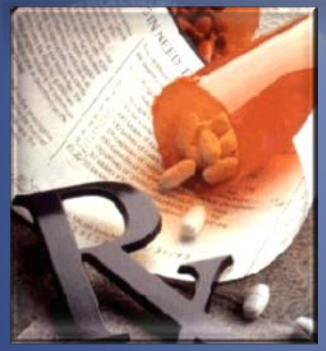
The United States Department of Justice

Drug Enforcement Administration



Drug Trends
Houston, Texas
September 2012

Joseph Rannazzisi
Deputy Assistant Administrator
DEA Office of Diversion Control

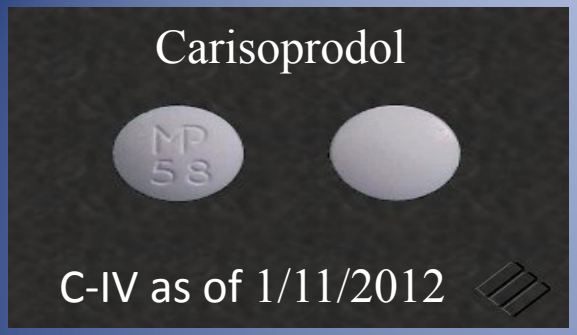
Legend Drugs v. Controlled Substances

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.

Commonly Abused Controlled Pharmaceuticals



OxyContin 80mg

Oxymorphone

Oxycodone 30 mg

The Perfect Storm

- Industry is producing a wider variety of controlled substance pharmaceuticals
- Use of Medicare / Medicaid or insurance to fund drug habits
- Information / Electronic era
  - Web sites such as Erowid & Bluelight

Inadequate Pain Control

Direct to Patient Advertising

2009 Current Users 2010

2009	2010
ANY ILLICIT DRUG: 21.8 million (8.7% of population)	ANY ILLICIT DRUG: 22.6 million (8.9% of population)
MARIJUANA: 16.7 million	MARIJUANA: 17.4 million
PSYCHOTHERAPEUTIC DRUGS: 7 million	PSYCHOTHERAPEUTIC DRUGS: 7 million
COCAINE: 1.6 million	COCAINE: 1.5 million
HALLUCINOGENS: 1.3 million	HALLUCINOGENS: 1.2 million
METHAMPHETAMINE: 502,000	METHAMPHETAMINE: 353,000

Source: 2009 & 2010 NSDUH

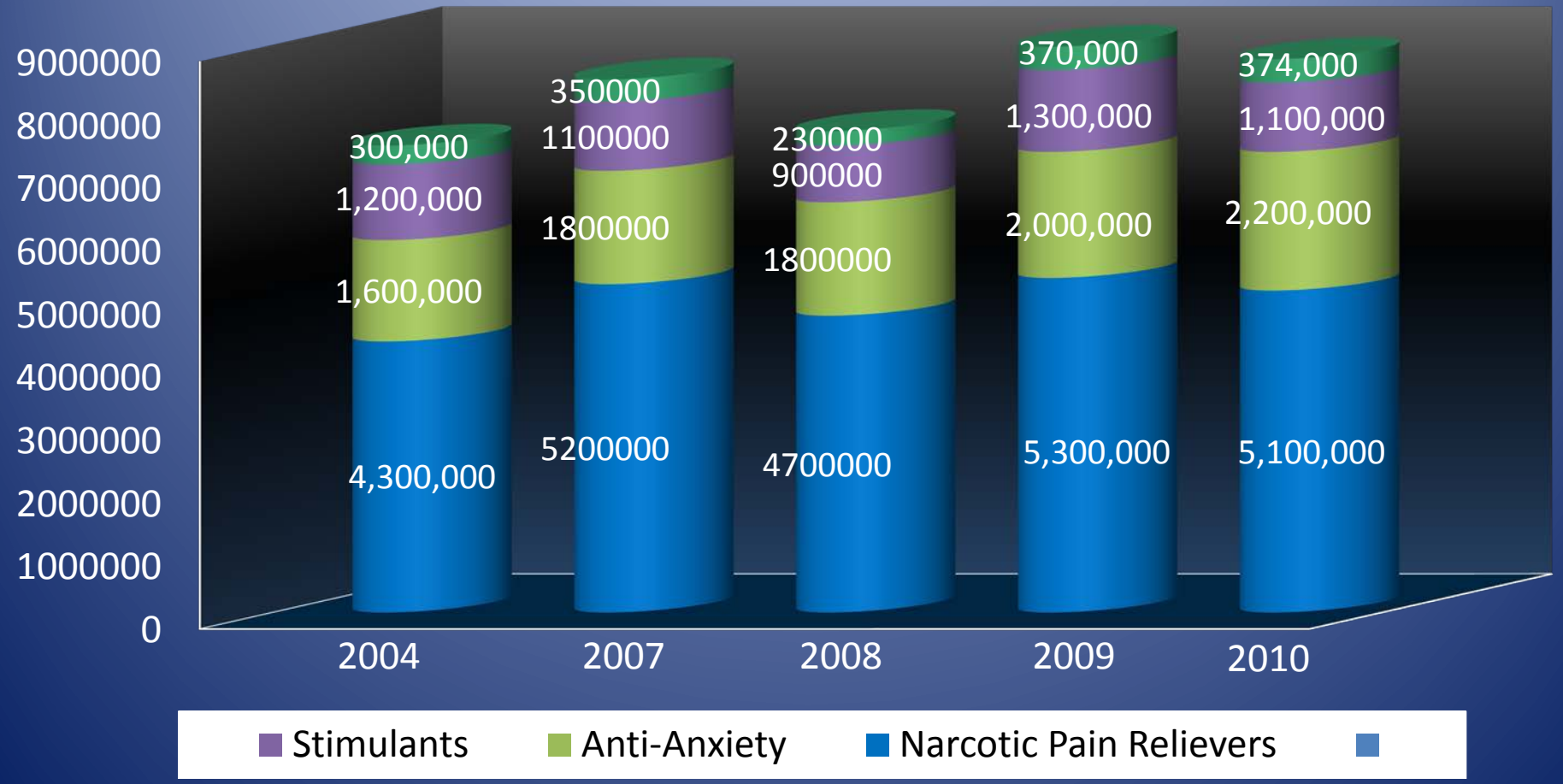
Prescription Drug Abuse

More Americans abuse prescription drugs than the number of:

Cocaine, Hallucinogen, Heroin, and Inhalant abusers

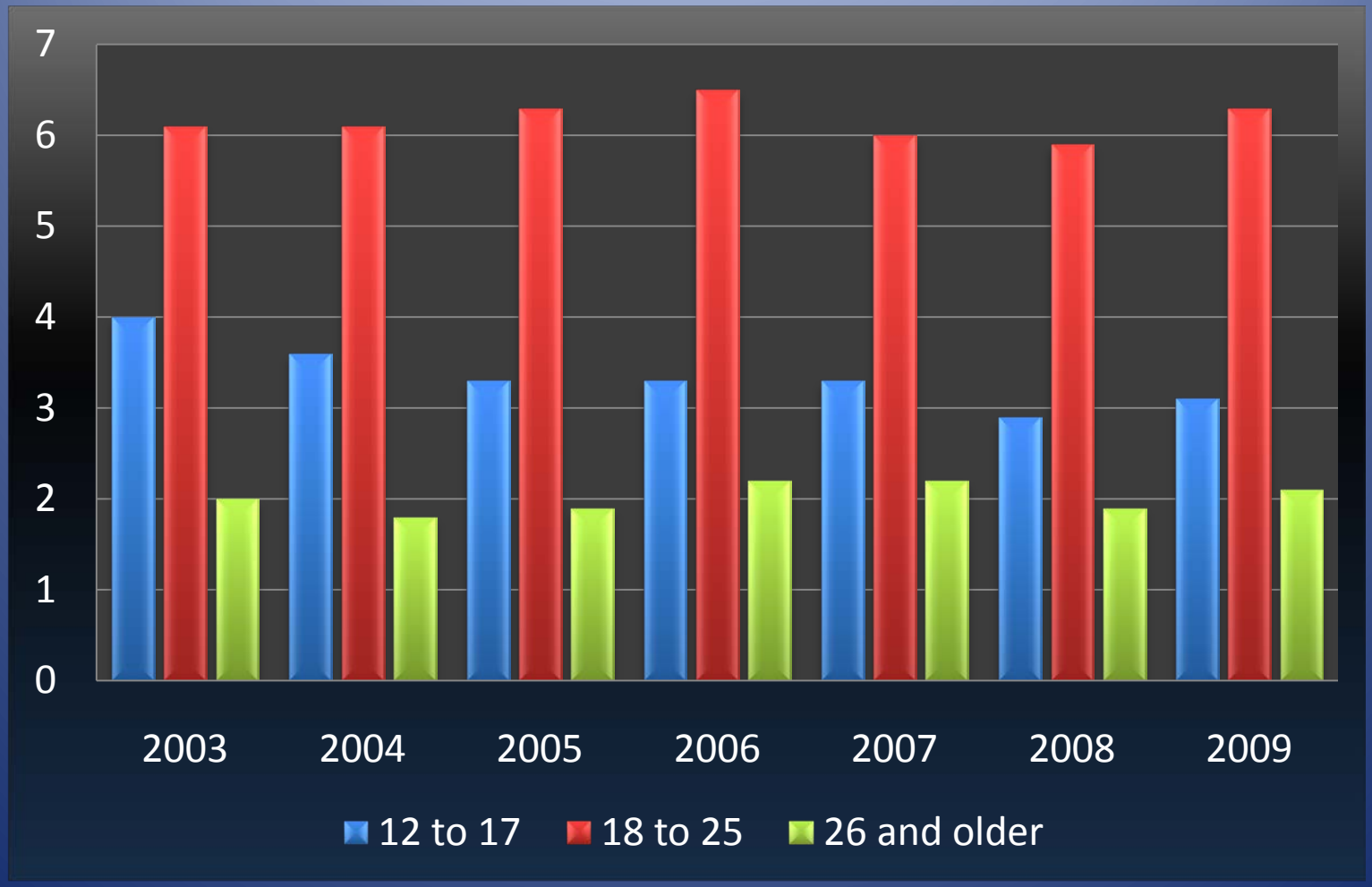
COMBINED!!!

Scope and Extent of Problem



Source: 2004, 2007, 2008, 2009, 2010 National Survey on Drug Use and Health

Percentage of Past Month Nonmedical Use of Psychotherapeutics by Age, 2003-2009



Source: National Survey on Drug Use and Health

Economic Impact – The Cascading Effect

2006 estimated cost in the United States from nonmedical use of prescription opioids

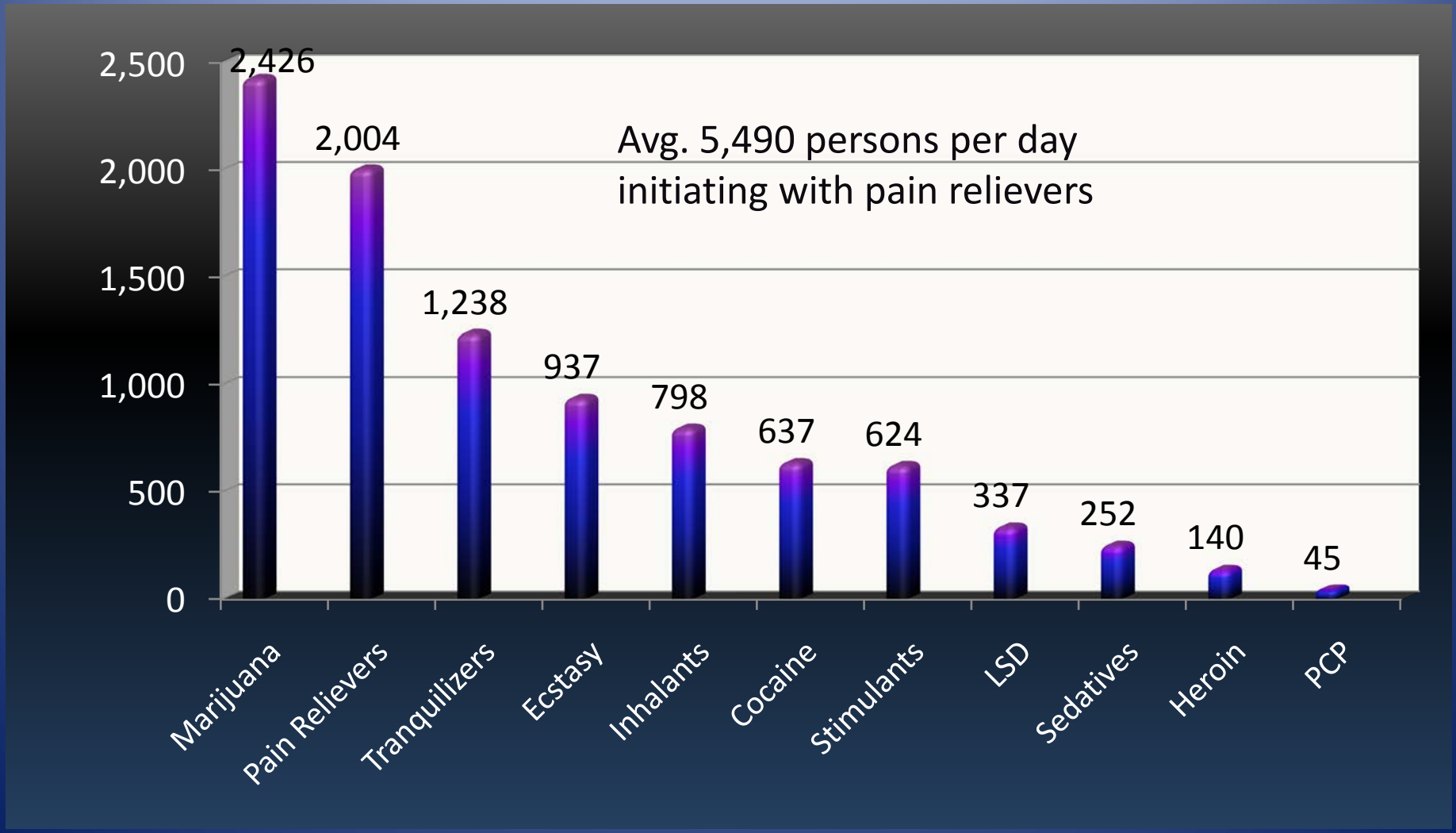
$53.4 BILLION

- $42 billion – Lost productivity
- $8.2 billion – Criminal justice costs
- $2.2 billion – Treatment costs
- $944 million – Medical complications

