

CADCA 19th Annual National Leadership Forum
National Resort and Convention Center
February 11, 2009

The Diversion and Abuse of Pharmaceutical Controlled Substances, Legend Drugs and Dietary Supplements

Joseph Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

Introduction

- Background and Statistics
- Regulatory Control
- Methods of Diversion
- Internet Diversion
- Commonly Diverted Pharmaceuticals
- Steroids
- Dietary Supplements
- hGH
- Salvia Divinorum

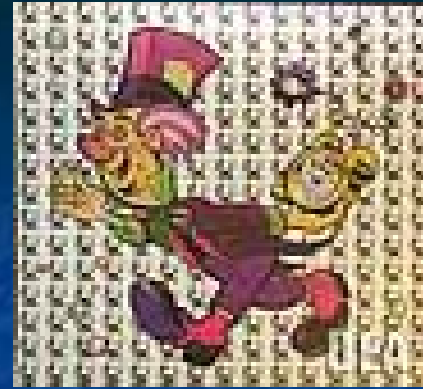
The 1960's



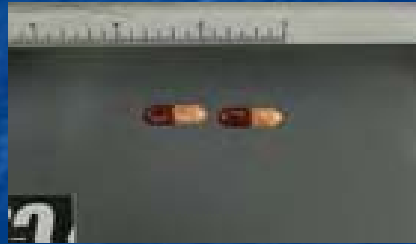
Marijuana



Seconal



LSD

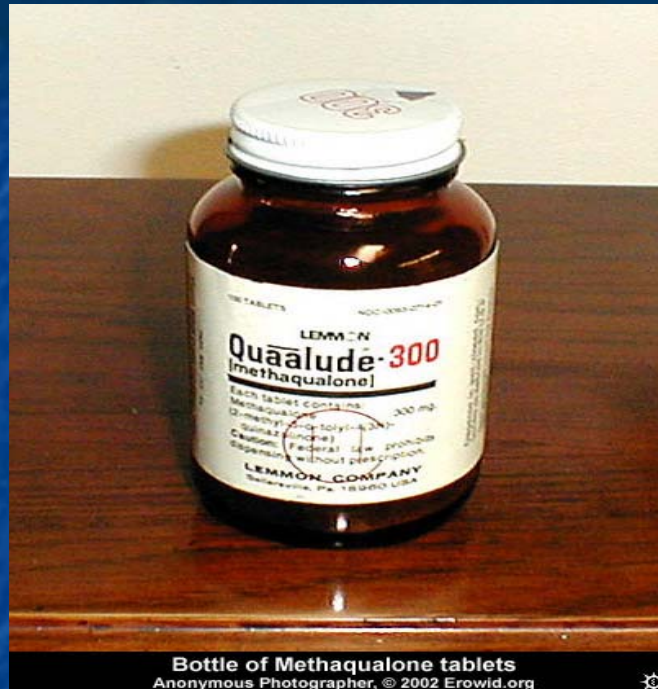


Dexedrine



Meprobamate

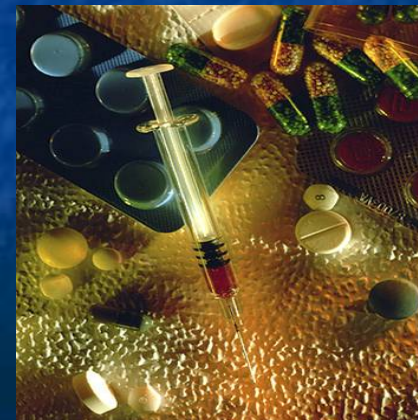
The 1970's



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



Heroin



T's and Blues

(Talwin and Pyrabenzamine)



The 1980's

4's and Doors

Tylenol w/Codeine and
Doriden



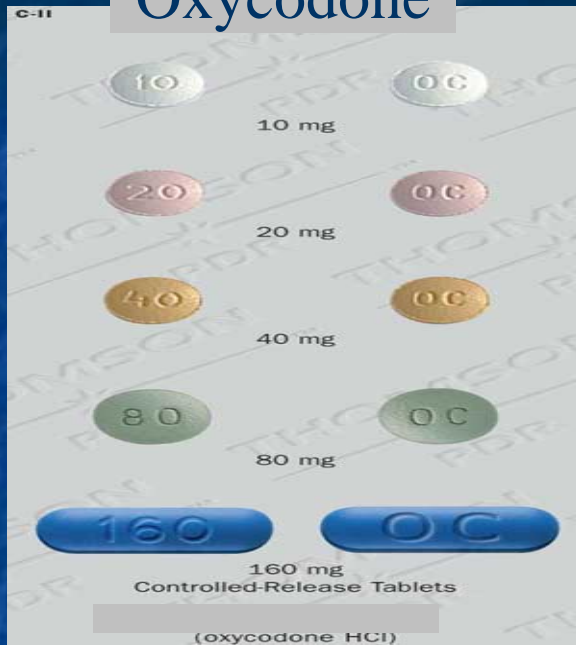
Hydromorphone



Cocaine

The 1990's

Oxycodone



Methamphetamine

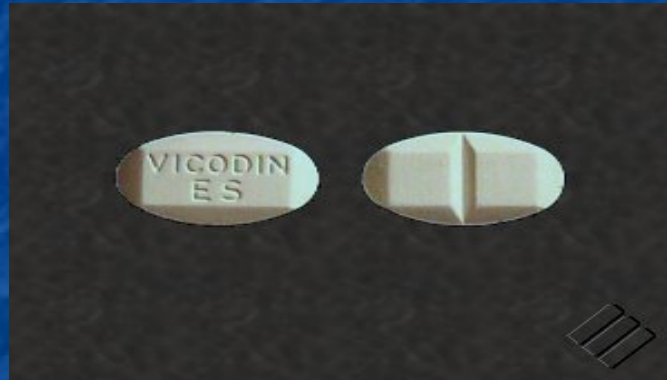


2000

Hydrocodone



Ketamine



Alprazolam

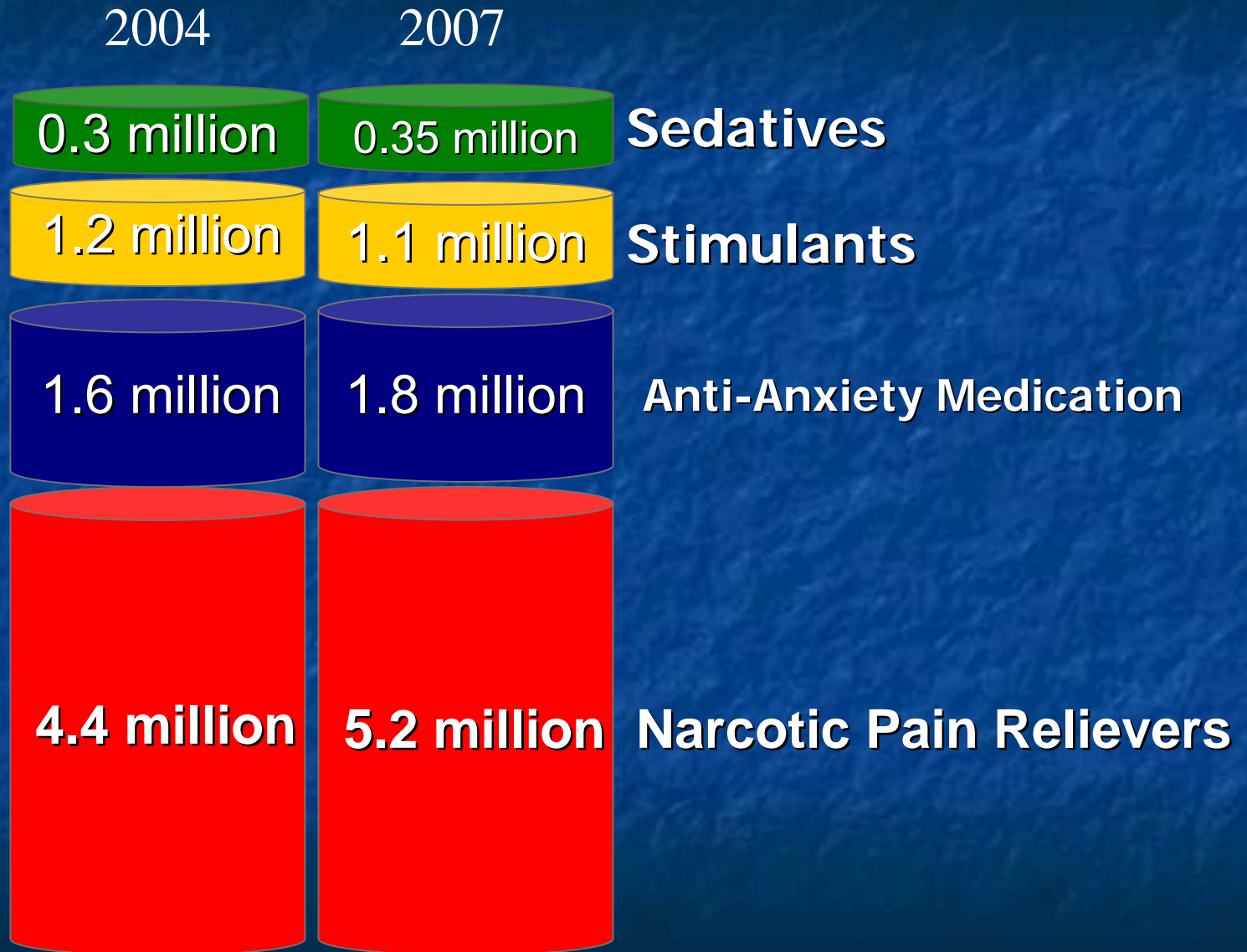


MDMA



Flunitrazepam
(Rohypnol)

Scope and Extent of Problem



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

Teens and Their Attitudes



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

Regulatory Control

Controlled Substances Act of 1970

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

Prescription Requirements

	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.

Prescription Drug Monitoring Programs

39 States with Legislation Enabling a Prescription Monitoring Program

29 Operational – 9 Enacted Legislation Only

(as of June 2008)

STATE	PROGRAM TYPE	SCHEDULES COVERED	YEAR ENACTED	DATA COLLECTION Started	
1	AL	Electronic	C II-V	2004	April 2006
2	AK*	Electronic	C I-V	2008	
3	AZ*	Electronic	C II-IV <i>July 2008</i>	2007	
4	CA	Single copy serialized, Electronic	C II-IV	2005	January 2007 (1939)
5	CO	Electronic	C II-V	2005	July 2007
6	CT*	Electronic	C II-V <i>2008</i>	2007	
7	HI	Electronic	C II-V	2002	July 1999 (1992 –II only)
8	ID	Electronic	C II-V	2001	Oct 1997
9	IL	Electronic	C II-V	1999	April 2000/ Jan 2008
10	IN	Electronic	C II-V	2004	January 2005
11	IA*	Electronic	C II-IV <i>2008</i>	2006	
12	KY	Electronic	C II-V	1998	January 1999
13	KS*	Electronic	C II-IV	2008	
14	LA*	Electronic	C II-V <i>2008</i>	2006	
15	ME	Electronic	C II-IV	2003	July 2004
16	MA	Electronic	C II	1992	April 2002
17	MI	Electronic	C II-V	2002	January 2003
18	MS	Electronic	C II-V	2005	May 2006
19	MN*	Electronic	C II-III <i>Jan 2009</i>	2007	
20	NV	Electronic	C II-V	1995	January 1997
21	NJ*	Electronic	C II-I	2008	
22	NM	Electronic	C II-IV	2004	July 2005
23	NY	Single copy, serialized/ Electronic (state issued)	C II, Benzos	1998	July 1982
24	NC	Electronic	C II-V	2005	July 2007
25	ND	Electronic	C II-V	2005	September 2007
26	OH	Electronic	C II-V	2005	May 2006
27	OK	Electronic	C II-V	1990	July 2006
28	PA	Electronic	C II	1972	Late 2002
29	RI	Electronic	C II-III	1997	July 1997
30	SC	Electronic	C II-IV	2006	2008
31	TN	Electronic	C II-IV	2002	December 2006
32	TX	Single copy, serialized/ Electronic (state issued)	CII II-V <i>Sept 2008</i>	1997	July 1982
33	UT	Electronic	C II-V	1995	January 1997
34	VT*	Electronic	C II-IV <i>2008</i>	2006	
35	VA	Electronic	C II-IV	2002	June 2006

Benefits

- The PDMP database allows investigators to obtain pharmacy data from multiple locations without having to visit each and every pharmacy.
- Deter and identify illegal activity such as prescription forgery, indiscriminate prescribing and "doctor shopping."
- Patient specific drug information upon request of the patient's physician or pharmacist.
- Notification of physicians when their patients are seeing multiple prescribers for the same class of drugs.
- Assists healthcare professionals in managing patient care.

21 CFR 1306.04

- To be effective, a prescription for a controlled substance must be issued
 - for a legitimate medical purpose by an individual practitioner
 - who is acting in the usual course of his professional practice



Methods of Diversion

- **Practitioners / Pharmacists**
 - Illegal distribution
 - Self abuse
 - Trading drugs for sex
- **Employee pilferage**
 - Hospitals
 - Practitioners' offices
 - Nursing homes
 - Retail pharmacies
 - Manufacturing / distribution facilities
- **Pharmacy / Other Theft**
 - Armed robbery
 - Burglary (Night Break-ins)
 - In-Transit Loss (Hijacking)
 - Smurfing
- **Patients**
 - Drug rings
 - Doctor-shopping
 - Forged / fraudulent / altered prescriptions
- **Internet availability**

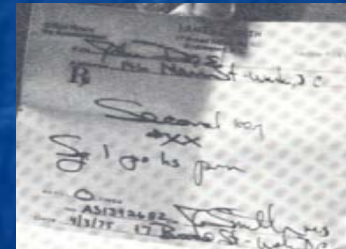
Internet Diversion

Rogue Internet Pharmacy



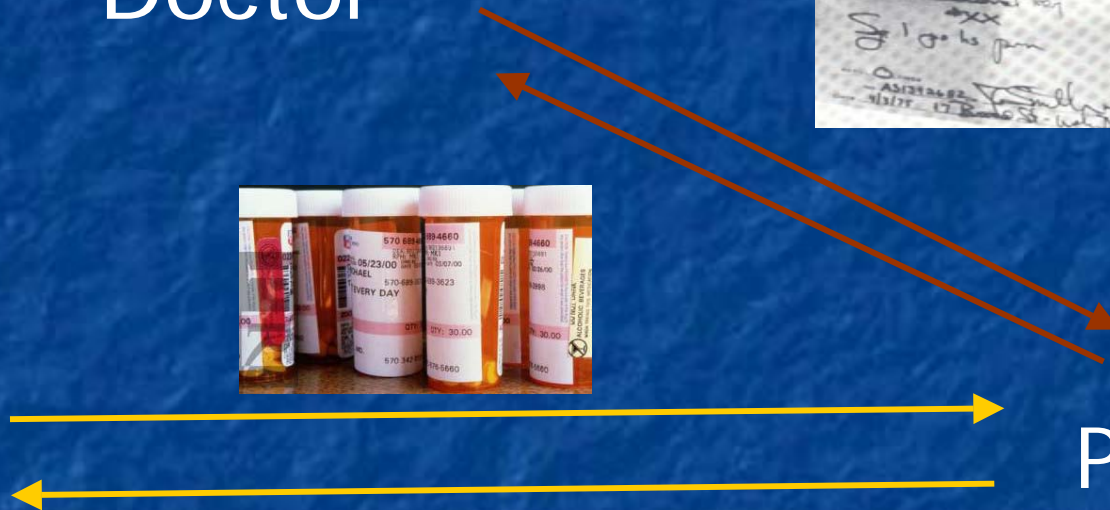
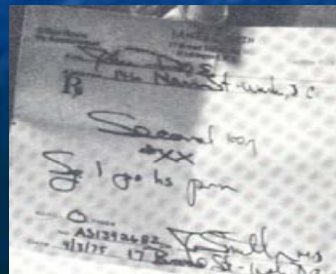
Checks and Balances

Doctor



Patient

Pharmacist



Ordering from a Rogue Site (Historically)



Web [Images](#) [Groups](#) [News](#) [Froogle](#) [more »](#)

buy hydrocodone

Google Search I'm Feeling Lucky

[Advanced Search](#)
[Preferences](#)
[Language Tools](#)

[Advertising Programs](#) - [Business Solutions](#) - [About Google](#)

[Make Google Your Homepage!](#)

©2004 Google - Searching 4,285,199,774 web pages

Google Web Images Groups News Froogle more »

buy hydrocodone Search [Advanced Search](#) [Preferences](#)

Web Results 1 - 10 of about 251,000 for [buy hydrocodone](#). (0.39 seconds)

[Order Hydrocodone Online](#) Sponsored Link
www.legalmedsonline.com \$37.94 shipped, huge savings. FDA approved, 100% legal purchase.

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

[Buy cheap hydrocodone Apap and Watson online - Vicodin - Cheap ...](#)
 Pillsionweb.com. **Buy Hydrocodone** and Vicodin Online. **Hydrocodone** relieves pain. Acetaminophen is a less potent pain reliever that increases ...
www.pillsionweb.com/ - 7k - [Cached](#) - [Similar pages](#)

[Top 10 hydrocodone links: cheapest prices, side effects, info, buy ...](#)
 ... <http://www.e-discountx.com/?r=s114/Hydrocodone> At PrescriptionAmerica.com
Buy Hydrocodone at PrescriptionAmerica.com. ... **Buy cheap Hydrocodone** online.
 ...
www.drug-prices-and-information.com/directory/H/Hydrocodone - 20k - Sep 16, 2004 - [Cached](#) - [Similar pages](#)

[buy hydrocodone from home - purchase hydrocodone online ...](#)
 - Click Here to order **Hydrocodone** Online - _____ Brand Name: **Hydrocodone/APAP**. The following product information ...
www.anzwers.org/free/pharmcast/ - 24k - [Cached](#) - [Similar pages](#)

[Xanax-Buy Adderall-Alprazolam-Vicodin-Hydrocodone](#)
 ... More. Xanax- Alprazolam Lortab-**Buy** Lortab **Hydrocodone-Buy Hydrocodone** Demerol-**Buy** Demerol codeine-**buy** codeine ativan-**buy** ativan. ...
www.pickyourpharmacy.com/ - 31k - [Cached](#) - [Similar pages](#)

[Buy Hydrocodone APAP Online, Cheap Prices](#)
Buy Hydrocodone APAP Online Cheap. **Buy Hydrocodone** APAP Online. Order **Hydrocodone** APAP Online **Hydrocodone** relieves pain. ... Copyrights. **Buy Hydrocodone** APAP. ...
hydrocodone-apap.t35.com/ - 22k - [Cached](#) - [Similar pages](#)

[Buy Diazepam Online](#)
 ... pregnancy vicodin and sex us.prescriptions valium Fioricet Online No Prescription GENERIC FIORICET Tramadol HCl **Buy hydrocodone** vicodin pills
valium-low-price.com

Sponsored Links

[Hydrocodone \\$20 Now](#)
 Free FedEx Shipping on All Orders
 Low Price Guarantee. US Pharmacy
www.usapharmacy.com

[Hydrocodone \\$20 Overnight](#)
 Medical Consultations & Free
 Overnight FedEx Ship on All Orders!
www.RefillRequest.com

[Buying Hydrocodone](#)
 Discussion forum about online
 pharmacies. Learn before you **buy**.
RxPharmacyForum.com

[Narcotic Pain Drugs](#)
Hydrocodone, Vicodin, Lortab,
 Oxycontin, Percocet, Codeine.
www.explainingmedicine.com

[Save - Hydrocodone](#)
 Before you get your prescriptions
 filled, read our free online guide.
www.infobert.com

[Pain Relief Solutions](#)
 How I relieved
 back pain naturally
www.mybacksolution.com

[Unbiased Hydrocodone Info](#)
 A Simple, easy to understand guide
 to **Hydrocodone**. Free and fast.
www.Consumers-Info.org

DRUG PRICES AND INFORMATION

Helping you locate the best drug prices and information

[About Us](#) - [Contact Us](#) - [Add YOUR Site](#) - [Link to us](#) - [Add us to your Bookmarks](#)

Drug Prices and Information

[Drug Prices and Information](#) > [H](#) > Hydrocodone

 Search

Top 10 Hydrocodone Results

[Buy Pain Medication From Home](#)

Simple And Affordable. Discreet Overnight Shipping. Nothing To Fax! No Doctor Visits. No Prior Prescription. Low Prices. US Doctor and Pharmacy. Hydrocodone(Watson), Vicodin, Diazepam, Others.

