



U.S. Drug Enforcement Administration

Pharmaceutical Trends & Updates

National Association of Boards of Pharmacy

Miami, Florida

May 2009

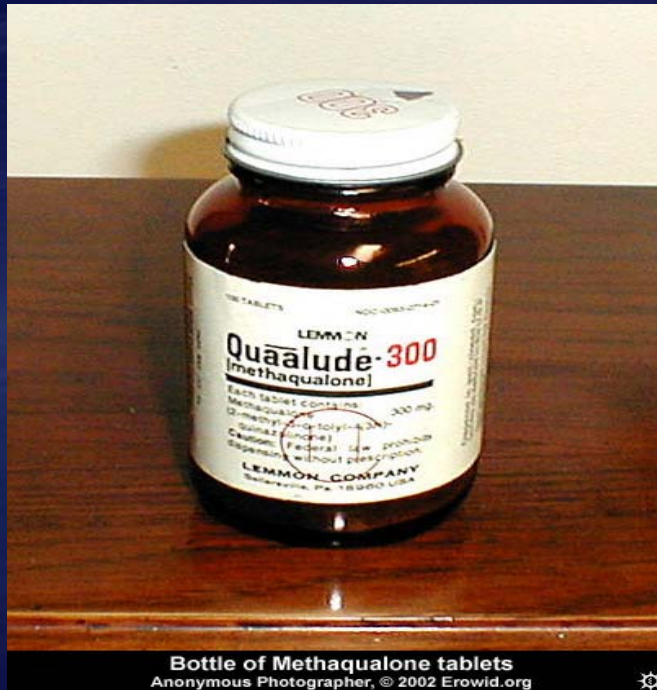
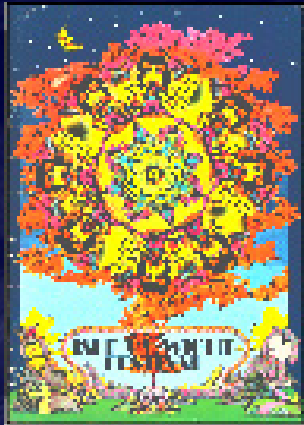


OBJECTIVES

- **Current state of prescription drug abuse**
- **Trends in the diversion of pharmaceuticals and chemicals**
 - **Rogue Internet Pharmacies**
 - **Ryan Haight Online Consumer Protection Act**
 - **Pain Clinics**
 - **Drugs of Abuse**
 - **CMEA Update**
 - **Diversion of Pseudoephedrine**
- **Current Issues**
 - **EPCS**
 - **Disposal of controlled substance pharmaceuticals**
- **Anabolic Steroids and Dietary Supplements**



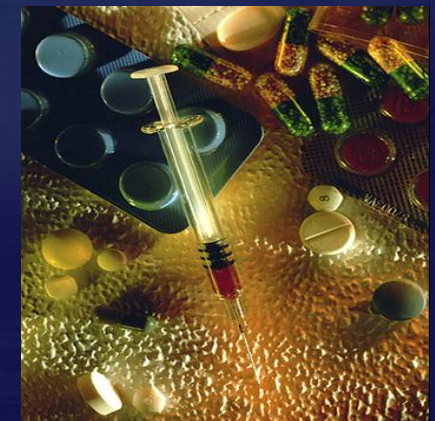
The 1970's



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



Heroin

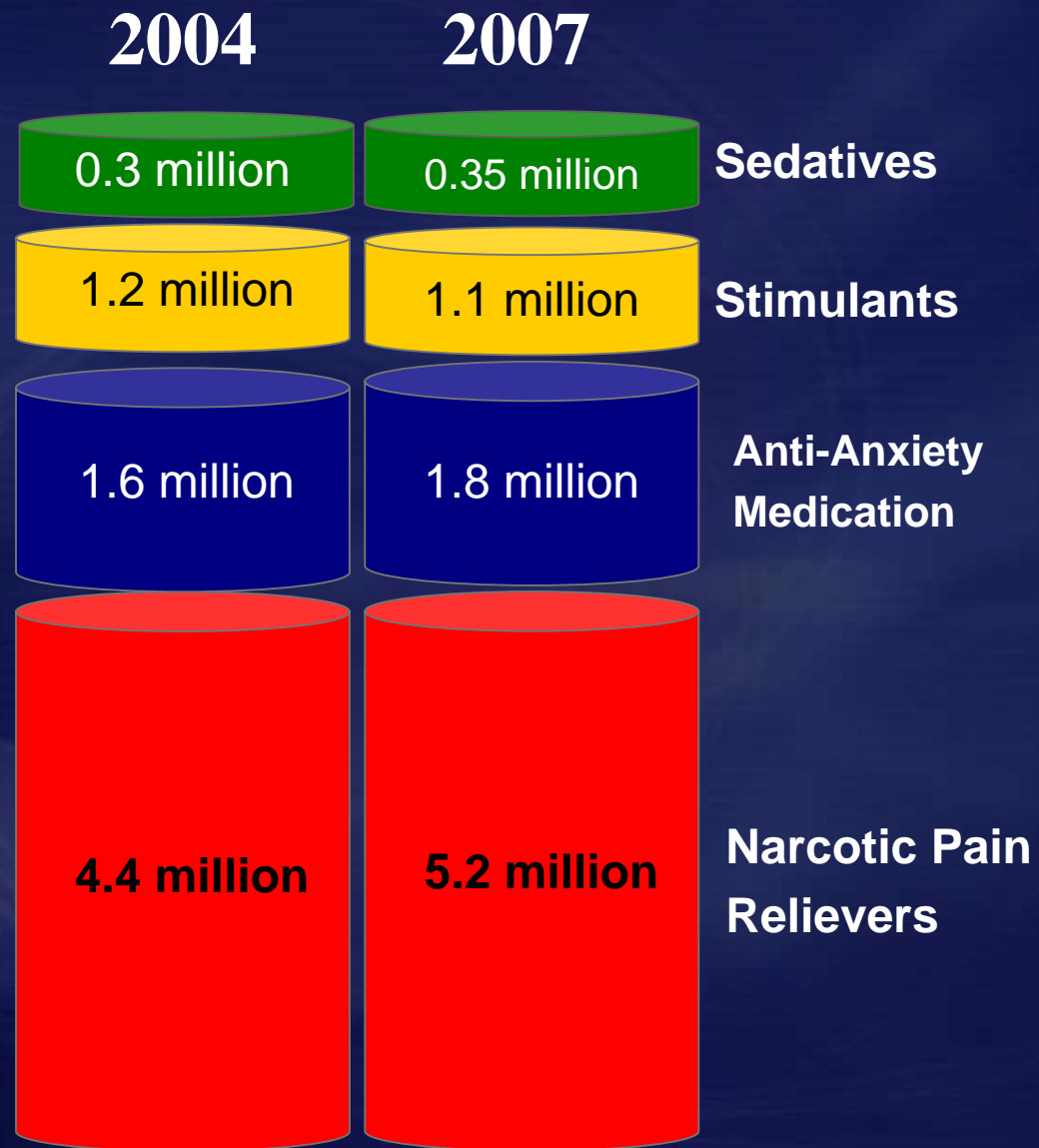


The Perfect Storm

- **Misperception: When we don't see specific drugs anymore the problem has gone away**
- **Industry is producing a wider variety of controlled substance pharmaceuticals**
- **Industry is producing record numbers of controlled substance pharmaceuticals**
- **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

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



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

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**



¹SOURCE: 2007 National Survey on Drug Use and Health



Emergency Data

- **From 2004 to 2006**
 - **No Significant Change: ER visits attributable to cocaine, heroin, marijuana, and stimulants (the major illicit drugs)**
 - **Increase of 44%: ER visits attributable to pharmaceuticals alone (*i.e.*, with no other type of drug)**
- **Drugs most frequently implicated in non-medical use:**
 - **benzodiazepines (36% increase)**
 - **hydrocodone/combinations (44% increase)**
 - **oxycodone/combinations (56% increase)**



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



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





Internet Diversion



Rogue Internet Pharmacy



Rogue Internet Pharmacy



Components for a Domestic Rogue Internet Operation

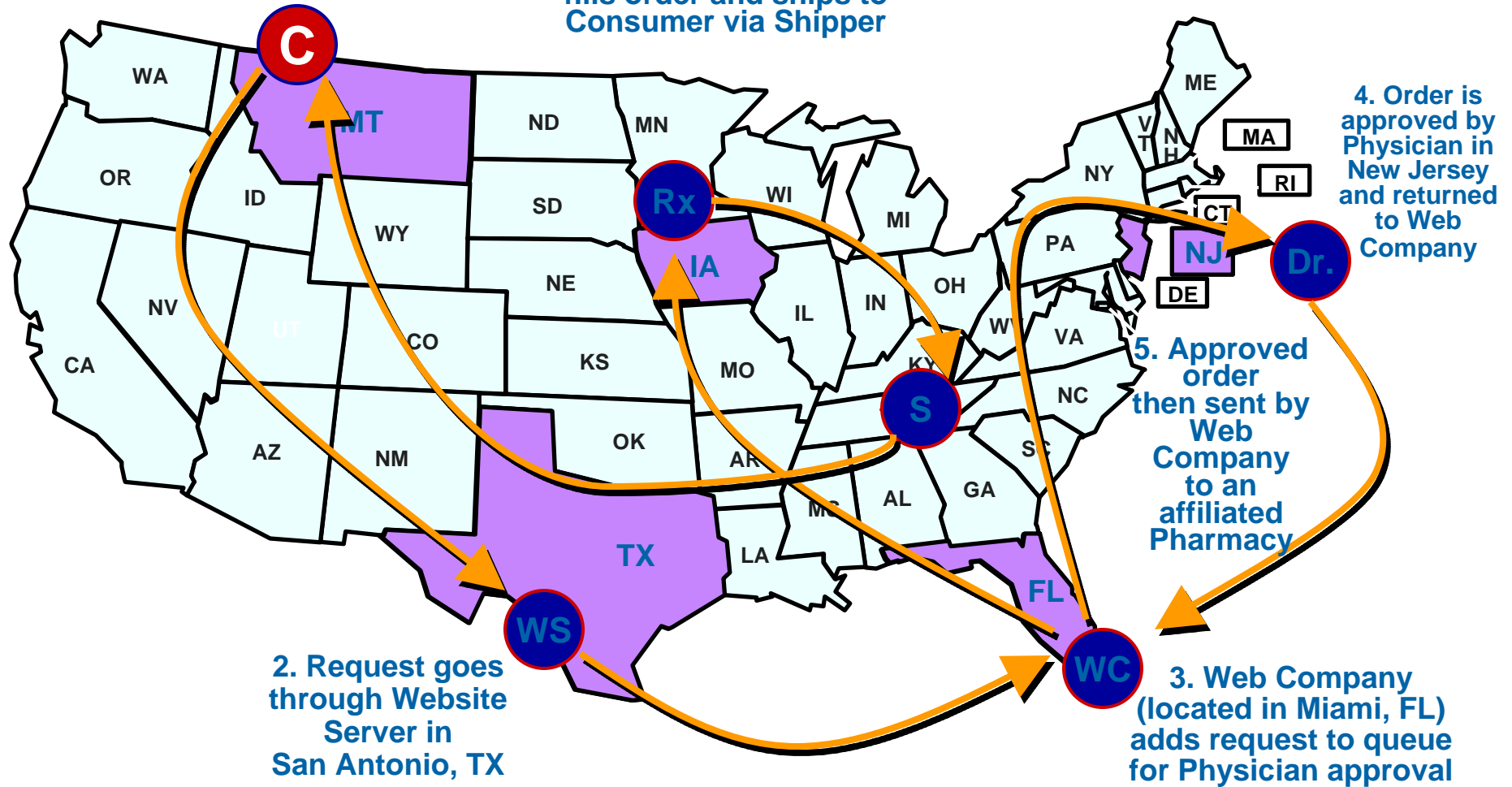
- Web Broker / Facilitator (optional)
- Practitioner
- Pharmacy
- **All members of scheme are complicit thereby eliminating all checks and balances
- Source of Supply





