

**Tufts Health Care Institute
Prescription Opioid Diversion
“SAMHSA Initiatives to Address Diversion While
Maintaining Opioid Access”**

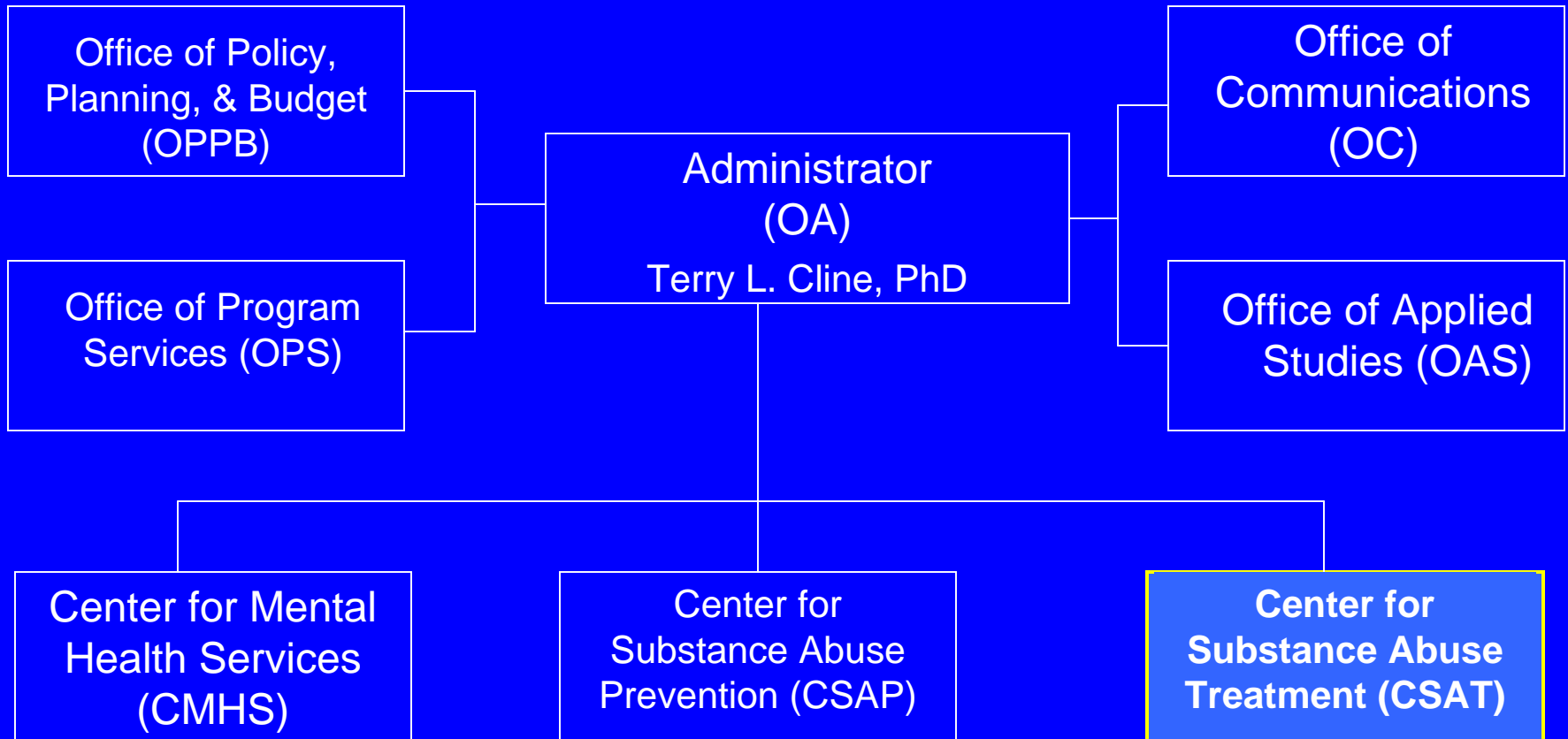
March 27, 2008
Boston, MA

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Overview

- SAMHSA – Substance Abuse and Public Health
- Prescription Drug Abuse Statistics
- SAMHSA Measures To Reduce Rx Drug Abuse
- Abuse of Two Specific Prescription Drugs
 - Methadone
 - Buprenorphine
- Risk Management

Substance Abuse & Mental Health Services Administration (SAMHSA)



Organization Chart

Substance Abuse and Mental Health Services Administration/CSAT

SAMHSA's Mission:

- To build resilience and facilitate recovery for people with or at risk for substance abuse and mental illness.

Center for Substance Abuse Treatment (CSAT)

Mission:

- To improve the health of the nation by bringing effective alcohol and drug treatment to every community.

SAMHSA/CSAT's Public Health Approach

- Population-based
- Comprehensive and holistic
- Incorporates early intervention, treatment, recovery support, and health promotion
- Works across systems and professions
- Involves people in recovery, the community, the public and private sectors
- Evidence-based

A Public Health Imperative

Substance Misuse can:

Lead to:

- **Worsened medical conditions** (e.g. diabetes, hypertension) and
- **Worsened brain disorders** (e.g. depression, psychosis, anxiety & sleep disorders)
- **Unintentional injuries & violence**

Result in:

- **Dependence**, which may require multiple treatment services
- **Low birth weight, premature deliveries, and developmental disorders, child abuse & neglect**

A Public Health Imperative

Substance Misuse can:

Contribute to or be associated with :

- **Homelessness**
- **Criminal justice involvement**
- **The effect and abuse of prescribed medications**
- **Unemployment**
- **Gambling**
- **Bankruptcy**
- **Legal Issues (e.g. DUI, DWI, domestic violence)**
- **Dropping out of school**

A Public Health Imperative

Substance Misuse can:

Induce or facilitate:

- **Medical diseases** (e.g. Stroke, dementia, hypertension, cancers)
- **Acquiring Infectious diseases & infections** (e.g. HIV, Hepatitis C)
- **Suicide attempts or tendencies**

Injection Drug Use and AIDS/HIV

According to CDC data on U.S. adolescents and adults
– in 2005:

- Approximately 20% of the reported new AIDS cases were related to injection drug use.
- 20% of males and 33% of females living with AIDS were exposed through injection drug use.
- Almost one-third (28.2%) of AIDS deaths were adolescents and adults infected through injection drugs.

The Issue...

- Each year, millions of patients in the US are treated for a variety of serious medical problems with prescription medications
- Non-medical use represents a relatively small percentage of all use of these medications and it is a problem that requires attention

Comparing the numbers of nonmedical and medical opioid analgesic users

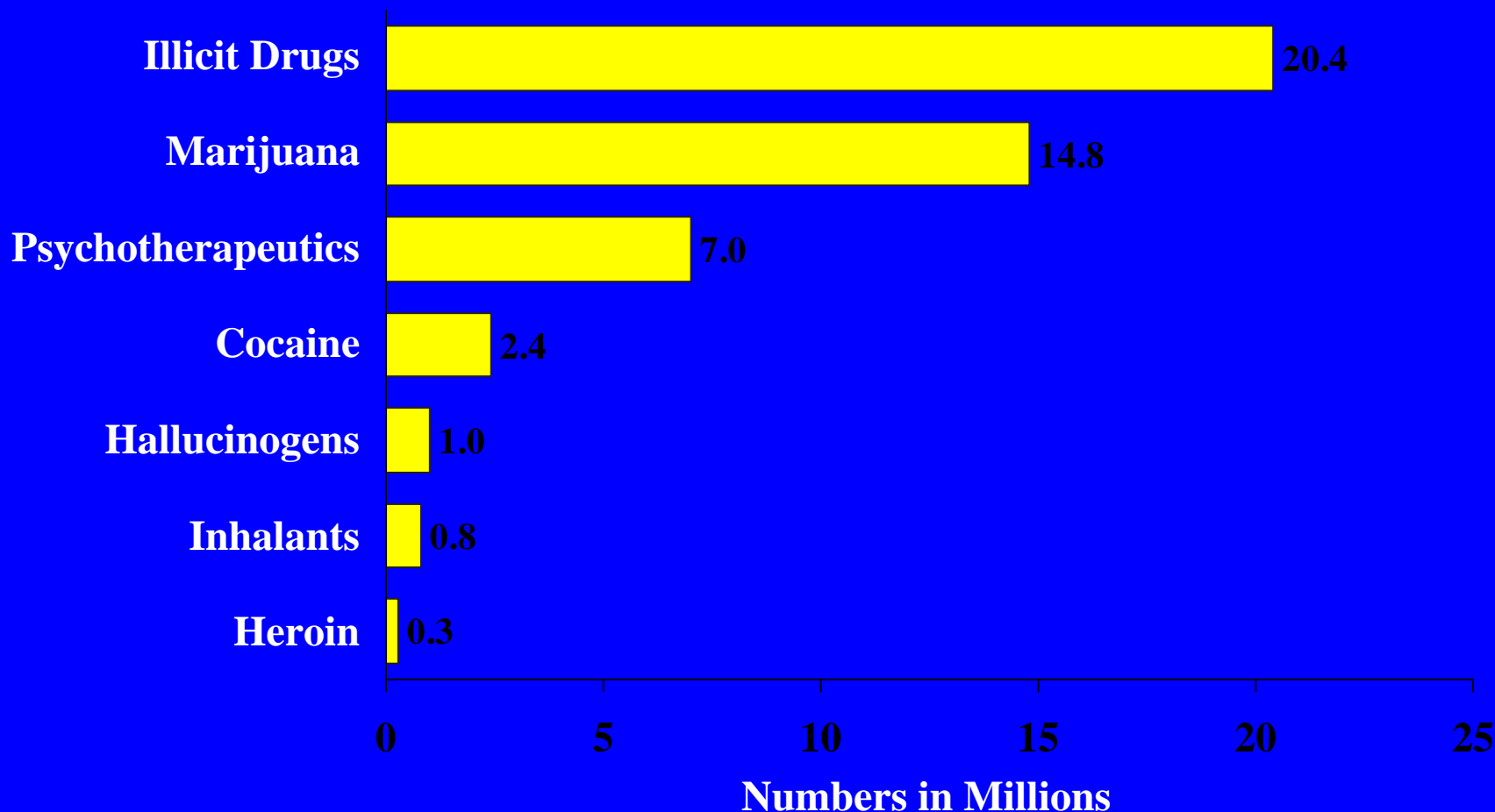
- ~9.0 million people used OAs in past month in 1999-2002 (4.2%, NHANES)
- ~4.6 million people used OAs nonmedically in past month in 2005 (1.9% of 12+, NSDUH)
- Therefore, from one third to one half of users may be using OAs nonmedically at least some of the time.

