



*U.S. Drug Enforcement Administration*

# The Role of DEA in Controlling Drug Abuse

American Society of Interventional Pain Physicians

Washington, D.C.

June 30, 2009



# OBJECTIVES

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- **Title 21/Background**
- **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**
  - **Dr. Shoppers**
  - **Drugs of Abuse**
- **Current Issues**
  - **EPCS**
  - **Disposal of controlled substance pharmaceuticals**

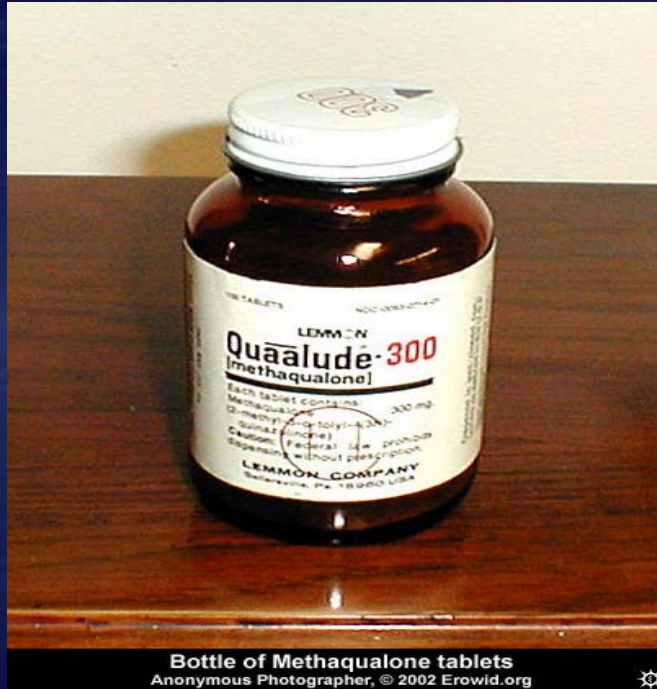


# Controlled Substances Act of 1970

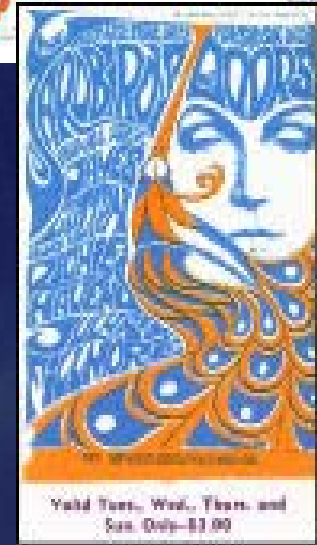
- Established a “closed system” of distribution
- Five “schedules” of controlled substances
- Created the Compliance Program (1971) to monitor the legitimate manufacture and distribution of controlled substances
- Clearly differentiated controlled substances from other “legend” drugs handled under the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



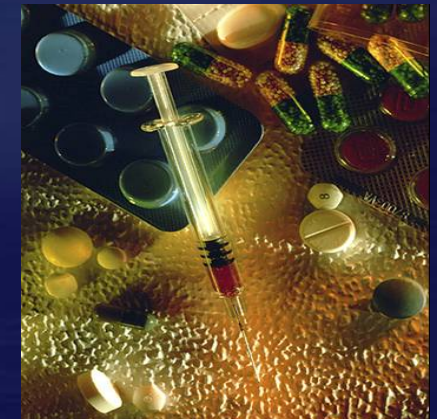
# The 1970's



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



Heroin



# The 1980's

## T's and Blues (Talwin and Pyrabenzamine)



Hydromorphone



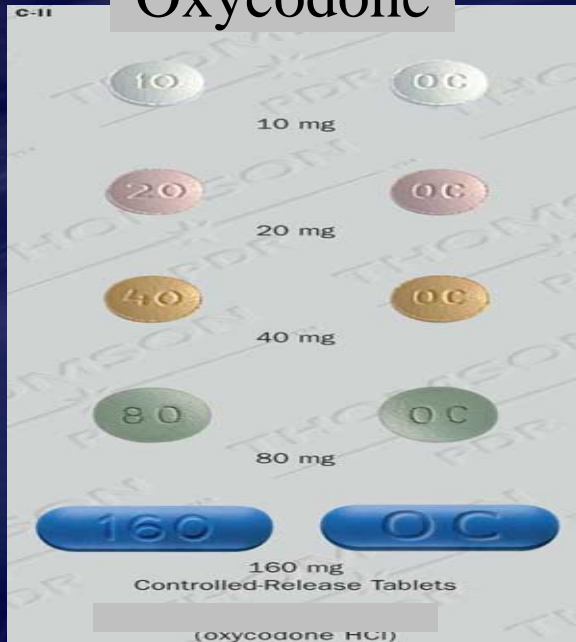
Cocaine

## 4's and Doors Tylenol w/Codeine and Doriden



# The 1990's

## Oxycodone



## Methamphetamine

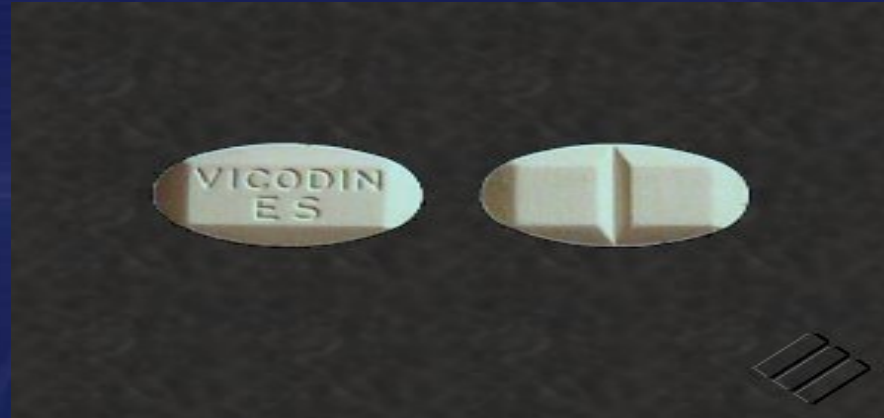


# 2000 and Beyond

## Hydrocodone



Ketamine



MDMA



Flunitrazepam  
(Rohypnol)



