

NASPER & Survey Results from NSDUH

Harold Rogers Prescription Drug Monitoring Program

September 25, 2009

Washington, DC



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Division of Pharmacologic Therapy
Center for Substance Abuse Treatment
Substance Abuse and Mental Health
Services Administration



Overview

- Prescription Drug Abuse- nature and extent of problem
- NASPER Implementation
- NASPER Changes?



Is prescription drug abuse a problem?

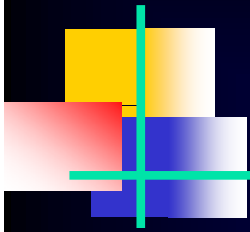
- National Survey on Drug Use and Health – NSDUH, formerly national household survey.
- Drug Abuse Warning Network – DAWN
 - Emergency Department
 - Medical Examiner
- Monitoring the Future

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NSDUH Design

- Representative nationally and in each State
- Civilian, noninstitutional population, age 12+
- Face-to-face interview
- Computer-assisted, self-administered
- 67,870 respondents in 2007
- 2007 data are comparable with 2002-2006, but not with data prior to 2002

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Illicit Drug Use

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2008 NSDUH Highlights

- New National Survey Reveals Significant Decline in the Misuse of Prescription Drugs + Sharp decline also continues for methamphetamine use
- The 2008 survey showed that the overall level of current illicit drug use has remained level at about 8 percent. (**22 million**)
- The misuse of prescription drugs decreased significantly between 2007 and 2008 among those aged 12 and older, including among adolescents,
- Progress has been made in curbing other types of the illicit drug use. For example, past month methamphetamine use among those aged 12 and older dropped sharply from approximately 529,000 people in 2007 to 314,000 in 2008. Similarly, the level of current cocaine use among the population aged 12 and older has decreased from 1.0 percent in 2006 to 0.7 percent in 2008.

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NSDUH 2008 -2

- Promising results from the latest survey also were also found for the most part among youth (**12 to 17 year olds**).
- a significant decline in overall past month illicit drug use, from 11.6 percent in 2002 to 9.3 percent in 2008. Although the rate of current marijuana use among youth has remained level at about 6.7 percent over the past few years there have been significant decreases in the current use of alcohol, cigarettes **and non-medical use of prescription drugs since 2007**. Non-medical use of prescription drugs dropped from 3.3 percent in 2007 to 2.9 percent in 2008.
- Historically, young adults have had the highest rates of substance abuse, and for most types of illicit substance abuse the levels have remained steady over the past year. However, over the past three years there has been a steady drop in the rate of heavy alcohol use by full time college students aged 18 to 22 – from a high of 19.5 percent in 2005 to 16.3 percent in 2008

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NSDUH 2008

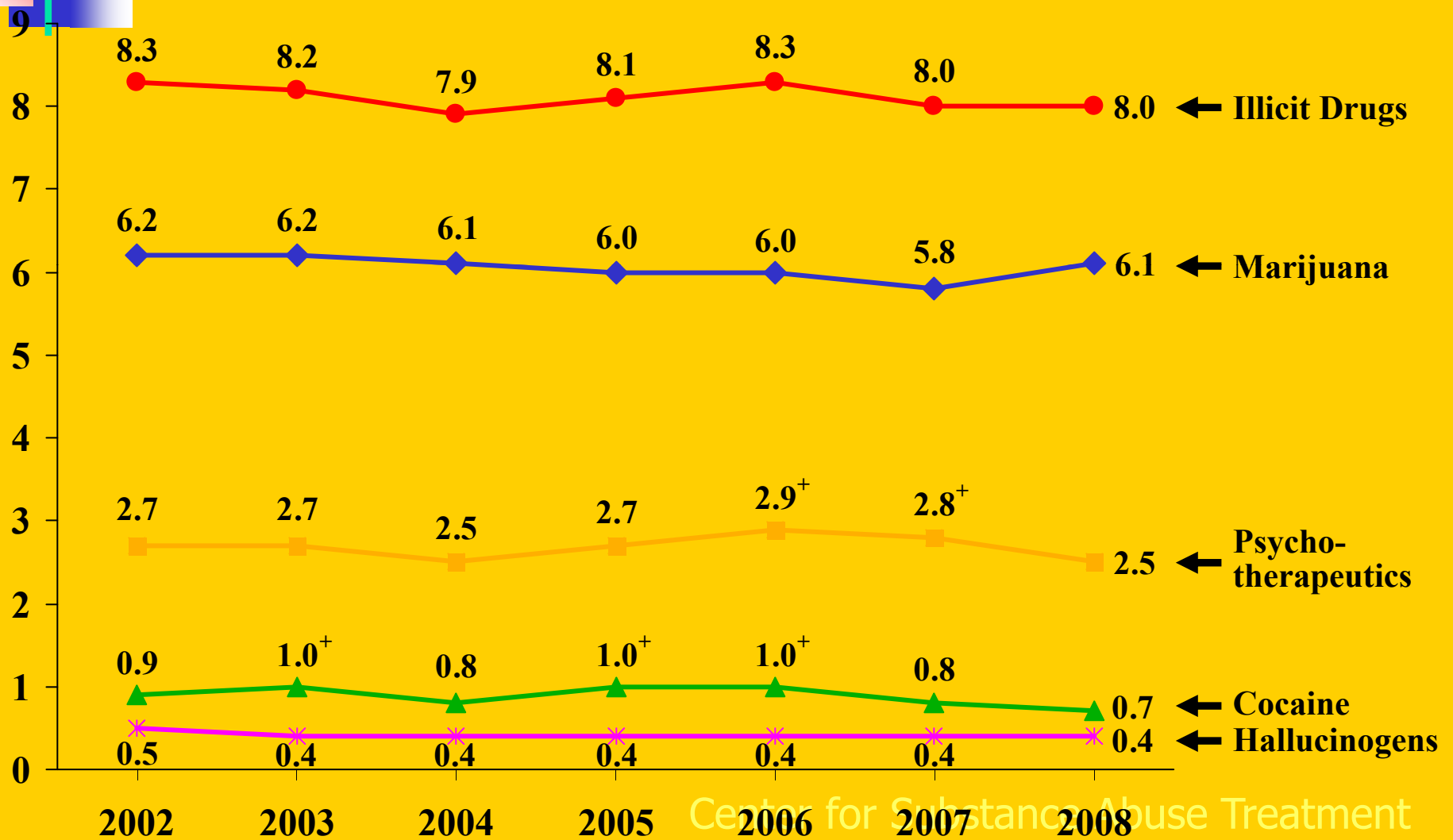
- Despite many positive trends, the most recent NSDUH survey also reveals continuing problems and setbacks. **For example there were significant increases in the rates of Ecstasy and LSD use among youth over past few years.** The level of past year Ecstasy use in 2008 for youth was 1.4 percent – lower than the 2.2 percent in 2002, but higher than the lowest level of 1.0 percent reported in 2005. Likewise, the 2008 level of past year LSD among youth of 0.7 percent, while lower than the 2002 level of 1.3 percent in 2002, is significantly higher than the lowest use rate of 0.4 percent reported in 2006.
- Treatment – 2008 NSDUH also continues to show a vast disparity between the number of number of people needing specialized treatment for a substance abuse problem and the number who actually receive it. According to the survey **23.1 million Americans need specialized treatment** for a substance abuse problem, but only 2.3 million (or roughly 10 percent of them) get it.

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Fig 2.2

Past Month Use of Selected Illicit Drugs among Persons aged 12 or Older: 2002-2008