WHO Guidelines

on review of psychoactive substances for international control

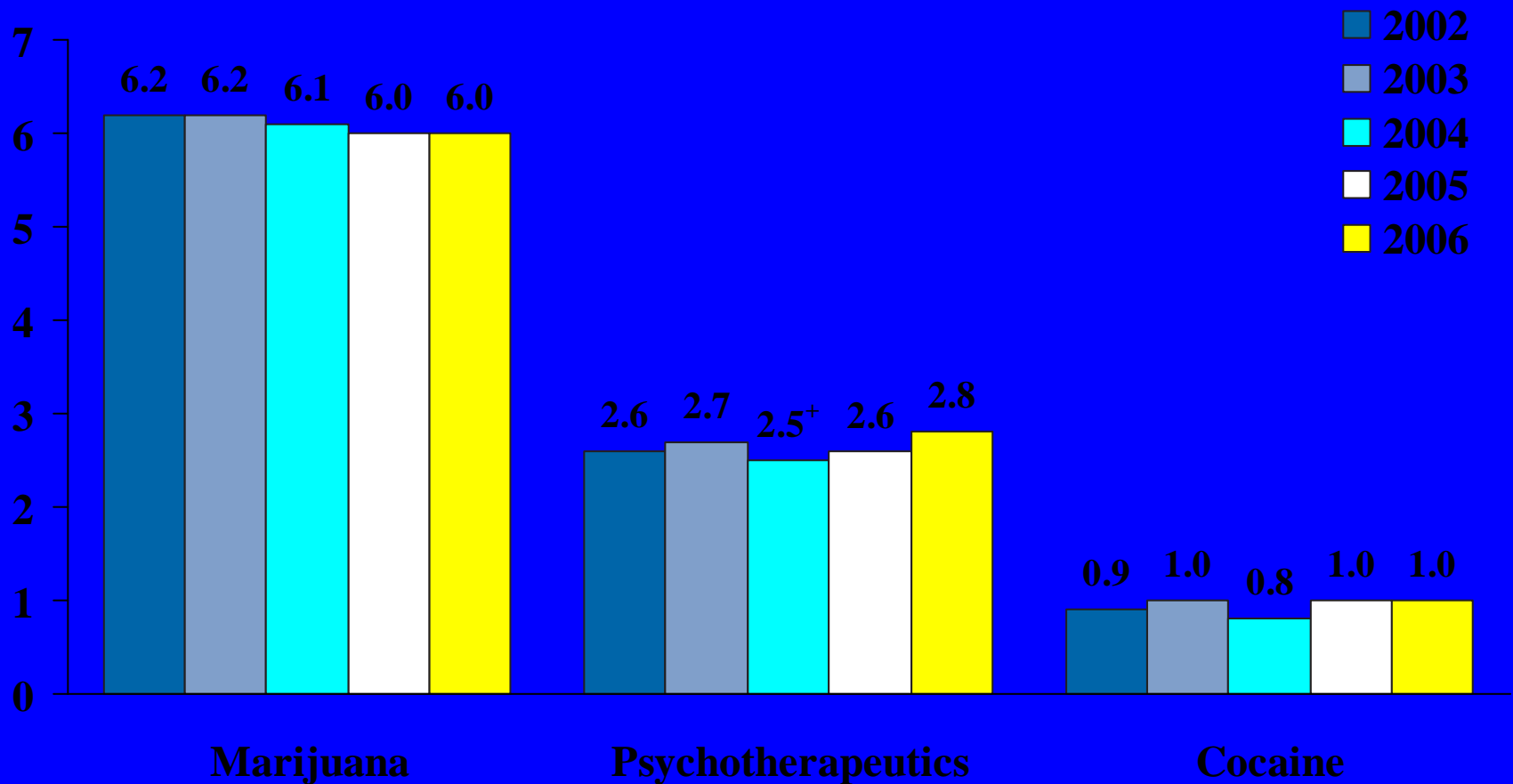
- UNDERLYING PRINCIPLES
- 4. The Preamble of the Single Convention on Narcotic Drugs, 1961 provides:
 - "The Parties,
 - Concerned with the health and welfare of mankind,
 - Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes,
 - Recognizing that addiction to narcotic drugs constitutes a serious evil for the individual and is fraught with social and economic danger to mankind,
 - Conscious of their duty to prevent and combat this evil,
 - Considering that effective measures against abuse of narcotic drugs require coordinated and universal action,

Past Month Use of Specific Illicit Drugs among Persons Aged 12 or Older: 2006



Past Month Use of Selected Illicit Drugs among Persons Aged 12 or Older: 2002-2006