1. Consumer in Montana orders hydrocodone on the Internet

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

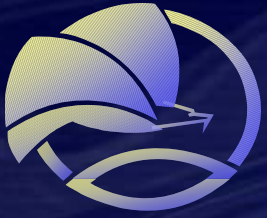


2. Request goes through Website Server in San Antonio, TX

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

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

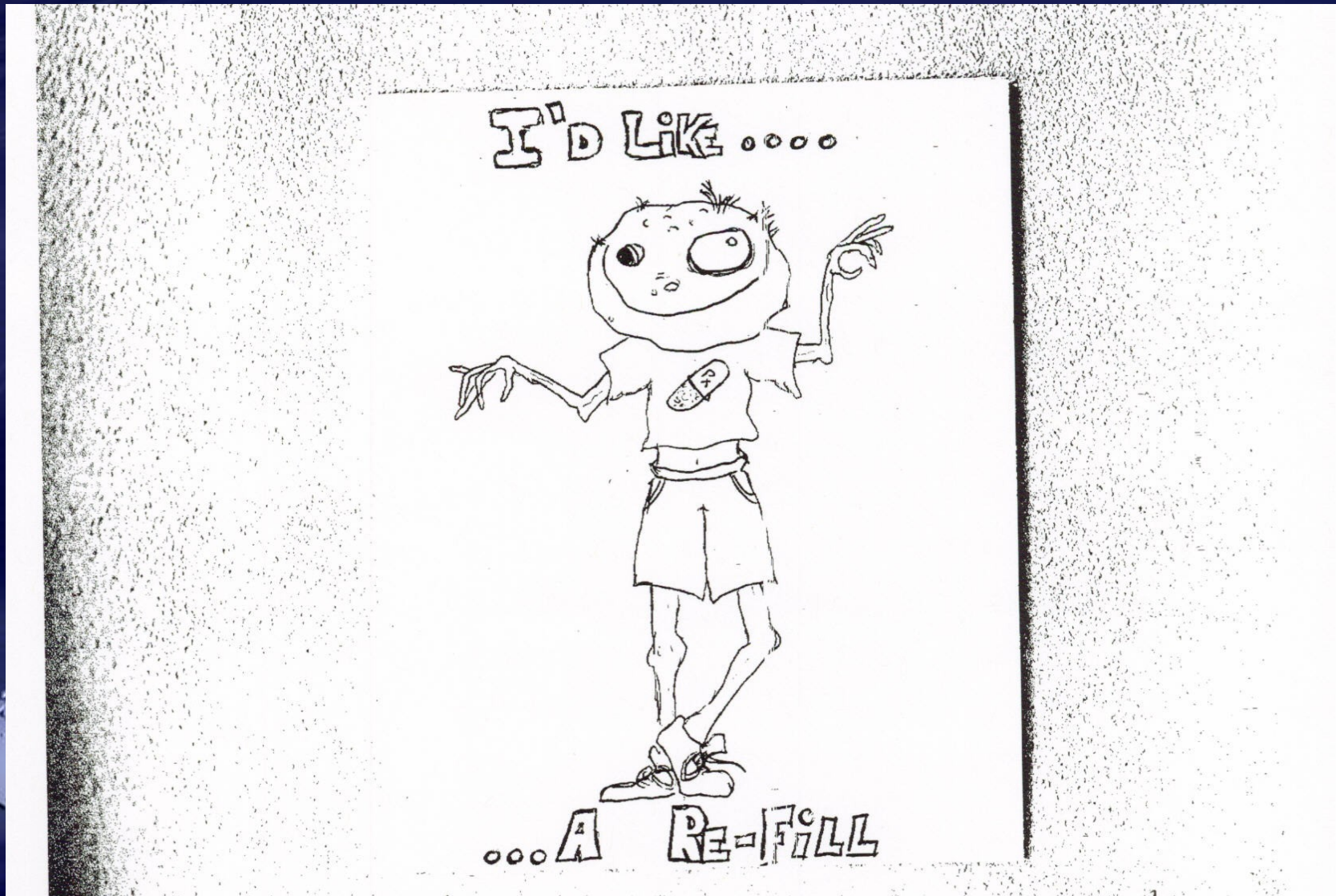
3. Web Company (located in Miami, FL) adds request to queue for Physician approval



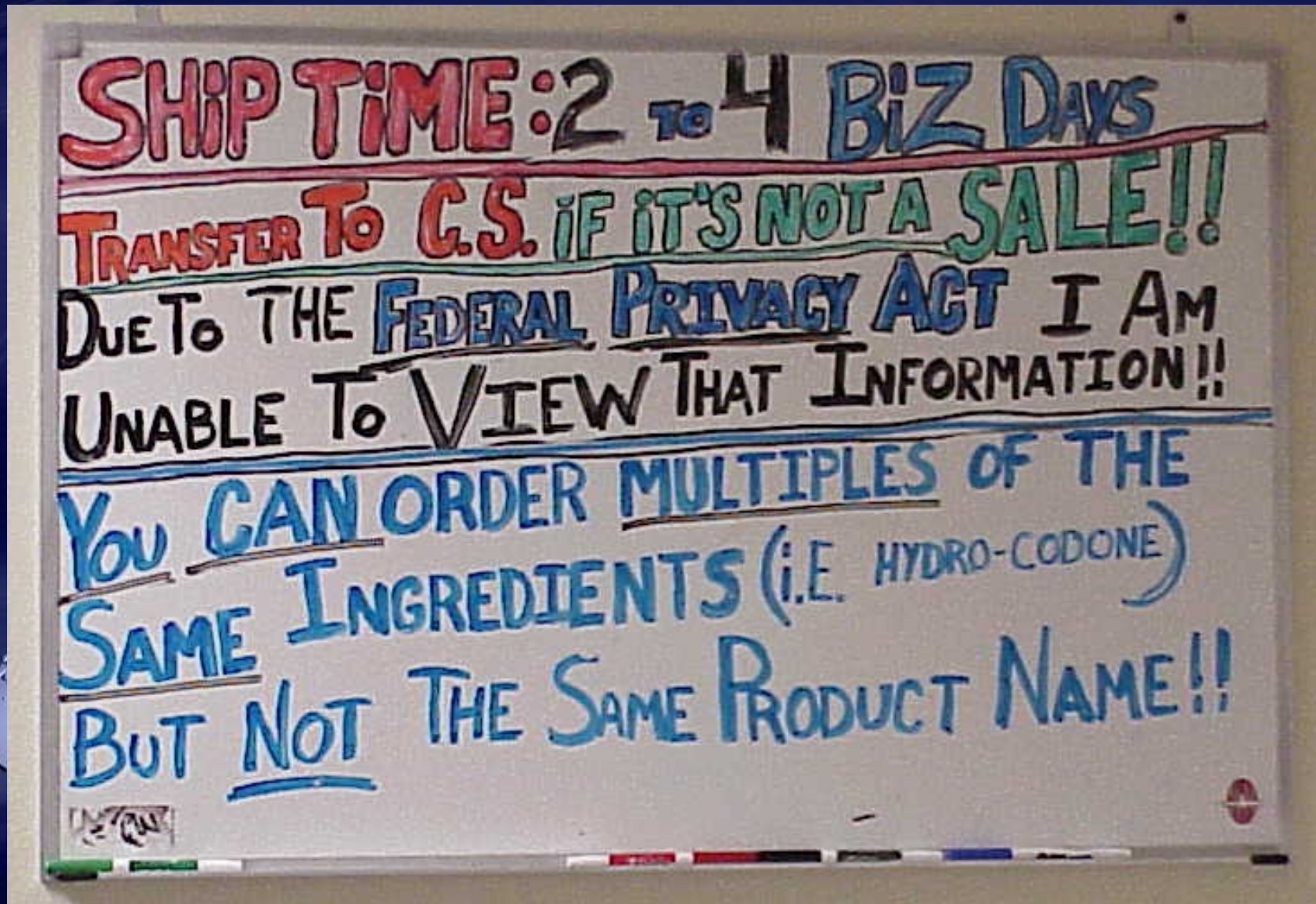
Case Example



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

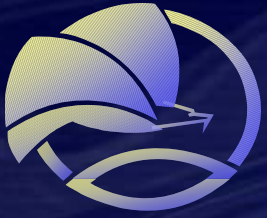
5/5/5
→ use: www.xpress-rx.com/digi/

REMINDER:

**NEW customers cannot ORDER
HYDRO-CODONE WITH MASTERCARD!!**

Ask For Discover Card 1st

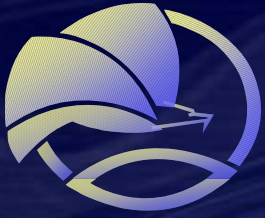
PAID WITH Discover Card



Total Forfeiture:

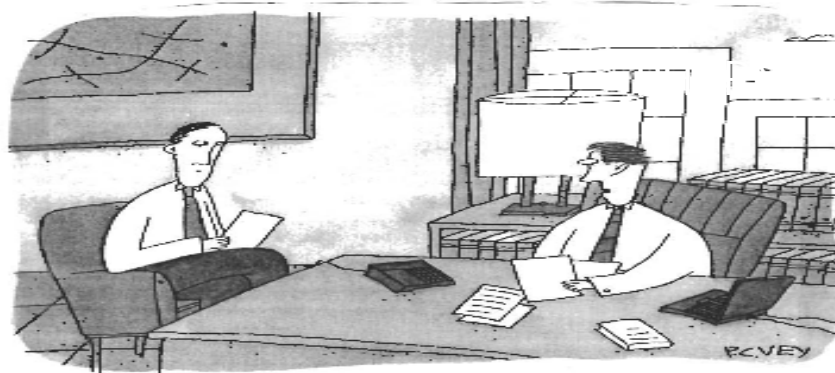
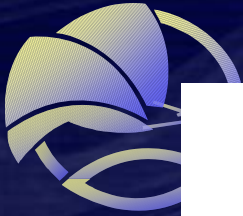
\$4,370,258.80





Internet Legislation & Implementing Regulations





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

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

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).**



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?????

