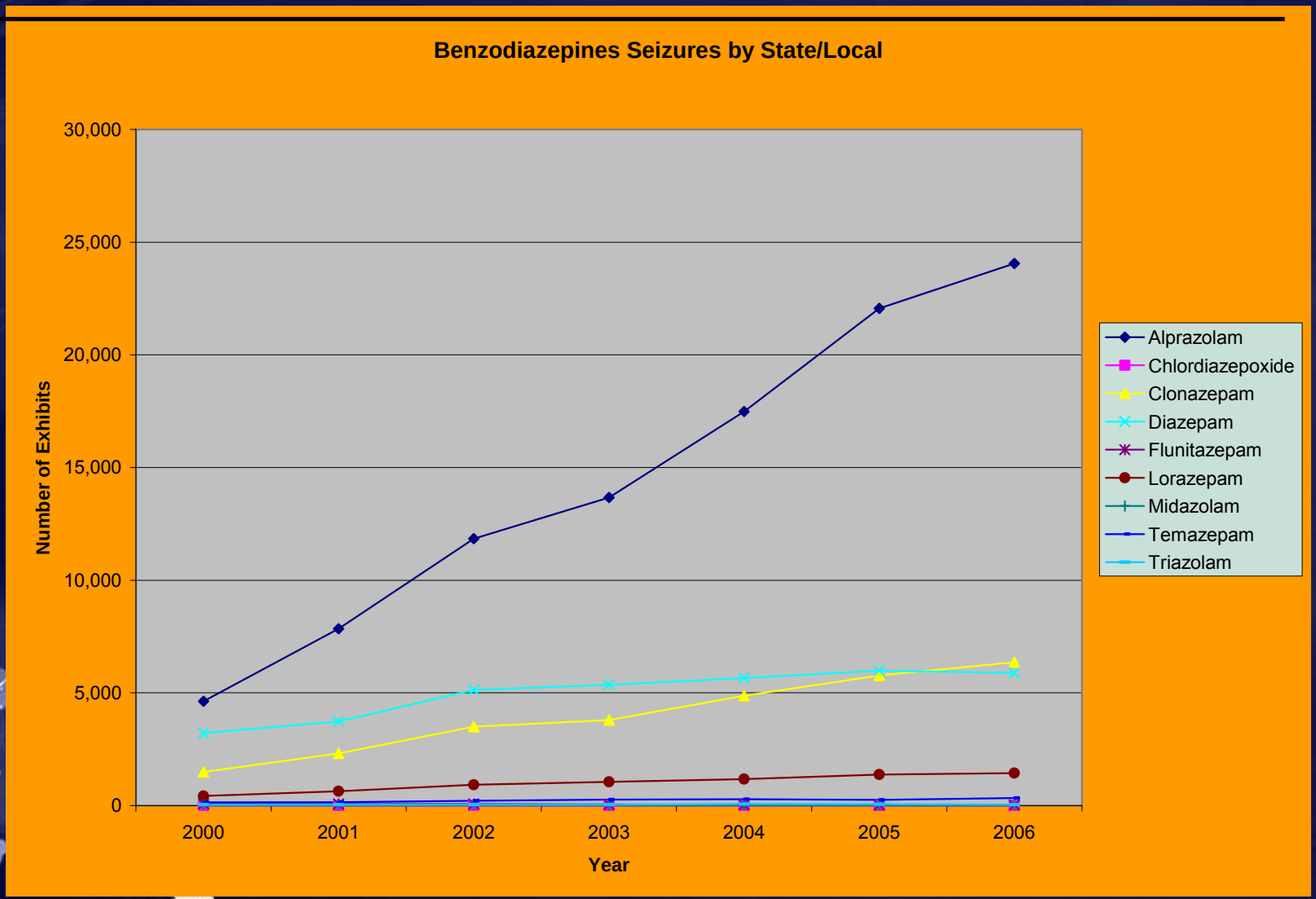
C-IV

- 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 7th**

Source IMS Health
** Source Verispan VONA



State and Local Seizure Data



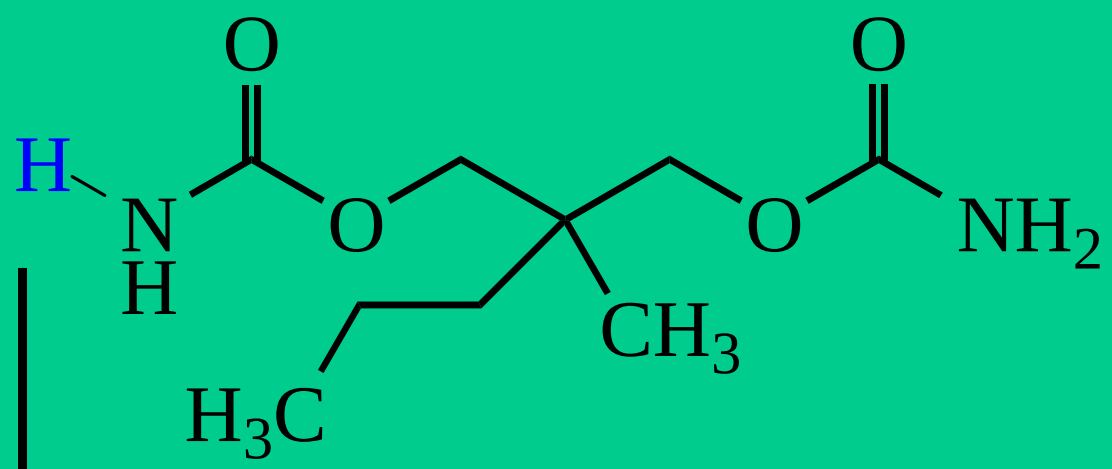
Other Controlled Substances

- Phentermine
- Phendimetrazine
- Amphetamine Alks
- Methylphenidate

Non-Controlled Substances

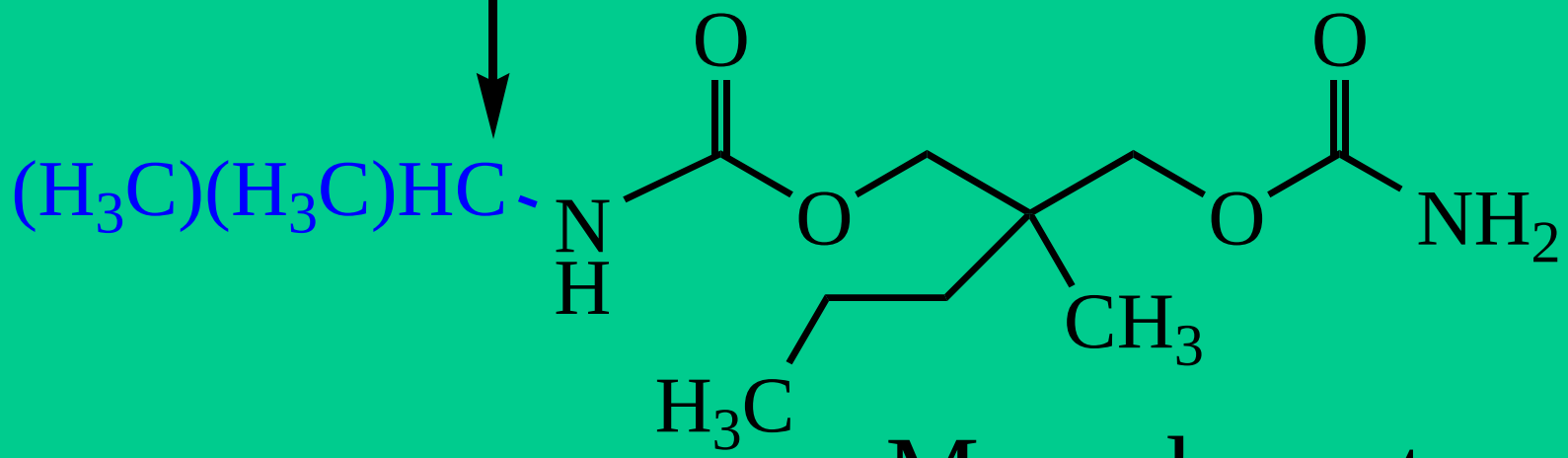
- Analgesic:
  - Tramadol (Ultram®, Ultracet®)
- Muscle Relaxant:
  - Carisoprodol (Soma®)
  - Cyclobenzaprine (Flexeril®)

Carisoprodol



Structural Change

by Enzymatic Action in the Body



Meprobamate

Trafficking Trends

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
  - The medicine cabinet
- The Internet

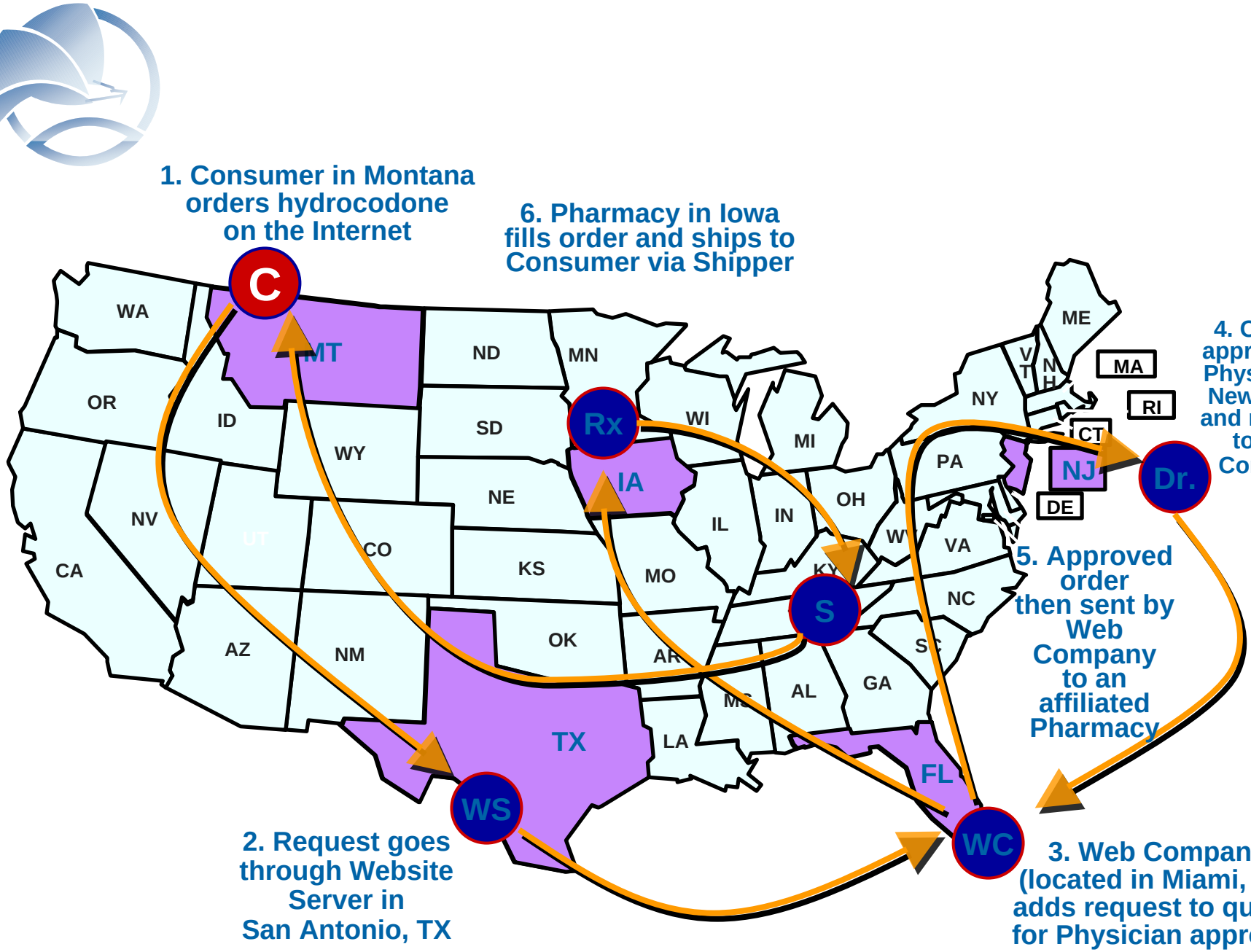
Sources for AAS/Other Drugs

- **Internet Pharmacy**

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


1. Consumer in Montana orders hydrocodone on the Internet
6. Pharmacy in Iowa fills order and ships to Consumer via Shipper
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
2. Request goes through Website Server in San Antonio, TX
3. Web Company (located in Miami, FL) adds request to queue for Physician approval
C
Rx
S
WS
WC
Dr.
WA
OR
CA
ID
NV
MT
WY
UT
AZ
CO
NM
ND
SD
NE
KS
OK
TX
MN
IA
MO
AR
LA
WI
IL
MI
IN
OH
KY
TN
MS
AL
GA
FL
SC
NC
VA
WV
PA
NY
ME
VT
NH
MA
RI
CT
NJ
DE

Ryan Haight Online Pharmacy Consumer Protection Act

- Ryan Haight Act was enacted on 10/15/08.
- Amends the CSA to prevent the illegal distribution of controlled substances by Internet.
- DEA issued regulations to implement the Act on April 6, 2009 (74 FR 15596).
- As of 5/5/2009, only 5 pharmacies had requested modification to online pharmacy.