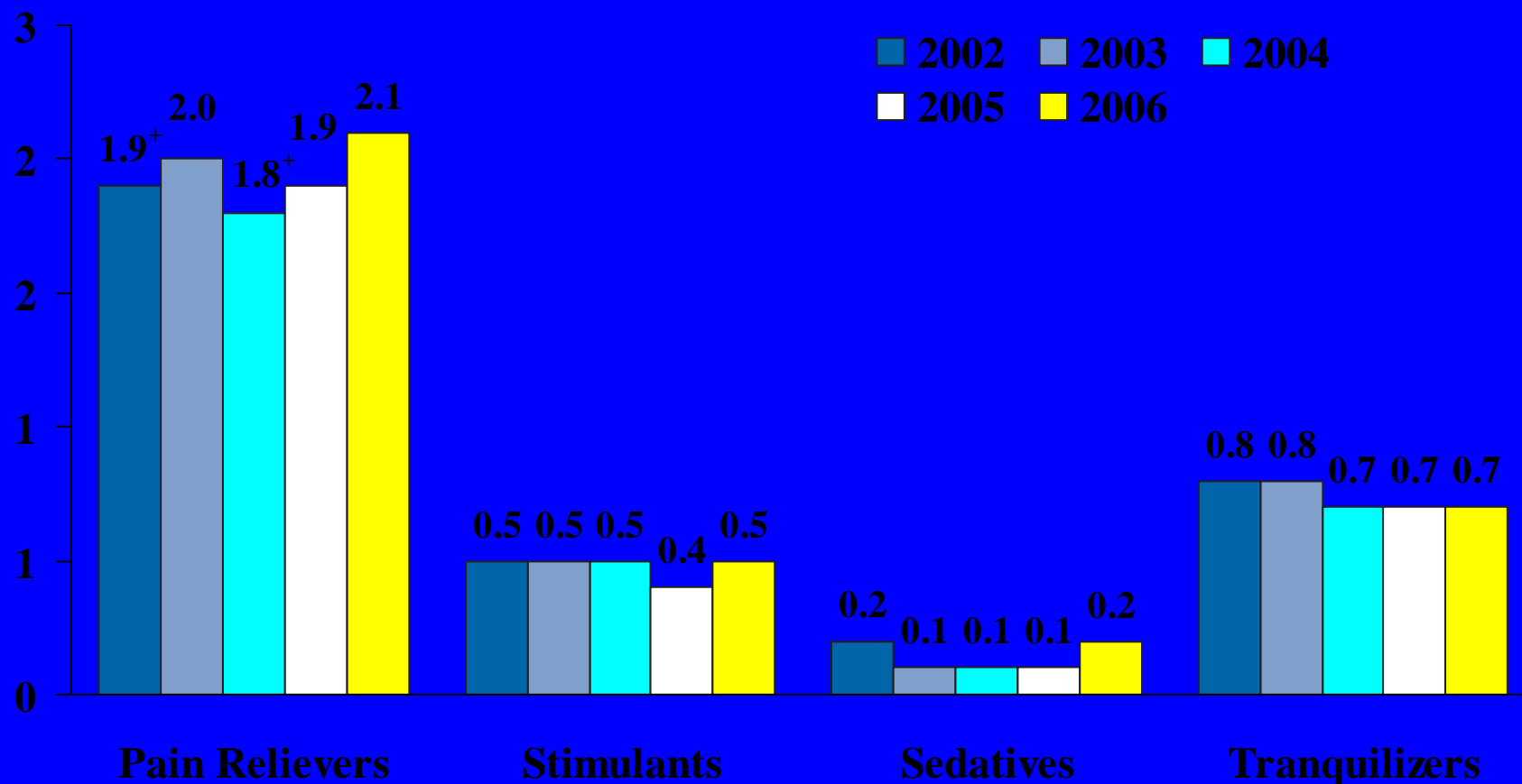
Percent Using in Past Month



+ Difference between this estimate and the 2006 estimate is statistically significant at the .05 level.

Past Month Nonmedical Use of Prescription Drugs (Psychotherapeutics) among Persons 12+:2002-2006

Percent Using in Past Month

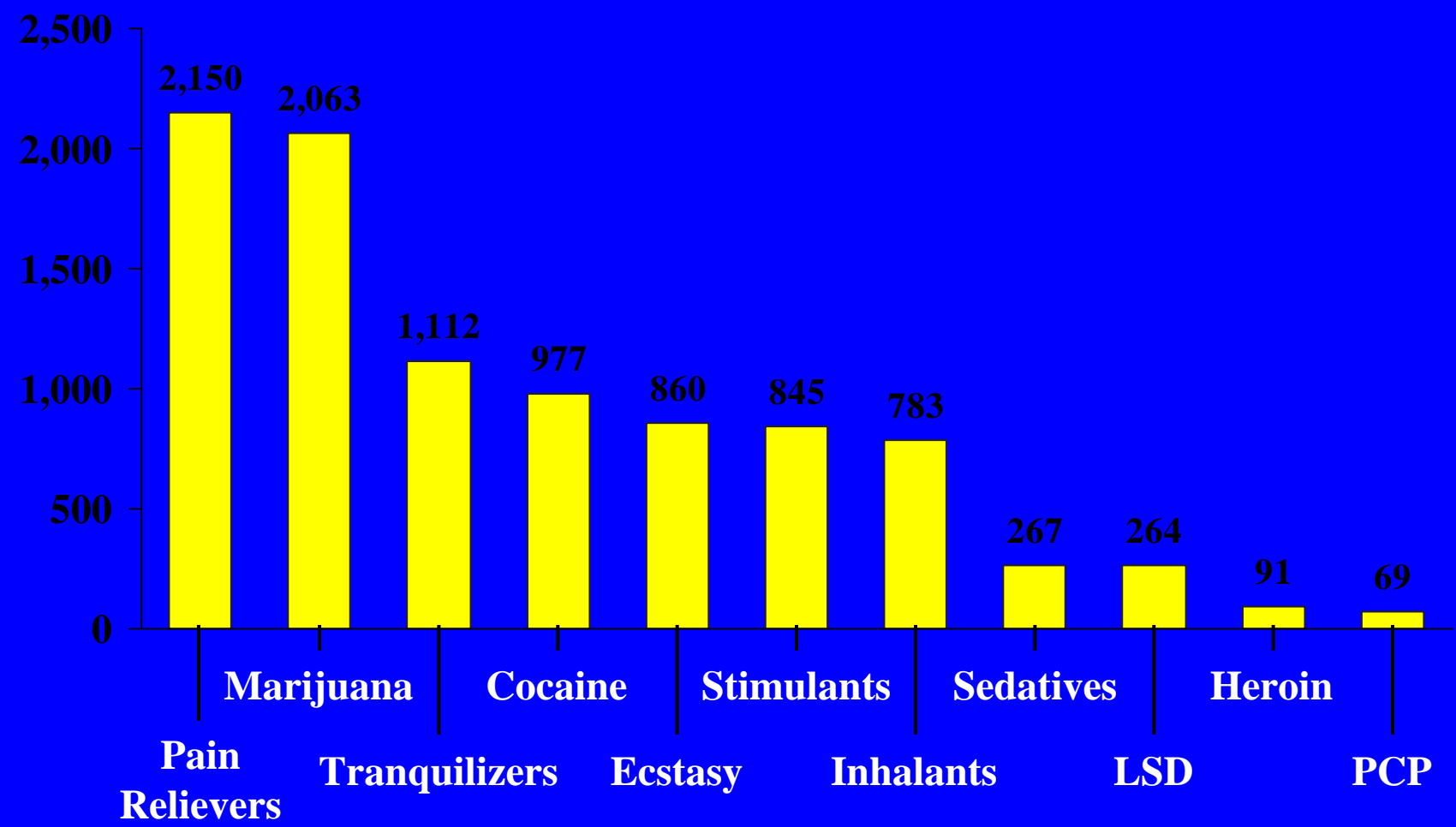


⁺ Difference between this estimate and the 2006 estimate is statistically significant at the .05 level.

Fig 5.1

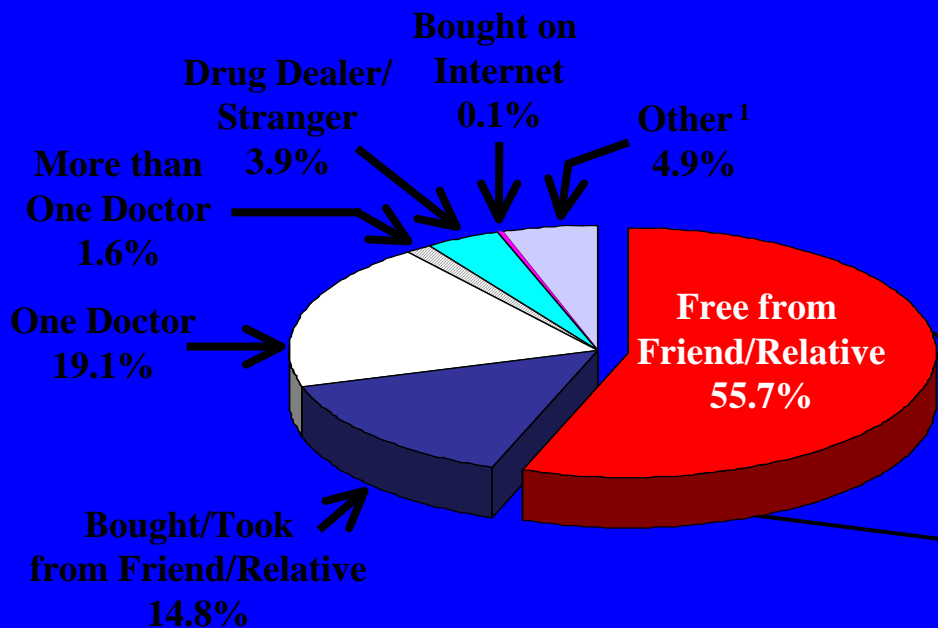
Past Year Initiates for Specific Illicit Drugs among Persons Aged 12 or Older: 2006

Numbers in Thousands

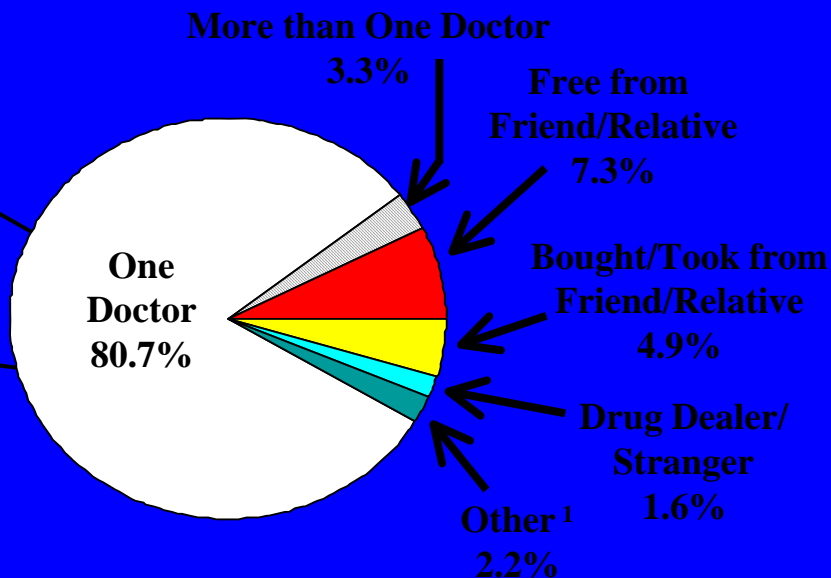


Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2006

Source Where Respondent Obtained



Source Where Friend/Relative Obtained



Note: Totals may not sum to 100% because of rounding or because suppressed estimates are not shown.