<http://www.e-discountrx.com?r=s114/>

[Hydrocodone At PrescriptionAmerica.com](#)

Buy Hydrocodone at PrescriptionAmerica.com. Ordering is easy, confidential, and secure. Order your online medications from a licensed U.S. pharmacist. Free Consultations. Order Today.

<http://www.prescriptionamerica.com/>

[Hydrocodone - COD ONLY - 99% Approval Guaranteed](#)

Buy Hydrocodone (Generic Vicodin) online with No Prescription, Free Consultations, 99% approval, Next Day Shipping with tracking. No Hidden Fee's, pay only medication and shipping costs. U.S. Pharmacy with U.S. physicians

<http://www.hydrocodonecod.com/>

[Hydrocodone - Watson](#)

In Pain? Need Pain Medication? US Pharmacy -US Doctors with Low Consult Fee. FREE SHIPPING!

<http://www.slimmeryou.com/>

[Order Hydrocodone Online - Onlinescripts.com](#)

Find real doctors and prescriptions online. It's fast, secure, and private. Overnight delivery available. Order your consultation now.

<http://www.Online-Scripts.com/>

[Buy Hydrocodone Hassle Free](#)

Order up to a 90 day supply of Hydrocodone from our exclusive pharmacies. Enjoy discreet deliveries to your home or office. Eliminate

N
E
W
S

HYDROCODONE

Order hydrocodone online from our U.S based licensed pharmacy. No prior prescription needed. No consultation fees. 2 Days shipping. Buy hydrocodone from the privacy of your own home. Still not convinced? Compare prices from the leading **hydrocodone** pharmacies. These pharmacies provide easy online consultations with No Consultation Fees!
Do not take acetaminophen and hydrocodone if you have taken a monoamine oxidase inhibitor (MAOI) such as isocarboxazid (Marplan), phenelzine (Nardil), or tranylcypromine (Parnate) in the last 14 days. Dangerous hydrocodone side effects could result. The most serious interactions affecting

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

hydrocodone. Avoid sleeping pills, tranquilizers, sedatives, and antihistamines except under the supervision of your doctor with hydrocodone. These medications also may cause dangerous sedation. Do not share acetaminophen and **hydrocodone** with others for whom it was not prescribed, since they may have a problem that is not effectively treated by hydrocodone.

[F.A.Q.](#) [Site Map](#) [Links](#) [Links Exchange](#) [Contact Us](#)



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

Online Pharmacy Consultations


- Easy to obtain
- Convenient

RXtoday.com - Netscape

File Edit View Go Bookmarks Tools Window Help

section 5 : your online medical consultation

Accurate information is required before any physician can write a prescription for any illness or condition. Once our physician receives this information, he will review it and either approve your prescription for Meridia or decline it.



If he declines your prescription, you will not be charged at all.

Your credit card will ONLY be charged if you are approved for this medication and your prescription is dispensed by our affiliated pharmacy.

Please tell our Physician a little about yourself :

What is your height (In Feet)? feet inches

What is your current weight (in lbs)? lbs

What is your Date of Birth? / /

Sex? Male Female

Smoking History

Do you smoke cigars or cigarettes? Yes No

If so, how many packs of cigarettes per day do you smoke? 0 1 2 3 More

How long have you been smoking? years

Do you consume more than 2 servings of alcohol a day? Yes No

Your General Medical History

Have you had a complete physical exam with blood tests within the last year? Yes No

How is your blood pressure? Normal High Low Controlled with Medication Dont Know

Do any diseases or disorders run in your family? Yes No

If yes, please specify:

Do you consider anything else in your medical history to be relevant? Yes No

If yes, please specify:

Please list all over-the-counter and prescription drugs you are currently taking and the length of time you have been taking them. Enter None if you are not taking any.

Are you allergic to any medications? Yes No

If yes, please specify:

Do you suffer from any of the following problems?

Coronary Artery Disease Congestive Heart Failure Valvular Heart Disease

Problems with Online Consultations

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



No Prescription Needed & No Questions Asked

Percodan Oxycodone Morphine Codeine

Valium Darvon Hydrocodone Vicodin



Components necessary for Domestic Rogue Internet Operation

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



Domestic 'Rx' Flow

- C** Consumer
- Dr.** Doctor
- Rx** Internet Pharmacy
- WC** Web Company
- WS** Website Server
- S** Shipper

1. **Consumer** in Montana orders hydrocodone on the Internet

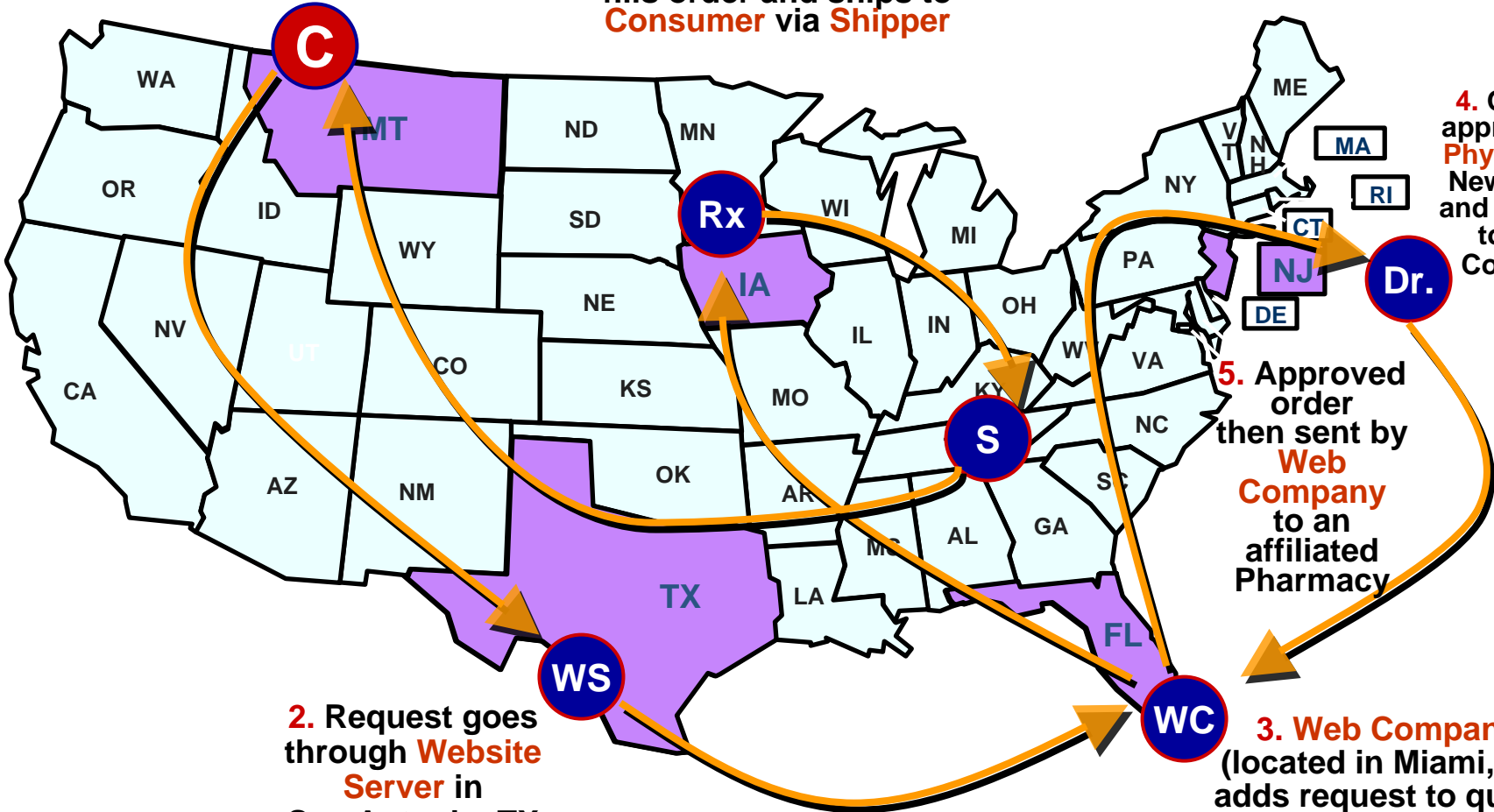
6. **Pharmacy** in Iowa fills order and ships to **Consumer** via **Shipper**

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



How Regulatory/Criminal Enforcement and Legislation Changed the Landscape

Cut off the Supply

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

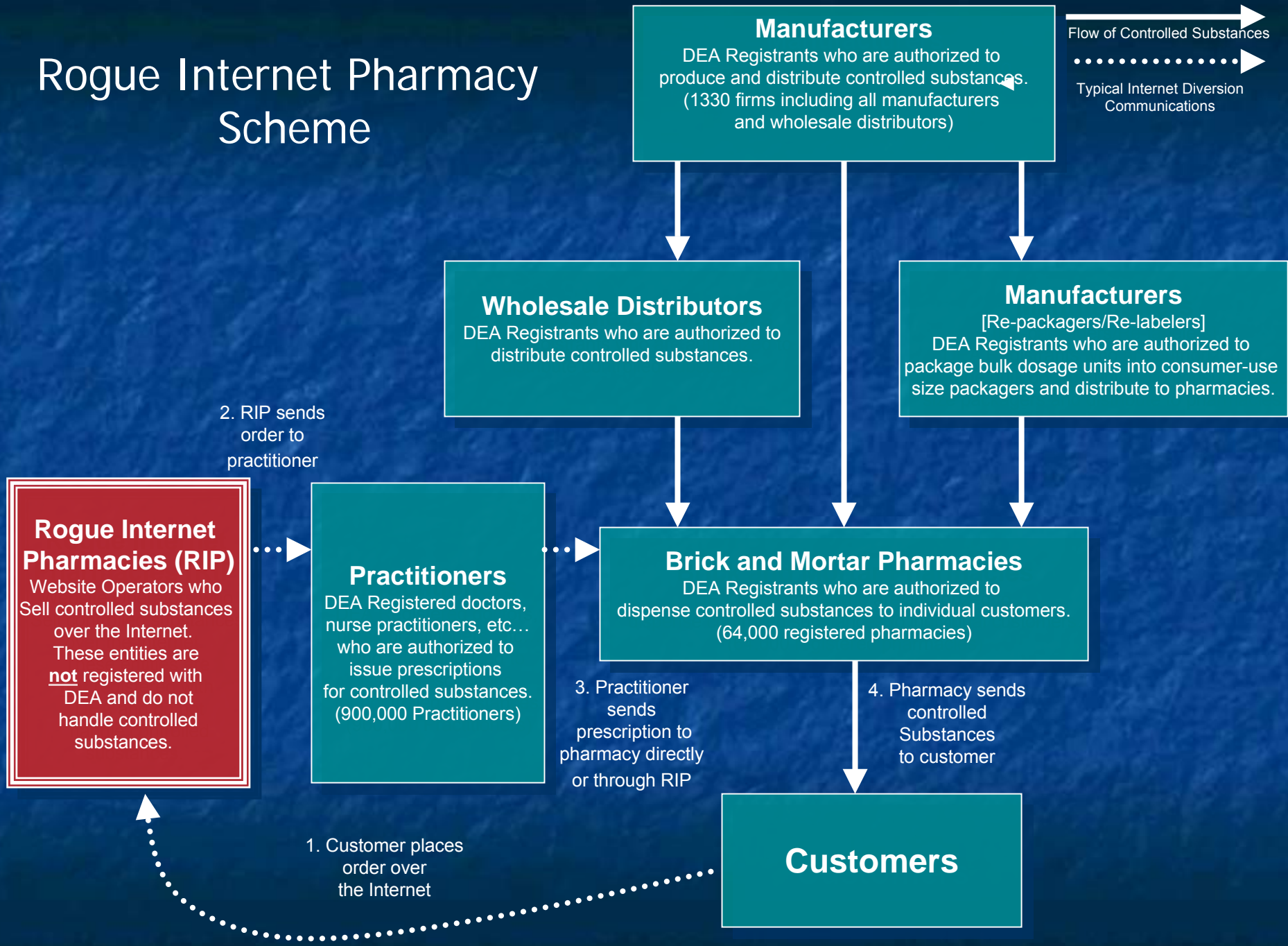
- Orders To Show Cause
- Immediate Suspensions

The Dirty Dozen

PHARMACIES CLOSED IN 2007 following Baywatch / Lightning Strike	Total 2006 Dosage Units
1.	15,596,380
2.	9,082,010
3.	9,081,976
4.	4,733,290
5.	4,220,840
6.	4,564,480
7.	1,988,600
8.	1,656,450
9.	2,731,420
10.	1,962,620
11.	793,350
12.	1,051,500
TOTAL DOSAGE UNITS	57,462,916

Names of the pharmacies have been left off due to ongoing investigations

Rogue Internet Pharmacy Scheme



Actions Taken

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



Cardinal Health Builds Out its 'Suspicious Order Monitoring Program':

*Settlement with DEA
results in a top-to-bottom
overhaul of controlled-
substances handling*

Illicit Online Pharmacies Get Congressional Attention:

*Ryan Haight law would
restrict controlled-
substances sales*

TOP NEWS

Current Legislation

■ Internet Legislation

- S-980
- H.R. 6353

■ Ryan Haight Online Consumer Protection Act

(signed by the President October 15, 2008)

- Requires online pharmacies to obtain special DEA registration
- Requires identifying information to be posted on the web site
- Defines terms such as “online pharmacy” and “telemedicine”
- Expands the definition of a valid prescription to include at least one in-person medical evaluation of the patient
- Penalty enhancements
- Reporting requirements regarding Rx sales

Ryan Haight Online Pharmacy Consumer Protection Act

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

(April 13, 2009)

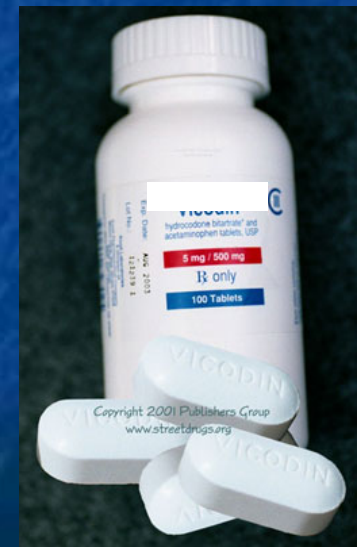
Adaptation

- From questionnaires - to asking for medical records
- From the doctor sending the Rx to the rogue pharmacy - to sending it to the "patient"
- From doctors located in other states - to sending "patients" to doctors within the same state

Commonly Abused Prescription Controlled Substances

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



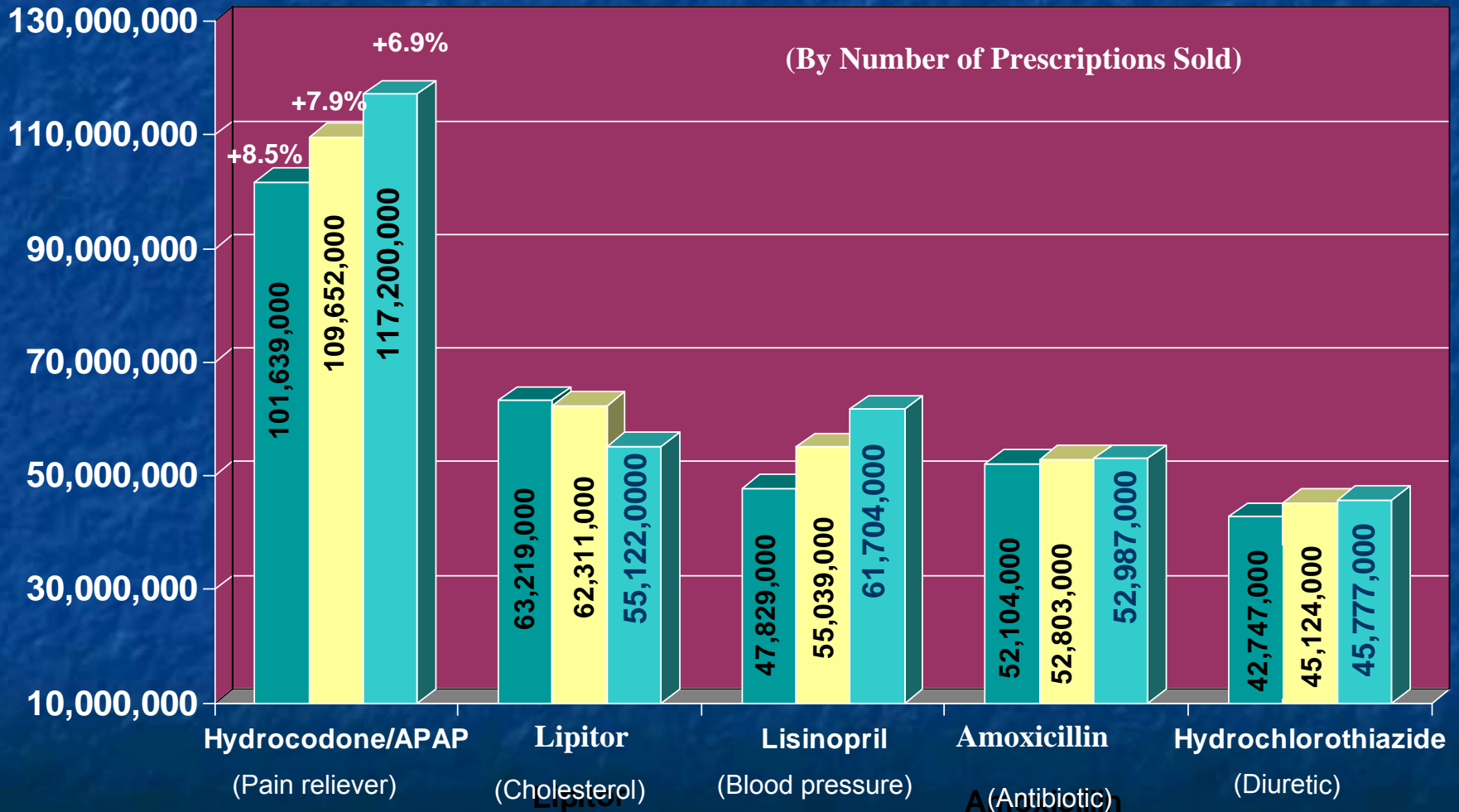
*SOURCE: JAMA, January 17, 2007 – Vol 297, No 3, *Opioid Prescriptions Soar*

