

# Prescription Opioids for Pain and Addiction

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# Addiction

- “Alcohol addiction and drug addiction continue to challenge our Nation. Addiction to alcohol or drugs destroys family ties, friendship, ambition, and moral conviction, and reduces the richness of life to a single destructive desire.”
  - *President George W. Bush*
  - *September 2003*

# 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

# SAMHSA's Role in Fighting Prescription Drug Misuse and Abuse

- At a policy level, SAMHSA works to ensure that science, rather than ideology or anecdote, forms the foundation for the Nation's addiction treatment system.
- SAMHSA and its component Centers serve health professionals and the public by disseminating scientifically sound, clinically relevant information on best practices in the treatment of addictive disorders, and working to enhance public acceptance of that treatment.

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

<b>Drug</b>	<b>N, millions</b>
Illicit drugs	20.4
Marijuana	14.8
Psychotherapeutics	7.0
Cocaine	2.4
Hallucinogens	1.0
Inhalants	0.8
Heroin	0.3

# Past Month Alcohol Use - 2006

<b>Use</b>	<b>Percentage</b>	<b>N, millions</b>
Any	51%	125
Binge	23%	57
Heavy	7%	17

- Current, Binge, and Heavy Use estimates are similar to those in 2002, 2003, 2004, and 2005
- Source: NSDUH, 2006

Non-Medical use of pain Relievers in Past Year among  
 Persons aged 12 or Older, by State: Percentages,  
 Annual Averages Based on 2005 and 2006 NSDUHs

<b>Percentage</b>	<b>State</b>
5.66-6.72%	HI, MD, MN, MS, ND, NJ, NY, PA, SD
5.31-5.65%	GA, IA, ME, NC, NE, NH, RI, TX, VA, WI
4.83-5.30%	AL, CA, DE, FL, KS, MI, OH, SC, VT, WY
4.40-4.82%	AK, AZ, CO, IL, KY, MA, MI, MT, NM, OR
3.85-4.39%	AR, CT, ID, IN, LA, NV, OK, TN, UT, WA, WV

# Past Month Nonmedical Percentage Use of Prescription Drugs (Psychotherapeutics) among Persons Aged 12 and Older: 2002-2006

<b>Year</b>	<b>Pain relievers</b>	<b>Stimulants</b>	<b>Sedatives</b>	<b>Tranquilizers</b>
<b>2002</b>	1.9% <sup>+</sup>	0.5%	0.2%	0.8% <sup>+</sup>
<b>2003</b>	2.0%	0.5%	0.1%	0.8%
<b>2004</b>	1.8% <sup>+</sup>	0.5%	0.1%	0.7%
<b>2005</b>	1.9%	0.4%	0.1%	0.7%
<b>2006</b>	2.1%	0.5%	0.2%	0.7%

<sup>+</sup> Difference between this estimate and the 2006 estimate is statistically significant at the 0.05 level.

# Estimated numbers, in thousands, of *new* nonmedical users in past year by type of drug, US, 1990-2006

Drug	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
Pain relievers	557	604	777	694	932	917	1,100	1,316	1,548	1,810	2,268	2,400	2,699	2,581	2,422	2,193	2,150
Tranquilizers	377	380	441	519	467	580	659	668	860	916	1,298	1,212	1,253	1,322	1,180	1,286	1,112
Cocaine	846	687	747	634	655	744	825	861	868	917	1,002	1,140	1,072	1,094	998	872	977
Stimulants	317	278	303	399	432	533	577	553	648	706	808	853	775	764	793	641	845
Heroin	50	63	109	59	79	111	140	114	140	121	114	154	147	96	118	108	91

- Source: SAMHSA NSDUH, 2006

# 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	Percentage
Free from friend/relative	55.7%
One doctor	19.1%
Bought/took from friend/relative	14.8%
Other <sup>1</sup>	4.9%
Drug dealer/stranger	3.9%
More than one doctor	1.6%
Bought on internet	0.1%

**Source where friend/relative obtained**

Source	Percentage
One doctor	80.7%
Free from friend/relative	7.3%
Bought/took from friend/relative	4.9%
More than one doctor	3.3%
Drug dealer/stranger	1.6%
Other <sup>1</sup>	2.2%

- Note: Totals may not sum to 100% because of rounding or because suppressed estimates are not shown.
- <sup>1</sup> The Other category includes the sources: "Wrote Fake Prescription," "Stole from Doctor's Office/Clinic/Hospital/Pharmacy," and "Some Other Way."