¹ The Other category includes the sources: "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

Smart Rx Disposal

- Using new technology that automatically selects the appropriate abuse prevention information sheet according to the prescription being purchased, a consumer will get one of three abuse prevention information sheets when they have their prescription for one of these drugs filled at a pharmacy participating in this program.

Smart Rx Disposal

- The abuse prevention information sheets address the following themes:
- Prescription drug abuse is a growing problem – particularly among young adults and teens,
- A high percentage of teens and young adults report that they can get ready access to someone else's prescription drugs from the family medicine cabinet,
- Prescription drugs should be stored in a safe, secure place and counted regularly to help ensure that they do not get into the hands of unauthorized users

Smart Rx Disposal

- Consumers should always check patient information accompanying the product to see if it contains specific directions for disposing of unused medication, and follow those directions.
- If no specific information is provided then unused medication should be properly disposed of by mixing it with undesirable substances (e.g., old coffee grounds, used kitty litter), sealing the mixture in a container and placing it in the trash.
- Whenever possible, unused medication may also be donated to authorized community prescription drug take-back programs.

Smart Rx Disposal

- This effort is a 26-week pilot project involving among 6,300 pharmacies throughout the country.
- The agency will measure the program's effectiveness by monitoring web-based feedback from the public and determining how widely and effectively the program has reached out to consumers with these abuse prevention messages.
- Based on these assessments, SAMHSA will determine whether to terminate, continue, modify and/or expand this effort.

Smart Rx Disposal

Results of the Prescription Drug Abuse Substance Abuse Prevention Safety Information Pilot Program

<u>Target Drug</u>	<u>Total Prints</u>	<u>Unique Patients</u>
Benzodiazepines	1,214,089	849,322
Oxycontin	173,470	89,586
Select Hydrocodones	2,980,504	1,928,776
Sleep Aids	958,144	594,209

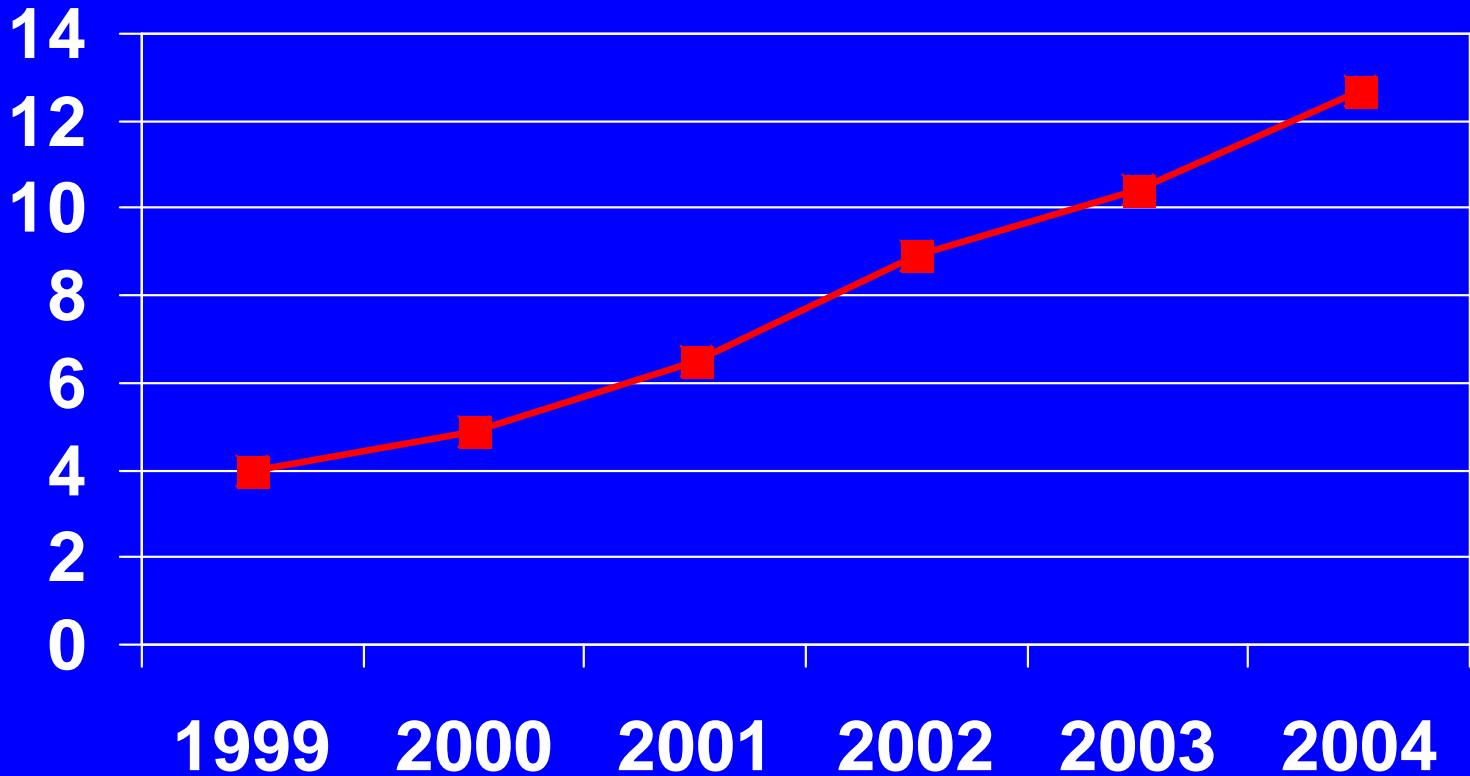
Prescription Drug Diversion of Particular Interest To CSAT

- Methadone –
 - 760,000 opioid analgesic pain treatment
 - 257,000 dependence/addiction treatment
- Buprenorphine
 - 15,000 opioid analgesic pain treatment
 - 305,000 dependence/addiction treatment

Methadone Related Deaths (% all Poisoning Deaths)