5

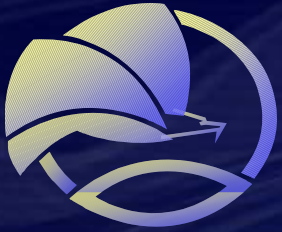
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Current Schemes

➤ Pain Clinics

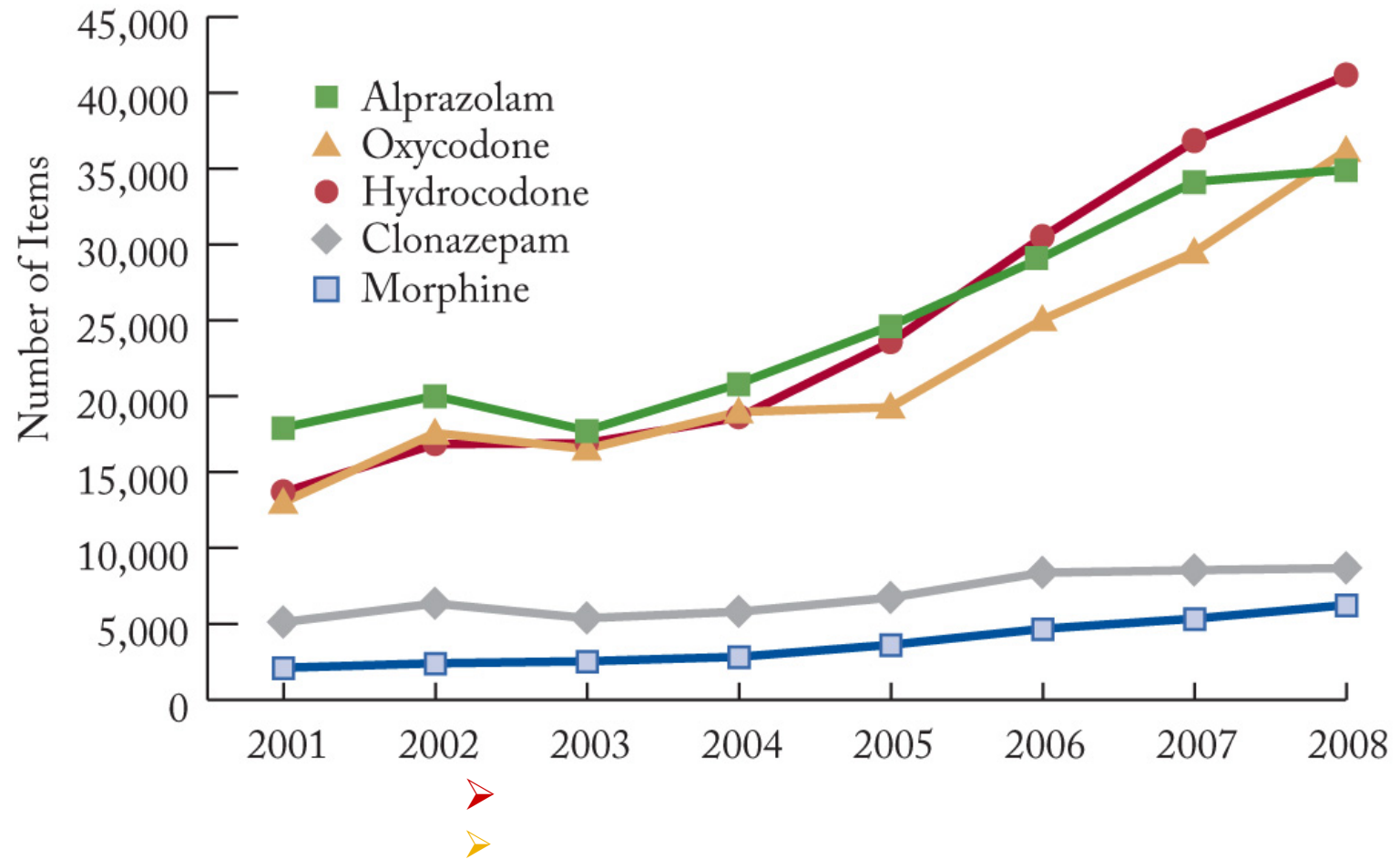
- A significant number are based in Florida
- Treat on avg 100+ “patients” per day
- \$150 - \$250 cash for Doctor’s visit
- \$200 - \$400 cash for prescription
- Dispensation directly from clinic or script is issued
 - Scripts are filled in numerous states
- They do not accept insurance, Medicare/Medicaid or credit cards
- “Patients” from Kentucky, Ohio, Tennessee, West Virginia
 - Travel to Florida individually by car, airplane or in groups on buses or chartered planes
- Drug dispensed
 - Oxycodone (avg. 120 tablets per script)



Commonly Abused Controlled Substance Pharmaceuticals



Number of Exhibits Submitted by S&L Law Enforcement



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*

NFLIS National Data - 2006

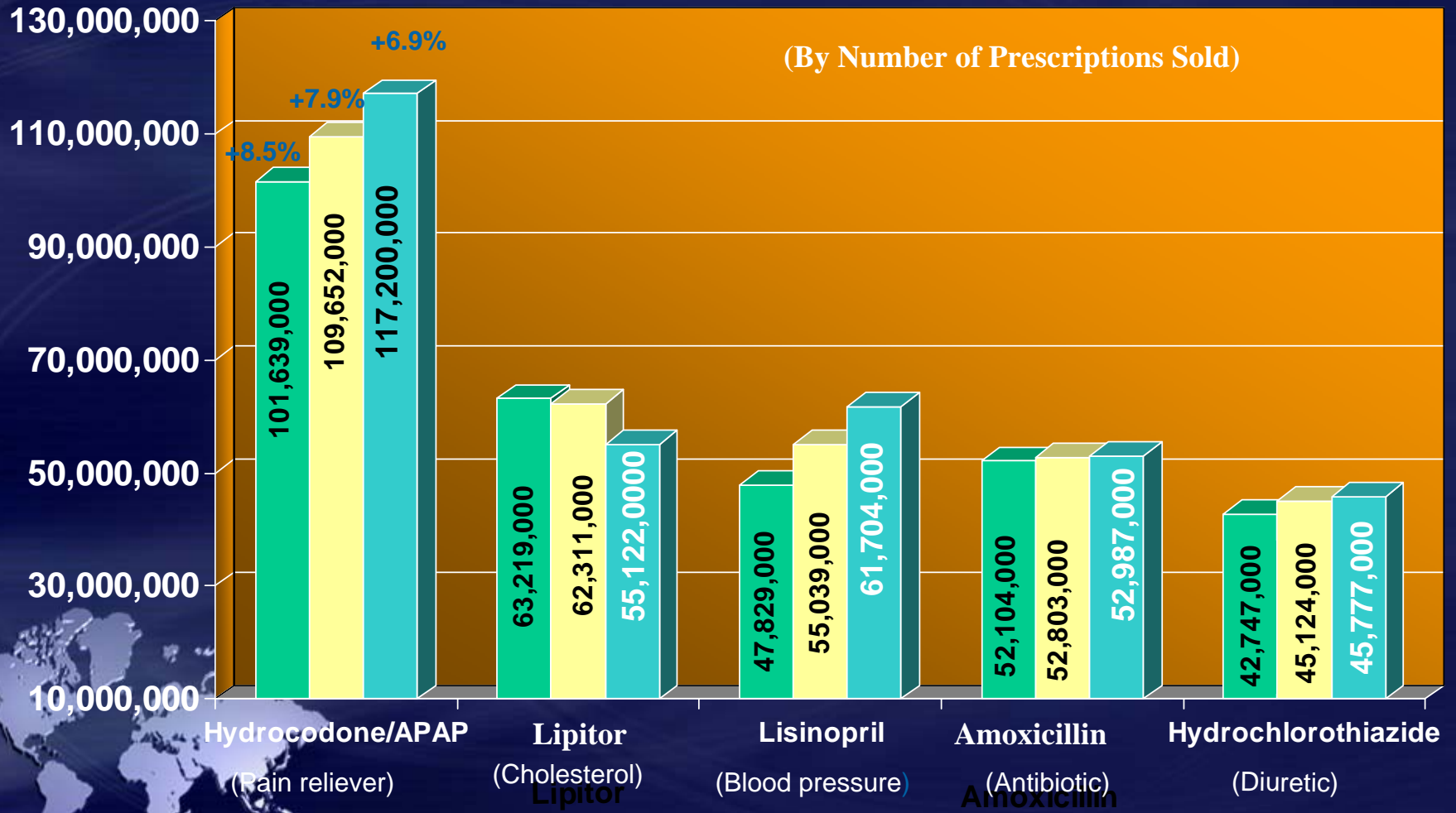
Narcotic Analgesics

	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%



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

OXYCODONE



NFLIS National Data - 2006

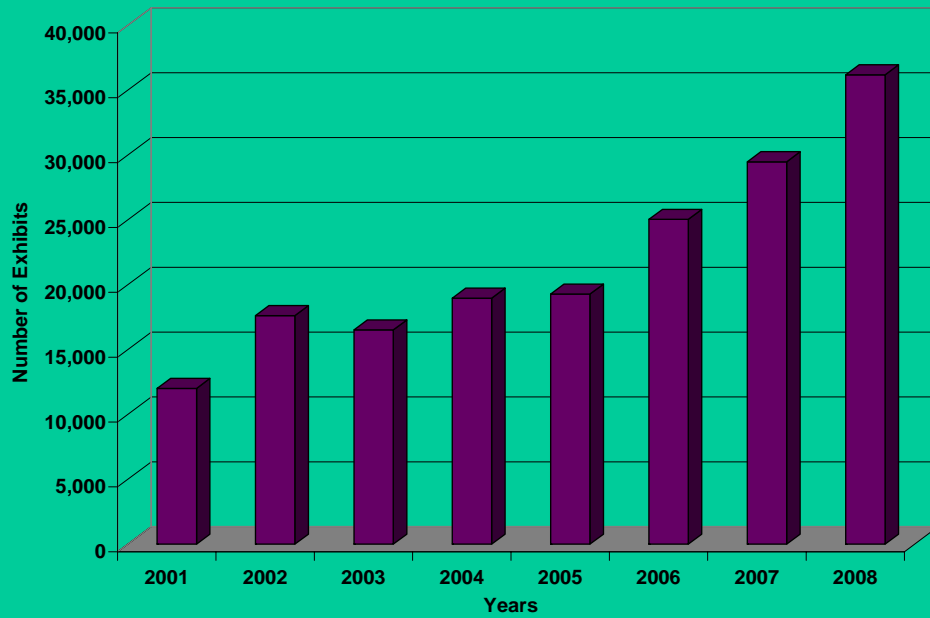
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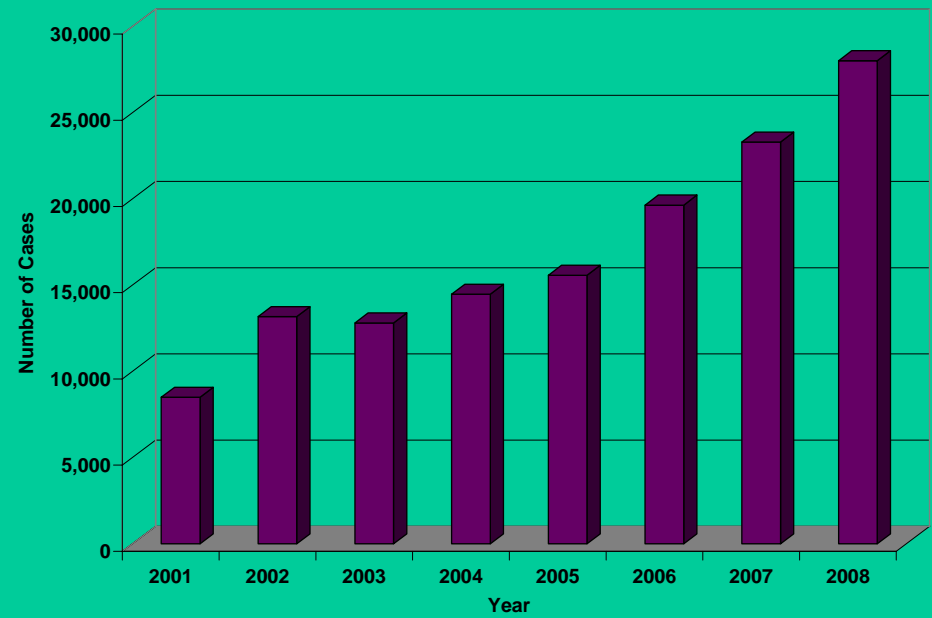