Alprazolam

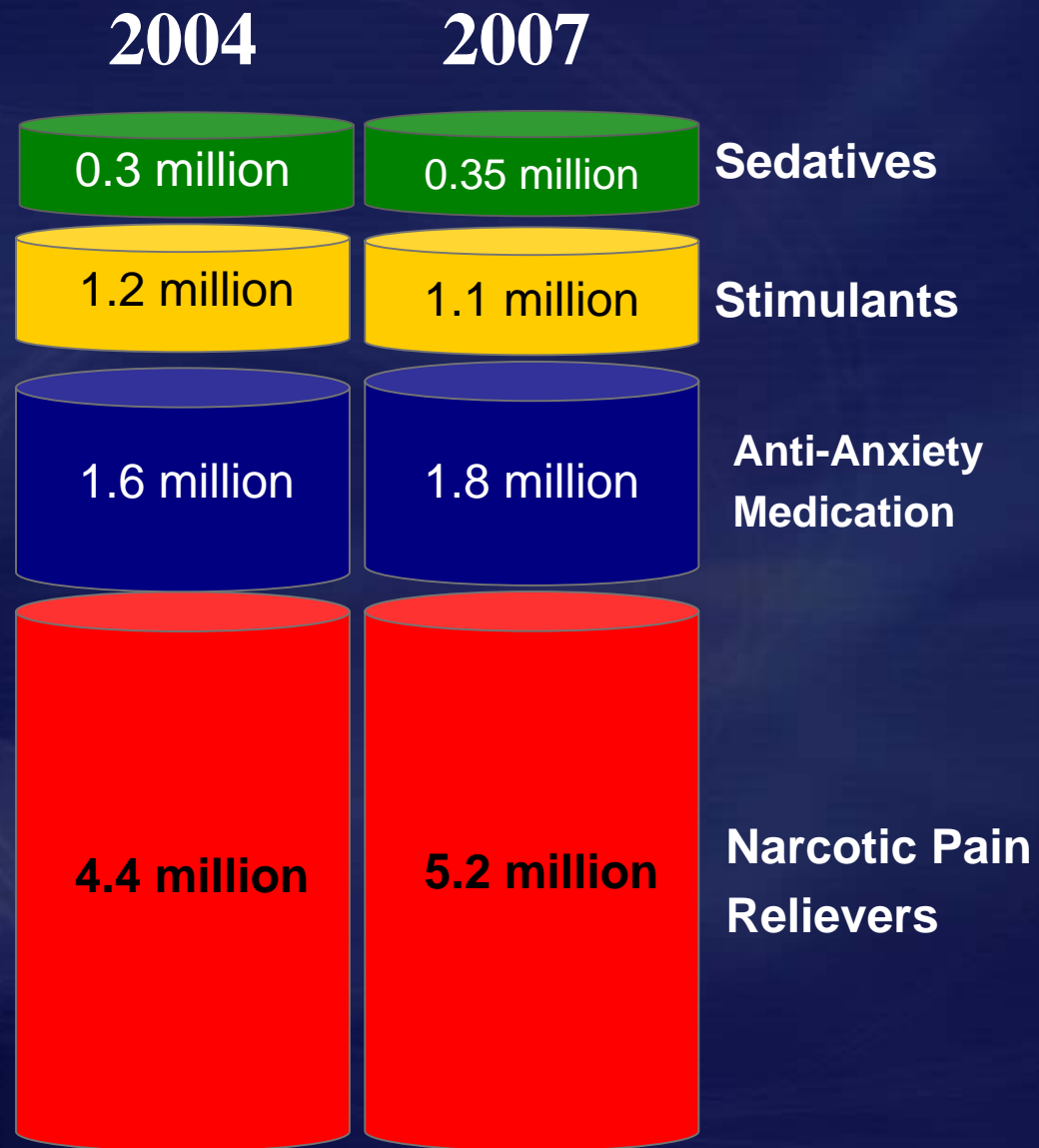
# The Perfect Storm

- **Misperception: When we don't see specific drugs anymore the problem has gone away**
- **Federal, State and local labs are reporting higher numbers of exhibits and cases related to pharmaceuticals**
- **Shift in the user / abuser population**
- **Fraudulent use of Medicare / Medicaid or insurance to fund drug habits**
- **Information / Electronic era**
  - **Web sites provide information on how to use drugs illegally and where to get them**
  - **Social networking – blogging, twitter, or chat rooms for instant exchanges of information**
  - **Anonymity – no more face-to-face meetings**





# Scope and Extent of Problem



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

# Trends in Prescription Drug Abuse

- **Non-medical use of prescription pain relievers was the category with the largest number of new initiates (2.1 million)<sup>1</sup>**
- **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**



<sup>1</sup>SOURCE: 2007 National Survey on Drug Use and Health



# Abuse

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



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

# Teens and Their Attitudes



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



# Teens and Their Attitudes

- **The abuse of prescription and over-the-counter medicines among teens continues to be a troubling trend**
  - **Teens mistakenly believe that abuse of prescription drugs is less dangerous than abuse of illegal street drugs**
  - **Teens report prescription drugs are easier to get than illegal drugs, up significantly from 2005**
  - **Majority of teens report abusing a prescription medication at least once in their lives**
  - **10% of teens report having abused a Rx pain reliever**
  - **7% of teens have abused OTC cough medicine**



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



## Teen Attitudes

- Parents are still not discussing the risks of abusing prescription and over-the-counter medicines despite the increase in parent/teen discussions about the risks of illegal drugs
  - Only 24% of teens report that their parents talked with them about the dangers of abusing prescription (Rx) drugs or use of medications outside of a doctor's supervision
  - Just 18% of teens say their parents discuss the risks of abusing over-the-counter (OTC) cough medicine

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



# 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





## Number of MDs and DOs Registered with DEA

CY	Registrants	Arrests	Percentage
2005	772,734	68	.0088
2006	786,206	72	.0092
2007	791,627	84	.0106
2008	808,480	80	.0099
2009*	807,759	22	.0027

CY 2009 = Jan 1 to May 31





# Internet Diversion



# Rogue Internet Pharmacy



# Rogue Internet Pharmacy



## Components for a Domestic Rogue Internet Operation

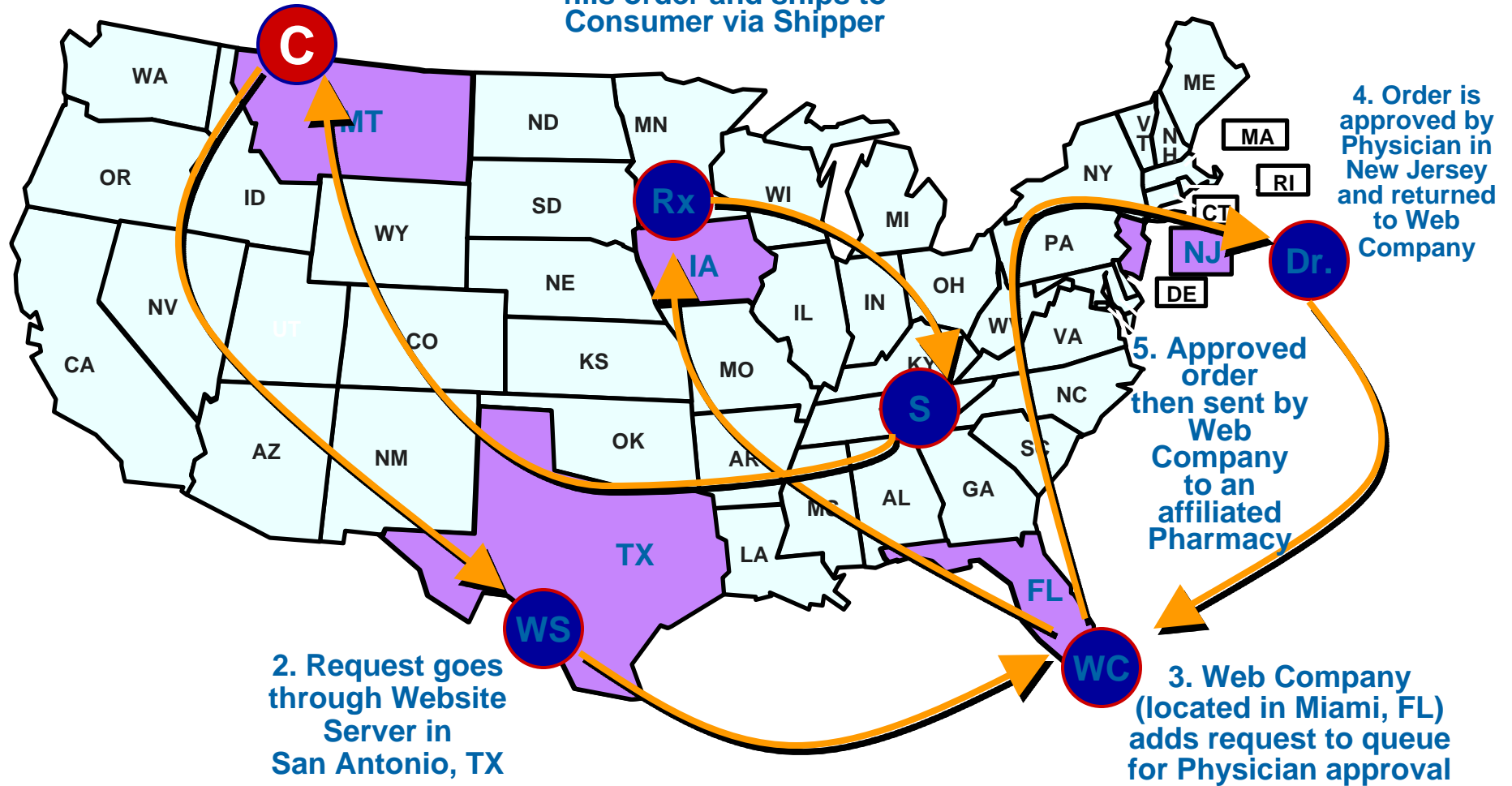
- Web Broker / Facilitator (optional)
- Practitioner
- Pharmacy
- \*\*All members of scheme are complicit thereby eliminating all checks and balances
- Source of Supply