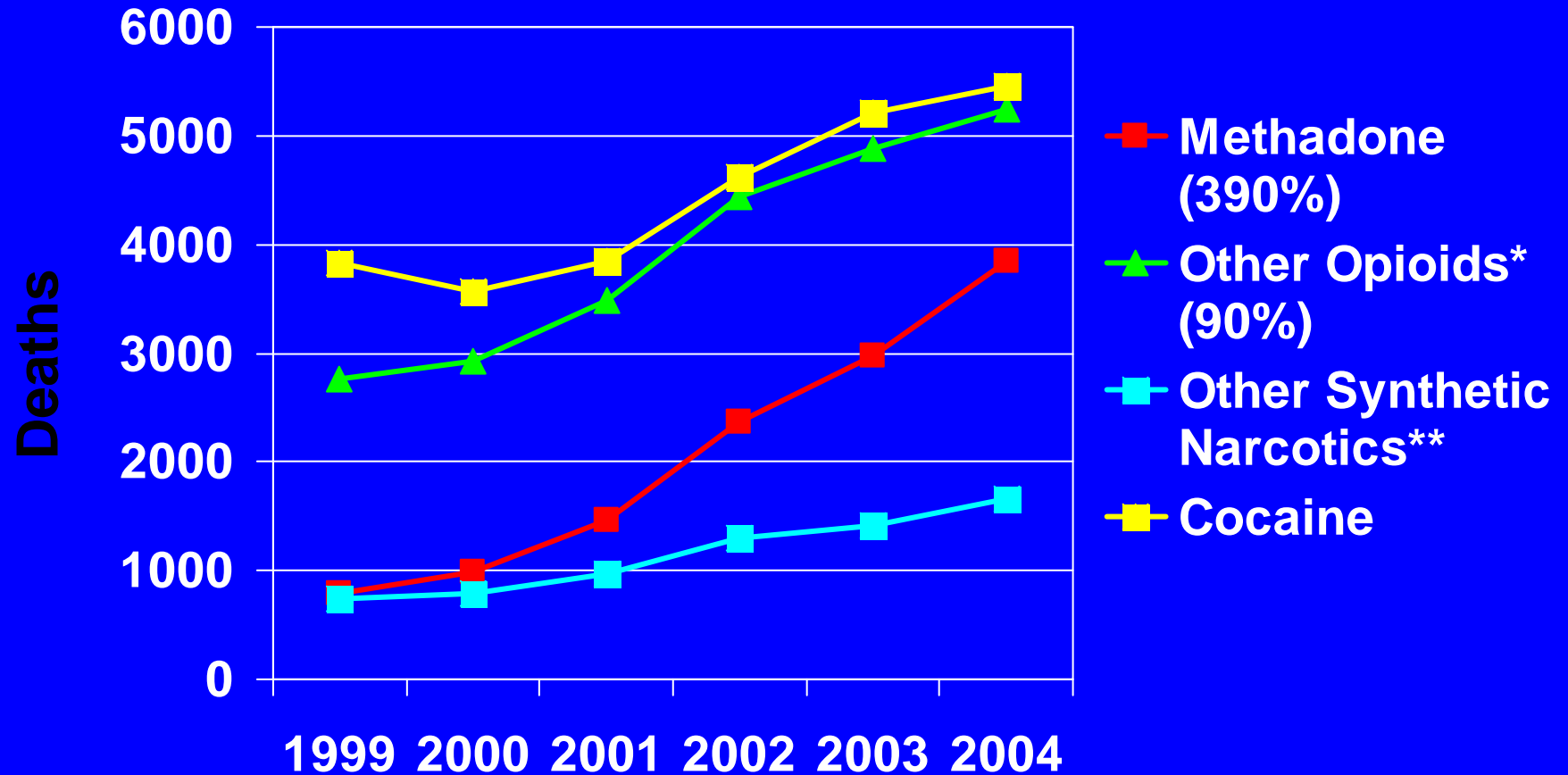
Source: CDC

Methadone related deaths
(% of all poisoning deaths)



Poisoning Deaths in the U.S.

Source: CDC

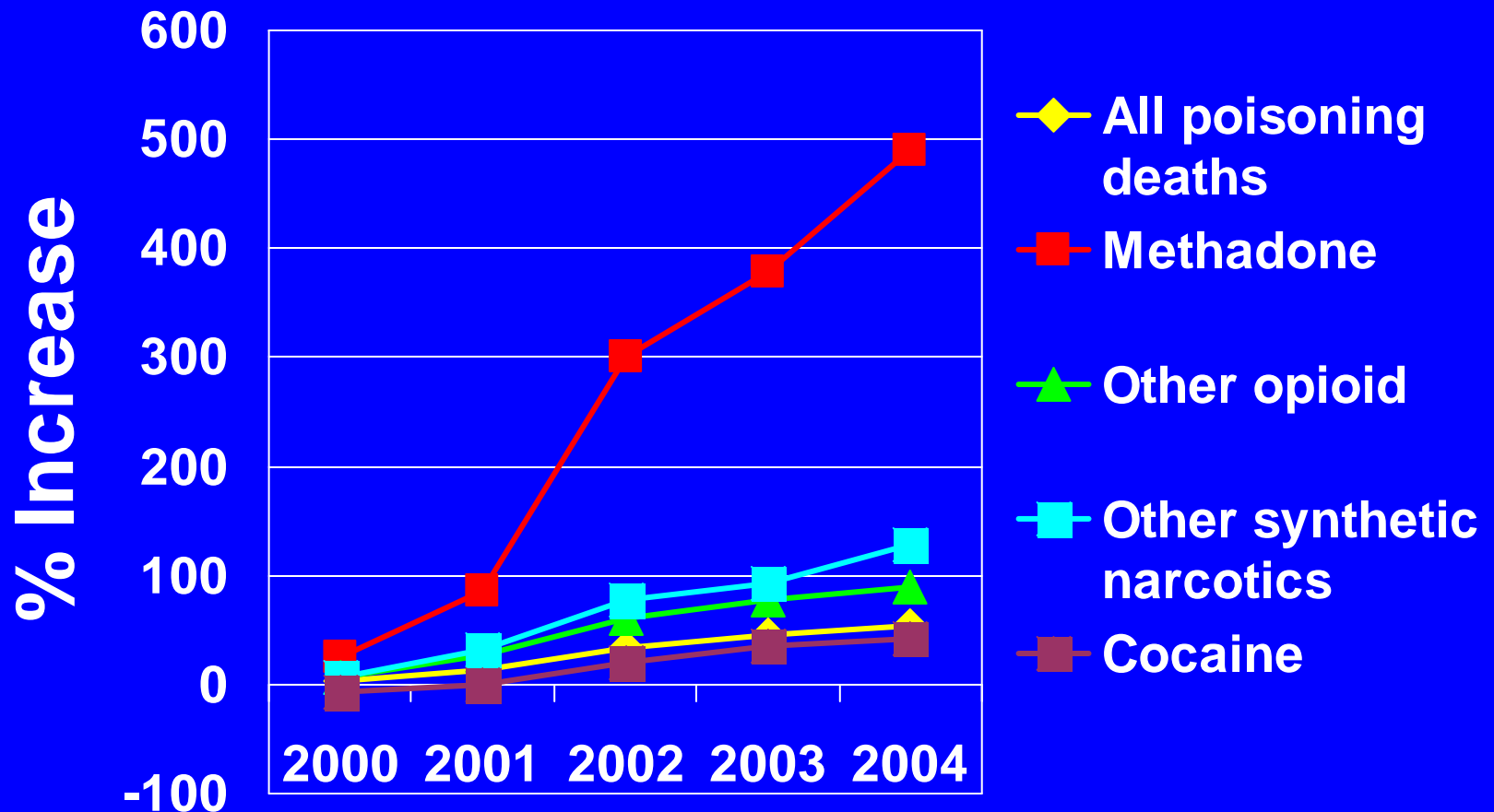


*Other Opioids include drugs like morphine, oxycodone, hydrocodone, hydromorphone

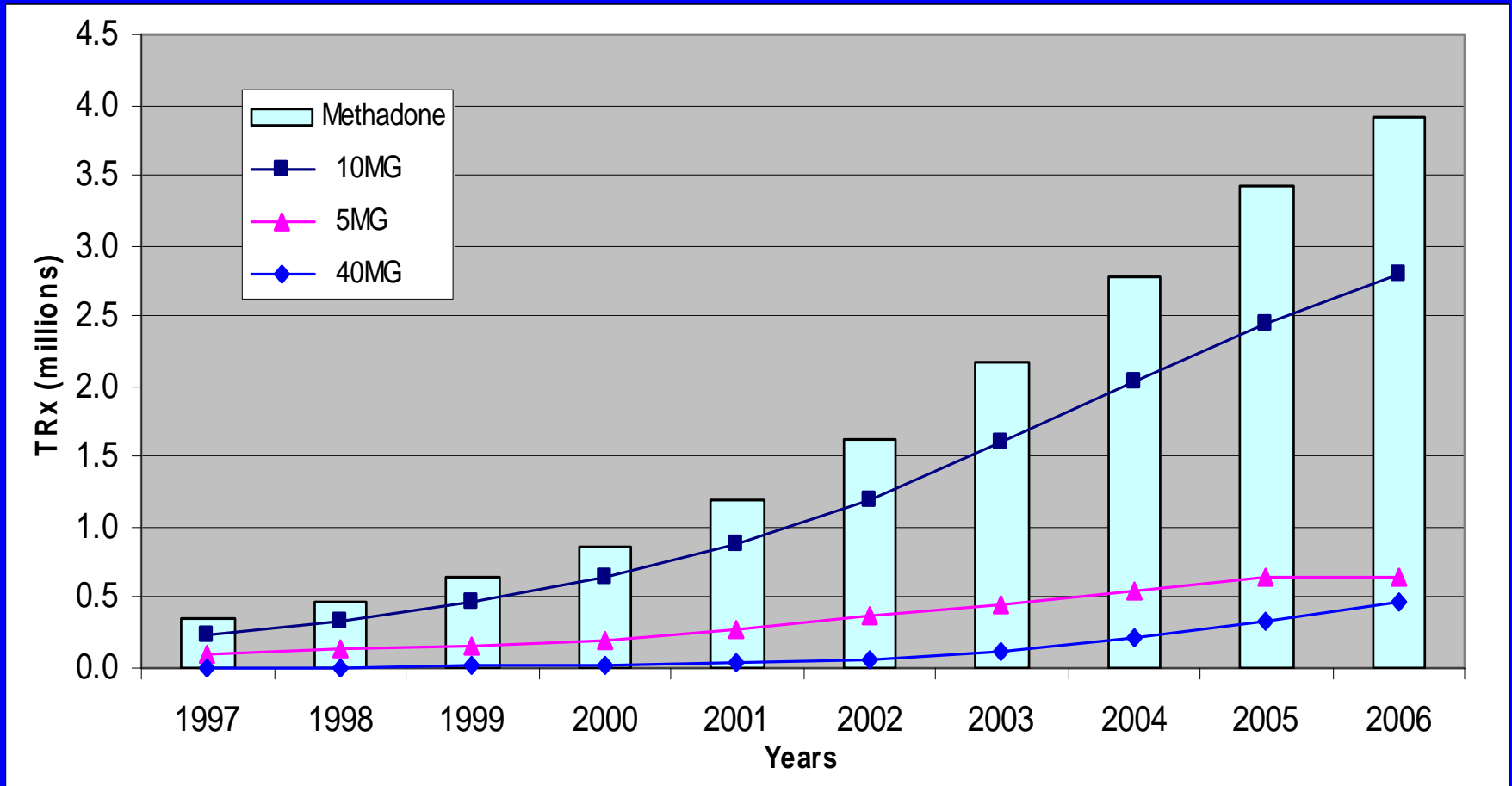
**Other Synthetic Narcotics include drugs like propoxyphene, fentanyl, meperidine

% Increase in Unintentional Poisoning Deaths in the U.S.