NFLIS National Estimates Oxycodone

Exhibits



Cases



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

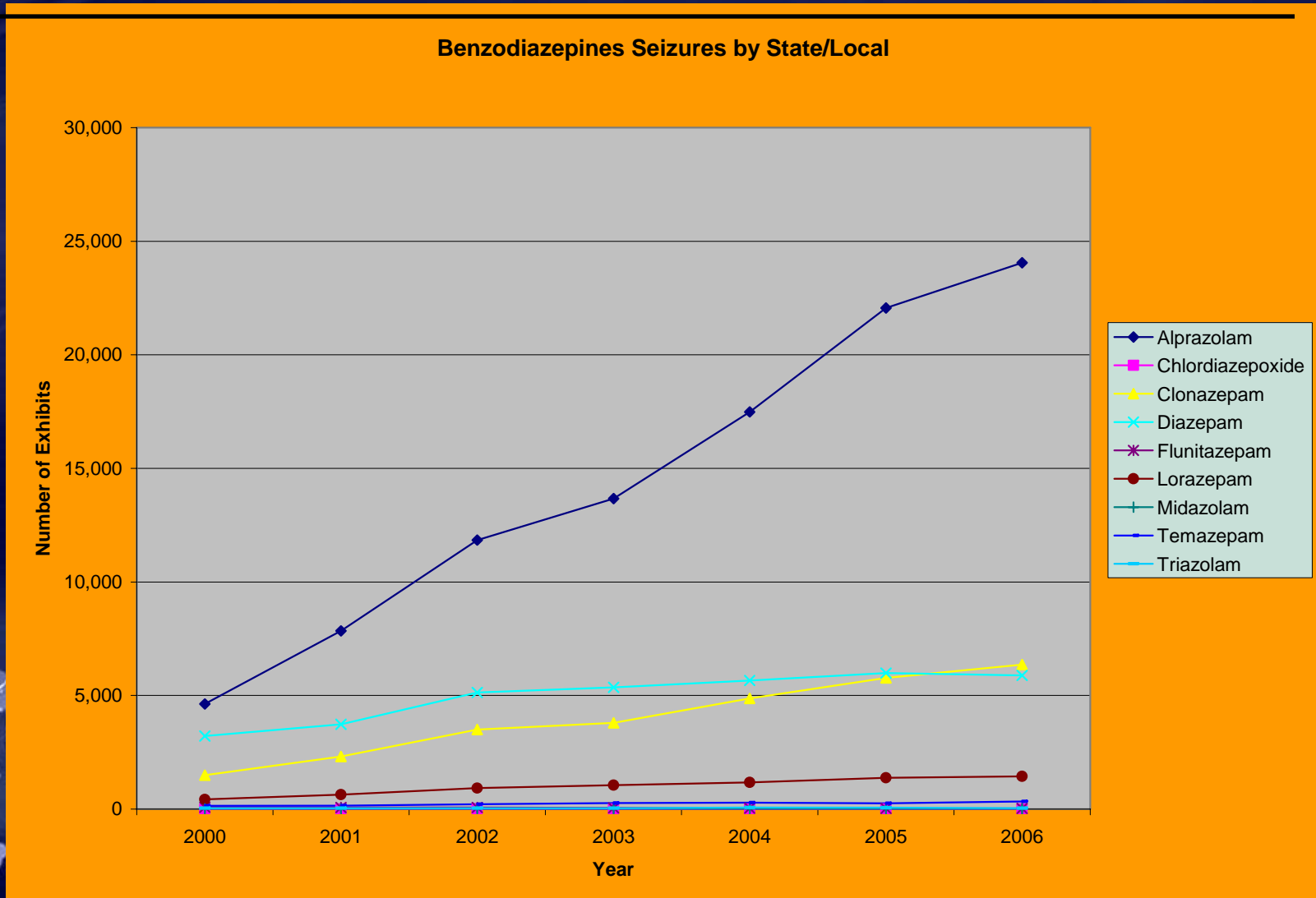
** Source Verispan VONA



C-IV



State and Local Seizure Data

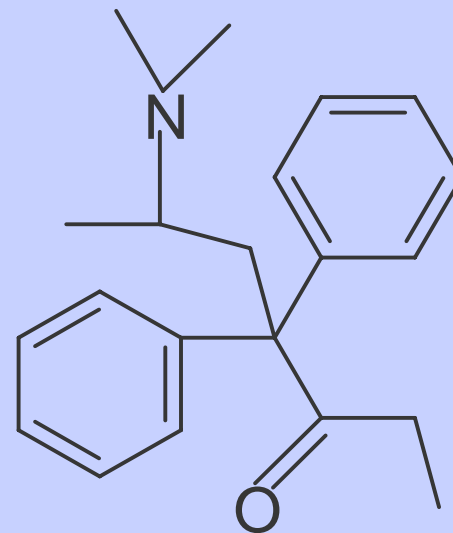


Other Controlled Substances

- Phentermine
- Phendimetrazine
- Amphetamine Alks
- Methylphenidate



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



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

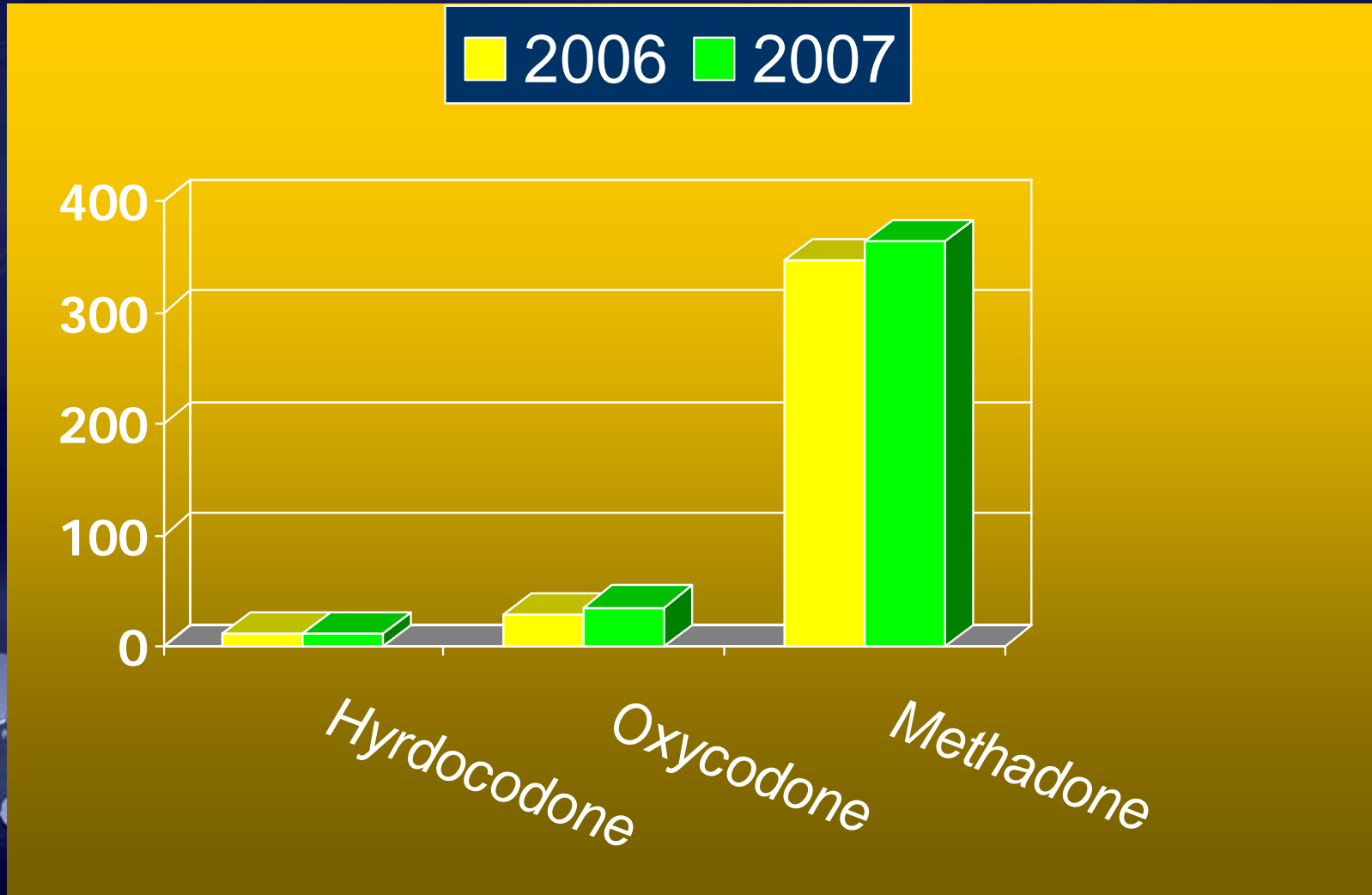
from drug treatment centers. Or it could lend credence to the prevailing view that more training is required for private physicians who prescribe methadone for pain.

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.

Deaths/100,000 Prescriptions in Florida

Deaths/100,000
Prescriptions



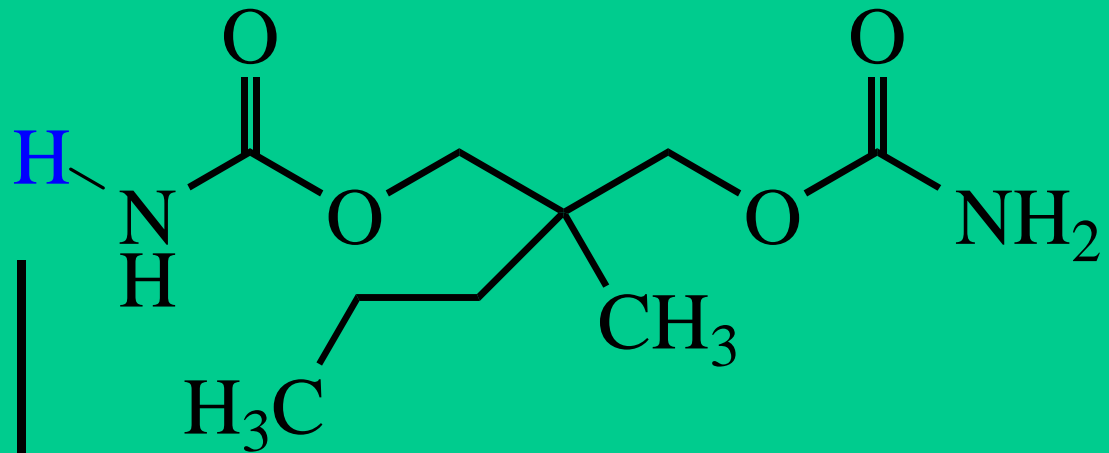
Source: FDLE and NPA Plus™

Non-Controlled Substances

- Analgesic:
 - Tramadol (Ultram®, Ultracet®)
- Muscle Relaxant:
 - Carisoprodol (Soma®)
 - Cyclobenzaprine (Flexeril®)
- Cough Suppressant:
 - Dextromethorphan (DXM)
 - Over-the-Counter (OTC) cold medication, such as: Coricidin® HPB Cough and Cold Tablets and Robitussin® Cough Syrup.