Hydrocodone Growth vs. Population Growth 1990-2007

- Between 1990 and 2007
 - 21% growth in population
- Between 1990 and 2007
 - *280% increase in the distribution of hydrocodone

Top Five Prescription Drugs Sold in the U.S. (2005-2007)

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



Source: Drug Topics
Revised September 19, 2008

■ 2005 ■ 2006 ■ 2007

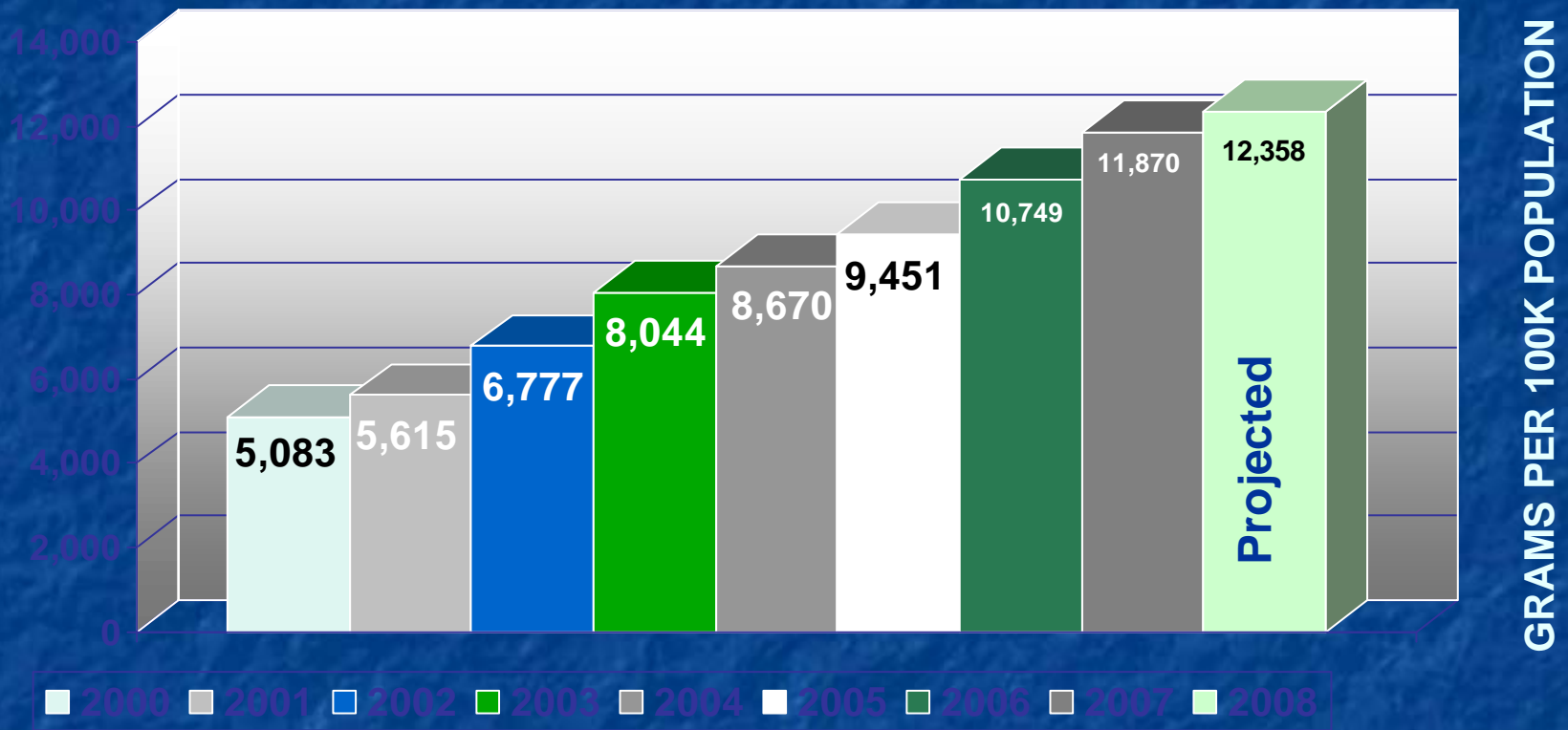
*In 2007 Levothyroxine was #5

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%

Hydrocodone Distribution* CY2000-2008 U.S. Average



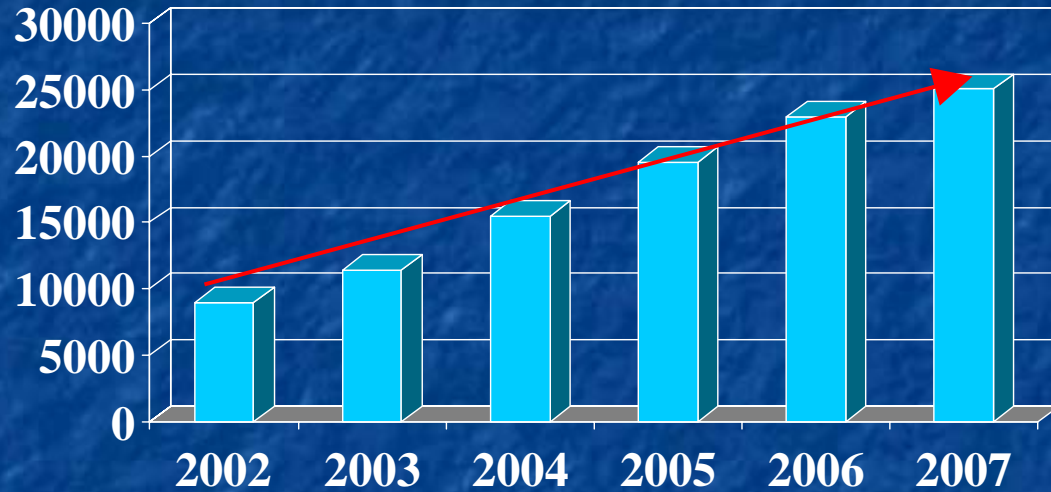
* Includes sales to Retail Registrants, i.e. pharmacies, hospitals, practitioners, teaching institutions, and mid level practitioners

* 01/01/2008-06/30/2008

National Forensic Laboratory Information System (NFLIS)

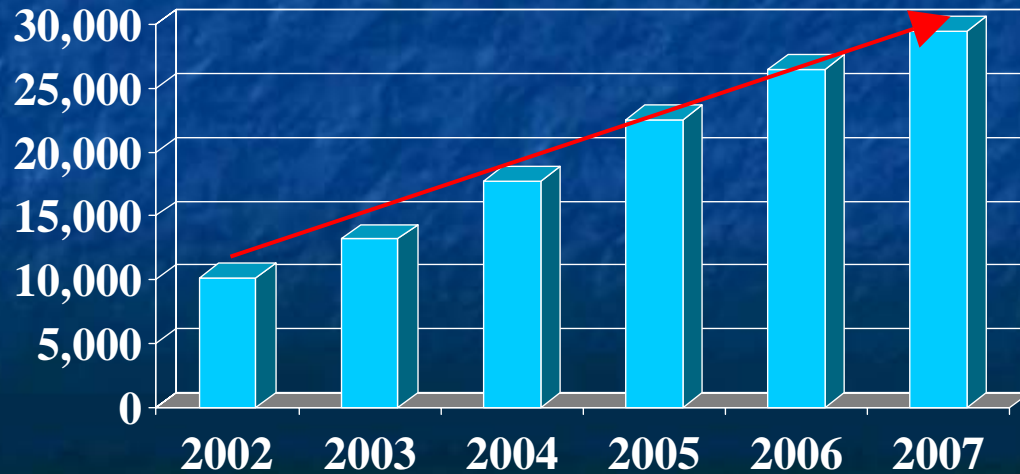
Hydrocodone

Cases



Hydrocodone

Exhibits



BENZODIAZEPINES

Benzodiazepines

- First benzodiazepine, chlordiazepoxide was approved for use in the early 1960's
- Benzodiazepines, as a class, are one of the most widely prescribed drugs in the world
- They are approved in the U.S. to treat anxiety, insomnia, and seizures (Sch IV depressant under the CSA)
- Adverse effects include: amnesia, restlessness, delirium, aggression, depression, hallucinations, and paranoia

NFLIS National Data - 2006

Benzodiazepines

	Number	Percent
Alprazolam	25,617	62.85%
Clonazepam	6,755	16.56%
Diazepam	6,314	15.48%
Lorazepam	1,574	3.86%
Temazepam	326	0.80%
Chlordiazepoxide	100	0.25%
Triazolam	50	0.12%
Flunitrazepam	35	0.09%
Midazolam	12	0.03%

Alprazolam Xanax[®] (Z-bars)

- 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

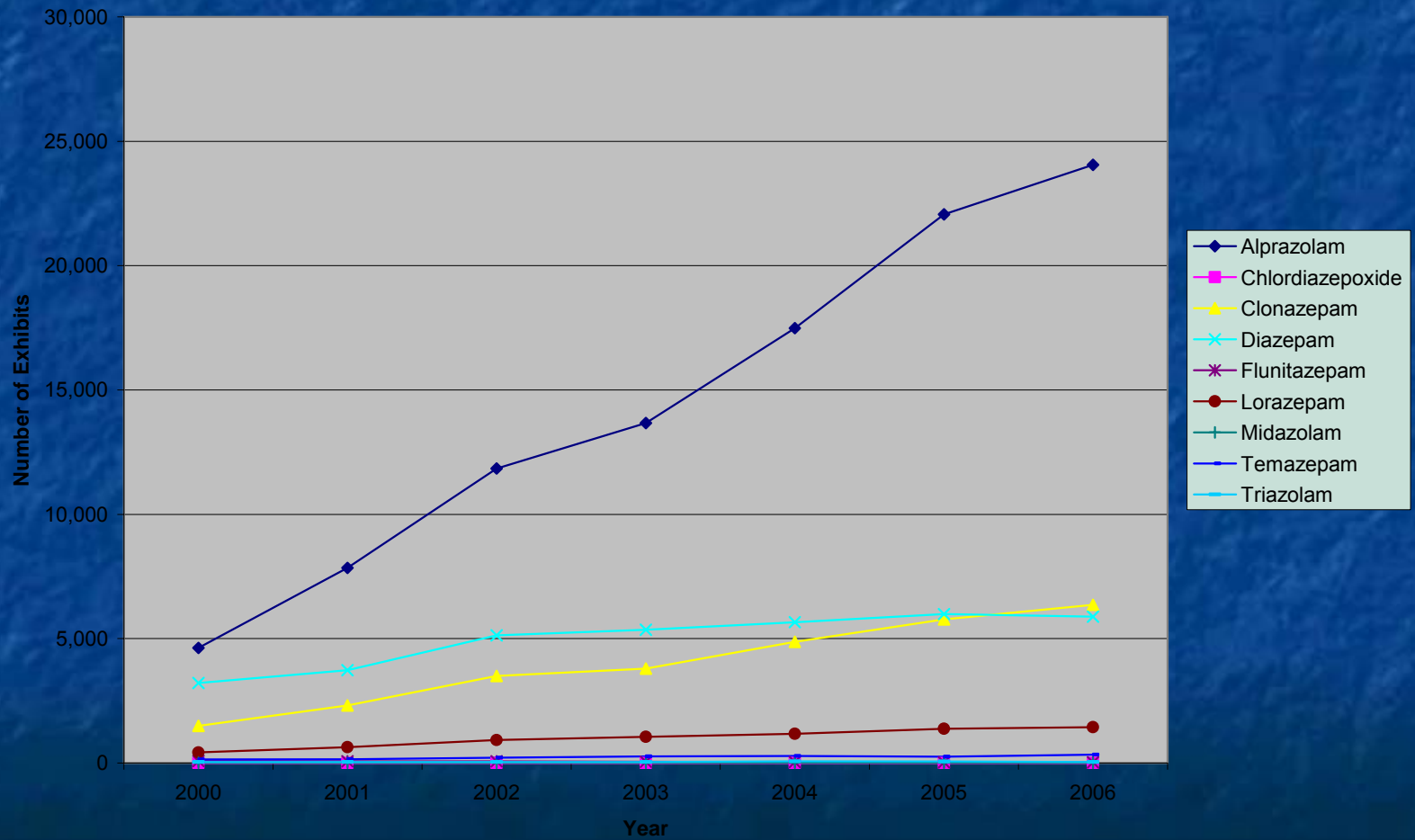


Statistical Data

- From 2001 to 2006, the number of seizures for alprazolam increased from 17,926 to 29,143 (62% increase)
- From 1995 to 2002, Emergency Department visits involving benzodiazepines increased 41% and from 2004 to 2005 they increased 19.4%

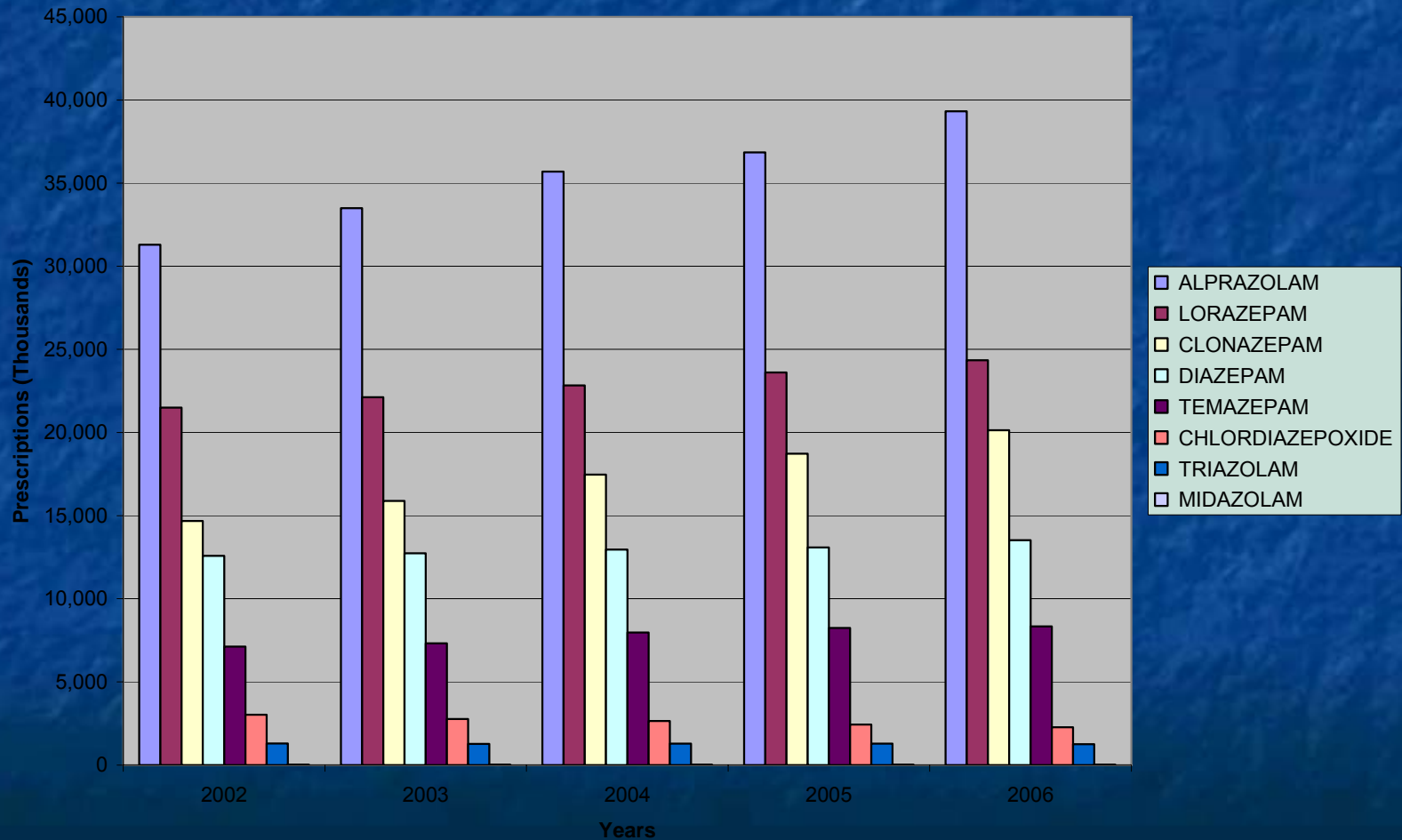
State and Local Seizure Data

Benzodiazepines Seizures by State/Local

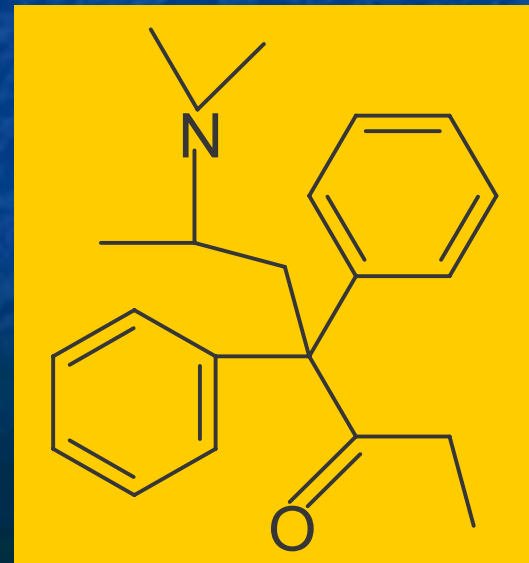


Prescription Data

Dispensed Prescriptions by Year from IMS Health



METHADONE



One Pill can Kill



CE Article: JACCME, CMI, ACEEI 1 CE credit for this article

By Jonathan J. Lipman, PhD

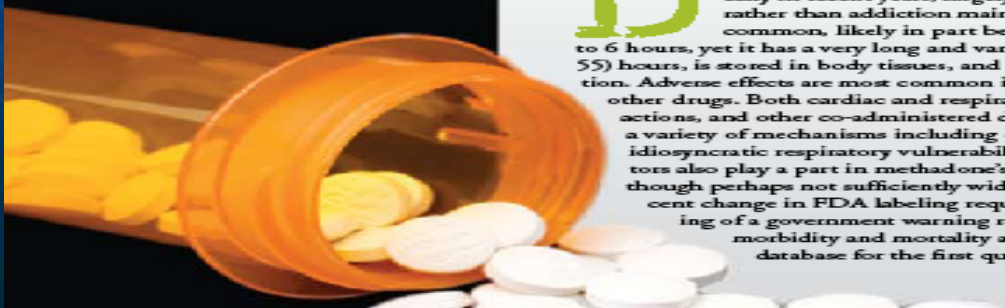
THE METHADONE POISONING "Epidemic"

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

Name _____ Date _____
Address _____

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.”

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



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

from drug treatment centers. Or it could lend credence to the prevailing view that more training is required for private physicians who prescribe methadone for pain.

At least 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

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

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

Danir 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 10. Toxicology tests showed the boy died from a massive methadone overdose. Masters later admitted that he had left the boy and his 4-year-old brother alone in the bathroom with a 100-milligram bottle of the prescription narcotic pain reliever. He returned 15 minutes later to find Benjamin holding the bottle.