Percent Using in Past Month

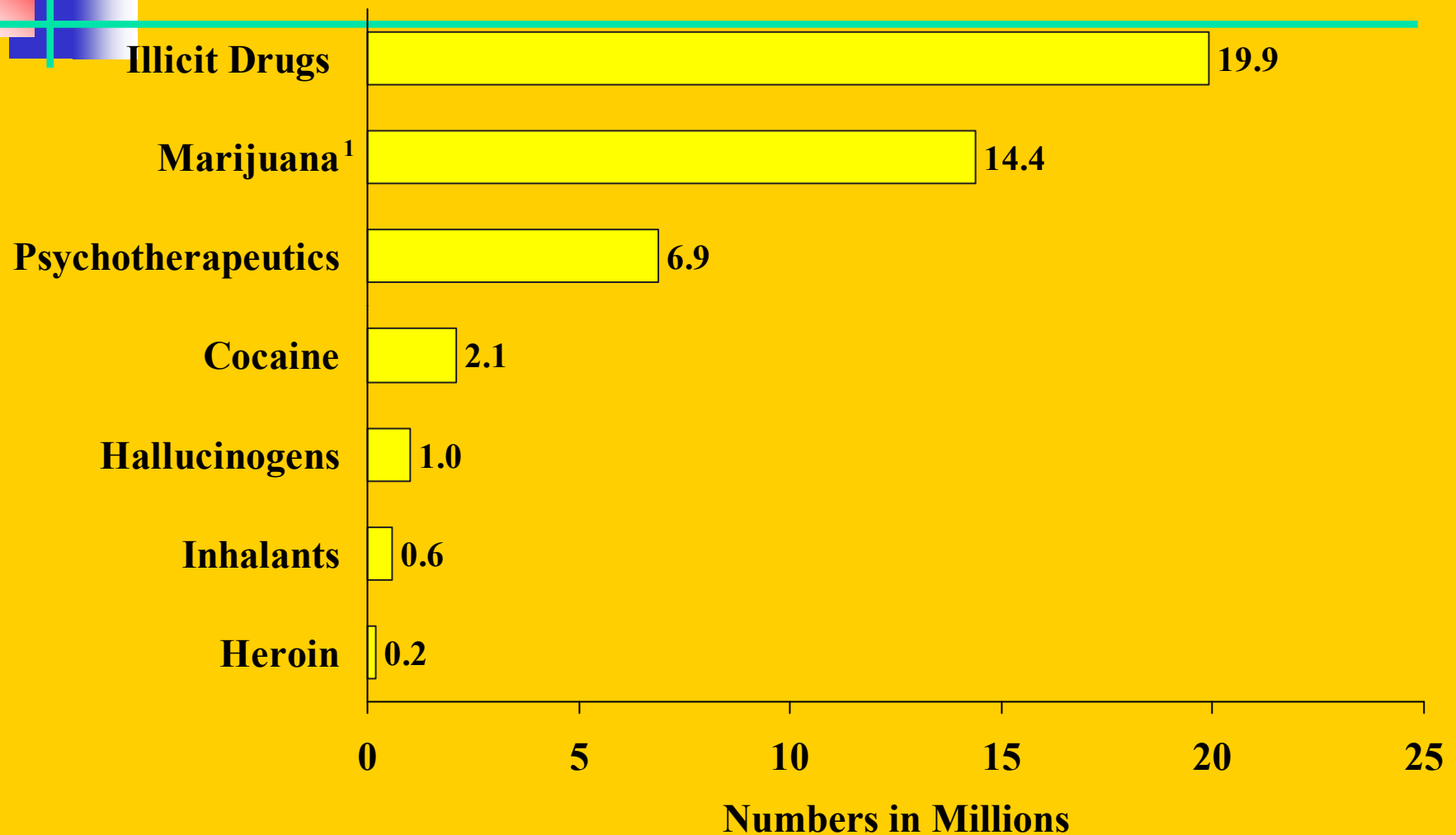


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⁺ Difference between this estimate and the 2008 estimate is statistically significant at the .05 level.

Fig
2.1

Past Month Illicit Drug Use among Persons Aged 12 or Older: 2007

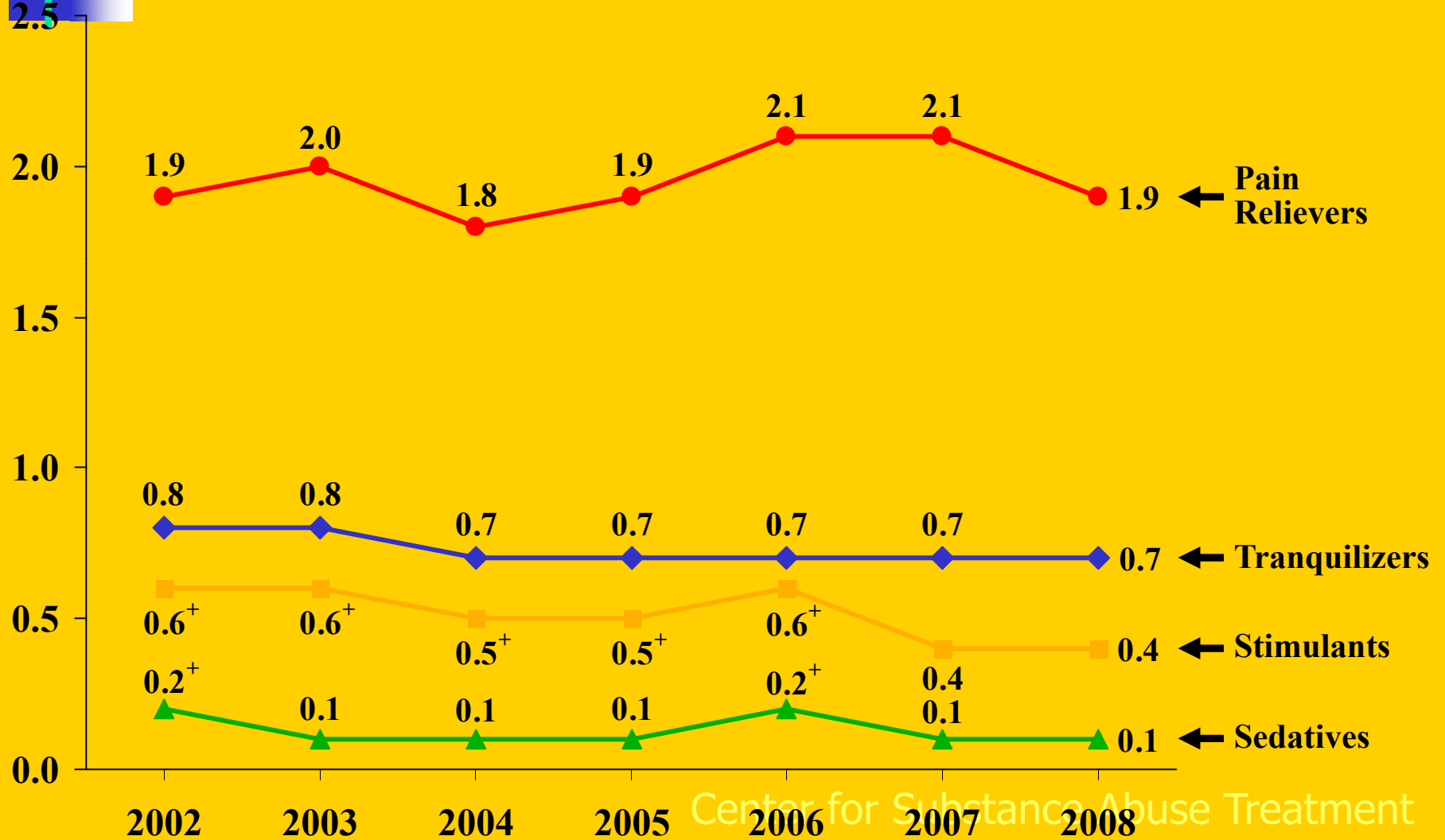


¹ Illicit Drugs include marijuana/hashish, cocaine (including crack), heroin, hallucinogens, inhalants, or prescription-type psychotherapeutics used nonmedically.

Fig 2.3

Past Month Nonmedical Use of Types of Psychotherapeutic Drugs among Persons Aged 12 or Older: 2002-2008

Percent Using in Past Month



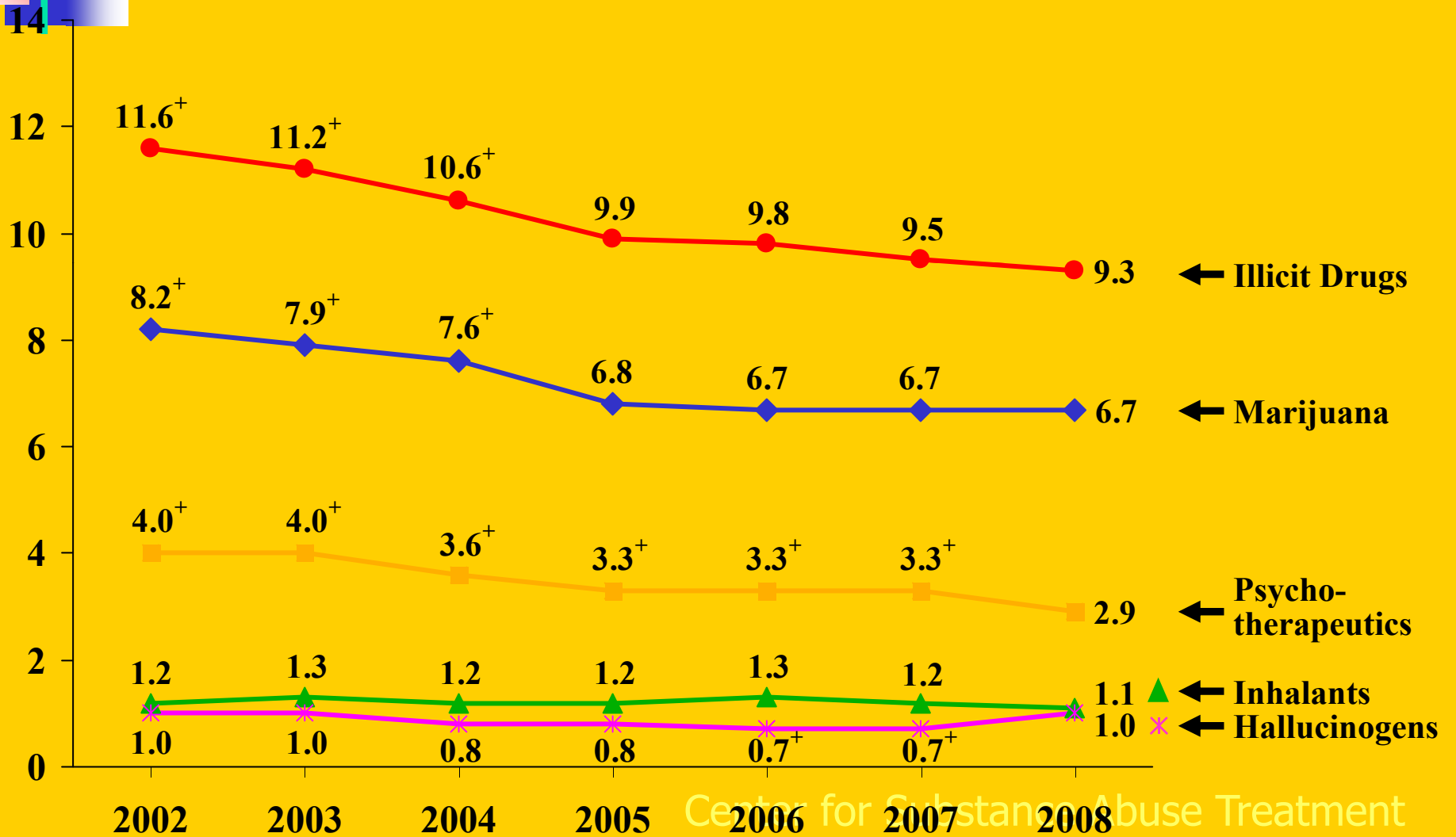
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⁺ Difference between this estimate and the 2008 estimate is statistically significant at the .05 level.