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

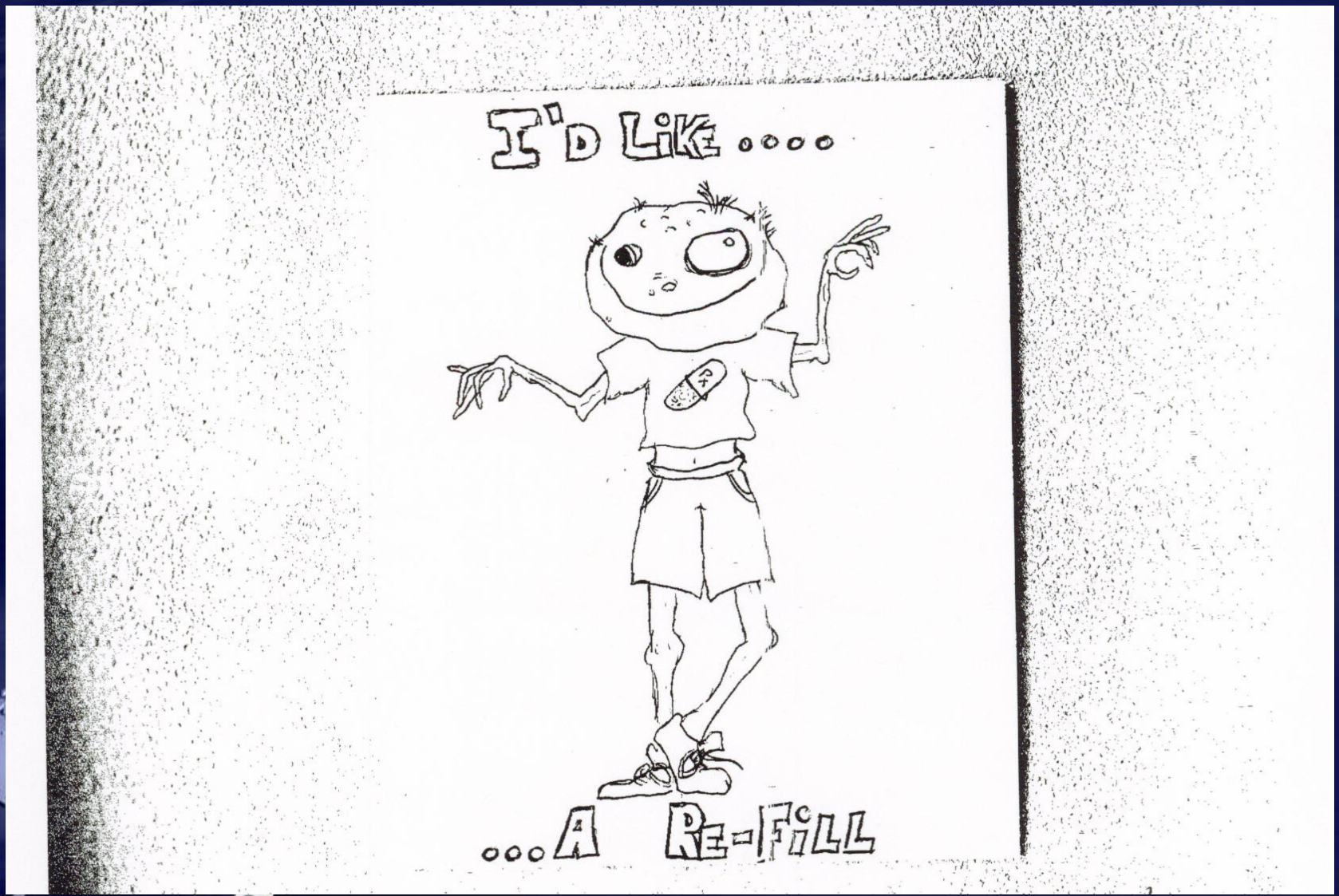
* Must be reduced in writing, and followed by sign, hard copy of the prescription.
** A signed, hard copy of the prescription must be presented before the medication is dispensed.
*** 72 hour time limitation.
# With medical authorization, up to 5 in 6 months.

Internet Diversion

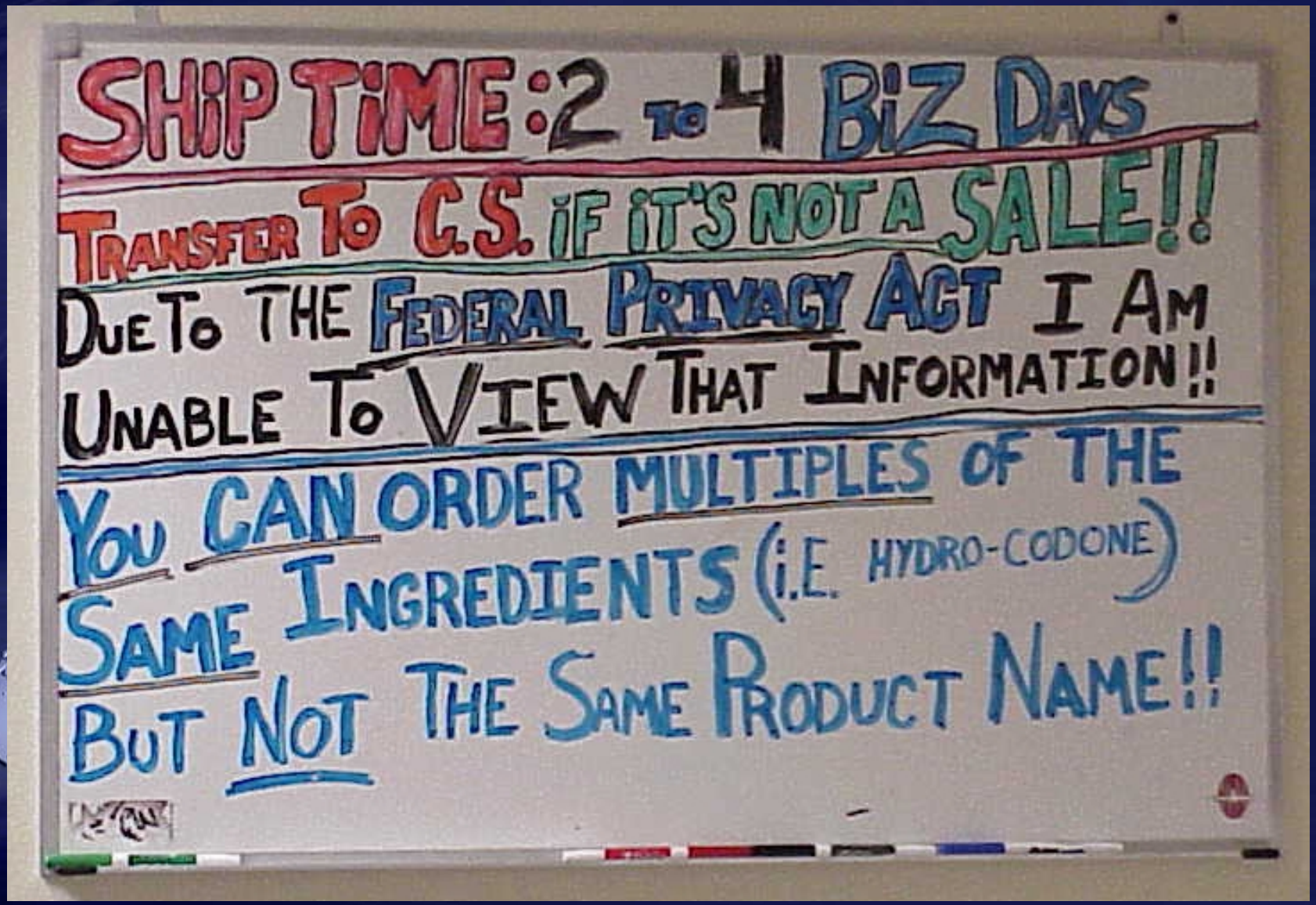
Case Example

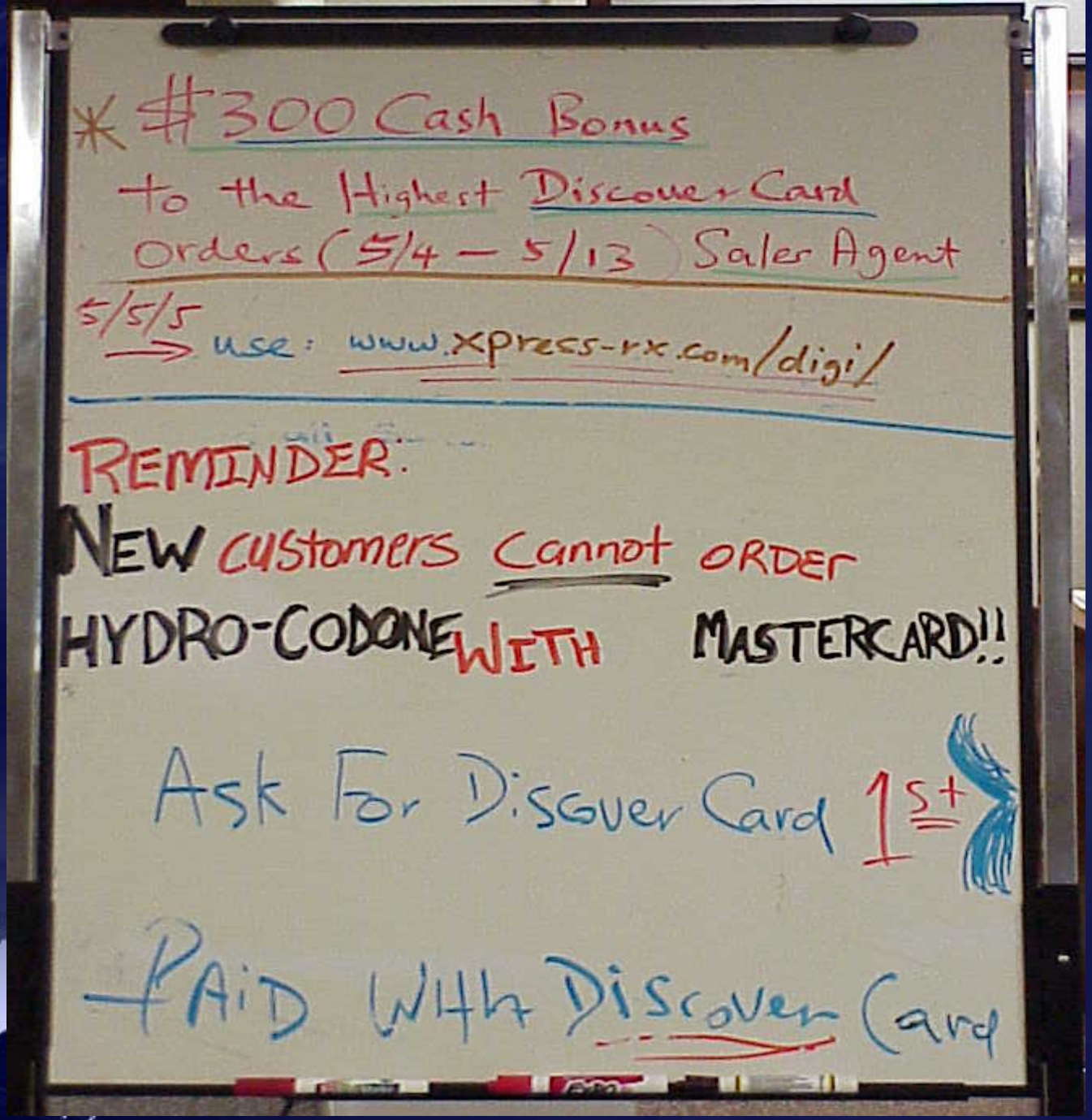
Minneapolis, Minnesota

Defendant's Attitude Toward His Customers



Defendant's Attitude Toward His Business




*#300 Cash Bonus
to the Highest Discover Card
orders (5/4 – 5/13) Sales Agent
5/5/5
use: www.xpress-rx.com/digi/
REMINDER:
NEW customers Cannot ORDER
HYDRO-CODONE WITH MASTERCARD!!
Ask For Discover Card 1st
PAID With Discover Card


GASOLINE
REG. U.S. PAT. OFF.