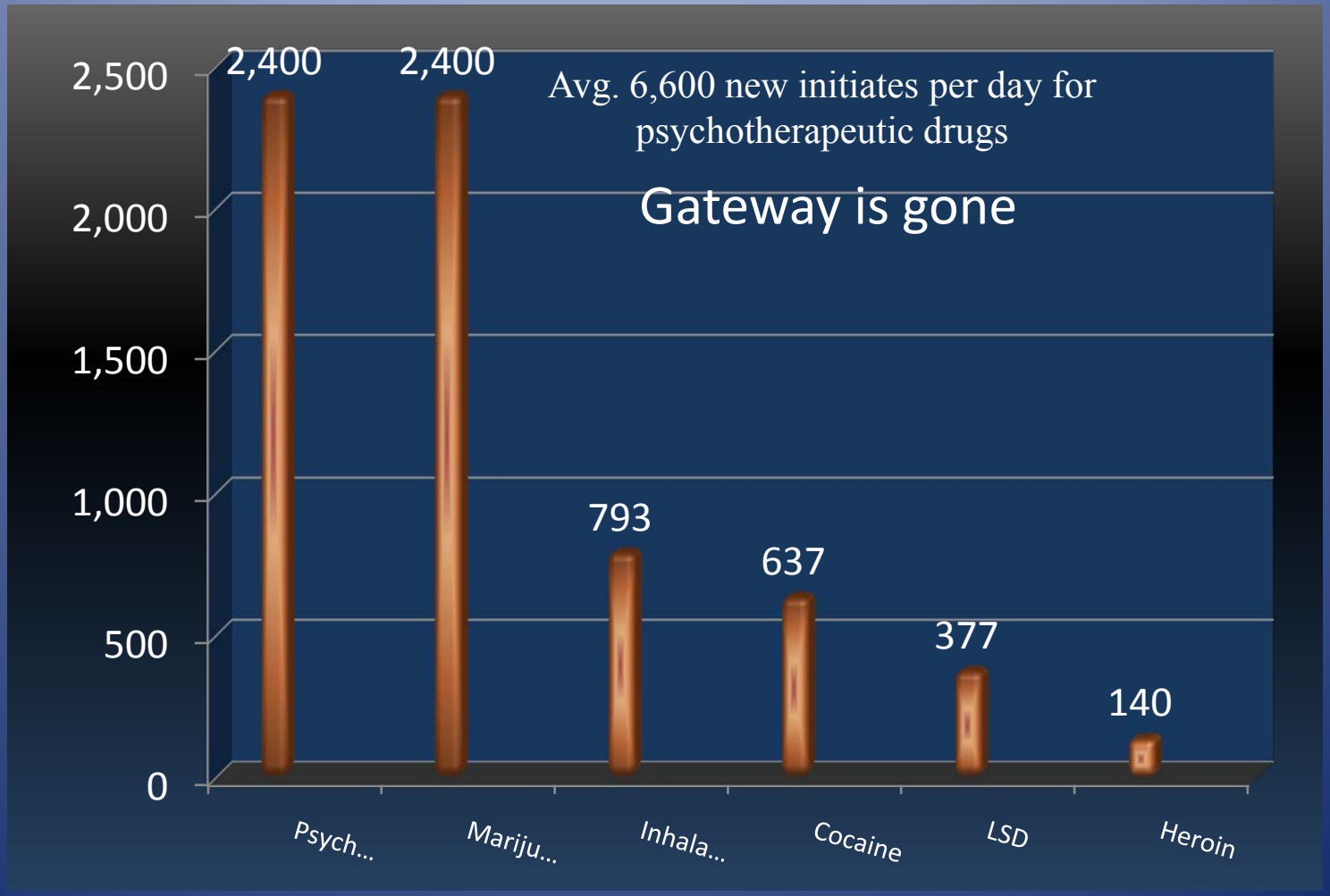
Five drugs –
OxyContin®, oxycodone, hydrocodone, propoxyphene, a nd methadone accounted for two-thirds of the economic burden

Source: Clinical Journal of Pain, December 2010, University of Washington, Hansen RN; Oster, G; Edelberg, J; Woody, GE; and Sullivan, SD

Past Year Initiates for Specific Drugs Persons Aged 12 or Older 2010



New Initiates 2010 - 12 years and older



Source: 2010 NSDUH

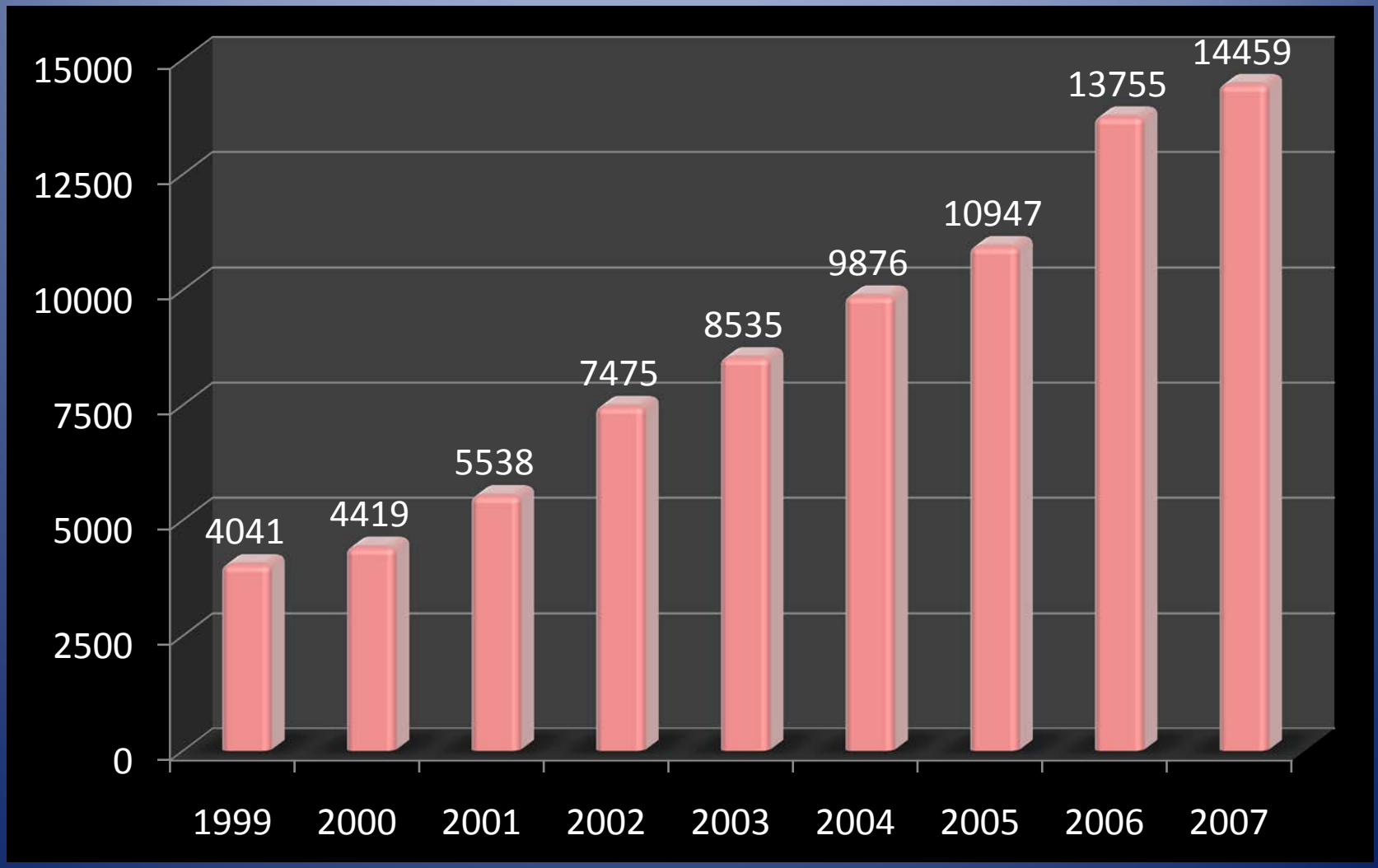
Psychotherapeutics Include: Pain Relievers, Tranquilizers, Stimulants, and Sedatives

Emergency Room Data 2004-2009

- Increase of 98.4%: ER visits attributable to pharmaceuticals alone
  (*i.e.*, with no other type of drug or alcohol) (627,291 to 1,244,679)
  - No Significant Change: ER visits attributable to cocaine, heroin, marijuana, or methamphetamine
- Rx Drugs most frequently implicated:
  - **Opiates/Opioids pain relievers**
    - Oxycodone products 242.2% increase
    - Hydrocodone products 124.5% increase
    - Fentanyl products 117.5% increase
  - **Insomnia or Anti-Anxiety medications**
    - Zolpidem 154.9% increase
    - Alprazolam 148.3% increase
    - Clonazepam 114.8% increase
  - **Carisoprodol 100.6% increase**
  - For patients aged 20 and younger misuse/abuse of pharmaceuticals increased 45.4%
  - For patients aged 20 and older the increase was 111%

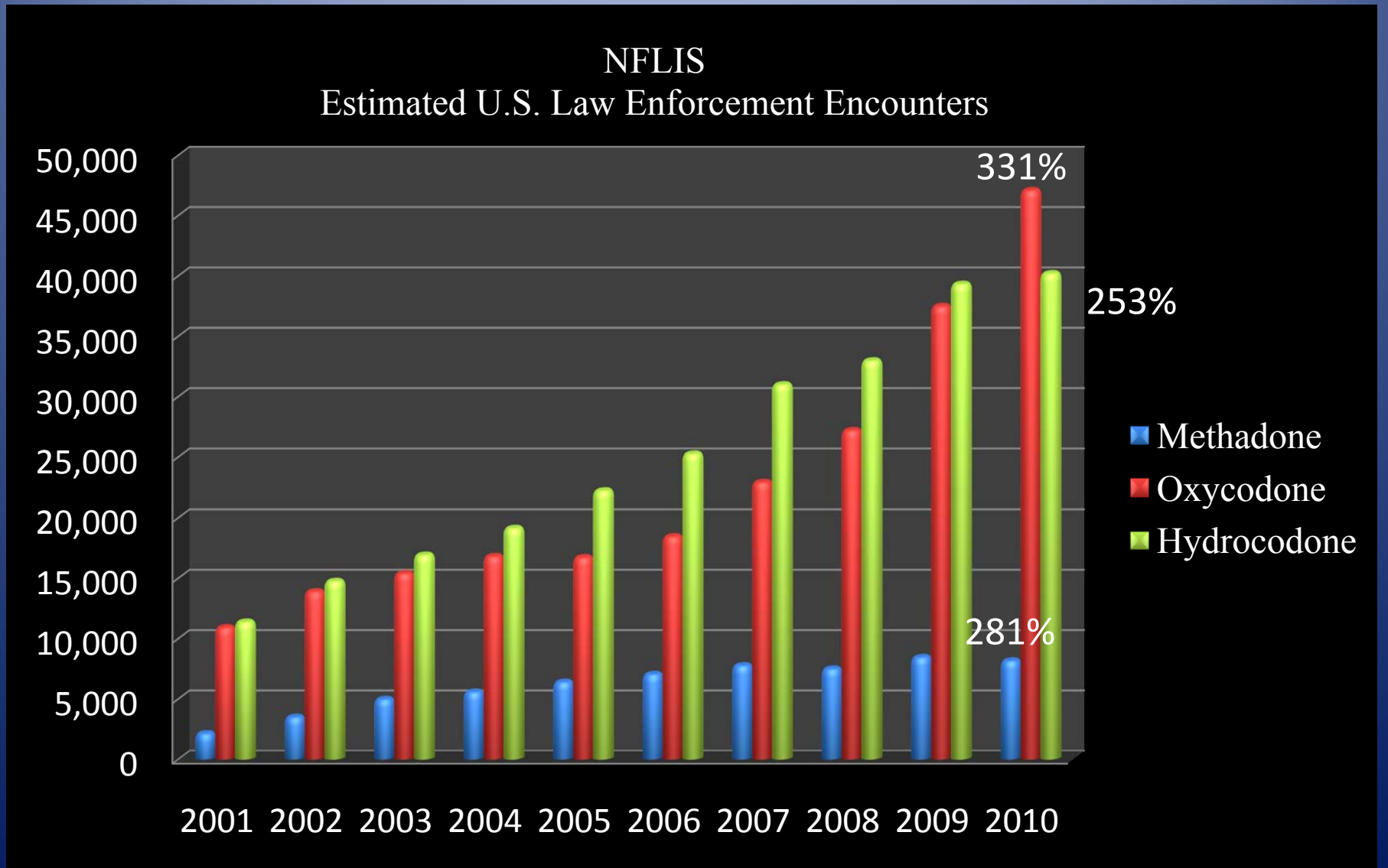
SOURCE: The DAWN Report, *Highlights of the 2009 Drug Abuse Warning Network (DAWN) Findings on Drug-Related Emergency Department Visits*, December 28, 2010

Poisoning Deaths: Opioid Analgesics

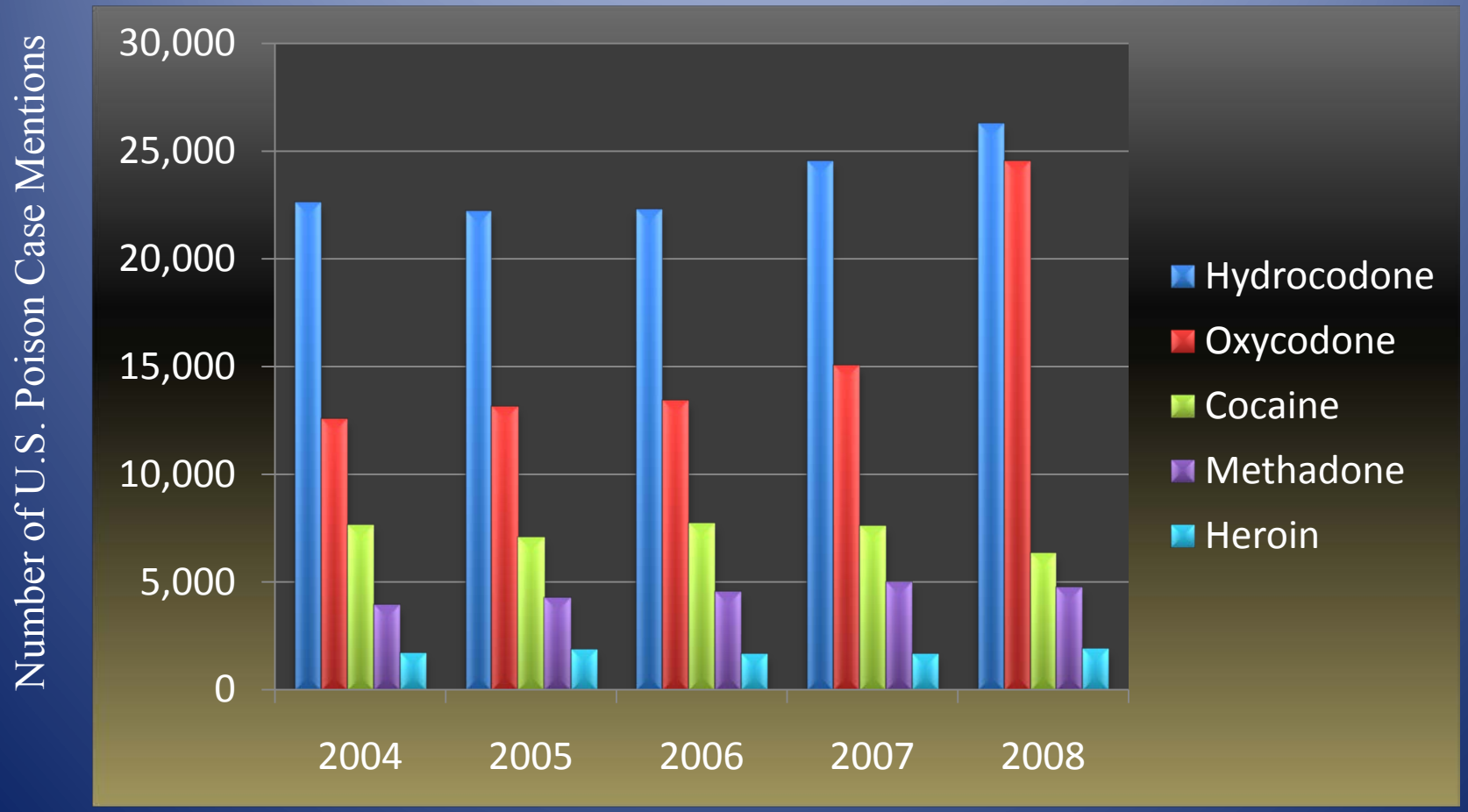


Source: CDC/NCHS, National Vital Statistics System

Number of Forensic Cases 2001-2010



National Poison Data Center
Number of U.S. Poison Exposure Case Mentions
2004 - 2008