1. Consumer in Montana orders hydrocodone on the Internet

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

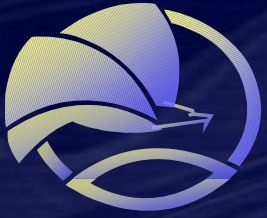


4. Order is approved by Physician in New Jersey and returned to Web Company

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

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

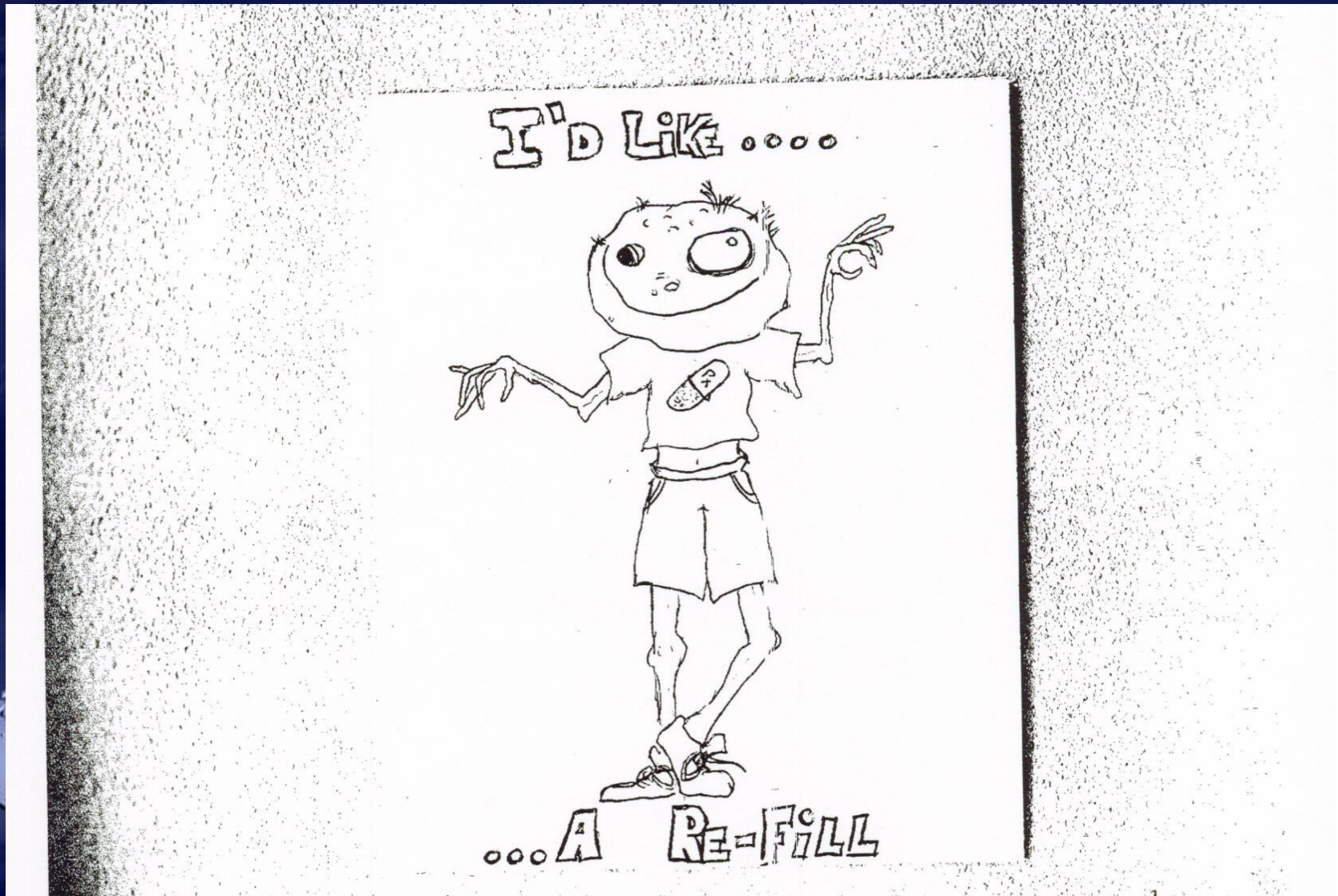
3. Web Company (located in Miami, FL) adds request to queue for Physician approval



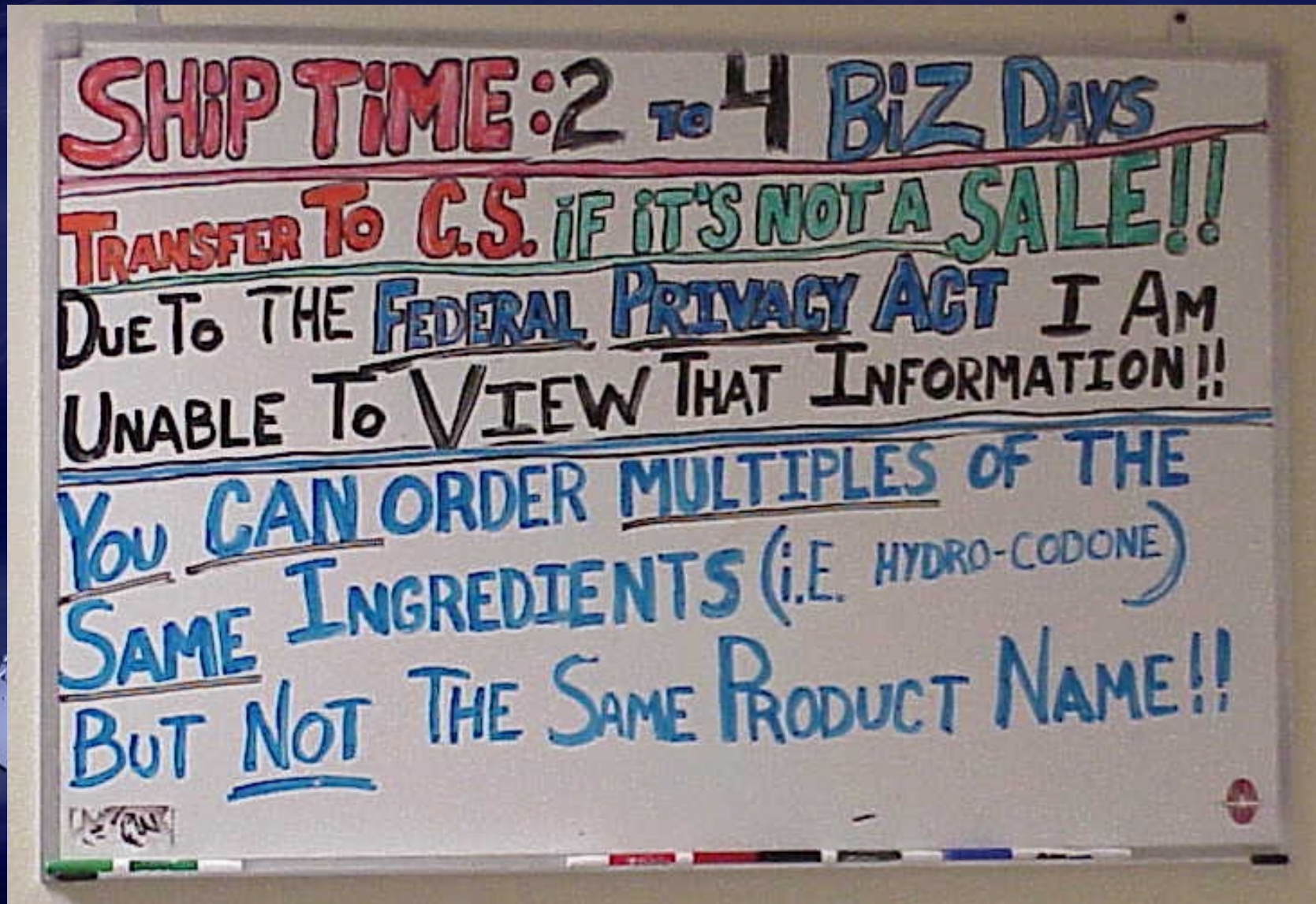
# Case Example



# 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

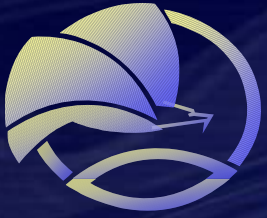
5/5/5  
→ use: [www.xpress-rx.com/digi/](http://www.xpress-rx.com/digi/)

**REMINDER:**

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

Ask For Discover Card 1st

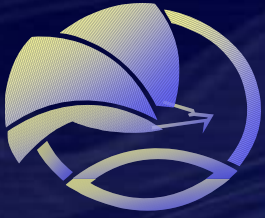
PAID WITH Discover Card



**Total Forfeiture:**

**\$4,370,258.80**





# **Internet Legislation & Implementing Regulations**



# **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 Internet Pharmacy  
registrations ??????

**5** (As of June 2009)





# Traffickers Are Adapting - Current Schemes





## Current Schemes – Pain Clinics

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





# Places of Interest

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





## Places of Interest

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





## Places of Interest

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





# Outside the Scope

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







## Outside the Scope

- Indicators/Probable Cause Factors  
(*continued*)
  - Patients receive same drugs, or combination, regardless of diagnosis/condition
  - Physician writes scripts in 3<sup>rd</sup> party patient names
  - Physician will not write refills
  - Patients travel long distances
  - Large amounts of cash patients
  - Large amount of narcotic prescribing by non-pain specialists





# DOCTOR SHOPPING



# *Doctor Shopping*

- What is it?
- Who is doing it?
- What's the cost?
- How is it done?
- Case reviews
- Investigative/Prosecution strategies
- Prevention/outreach



# What is it?

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



# Characteristics

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



# Characteristics

- Complain of severe pain, stress, or insomnia
- From out of state or recently arrived in area
- Provide suspicious letters or medical tests with diagnosis and need for medication
- Medically knowledgeable
- Asking for specific medication
- Loss of prescriptions from theft, accidents, etc
- Lost or False identification