DODGE

Total Forfeiture:

$4,370,258.80

Internet Legislation
&
Implementing Regulations

Ryan Haight Online Pharmacy Consumer Protection Act

- Ryan Haight Act was enacted on 10/15/08.
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Ryan Haight Online Pharmacy Consumer Protection Act

- New DEA registration requirements for all Internet pharmacies
- 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 on October 15, 2008 (April 13, 2009)

Registration, Reporting and Disclosure Requirements

- New DEA registration requirements for all Internet pharmacies
  - Modification of existing Retail Pharmacy registration
- Reporting requirements
  - Monthly basis
  - All controlled substances dispensed (total of each)
  - Thresholds
    - 100 or more CS prescriptions
    - 5,00 or more total dosage units
- Disclosure requirements on home page
  - Identify servicing pharmacies, pharmacist in charge, and physicians

Per Se Violations

Automatic Violation of the CSA if any of the following occurs:

- **No in-person medical evaluation by prescribing practitioner**
- **Online pharmacy not properly registered with *modified registration.***
- **Website fails to display required information**

New Felony Offense
Internet Trafficking

- **21 USC 841(h)(1): It shall be unlawful for any person to knowingly or intentionally**

  (A) deliver, distribute, or dispense a controlled substance by means of the Internet, except as authorized by this title; or

  (B) aid or abet any violation in (A)

Current CSA Registrant Population

Total Population: 1,311,208

- Practitioner - 1,055,392
- Mid-Level Practitioner - 159,488
- Pharmacy - 65,643
- Hospital/Clinic - 16,036
- Manufacturer - 515
- Distributor - 810
- Researcher - 6,115
- Analytical Labs - 1,494
- NTP - 1,246
- ADS Machine - 161

as of 5/11/2009

SOOOO…How many have applied for registration for Internet Pharmacy Operations?????

3

Traffickers Adapt Current Schemes

Physicians in every state

Current Schemes – Pain Clinics

- East Coast Hub: 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 Hub: 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 Hub:
  - 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 Hub (*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

Investigation

- Law enforcement contact/leads from pharmacies, physicians, family, staff, etc.
- PMP review to document extent of diversion
- Surveillance/Covert inquiries
- Conducting interviews of involved parties
- Collect evidence
  - Identification; logs, ID, photo line-up
  - Prescriptions, receipts
  - Tapes
  - Controlled substances, bottles
  - Statements, admissions
- Arrest/Search Warrant
- Prosecution

DOCTOR SHOPPING

What is it?

- Wikipedia:
  - “Patients requesting care from multiple physicians, often simultaneously, without making efforts to coordinate care or informing the physicians of the multiple caregivers.”
- NDIC:
  - “A practice whereby persons who may or may not have legitimate medical condition visit numerous physicians to obtain drugs in excess of what should be legitimately prescribed.”

Characteristics

- Frequent, simultaneous use of multiple physicians and pharmacies
- Providing false information or withholding information to physicians
- Doesn’t tell physician about other treating physicians
- Frequent use of emergency rooms

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

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

Sources for AAS

- Internet Pharmacy
- Internet
- Physician Prescription
- Gyms
- Nutritional stores
- Foreign

Illicit Steroid Market

- By 1990s, several pharmaceutical companies had discontinued AAS programs
- Anabolic Steroid Control Act of 1990
- Approximately the same time, black market sales and counterfeit products appeared
- Internet shopping and availability

TRAFFICKING TRENDS - Anabolic Steroids

- 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

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.

Operation Raw Deal

Operation Raw Deal

11.4 million steroid dosage units were seized

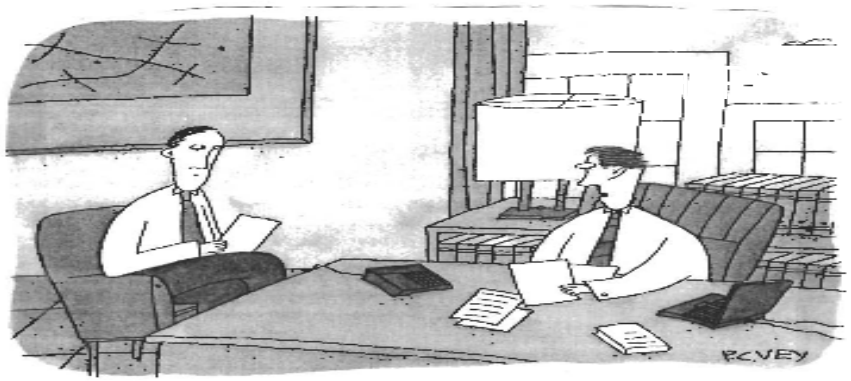
Operation Raw Deal

- 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

Dietary Supplements



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

These new regulations will fundamentally

Change the way we get around them

Dietary Supplement 6-OXO

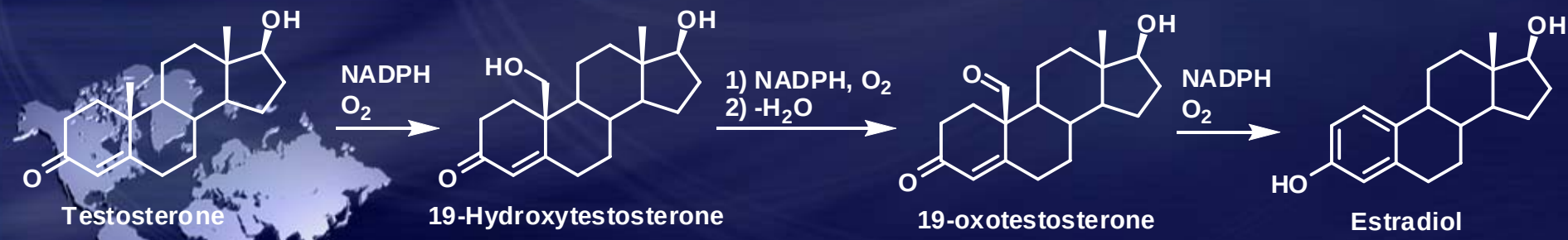
- Aromatase inhibitor, androst-4-ene-3,6,17-trione
- Banned by WADA
- Product found to be adulterated with CIII anabolic steroid androstendione
- Clinical study found that 6-OXO 300 mg/d and 600 mg/d increased free-testosterone levels by 90% and 84%, respectively

Dietary Supplement Novedex XT

- Aromatase inhibitor
- Banned by WADA
- Willoughby et *al.* conducted an eight week study of Novedex XT in men. Found that Novedex XT increased total testosterone, free testosterone, and dihydrotestosterone levels in young, eugonadal men by 283%, 625%, and 566%, respectively
- Steroid found in Novedex XT is metabolized into boldenone and a boldenone metabolite

Conditions Aromatase Inhibitors maybe Prescribed

- Low sperm count
- Prostate cancer
- Breast cancer
- Elevated estrogen levels
- Low testosterone levels



Synthesis of Testosterone

cholesterol

P450ssc

pregnenolone

P450c17

3ϑ-DH Δ4,5-isomerase

17- OH pregnenolone

progesterone

17,20 desmolase

3ϑ-DH Δ4,5-isomerase

P450c17

dehydroepiandro-sterone (DHEA)

17- OH progesterone

3ϑ-DH Δ4,5-isomerase

17,20 desmolase

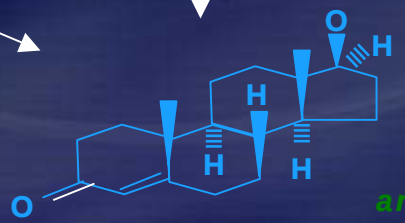
4-androstene-3,17-diol

4-androstene-3,17-dione

3ϑ-DH Δ4,5-isomerase

17-keto-reductase

aromatase



estrone

17-keto-reductase

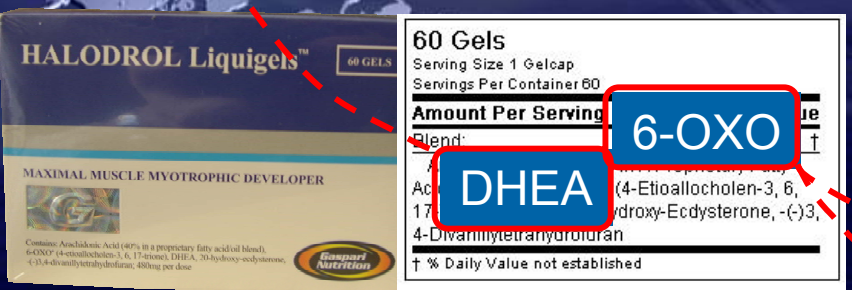
testosterone

aromatase

estradiol

5α - reductase

dihydrotestosterone



Dietary Supplement Act

- Expansion of definition by US Congress (1994) to include all products intended as a supplement to diet
- Labeling requirements put forth by the Dietary Supplement Health and Education Act of 1994
  - Name of each ingredient is to be listed
  - Quantity of each ingredient
  - Identity and strength of the supplement

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.

DRUGS

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

SUPPLEMENTS

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

SUPPLEMENTS GONE BAD

HYDROXYCUT

AAS Contamination in Dietary Supplements

The analysis of dietary supplements for AAS has been of great interest:

- **Van Poucke *et al.* analyzed 19 dietary supplements, of which 11 contained at least one anabolic steroid**
- **Green et al. 11 of 12 products were mislabeled and 1 product contained 10 mg testosterone**
- **Baume *et al.* analyzed 103 OTC dietary supplements purchased via the web, 18% mislabeled**

Issues with AAS and Sources

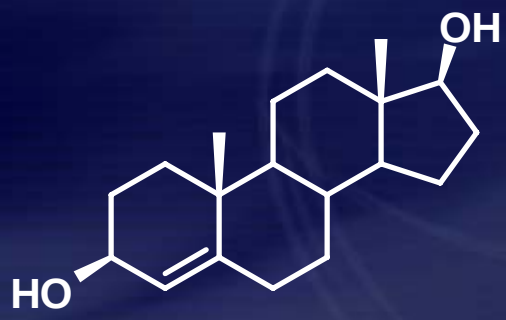
- Mislabelling
- Insufficient surveillance and quality controls for dietary supplements
- Who is overseeing dosage regimen?
- Lack of quality controls in manufacturing and formulation procedures
  - Contamination and adulteration common
- Lack of pharmacokinetic data to demonstrate effect and safety
  - Especially at suprapharmacological dosages

Nutritional Supplements

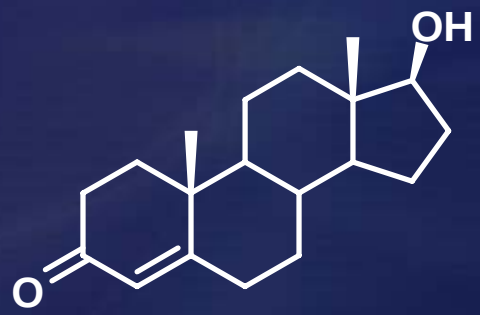
- Nutritional supplements have been found to be contaminated with AAS and prohormones
- Non declared agents are routinely detected
- It is believed that the situation has worsened in regards to supplement contamination
- The appearance of new designer steroids is a continuing problem in an attempt to circumvent the law