Source: American Association of Poison Control Centers (AAPCC) Annual Reports, 2004-2008

Sources of Information and Risks

% Learned a lot about risks of drugs from…	1998	2004	2005	2007	2008	2009
School	41	42	38	37	44	39*
Parents	26	28	28	29	35	31
TV Commercials	17	36	26	31	31	26*
The Internet	11	23	22	25	29	29
Websites like YouTube	NA	NA	NA	NA	14	17*

* = Significant at the .05 level vs 2008

Source: Partnership for Drug Free America, March 2, 2010

Teens and Their Attitudes

% Agree strongly/somewhat	2008	2009	2010
Prescription drugs are available everywhere	42	55	38
Its easy to get prescription drugs from parent's medicine cabinets	56	63	47
Most teens get prescription drugs from their own family's medicine cabinets	59	62	51
Most teens get prescription drugs from their friends	53	62	49

Parents and Their Attitudes

Parents are still not discussing the risks of abusing prescription and over-the-counter medicines

Percent	2008	2009	2010
Beer/alcohol	79	79	81
Marijuana	79	79	77
Cocaine/crack	36	35	30
Prescription pain reliever w/o doctor's Rx	20	20	23
Any prescription drug used w/o doctor's Rx	21	20	22
Heroin	23	23	21
Ecstasy	21	20	21
Methamphetamine	23	21	21
Non-prescription cold/cough medicine to get high	15	14	15

SOURCE: 2010 Partnership Attitude and Tracking Study (PATS) Released Apr. 2011

We will not arrest our way out of this problem!!!!!

- Enforcement is just as important as….
- Prevention/Education
- Treatment

ONDCP Strategy

"Epidemic: Responding To America's Prescription Drug Abuse Crisis" (Released in April 2011)

Highlights:

- Education
  - Healthcare Provider Education
  - Parent, Youth, and Patient Education
- Tracking and Monitoring
  - Work with states to establish effective PDMPs
  - Support NASPER
  - Explore reimbursements to prescribers who check PDMPs before writing a prescription

ONDCP Strategy con't

- Proper Medicine Disposal
- Enforcement
  - Assist states address doctor shopping and pill mills
  - Increase HIDTA intelligence-gathering and investigation of prescription drug trafficking
  - Expand the use of PDMPs to identify criminal prescribers and clinics
- Prescription Drug Abuse Plan Goals
  - 15% reduction in non-medical use of prescription-type psychotherapeutic drugs;
  - Write and disseminate a Model Pain Clinic Regulation Law within 12 months;
  - Implement REMS for long-acting and extended release opioids within 12 months

Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

Friends and Family…For Free!!

The Medicine Cabinet and the Problem of Pharmaceutical Controlled Substance Disposal

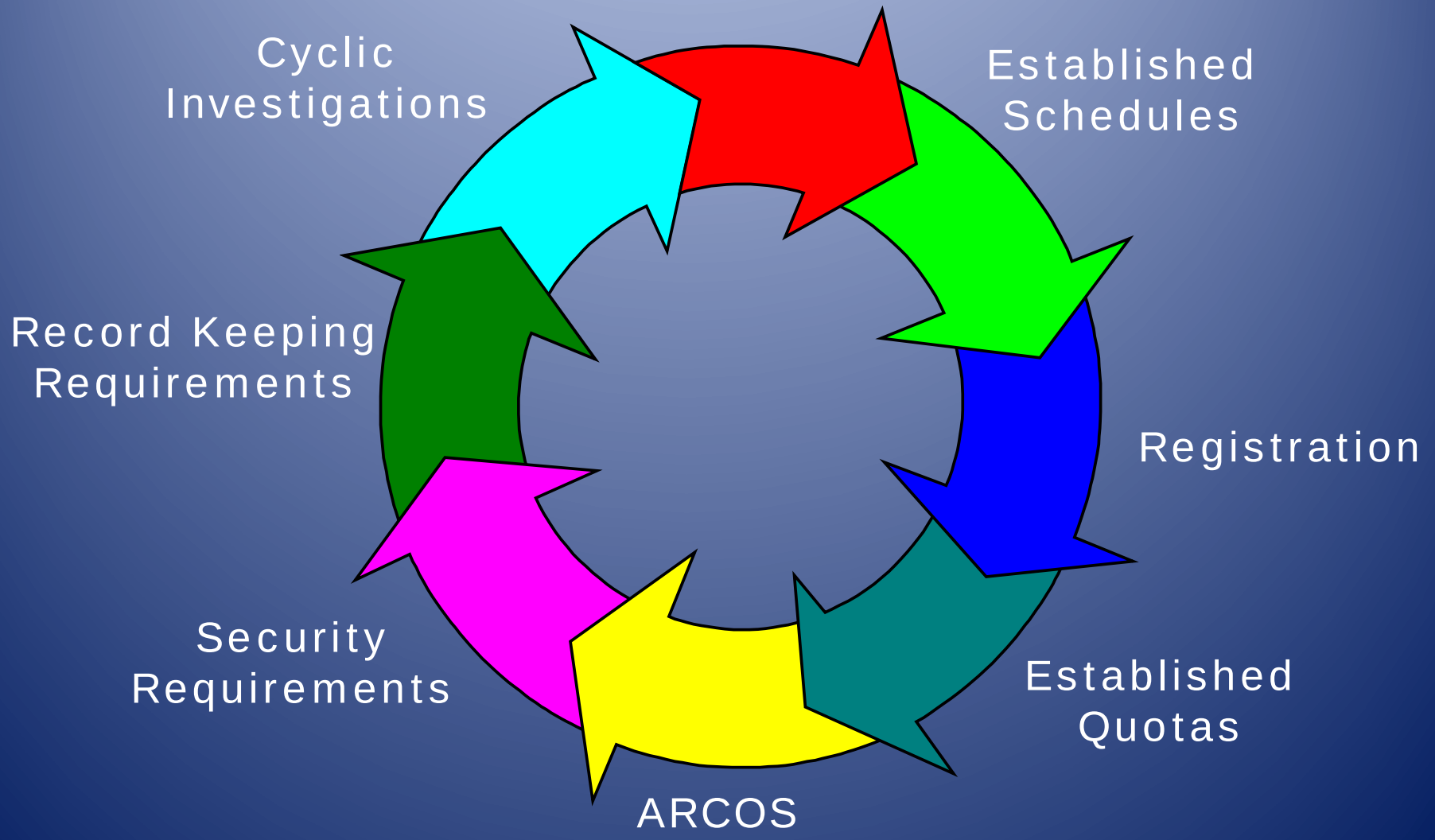
So Many Drugs in the Household – Why?

- Unreasonable quantities being prescribed
- Insurance rules

Controlled Substances Act of 1970

- Legal foundation of federal government's authority for controlled substances and listed chemicals.
- System of U.S. compliance with international treaties.
- Established a "closed system" of distribution

The CSA's Closed System of Distribution



How Do You Lose Your Registration?

The Order to Show Cause Process

21 USC § 824

a) Grounds –

1. Falsification of Application
2. Felony Conviction
3. State License or Registration suspended, revoked or denied – no longer authorized by State law
4. Inconsistent with Public Interest
5. Excluded from participation in Title 42 USC § 1320a-7(a) program

b) AG discretion, may suspend any registration simultaneously with Order to Show Cause upon a finding of Imminent Danger to Public Health and Safety

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

- 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.

21 U.S.C. 802

The Ultimate User and Drug Disposal

ONDCP Guidelines

- ONDCP guidelines for the disposal of ultimate user medications, including dispensed controlled substances (2/20/07).

- 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.

Law Enforcement Involvement

- Law enforcement officers, acting to enforce laws regarding the abandonment of controlled substances, 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 Coordination/Involvement

Statute or Regulation Change?

DEA

U.S. Drug Enforcement Administration

Got Drugs?

Turn in your unused or expired medication for safe disposal Saturday, Sept. 25th

Click here for a collection site near you.

U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

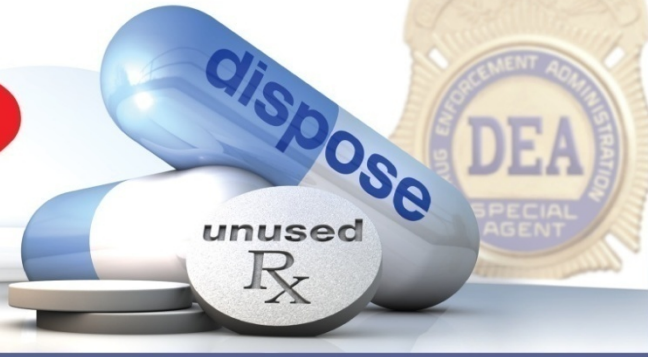
Nationwide Take-back Initiative

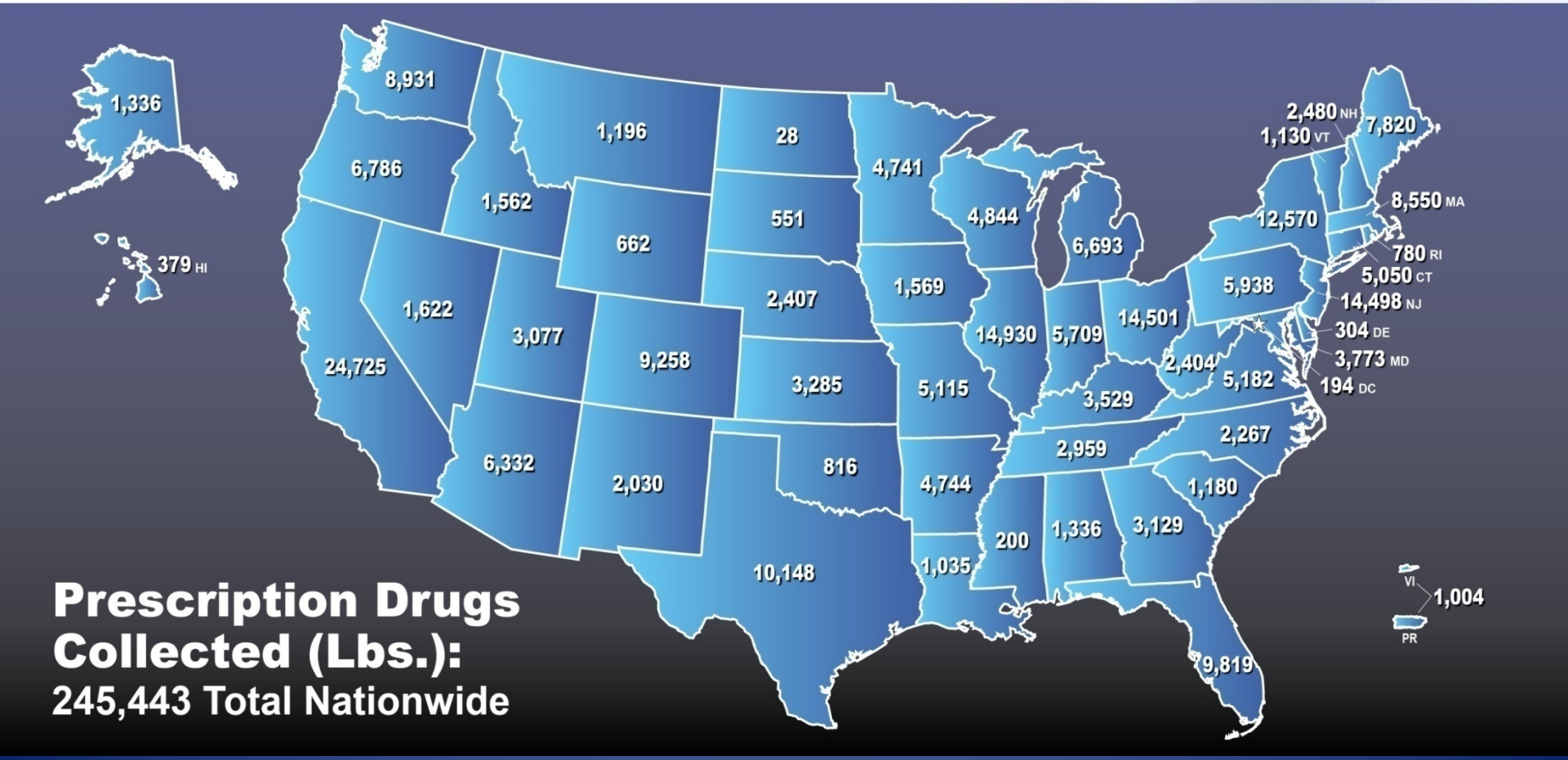
- On September 30, 2010, the American public turned in more than 245,000 lbs of prescription drugs for safe and proper disposal. More than 4,000 take back sites were available in all 50 states with approximately 3000 agencies participating in the initiative.

- The second nationwide take-back event, on April 30, 2011 featured over 5200 collection sites with over 3800 Federal, state and local agencies involved in the initiative. This initiative took in approximately 188 tons of unwanted, unused or expired medication at collection sites throughout the U.S. This includes collections from Long Term Care Facilities that were not involved in the previous collection event.

- The third nationwide take-back event, on October 29, 2011 featured over 5300 collection sites with over 3900 Federal, state and local agencies involved in the initiative. This initiative took in approximately 189 tons of unwanted, unused or expired medication at collection sites throughout the U.S. This includes collections from Long Term Care Facilities, tribal lands and military installations. Collections were greater than previous initiative dates despite the snow storm that crippled many parts of the northeast that limited access to collection sites.

Got Drugs?


dispose
unused
Rx
DEA
SPECIAL AGENT


1,336
379 HI
8,931
6,786
1,562
1,196
662
28
551
2,407
4,741
1,569
4,844
6,693
14,930
5,709
14,501
5,938
12,570
2,480 NH
1,130 VT
7,820
8,550 MA
780 RI
5,050 CT
14,498 NJ
304 DE
3,773 MD
194 DC
2,404
5,182
3,529
2,267
2,959
1,180
3,129
1,336
200
1,035
4,744
5,115
3,285
816
10,148
9,258
3,077
1,622
24,725
6,332
2,030
9,819
VI
1,004
PR
Prescription Drugs Collected (Lbs.):
245,443 Total Nationwide

Secure and Responsible Drug Disposal Act of 2010

- Enacted in October 2010 (Pub. L. 111-273, codified at 21 U.S.C. 822(g) and 823(b)(3))
- Act allows an ultimate user to "deliver" a controlled substance "to another person for the purpose of disposal" in accordance with regulations issued by DEA
- If the ultimate user dies while in lawful possession of the controlled substance, then any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal.
- DEA may also, by regulation, authorize long term care facilities (LTCFs) to dispose of controlled substances on behalf of ultimate users who reside or have resided at the LTCF.
- DEA is working to promulgate regulations to implement this Act. DEA must consider:
  - Public health and safety
  - Ease and cost of program implementation
  - Participation by various communities
  - Diversion Control
- Participation is voluntary. DEA may not require any person to establish or operate a delivery or disposal program.