Fig 2.5

Past Month Use of Selected Illicit Drugs among Youths Aged 12 to 17: 2002-2008

Percent Using in Past Month



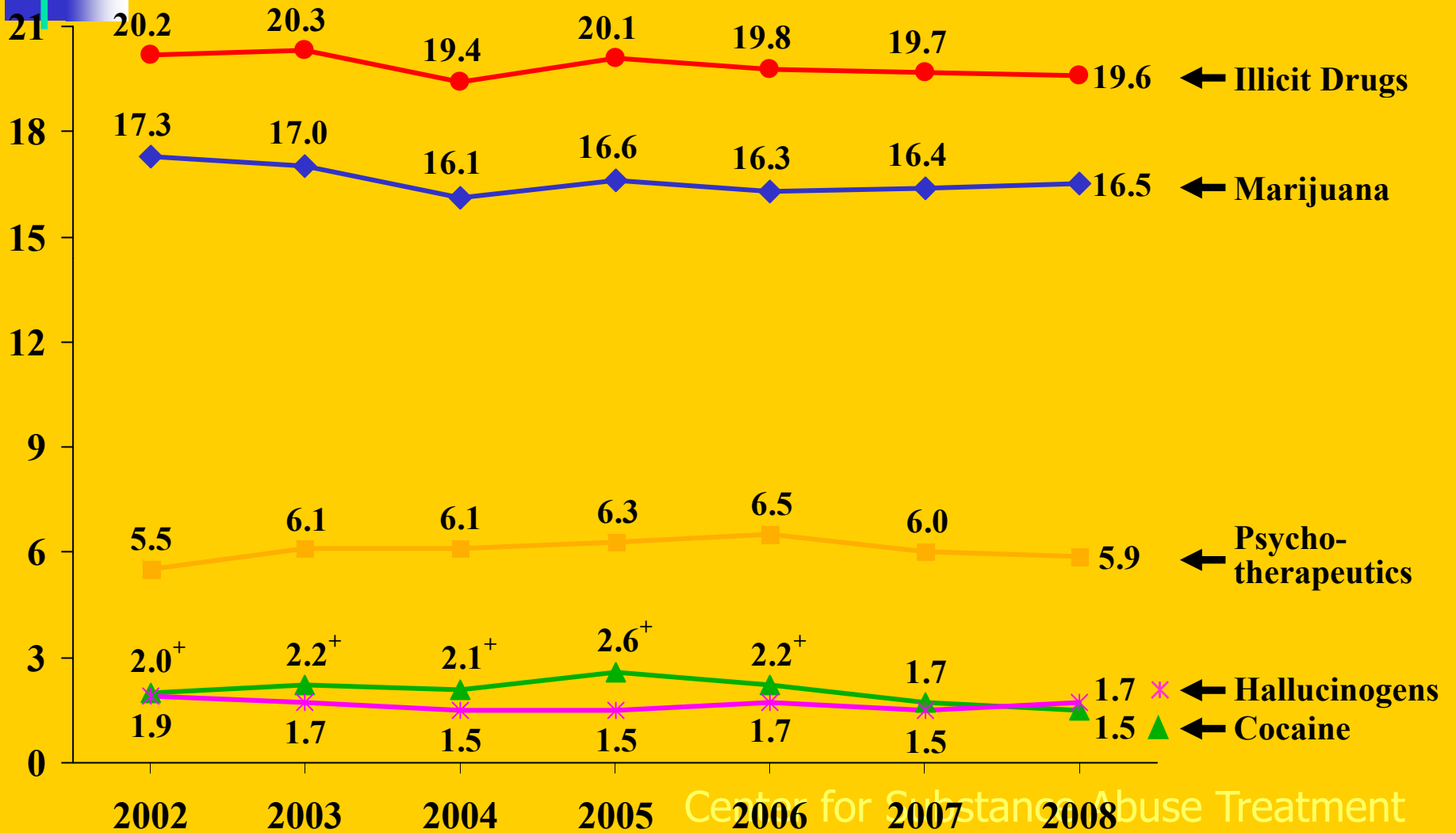
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⁺ Difference between this estimate and the 2008 estimate is statistically significant at the .05 level.

Fig 2.6

Past Month Use of Selected Illicit Drugs among Young Adults Aged 18 to 25: 2002-2008

Percent Using in Past Month

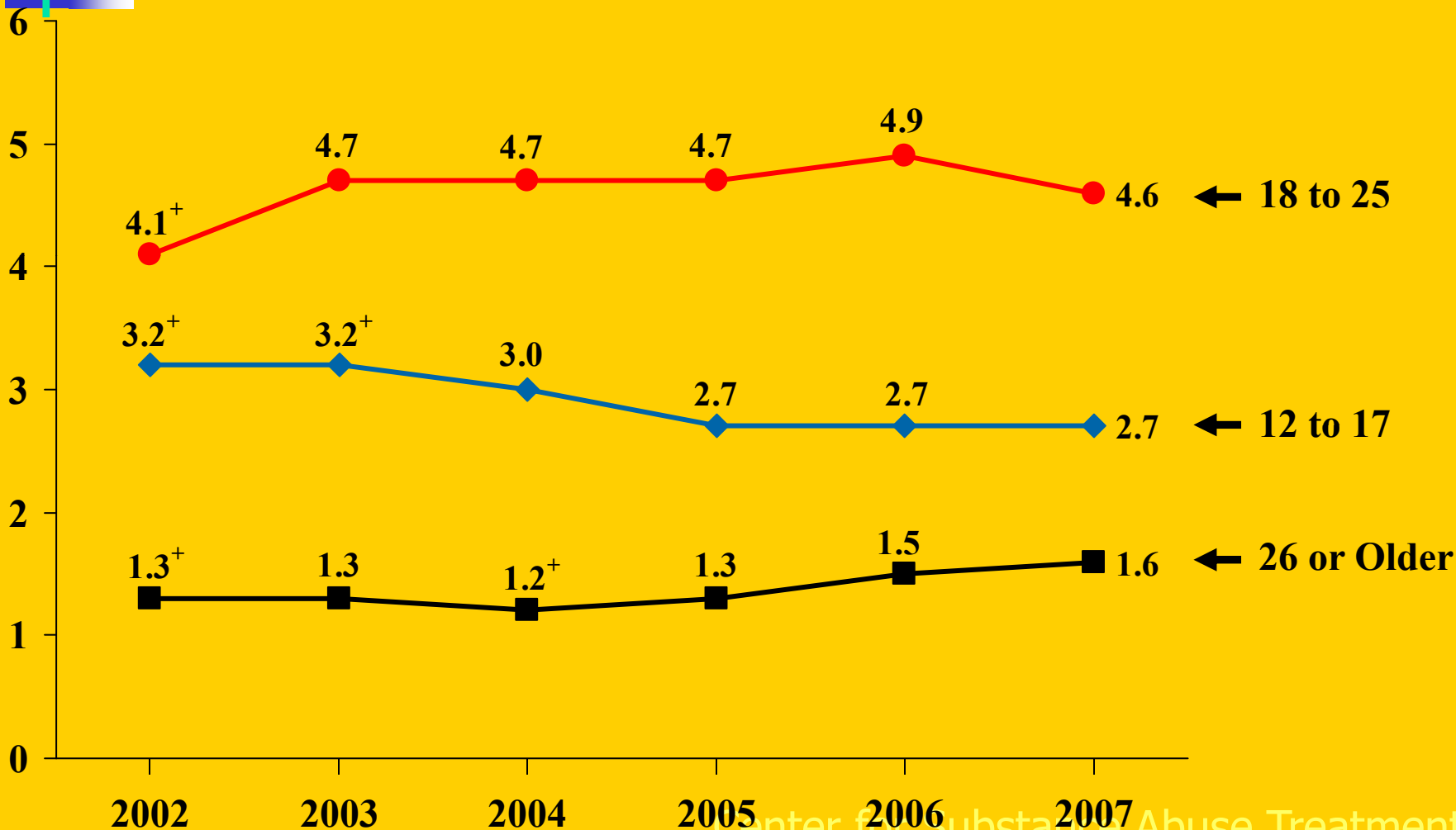


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⁺ Difference between this estimate and the 2008 estimate is statistically significant at the .05 level.