Prohormones

- **Steroids metabolically transformed into active anabolic steroids**
- **Intended to circumvent controls**



4-androstenediol



testosterone

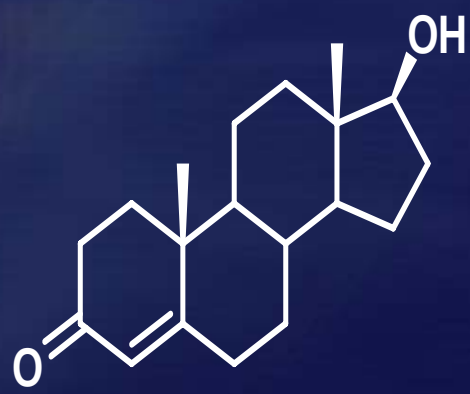
Buyer be aware - Prohormone Issues

- In a 2001 study by Geyer *et al.* a single recommended dose of a nandrolone prohormone resulted in the finding of norandrosterone metabolite more than ten days later
- Creatine product was found to contain seven different prohormones and testosterone not declared on label (Geyer *et al.*, 2008)
- 15% of 634 non-hormonal nutritional supplements found to contain an AAS (Geyer *et al.*, 2004)
- Parr *et al.* identified high levels of AAS in effervescent tablets
- Vitamin C, Multivitamin, and Magnesium tablets containing AAS (Geyer et al, 2006)

Designer Steroids

Regulatory Control

- Anabolic Steroid Act of 1990
- Dietary Supplement Health and Education Act of 1994
- Anabolic Steroid Act of 2004
- Proposed Rule of 2008



Testosterone

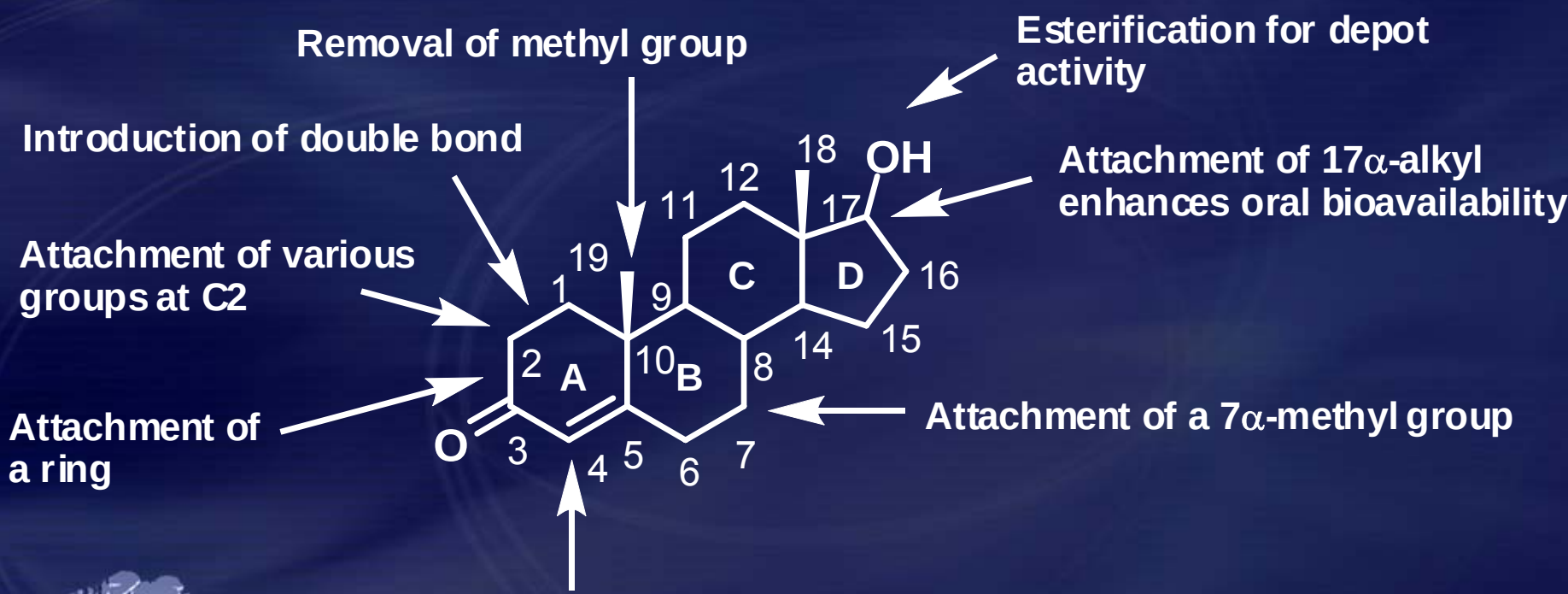
Designer Steroids to Circumvent Controls

- **New designer steroids specifically synthesized for misuse**
  - **Norbolethone – 2002**
  - **Tetrahydrogestrinone (THG) – 2003**
  - **Madol – 2004**
  - **Halodrol – 2005**
  - **Superdrol – 2005**
  - **Prostanozol - 2005**

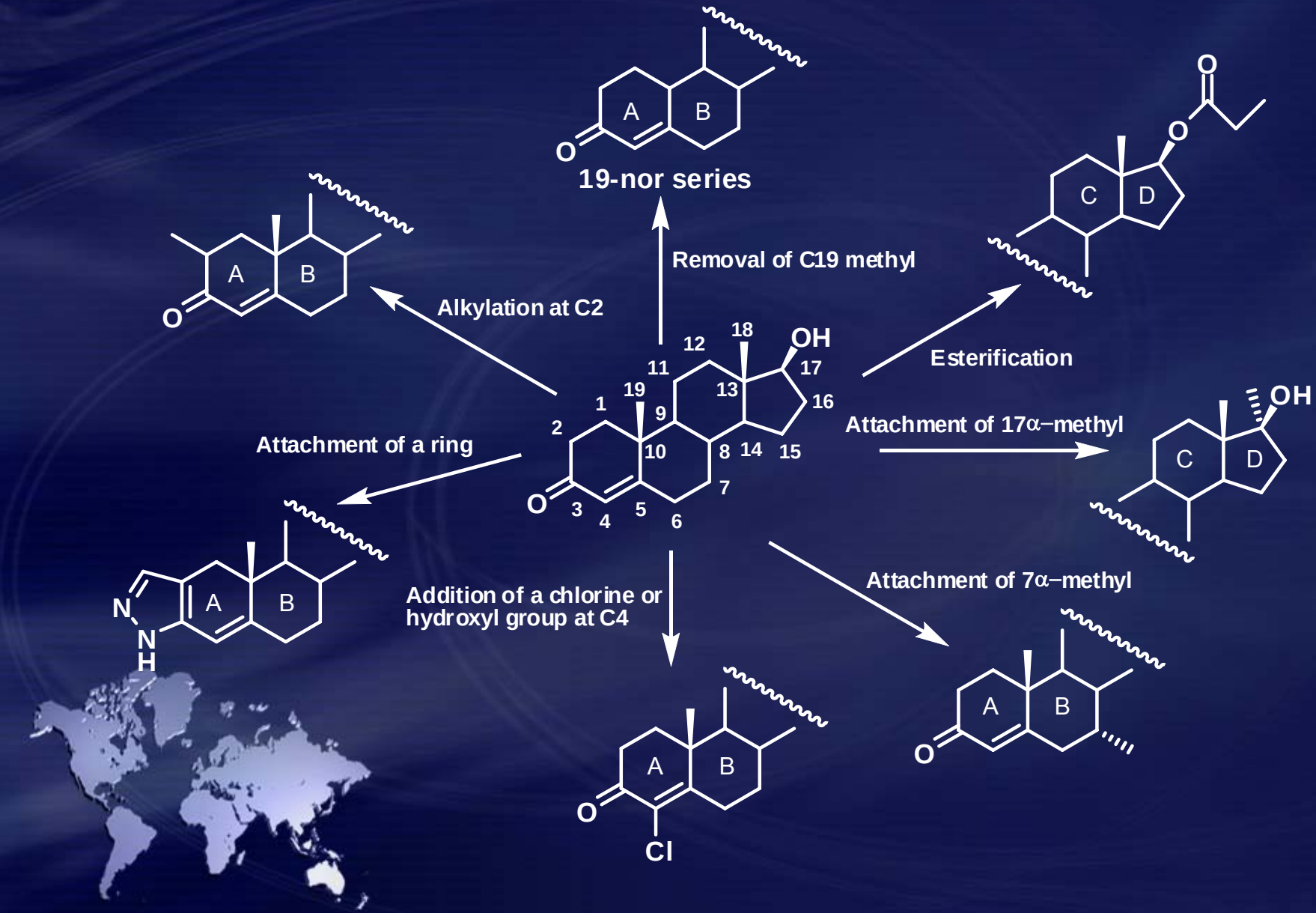
Requirements for Scheduling

The Anabolic Steroid Control Act of 2004 classifies a drug or hormonal substance as an anabolic steroid if the following four criteria are met: (A) the substance is chemically related to testosterone; (B) the substance is pharmacologically related to testosterone; (C) the substance is not an estrogen, progestin, or a corticosteroid; and (D) the substance is not dehydroepiandrosterone (DHEA). Any substance that meets the criteria is considered an anabolic steroid and must be listed as a schedule III controlled substance.

Modification to the Steroid Structure



Structural Modifications of Testosterone

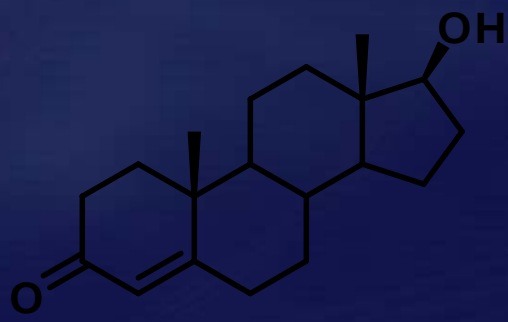


Requirements under the CSA

to be Controlled as an Anabolic Steroid

As per Anabolic Steroid Control Act of 2004:

1. **Structurally similar to testosterone**
2. **Pharmacologically related to testosterone**
3. **Substance is not an estrogen, progestin, or a corticosteroid**
4. **Substance is not DHEA**



Testosterone
Schedule III

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:

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

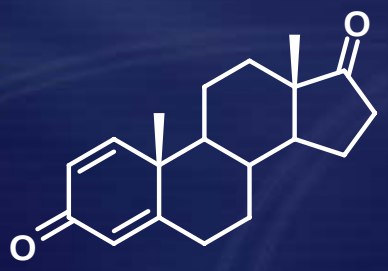
These drugs are chemically and pharmacologically similar to testosterone; are not progestins, estrogens or corticosteroids and are not DHEA

Three Steroids to be added to CSA

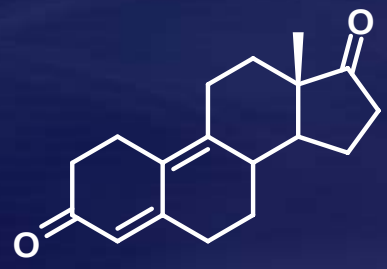
- **DEA in process to control three anabolic steroids in schedule III of the CSA**
- **As of August 2008, 58 dietary supplements were purported to contain one or more of these three steroids**