# Impact-Cost to Consumers

- One insurance company reported: Half of all member fraud cases in 2006 involved prescription fraud cases, primarily *doctor shopping*
- Coalition Against Insurance Fraud (CAIF):
  - Typical doctor shopper can cost an insurers between \$10,000 to \$15,000 per year
  - Diversion of pharmaceuticals costs health insurance companies up to \$72.5 billion annually
  - Costs include physician office visits, emergency room treatment, tests, and rehabilitation for addicted doctor shoppers



# AMA/CDC Study-Overdose Deaths

- West Virginia
  - Overdose deaths increased 550% between 1999 and 2004
  - In 2006, 93% of unintentional overdose deaths involved non-medical use of prescription drugs (93% of those involving opioid analgesics).
  - Reviewed records, categorized between “drug diversion activities” (no prescription) and “doctor shopping” (five or more physicians in one year period)
  - 63% drug diversion deaths, 21% doctor shopping deaths





# AMA/CDC Study-Overdose Deaths

- Characteristics
  - “**Diversio**n” deaths showed same indicators as deaths from illicit drugs,
    - 2/3 male
    - most younger than 35,
    - non-medical route of administration
    - combined pharmaceuticals with illicit drugs
  - “**Doctor Shopping**” deaths showed significantly different characteristics
    - Twice as many female as male
    - Greatest rate in ages 35 to 44
    - Twice as many had previous overdose
    - Administer drug as prescribed
  - Only 8% showed indications of both diversion and doctor shopping



# Doctor Shopping

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



# Doctor Shopping

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



# Doctor Shopping

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



# Reducing Activity

- Physicians play critical role
- Physicians utilize pain management guidelines regarding analgesic prescribing published by professional organizations and state medical boards
- Refer patients with chronic pain issues to pain management specialists (MDs with board certification in: Anesthesiology, Physical Rehabilitation, Psychiatry or Neurology)
- Physicians and pharmacists utilize state prescription monitoring programs





# Prescription Fraud

- **Fake prescriptions**
  - Highly organized
  - Use real physician name and DEA Registrant Number
    - Contact Information false or “fake office”
    - Organizations set-up actual offices with contact information and staff (change locations often to avoid detection)
  - Prescription printing services utilized
    - Not required to ask questions or verify information printed
- **Stolen prescriptions**
  - Forged
  - “Smurfed” to large number of different pharmacies

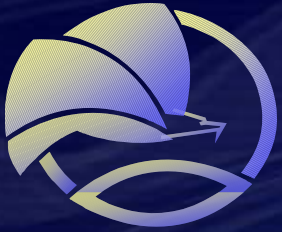




# Street Gangs

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





# Commonly Abused Controlled Substance Pharmaceuticals





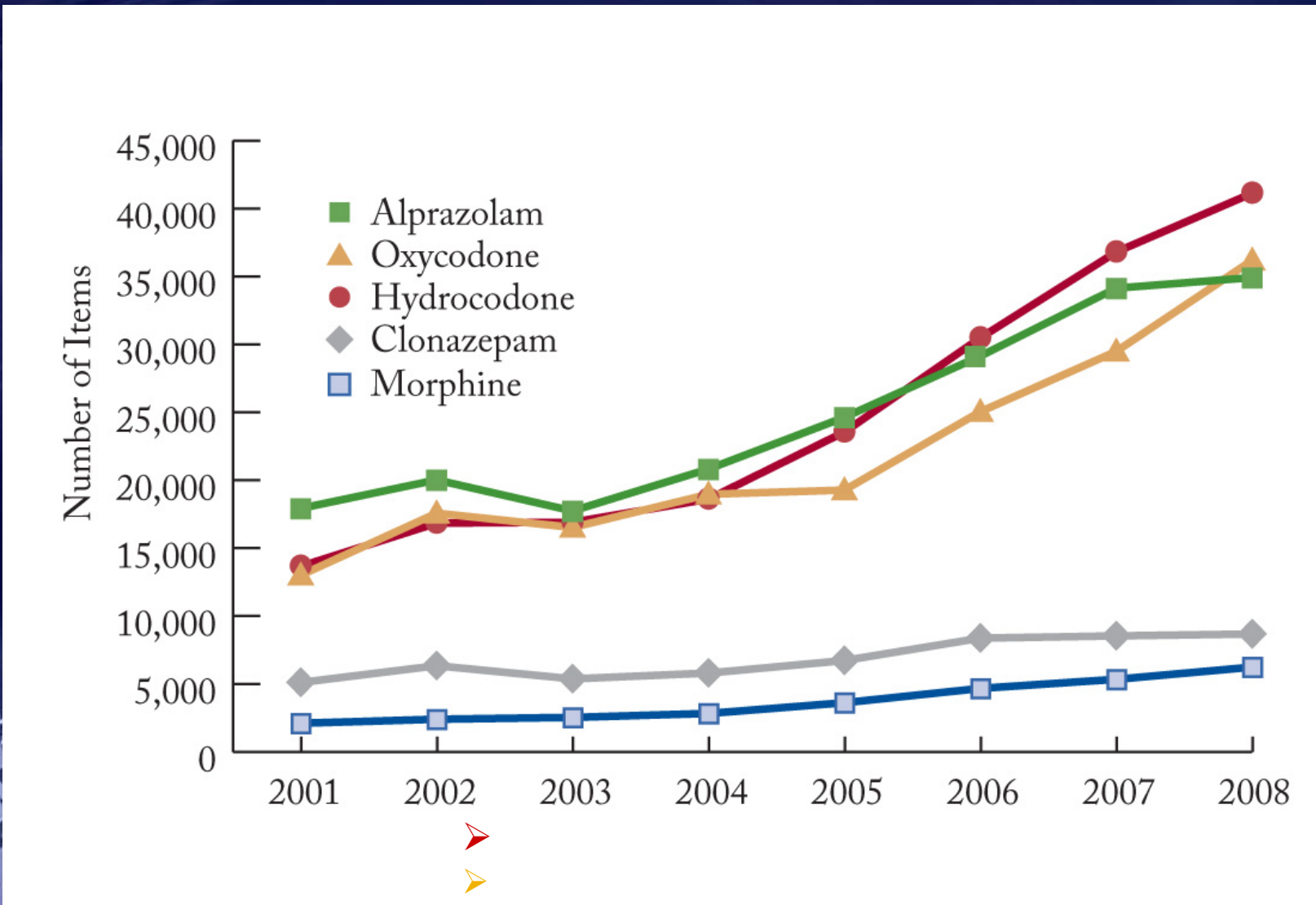


# Cocktails

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



# Number of Exhibits Submitted by S&L Law Enforcement



# Hydrocodone, APAP C-III

- Brand Names: Vicodin<sup>®</sup>, Lortab<sup>®</sup>, Lorcet<sup>®</sup>
- “Cocktail” used by drug abusers
  - Hydrocodone
  - Soma / carisoprodol
  - Alprazolam / Xanax<sup>®</sup>
- 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*