Source: CDC



Prescription data: Total prescriptions dispensed in U.S. outpatient retail pharmacies for methadone by strength, Years 1997 – 2006, Verispan, VONA



Verispan, VONA, Years 1997 - 2006, Extracted July 2007.

Risk Management for Methadone

- Pain Treatment – no required Risk management plan
 - FDA – modified labeling, 2006
 - DEA – voluntary restriction on distribution – 2008
- Addiction/Dependence Treatment
 - Distribution limited to certified, accredited, registered programs
 - Initial dose limit
 - Restrictions on dispensing

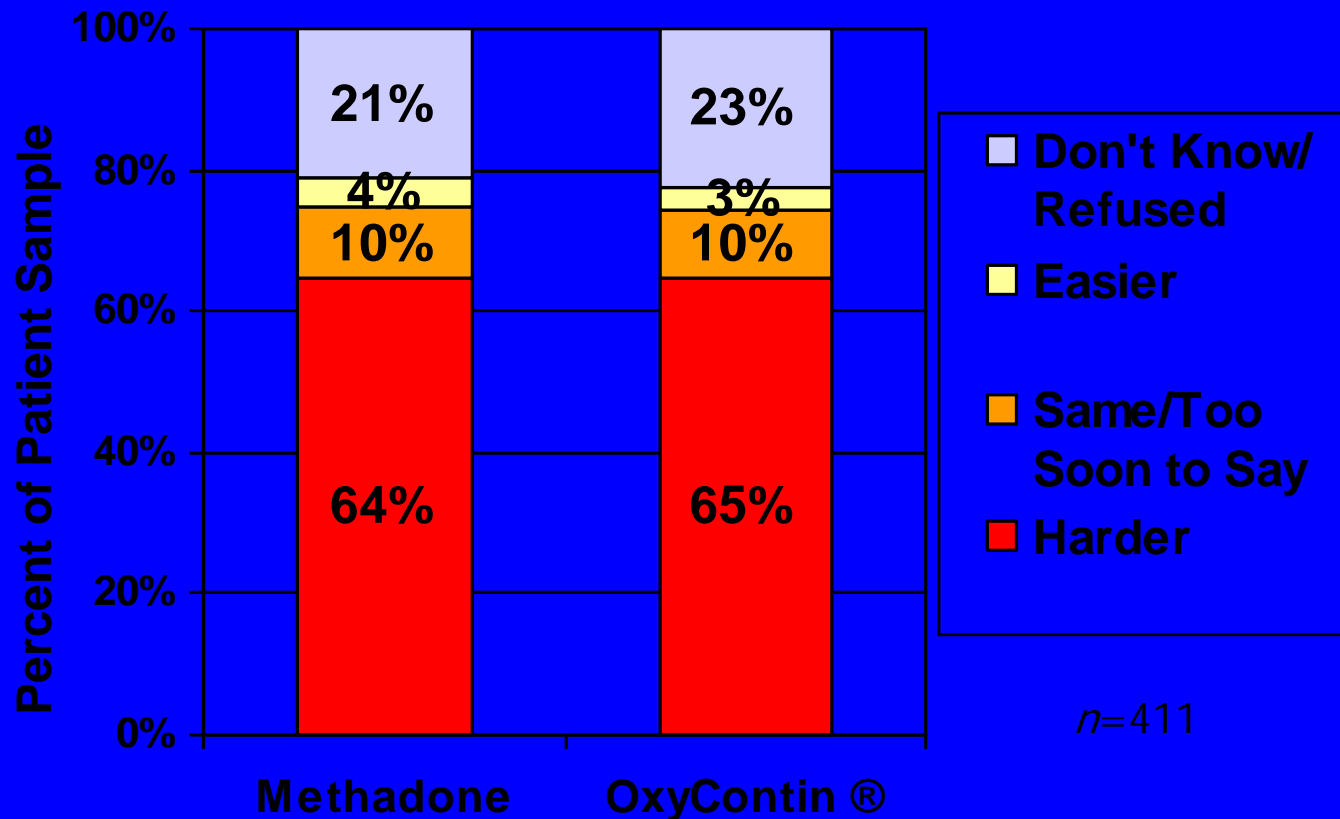
Buprenorphine Diversion Risk Management

- Legislation
 - restricted distribution to “certified” (trained or credentialed).
 - Limited number of patients
 - CSAT Evaluation
 - Increase capacity
 - Effective treatment
 - Adverse consequences to public health
- FDA/Manufacturer
 - Formulation – Suboxone/naloxone
 - Risk management program

Buprenorphine Patient Reports of Diversion, 2005

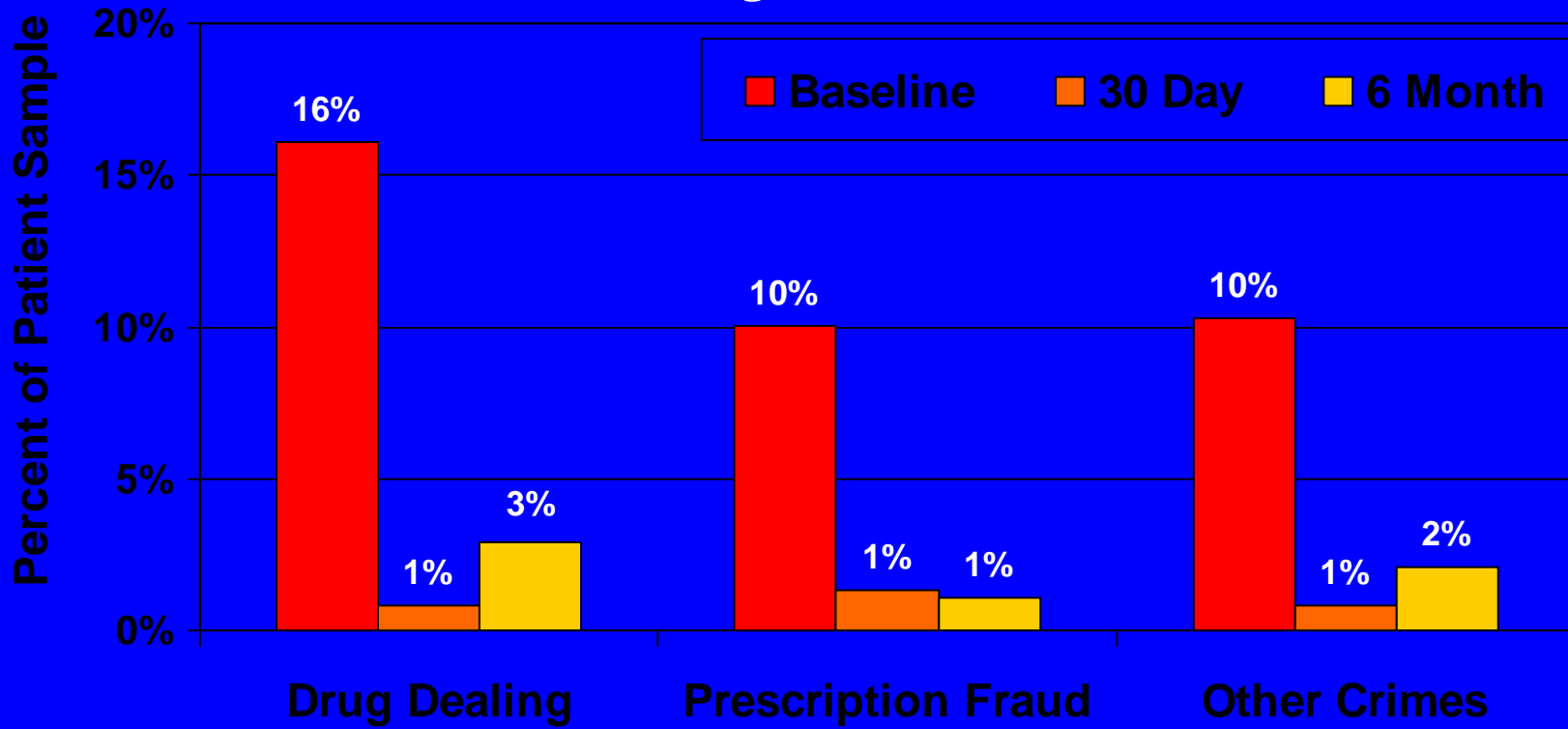
“Compared to OxyContin® or methadone, how easy or hard do you think it is to buy or sell BUP on the street?”