Ultimate User Disposal

- ANPRM published on January 21, 2009 in the Federal Register
- "*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 distributor**
- ✓ **state regulatory agencies**
- ✓ **other interested parties**

158 Comments Received

Secure and Responsible Drug Disposal Act Public Meeting – January 19-20 2011

- Many different views on how to proceed
- Questions concerning who will fund

Other trends related to the medicine cabinet

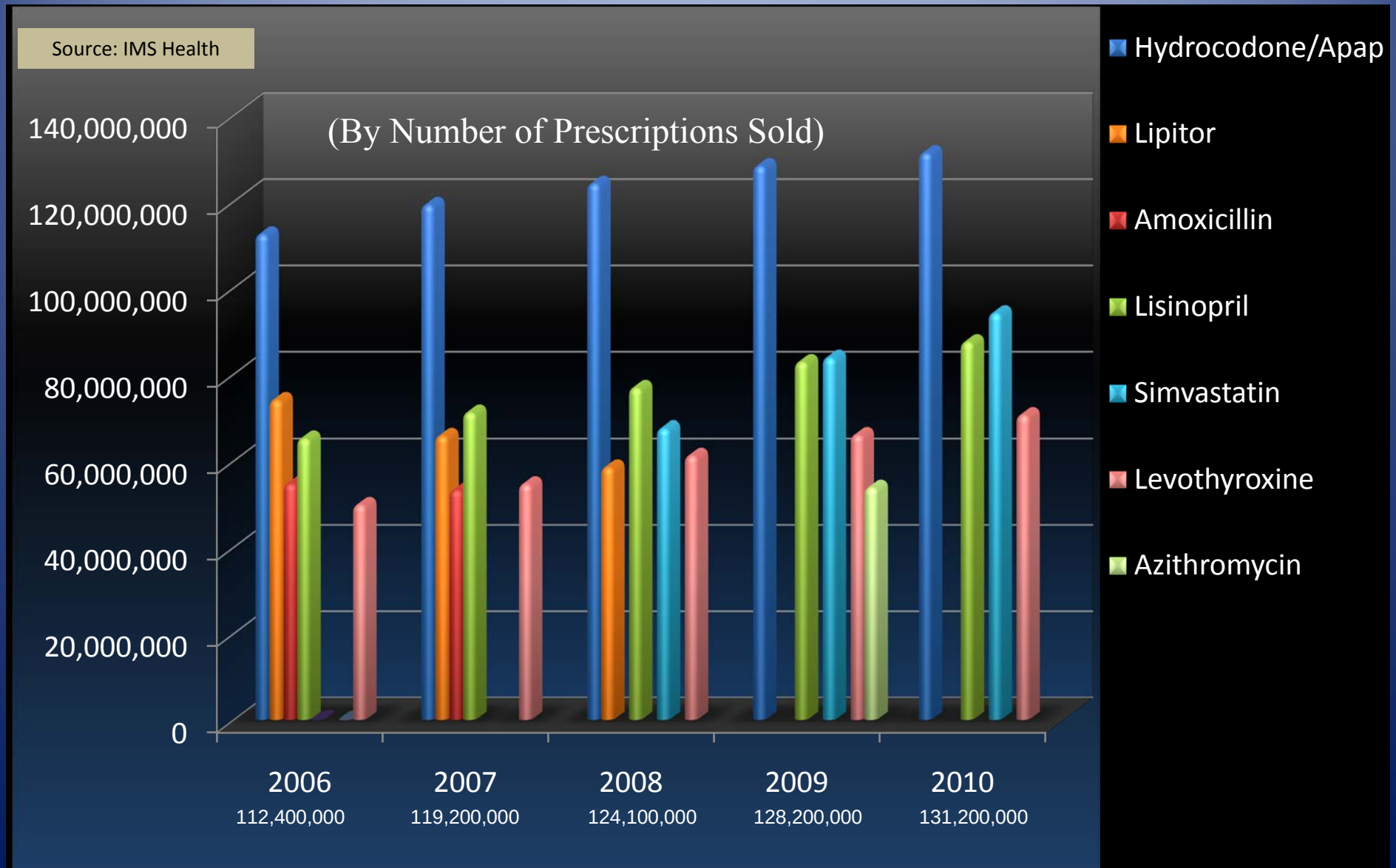
- Real estate
- Trip to relatives/friends house
- Easy access at home

Controlled and Legend Pharmaceuticals

Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen

Top Five Prescription Drugs Sold in the U.S. (2006-2010)



OXYCODONE

OxyContin® (Schedule II)

- Controlled release formulation of Schedule II oxycodone
  - The controlled release method of delivery allows for a longer duration of drug action so it contains much larger doses of oxycodone
  - Abusers easily compromise the controlled release formulation by crushing the tablets for a powerful morphine-like high
  - Street Slang: “Hillbilly Heroin”
  - 10, 15, 20, 30, 40, 60, 80mg available
- Effects:
  - Similar to morphine in effects and potential for abuse/ dependence
- Street price: Approx. $80 per 80mg tablet
- Since 2002, use among 12th graders has remained between approximately 4% and 5%*

*SOURCE: 2007 Monitoring the Future study released April 2008

OxyContin® v. Heroin

Circle of Addiction

& the Next Generation

Oxycodone

OxyContin®

Roxicodone

Hydrocodone

Heroin

OPANA® ER (Oxymorphone Hydrochloride) Extended-Release Tablets – 5mg, 10mg, 20mg, and 40mg CII

Bluefield Daily Telegraph

William "Randy" Deason
Publisher

Thomas A. Colley
Executive Editor

Samantha Perry ... Managing Editor

... Ads Coordinator
... Billing Manager
... City Editor
... Circulation Director

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

(Zechariah 4:6 ARJV)

Overdose deaths

Prescription drugs take deadly toll in WV

An alarming new study has found that prescription drugs killed more people in West Virginia in 2008 than illegal drugs. According to the report, nine out of the 10 accidental overdose deaths reported in the Mountain State involved prescription drugs. Researchers in a joint state-federal study came to the troubling conclusion after studying 482 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.

Aron 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 16 of the overdose victims were enrolled in a methadone clinic for drug-abuse treatment.

The report found that other opioid drugs frequently linked to accidental overdose deaths included hydrocodone and oxycodone. The two narcotics contributed to one in five deaths. Morphine contributed to about one in seven deaths, the report found. Anti-anxiety drugs were found in 43 percent of the deaths.

> *We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.*

While law enforcement officials have been fighting the illegal drug scourge in our region for years, accidental overdose deaths associated with the misuse of prescription narcotics now represents an emerging epidemic for the Mountain State.

The alarming new study from the West Virginia Department of Health and Human Resources should be viewed as a call to action for our community. We must take steps now to educate citizens of the growing number of accidental overdose deaths in the state associated with the misuse of legally prescribed drugs.

We must act now to educate our community. If we fail to act, the number of accidental overdose deaths in the state and the region could continue to rise. It will take a combined effort of public education and law enforcement cooperation to reduce these alarming statistics.

Rising methadone deaths

Our view: Baltimore public health officials are trying to find out if treatment for chronic pain sufferers accounts for increase in methadone overdoses

THE JUNE LETTER FROM THE BALTIMORE HEALTH DEpartment alerted physicians, nurses and other providers to a significant increase in methadone-related overdose deaths. The letter from Dr. Laura Herrera, a deputy city health commissioner, raised the possibility that the overdoses involved prescriptions for pain. It was a cautionary reminder that health care providers should educate their patients about the proper use of methadone and the lethal risks of taking extra doses.

Dr. Herrera was right to be concerned: Methadone-overdose deaths of city residents have risen from seven in 1995 to 74 in 2007. In 2007, the last year for which statistics are available, there was a 23 percent increase in such deaths over the previous year. The city deaths coincide with a similarly disturbing fivefold increase in methadone-related deaths nationally between 1999 and 2005. But proving that the use of methadone as a pain reliever caused these deaths isn't easy — no one tracks how many physicians prescribe methadone to relieve chronic pain from cancer or arthritis, for example.

Prescribing methadone has been an accepted form of treatment for chronic pain for some time, according to pain specialists at Johns Hopkins Hospital and the University of Maryland Medical Center. They add that they have seen no methadone-related deaths among their patients. Methadone used for pain treatment is prescribed in pill form; its risk stems from the drug's potency and its lingering presence in the body once its pain-relieving function has ceased. An extra dose could slow down a patient's breathing, resulting in coma or death.

To identify the extent of the problem and the patients most at risk, the city Health Department has reviewed data from the medical examiner's office. It also has asked the quasi-public city agency that oversees drug treatment in Baltimore to cross-check methadone overdose victims against its patient rosters. That's a critical aspect of the review because it could uncover misuse, abuse or diversion of methadone from drug treatment centers. Or it could lend credence to the prevailing view that more training is required for private physicians who prescribe methadone for pain.

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

At least 29 states have prescription monitoring programs that would identify indiscriminate prescribing, doctor-shopping and other abuses. A task force established this year in Maryland is studying the possibility of establishing a similar tracking system for methadone and other controlled substances.

Until then, Dr. Herrera and her colleagues at the Health Department have moved expeditiously and forthrightly to unravel this mystery. The results of their findings are the key to understanding and reversing this disturbing trend.

The Union Democrat
SINCE 1854
THE MOTHER LODE'S LEADING INFORMATION SOURCE

Report finds trends in child deaths

By ALISHA WYMAN
The Union Democrat

Prescription drug abuse, suicide and vehicle accidents were the most prevalent causes of death last year among children and young adults in Tuolumne County, according to a recently-released report.

The Child Death Review Team, made up of officials from the Sheriff's Office, the Sonora Police Department, the Public Health Department, Child Welfare Services and other agencies, examined 11 deaths of youths through age 25. Most were teens and young adults.

One of the concerning trends was a rise in abuse of prescription drugs, particularly methadone, Sheriff's spokesman Lt. Dan Bressler said.

"What we're finding is even small amounts of methadone mixed with alcohol can cause death," he said. "It doesn't take much."

Three young people died of accidental overdose in 2007, two of which involved a mixture of alcohol and methadone, a painkiller also used to help with withdrawals of harsher drugs such as heroin.

Tuolumne County isn't the only area to see a rise in prescription drug abuse, said Dr. Todd Stolp, county public health officer.

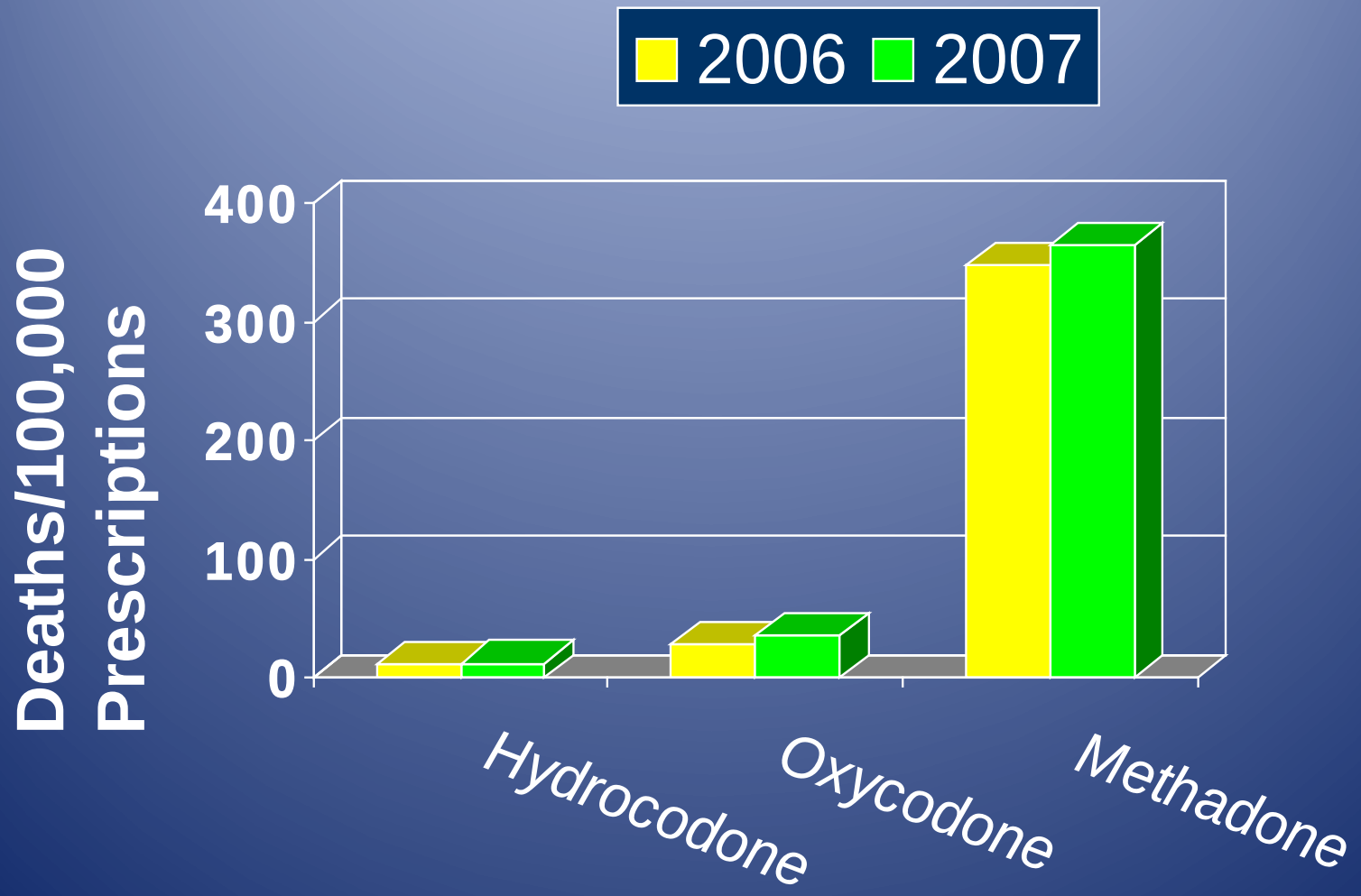
"It's a national issue, but we're in the process of identifying the extent of the problem and how to address the problem," he said.