# Vicodin®-5/500mg



# Norco® 7.5/325mg





## Hydrocodone (Schedule III)

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



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

## NFLIS National Data - 2006

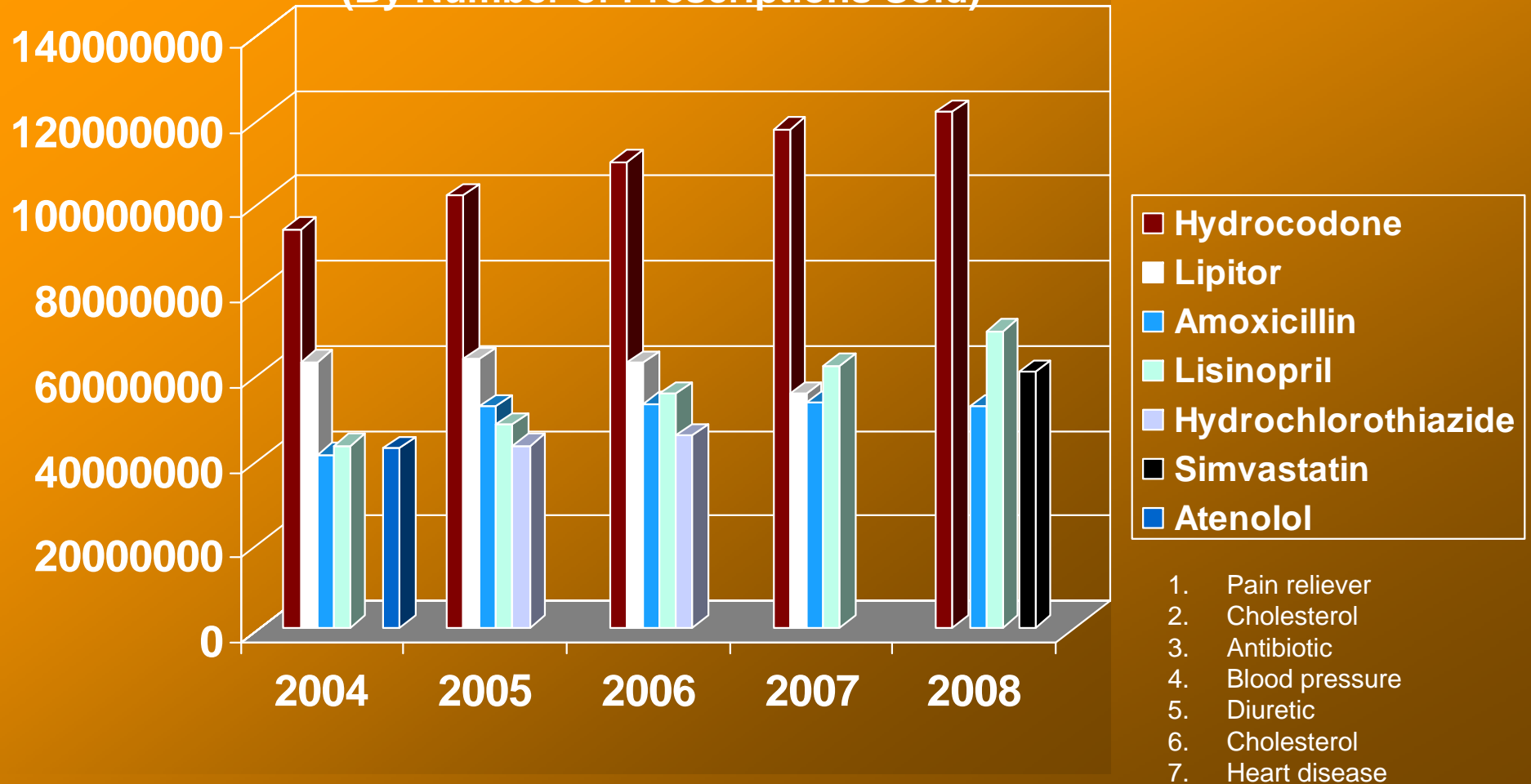
### Narcotic Analgesics

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



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

(By Number of Prescriptions Sold)





OXYCODONE



# NFLIS National Data - 2006

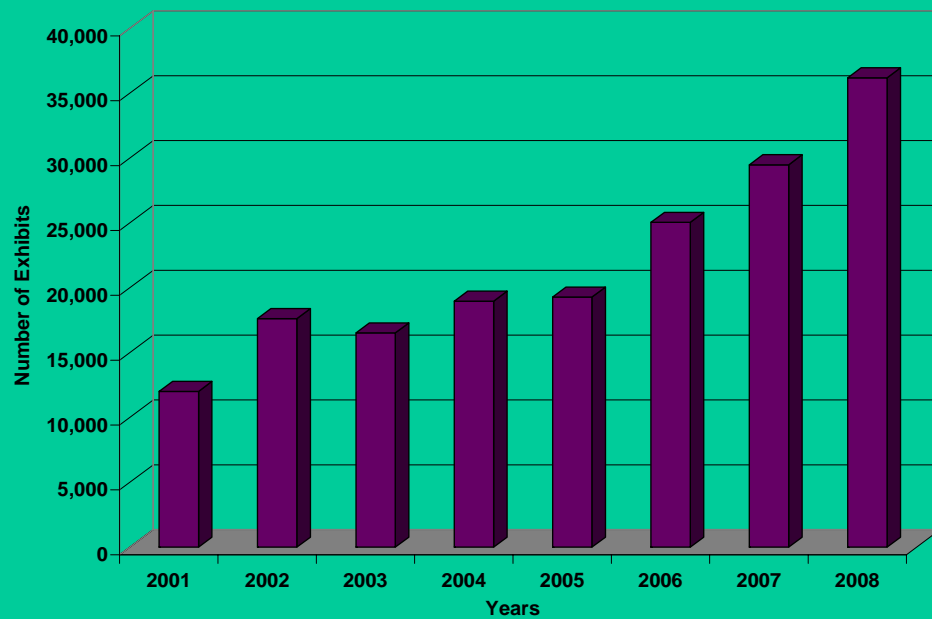
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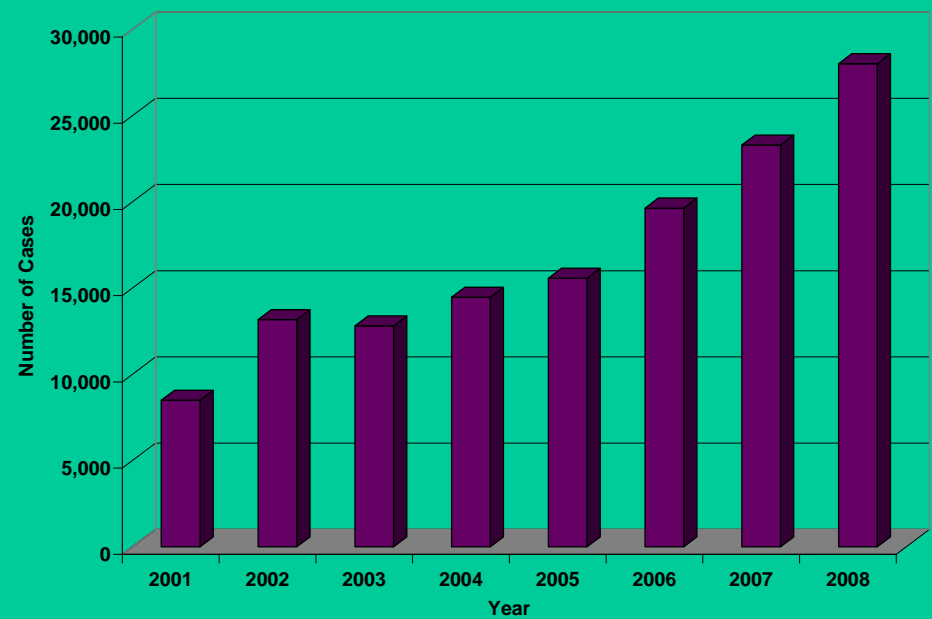