Anabolic Steroids to be placed in Schedule III

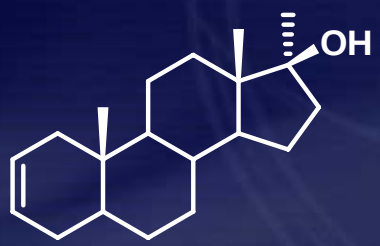
Administrative Scheduling in Process



Bolidone



19-Nor-4,9(10)-androstadienedione

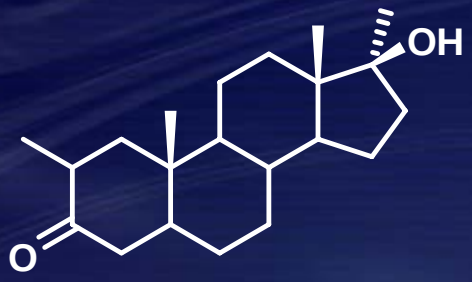


Desoxymethyltestosterone

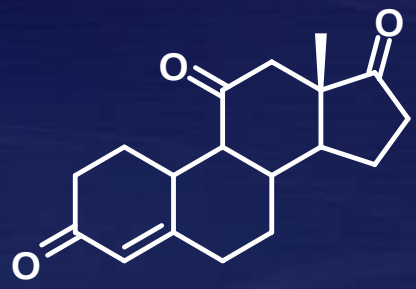
Steroids under Evaluation

- Recently, DEA supported testing of three steroids reportedly being abused for anabolic effects
  - methyldrostanolone
  - prostanozol
  - adrenosterone
- All three found in dietary supplements
- Two of the steroids found to be more potent than testosterone
- DEA to draft proposed rule for placement in schedule III as anabolic steroids

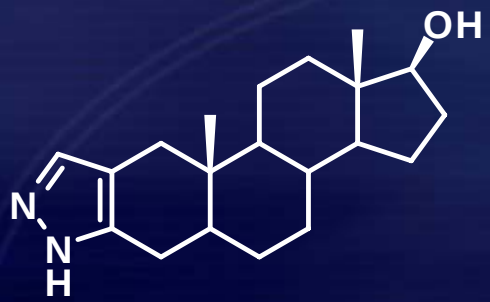
Undergoing Evaluation



2,17-Dimethyl-17-hydroxy-5-androstan-3-one

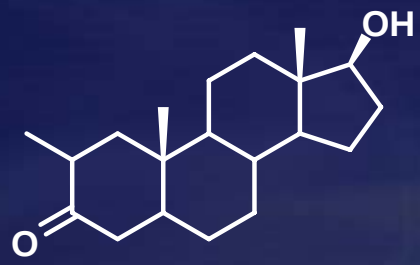


4-Androsten-3,11,17-trione

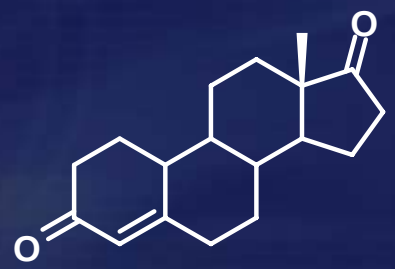


17-Hydroxy-androstan-2-eno [3.2-c]-pyrazole

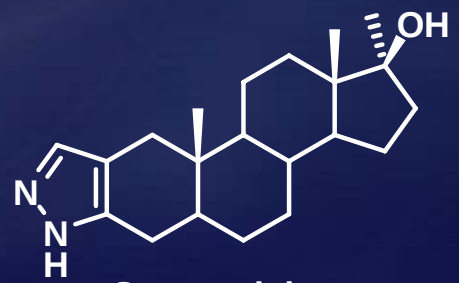
CIII Anabolic Steroids



Drostanolone



4-Androstenedione

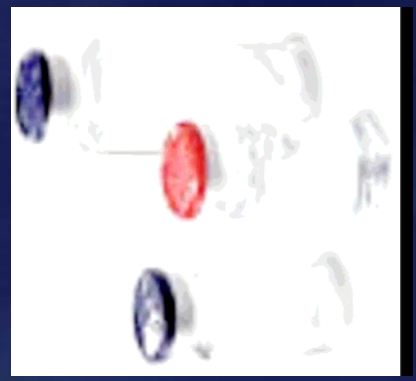


Stanozolol

Human Growth Hormone (hGH)

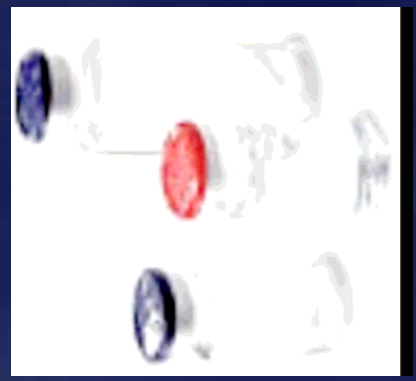
Human Growth Hormone

- The 1990 law inserted growth hormone into 21 U.S.C. § 333, the Steroid Trafficking Act.
- Indicated in children for poor growth due to certain medical conditions and for children born small for gestational age. Treatment in adults for Aids wasting, short bowel syndrome and hGH deficiency.
- Regulates body composition, glucose and lipid metabolism, skeletal muscle and bone growth.
- 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*.
- DEA has authority to investigate



Human Growth Hormone
U.S. Products

- Genotropin
- Humatrope
- Norditropin
- Nutropin
- Saizen



HGH

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

Human Growth Hormone (hGH)

- Naturally occurring hormone
- Major action is to stimulate protein synthesis
- Prescribed for delayed growth in children
- Also has veterinary uses:
  - Enhancing milk production in cows
  - Stimulates muscle growth and reduces fat deposition in pigs
- hGH abused for synergistic effects in combination with anabolic steroids

Complimentary Effects of GH and IGF-1

- **Growth hormone (GH) and insulin-like growth factor-I (IGF-I) are believed to enhance to testosterone's anabolic effects. Strategies:**
  - **Stimulation of GH secretion**
  - **Hepatic production of IGF-1; stimulating skeletal muscle formation**
- **Therefore, administration of hGH and insulin are common practice**

Detection of hGH

- Not currently screened difficult process
- Endogenous GH secretion and exogenous rhGH can be distinguished
  - The absence of 20 kDa isomer when 22 kDa is present in substantial amounts suggests exogenous rhGH admin
- Biomarkers from liver, collagen, and bone

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***

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.

Testing

Laboratory abnormalities and Methods of Analysis

- Urinalysis
  - Presence of AAS or metabolite
- Blood Work
  - Muscle enzymes
  - Liver function
  - Cholesterol levels
  - Hormonal levels
  - Blood count
- Hair

Methods of Detection

- Detection by:
  - Urine
  - Blood
  - Hair
- Sample Prepared
- Sample analyzed by instrumentation
- Detection limits below ng/mL
- Confirmatory analysis, results compared to standards

Steroid Detection

- Typically, anabolic steroids are self-administered at dosages ranging from 200 to 3200 mg/wk
- Anabolic steroids are metabolized in the body and dependent on structure, may be remain detectable in excess of a month
- Urine, blood, and hair contains the steroid and metabolite(s)
- Detection limits for steroid and metabolites are roughly 2 ng/mL (0.000002 mg/mL)
- Standards for steroids and metabolites are used for confirmatory analysis
- Reason for concern: drug tested professionals and athletes have tested positive for steroids as result of contaminated dietary supplements

General Analysis for Anabolic Steroids

Steroid administered → metabolized → Steroid + metabolites → urine collected → Sample prepared → injected into instrument → Results compared to standards

- Steroid metabolized in liver
- Analysis identifies predetermined metabolites
- Many steroids and their metabolites detectable up to 30-days post administration

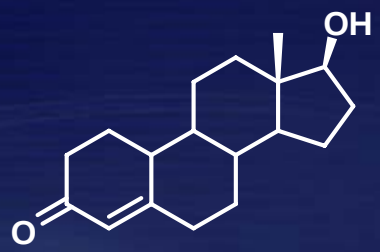
Attempts to evade (generally not successful)

- Epitestosterone
  - testosterone/epitestosterone ratio used to suggest doping
  - ratio > 4:1 results in further testing
- Prebenecid interferes with renal elimination of anabolic steroids and metabolites
- Clenbuterol
- Amineptine interferes with sample prep (hydrolysis)
- Finasteride/Dutasteride alter natural steroid profiles
- Diuretics increase urine flow and reduces steroid concentration

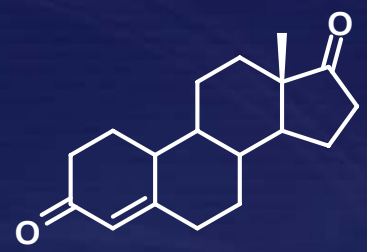
Study Monitoring of Testosterone Self-Administration

- Subjects were administered a low dose of testosterone cypionate,100 mg/wk
- Urine test for testosterone
  - By T/E ratios detected 1.6 weeks (average) after administration ceased
  - By T/LH ratios detected 2.3 weeks (average) after administration ceased
- Results represent a dose smaller than average of 1500 mg/week. Therefore, a larger dose would be detectable for a longer period.

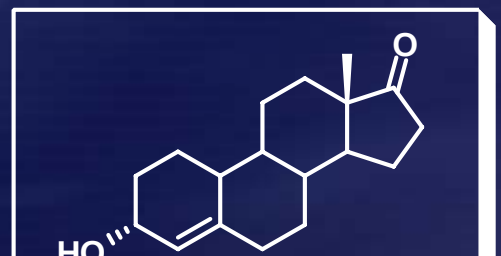
19-Nor Series Detection



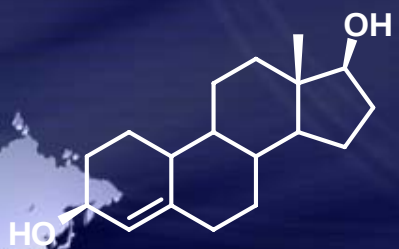
Nandrolone



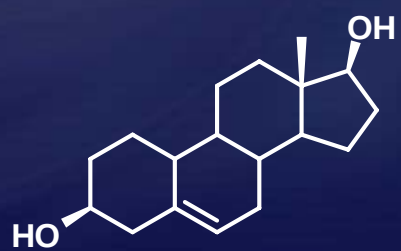
19-Nor-4-androstene-3,17-dione



19-Norandrosterone

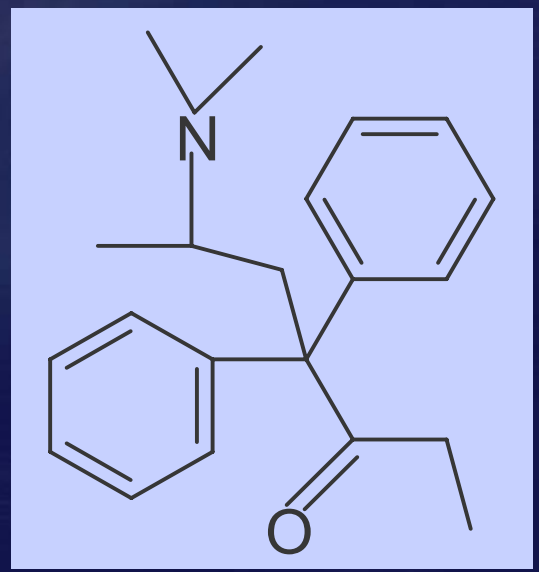


19-Nor-4-androstene-3β,17β-diol



19-Nor-5-androstene-3β,17β-diol

METHADONE



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 74 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 1999 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.

Methadone tablets in a cup. BALTIMORE SUN PHOTO: JED KIRSCHBAUM

At least 29 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.

NEWS BRIEFS

NEWARK

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

A Licking County man who pleaded guilty last month in the methadone overdose death of his 2-year-old son was sentenced to four years in prison yesterday.

Dennis Masters, 34, of Newark, had pleaded guilty to involuntary manslaughter and child endangering in the death of his son, Benjamin Scott Masters.

Benjamin died March 6. Toxicology tests showed the boy died from ingesting methadone. Masters has admitted that he had left the boy and his 3-year-old brother alone in the bathroom with an open bottle of the prescription narcotic pain reliever. He returned 5 minutes later to find Benjamin not making the battle.

Masters told police in March he didn't know what had happened, but he later told them he'd given him a bath. He was arrested in May.

— Linda Jarman
ljarman@thisweekpublishing.com

3 more arrests in OD case

Incident involved liquid methadone

By Julie Arrington
Staff Writer

Authorities have charged three South Forsyth High school students in connection with a suspected overdose on campus earlier this month.

The three 15-year-old male sophomores were taken Oct. 3 to Northside Hospital-Forsyth after they ingested what authorities first thought was an over-the-counter medication.