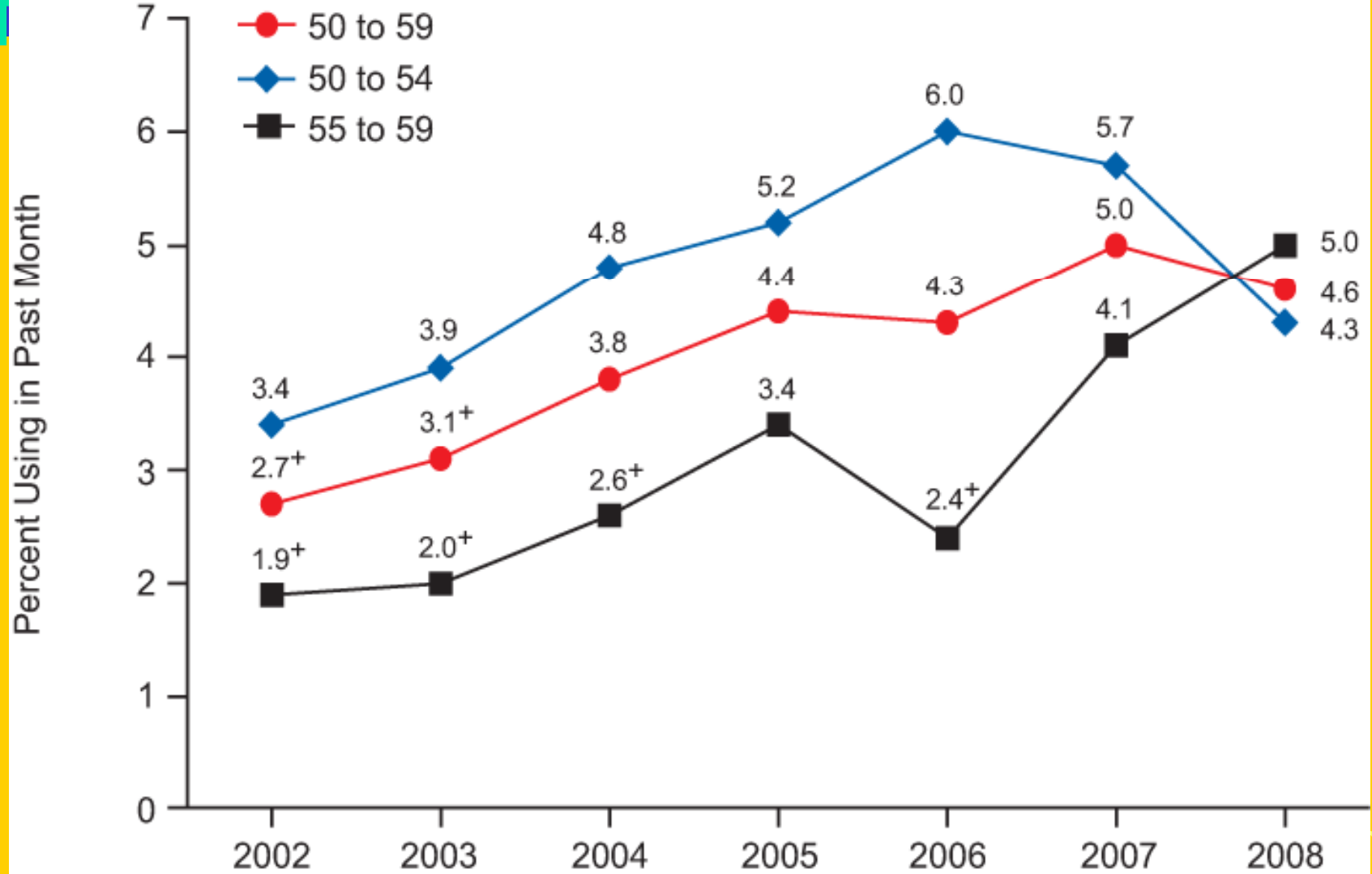
Past Month Nonmedical Use of Pain Relievers among Persons Aged 12 or Older, by Age: 2002-2007

Percent Using in Past Month



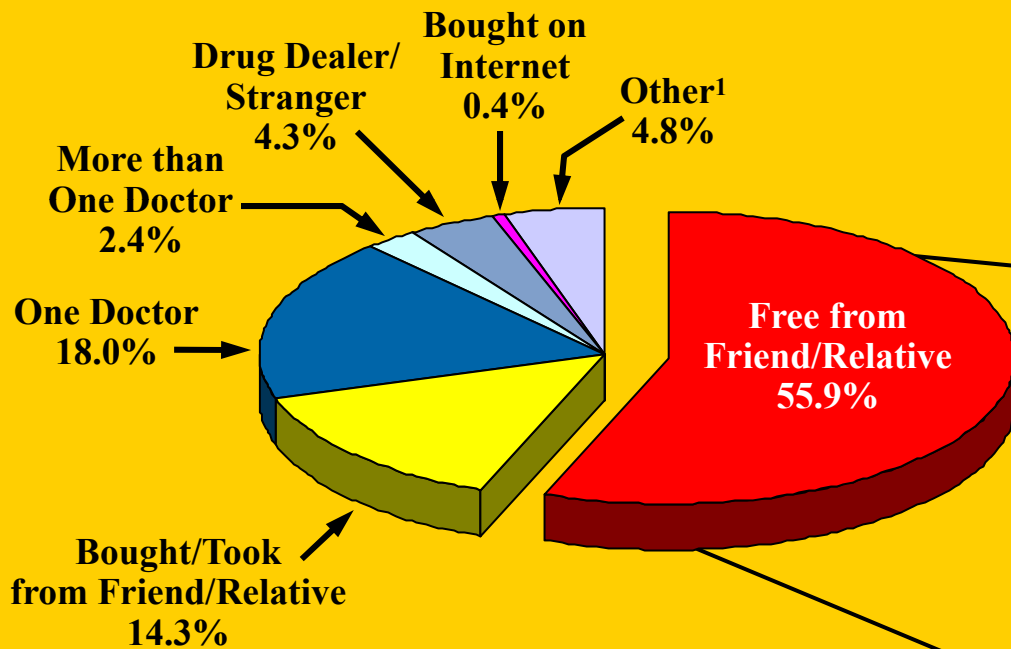
⁺ Difference between this estimate and the 2007 estimate is statistically significant at the .05 level.

Figure 2.7 Past Month Illicit Drug Use among Adults Aged 50 to 59: 2002-2008

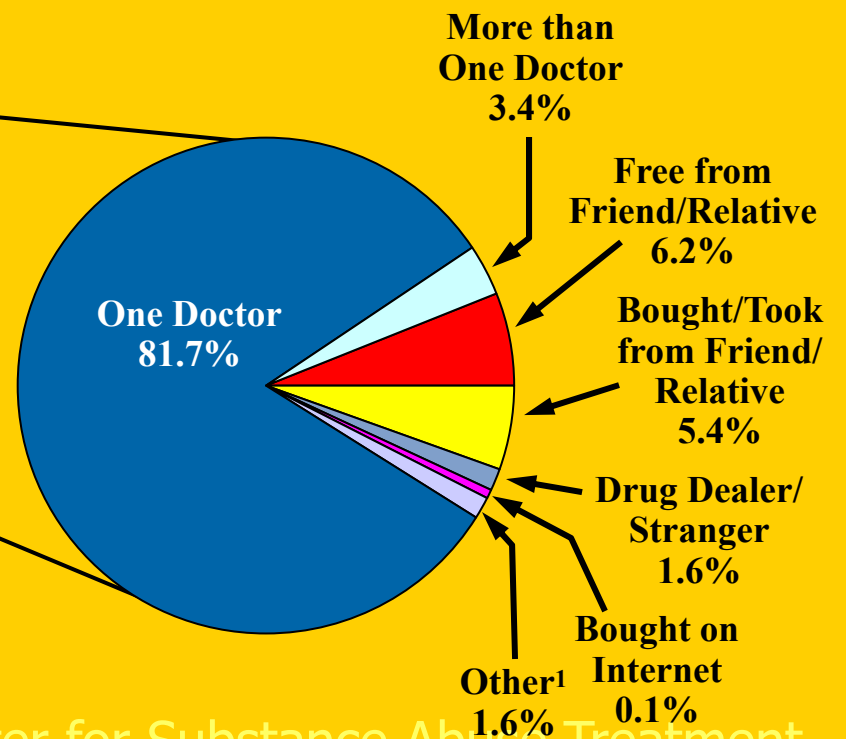


Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2007-2008

Source Where Respondent Obtained



Source Where Friend/Relative Obtained



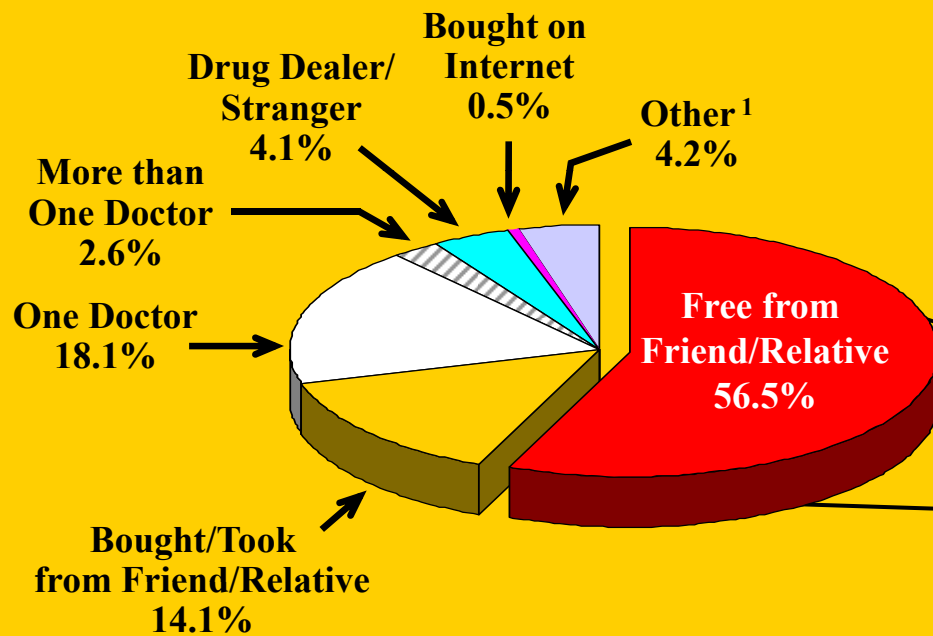
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Note: Totals may not sum to 100 percent because of rounding or because suppressed estimates are not shown.