# NFLIS National Estimates Oxycodone

## Exhibits



## Cases





## OxyContin<sup>®</sup> (Schedule II)

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



# OxyContin®- 80mg



# Alprazolam / Xanax<sup>®</sup> (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 7<sup>th</sup>\*\*

Source IMS Health

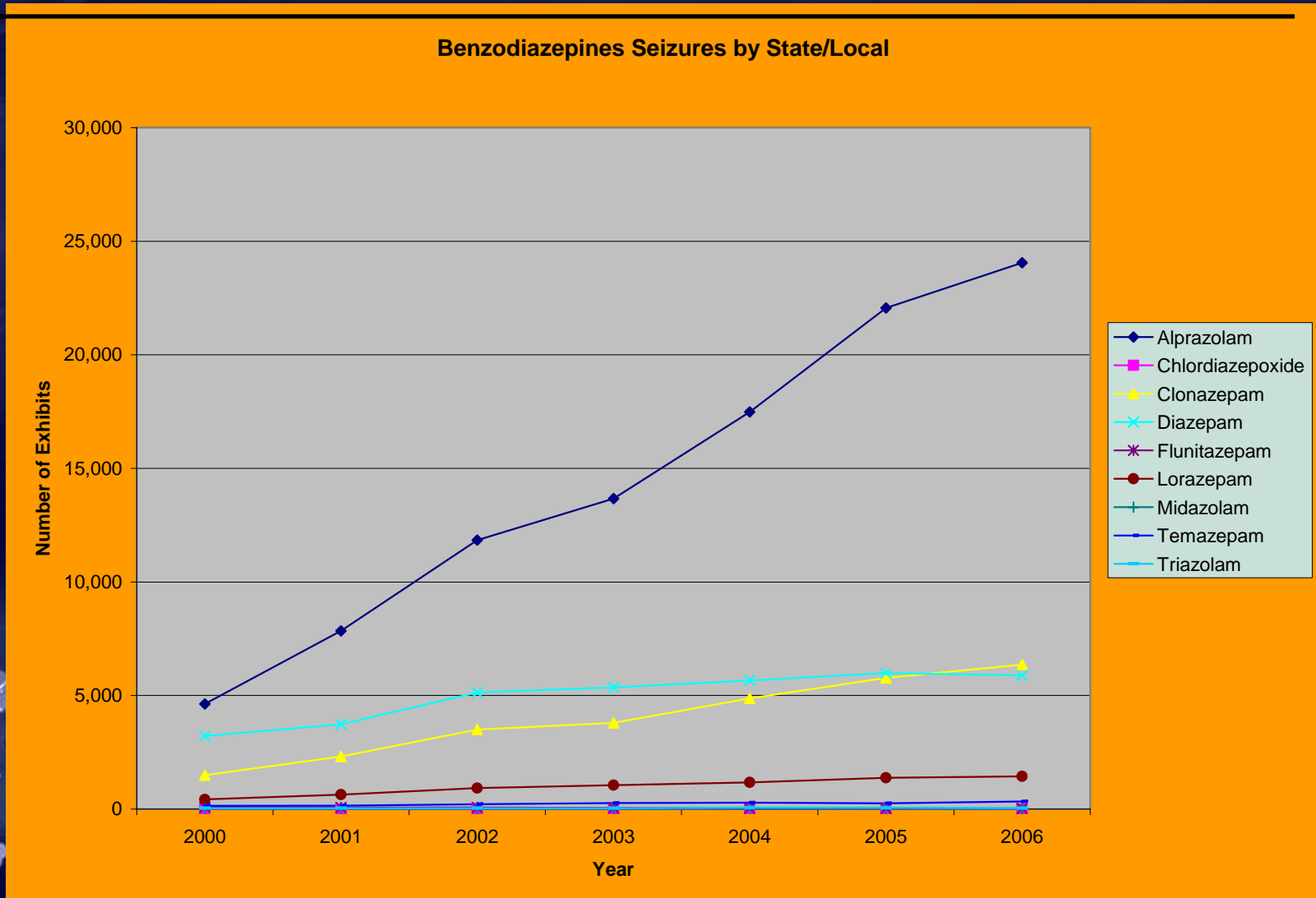
\*\* Source Verispan VONA



C-IV



# State and Local Seizure Data



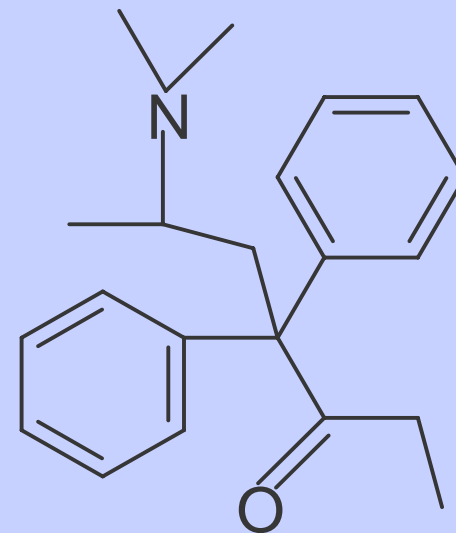
# Other Controlled Substances

- Phentermine
- Phendimetrazine
- Amphetamine Alks
- Methylphenidate





# METHADONE



# Methadone-10mg



Mallinckrodt Pharmaceuticals 10mg

# 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

**T**HE 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 NIRSCHING

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.

## Approved Indications for Methadone

- Pain Treatment
- Narcotic Addiction Treatment/Maintenance



# WHY Use Methadone ???????

Cheapest narcotic pain reliever – synthetic

Insurance companies



# Methadone - Retail Prices

Methadone 5 mg tablets – 100 count	\$13.89 (Brand Name)
Methadone 5 mg tablets – 100 count	8.68 (Generic)
Methadone 10 mg tablets – 100 count	\$21.29 (Brand Name)
Methadone 10 mg tablets – 100 count	14.10 (Generic)
Methadone 40 mg diskettes – 100 count	\$49.59 (Brand Name)
Methadone 500 ml oral solution	\$71.39

(Source: Eckerd's Drugs)



# One Pill can Kill



CE Article: JACCME, CMI, ACEP | 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 \_\_\_\_\_

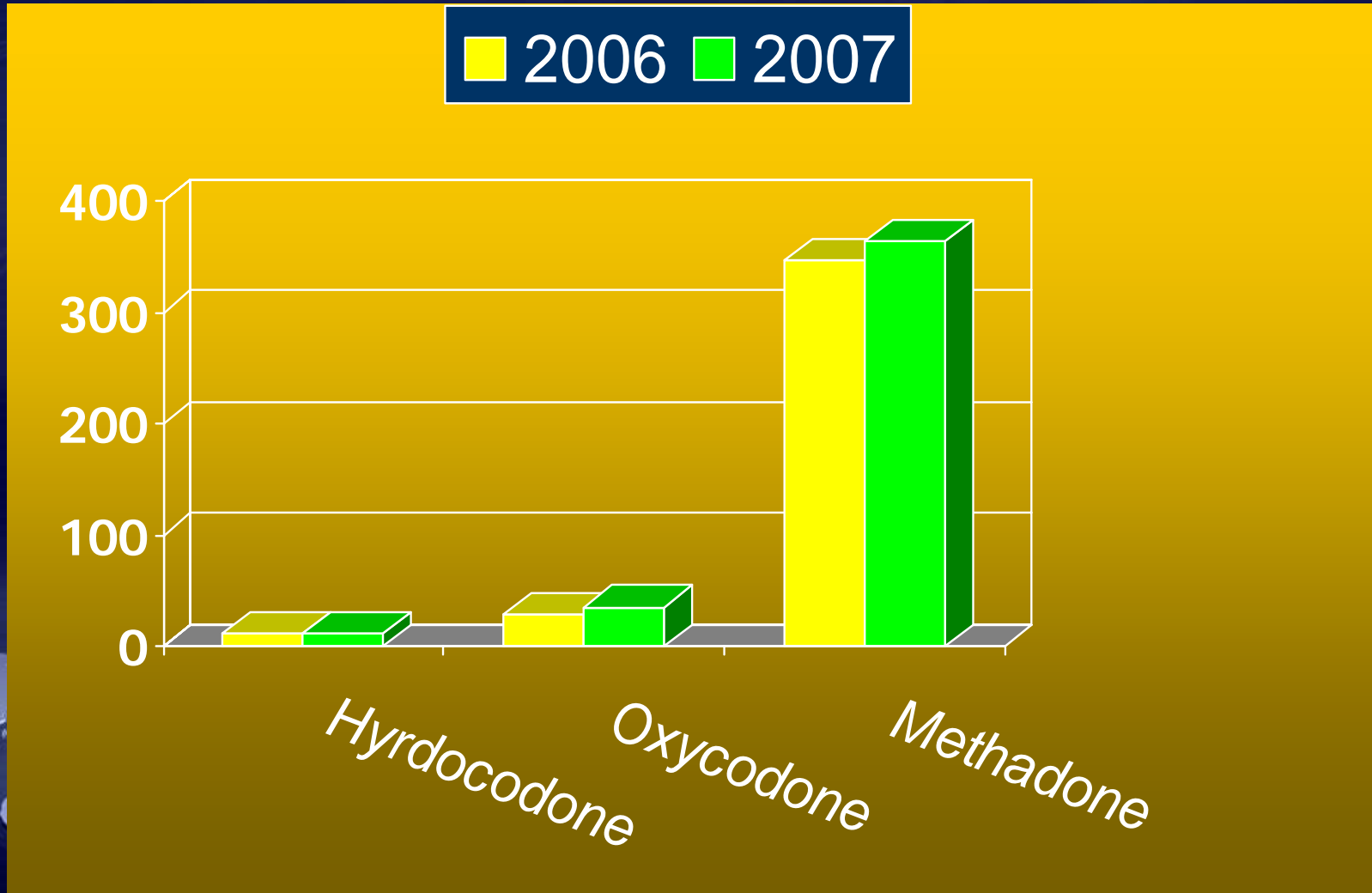
**Rx**

**D**eath 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.



# Deaths/100,000 Prescriptions in Florida

Deaths/100,000  
Prescriptions



Source: FDLE and NPA Plus™



# Methadone-Associated Mortality Assessment Findings

- Methadone is becoming more widely available due to increased use for pain management and a relaxation in regulations regarding take-home doses of methadone from narcotic treatment programs (NTPs).
- There is no comprehensive database of drug-related deaths in the U.S.
- Problems with uniform definition by Medical Examiners preclude uniformity in reporting “cause of death” on death certificates.
- It seemed more likely that the increased availability of methadone was the result of use in pain management as there was not a great increase in NTP patient population. In addition, the increased incidents of death started prior to a change in take-home regulations.



# Methadone-Associated Mortality Assessment Findings

- Three primary scenarios were seen in methadone associated 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 in combination with other CNS depressants (i.e., alcohol, benzodiazepines or other opioids).