Forsyth County Sheriff's Lt. Col. Gene Moss said Wednesday it has since been determined they used a prescription medication.

All three of the teens were charged Wednesday with possession of a Schedule 2 narcotic on school grounds. One of them also was charged with distribution. The boys were released to their parents.

Moss said the on-campus incident was "directly related to liquid methadone being mixed with some substance."

According to the Web site for the National Drug Intelligence Center of the U.S. Department of Justice, methadone is a synthetic narcotic administered in pills, liquid or injections.

It is used to treat addiction to heroine and other narcotics, as well as a painkiller for cancer patients and those suffering terminal illnesses.

"Methadone overdoses are associated with severe respiratory depression, decreases in heart rate and blood pressure, coma, and death," according to the drug intelligence center.

Moss said Sheriff's Investigator Gus Sesin applauded the "quick response" of school staff and nurses in the incident.

"If these kids hadn't been at school, and had been anywhere where they wouldn't have gotten immediate professional help, they would have died," Moss said.

Sheriff's Capt. Paul Taylor echoed their remarks.

"That can be a chaotic situation, but the school administrators did a good job of keeping things under control, assisting law enforcement and medical personnel and the kids that were in trouble," Taylor said.

A 16-year-old girl, whose identity has not been released, was arrested Oct. 3 in connection with the incident, which resulted in the school being locked down three times that day.

See ARRESTS, Page 2A

ARRESTS from 1A

She was charged with possession and sale of a Schedule 2 narcotic on school grounds. Authorities said she is in custody at the Regional Youth Detention Center in Gainesville.

Moss said it appears she brought the liquid methadone from home and "that's currently under investigation."

An unrelated arrest was also made Oct. 3 as a result of a search conducted during the lockdown.

A 17-year-old female student was charged with possession of marijuana and drugs not being kept in original container.

In addition, a drug search of the school Thursday morning resulted in another arrest, also for marijuana possession.

E-mail Julie Arrington at juliearrington@forsythnews.com.

New Hampshire Deaths Soaring: Alarmed Officials Point to Methadone

N.H. drug deaths soaring

Alarmed officials point to methadone

By ANNMARIE TIMMINS
Monitor staff

Last year, 129 people died in traffic accidents on New Hampshire roads. What may be a surprise is this statistic: More people – 168 – died from drug overdoses. And that was up from 2006, when 142 people overdosed on drugs and died, according to state officials.

Law enforcement officials, some of whom tie the jump in deaths to the increased availability of methadone, are taking notice. They wish the public was too.

"It's not talked about," said Merrimack County Sheriff Scott Hilliard. "I have a huge concern for the level of addiction."

Attorney General Kelly Ayotte shares that concern and has tried for three years to sell legislators on a prescription monitoring system she believes will prevent patients from "doctor shopping" in search of multiple prescriptions for the same drugs.

"I think this is a really important issue for our state," Ayotte said. "This is very important public health and public safety issue."

If the numbers alone don't get your attention, Hilliard [illegible] will. "When the add[illegible] rises, the crime lev[illegible] said. "Addicts are go[illegible] into houses. They are [illegible] from family members. [illegible] going to commit [illegible] talk about it [illegible] of quality of life issue."

Dr. Th[illegible]drew, the state's chief medical examiner, began [illegible] the state's drug overdose d[illegible] years ago. He [illegible] on vacation last [illegible] unavailable for comment [illegible] office shared his count[illegible]

Ten years ago, the number of drug deaths in New Hampshire was under [illegible] it had climbed to [illegible] in 2005, the number [illegible] according to Andr[illegible] Each year, meth[illegible] responsible for a large number of those deaths.

The story has been similar in Concord.

In 2003, the Concord police recorded three drug overdose deaths in the city [illegible] linked to methadone [illegible] year, the police recorded [illegible] drug deaths, at least two [illegible] were linked to methadone. Last year, there were 12 drug overdose deaths in Concord, according to the police. At least seven of those were tied to methadone.

A few of those deaths were ruled suicides but most were not, the police said. And those are just the drug deaths.

In the last three years alone, the Concord Fire Department has responded to just over 200 overdose calls where the person treated

See DRUGS — A10

DRUGS

Continued from A1

admitted to drug use, said Fire Chief Dan Andrus. Lt. Keith Mulholland, a paramedic, said the calls have involved a variety of drugs, legal and illegal.

In Concord, those drugs have included cocaine and heroin as well as prescription drugs like oxycodone and medications prescribed for depression or allergies. But methadone was a factor in 16 of the city's 38 drug overdose deaths.

Two ways to drug

Methadone is available two ways, through methadone clinics, like the one on Loudon Road, and by prescription. The clinics get a lot of negative publicity, but the police said it's the supply available by prescription, not at the clinics, that's being abused.

An addict who gets methadone at a clinic for heroin withdrawal typically gets only one methadone dose per visit. The supply and the amount dispensed [illegible] closely monitored, the police [illegible] it almost impossible [illegible] sell.

[illegible] doctors for chronic pain. [illegible] patients are given m[illegible] supply when they fill a pre[illegible], making it easy [illegible] them [illegible] abuse or sell their tab[illegible] on the street.

Laconia knows th[illegible] hand, said police Chief Mich[illegible]

In that city last ye[illegible] eigh[illegible] people died of methado[illegible] overdoses, prompting Moyer, the county sheriff and county attorney to team up and tackle the problem in a number of ways, including prosecution and education.

"The reason [illegible] increase," M[illegible] doctors [illegible] (methadone) for [illegible] [illegible]ily available [illegible] [illegible]re's anoth[illegible] problem with met[illegible]one, Hilliard and Moyer [illegible] it creates a delayed rather than instant high. If someone takes one dose, fails to get high and takes more doses, the amount in their system compounds and can become lethal.

"Before they know it, they don't wake up," Moyer said. The eight people who died in Laconia in 2007 ranged in age from 18 to 49, according to the police.

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 for methadone prescr[illegible] c[illegible]nic [illegible] In [illegible]ses, patients are given many days' supply when they [illegible] a pres[illegible]

How to respond

New Hampshire is still learning how best to respond to the increase in drug overdoses.

Laconia and Belknap County have been among the most aggressive. The eighth overdose in Laconia 2007 came about the time Moyer became police chief.

On[illegible] first m[illegible] chief was to ta[illegible] County Sheriff C[illegible] and County Attorney Jim Carroll about tackling the problem. Late last year, they began a campaign that combin[illegible] law enforcem[illegible] education[illegible]

They create[illegible] titled "[illegible] ages [illegible] first nam[illegible] [illegible] The[illegible] included [illegible] overdose victims whose families agreed to share a photo. The poster put this challenge to the community: "Why do we stand by and let our family and friends die?"

In addition, the police agencies and county attorney's office decided to begin prosecuting people who supplied the drugs in fatal overdose cases. A conviction can be punished by a maximum sentence of life in prison. They can be hard cases to prove, but Belknap County has had some success.

Earlier this year, Carroll reached a plea deal that sent 55-year-old Edward Costello to prison for 15 to 40 years for supplying methadone to a 20-year-old Lakeport man who died of an overdose. Costello's wife, Diana, 44, and his daughter, Lisa, 18, also pleaded guilty to related charges and are serving shorter sentences.

In May, Carroll indicted two others, Bernard Huard, 48, of Gilford, and Anthony Shaner, 53, of Laconia, with drug sales where death resulted. Each is accused contributing to separate overdoses. Rockingham County's deputy county attorney, Tom Reid, has also prosecuted similar drug sales. Merrimack County has not brought any cases.

Carroll said the case are difficult to prosecute because there isn't always much evidence at the scene, and witnesses may not cooperate with the police if they too are connected to the drug scene. For those reasons, Moyer has instructed his officers to treat all drug overdose deaths like a crime scene so they'll be more likely to gather any evidence available.

Carroll said the challenge of the cases can't be a deterrent. "When the number of deaths resulting from a drug overdose reaches the level it was in a community this size, I think you have to reflect on the level of availability (of the drugs)," Carroll said. "I've tried to be aggressive."

Word on the street

Moyer said the poster and aggressive law enforcement response have gotten the right kind of attention. The city hasn't had a drug overdose death since last year, and Moyer said the word on the street is that drug dealers know they can go to prison if their drugs lead to a death.

He's also heard from other law enforcement communities all over the country who want help implementing a similar approach in their own areas. Here's another selling point: Moyer said the effort has cost almost nothing but the salaries of a couple of police officers he's asked to work on the drug overdose death problem.

Ayotte said she remains committed to tackling the drug overdose problem, too, and will again advocate for a prescription drug monitoring program that will track a person's prescriptions. She said 32 other states have such a program; New Hampshire is the only New England state that doesn't.

The monitoring program would make it harder, maybe even impossible, for someone to visit doctor after doctor in search of prescriptions for the same ailment. Ayotte said well-meaning doctors do not have the ability to determine whether a patient has received a prescription elsewhere. The same is true of pharmacies, she said.

Critics have cited privacy concerns, but Ayotte said she knows of no case in which a person's privacy has been compromised.

Ayotte has also talked with state safety Commissioner John Barthelmes about joining efforts to tackle the problem. She'd like to include state health experts too. "I'd like to have a much more coordinated approach from the state," she said.

Drugs' death toll in Concord

There have been at least 38 drug overdose deaths in Concord since 2003, according to Concord police records. A few were deemed suicides. Many were connected to methadone. Below is a year-by-year tally of the deaths that includes the gender and age of the person and the drug involved or suspected.

2008	GENDER	AGE	DRUG INVOLVED
Feb. 10	F	51	Morphine and oxycodone
June 26	M	33	Drug cocktail; [illegible] drugs [illegible] pending

2007	GENDER	AGE	DRUG INVOLVED
March 15	[illegible]	3[illegible]	[illegible] including hydrocodone, [illegible]codone and methadone
Ma[illegible]	[illegible]	45	Multiple drugs, including [illegible] alcohol
July 26	M	56	Salicylate [illegible]
Aug. 5	M	[illegible]	Alcohol a[illegible] drugs
Aug. 6	F	[illegible]	Opiates
Sep[illegible]	M	[illegible]5	[illegible]hadone
Sep[illegible]	[illegible]	41	Morphine and other drugs
[illegible]2	F	45	Methadone
Nov. 4	M	30	Methadone
Nov. 17	F	49	[illegible]
Nov. [illegible]	M	54	Met[illegible], morphine and other drugs
D[illegible]	F	[illegible]	Methadone

2006	GENDER	AGE	DRUG INVOLVED
Feb. 24	M	40	Multiple drugs

2005	GENDER	AGE	DRUG INVOLVED
Jan. 5	M	24	Undetermined drugs
Jan. 7	F	28	Multi[illegible] drugs; [illegible] a suicide
March 30	M	37	Cocain[illegible]
April 7	[illegible]	47	[illegible]
April 1[illegible]	[illegible]	28	[illegible] and alcohol
M[illegible]	F	[illegible]	Methadone
[illegible]	F	59	Undetermined drugs

2004	GENDER	AGE	DRUG INVOLVED
March 16	M	23	Methadone
March 27	F	35	Morphine suspected
May 24	M	30	Fentanyl suspected
May 28	F	46	Methadone and other drugs
July 11	M	43	Hydrocodone suspected
Sept. 4	M	21	Klonopin suspected
Nov. 1	M	32	Opiates
Nov. 18	M	36	Multiple drugs
Nov. 29	M	44	Undetermined drugs

2003	GENDER	AGE	DRUG INVOLVED
Aug. 9	M	39	Oxycodone

New Hampshire drug deaths 1995-2007

Source: State Medical Examiner's Office CHARLOTTE THIBAULT / Monitor staff

Man faces charges in woman's overdose death

GLOVERSVILLE — An East Fulton Street man faces multiple charges for allegedly providing the drugs and needle used last year in the overdose death of a city woman, Gloversville police said.

Joseph Labadia, 27, allegedly provided Stephanie Hawkins, 33, with the methadone and needle that led to her death on May 19. Police also said Labadia failed to seek medical attention for Hawkins when she had a severe reaction to the drugs.