Masters told police in March he didn't know what had happened, but he later told them this account. He was arrested in May.

— Linda Jarman
ljarman@wex.net

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 from AIDS.

"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 and Sheriff's Investigator Gus Scan applauded the "quick response" of school staff and aides 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.

N.H. drug deaths soaring

Alarmed officials point to methadone

By ANNMARIE DIMMINS
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 talk about it like 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 likes to raise the crime level. He said, "Addicts are going into hospitals, and they're coming from family members. All they are going to come home with is a series of life issues."

Tom Moyer, the state's chief medical examiner, began looking at the state's drug overdose deaths a few years ago. He was unavailable for comment but shared his concerns. In 2005, he said, there were 117 drug deaths in New Hampshire, and that number rose to 168 in 2007. Each year, methadone was 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. Last year, the police recorded 12 drug deaths, at least two of which 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

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 are closely monitored, the police said. It's almost impossible to use it to sell.

On the street, however, addicts can get multiple doses. Patients are given methadone supply when they fill a prescription, making it easy to resell. The police said they can't trace the source or sell their tabs on the street.

Laconia knows this firsthand, said police Chief Michael Hilliard. In that city last year, a 26-year-old man died of methadone 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 we're seeing these overdoses is that the doctors aren't prescribing methadone for their patients. It's not available."

Moyer's another problem with methadone, Hilliard and Moyer said, is that 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.

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.

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 prescribed for chronic pain. In those cases, many days are given many days' supply when they fill a prescription.

On the street, however, addicts can get multiple doses. Patients are given methadone supply when they fill a prescription, making it easy to resell. The police said they can't trace the source or sell their tabs on the street.

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, 49, of Gil-

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	2005	GENDER	AGE	DRUG INVOLVED
Feb. 10	F	51	Morphine and oxycodone	Jan. 5	M	24	Undetermined drugs
June 26	M	33	Drug cocktail, including oxycodone, morphine and other drugs	Jan. 7	F	28	Multiple drugs, including a suicide
2007	GENDER	AGE	DRUG INVOLVED	March 30	M	37	Cocaine
March 15	M	33	Multiple drugs, including hydrocodone, oxycodone and methadone	April 7	F	47	Methadone
May	F	45	Multiple drugs, including alcohol	April 15	M	28	Methadone and alcohol
July 26	M	56	Salicylates, death row, suicide	May	F	59	Methadone
Aug. 5	M	Alcohol	near drug	May 15	F	59	Undetermined drugs
Aug. 6	F	28	Opiates	2004	GENDER	AGE	DRUG INVOLVED
Sept. 2	M	45	Methadone	March 16	M	23	Methadone
Sept. 2	F	41	Morphine and other drugs	March 27	F	35	Morphine suspected
Nov. 4	M	30	Methadone	May 24	M	30	Fentanyl suspected
Nov. 17	F	49	Undetermined drugs	May 28	F	46	Methadone and other drugs
Nov. 17	F	94	Morphine and other drugs	July 11	M	43	Hydrocodone suspected
Dec. 1	F	41	Methadone	Sept. 4	M	21	Klonopin suspected
2006	GENDER	AGE	DRUG INVOLVED	Nov. 1	M	32	Opiates
Feb. 24	M	40	Multiple drugs	Nov. 18	M	36	Multiple drugs
				Nov. 29	M	44	Undetermined drugs
				2003	GENDER	AGE	DRUG INVOLVED
				Aug. 9	M	39	Oxycodone

ford, and Anthony Shaner, 33, of Laconia, with drug sales where death resulted. Each is accused contributing to separate overdoses. Rockingham County's deputy county attorney, Tom Heid, 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 like this, 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 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

New Hampshire drug deaths 1995-2007



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

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 Barthelemy 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.

Man faces charges in woman's overdose death

GLEOVERSVILLE — 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, Groversville 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 deadly weapon.

He was arraigned Tuesday in Fulton County Court and sent to the county jail in lieu of \$25,000 bail.

—David Blain

Teen dies of suspected overdose

BY REX HALL JR.
rhall@kalamazoo Gazette.com
353-7784

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 50 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 Maloney, asked Superior Court Judge Charles W. Er-

vin for a four-year prison sentence.

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

Tracy Mae, 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," Mae 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.

Angelica Martinez:
(619) 293-1317;
angelica.martinez@uniontrib.com

Bluefield Daily Telegraph

William Randy Deason
Publisher

Thomas A. Colley
Business Editor

Samuelson Perry, Managing Editor

Special Advertising Section
Special Advertising Editor

Senior Editor
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 A.R.V.)

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 2010 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 432 accidental overdose autopsy reports, excluding suicides and overdoses, the Associated Press reported.

The report found that one-third of the prescription drugs taken during the fatal incidents were being used as a result of 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.

Alan 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



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.

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.

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.

DIGEST

Charge is filed in drug death

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

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

According to the complaint:

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

Ian Dieter-Fox, another resident of the apartment, told police that Fristoe told him that "Jamie" had given him some pills, but he hadn't taken them yet.

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

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

Swenby faces up to 25 years in prison and a fine of up to \$100,000.

Woman held on bail in methadone death

BY ANDY NELESEN
anelesen@caribaypress.com

A 41-year-old Occochee woman accused of providing the methadone that led to a 22-year-old man's fatal overdose in May is facing a first-degree reckless homicide charge.

Joyce Madison made her initial appearance in Brown County intake court Friday and was ordered held in lieu of \$75,000 cash bail. She is due in court to complete her initial appearance Thursday.

Clearing staff found Jordan Jamison dead in a Green Bay motel room on May 24. Investigators found no signs of foul play but did notice signs of a drug overdose, according to the criminal complaint filed Thursday.

Jamison had an unlit cigarette in his hand, indicating that he died suddenly, the complaint said.

In June, detectives learned Madison told Jamison's mother that she had given Jamison methadone the night prior to his death, the complaint said.

In July, police learned that when Madison found out Jamison had died, she asked if the police would be coming to talk to her and that she did not think she had given Jamison enough drugs for a fatal dose, the complaint said.

Toxicology tests revealed methadone, the anti-depressant fluoxetine, marijuana and amphetamines in Jamison's system, according to the complaint.

The methadone in Jamison's system caused his death, according to Dr. Mark Wittek, the pathologist who conducted Jamison's autopsy.

Brown County Assistant District Attorney Kevin Greene characterized the matter as a "confession case."

Guy Grabner, Madison's fiancé, said he doesn't believe Madison provided the drugs, but rather that Jamison stole them while at Madison's house a day earlier in sleep and shower.

Grabner said Madison

was undergoing methadone treatment over the last year for a painkiller addiction.

"She was really cleaning up her act," he said.

400 Greenley Road
Sonora, CA 95370



The Union Democrat

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.

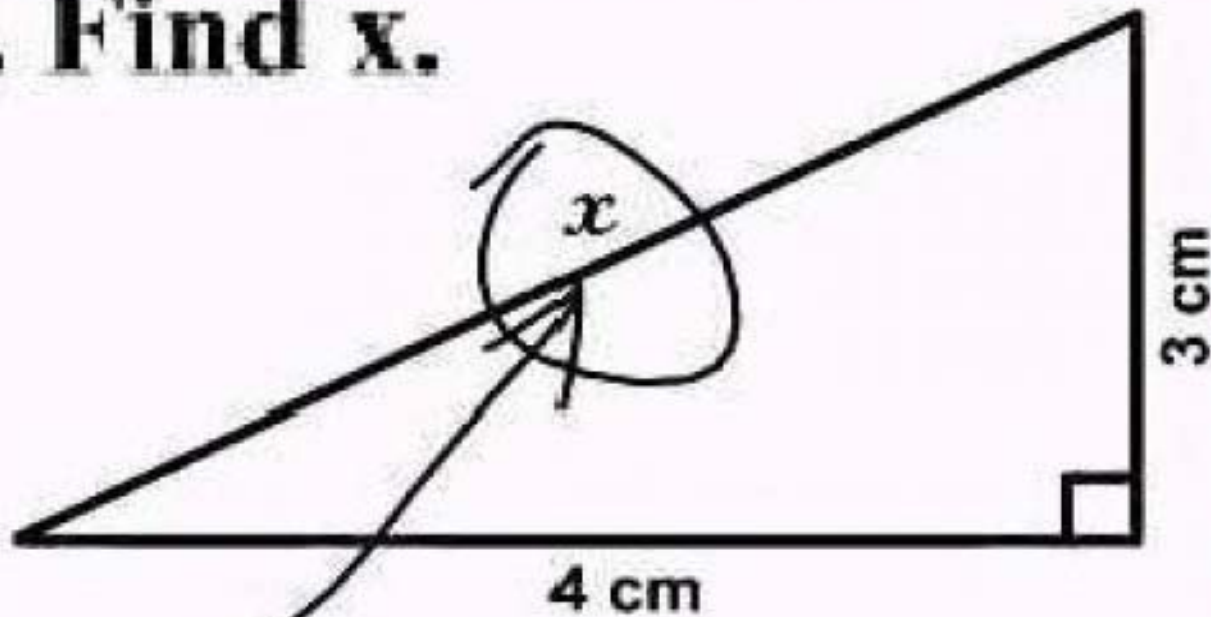
"It's a national issue, but we're in the

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 PAGE 2

3. Find x .



Here it is

SIMPLICITY

The simplest solutions are often the cleverest
They are also usually wrong

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

INDICATIONS

- Pain Treatment
- Narcotic Addiction Treatment/Maintenance

Dosage Forms

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

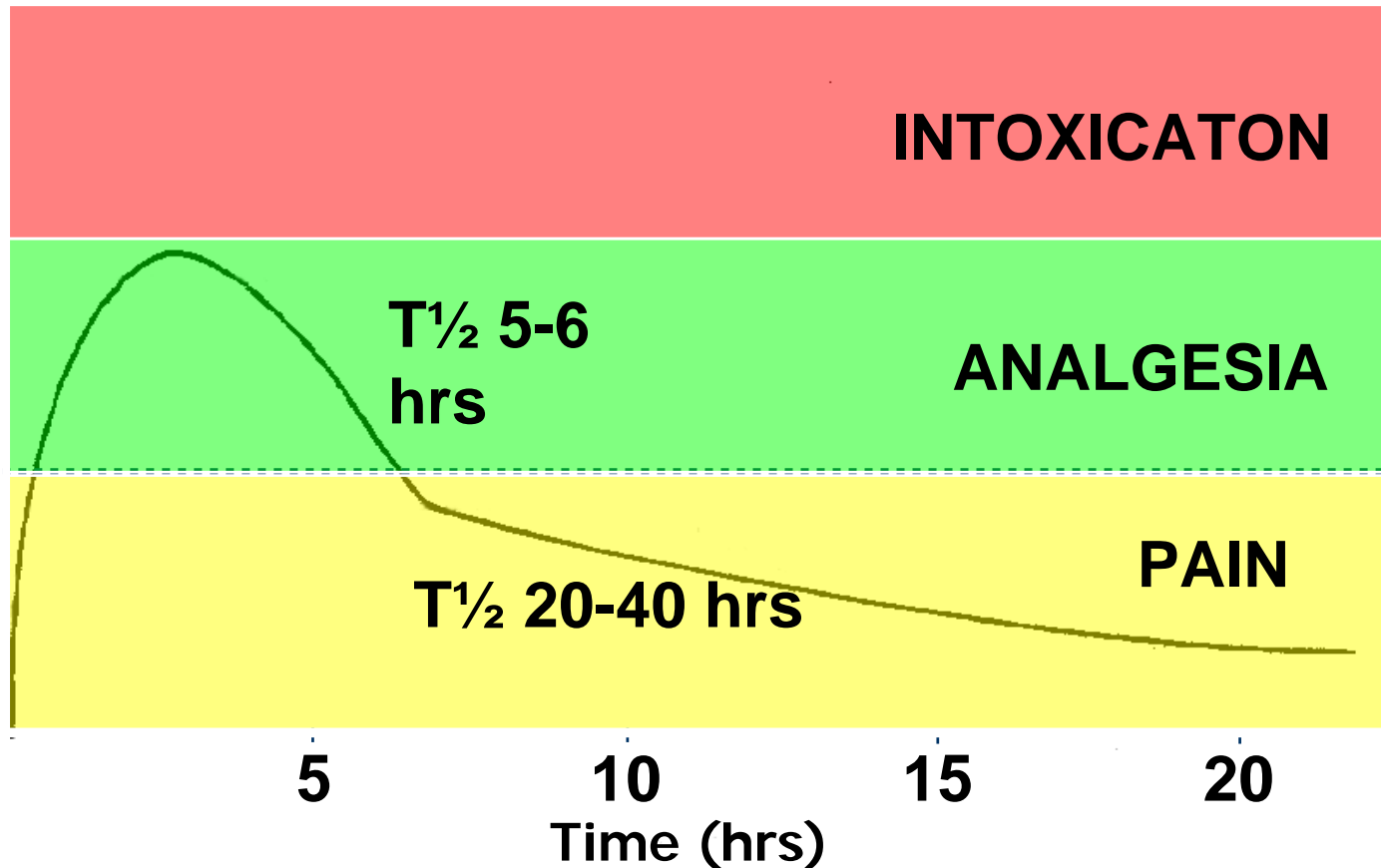
Methadone - Pharmacology

- Methadone belongs to pharmacological class called "Opioids"
- **Opioids** (e.g., hydrocodone, oxycodone, morphine, hydromorphone, fentanyl) are among the most potent analgesic drugs and are widely used
- **Opioids** are used in the management of acute and cancer-related pain, and chronic non-cancer pain
- **Opioid analgesics** affect number of systems – CNS, cardiovascular, GI tract, Immunological etc.

Methadone – Analgesia

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

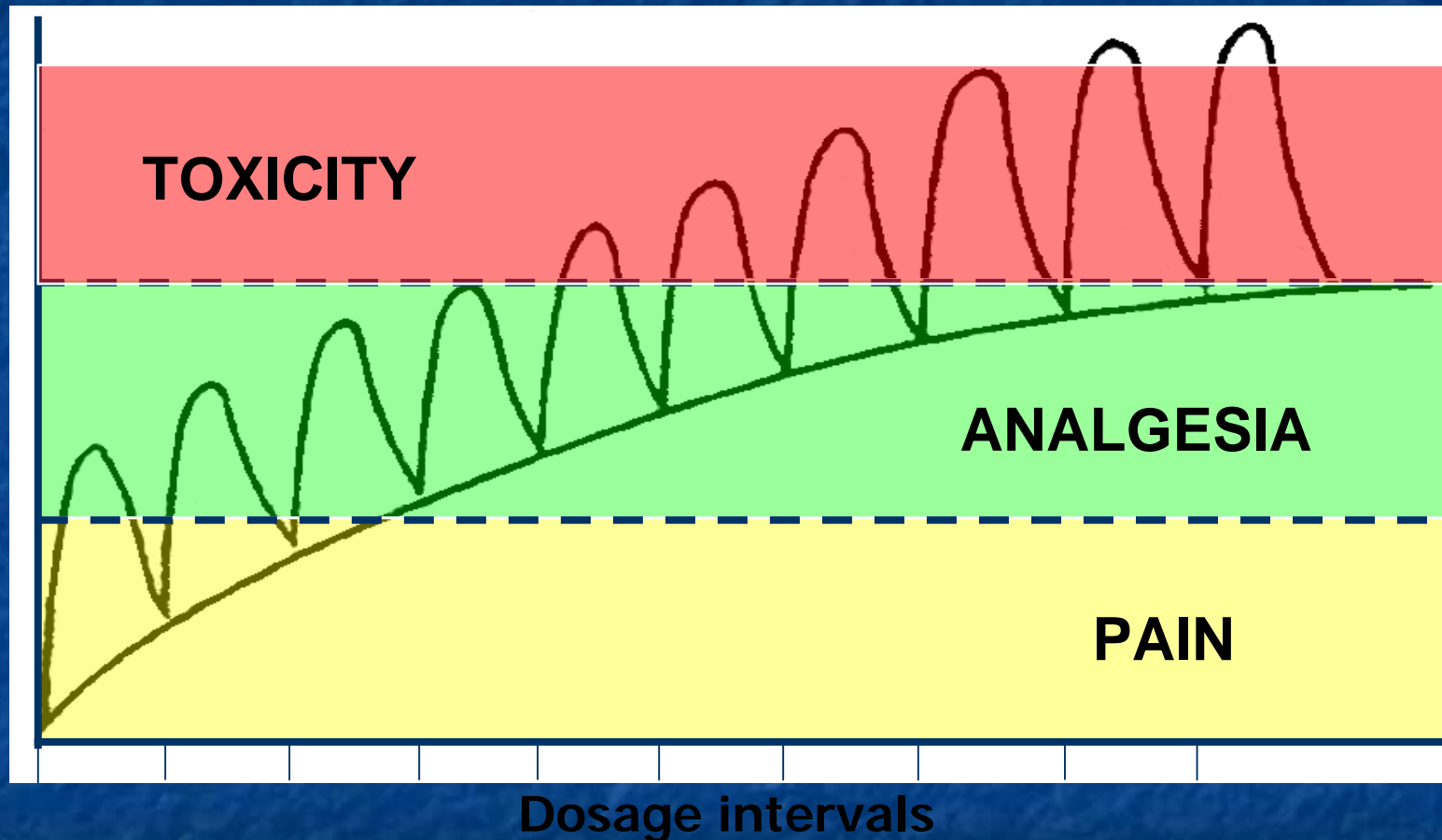
Methadone Single Dose Kinetics



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 from CSAT, SAMHSA

Fixed Methadone Dose Interval



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 from CSAT, SAMHSA

Methadone Use in Pain Management

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

Methadone - Toxicity

- **Respiratory depression**
 - Major hazard (Similar to other opioid analgesics)
 - Respiratory depression typically occurs later and persist longer than its peak analgesic effects
- **Drug Interactions**
 - CNS depressants (Alcohol, other opioids or CNS depressants)
 - CYP3A4 inhibitors (some antifungal agents, macrolide antibiotics, and SSRIs)

Methadone Deaths– Two Major Mechanisms

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

Methadone Mortality Assessments by SAMHSA- Findings

- SAMHSA convened two meetings (2003 and 2007) to assess the factors behind increase in methadone related deaths
- Accumulation to toxic levels of methadone during the start of opioid treatment or pain management due to overestimation of tolerance and methadone's long, often variable, half-life.
- Misuse of diverted methadone by individuals with little or no opioid tolerance.
- Synergistic effects of methadone combined with other CNS depressants (i.e., alcohol, benzodiazepines or other opioids).
- Increasing use of methadone in pain management may be an important contributing factor

Who is Prescribing Methadone?