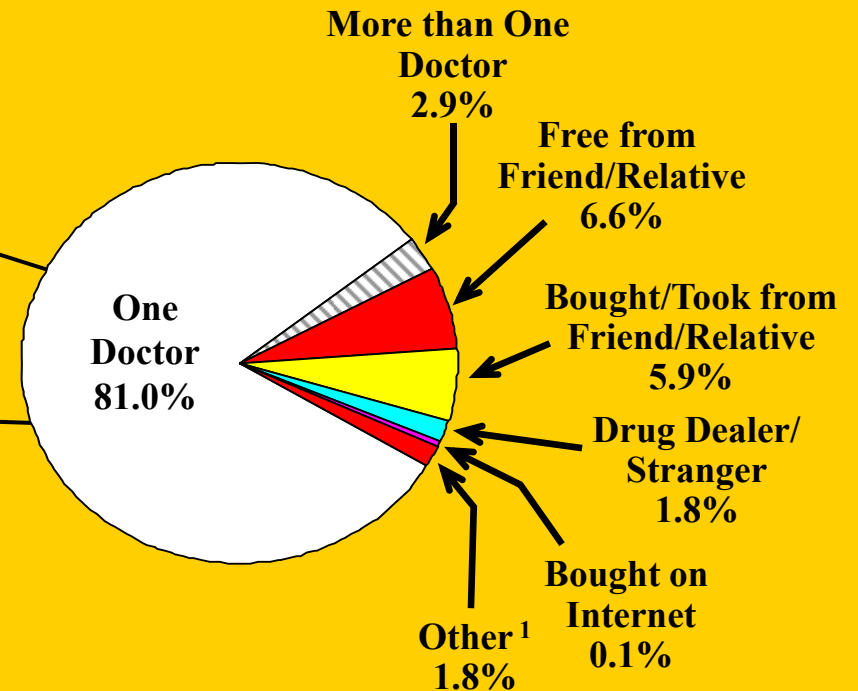
¹The Other category includes the sources "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2007

Source Where Respondent Obtained



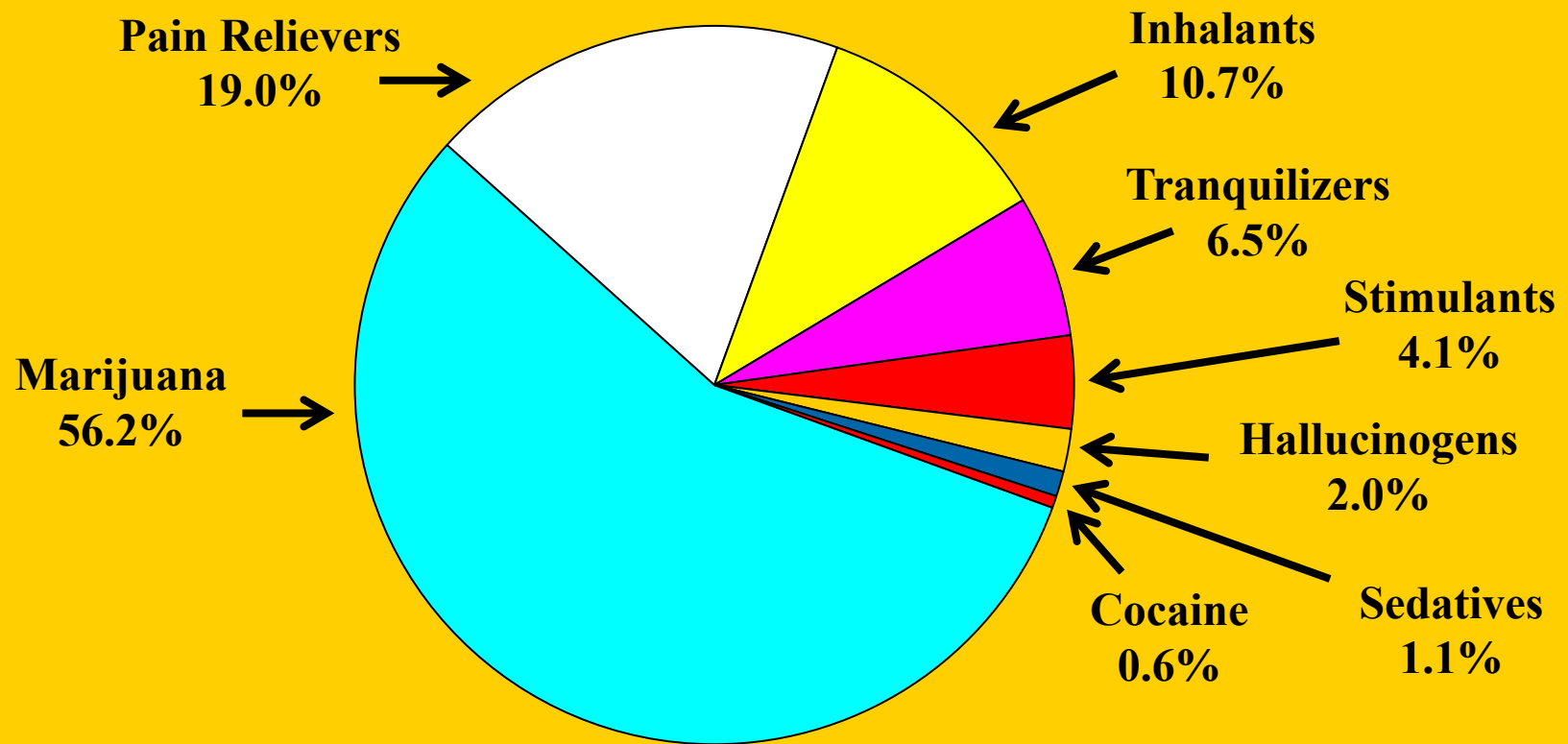
Source Where Friend/Relative Obtained



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."

Specific Drug Used When Initiating Illicit Drug Use among Past Year Initiates of Illicit Drugs Aged 12 or Older: 2007