Labadia was charged with criminally negligent homicide, fourth- and fifth-degree sale of a controlled substance and criminal possession of a hypodermic needle. He was arraigned Tuesday in Fulton County Court and sent to the county jail in lieu of $25,000 bail.

— David Fleet

Teen dies of suspected overdose

BY REX HALL JR.
rhall@kalamazoogazette.com
388-7784

KALAMAZOO — An accidental overdose of the drug methadone is suspected in the death of a 16-year-old Kalamazoo boy found unresponsive by police last week at his home, authorities said Thursday.

The teen, whose name was not released, was found at about 4:45 p.m. July 29 in the 1200 block of Jefferson Avenue, said Detective Lt. Scott Merlo of the Kalamazoo Department of Public Safety. He died the next day at Bronson Methodist Hospital.

Merlo said it may be "four to six weeks" before investigators receive the results of toxicology tests to confirm how the teen died, but he said that "based on our investigation, we suspect that it was an overdose of methadone."

He declined to elaborate or comment on how the teen may have gotten the methadone.

Methadone is a synthetic form of opium commonly used for treatment of narcotic withdrawal. It has been used for more than 30 years to treat addiction to other opiate narcotics, such as heroin and morphine, according to the Office of National Drug Control Policy.

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 Mahowney, asked Superior Court Judge Charles W. Erlin for a four-year prison sentence.

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

Tracy Moe, 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," Moe 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 opiates such as heroin.

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Bluefield Daily Telegraph

William "Randy" Deason
Publisher

Thomas A. Colley
Executive Editor

"Then he answered and spoke to me, saying, This is the word of the LORD to Zerubbabel, saying, Not by might nor by power, but by my spirit, said the LORD of hosts."

(Zechariah 4:6 ARJV)

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 2008 than illegal drugs. According to the report, nine out of the 10 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 442 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 a prescription 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 Epidemic 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 43 percent of the deaths.

❑❑❑

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.

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.

480 Greenley Road
Sonora, CA 95370

The Union Democrat

SINCE 1854

THE MOTHER LODE'S LEADING INFORMATION SOURCE

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 report.

The Child Death Review Team, made up of officials from the Sheriff's Office, the Sonora Police Department, the 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 rise in abuse of prescription drugs, particularly methadone, Sheriff's spokesman Lt. Dan Bressler 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 overdose 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.

Tuolumne 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

SEE DEATHS/A

Methadone - Background

- In late 1940s - marketed as analgesic drug, but was not extensively used.
- In the 70s - shown to be effective as once-daily medication for opioid addiction treatment.
- In the US – Established as the standard for treatment of opioid addiction.
- Since late 1990s – methadone is being increasingly used in pain management

WHY??????

Cheapest narcotic pain reliever – synthetic

Insurance companies

- Pain Treatment
- Narcotic Addiction Treatment/Maintenance

Dosage Forms

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

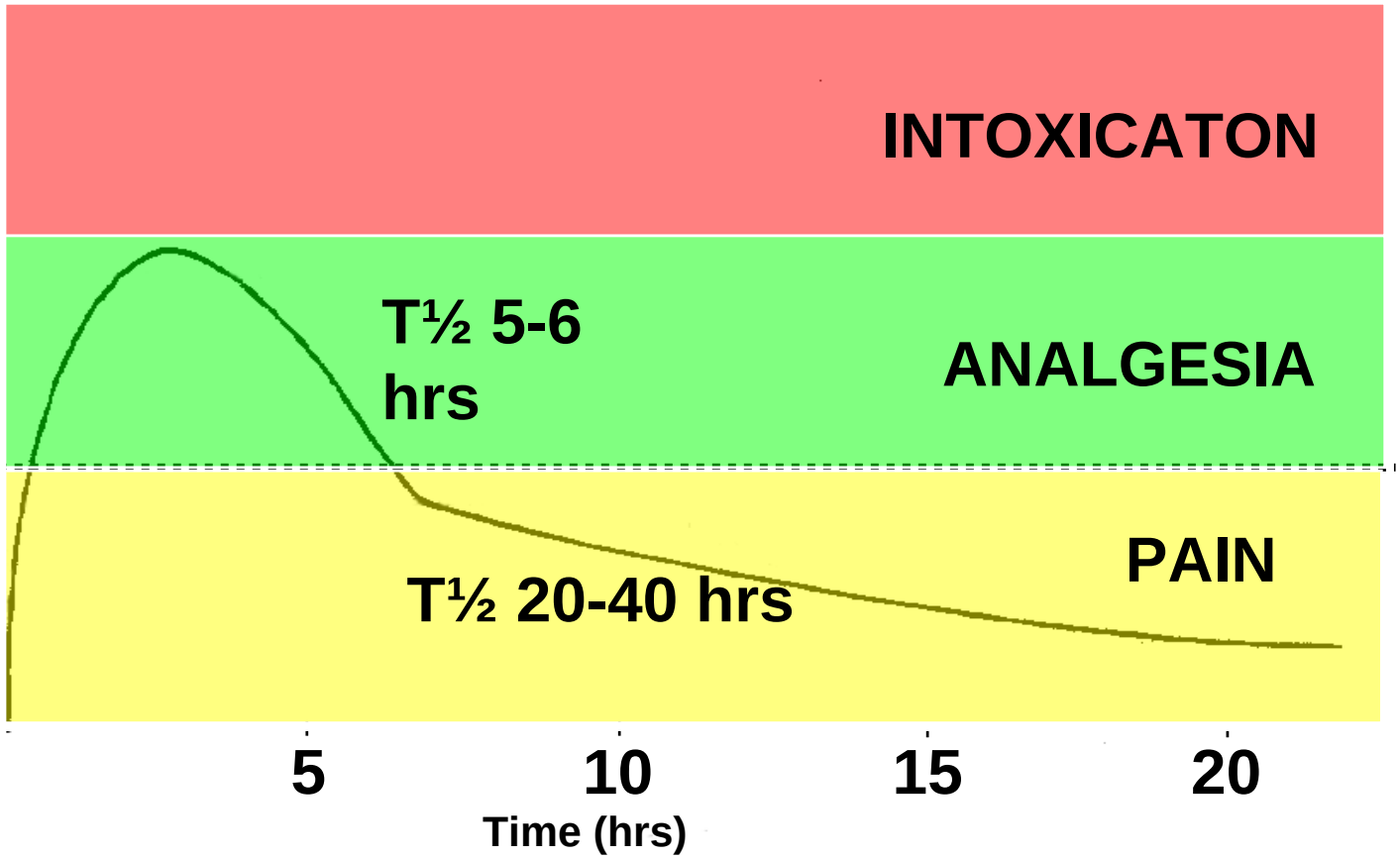
Methadone - Pharmacology

- 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
- 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
- Elimination half life – Variable (8-59 hours)

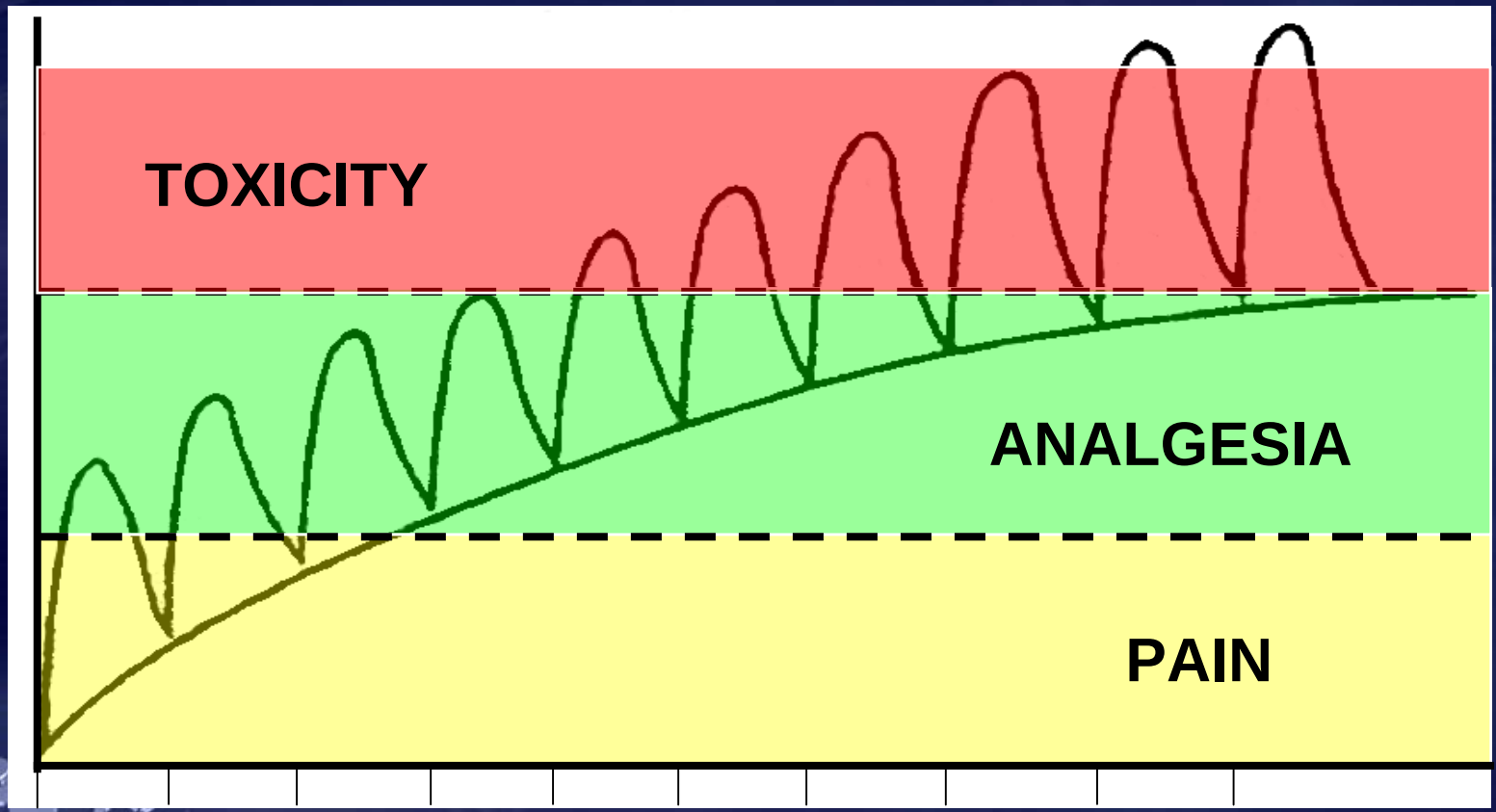
Methadone Single Dose Kinetics



Ref: Nilsson MI, et al. Acta anaesth. scand 1982, Suppl 74, 66-69

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



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Methadone - Toxicity

Respiratory Depression

Major hazard (Similar to other opioid analgesics)

Respiratory depression typically occurs later and persist longer than its peak analgesic effects

Toxicity on Heart

QT Interval prolongation and Torasdes de Pointes (TdP) – Shared by LAAM, but not by other opioids