5 and 10 mg tablets

Rx

Top Prescribers:

- Anesthesiologists
- Family Practitioners
- Internists
- Osteopaths
- Physical Med. & Rehab
- Neurologists
- Nurse Practitioners

40 mg diskettes Rx

Top Prescribers:

- Family Practitioners
- Anesthesiologists
- Internists
- Osteopaths
- Physical Med. & Rehab
- Nurse Practitioners
- General Practitioners

Source: IMS Health, National Prescription Audit, November 2006

METHADONE
POISONING/DEATH
DATA

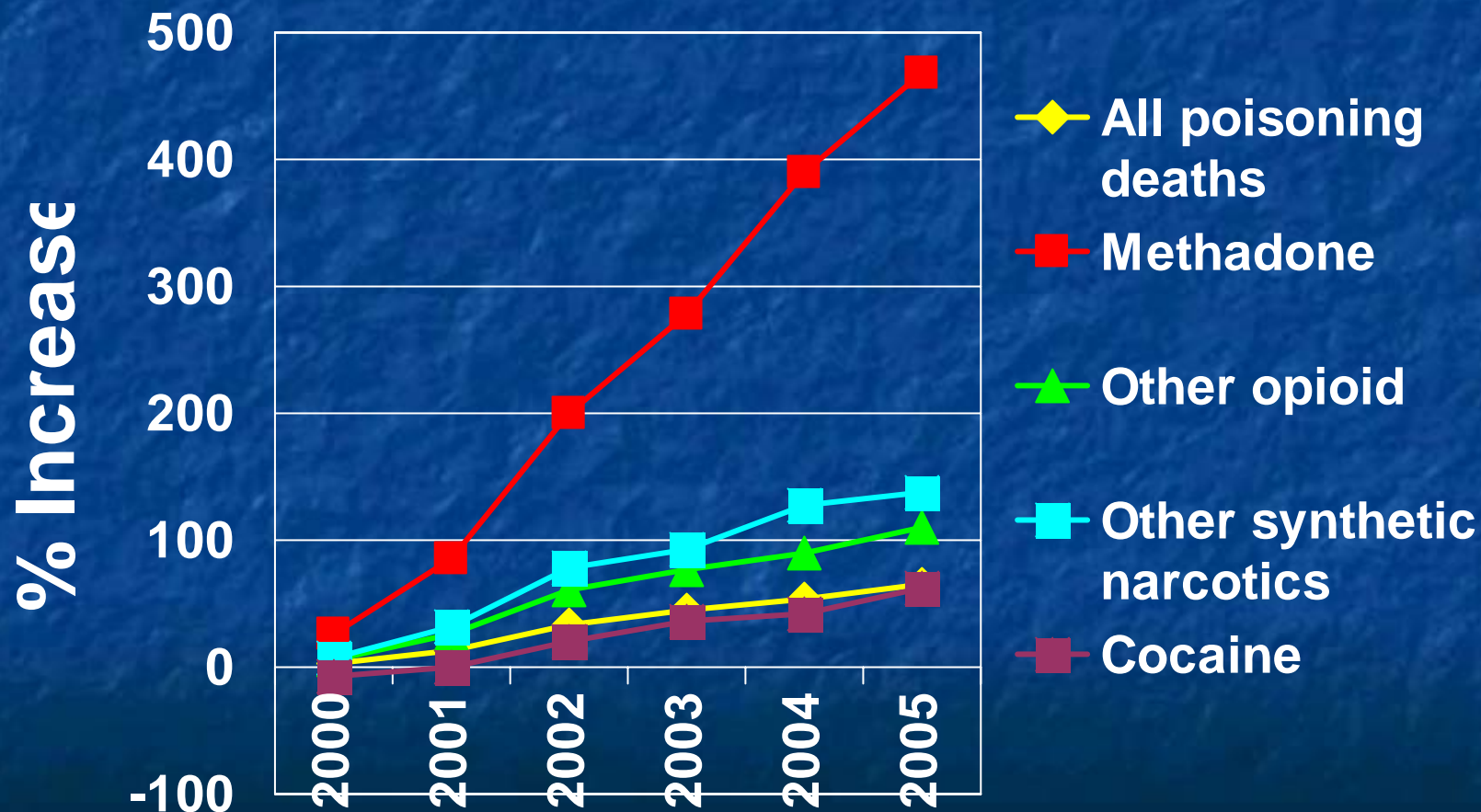
NFLIS National Data - 2006

Narcotic Analgesics

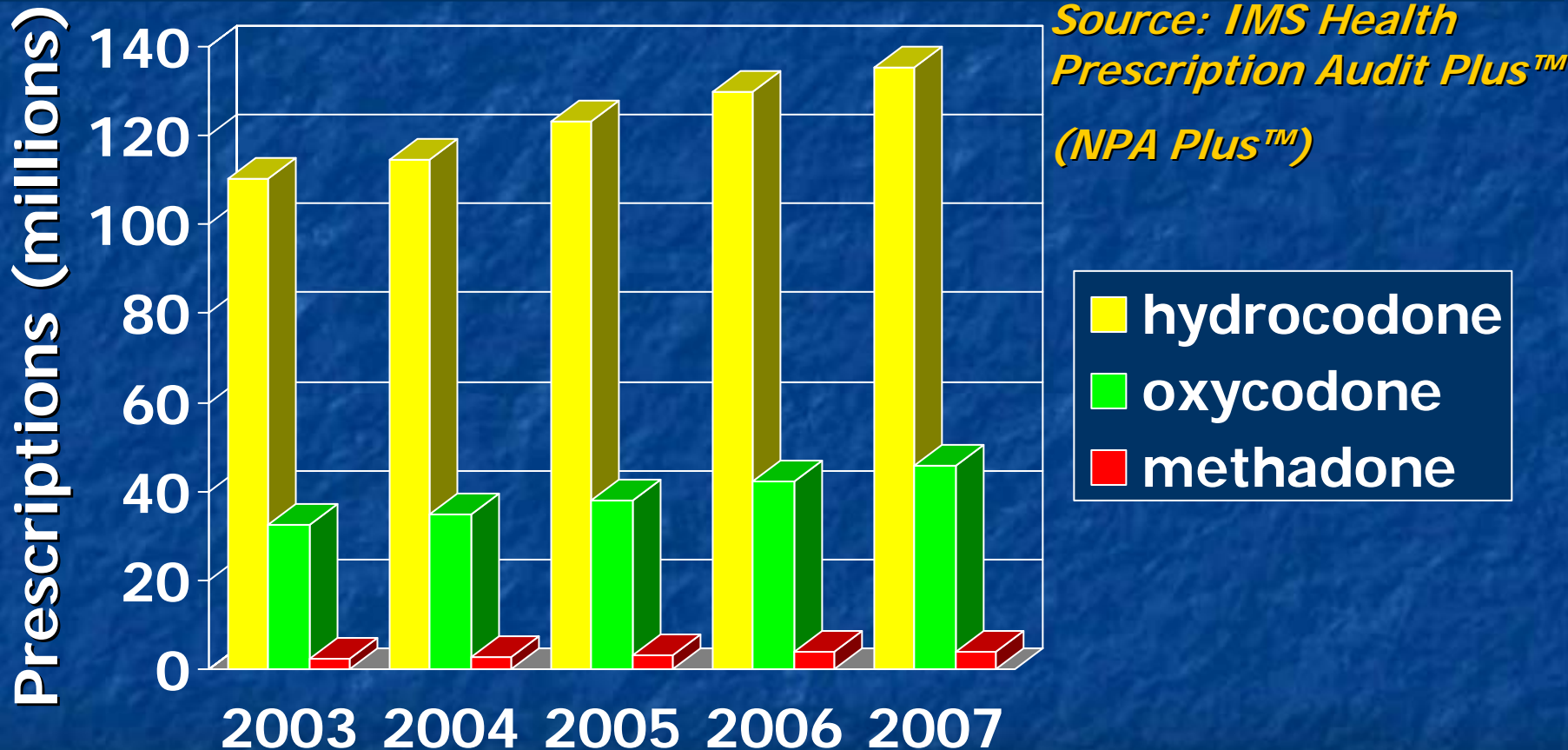
	Number	Percent
Hydrocodone	26,017	38.85%
Oxycodone	19,923	29.75%
Methadone	7,023	10.49%
Morphine	3,887	5.81%
Codeine	2,597	3.88%
Propoxyphene	1,488	2.22%
Hydromorphone	1,303	1.95%
Dihydrocodeine	1,290	1.93%
Fentanyl	1,270	1.90%
Buprenorphine	1,113	1.66%

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

Source: CDC



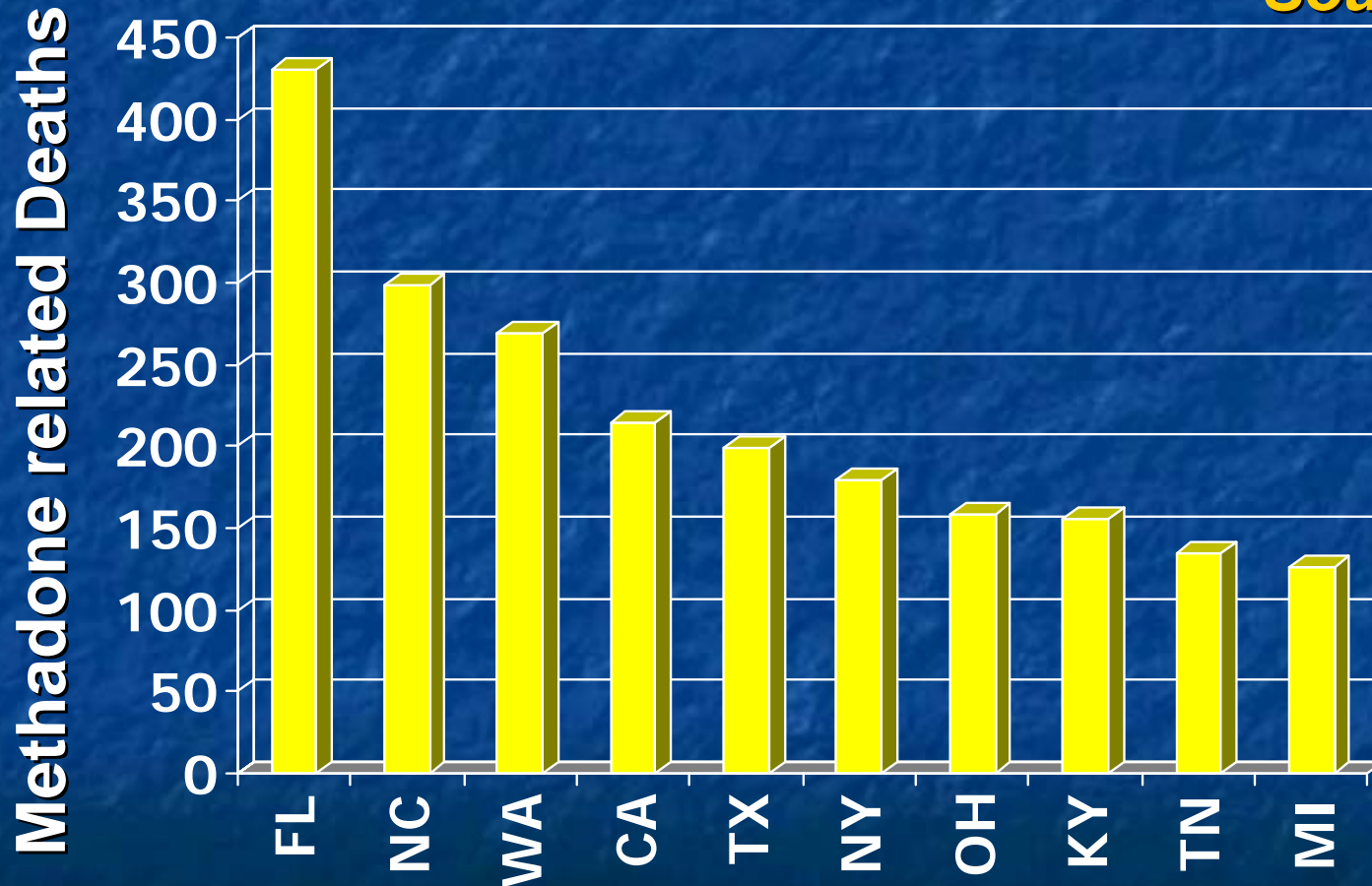
Total Prescriptions – Selected Opioid analgesics



Note: In 2006, there were about 33-fold more hydrocodone prescriptions, 11-fold more oxycodone prescriptions compared to methadone prescriptions

Methadone Related Deaths - Top 10 States (2005)¹

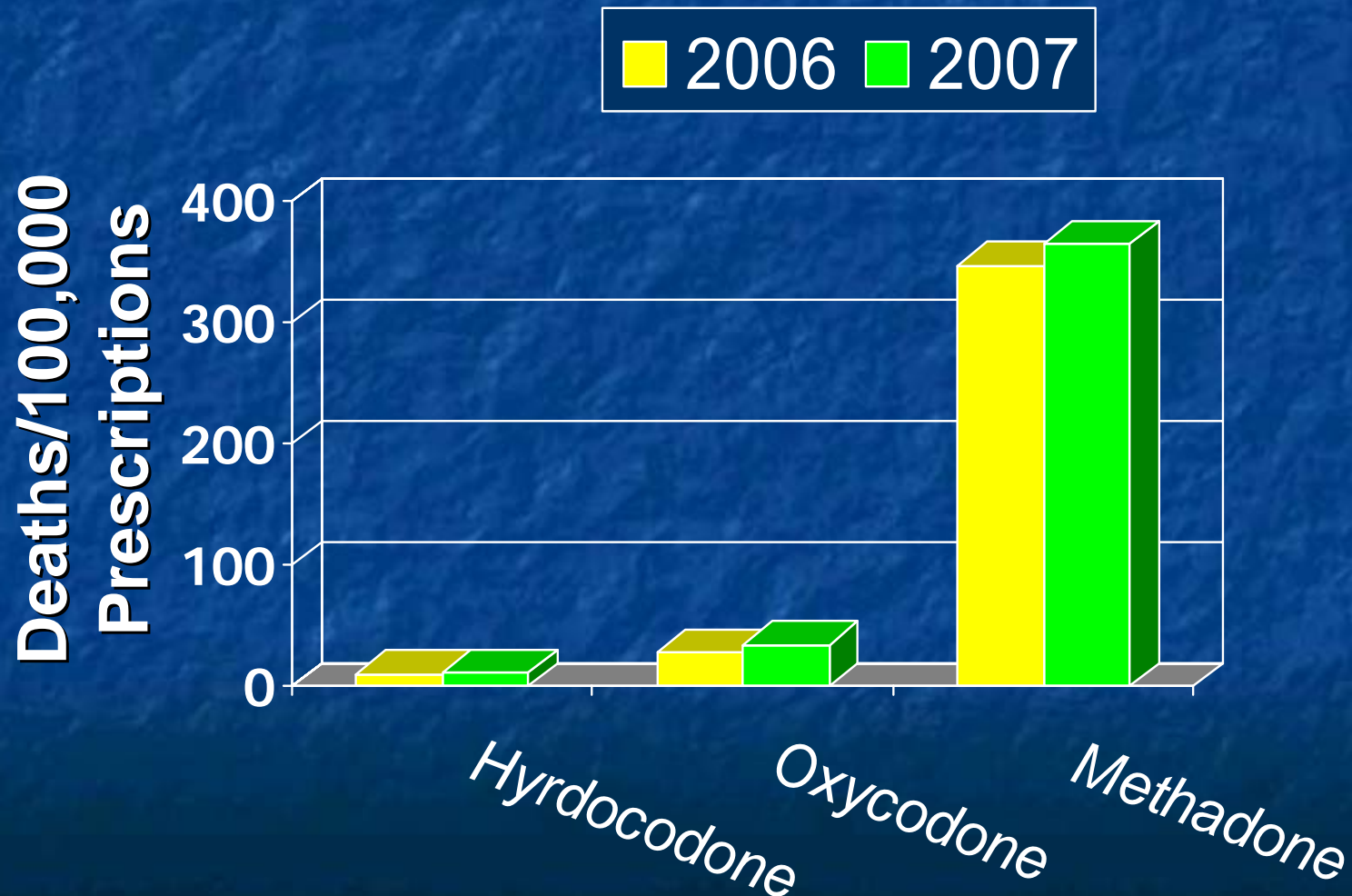
Source: CDC



¹ Death certificate listed methadone as contributing to the death. Underlying cause of death is all poisoning, regardless of intent