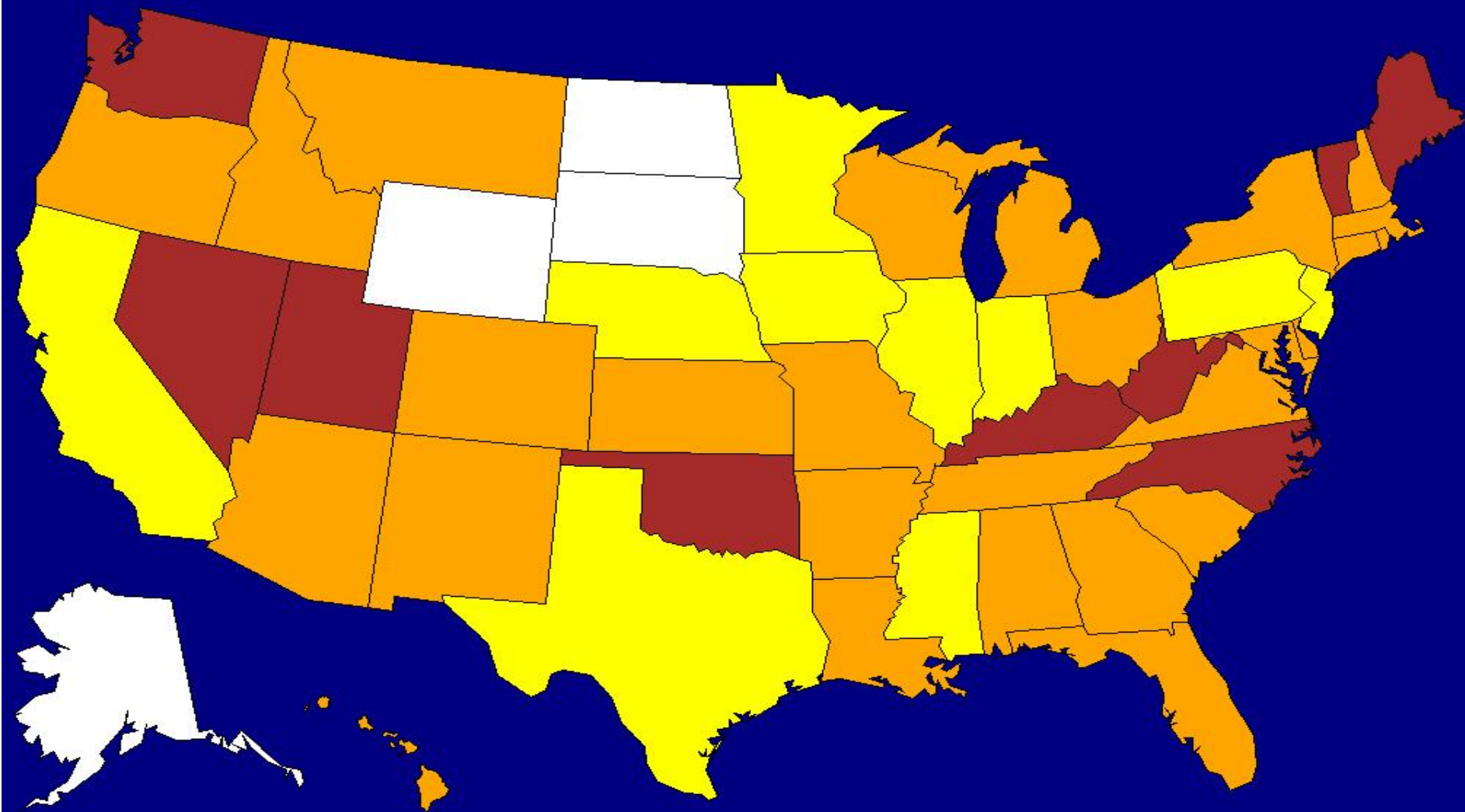
## Distribution of Methadone 40 mg -- Restricted

- As of January 1, 2008, manufacturers of methadone agreed to restrict distribution of 40 mg tablets. The 40 mg formulation is not FDA approved for use in pain management. Under an agreement reached with the DEA, 40 mg tablets will only be available to facilities authorized for detoxification or maintenance treatment of opioid addiction.



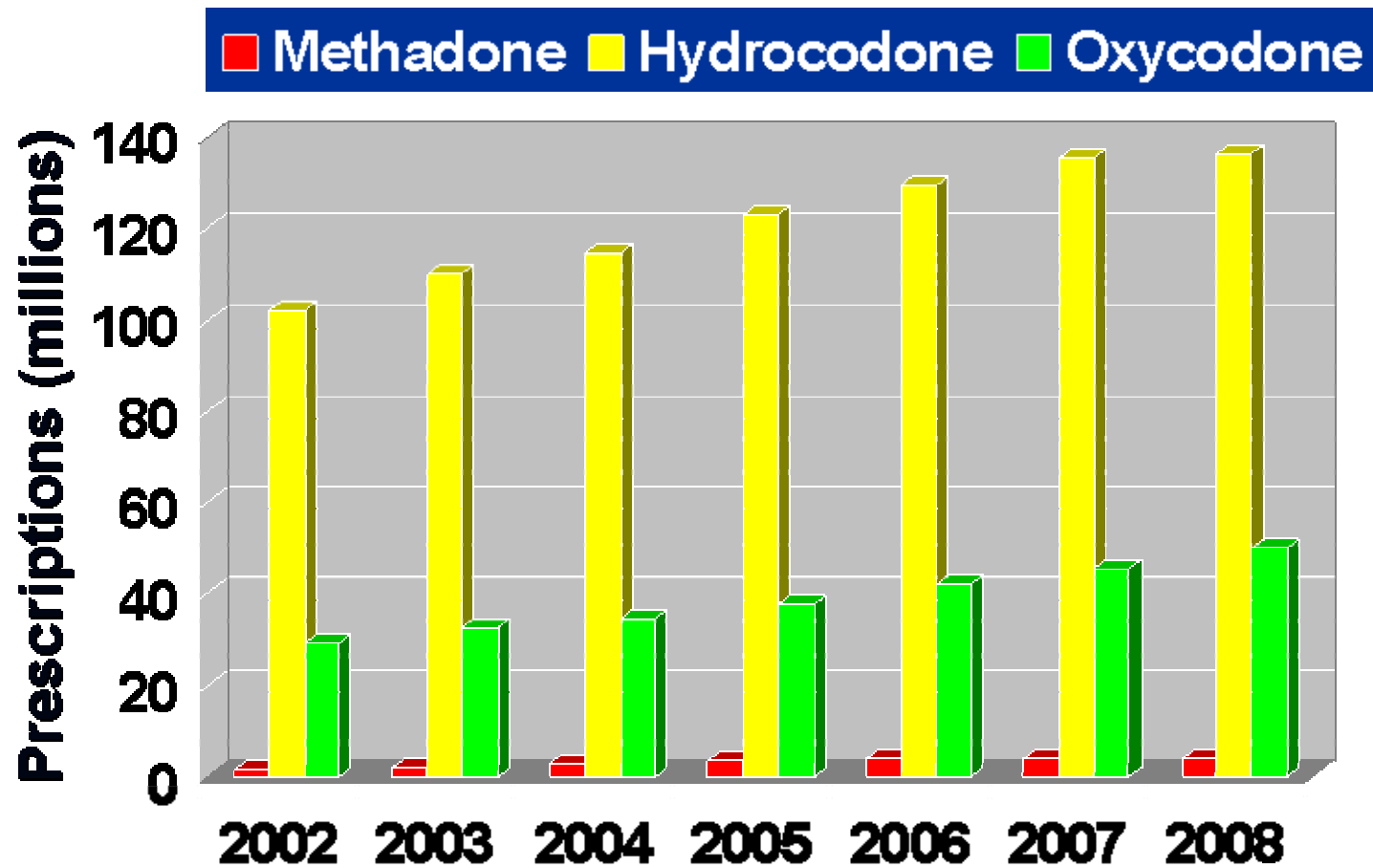
# Methadone death rates by state

2005-2006



Age adjusted death rates per 100,000 population Figure unreliable\* ≤0.9 1.0-3.5 3.6 and over

## Total Prescriptions Issued/Dispensed



Data Source: IMS Health, National Prescription Audit *Plus*<sup>TM</sup> (NPA *Plus*<sup>TM</sup>)



## Methadone (Schedule II)

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



SOURCE: UPI, Inc. articles published February 2007

# Solutions?

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





## Fentanyl (Schedule II)

- Trade-Names:
  - Actiq<sup>®</sup>: dispensed in a berry flavored lollipop-type unit
  - Duragesic<sup>®</sup>: trans-dermal patch for chronic pain
  - Fentora<sup>™</sup>: effervescent tablet formulation
    - Approved by the FDA September 2006
    - Compared to same dose as Actiq<sup>®</sup>, the effervescent tablet allows a larger amount of Fentanyl to be absorbed rapidly through the oral membranes
- Street prices: \$25 to \$40 per patch/lollipop