May lead to ventricular fibrillation and death

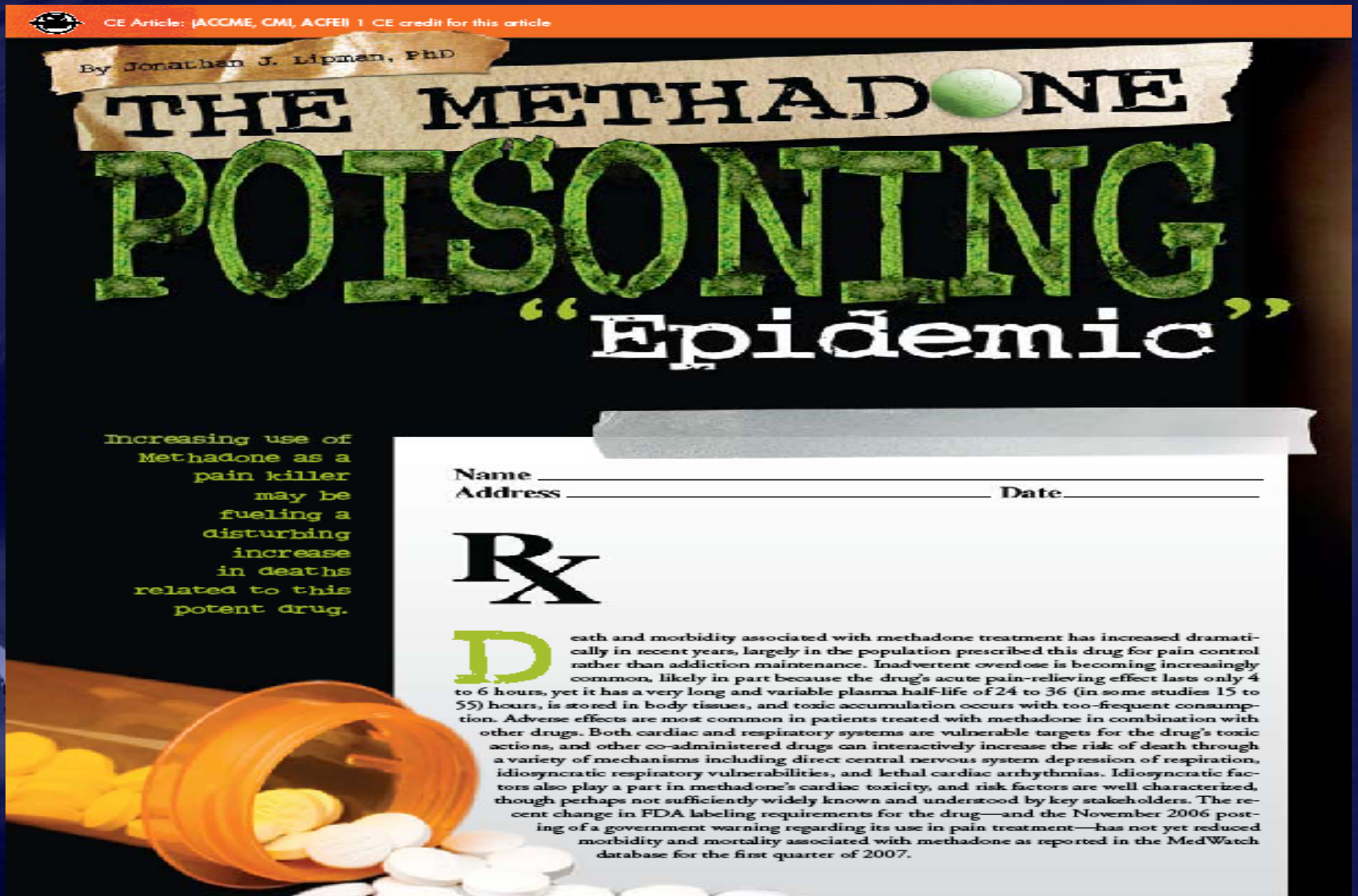
Methadone – Drug Interactions

- CNS depressants (e.g., alcohol, anesthetics, sedatives, other opioids) - Additive effect
- Antiretroviral drugs have variable interactions
- CYP3A4 inhibitors (some antifungal agents, macrolide antibiotics, and SSRIs) – Inhibits elimination
- Grapefruit juice inhibits methadone elimination
- Smoking enhances (CYP1A2) methadone elimination
- Self-inducer – Enhances (3.5 fold between 1st dose and steady state) its own elimination
- Anticonvulsants – Enhances methadone elimination

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

One Pill can Kill



CE Article: jACCME, CMI, ACFEII 1 CE credit for this article

By Jonathan J. Lipman, PhD

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.

Name _____

Address _____ Date _____

Rx

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 36 (in some studies 15 to 55) 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 interactively increase the risk of death through a variety of mechanisms including direct central nervous system depression of respiration, idiosyncratic respiratory vulnerabilities, and lethal cardiac arrhythmias. 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.

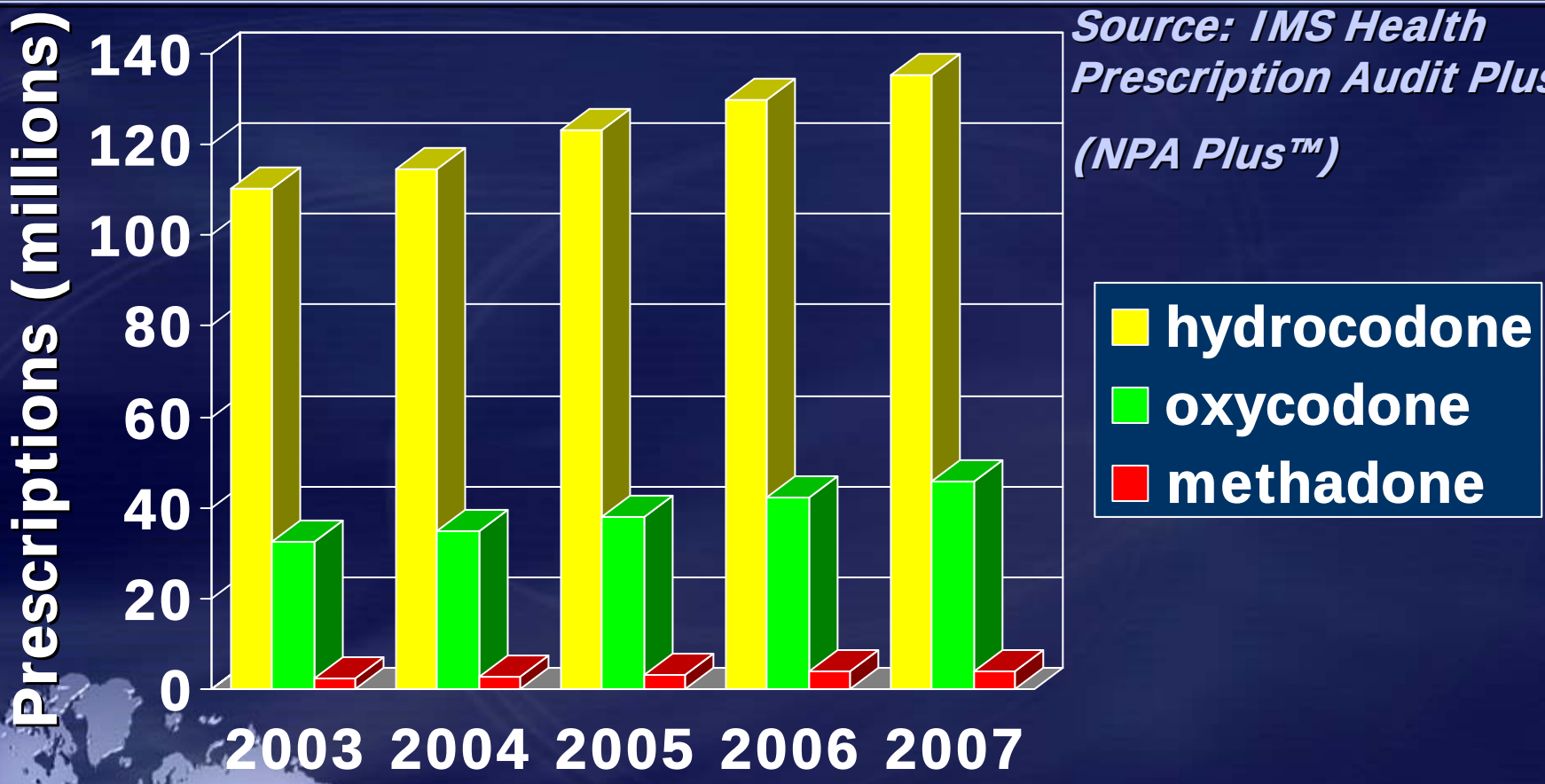
“Death and morbidity associated with methadone treatment has increased dramatically in recent years, largely in the population prescribed this drug for pain control rather than addiction maintenance.”

Methadone Mortality Assessments by SAMHSA- Findings

Why the increase in methadone 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 (opiate naïve). Friends, Dealer, Med Cabinet
- 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

Total Prescriptions – Selected Opioid analgesics

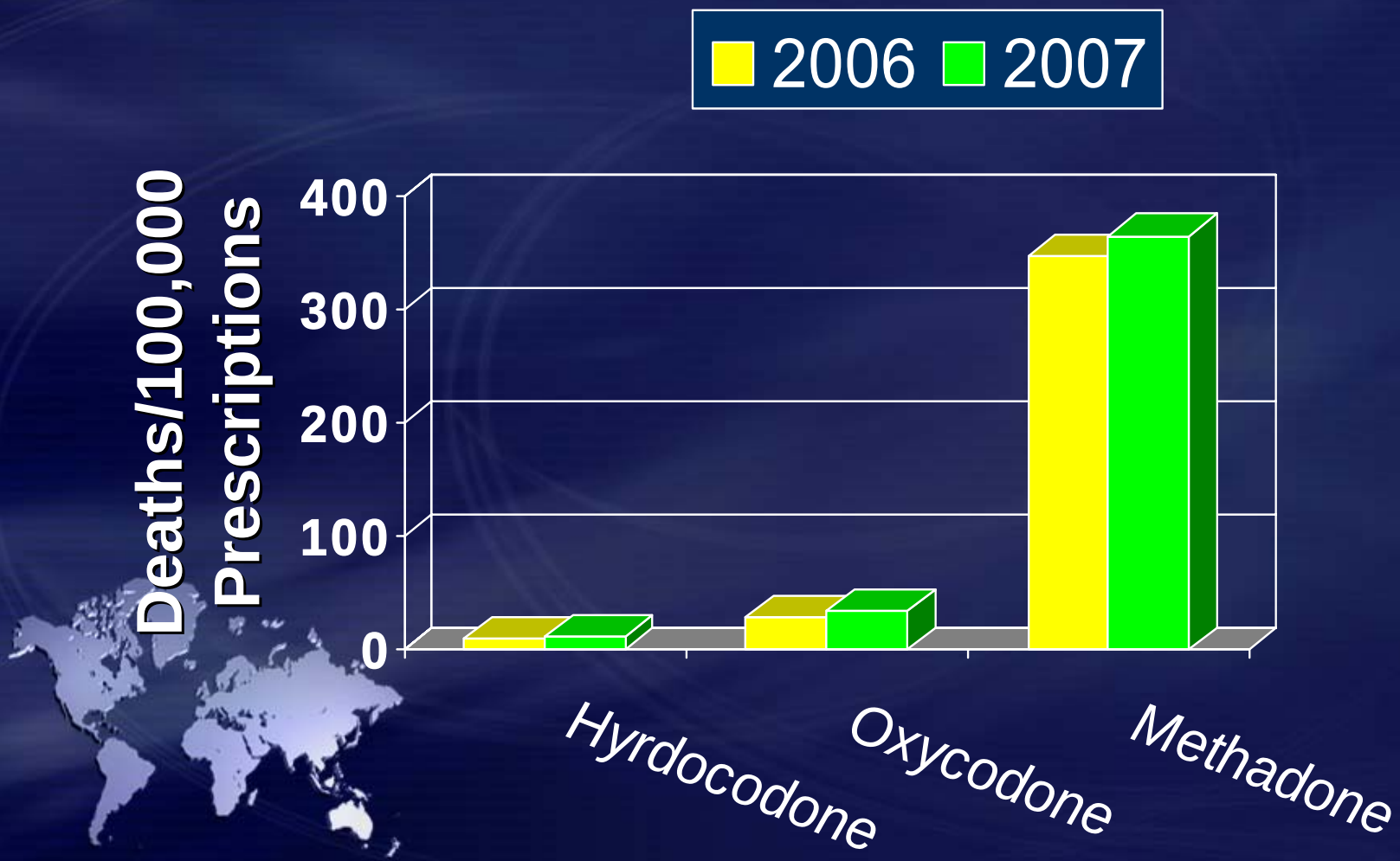


Source: IMS Health Prescription Audit Plus™ (NPA Plus™)

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 (Schedule II)

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

SOURCE: UPI, Inc. articles published February 2007

Solutions?

- Education/Prevention – public and professional
- Medical Examiners
- Medical/Professional Outreach
- Pharma Outreach
- Treatment
- Enforcement

QUESTIONS???

Thank You !

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