Responses were similar at baseline and 6 month followup.



Buprenorphine Patient Outcomes: Specific Criminal Activities

“In the past 30 days were you involved in any of the following activities...?”



n=379

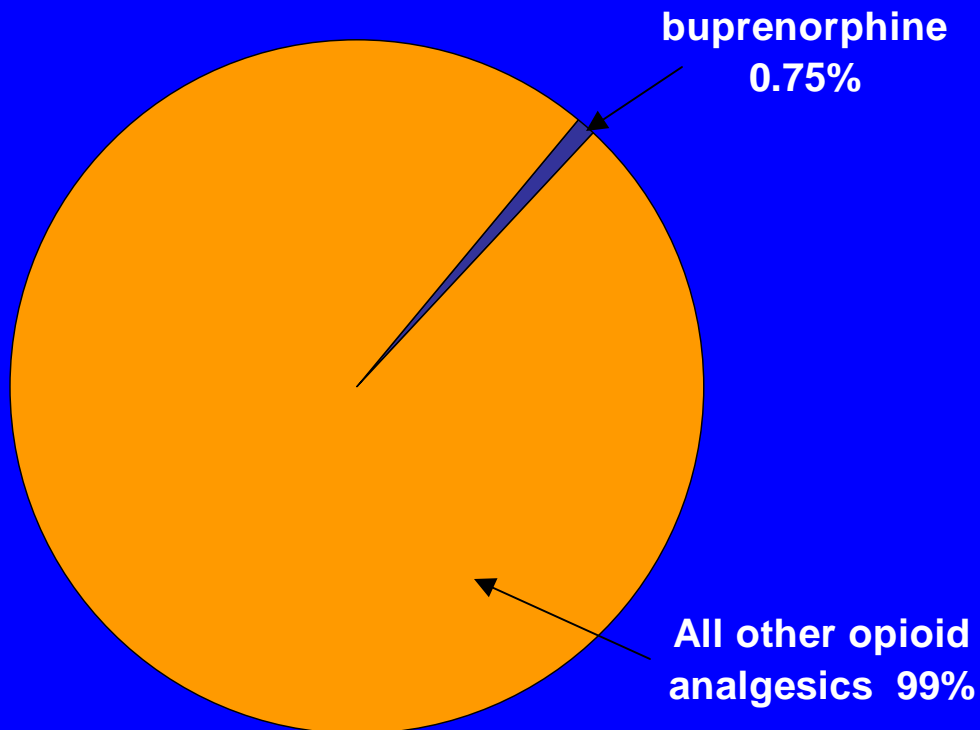
Buprenorphine Risk Management

- Physician Surveys
- Patients reporting to SA Treatment centers
- Internet Newsgroups
- Poison Control
- DAWN
- Ethnographic studies

Emergency Department Visits - 2006

- In 2006, of 346,946 reported Emergency Department visits, 47,538 involved opioid analgesics – only 356 of which involved buprenorphine or a combination of buprenorphine and other medications.
- Of those involving buprenorphine:
 - 52 were due to adverse reactions
 - 63 were seeking detox
 - 225 were due to nonmedical use
 - 11 were due to accidental ingestion

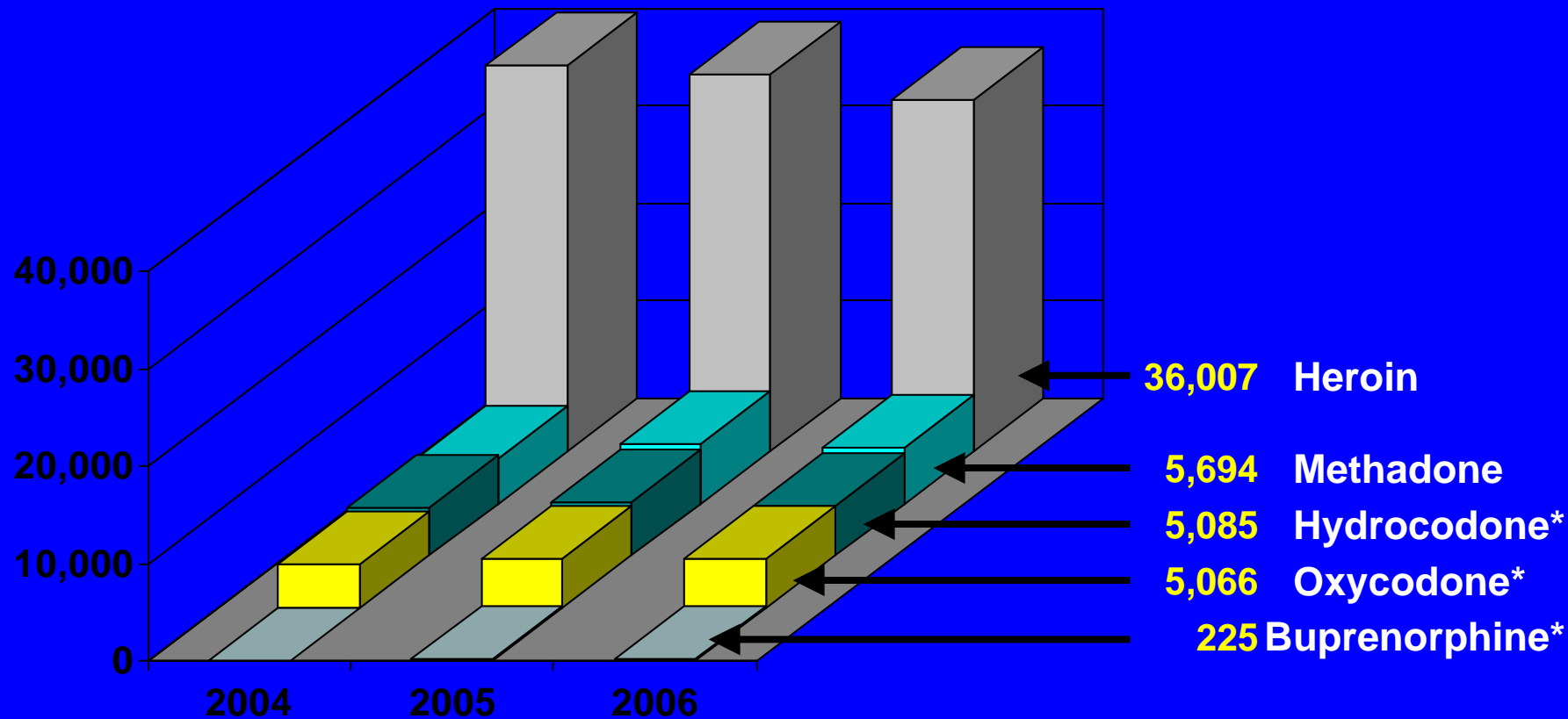
Opioid Analgesics in Drug-related ED Visits 2006



Of the 47,538 opioid analgesics reported in drug-related ED visits, 358 were buprenorphine (all case types)

*Includes single and multi-ingredient product

Opiate Reports in Emergency Department Visits Related to Drug Misuse/Abuse



Unweighted reports from
243-445 U.S. hospitals

* Includes single- and multi-
ingredient products

Surveillance Report Conducted by CRS Associates LLC

- Monitoring of discussions within Internet newsgroups and interviews found that the buprenorphine products are viewed primarily as medications to avoid or ease withdrawal symptoms rather than means of getting high.
- There is evidence that there is experimental use and illegal diversion of buprenorphine...However, the extent of abuse and diversion does not come close to approaching that of methadone or OxyContin.
- Intravenous drug use of either Suboxone or Subutex appears to be rare, but it is evident from street interviews.