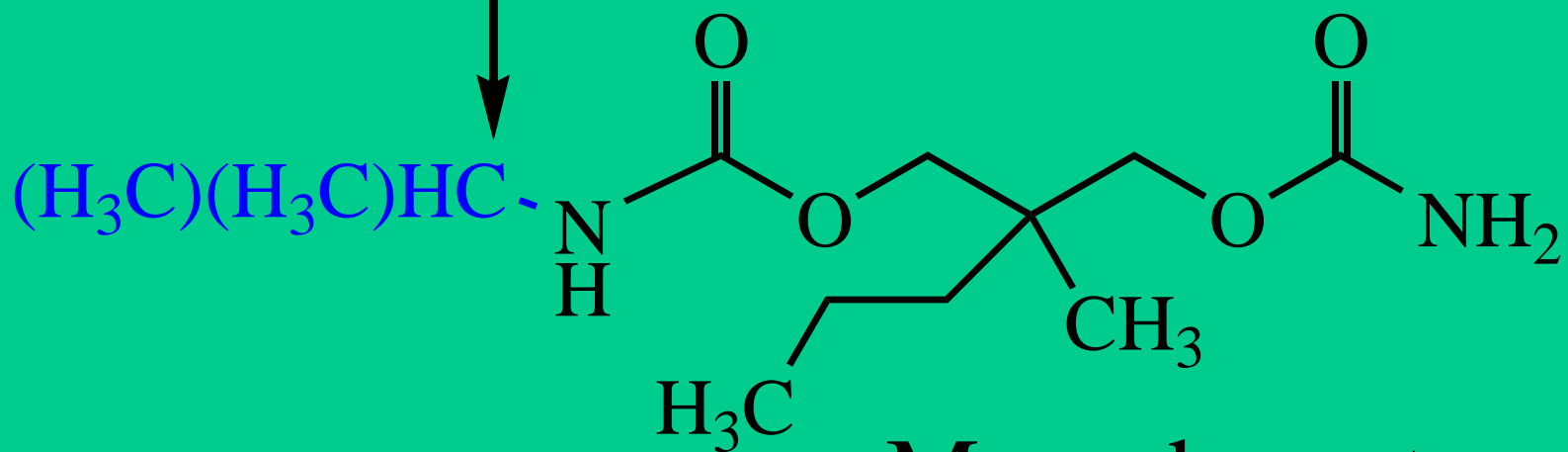


Carisoprodol

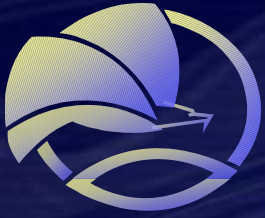


Structural Change

by Enzymatic Action in the Body



Meprobamate



**Registration,
CMEA Self-Certification, and
Clandestine Methamphetamine
Manufacture**



Self-Certification

- Seller self-certifies that –
 - Employees have been trained in retail sales regulations
 - Understands & agrees to comply with laws
 - Maintains copy
- Internet-based
 - Automated -- no need for direct interaction
 - Certification, NOT registration
 - Available to state & local officials
- Approximately 64,000 vendors have self-certified



CMEA Self-Certification Status

as of 5/11/2009

General Merchandise Stores	233
Convenience Stores	5,857
Discount Department Stores	1,862
Gas Stations	9,423
Grocery Stores	6,451
Other Health & Personal Care	312
Pharmacy and Drug Stores	35,557
Specialty Food Stores	27
Warehouse Clubs & Superstores	4,535

Total 64,268 Regulated Sellers

Self-Certification Fee

- **Effective on February 1, 2009**
- **Established \$21 self-certification fee for regulated sellers of scheduled listed chemical products.**
- **DEA registered pharmacies are exempt from fee.**



Smurfing



Smurfing

- **30 pounds of PSE seized after a day-long surveillance of five associated individuals conducting smurfing activities.**
- **Three members of the same organization were followed as they purchased PSE from 22 different stores and were not denied sales during any of the transactions (2 alerts were received, no stop sales).**
- **Due to the deterrent effects from the CMEA "smurfers" in the Mid-West are being paid between \$50 to \$ 75 dollars per box of tablets.**





1- True West-Pharm
Pseudoephedrine





Methamphetamine Production Prevention Act of 2008

- **S. 1276 and Public Law 110-415 sponsored by Sen. Richard Durbin {D-IL}**
- **Signed by the President on October 14, 2008**
- **Amended the CSA to expand written and electronic logbook requirements applicable to sales of scheduled listed chemical products**
- **Permits mix of manual and electronic capture of information**



Logbook Access Issues

➤ **21 CFR §1314.30(i)**

“The records required to be kept under this section must be readily retrievable and available for inspection and copying by authorized employees of the Administration under the provisions of 21 U.S.C. 880.”

➤ **21 U.S.C. §830(c)(2)**

“Information referred to in paragraph (1) may be disclosed only –

(D) to a State or local official or employee in conjunction with the enforcement of controlled substance laws or chemical control laws.”



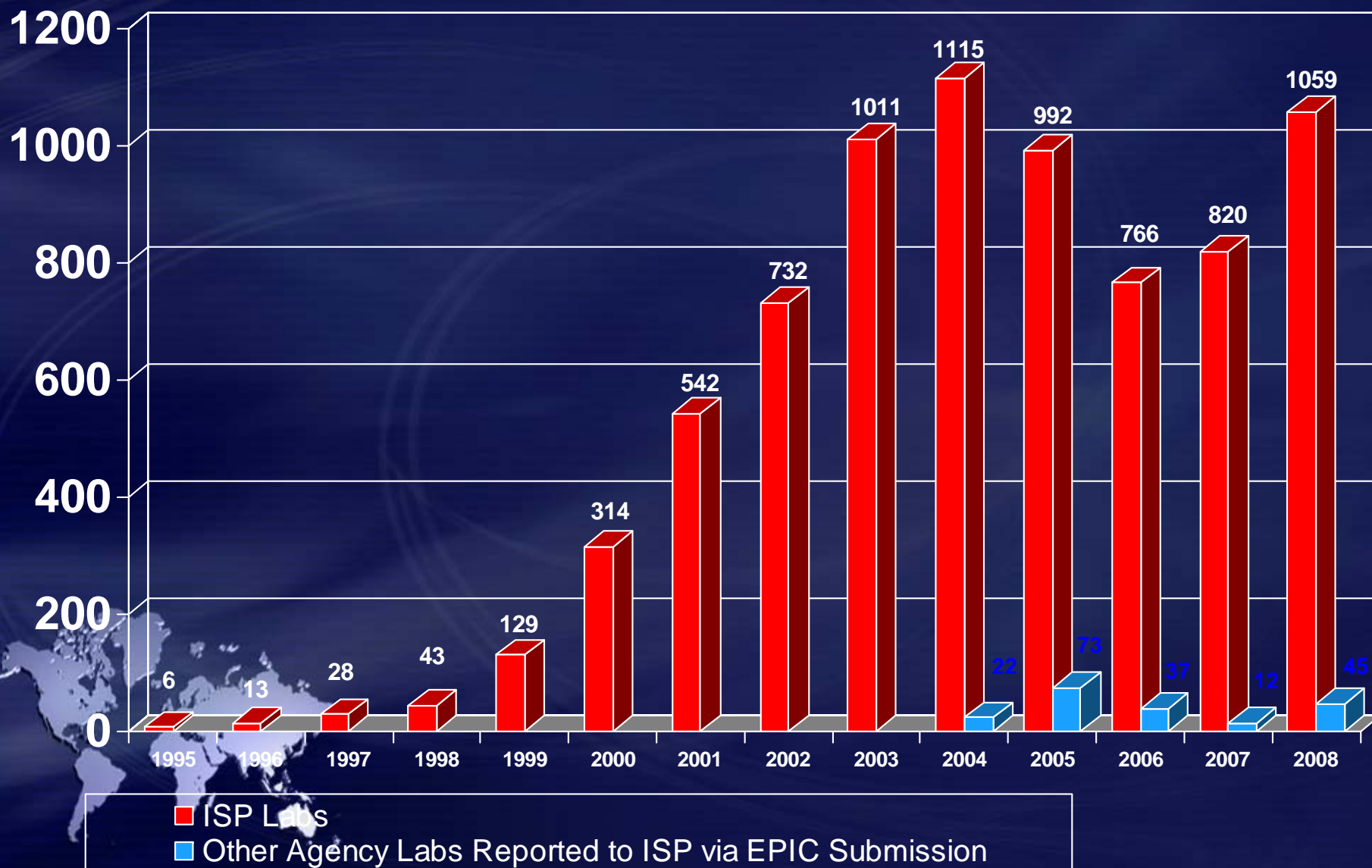
DEA & State / Local Clan Lab Seizure Stats

Meth Labs / All Drug Labs***

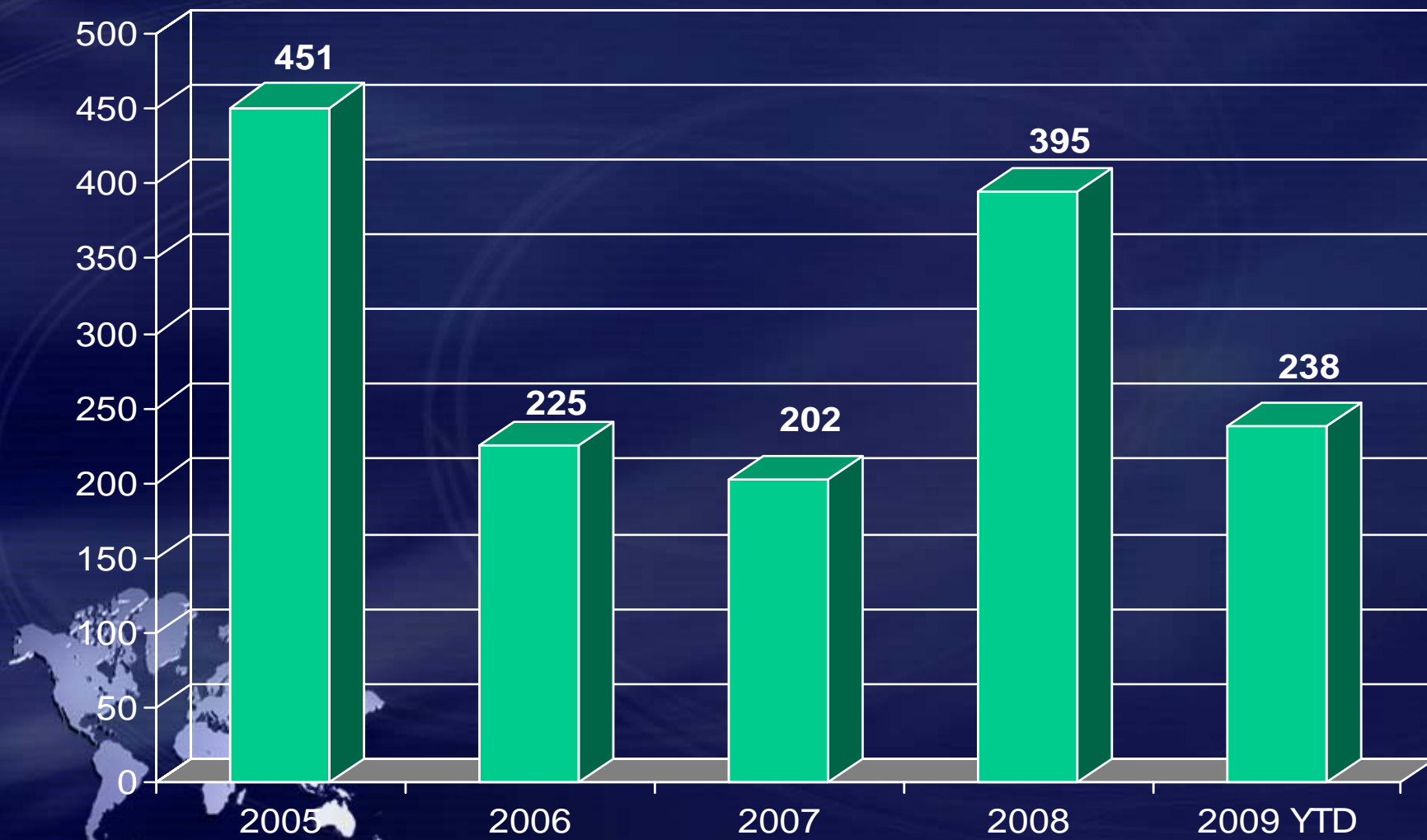
CY Year	All Incidents*	Labs Only*	Super Labs*	California Super Labs*	Children Affected/Injured/Killed**	Law Enforcement Injured	Suspects Injured/Killed**
2004	18,584	10,335	54	42	3,092 / 12 / 3	95	167 / 26
2005	13,408	6,308	34	28	1,873 / 4 / 1	32	78 / 13
2006	8,445	4,072	18	14	1,325 / 0 / 0	22	28 / 7
2007	6,153	3,068	11	10	849 / 7 / 1	42	49 / 8
2008	6,972	3,632	18	15	1,106 / 6 / 0	51	82 / 9
2009 1 st Qtr	935	506	7	1	113 / 4 / 0	1	7 / 0