There were three suicides in 2007. The number could be higher, however, because there were some drug-related cases in which there wasn't enough

SEE DEATHS/B

Deaths/100,000 Prescriptions in Florida

Source: FDLE and NPA Plus™



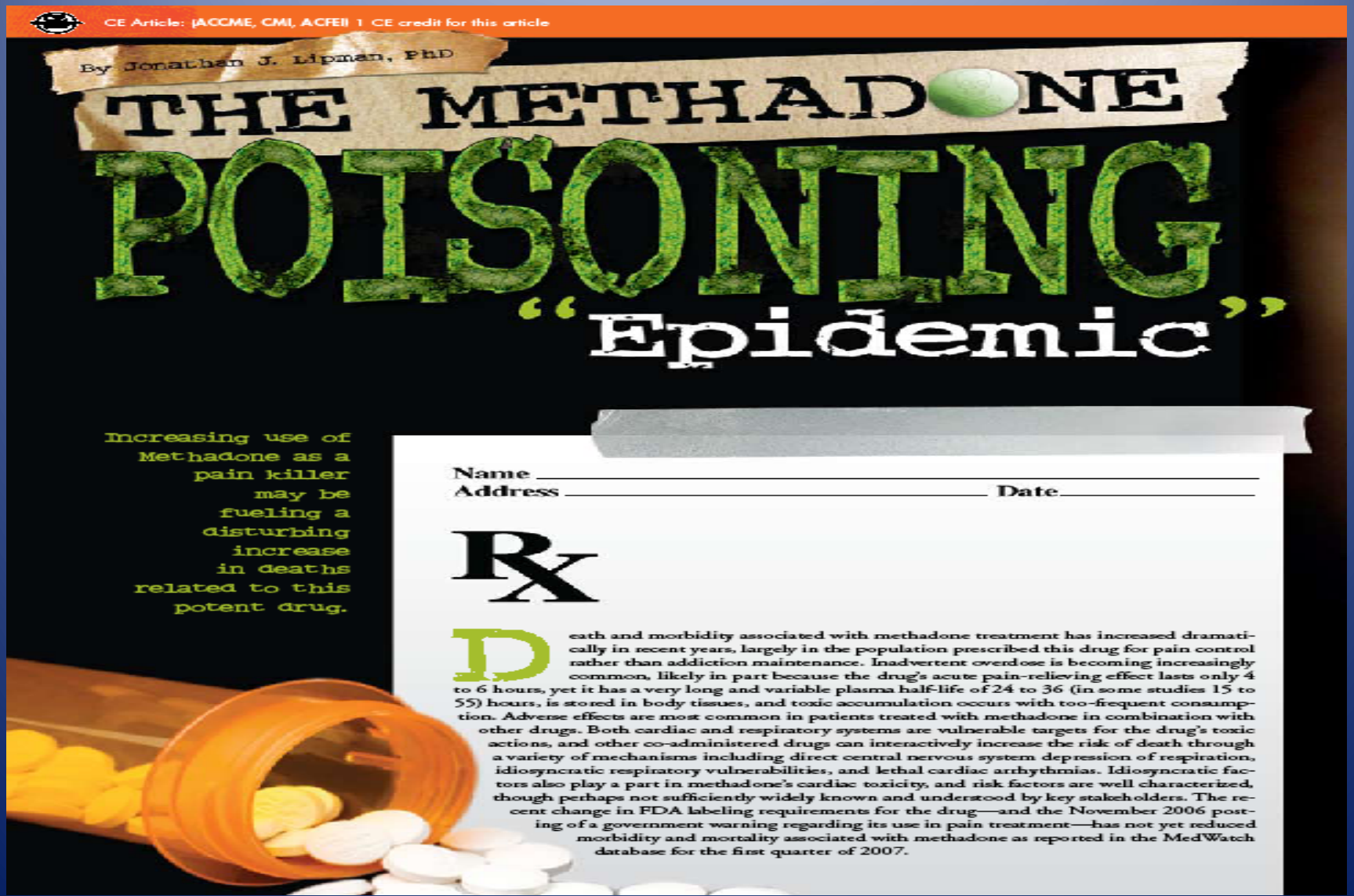
WHY IS IT ALSO USED AS AN ANALGESIC??????

Cheapest narcotic pain reliever – synthetic

Insurance companies

What's the problem?

One Pill Can Kill



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

By Jonathan J. Lipman, PhD

THE METHADONE POISONING "Epidemic"

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

Name _____

Address _____ Date _____

Rx

Death and morbidity associated with methadone treatment has increased dramatically in recent years, largely in the population prescribed this drug for pain control rather than addiction maintenance. Inadvertent overdose is becoming increasingly common, likely in part because the drug's acute pain-relieving effect lasts only 4 to 6 hours, yet it has a very long and variable plasma half-life of 24 to 36 (in some studies 15 to 55) hours, is stored in body tissues, and toxic accumulation occurs with too-frequent consumption. Adverse effects are most common in patients treated with methadone in combination with other drugs. Both cardiac and respiratory systems are vulnerable targets for the drug's toxic actions, and other co-administered drugs can interactively increase the risk of death through a variety of mechanisms including direct central nervous system depression of respiration, idiosyncratic respiratory vulnerabilities, and lethal cardiac arrhythmias. Idiosyncratic factors also play a part in methadone's cardiac toxicity, and risk factors are well characterized, though perhaps not sufficiently widely known and understood by key stakeholders. The recent change in FDA labeling requirements for the drug—and the November 2006 posting of a government warning regarding its use in pain treatment—has not yet reduced morbidity and mortality associated with methadone as reported in the MedWatch database for the first quarter of 2007.

Other Narcotics

Fentanyl

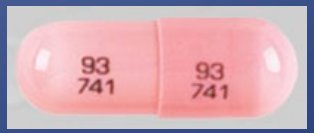
Hydromorphone

Meperidine

Morphine

Codeine

Propoxyphene



Fentanyl

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

Fentora®

Actiq®

Alprazolam Xanax® (Z-bars)

C-IV

- Drug abusers often prefer alprazolam due to its rapid onset and longer duration of action
- Alprazolam was ranked third in the number of prescriptions for controlled substances in 2003, 2004, 2005 and 2006*
- For all sales of generic pharmaceuticals, alprazolam was ranked 7th**

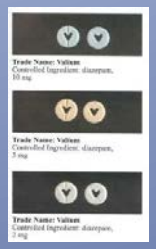
* Source IMS Health
** Source Verispan VONA

Benzodiazepines

Alprazolam

Clonazepam

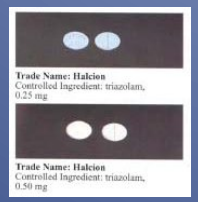
Diazepam



Lorazepam

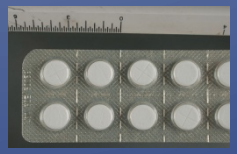
Midazolam

Triazolam



Temazepam

Flunitrazepam



Other Controlled Substances

- Phentermine C-IV
- Phendimetrazine C-III
  - Bontril®

- Amphetamines
  - Adderall C-II
  - Methylphenidate C-II
    - Ritalin®
    - Concerta®

Ritalin® / Concerta® / Adderall

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

Methods of Diversion

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

Where are the Pharmaceuticals Coming From?

- Medicine Cabinet
- Internet
- Pain Clinics
- Doctor Shoppers; RX Fraud; Practitioner Diversion

Prescription Fraud

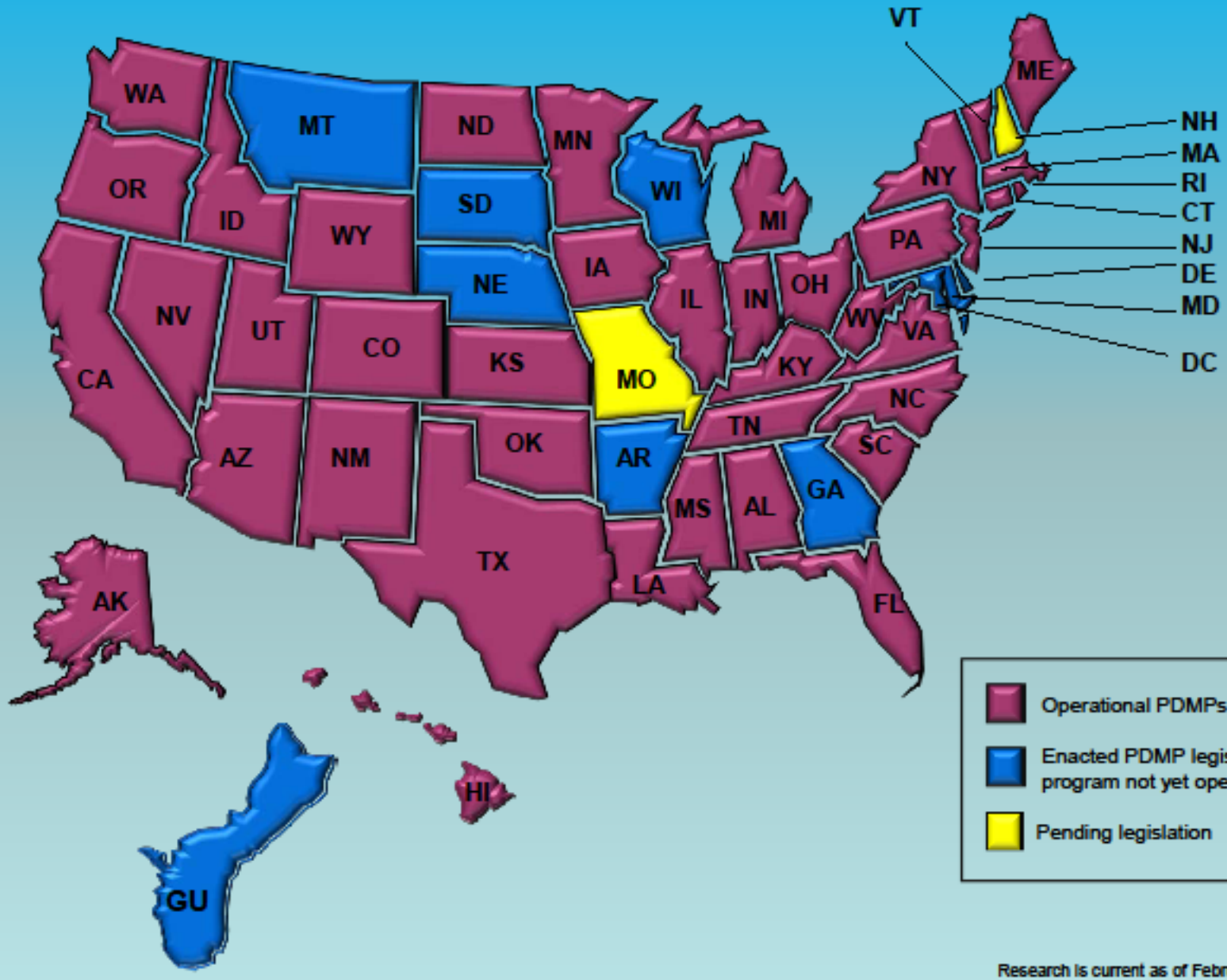
- **Fake prescriptions**
  - Highly organized
  - Use real physician name and DEA Registrant Number
    - Contact Information false or “fake office”
      - (change locations often to avoid detection)
  - Prescription printing services utilized
    - Not required to ask questions or verify information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

Doctor Shopping

Prescription Drug Monitoring Programs

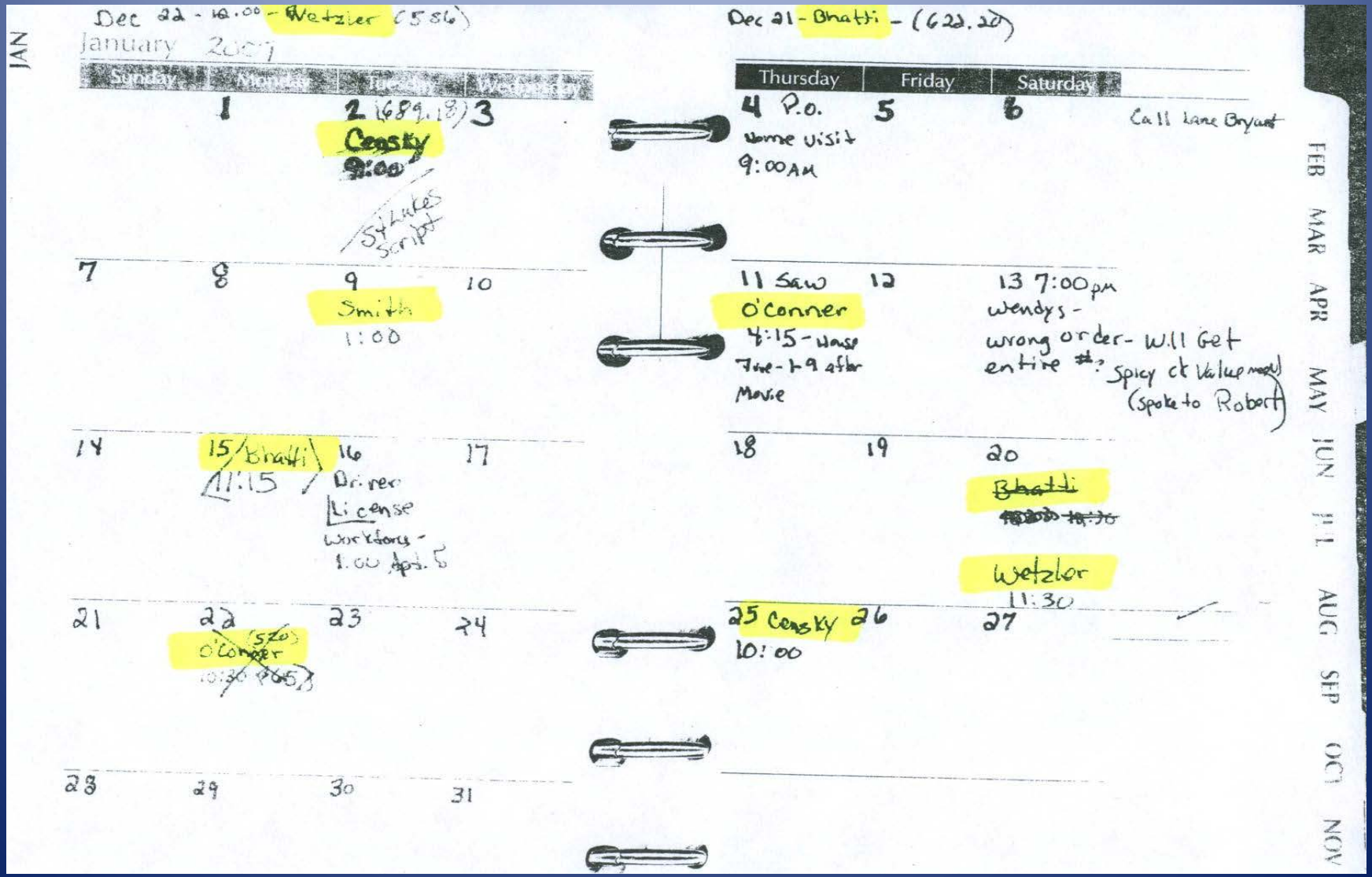
Alliance of States with Prescription Monitoring Programs

Status of Prescription Drug Monitoring Programs (PDMPs)