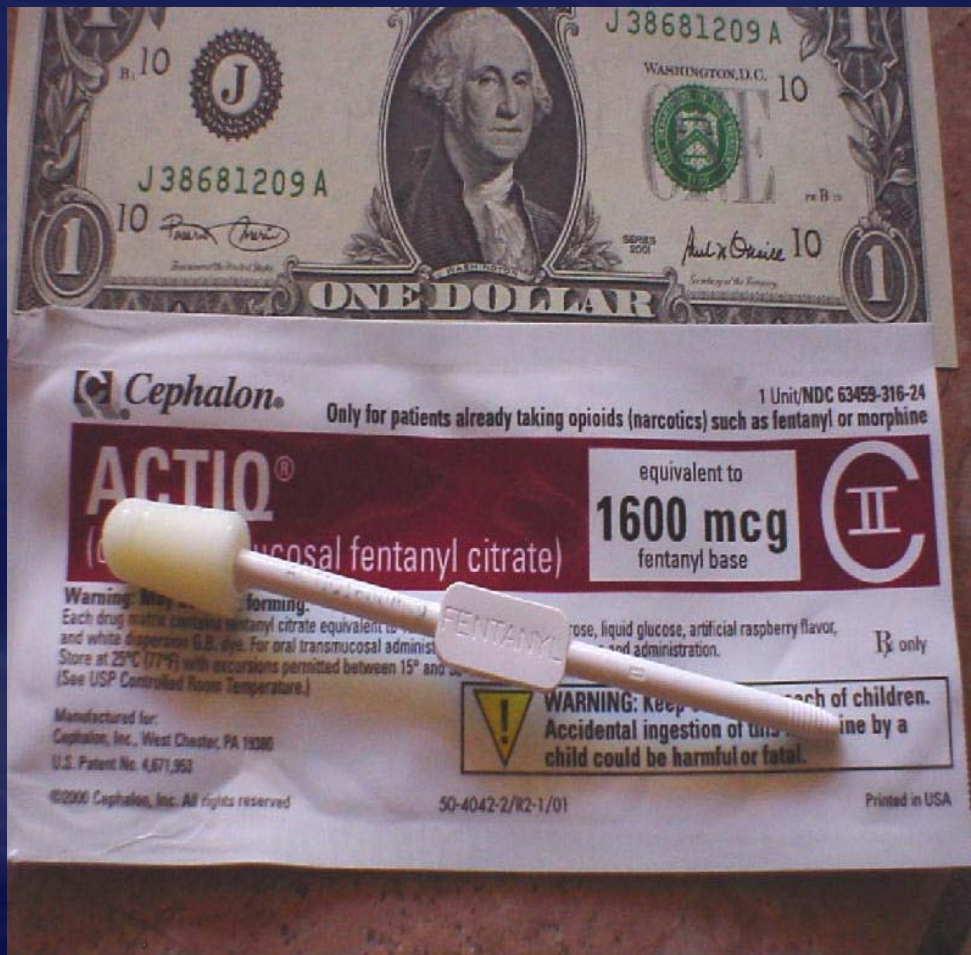


# Fentanyl - Abuse

- Numerous reports of overdose deaths resulting from mixing Fentanyl with heroin or cocaine, or ingesting patch
- While most illegal use of Fentanyl is from diverted products
  - Recent epidemic is linked mainly to illicitly manufactured Fentanyl
    - Previously, Fentanyl could only be made by expert chemists
    - New, easier synthetic method now available on the Internet
    - Inexpensive to manufacture with very high profit margin



# Fentanyl-Actiq® 1600mcg





## Cough Syrup (Schedule V)

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



# Promethazine with Codeine





# Cough Syrup

- Large profit margin
  - Diverted wholesale/retail price (\$8 to \$12/pint) vs. street price (\$250 to \$600/pint)
- Remedies
  - Target money laundering prosecution and asset forfeiture
  - Schedule V, federal misdemeanor offense (state felony)
  - Ryan Haight increased guidelines for Schedule V (second offenders)

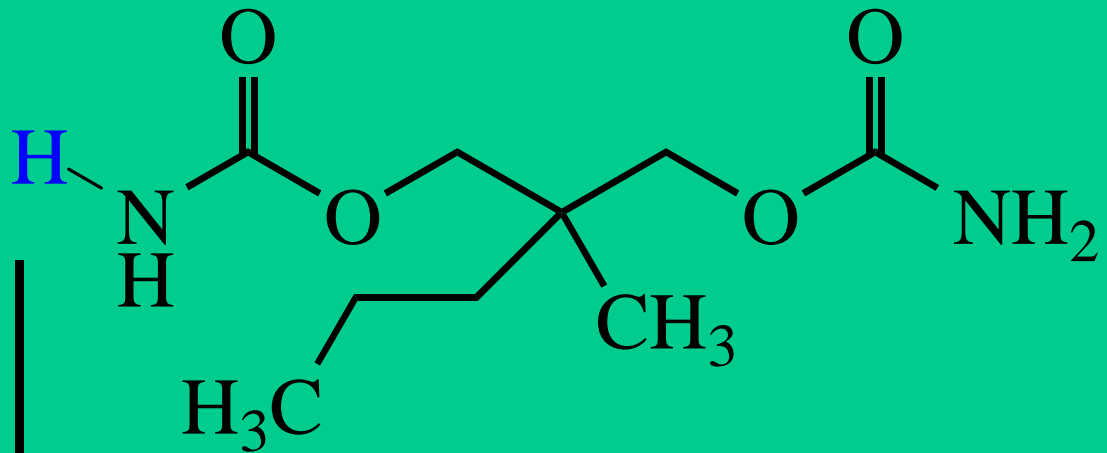


# Non-Controlled Substances

- 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.

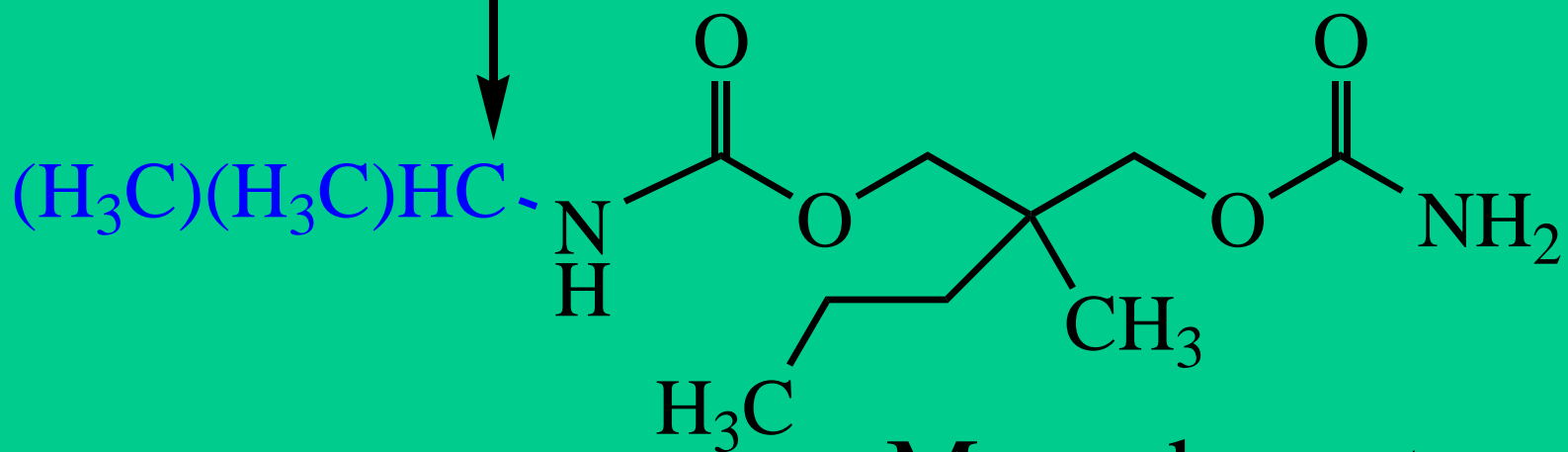


# Carisoprodol

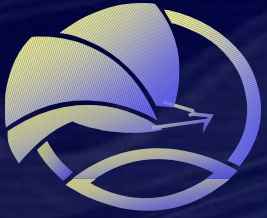


Structural Change

by Enzymatic Action in the Body



# Meprobamate



# 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

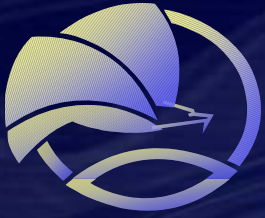
- **House Resolution 1359, Secure and Responsible Drug Disposal Act of 2009**
  - **Introduced on 3/5/2009 by Rep. Stupak (MI)**
  - **Amend the CSA to allow ultimate user (and LTCF) to deliver drugs to an entity authorized to dispose of them**
  - **Grant the Attorney General discretion to promulgate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

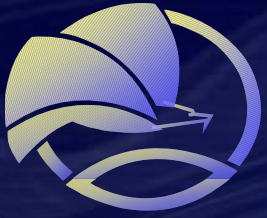
- **NPRM Published on June 27, 2008 in the Federal Register**
- **Proposal to provide DEA registered practitioners and pharmacies with the ability to electronically create, transmit, receive, and archive C II-V controlled substance prescriptions.**



# 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**





# Clandestine Methamphetamine Manufacture



# One Pot Meth Production







**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 other finger placement)  
firmly, curling fingers in, until the inner bladder breaks and you  
SHAKE package well to mix contents after activation. Do not p

Stays cold for up to 30 minutes.

**KEEP OUT OF REACH OF CHILDREN.**

**Contents:** Water and Ammonium Nitrate (2

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*Thank You !*

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