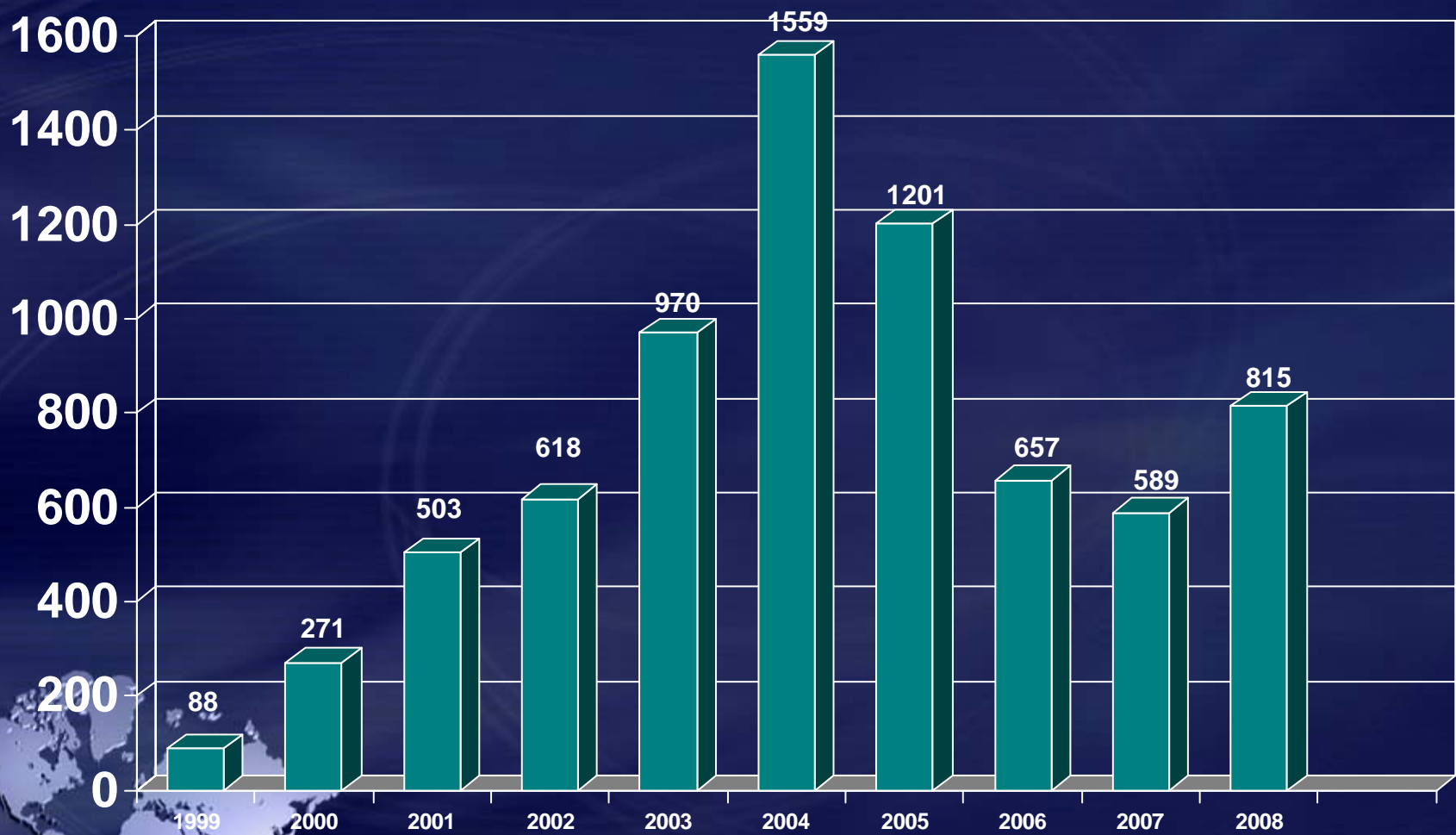
Indiana Clan Labs Reported 1995-2008



Michigan Methamphetamine Incidents 2005-2009



Tennessee Lab Incidents 1999-2009*



Oregon Lab Stats 2003-2007

<u>2003</u>		<u>2004</u>		<u>2005</u>		<u>2006</u>		<u>2007</u>	
January	34	January	40	January	24	January	9	January	3
February	38	February	42	February	19	February	6	February	0
March	36	March	49	March	23	March	15	March	1
April	49	April	39	April	31	April	8	April	1
May	51	May	59	<u>May</u>	<u>26</u>	May	4	May	4
June	26	June	42	June	15	<u>June</u>	<u>6</u>	June	0
July	37	July	42	July	7	July	4	July	0
August	42	August	30	August	10	August	6	August	1
September	52	September	28	September	8	September	2	September	3
October	53	<u>October</u>	<u>34</u>	October	13	October	2	October	2
November	33	November	18	November	9	November	1	November	3
<u>December</u>	<u>22</u>	<u>December</u>	<u>25</u>	<u>December</u>	<u>7</u>	<u>December</u>	<u>0</u>	<u>December</u>	<u>0</u>
473		448		192		63		18	

Purple Behind counter PSE sales

Blue Pharmacy only sales of PSE

Green PSE became Schedule

One Pot Meth Production

- Combine
 - PSE tablets – whole or ground up
 - Solvent – ether, camp fuel
 - Lithium
 - Sodium Hydroxide
 - Water
- Exothermic Reaction
 - Filter off liquid
 - Use HCl generator to crash out Meth







IcyHOT.
Pro-Therapy™
Pain Relief System Refill

Instant Cold Pack

For use in Icy Hot® Pro-Therapy™ Support Braces

Helps prevent swelling and relieves pain
due to stress or over-exertion

the package against your thumb (or index finger) firmly, curling fingers in, until the inner bladder breaks and you hear a popping sound. **SHAKE** package well to mix contents after activation. Do not place in freezer.

Stays cold for up to 30 minutes.

KEEP OUT OF REACH OF CHILDREN.

Contents: Water and Ammonium Nitrate (200g)

Distributed by Chattem, Inc.

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Chattanooga, TN 37409-0219 U.S.A.

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1990-02

INDEX











One Pot Conclusion

- With this method, they no longer have to use anhydrous ammonia.
- Nearly 100% of the labs in northern Indiana and Southern Michigan are one pot labs
- These are bottle bombs if they don't relieve the pressure.
- Soup dope is a similar method but they throw everything including the Anhydrous Ammonia into one pot to make the meth

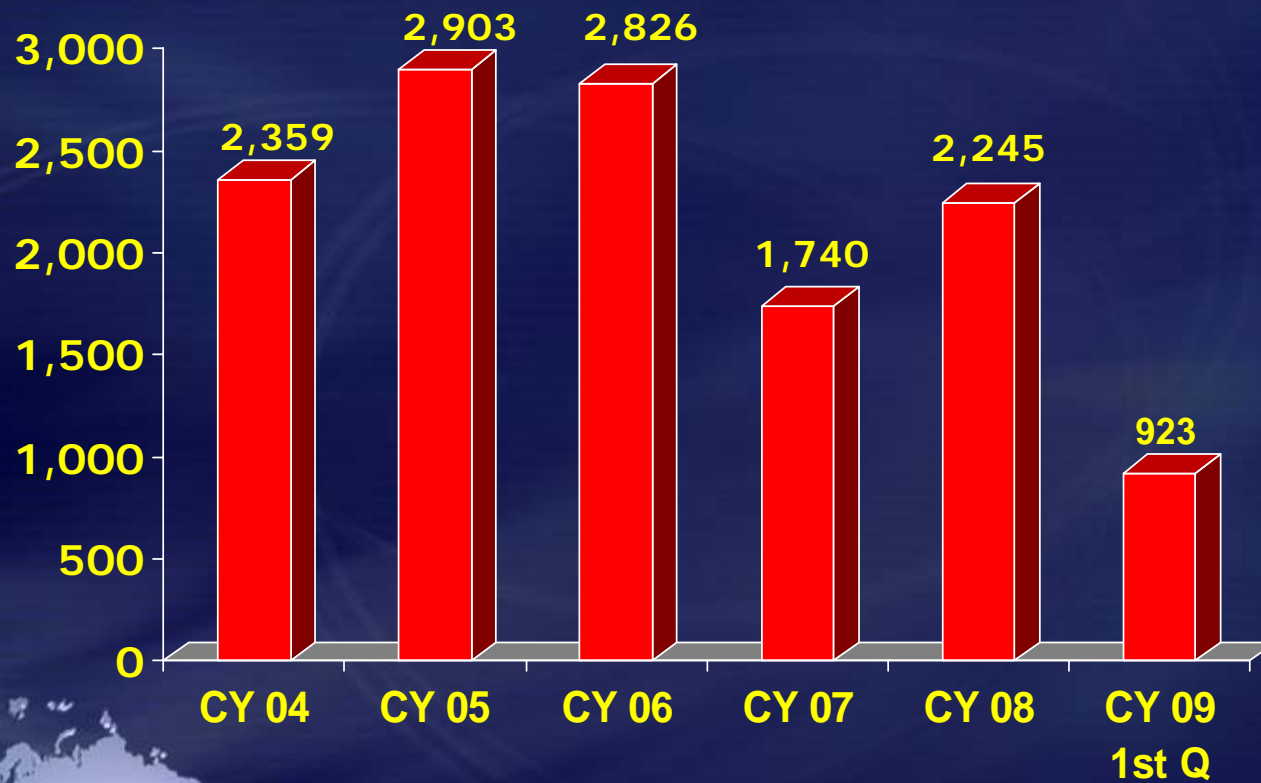




Easy-Bake Meth Lab

Methamphetamine Seizures at the U.S. Southwest Border

(In Kilograms)



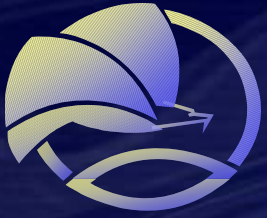
*Source: EPIC, SWB Seizure Statistics, as of 3/31/09; these methamphetamine statistics are for Texas, New Mexico, Arizona and California.