Research is current as of February 1, 2012

Doctor Appointment Records



		OX	ROX	LOR	X's	SOMMAS	
DR. COOPER		90		150	90		60
WORLD WIDE	500						
DR. PRETO		120	180		60		
JERRY'S	820						
DR. FALLER		170	130		190		
P. LL STORE	740						
DR WEED		240	270	150	90		
GENERIC DEPOT	1110						
DR. OSSORIO				120	60	100	
OFF PHAR	240						
DR. COSBY		40	90		30		
TOWN	540						
DR. MENDEZ			110	90	45	45	
OFF. PHAR.	288						
DR. SULKIN				90	22		
HLWD	180						
DR. MELLON		240	270	150	120		
ALPHA	1200						
DR SMITH		120 (2 1/5)	120		60		
GARDEN DRUG	772						
DR. LAZZOPINA			120		60	120	
PRO-SCRIPT	315						

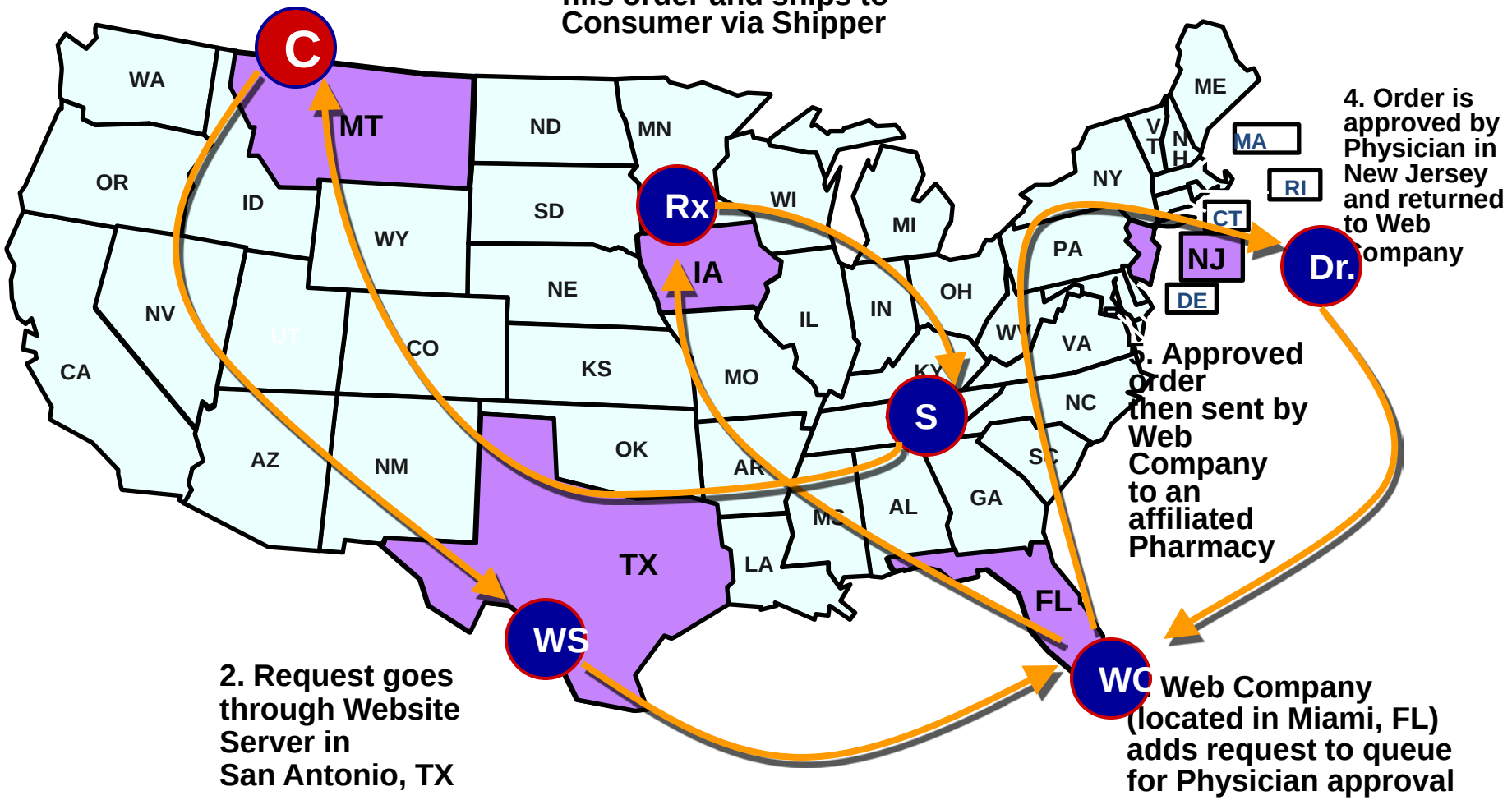
Extra effort on pain pills for doctors and pharmacists is needed

"First, do no harm," the Hippocratic oath tells doctors. But how can physicians prescribing narcotics manage this without checking to see if patients are addicts? Painkiller prescriptions, related deaths and hospital admissions have skyrocketed on Long Island over the past few years. Two deadly drugstore robberies in 2011 highlighted the crisis on Long Island. A plan introduced by the state's attorney general could help by forcing doctors and pharmacists to check a database before providing narcotics to patients. It's necessary, but lobbying groups for doctors oppose it, fearing the administrative burden, and pharmacists are protesting too. Doctors and pharmacies seem to determine whether a patient is covered by insurance with ease. They should dedicate the same effort to determining whether patients can safely have medications.

2012 Newsday

Diversion via the Internet

Domestic 'R_X' Flow



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)

What has been the reaction????

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

Current CSA Registrant Population

Total Population: 1,341,505

- **Practitioner - 1,040,496**
- **Mid-Level Practitioner - 170,115**
- **Pharmacy - 65,946**
- **Hospital/Clinic - 15,702**
- **Manufacturer - 525**
- **Distributor - 805**
- **Researcher - 6,357**
- **Analytical Labs - 1,504**
- **NTP - 1,247**
- **ADS Machine - 161**

as of 1/21/2010

What took the place of Internet Medical Care and Internet CS pharmaceutical Distribution?

Florida Pain Clinics

U.S. v. Moore 423 US 122 (1975)

Increased Law Enforcement Pressure

- Clinics migrating north and west
- Funded by owners in Florida

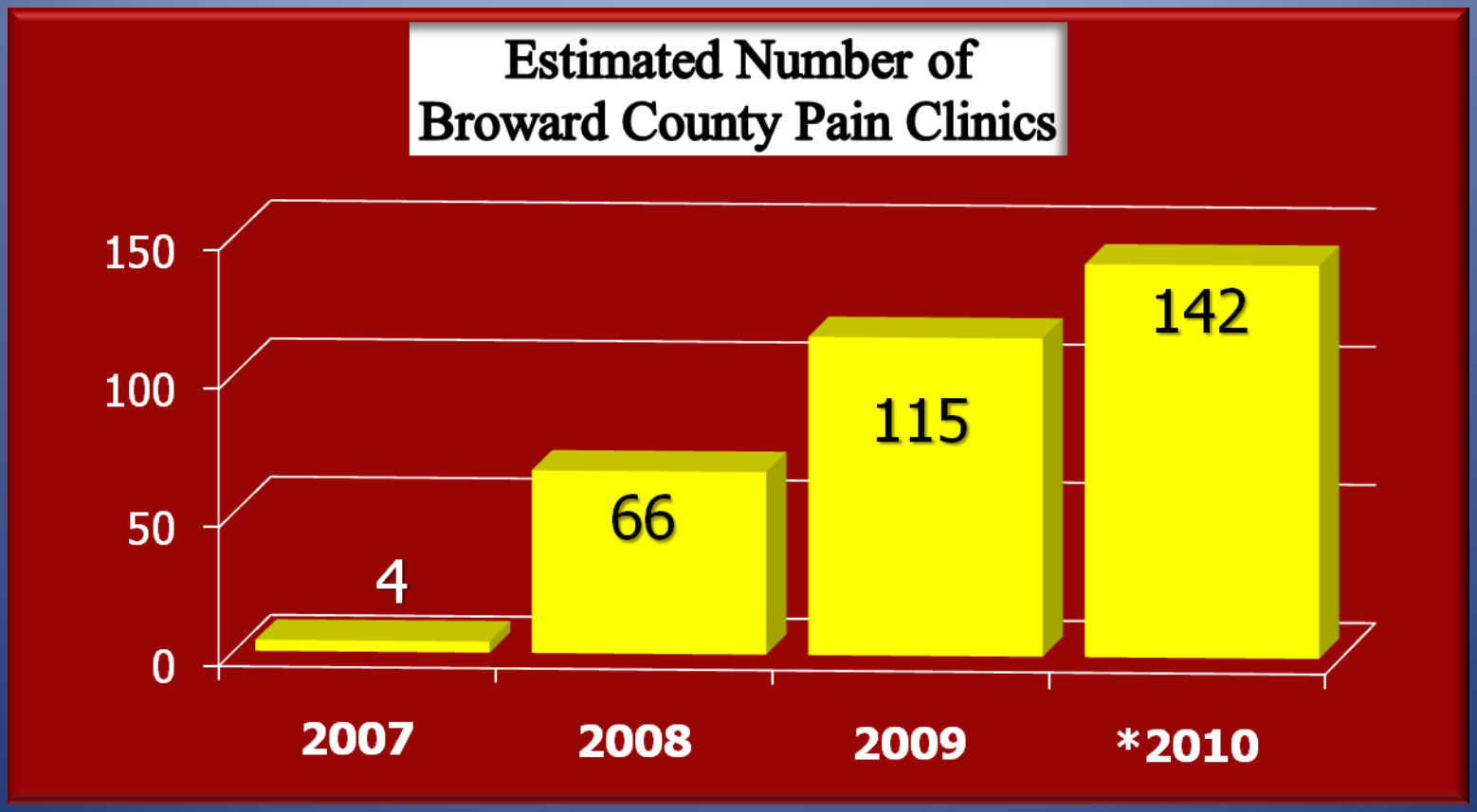
Why Florida?

- No PDMP
- Law Enforcement v. Regulatory Boards

Medical Care ?

- Many of these clinics are prescription/dispensing mills.
- Minimal practitioner/patient interaction

Explosion of South Florida Pain Clinics



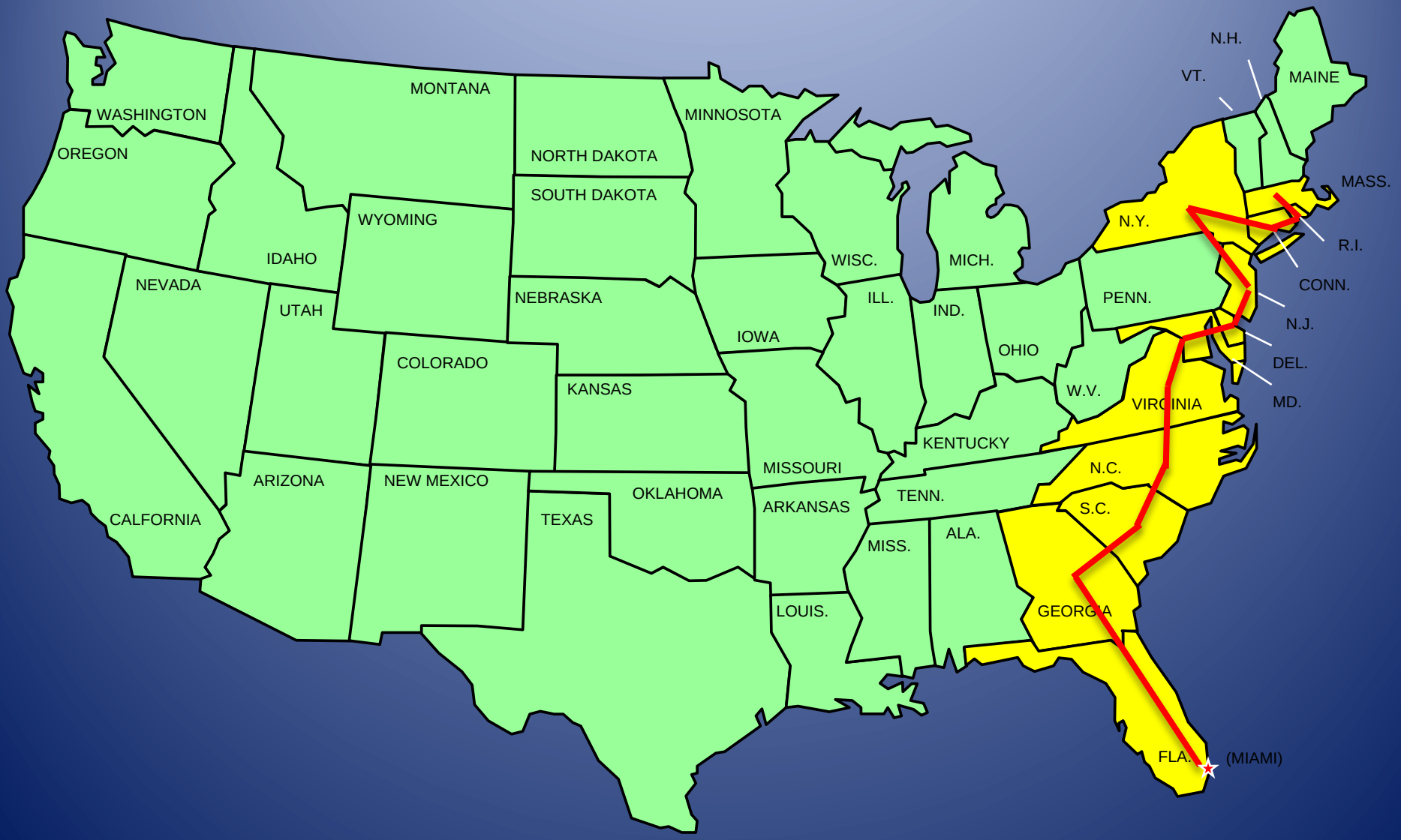
As of June 4, 2010, Florida has received 1,118 applications and has approved 1026

*As of May 14, 2010, Broward 142; Miami-Dade 79; Palm Beach 111

‘The Florida Migration’

- Vast majority of “patients” visiting Florida “pain clinics”come from out-of-state:
  - Georgia
  - Kentucky
  - Tennessee
  - Ohio
  - Massachusetts
  - New Jersey
  - North and South Carolina
  - Virginia
  - West Virginia

THE MIGRATION



Drugs Prescribed

- A ‘cocktail’ of oxycodone and alprazolam (Xanax®)
- An average ‘patient’ receives prescriptions or medications in combination

Schedule II	Schedule III	Schedule IV
Oxycodone 15mg, 30mg	Vicodin (Hydrocodone)	Xanax (Alprazolam)
Roxicodone 15mg, 30mg	Lorcet	Valium (Diazepam)
Percocet	Lortab	
Percodan	Tylenol #3 (codeine)	
Demerol	Tylenol #4 (codeine)	
Methadone		