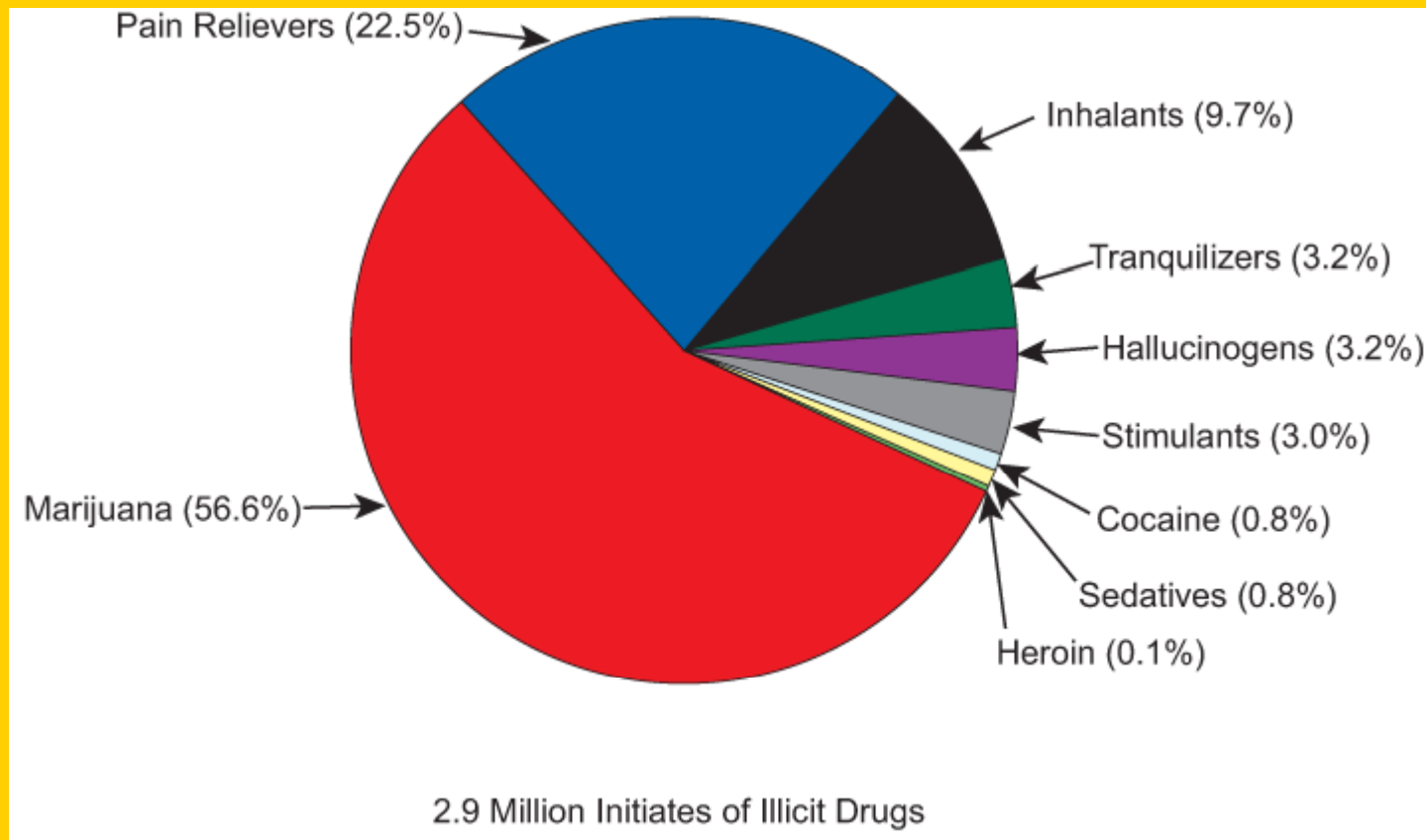


2.7 Million Initiates of Illicit Drugs

Note: The percentages add to greater than 100 percent because of a small number of respondents initiating multiple drugs on the same day.

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Figure 5.1 Specific Drug Used When Initiating Illicit Drug Use among Past Year Initiates of Illicit Drugs Aged 12 or Older: 2002



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Fig 5.2 Past Year Initiates for Specific Illicit Drugs among Persons Aged 12 or Older: 2007

Numbers in Thousands

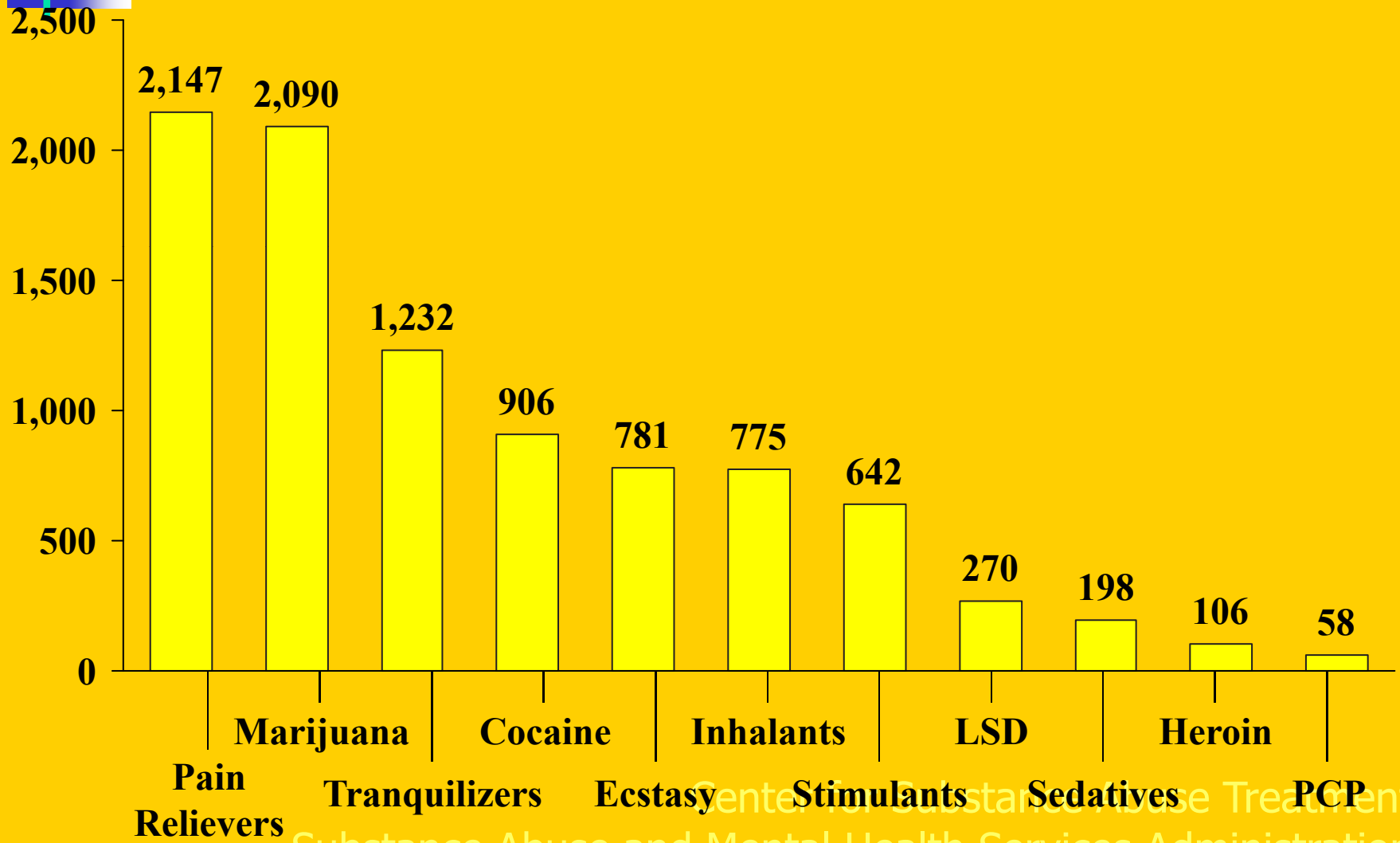
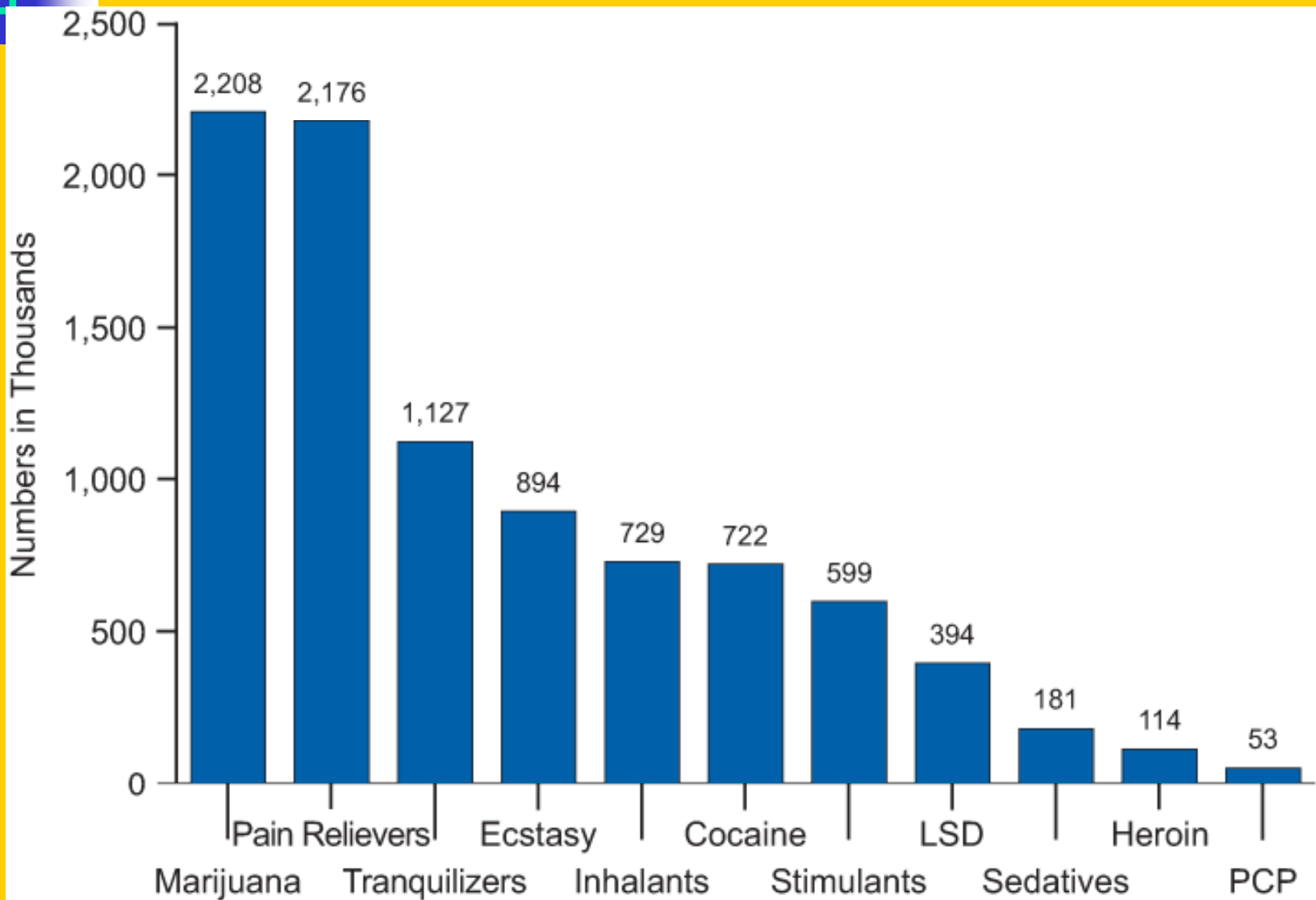