Percentage of Antihistamine Drugs Found in Methamphetamine Seizures POE Mexico - U.S. Border

➤ Chlorpheniramine	42%
➤ Triprolidine (Actifed)	23%
➤ Loratadine (Claritin)	18%
➤ Brompheniramine	8%
➤ Dextromethorphan	5%
➤ Carbinoxamine	0%

4th Qtr - 2008





Disposal of Controlled Substances



Current ONDCP Guidelines

- **ONDCP guidelines for the disposal of ultimate user medications, including dispensed controlled substances (Feb. 20, 2007).**
- **Advise public to flush medications only if the prescription label or accompanying patient information specifically states to do so.**
- **ONDCP recommends a minimal deactivation procedure, and disposal in common household trash.**



Ultimate User Disposal

- ANPRM published on January 21, 2009 in the Federal Register.
- Entitled “*Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*”.
- Seeking options for the safe and responsible disposal of patient owned controlled substances consistent with CSA.
- Comment period ended March 23, 2009.



Ultimate User Disposal

➤ Solicited information on the disposal of CS dispensed to ultimate user from:

- ✓ ultimate users
- ✓ law enforcement
- ✓ interest groups
- ✓ long-term care facilities
- ✓ hospices and in-home care groups
- ✓ pharmacies
- ✓ reverse distributors
- ✓ state regulatory agencies
- ✓ other interested parties



158 Comments Received

Closed System

- Under the CSA, Congress established a "closed system" of distribution to prevent the diversion of controlled substances.
- All persons who lawfully handle controlled substances must be registered with DEA or exempt from registration.
- Ultimate users are not required to register with DEA to possess controlled substances.



CSA Definitions

Under the Controlled Substances Act...

- An “ultimate user” is a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.
- To distribute means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.

Registration Requirement

- **Ultimate users are not permitted to distribute controlled substances for the purpose of destruction without being separately registered.**
- **Because of the registration requirement, it is unlawful for ultimate users to give their controlled substances to pharmacies, reverse distributors, etc. for destruction.**



Law Enforcement Involvement

- **Registration is waived for “Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his/her official duties.”**



Law Enforcement Involvement

- Law enforcement officers, acting in an official capacity may receive controlled substances from ultimate users.
- Law enforcement must safeguard the controlled substances and ensure that they are destroyed properly.
- Law enforcement must be present during the destruction of the controlled substances.



Law Enforcement Involvement

- **DEA regulations outline the procedure for the disposal of controlled substances by persons who are not registrants.**
- **Nonregistrants may submit a letter to the local DEA Special Agent in Charge.**

Legislation in the 111th Congress

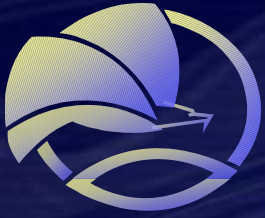
- **House Resolution 1359, Secure and Responsible Drug Disposal Act of 2009**
 - **Introduced on 3/5/2009 by Rep. Stupak (MI)**
 - **Amend the CSA to allow ultimate user (and LTCF) to deliver drugs to an entity authorized to dispose of them**
 - **Grant the Attorney General discretion to promulgate regulations**



Legislation in the 111th Congress

- **House Resolution 1191, Safe Disposal Act of 2009**
 - Introduced on 2/25/2009 by Rep Inslee (WA)
 - Amend the CSA to allow states to operate disposal programs
 - Direct the Attorney General to create five models to permit an ultimate user (and caretaker) to dispose to a designated facility





Electronic Prescriptions for Controlled Substances



Electronic Prescriptions for Controlled Substances

- **NPRM Published on June 27, 2008 in the Federal Register**
- **Proposal to provide DEA registered practitioners and pharmacies with the ability to electronically create, transmit, receive, and archive C II-V controlled substance prescriptions.**



Electronic Prescriptions for Controlled Substances

- **Comment period ended 9/25/08. More than 230 comments received.**
- **Processes and procedures proposed include:**
 - **Initial identity verification**
 - **Two-factor authentication**
 - **Use of HHS transmission standards**
 - **No alteration of prescription during transmission**

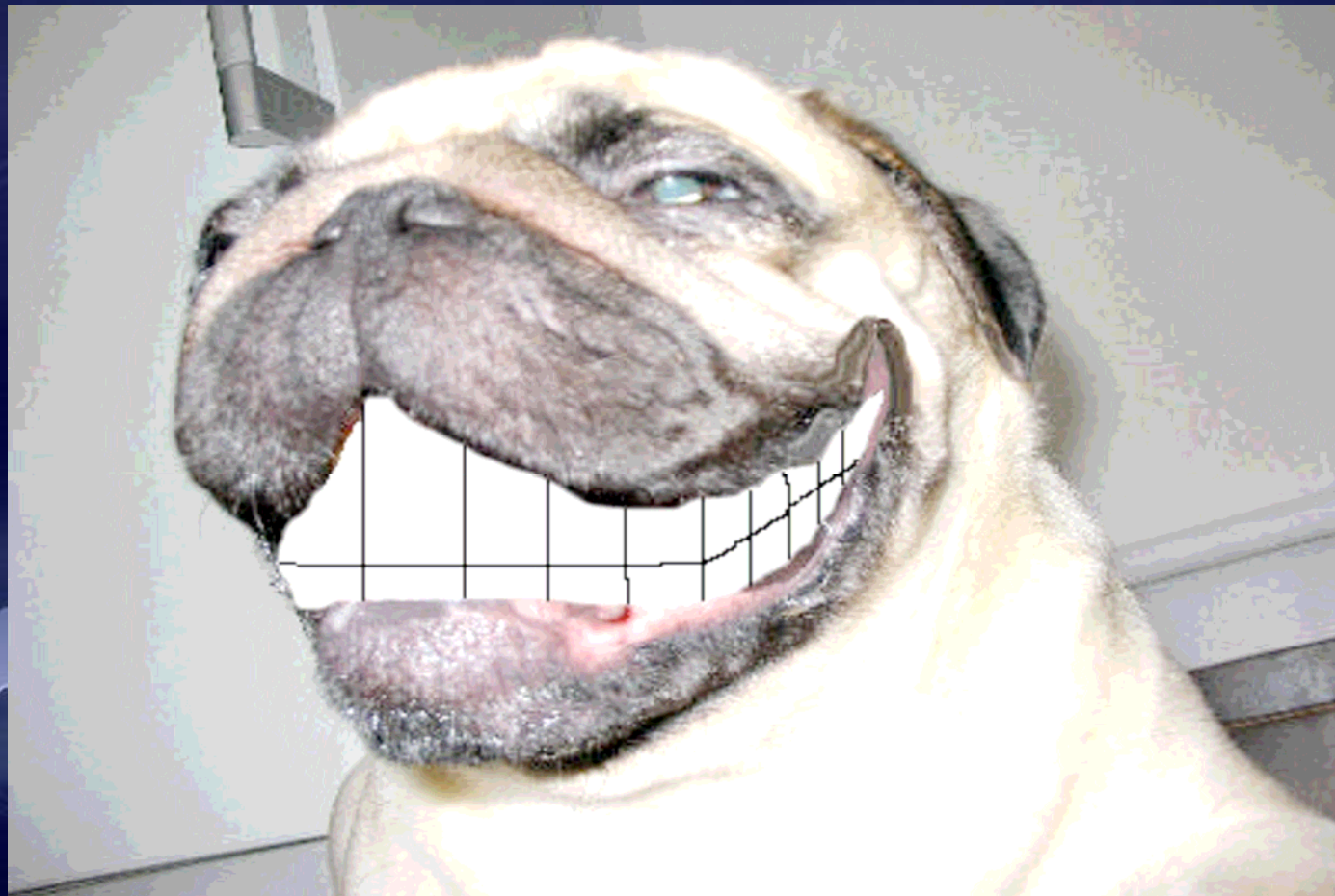




Steroids and Dietary Supplements

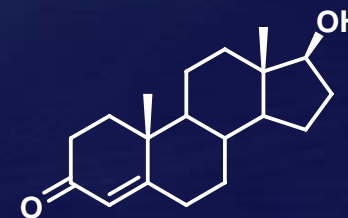


**Steroid Use is all about
appearance, not performance**



Timeline of Regulatory Control

- **Anabolic Steroid Control Act of 1990**
 - Placed 24 steroids under the CSA
- **Dietary Supplement Health and Education Act of 1994**
 - Labeling requirements
- **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