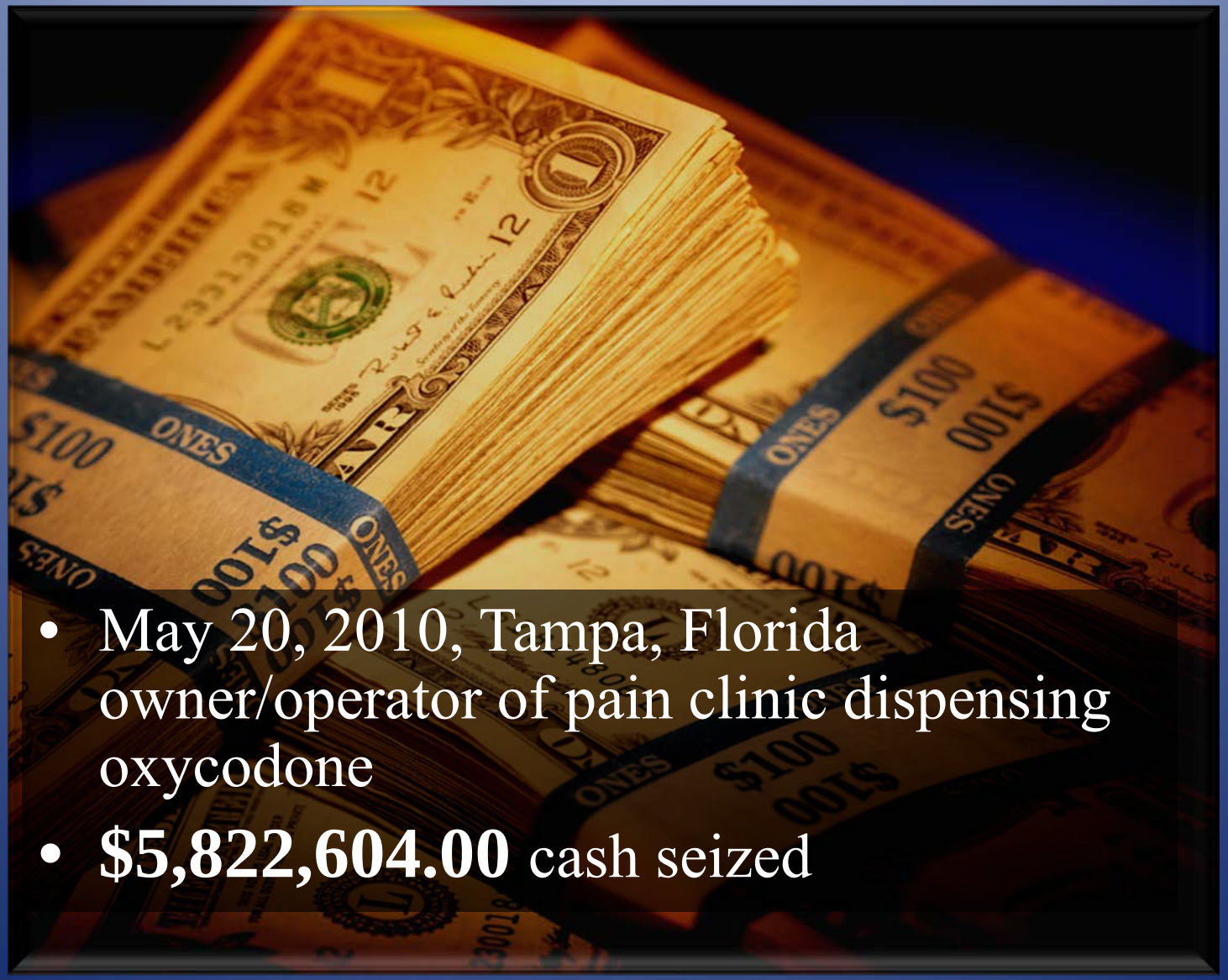
Average Charges for a Clinic Visit

- Price varies if medication is dispensed or if customers receive prescriptions
- Some clinics advertise in alternative newspapers citing discounts for new patients such as 'buy one get one free‘ or “50% off with this ad”
- Typically, initial office visit is $250; each subsequent visit is $150 to $200
- Average 120-180 30mg oxycodone tablets per visit

Cost of Drugs

- The ‘cocktail’ prescriptions go for $650 to $1,000
- According to medical experts, most clinics do not require sufficient medical history and tests for proper prescribing of Schedule II substances
- Each oxycodone 30mg tablet costs $1.75 to $2.50 at the clinics
  - On the street in Florida, that pill can be re-sold for $7 to $15
  - Outside of Florida, it can be re-sold for $25 to $30 ($1 per mg)

What's the Profit?

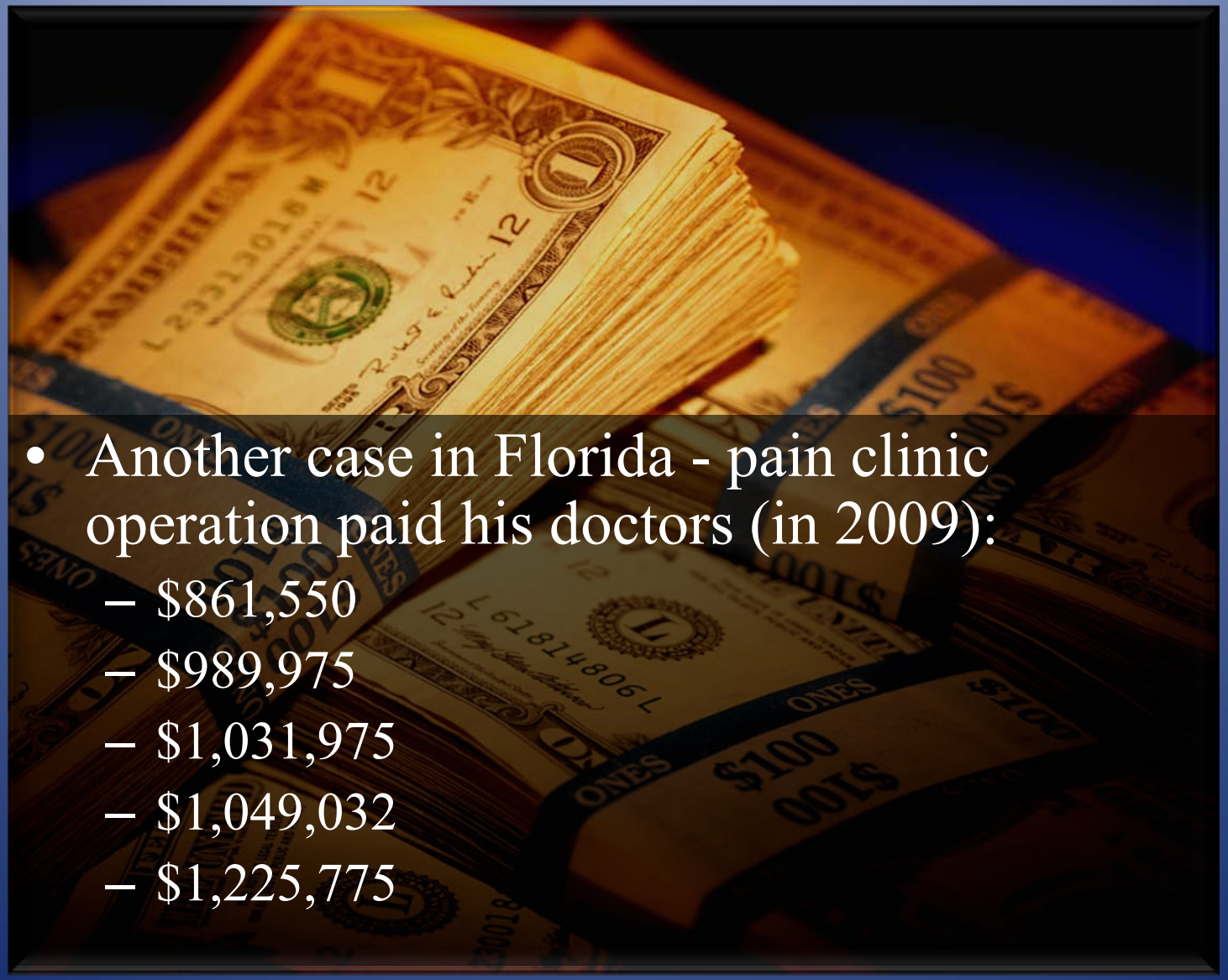


- May 20, 2010, Tampa, Florida owner/operator of pain clinic dispensing oxycodone
- **$5,822,604.00** cash seized

What's the Profit?

- One case in Florida owner/operator of pain clinic allegedly generated $40 million in drug proceeds
- Houston investigation $41.5 million in assets

What's the Profit?



- Another case in Florida - pain clinic operation paid his doctors (in 2009):
  - $861,550
  - $989,975
  - $1,031,975
  - $1,049,032
  - $1,225,775

Operation Pill Nation

This operation involved the mobilization of eleven Tactical Diversion Squads from across the United States to marshal with the Miami TDS and other state and local agencies in a concerted effort to attack and dismantle the hundreds of rogue pain clinics that continue to plague South Florida.

- On February 23, 2011, as part of *Operation Pill Nation* DEA conducted a coordinated effort with more than 500 state and local law enforcement officers in a massive takedown which included:
  - 21 search warrants executed at clinics, residences, and other locations in south Florida;
  - 25 arrested on various federal and state drug and money laundering charges, of which 5 were medical doctors and 5 were pain clinic owners;
  - Seizure of approximately $7 million in assets. ($3 million dollars in US currency, a variety of other real property, jewelry, and assets including 62 vehicles, some of which were exotic cars; and
  - Immediate Suspension Orders issued against 14 DEA registrations, 1 Order to Show Cause issued against 3 DEA registrations, and the surrender of 7 DEA registrations.

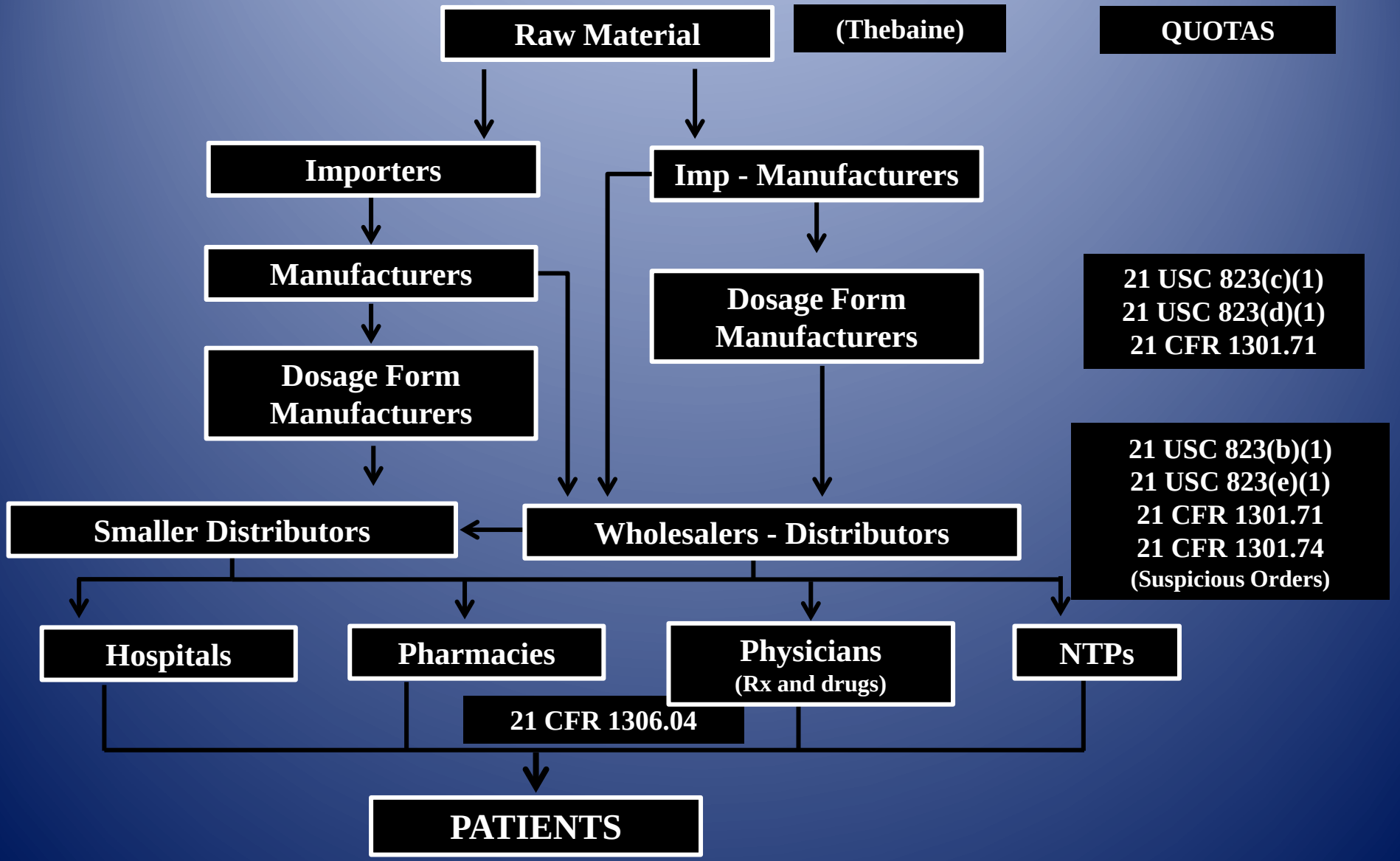
Operation Pill Nation con't

As of April 2011, *Operation Pill Nation* has resulted in:

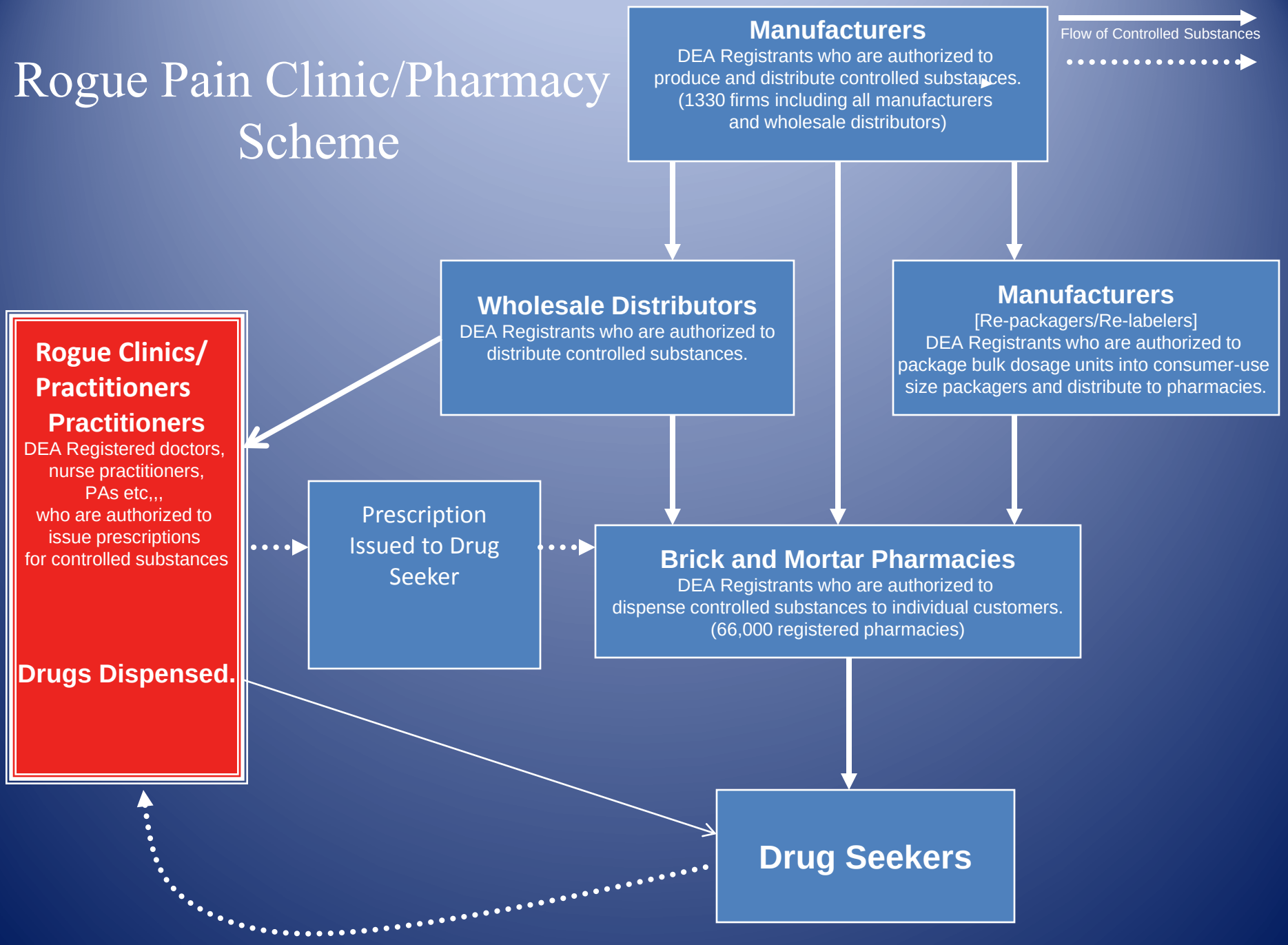
- The surrender of 83 DEA registrations (71 physicians, 8 pharmacies and 4 wholesale distributors);
  - 1 wholesale distributor's civil fine was $8 million
- Immediate Suspension Orders issued against 63 DEA registrations (33 physicians, 1 distributor);
- Orders to Show Cause issued against 6 DEA registrations;
- 38 clinics closed;
- 32 arrests (12 physicians, 5 clinic owners and 15 clinic employees)
- Seizure of more than $16.4 million in assets ($11.9 million in US currency and approximately $4.5 million in vehicles, jewelry, real property, and other assets).

Florida Pain Clinic Raid

The Flow of Pharmaceuticals



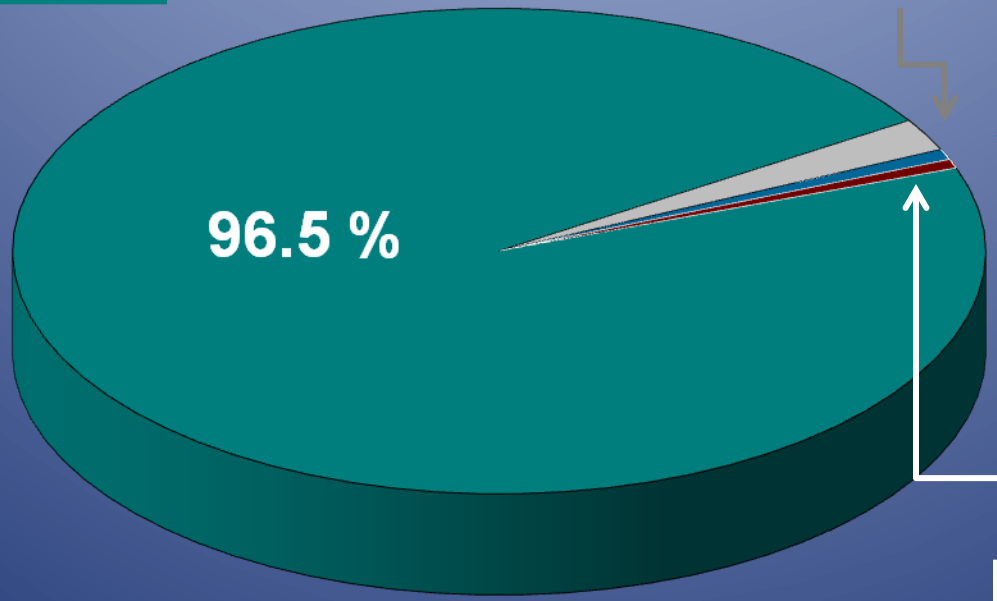
Rogue Pain Clinic/Pharmacy Scheme



Top 100 Practitioner Purchasers of Oxycodone Nationwide
January 1, 2009 – September 30, 2009

97 Practitioners in Florida Purchased 20,760,567 units

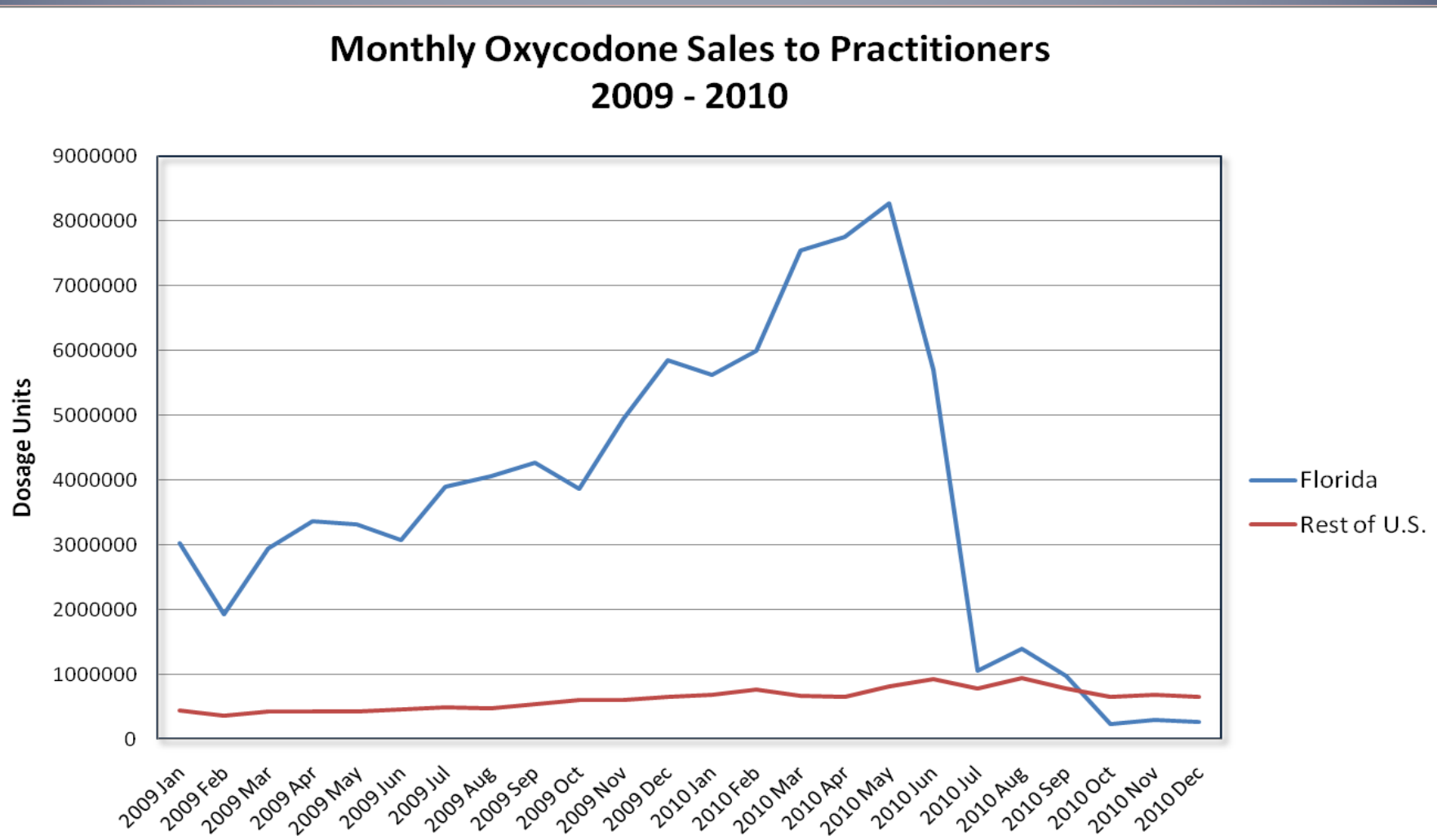
1 Practitioner in Ohio Purchased 465,200 units – 2.2%



1 Practitioner in North Carolina Purchased 153,200 units – 0.7%

1 Practitioner in California Purchased 130,000 units – 0.6%

Source: ARCOS
Date Prepared: 01/12/2010



June 2010 DEA takes action against four wholesale distributors supplying doctors who were dispensing from rogue pain clinics.

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

21 CFR §1306.04

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner , but a corresponding responsibility rests with the pharmacist who fills the prescription.

An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Section 309 of the act (21 USC § 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

State of Florida Legislative Actions

- Effective October 1, 2010
  - Pain clinics are banned from advertizing that they sell narcotics
  - They can only dispense 72-hour supply of narcotics
    - Violation is a 3rd degree felony
  - Increased training for physicians will be required
    - Effective July 1, 2012, a physician cannot practice at a pain clinic if:
      - Has not completed a pain medicine fellowship, or
      - Has not completed a pain medicine residency, or
      - Grandfather physicians currently practicing in clinics prior to July 1, 2012 and complying with Board rules
  - State Department of Health will now be able to pass on any information in the PDMP database to law enforcement
  - Prohibits the registration of pain clinics unless they are owned by physicians or licensed by non-physicians as a health care clinic
    - Will deny any registration if doctor's DEA registration was ever revoked
    - Will deny if applicant has ever been convicted of a felony drug offense

Florida HB 7095:

“Pill Mill Crackdown”

Effective July 1, 2011

- Clinics must turn over their supply of C-II and C-III controlled substances
- Clinics are no longer able to dispense these drugs
- Clinics cannot have ANY affiliation with a doctor that has lost a DEA number

- Pharmacies must report all prescription fraud: failure to do so can result in a 1º misd.
- 3rd degree felony for burglary structure or conveyance where there is theft of controlled substance
- Amends PDMP from 15 day reporting to 7 day reporting

Clinic response to the Florida legislation prohibiting the sale of CS from pain clinics?

Buy Pharmacies!!

Beef prices on the way up

Low cattle supplies, strong foreign demand for U.S. beef help fuel price boost. 1B.

Preserving pets after death growing popular as an option

Taxidermist Daniel Ross acknowledges it's a controversial topic, but says the owners "aren't weird, they just really love their pets." 3A.

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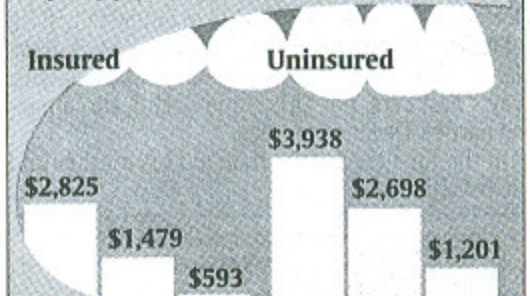
A bite into dental costs

Average out-of-pocket costs Americans say they pay for dental procedures:



cartoonish persona, self-promotion and a criminal record of pump-and-dump stock fraud.

The former computer hacker is the principle figure behind Megaupload, which U.S. prosecutors charge was a global empire that reaped a mega-fortune from illegal digital distribution of movies, songs and other copyright works.

In a New Zealand jail awaiting extradition to the USA on charges of racketeering, money-Dotcom's flamboyant life of riches and creating one of the Web's most popular and controversial sites — a site that came into the government's cross-hairs two years ago after a complaint from the Motion Picture Association of America.

In the days after Dotcom's arrest, the case has triggered an angry response from the hacker

Please see COVER STORY next page ▸

Dealers creative in oxycodone bid

They try to open pharmacies after Florida targets 'pill mills'

By Donna Leinwand Leger
USA TODAY

Drug dealers are finding creative ways around new laws that crack down on "pill mills" dispensing powerful painkillers such as oxycodone.

In Florida, hundreds of people tried to open pharmacies after the state barred doctors from dispensing the narcotics directly from their clinics and forced patients to fill their prescriptions at pharmacies. Others moved their operations to Georgia, state police and federal agents say.

"Traffickers adapt to situations," says Mark Trouville, special agent in charge of the Drug Enforcement Administration's field offices in Florida. "We knew once we put pressure on the pill mills, the wrong people would start opening pharmacies."

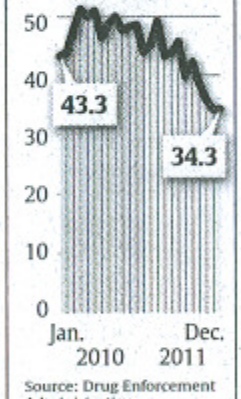
Florida was the nation's center of prescription-painkiller distribution until the state enacted laws last year aimed at pill mills — clinics where doctors perform cursory examinations on people with dubious injuries and dispense addictive painkillers.

Since then, the number of Florida doctors among the nation's top 100 oxycodone-purchas-

Fewer pills

Number of oxycodone pills purchased by Florida pharmacies and practitioners:

(in millions)



Source: Drug Enforcement Administration

By Julie Snider, USA TODAY

A pharmacy must register with the DEA and be licensed by the state to dispense controlled substances, which include many drugs that require a doctor's prescription. The DEA can deny a registration if an applicant has been convicted of a drug-related crime or agents find a connection to a pill mill or other activity that poses a threat to public health and safety.

At least 37 pharmacy applicants withdrew their applications in 2011, Trouville says. "They feel the squeeze and move on," he says.

Still, questionable pharmacies are selling thousands of oxycodone and hydrocodone pills to people recruited by drug dealers to get prescriptions from pain clinics. "They're not selling Band-Aids and aspirin," Trouville says. "There's nothing but an empty room with a bulletproof window."

Pharmacy applicants turned down in Florida often try their luck in Georgia, says Rick Allen, director of the Georgia Drugs and Narcotics Agency. Of new non-chain drugstore applications, about 95% have some connection to Florida, he says.

"The people come completely out of left field without any pharmacy background and open a pharmacy in a sleazy strip mall right down the road from a pain clinic," Allen says. "You do a cursory background on them, and they're living in a doublewide in Pembroke Pines, Fla."

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Pharmacy Applications for Registration

	2008	2009	2010	2011 (as of 9/22/11
Registered Pharmacies in US	65,065	65,991 1.4%	66,766 1.2%	66,934 .03%
Registered Pharmacies in FL	4,343	4,403	4,741	4,809
New Applications in US (Independent Pharmacies)	2,230	2,192 <1.73%>	2,010 <8.3%>	1,840 <8.5%>
New Applications in FL (Independent Pharmacies)	271	250 <7.7%>	388 55.2%	290 <25.25%>
New Applications in Miami area (Independent Pharmacies)	130	79 <39.2%>	118 49.4%	126 6.8%
New Applications in Ft. Lauderdale area (Independent Pharmacies)	37	52 40.5%	81 55.8%	58 <28.4%>

Questions

DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
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Thank You!