Deaths/100,000 Prescriptions in Florida

Source: *FDLE and NPA Plus™*

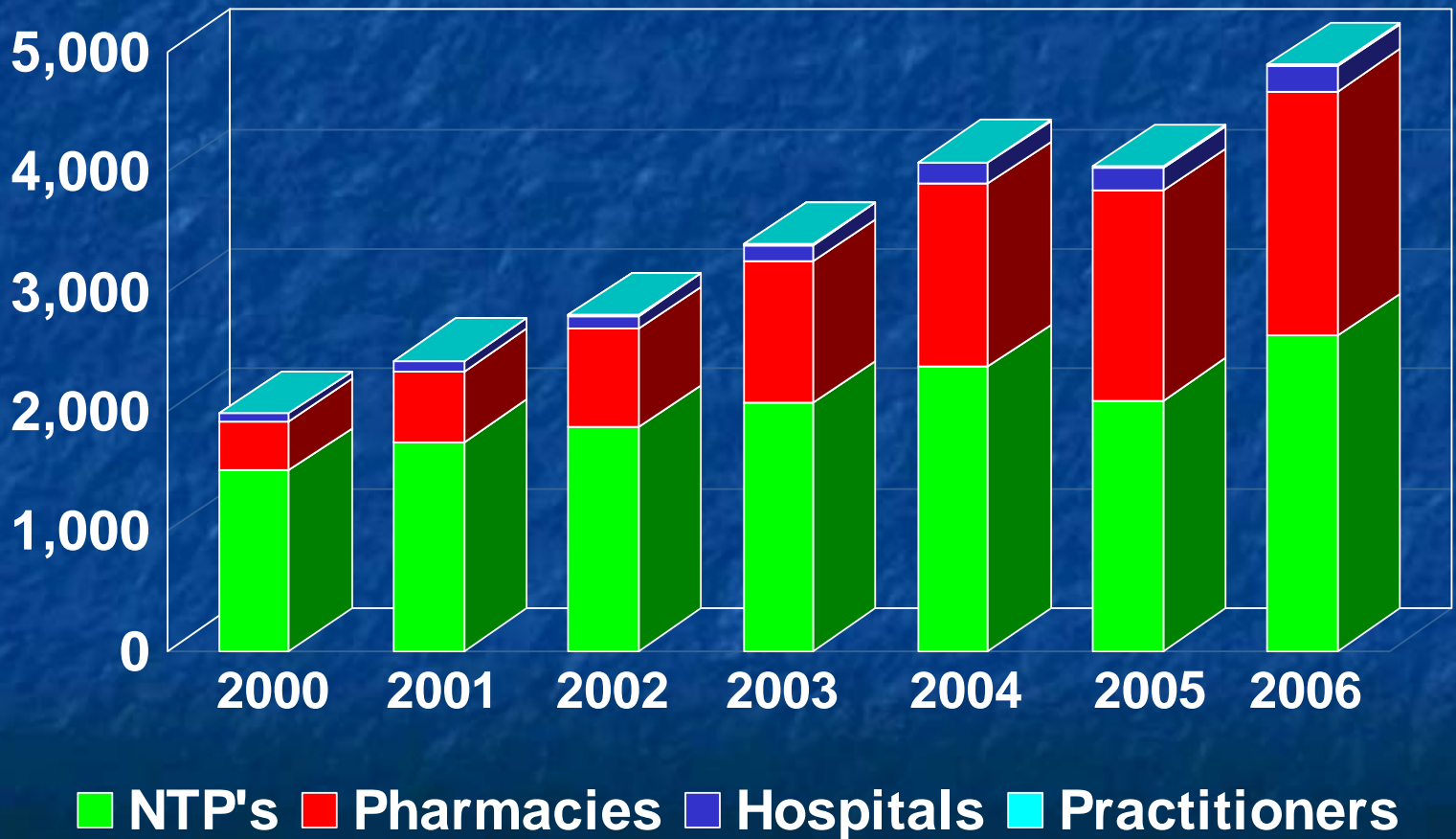


Methadone Distribution Data

Methadone Distribution by Business Activity

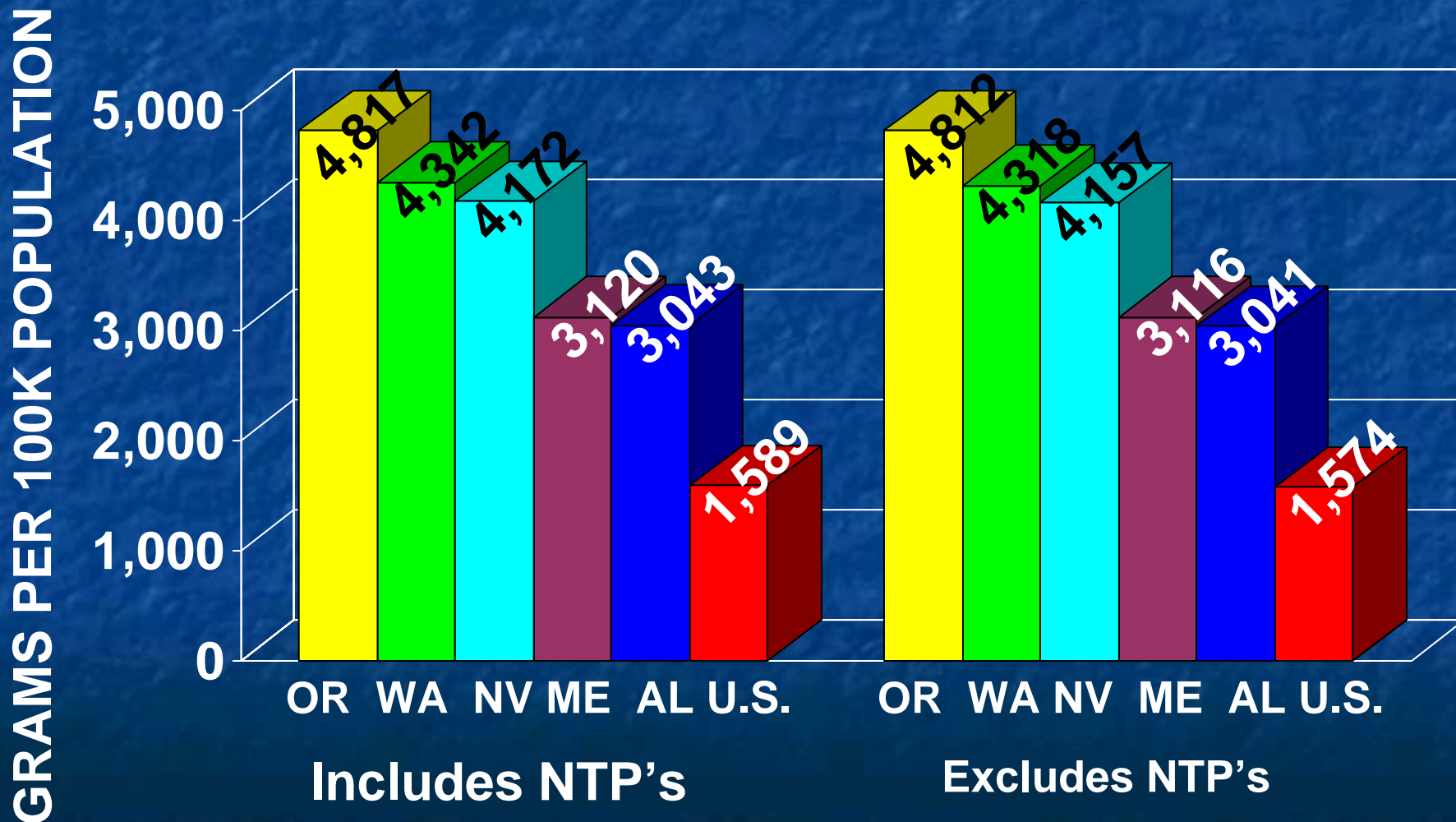
Source: DEA ARCOS

GRAMS PER 100K POPULATION



Distribution of 5 and 10 mg Tablets - TOP 5 STATES (2006)

Source: DEA ARCOS



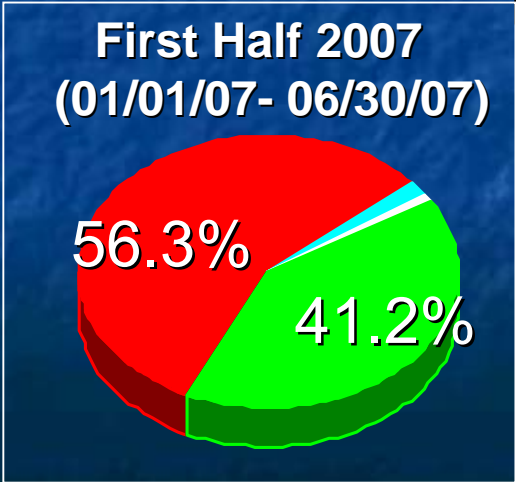
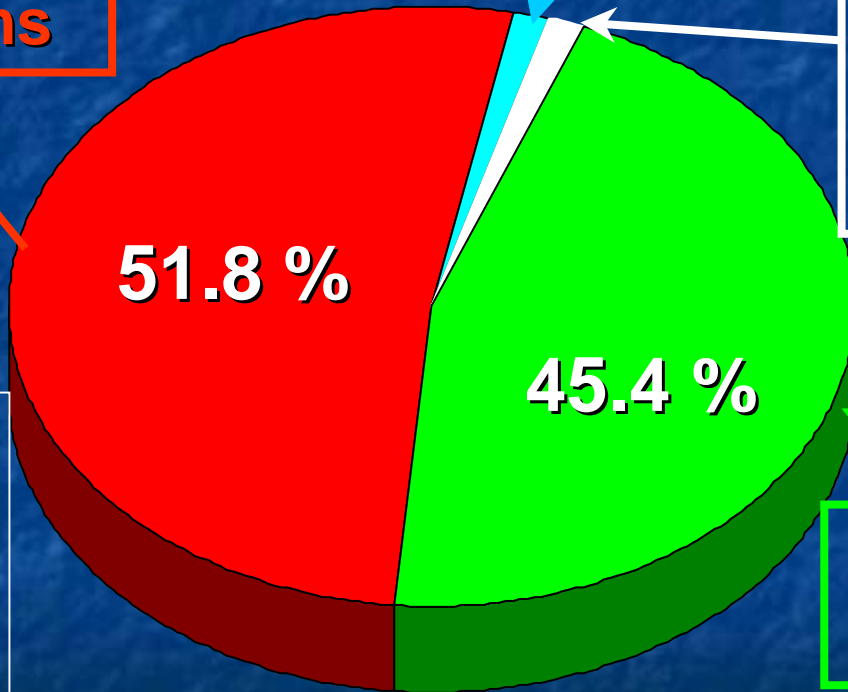
Purchases* of 40 mg Diskettes by Business Activity - 2006

Source: DEA ARCOS

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

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

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



**424 NTP's
1,470,566 grams**

* Based on total gram amount

Methadone Hydrochloride 40 mg Advisory

- As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution.
- The 5mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies.

OXYCODONE



OXYCODONE PRODUCTS

- OxyContin
- Tylox
- Percocet
- Percodan

NFLIS National Data - 2006

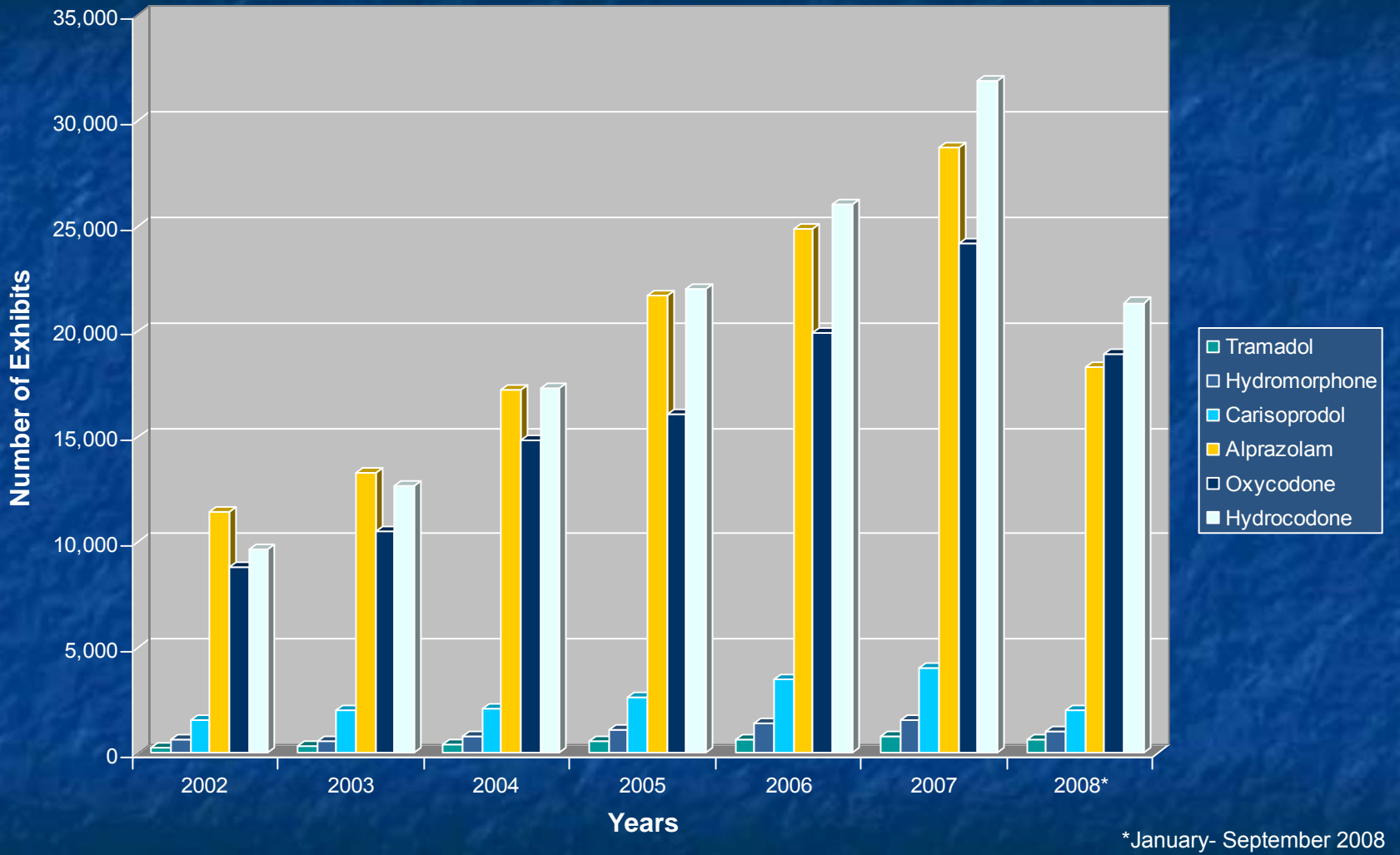
Narcotic Analgesics

	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%

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

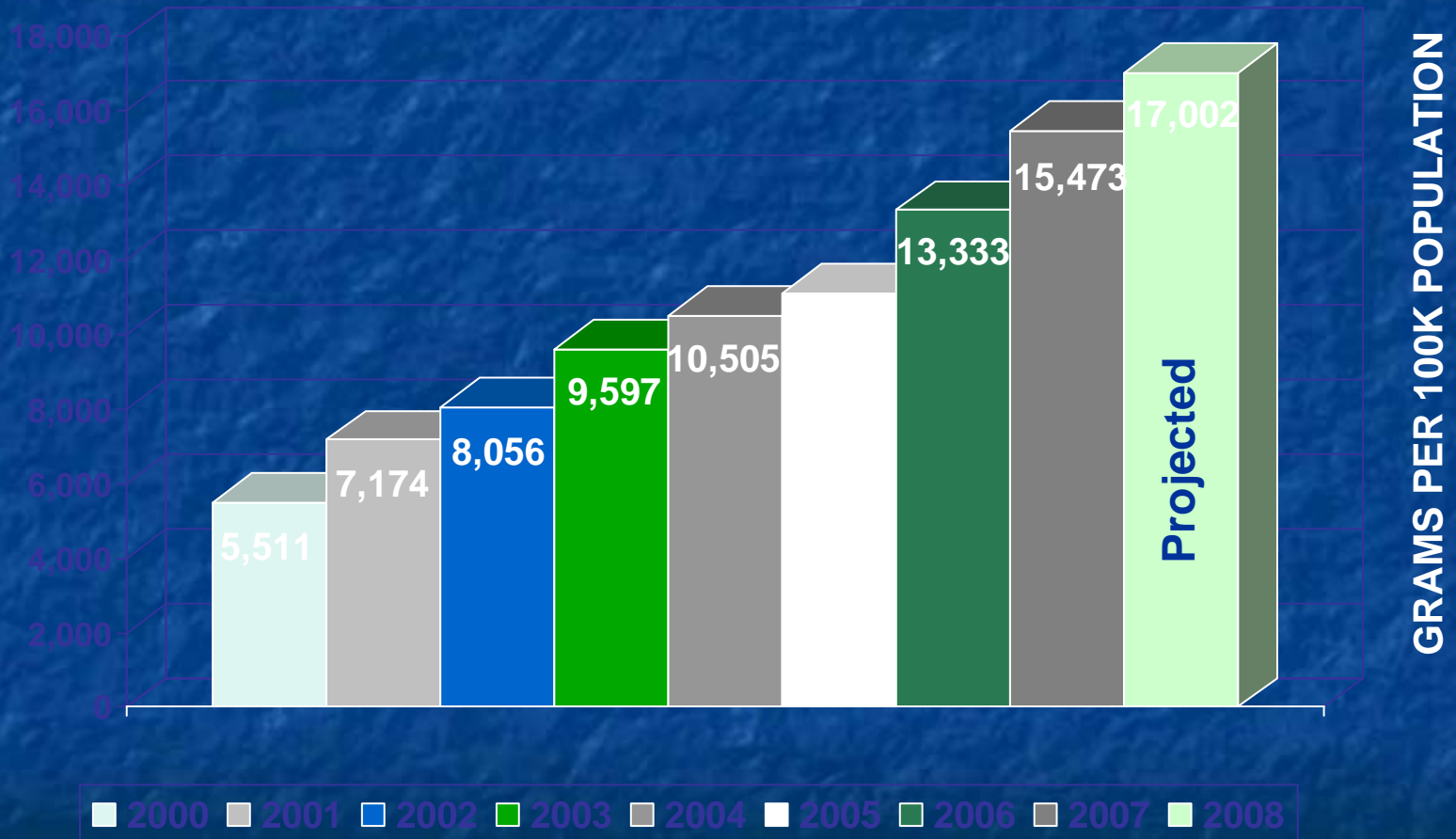
Drug	Product Type	2002	2003	2004	2005	2006	2007
Oxycodone	All Products	29,387	32,523	34,790	37,895	42,292	45,878
	Combination oral solid products	19,873 (45.9)	22,022 (48.5)	24,011 (50.9)	26,547 (53)	29,366 (54.5)	31,404 (56.6)
	Single entity extended-release oral solid products	7,112 (69.8)	7,561 (70.64)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

NFLIS Exhibits by Year



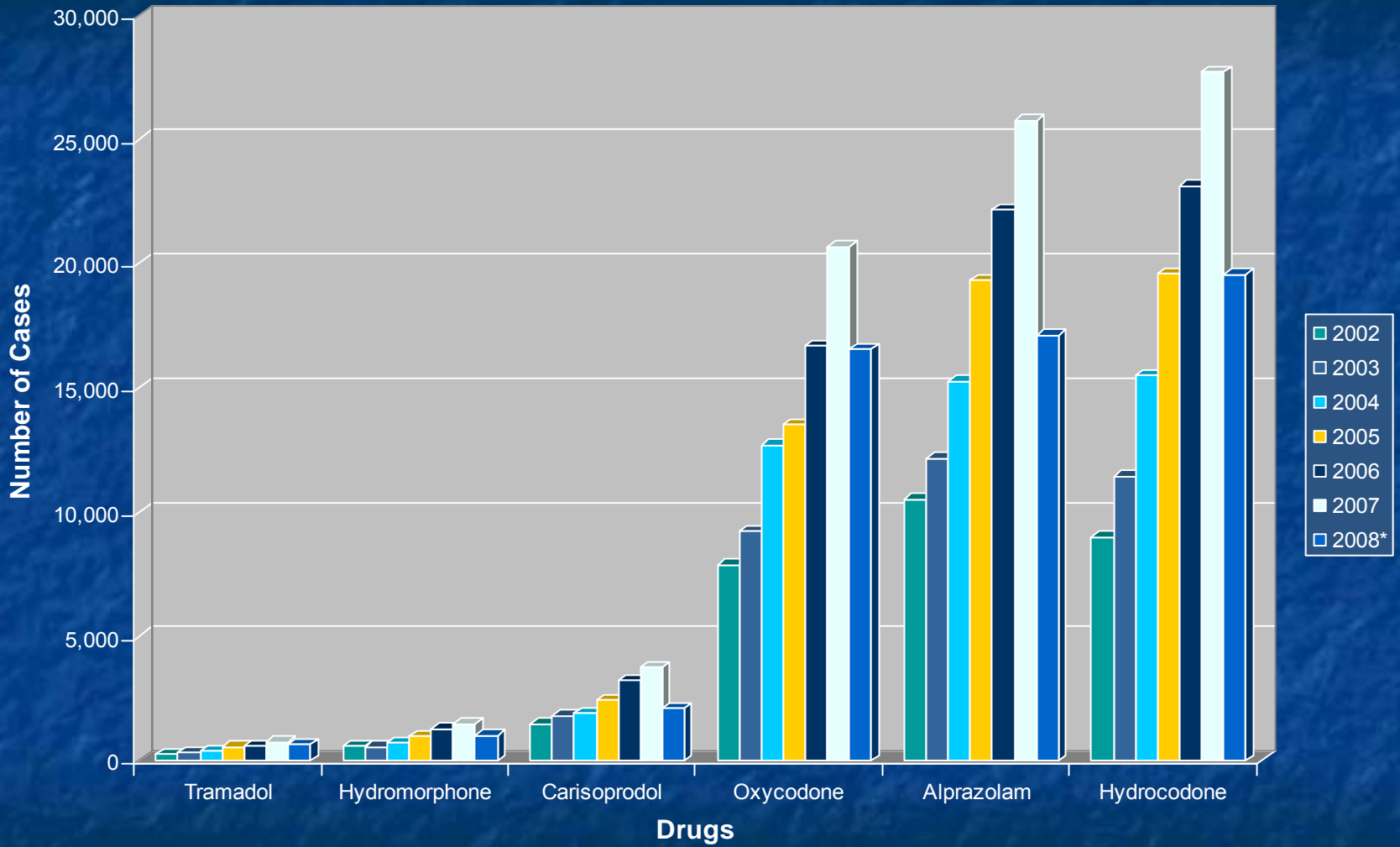
Oxycodone Distribution*

CY2000-2008 U.S. Average



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

NFLIS Cases by Drug



*January- September 2008

Other Controlled Substances

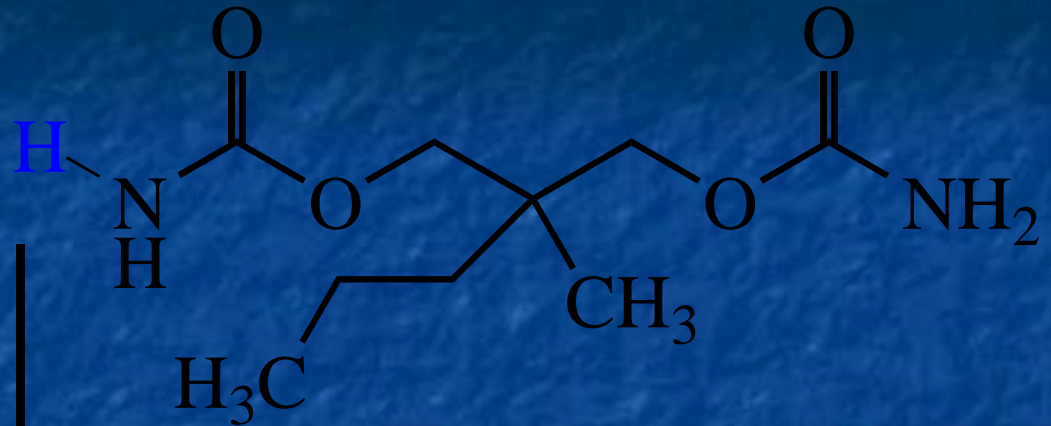
Stimulants

- Phentermine
- Phendimetrazine
- Methylphenidate (CII)
- Amphetamine ALKS (CII)