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**

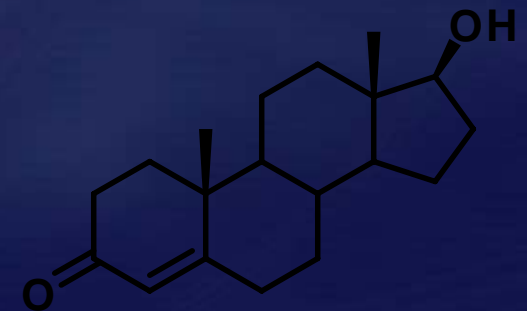


Requirements under the CSA

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



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 - Designer Steroids

DRUGS

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

SUPPLEMENTS

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

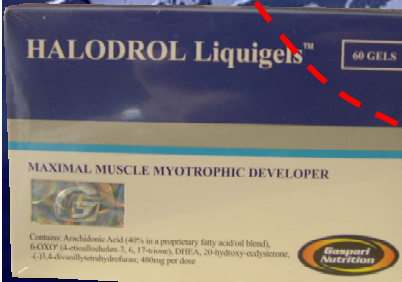
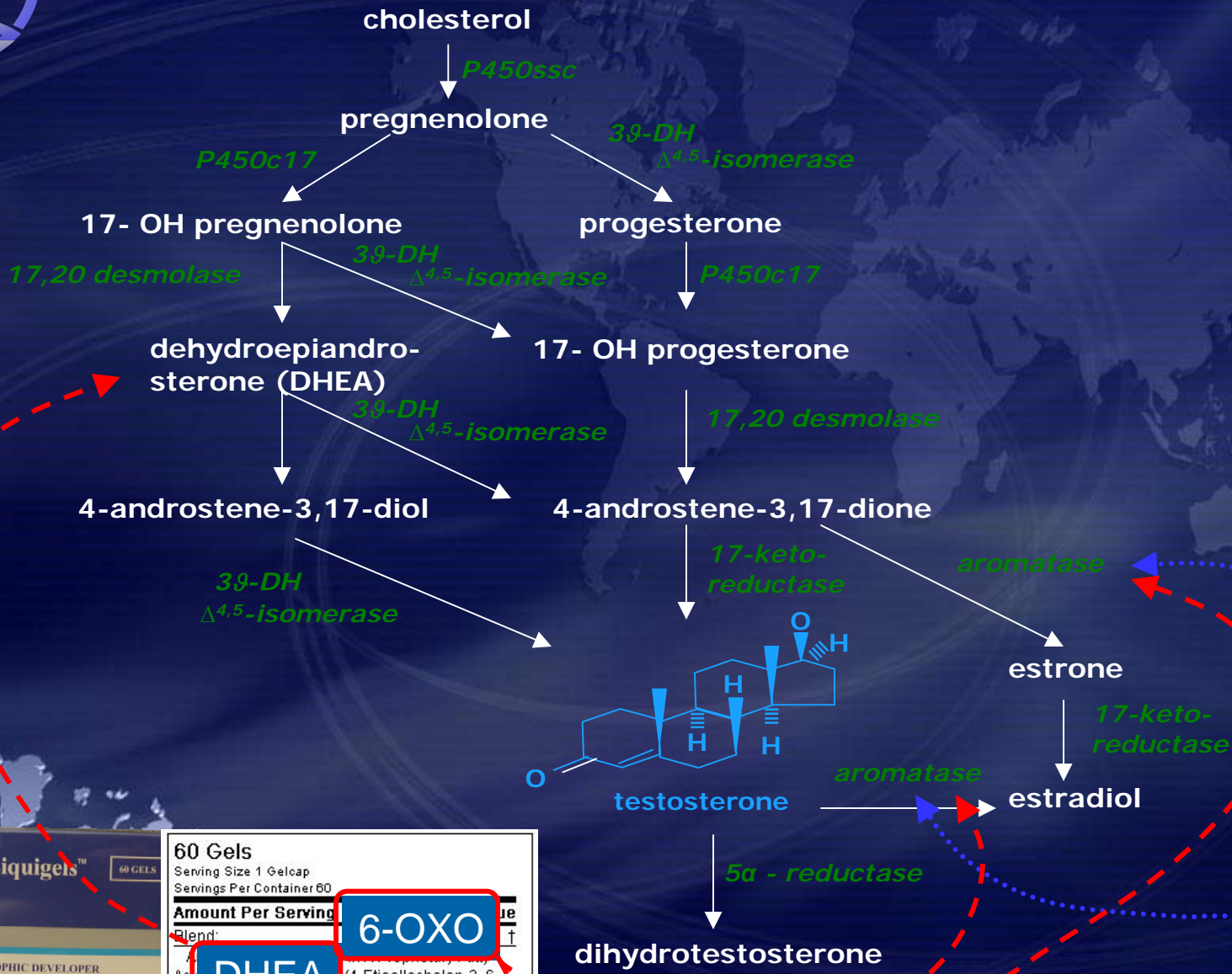


SUPPLEMENTS GONE BAD

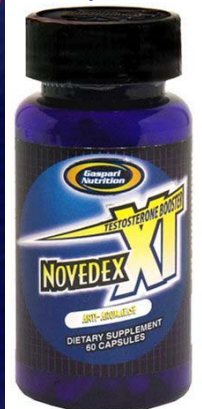
HYDROXYCUT



Synthesis of Testosterone



60 Gels	
Serving Size 1 Gelcap	
Servings Per Container 60	
Amount Per Serving	6-OXO
Blend:	
Ac	(4-Etioallocholen-3,6,17-trione)
17	hydroxy-Ecdysterone, -(-)3,4-Divanyltetranoruridin
† % Daily Value not established	





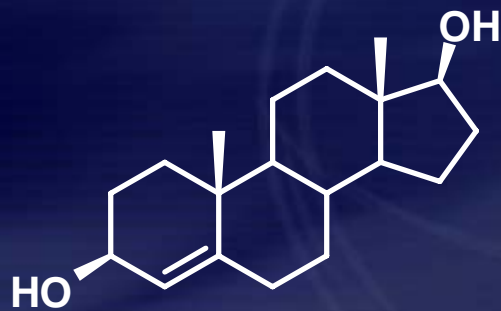
Indiana Drug Enforcement Association
23rd Annual Training Conference
February 26, 2009

Pharmaceutical Controlled Substance Diversion, Performance Enhancement Drugs and the Internet

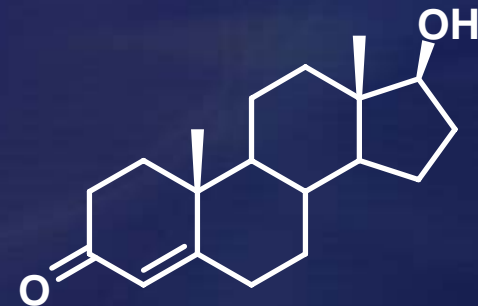
Joseph Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

Prohormones

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



4-androstenediol



testosterone



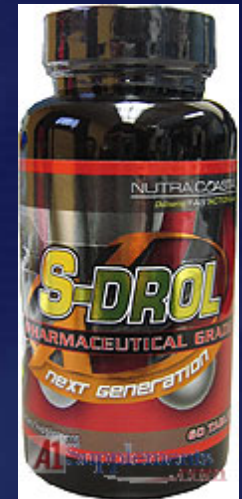
Three Steroids to be added to CSA

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



Steroids under Evaluation

- Recently, DEA supported testing of three steroids reportedly being abused for anabolic effects
 - methyldrostanolone
 - prostanazol
 - 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



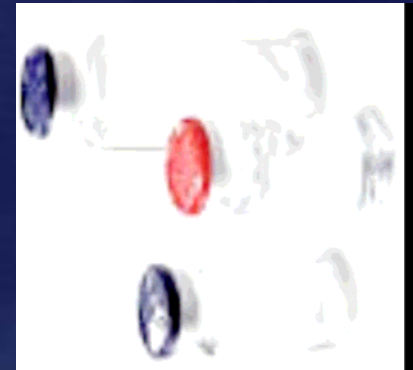
DEA Actions

- **DEA monitors appearance of new steroids**
- **Collects data on pharmacological activity**
- **Evaluate scientific literature to support DEA efforts:**
 - **over 600 dietary supplements have been analyzed for purity and 15% were found to contain anabolic steroids not reported on the labels**
 - **New steroids are intended to evade regulatory controls but have unknown pharmacology**
- **Initiates scientific testing**



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 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 (hGH)

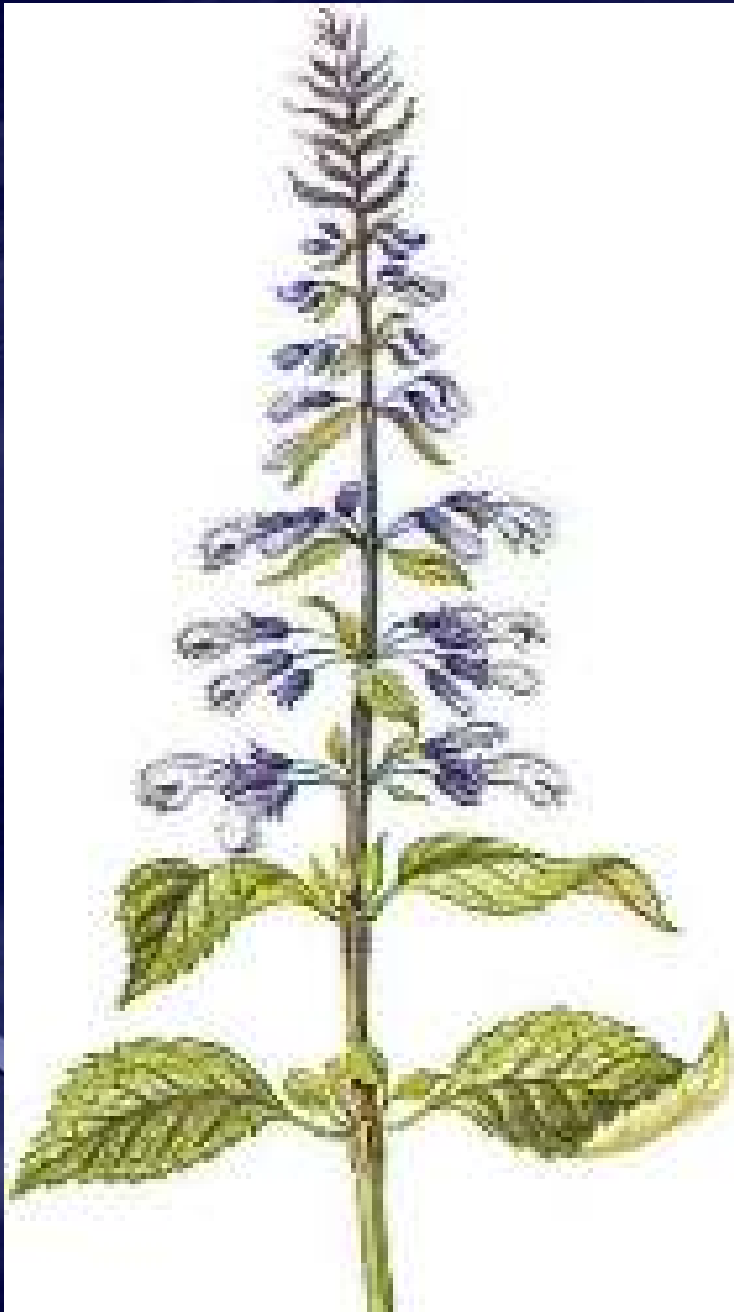
- Naturally occurring hormone
- Major action is to stimulate protein synthesis
- Prescribed for delayed growth in children
- Also has veterinary uses:
 - Enhancing milk production in cows
 - Stimulates muscle growth and reduces fat deposition in pigs
- hGH abused for synergistic effects in combination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



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



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Ecstasy Products 1-800-365-0000
Retail only website link.
Prices and offer subject to change without notice.
Visit website prior to purchase.
Salvia Divinorum not intended for human consumption.
No Sales to Minors



STEP BY STEP GUIDE TO CLONING

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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.

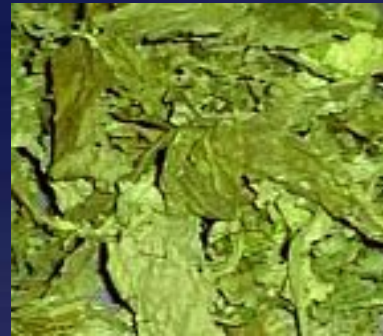


Salvia Divinorum As Sold Over the Internet

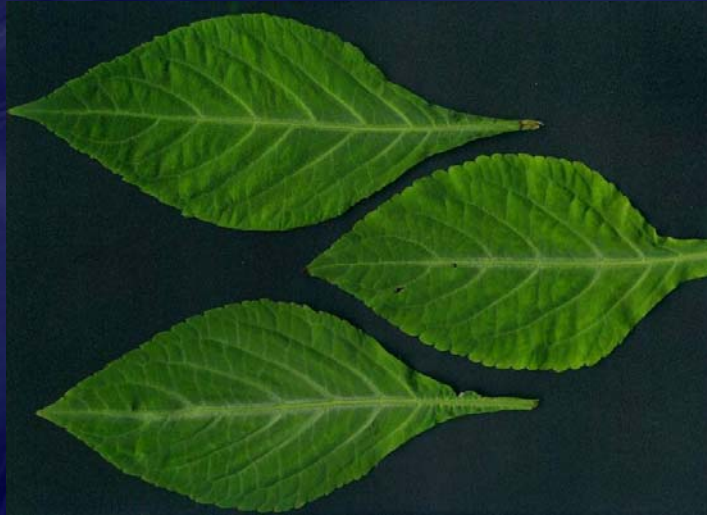
Internet sites advertise Salvia as a legal alternative to other controlled hallucinogens.

Sold as:

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



Salvia Divinorum Use in the U.S.



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

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



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

Effects

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



DEA Diversion Website

www.DEAdiversion.usdoj.gov

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
IIFLIS
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
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REGISTRATION SUPPORT

SAVE TIME
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



Thank You