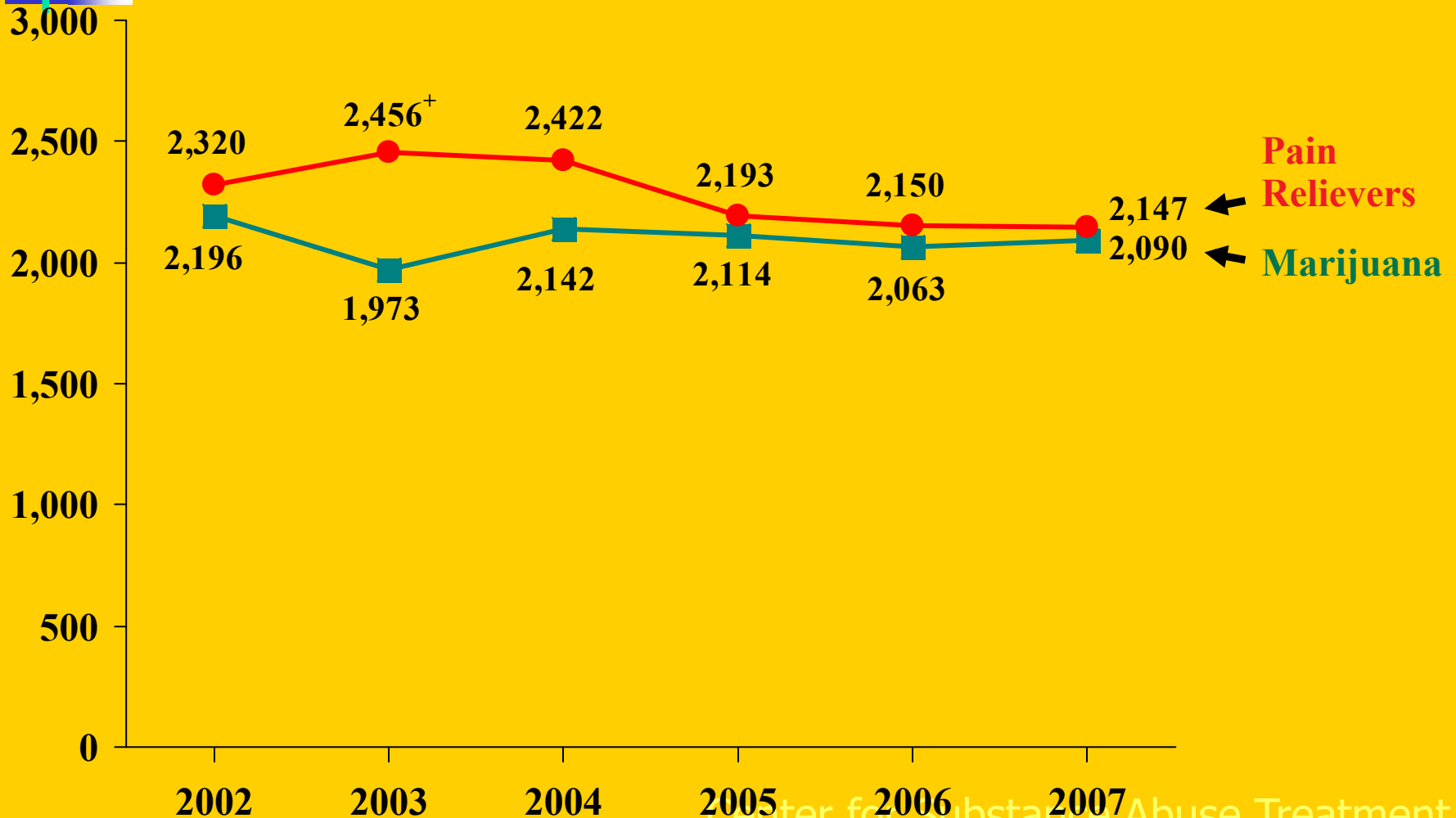
Figure 5.2 Past Year Initiates for Specific Illicit Drugs among Persons Aged 12 or Older: 2008



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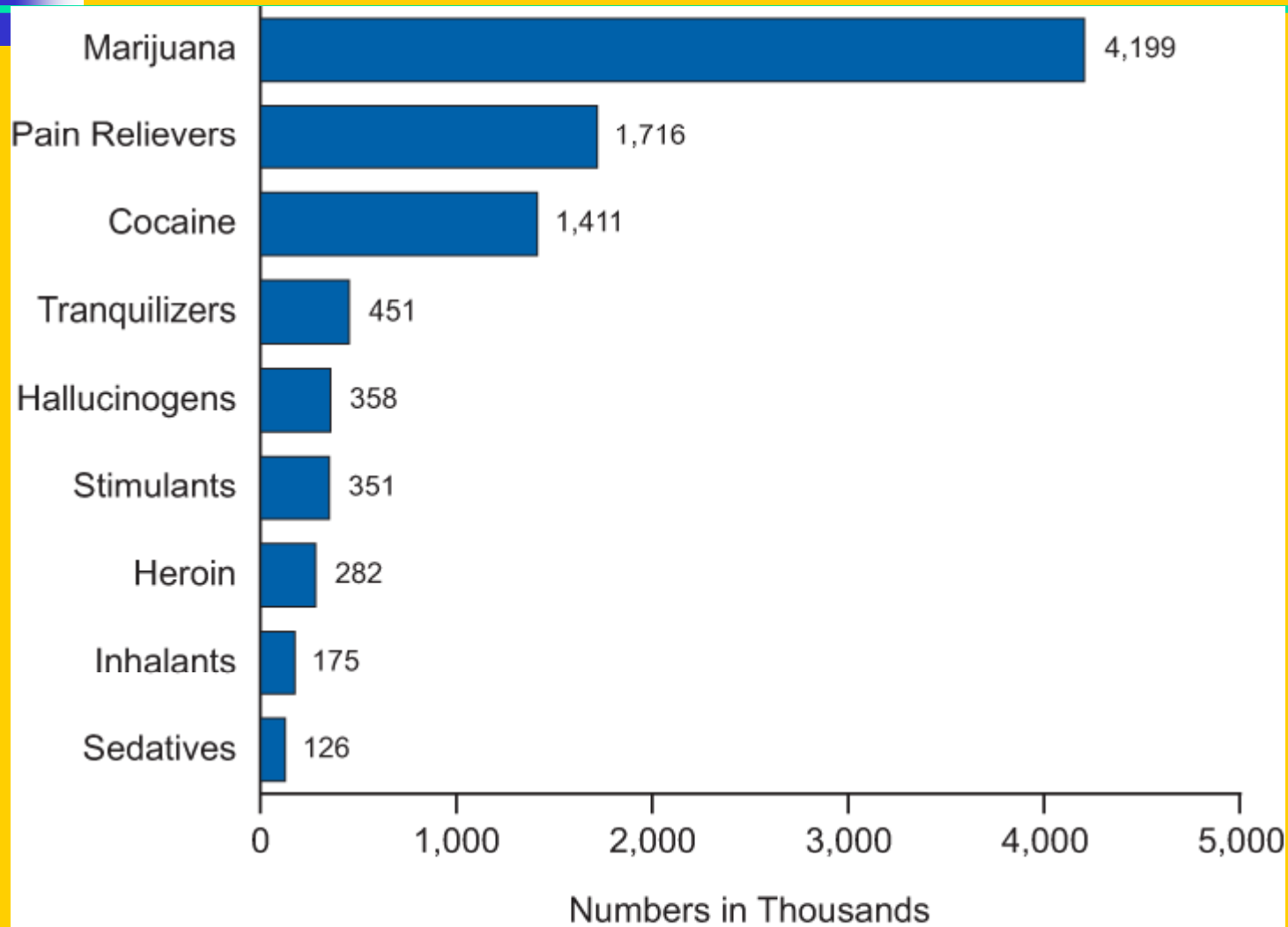
Past Year Initiates for Specific Illicit Drugs among Persons Aged 12 or Older: 2002-2007

Numbers in Thousands



⁺ Difference between this estimate and the 2007 estimate is statistically significant at the .05 level.

Figure 7.2 Dependence on or Abuse of Specific Illicit Drugs in the Past Year among Persons Aged 12 or Older: 2008



The logo graphic consists of several overlapping squares in yellow, red, and blue, with a white crosshair overlaid on them.

NASPER

- National
- All
- Schedules
- Prescription
- Electronic
- Reporting
 - Act of 2005

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NASPER - P.L. 109-191 – Intent

- 1. to foster the establishment or enhancement of State-administered controlled substance monitoring systems in order
- 2. to ensure that health care providers have **access to accurate, timely prescription history information.**
- 3. for assisting in the early identification of patients at risk for addiction. Early identification will lead to enhanced substance abuse treatment interventions.

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Alliance Goals for PMPs

- Education and information
- Public health initiatives
- **Early intervention and prevention**
- Investigations and enforcement
- Protection of confidentiality

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How – Formula grant, annual

Establishes the authority for a grant program with the Secretary, HHS, wherein a State may submit an application to

- 1. **implement a new** controlled substance prescription monitoring system, or
- 2. to **make improvements** upon an existing State controlled substance monitoring system.