Non-Controlled Substances

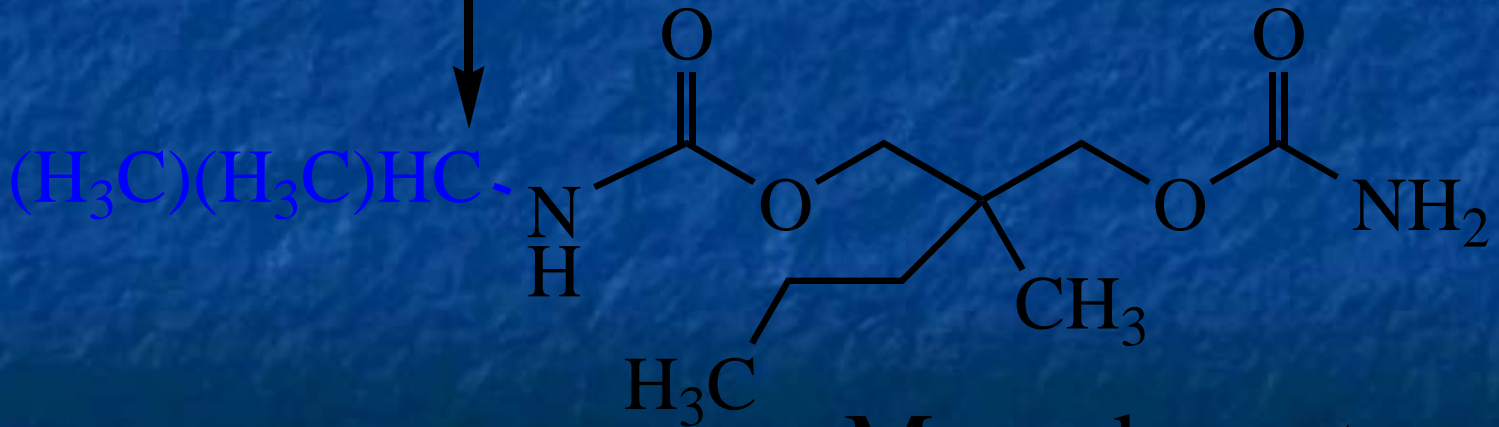
- Analgesic:
 - Tramadol (Ultram®, Ultracet®)
 - Controlled Substance in OK, AR, KY
- Muscle Relaxant:
 - Carisoprodol (Soma®)
 - Controlled in 18 States

Carisoprodol



Structural Change

by Enzymatic Action in the Body

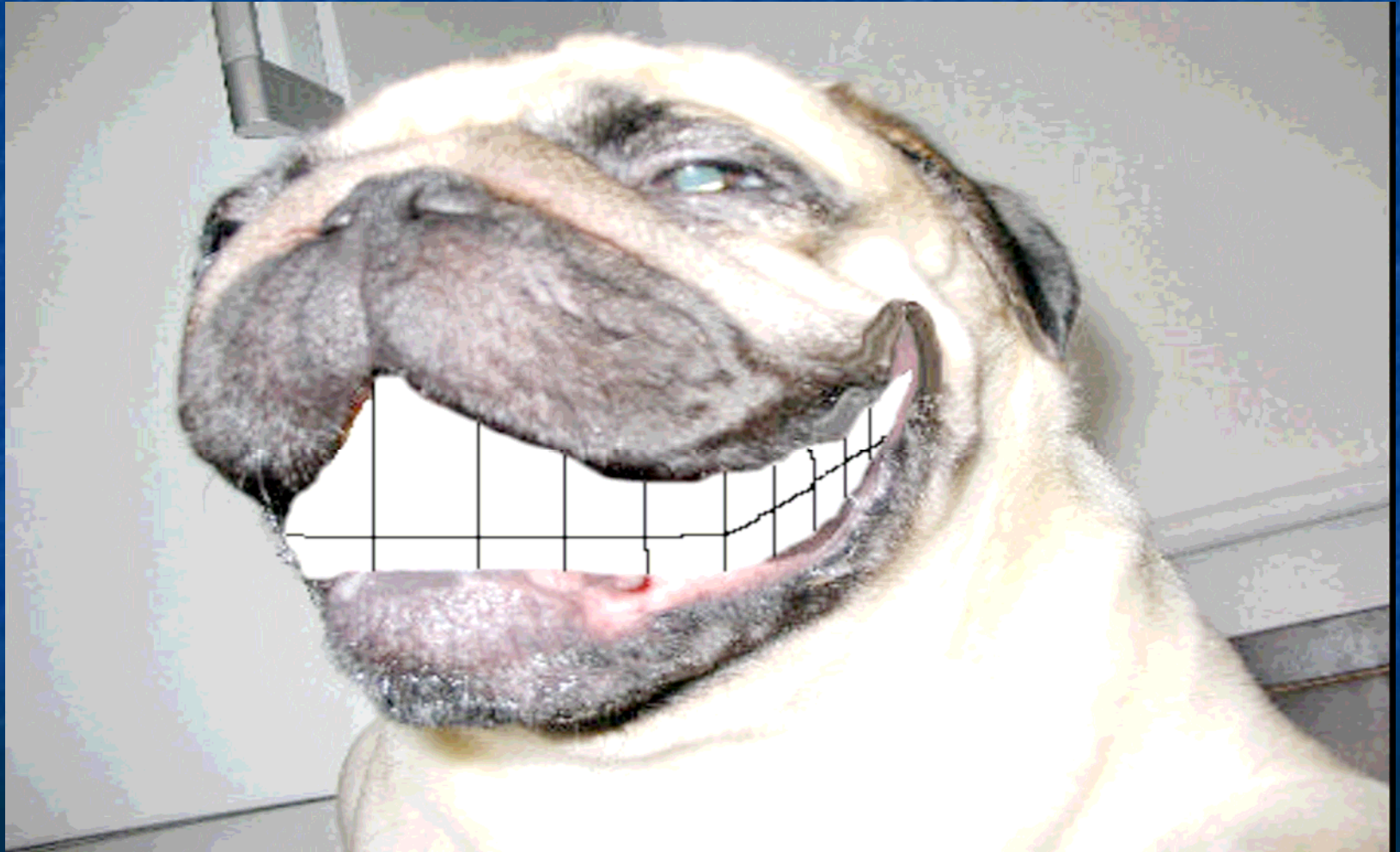


Meprobamate

Anabolic Steroids, Dietary Supplements and hGH



**Steroid Use is all about
appearance, not performance**



WHY????

- To Gain an Edge on the Competition....

Anabolic Steroids in the USA

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



Legislation

- 1988- *Anti-Drug Abuse Act*, making the distribution or possession of anabolic steroids for non-medical reasons a Federal offense.
- 1990- The *Anabolic Steroids Control Act of 1990*, placed 27 (23) 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.

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).

Chemistry & Pharmacology

- Promote growth of skeletal and cardiac muscle; Increase bone density; Increase red blood cells
- Indicated for treating specific types of anemia, some breast cancers, osteoporosis, endometriosis
- Endocrine dysfunction/hypogonadism/growth retardation

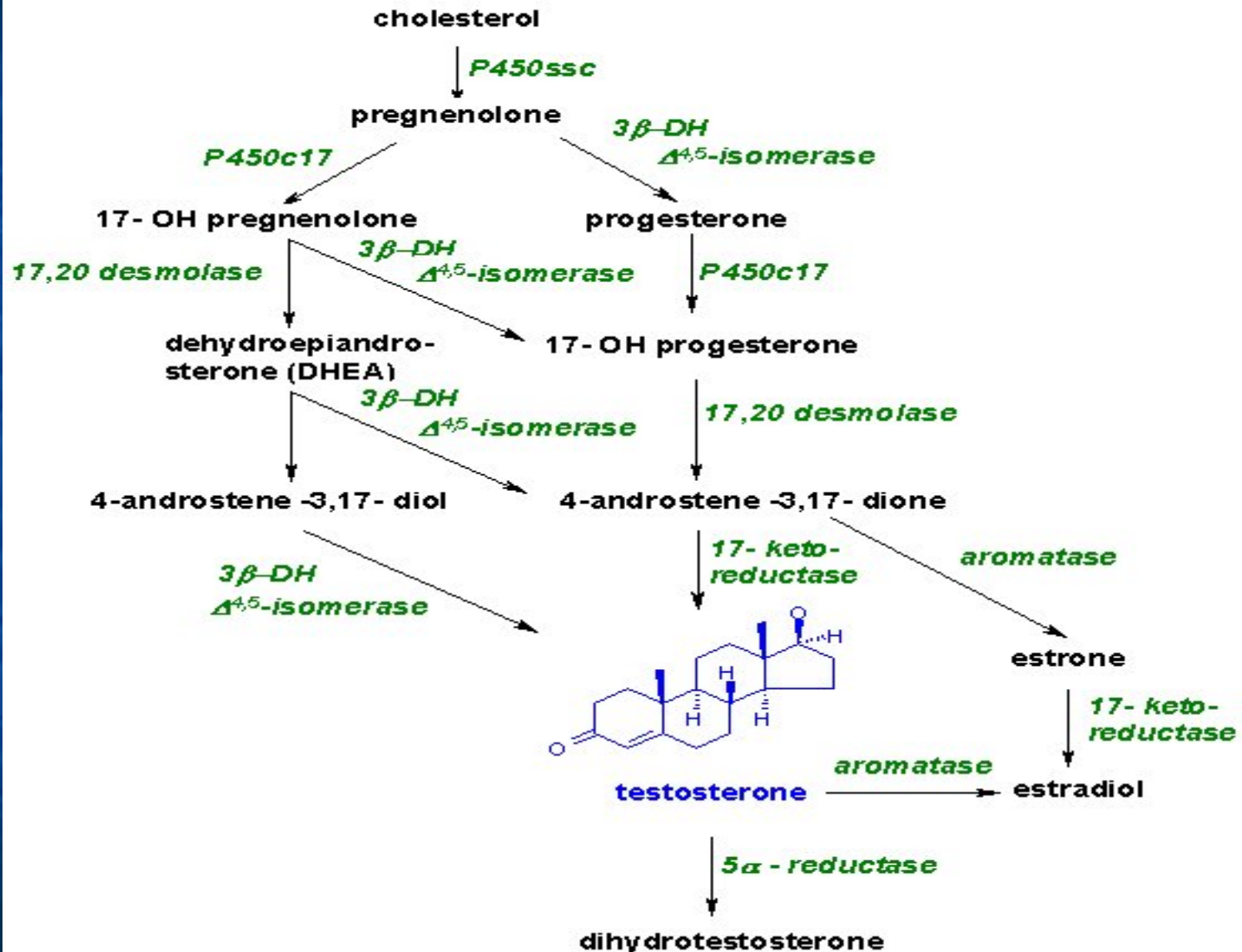


Illicit Use

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



Synthesis of Testosterone



Injectable Steroids

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

One Cycle – Approximately 12 Weeks

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

35 Pound Increase in Body Weight

Single Workout Bench Press Increase of 30 Pounds

Health effects of steroids

Men

Baldness

Oily skin, acne

Bigger breasts

Liver cancer

Reduced sperm count, shrinking of the testicles

Symptoms also include rage, mania, delusions and heart attacks in both sexes.

Women

Hair loss

Deeper voice

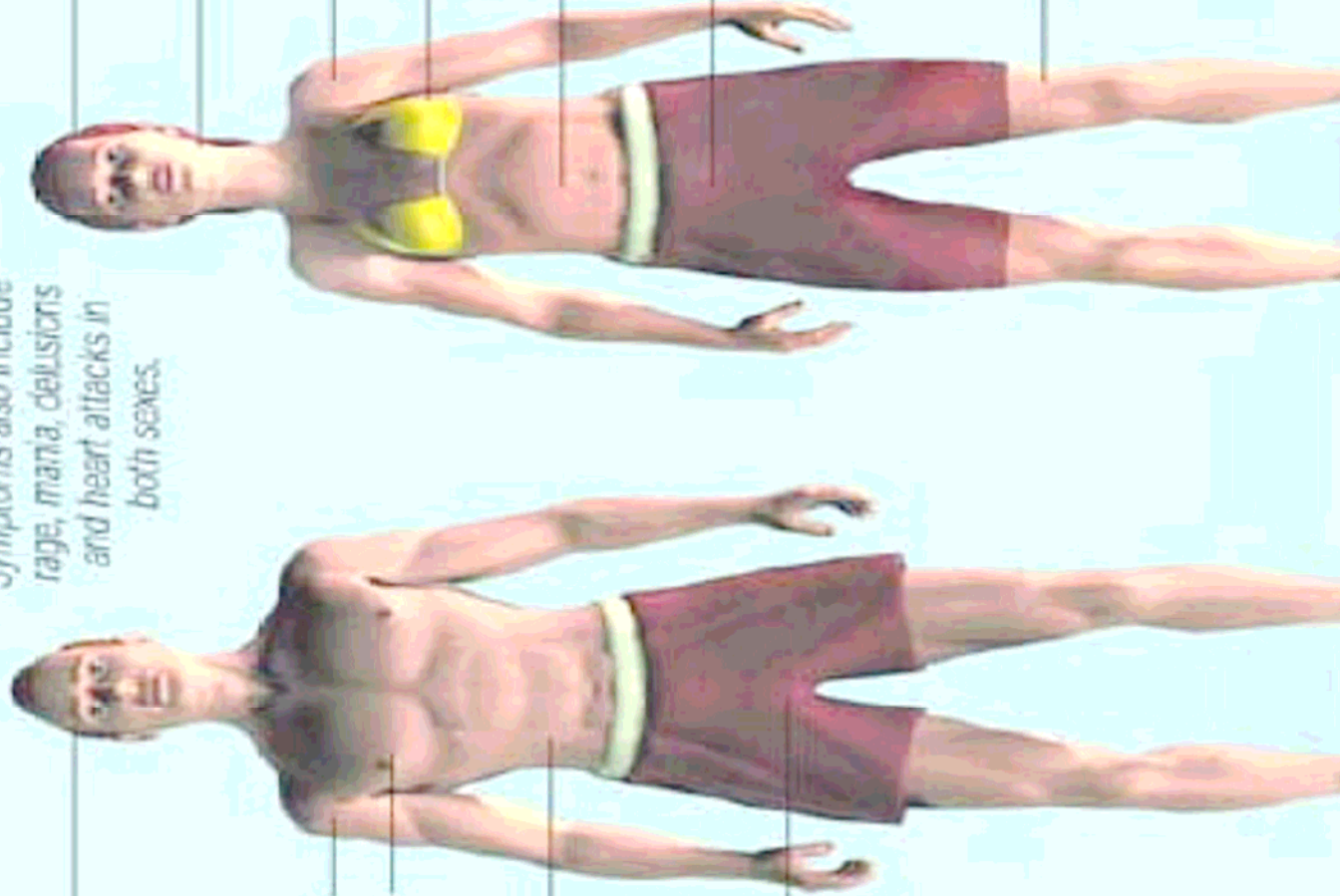
Oily skin, acne

Smaller breasts

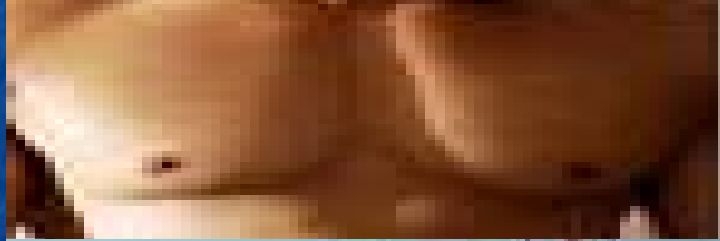
Liver cancer

Loss of menstrual periods

Excessive growth of body hair



Side Effects of Steroid Use: Women



so include delusions attacks in eyes.

Women

- Hair loss
- Deeper voice
- Oily skin, acne
- Smaller breasts
- Liver cancer
- Loss of menstruation
- Excessive growth of body hair

The diagram shows a woman's body with lines pointing to various areas, corresponding to the listed side effects. The labels are: Hair loss, Deeper voice, Oily skin, acne, Smaller breasts, Liver cancer, Loss of menstruation, and Excessive growth of body hair.