Surveillance Report Conducted by CRS Associates LLC - 2

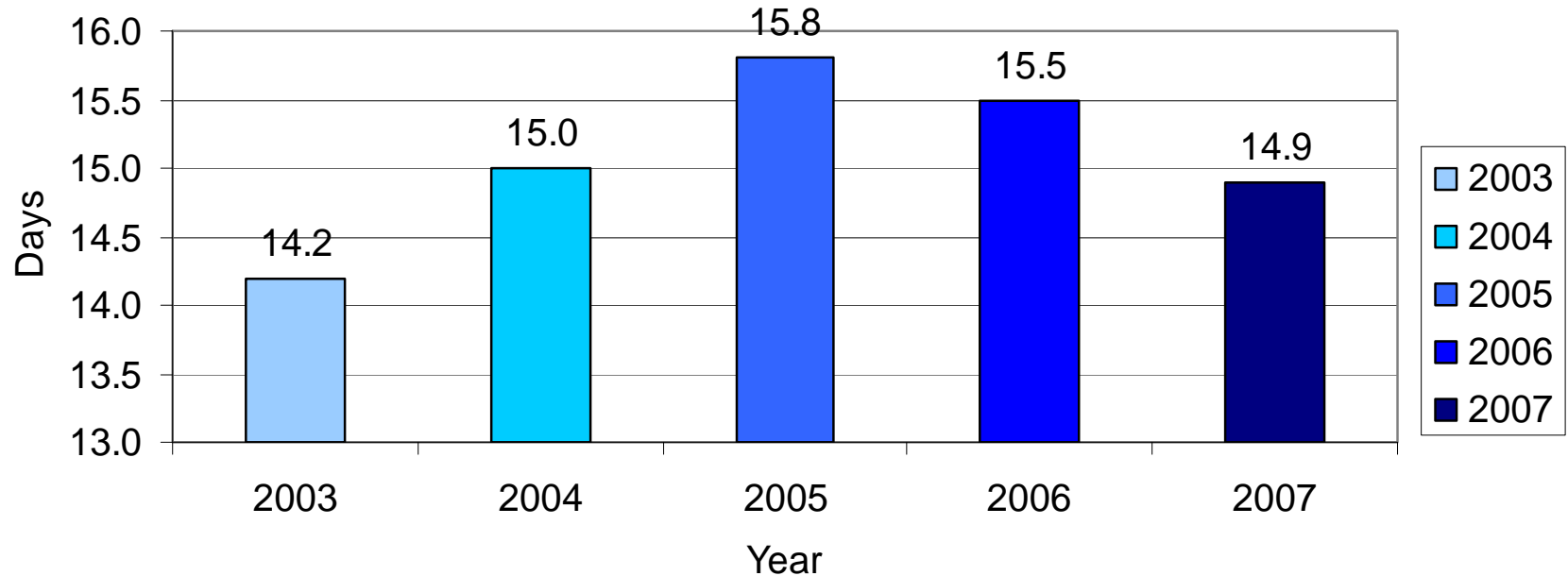
- Poison Control – 2006-2007, Suboxone implicated in 6 deaths, two suicides
- More than a quarter of 1,876 buprenorphine exposures involved children under 6 years of age from Jan. 1, 2006, to Sept. 30, 2007.
- Buprenorphine exposure rate in children was higher than the rates for methadone and oxycodone
- The children who ingested buprenorphine, whose names and locations were not stated, all recovered.

Surveillance Report Conducted by CRS Associates LLC - 3

- A major source of illegal Suboxone, according to 17 percent of doctors surveyed, was **"lax or inappropriate" prescribing of the drug by their peers.** More than half the doctors questioned in New England, where Suboxone is most widely available as an addiction treatment, said they believed it was just as easy to buy illegally as methadone and other widely abused narcotics.

Mean Days Therapy for a Retail Prescription Dispensed for Buprenorphine, 2003-2007

Verispan Vector One® : National, 2003 -2007, data extracted 3-5-2008

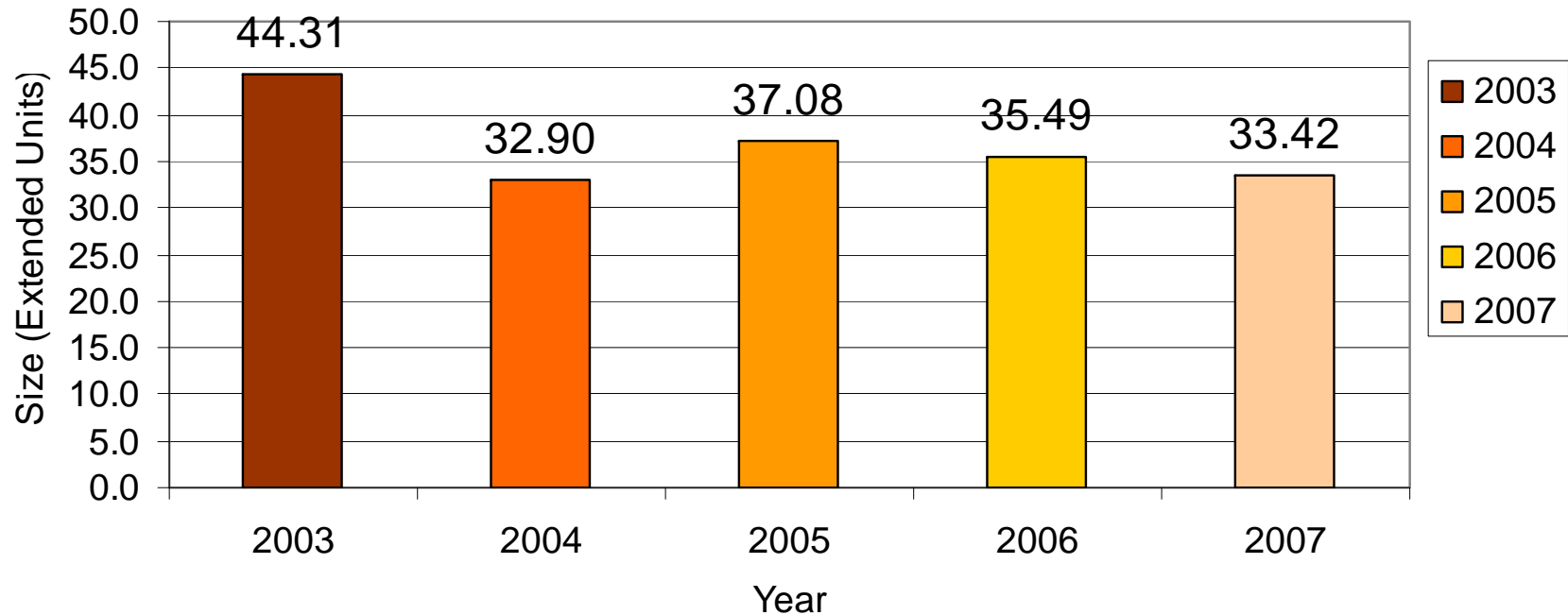


Mean Days Therapy: The average number of days of therapy dispensed to patients. The calculation is therapy days divided by prescriptions.

Source File: VONA 2007-1925 Reuter buprenorphine therapy 3-5-08.xls

Average Size of a Retail Prescription Dispensed for Buprenorphine, 2003-2007

Verispan Vector One® : National, 2003 -2007, data extracted 3-5-2008



Average Size: An average number of extended units dispensed per prescription. The calculation is extended units divided by prescriptions.

Source File: VONA 2007-1925 Reuter buprenorphine therapy 3-5-08.xls

Projected Occurrences, stratified by Prescribed Days of Therapy, for Buprenorphine During Patient Visits in Office-Based Practices in the U.S., 2003-2007.

	2003-2007	
	Occurrences N (000)	Share %
Therapy Days Total	1,592	100.0%
0-15 Days	275	17.3%
16-30 Days	615	38.6%
31-45 Days	12	0.7%
46-60 Days	6	0.4%
61-90 Days	27	1.7%
UNSPEC.	658	41.4%

Verispan, Physician Drug and Diagnosis Audit (PDDA), Data extracted 3-2008. Source File: PDDA 2007-1925 3-12-08 Reuter buprenorphine.xls

CSAT Programs & Initiatives to Combat Diversion

Additional and Expanded Training Materials

- Materials have been developed – many through the NIDA-SAMHSA “Blending Initiative.”
- The initiative is a unique partnership that uses the expertise of both agencies to quickly apply research results to practical use in improving the treatment of substance use disorders.
- Web site: www.nida.nih.gov/blending

CSAT Programs & Initiatives to Combat Diversion

The Physician Clinical Support System (PCSS) for Buprenorphine

- Created in collaboration with the American Society of Addiction Medicine (ASAM).
- The PCSS is a free, national service staffed by 45 trained physician mentors, a PCSS medical director and 5 physicians, who are national experts in the use of buprenorphine.
- Physicians who prescribe or dispense buprenorphine can contact the PCSS for support is via telephone, email, and/or at the place of clinical practice.
- Web site: www.PCSSmentor.org

Summary

- Prescription opioids significant public health problem
- Increased effort to identify those at risk
- Increase efforts to identify source
- Prescriber education/training
- Effective treatment interventions available.

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