How Much??

Authorizations, Future appropriations - \$15 million, no appropriation until March 2009 (\$2 million)

- Minimum Amount – no less than 1% of the amount appropriated. (\$20,000)
- Additional Amounts = appropriated amount x **number of pharmacies in the state/total number of pharmacies in all approved states.**

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Who is Eligible-requirements

- D. To participate
- (1) The State shall require dispensers* to report to such State each dispensing in the State of a controlled substance to an ultimate user **not later than 1 week** after the date of such dispensing.
- (2) The **State may exclude** from the reporting requirement of this subsection—
 - Direct administration to body of ultimate user
 - Dispensing in quantity 48 hours or less
 - Any other exclusion identified by the Secretary



Improve vs Establish/Implement

- Improve – assurance of compliance or statement why not feasible or contrary to best interest
- Establish/Implement – assurance of compliance only



What must be reported

- (3) The information to be reported under this subsection with respect to the dispensing of a **controlled substance (II-IV)** shall include the following:
 - (A) DEA Number dispenser.
 - (B) DEA Number and name of the practitioner who prescribed the drug.
 - (C) **Name, address, and telephone number of the ultimate user or such contact information of the ultimate user as the Secretary determines appropriate.**
 - (D) Identification of the drug by a national drug code number.
 - (E) Quantity dispensed.
 - (F) Number of refills ordered.
 - (G) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
 - (H) Date of the dispensing.
 - (I) Date of origin of the prescription.
 - (J) Other information as may be required by State law to be reported under this subsection.

- 4. Database State shall establish and maintain an electronic database containing the information reported to the State under subsection (d).

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Other Requirements - 1

- D. Electronic Standards
 - i. an agreement to adopt health information **interoperability standards**, including health vocabulary and messaging standards, that are consistent with any such standards **generated or identified by the Secretary** or his or her designee;
 - ii. criteria for meeting the uniform electronic format requirement
 - iii. criteria for availability of information and limitation on access to program personnel;
 - iv. criteria for **access** to the database, and procedures to ensure that information in the database is **accurate**;
 - v. criteria for the use and **disclosure** of information, including a description of the certification process to be applied to requests for information under subsection
- E. Electronic Format- The Secretary **shall specify a uniform electronic format** for the reporting, sharing, and disclosure of information under this section.



Disclosure Requirements

- A State may disclose only....
- Practitioner who certifies
- State, Local, Federal law enforcement who certifies
- Another state PMP with agreement
- Researchers



Drug Diversion

- States, after consultation with stakeholders :
- **Shall** establish a program to notify practitioners, dispensers with info to help identify and prevent unlawful distribution, and
- **May** notify drug diversion investigators.



2009 Appropriation - Process

- Consult with States, other parties
- Propose minimum requirements solicit comments - 04/29/09
 - 9 comments received
 - 6 States
 - Alliance, NACDS, ASAP
- SAMHSA Request For Grant App – 7/27/09
- 13 applications received and approved
- Entire \$2 million awarded

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Minimum Std. Criteria

- 1. Criteria for security for information handling and for the database maintained by the State under subsection (e) generally including efforts to use appropriate encryption technology or other appropriate technology to protect the security of such information.
- 2. Criteria for availability of information and limitation on access to program personnel (42 U.S.C. 280g–
- 3. Criteria for access to the database, and procedures to ensure that information in the database is accurate
- 4. Criteria for the use and disclosure of information, including a description of the certification process to be applied to requests for information under subsection (f)

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Data Security

- HIPAA security regulations include technical safeguards for access control, audit controls, integrity, person or entity authentication, and transmission security.
- The access control standards require, at a minimum, unique user identification, and an emergency access procedure, with automatic logoff and encryption decryption as addressable implementation specifications.

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Master Administrator

- Master Administrator - an individual with the responsibility of controlling and monitoring access to the PMP database
- assigning usernames and passwords to those who are granted access to PMP data
- Background Check - suggested

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Accuracy

- PMPs must adopt the most recent version of (ASAP) standard for electronic prescription formatting.
- Comments - ASAP 95 or newer as the minimum standard for formatting (New PMPS use most recent)
- PMPs do not correct errors, dispensers do.

Use and Disclosure of PMP Information

- State May Disclose to Five Entities
 - (a) A practitioner (or the agent thereof),
 - (b) any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program authority,
 - (c) the controlled substance monitoring program of another State or group of States with whom the State has established an interoperability agreement,
 - (d) any agent of the Department of Health and Human Services, a State Medicaid program, a State health department, or the Drug Enforcement Administration
 - (e) agent of the State agency or entity of another State that is responsible for the establishment and maintenance of that State's controlled substance monitoring program.
 - Patients?

- **Authentication** – written notarized,
 - permit States until September 30, 2010, to modify their procedures for authentication, and to “grandfather” existing authentications, but not for law enforcement.
 - Separate category for pharmacists

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Disclosure to patients

- Patient Disclosure - Comment recommended that a requesting patient must submit a written notarized request with the name, address, phone number, and a copy of a Government issued photo identification. Accepted

Disclosure to Medicaid, Drug Courts, etc.

- NASPER House Committee Report reflects the Committee's intention that "program authority" should be interpreted to include State Medicaid authorities, or other State or Federal authorities responsible for investigating health care fraud and abuse.
- NASPER does not restrict the ability of any authority to carry out its functions authorized by law and that the State's controlled substance monitoring program is independent of any other program carried out by any authority. Accordingly, Subsection (i)1) may be interpreted to apply to cases where there are requests for information from an authority other than one listed in subsection (f)(1) and such request is made to enable the authority to perform functions authorized by law.



Unsolicited Disclosures

- Proposed minimum standard –
 - “The threshold for notifying prescribers and dispensers is when an individual has filled five or more controlled substance prescriptions from five different prescribers, or five different dispensers in the State, within a six month period.”

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Unsolicited Disclosures (2)

- Applications for NASPER grants must include proposals for unsolicited notifications, or alternative proposals that demonstrate that information and analysis from the PMP is being used to reduce prescription drug misuse and diversion, or being used to direct individuals to treatment.



2009 Awards

State	Allotment
Alabama	\$115,396
California *	\$454,587
Connecticut	\$65,976
Illinois	\$188,843
Indiana	\$108,079
Kansas *	\$66,407
Kentucky	\$101,409
Maine	\$40,514
Michigan	\$193,362
Mississippi	\$79,246
Nevada	\$52,922
New York *	\$342,264
Ohio*	\$190,995



Other NASPER Requirements

- Implementation Report/Impact Study – “Because most of the electronic PMPs have been implemented recently, it is not possible to assess whether or not they have a substantial negative impact on access to treatment.”

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Progress Report – 3 years post

- Secretary shall complete a study
 - New programs under NASPER
 - Reduced inappropriate use/diversion or affected access to pain treatment.
 - Progress on interoperability
 - Feasibility of real-time/costs
 - Privacy protections
 - Feasibility of alternatives to centralized databases – peer to peer file sharing –data pointing systems.
 - Evaluates penalties for unauthorized use/disclosure

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WHY HHS??

- Electronic Health Record Initiative
- CMS Utilization
- Public Health
- Unite with SA Treatment
- HHS/SAMHSA Drug Abuse Measurement Instruments

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PMPS – Intervention and Prevention



- Physician Education –
 - Prescribing practices
 - Identifying dependence addiction
 - Intervention
 - Screening and referral
 - Treatment

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PMP's Part of Solution

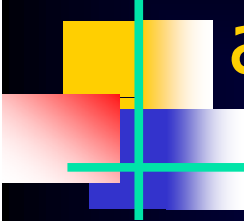
- Expanded/enhanced PMP use
- Doctor Shopping Laws? Tennessee
- Pain Clinic Regulation at State Level

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Changes to NASPER?

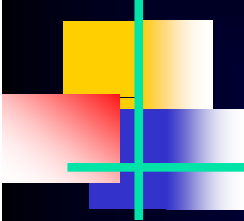
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S-754- Methadone Treatment and Protection Act of 2009 (1)

- (1) in subsection (d)(1), by inserting “(including prescribers of methadone)” after “dispensers”;
- (2) Subject to the requirements of section 543, the State shall, at the request of a Federal, State, or local officer whose duties include enforcing laws relating to drugs, provide to such officer information from the database relating to an individual who is the subject of an active drug-related investigation conducted by the officer’s employing government entity.
- (3) APPROPRIATIONS.—There is authorized to be appropriated, and there is appropriated, to carry out this section \$25,000,000 for each of fiscal years 2010 through 2014.

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S-754- Methadone Treatment and Protection Act of 2009 (2)

- As a condition for receiving funds under section 3990, each State shall require that any individual who signs a death certificate where an opioid drug is detected in the body of the deceased, or where such drug is otherwise associated with the death, report such death to the Administrator by submitting a Model Opioid Treatment Program Mortality Report
- Such report shall be submitted to the Administrator on or before the later of
 - (A) 90 days after the date of signing the “(B) as soon as practicable after the date
 - 26 on which the necessary postmortem and toxicology reports become available to such individual, as required by the Secretary.

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Conclusions

- SAMHSA recognizes the significant public health problem, current and future associated with prescription drug abuse.
- Agency is prepared, under NASPER framework, to work with States, other stakeholders to establish, advance PMPs.

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www.samhsa.gov/statistics