Men

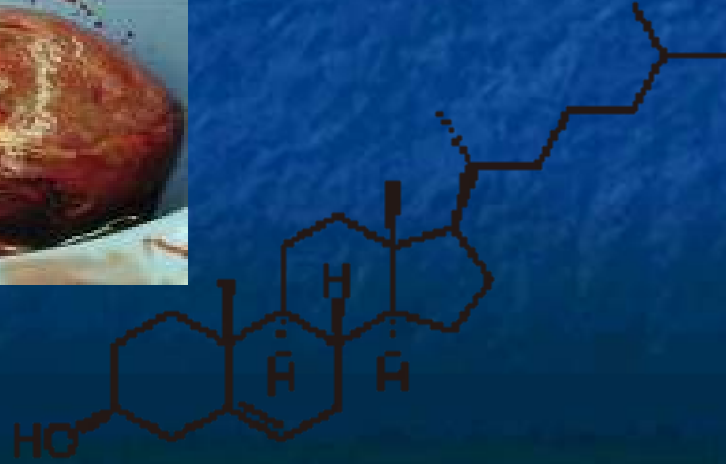
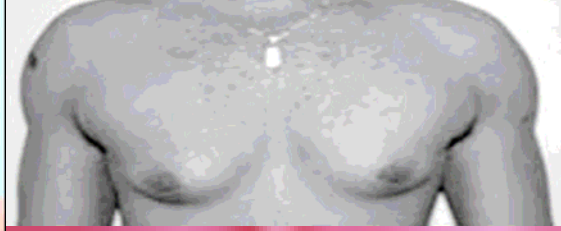
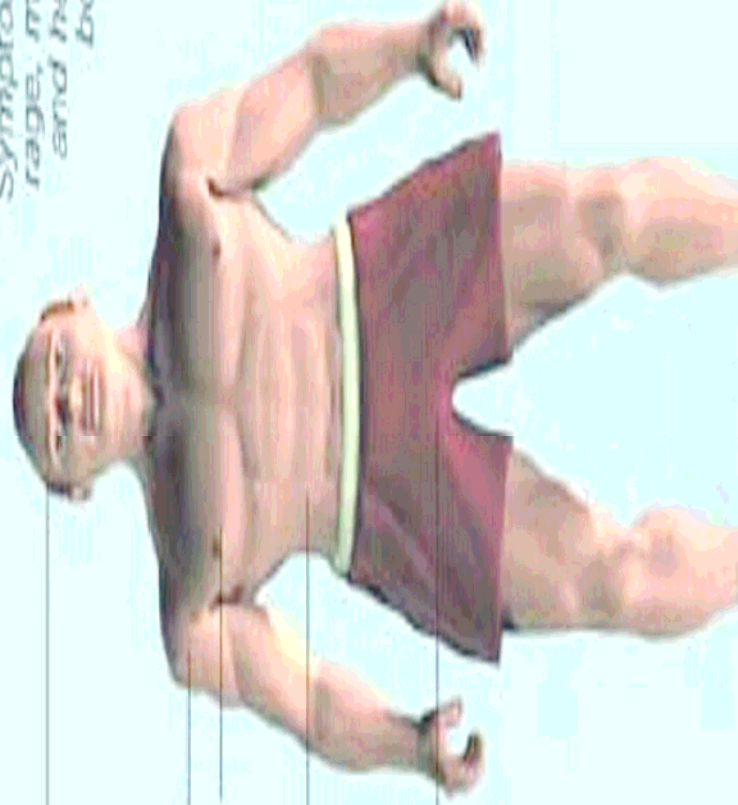
Baldness

Oily skin, acne
Bigger breasts

Liver cancer

Reduced sperm
count,
shrinking of
the testicles

*Symptoms:
rage, mania
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

Steroid Abuse



DECA
DURABOLIN



DIANABOL Tabs.



SUSTANON

Common Steroids Abused

Commonly Abused Steroids

■ Oral Steroids

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

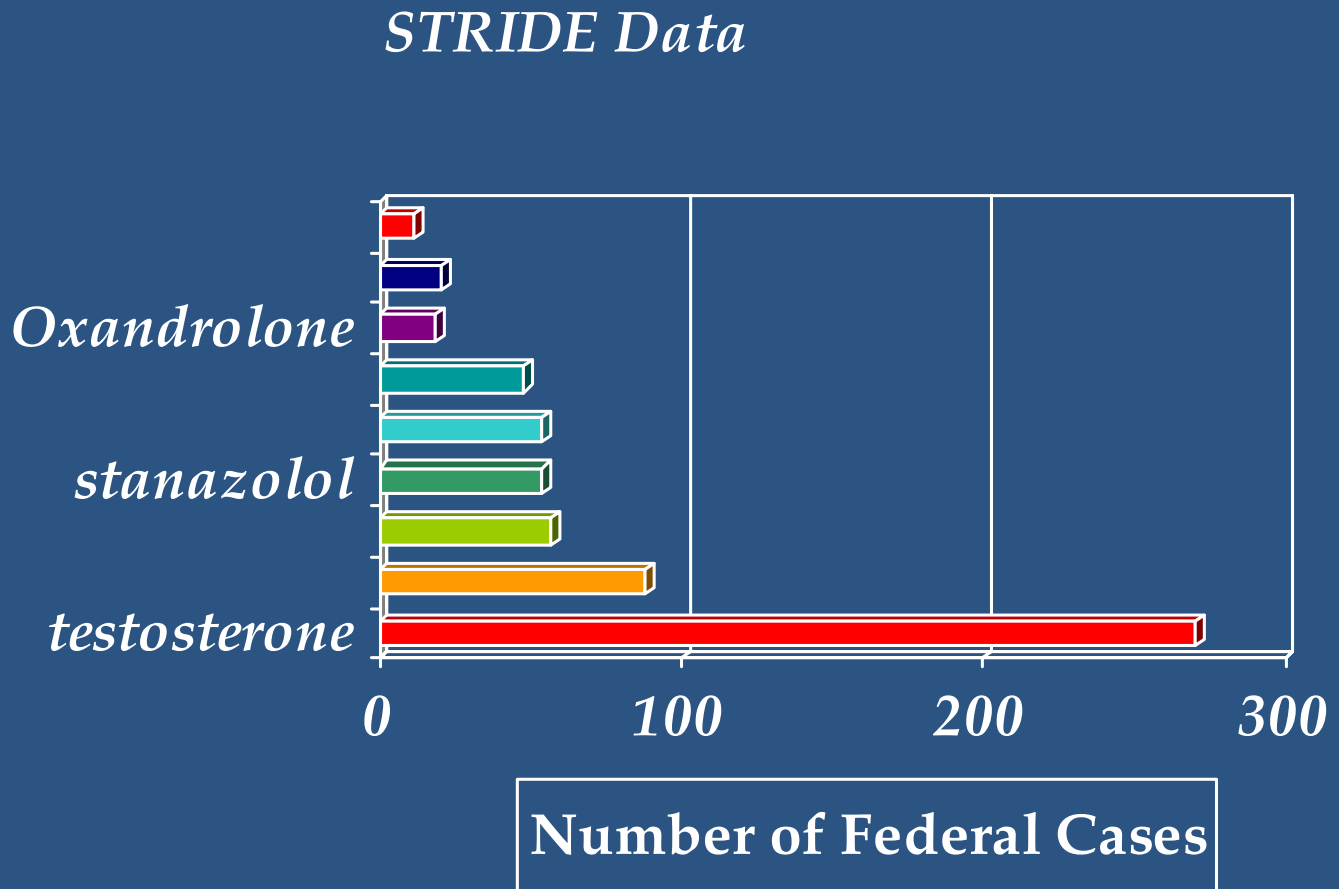
■ Injectable Steroids

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

Patterns of Steroid Abuse

- **Cycling:** alternating periods of anabolic steroid use (on cycle) with periods of either no use or the use of low doses of anabolic steroids.
- **Stacking:** concurrent use of two or more steroids together.
- **Stacking the Pyramid or Pyramiding:** increase in the dose/type early in the cycle and tapering the dose in the latter part of the cycle.

Steroid Abuse



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

Dietary Supplements

DRUGS

Must be proven
safe before
approved for
market

SUPPLEMENTS

Must be proven
harmful before
removed from
market

Dietary Supplements

- Definition of products that can be sold as dietary supplements:
 - ▶ A product (other than tobacco) intended to supplement the diet. The product contains one or more of the following: vitamin; mineral; herb or other botanic; amino acid; dietary substance for use by humans; or a concentrate, metabolite, constituent, extract or combination of these ingredients.
 - ▶ The product must also be intended for ingestion and cannot be advertised for use as a food.

Designer Steroids

Anabolic Steroid Control Act of 2004

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

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

TRAFFICKING TRENDS

- 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.

Straight Talk is the Best Deterrent in Steroid Use

Florida chose not to fund its steroid-testing program for high school athletes this school year after snagging only one violator among the 600 subjects who were randomly tested last year - not much muscle for a \$100,000 flex. New Jersey got the same result, only one violator. Texas tested more than 10,000 students and nabbed two. The price tag for two dirty urines? \$3 Million

Washington Post 11/06/08 "Straight Talk is the Best Deterrent to Steroid Use"

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



Human Growth Hormone (hGH)

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

hGH

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

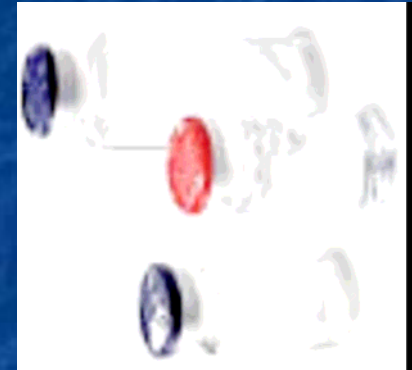
Human Growth Hormone

- The 1990 law inserted growth hormone into 21 U.S.C. § 333, the Steroid Trafficking Act.
- Indicated in adults for Aids Wasting, Short Bowel Syndrome and hGH deficiency (1 in 10,000).
- Technically, *not* a controlled substance (federal). But, ... federal law criminalizes whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans *other than the treatment of a disease or other recognized medical condition*. 21 USC 333(e)
- DEA has authority to investigate.



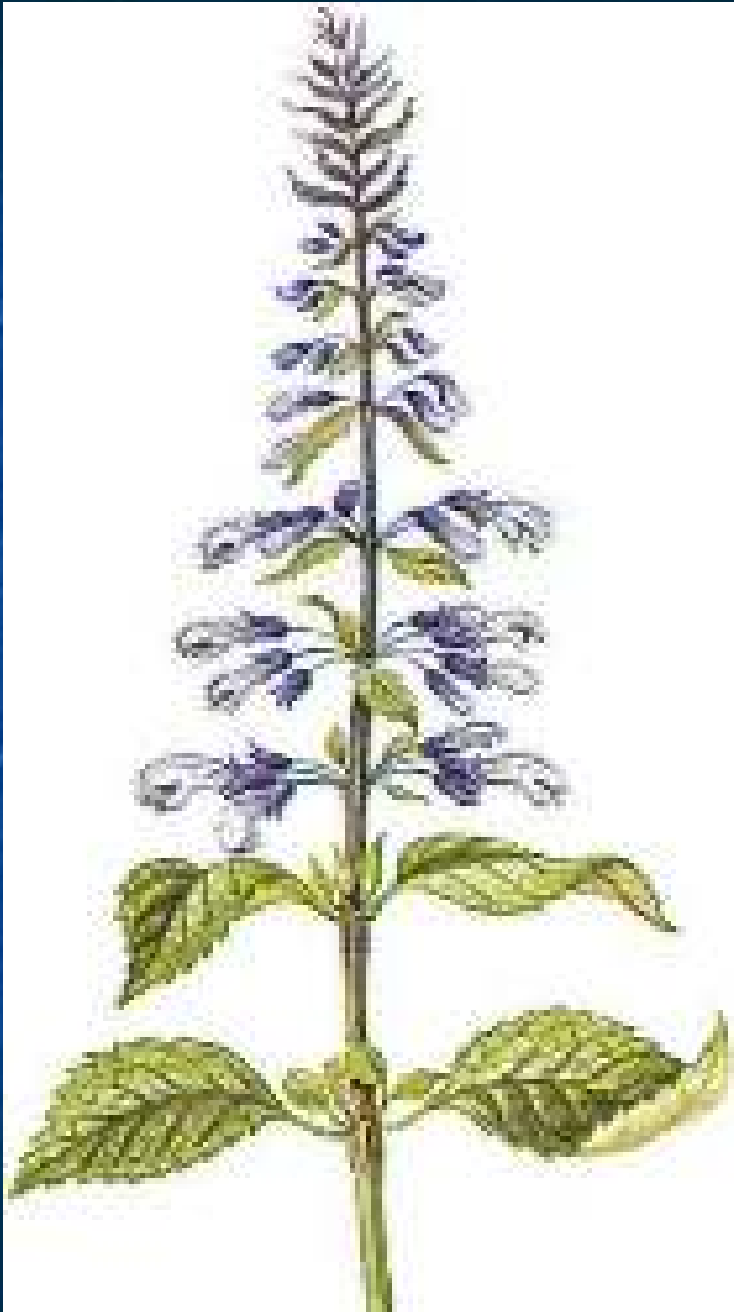
Human Growth Hormone U.S. Products

- Genotropin
- Humatrope
- Norditropin
- Nutropin
- Saizen



Growth Hormone Releasers

- Also called "hGH Releasers," "hGH Precursors," "hGH Secretagogues"
- They do not contain hGH, they will read "hGHR" – a compilation of amino acids.



Salvia Divinorum And Salvinorin A

Salvia Divinorum

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



Other Names

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



Characteristic Features of Salvia Divinorum Plant

- Grows to well over one meter in height.
- Has large (6 inches) ovate green leaves finely dentated along the margin.
- Has hollow square stems.
- Has blossoms with white corollas and purple calyces.

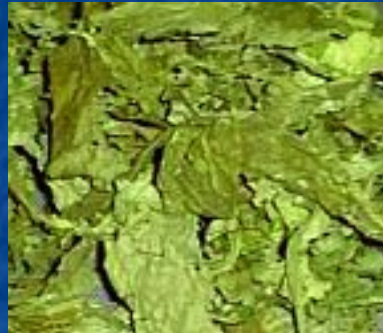


Salvia Divinorum As Sold Over the Internet

Internet sites advertise Salvia as a legal alternative to other controlled hallucinogens.

Sold as:

- Seeds
- Fresh Leaves
- Dried Leaves
- Whole Plants
- Cuttings
- Extracts (5x, 10x, 15x, 20x)



Exhibits of Salvia Found to Contain Salvinorin A



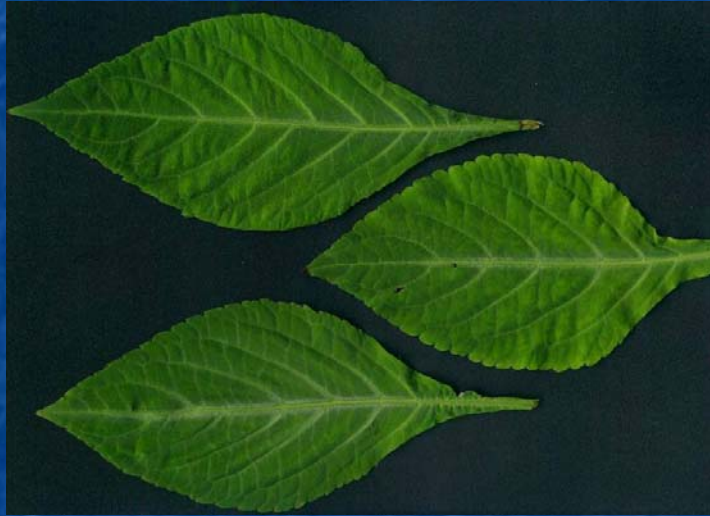
Salvia from Rochester, Minnesota.



Salvia from Dade County, Florida

Images were obtained from Microgram

Salvia Divinorum Use in the U.S.



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

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



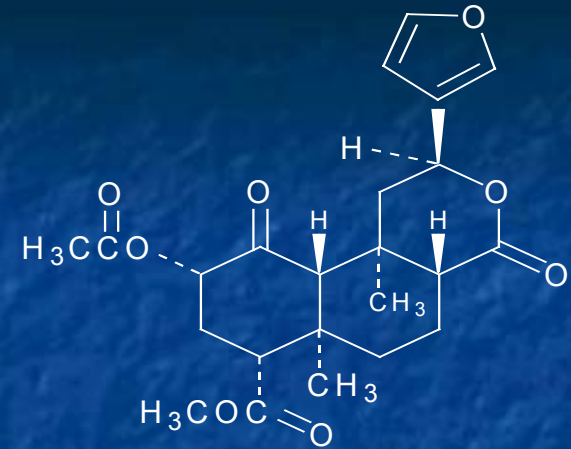
There are anecdotal reports of abuse, but no data from standard drug abuse databases (e.g., DAWN and Poison Control) within the U.S. to accurately estimate the extent of abuse

Effects

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

Salvinorin A

- Substance thought to be responsible for the psychoactive effects of salvia.
- Has a unique chemical structure unlike other hallucinogens.
- Only recently have analytical techniques been developed to evaluate this chemical in humans.
- Present in dry leaves at concentrations of about 1-4 mg per gram of dry leaf
- In human studies -
 - Smoking of dried leaves or up to 2.6 mg Salvinorin A, produced psychoactive effects in about 30 seconds, peaking at about 10 minutes and lasting 15-30 minutes



Salvinorin A

How may it exert psychoactive effects?

- Does not bind at receptors normally associated with the psychoactive effects of currently controlled substances including dopamine, serotonin, benzodiazepine, or cannabinoid receptors.
- Does bind with high affinity to opioid kappa receptors.
- Kappa receptor activation is known to be associated with hallucinations and other dysphoric (unpleasant) effects.

Regulatory Controls

- Salvinorin A is not currently controlled under the Controlled Substances Act in the United States.
- Bill in 2002 - "Hallucinogen Control Act of 2002" -
Proposed to place Salvinorin A and *Salvia Divinorum* into Schedule I. It was not reintroduced in 2003.
- A number of US states have taken legal action
- Salvinorin Divinorum is controlled in Finland, Denmark, Australia and Italy. In Norway it is not controlled but listed as a psychoactive drug.

DEA Web sites

U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
OFFICE OF DIVERSION CONTROL

HOME PRIVACY POLICY CONTACT US WHAT'S NEW HOT ITEMS SITEMAP SEARCH

DIVERSION PROGRAMS
APPLICATIONS & ON-LINE FORMS
ARCOS
CHEMICALS
CONTROLLED SUBSTANCE
SCHEDULES
IMPORT AND EXPORT
IFLIS
QUOTAS
REGISTRATION SUPPORT
REPORTS REQUIRED BY 21 CFR

RESOURCES
CAREER OPPORTUNITIES
DRUGS/CHEMICALS OF CONCERN
E-COMMERCE INITIATIVES
FEDERAL REGISTER NOTICES
MEETINGS & EVENTS
OFFICES & DIRECTORIES
PROGRAM DESCRIPTION
PUBLICATIONS
QUESTIONS & ANSWERS
REGULATIONS & CODIFIED CSA

LINKS
FEDERAL AGENCIES & RELATED
INDUSTRY RELATED
PUBLIC INTEREST

REGISTRATION VALIDATION

CASES AGAINST DOCTORS

**WELCOME TO THE
DIVERSION CONTROL PROGRAM**

Registration Number
Toll Free: 1-800-882-9539

REGISTRATION SUPPORT

Save time by applying for and/or renewing your DEA Registration on-line. Data will be entered through a **secure connection** to the **ODWIF** on-line web application system. Minimum requirements: Credit Card and a web browser that supports **128-bit encryption**.

NEW REGISTRATION FEE EFFECTIVE NOVEMBER 1, 2006

- To Apply for Renewal Applications for Registration On-Line
- To Apply for New Applications for Registration On-Line
- To Apply for Registration by Mail
- For Registration Changes
(Address, Drug Codes, Name, Schedules)
- Duplicate Certificates
- Order Forms

For Registration Matters
1-800-882-9539

WHAT'S NEW

RENEWAL
Apply On-Line
REGISTRATION APPLICATIONS
Renewal Applications

NEW APPLICATIONS FOR REGISTRATION
New Registration Applications

DEA FORM 106 ONLINE
REPORT THEFT OR LOSS OF CONTROLLED SUBSTANCES

Sales of Ephedrine & Pseudoephedrine Products
COMBAT METH ACT 2005
Combat Methamphetamine Epidemic Act 2005

For Additional
Information

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

Thank You!