# Increased Issuance of Prescriptions

- Since 1991, stimulant prescriptions increased 7-fold (5 - 35 million)
  - Opioid prescriptions increased 4-fold (40 -180 million)

# Opiate Reports in Emergency Department Visits Related to Drug Misuse/Abuse: 2006

<b>Drug</b>	<b>ER reports</b>
Heroin	36,007
Methadone	5,694
Hydrocodone*	5,085
Oxycodone*	5,066
Buprenorphine*	225

Unweighted reports from 243-445 U.S. hospitals

Includes single- and multi-ingredient products

Source: U.S. SAMHSA; DAWN Live! Oct 2, 2007

# Poisoning Deaths in the U.S.

<b>Year</b>	<b>Methadone</b>	<b>Other opioids*</b>	<b>Other synthetic narcotics**</b>	<b>Cocaine</b>
<b>1999</b>	786	2,757	732	3,832
<b>2000</b>	988	2,932	784	3,656
<b>2001</b>	1,456	3,484	962	3,840
<b>2002</b>	2,360	4,431	1,301	4,612
<b>2003</b>	2,974	4,877	1,406	5,212
<b>2004</b>	3,849	5,242	1,668	5,461
<b>2005</b>	4,462	5,789	1,744	6,228

- \*Other Opioids include drugs like morphine, oxycodone, hydrocodone, and hydromorphone
- \*\*Other Synthetic Narcotics include drugs like propoxyphene, fentanyl, and meperidine
- Source: CDC

# Prescription Drug Abuse

## Role of Federal Government

- Restrictions on Drugs
  - Food and Drug Administration
  - Federal Controlled Substance Act
  - Drug Schedules
- Restrictions on Practitioners
  - Federal Laws and regulations

## Role of State Governments

- Regulation of professional practice occurs at the State level
- Numerous State laws, regulations, and policies govern the use of controlled drugs by physicians, nurses, dentists, veterinarians, and other health professionals

# Prescription Drug Abuse

## Role of Health Care Providers

- Treat 191 million Americans (70 percent) at least once every two years
- In unique positions to:
  - Prescribe needed medications
  - Encourage compliance
  - Identify problems as they arise
  - Help patients recognize their problems
  - Adopt strategies to address problems

# CSAT's Prescription Drug Abuse Initiative: Non-Medical Use of Prescription Drugs

- **4.8 %** of persons aged 12 or older (11.4 million persons) used a prescription pain reliever non-medically in the past 12 months (combined data from 2002-2005)
  - Of these, 57.7 % used hydrocodone products and 21.7 % used oxycodone products
- **55.7 %** reported that they accessed the pain relievers from a friend or relative for free.
  - Of these, 80.7 % indicated that their friend or relative<sup>16</sup> had obtained the drugs from just one doctor.

# CSAT's Prescription Drug Abuse Initiative: Key Activities

- Methadone Associated Mortality Meetings (2003, 2007)
  - Findings:
    - Increased use of methadone for the treatment of pain is a major factor behind the increased rate of methadone-associated mortality.
    - There is a need to focus on educating health professionals and consumers about the dangers of misusing prescription medications.
- SAMHSA initiative: Disposing & safeguarding of prescription medication to reduce potential misuse.

# CSAT's Prescription Drug Abuse Initiative: Key Activities

- Fentanyl-related Overdoses and Death Meeting (2007)
  - Combining Fentanyl and heroin or cocaine
- Cheese Heroin Meeting: Fentanyl-heroin combination and the combination of heroin and Tylenol PM (2007)
  - Popularized in certain parts of Texas
- CSAT Treatment Strategies for Prescription Drug Misuse and Abuse initiative
  - Emergency medicine & trauma surgery residents' curriculum
  - Training program on proper prescribing of controlled substances

# CSAT's Prescription Drug Abuse Initiative: Stakeholder Outreach

- Open Dialogue meetings with pharmaceutical industry.
- Buprenorphine Summits (2004, 2005, 2007)
- Rx Action Alliance (consortium of addiction experts, medical societies, patient advocacy groups, regulatory and law enforcement organizations, and pharmaceutical manufacturers)
- Advisory Committee on Non-Medical Use of Stimulant Drugs (prescription stimulant abuse by high school and college youth)
- National Association of Drug Diversion Investigators (NADDI)

# SAMHSA Regulation of Methadone Treatment – Key Elements

- Federal and State Approval is required to operate
  - Federal law does not preempt state right to regulate
  - DEA assures medication security
  - SAMHSA sets Federal treatment standards and requires independent oversight with standards appropriate to the treatment

# Independent Oversight of Methadone Treatment

- Accreditation by Private or State organization
  - Joint Commission on Accreditation of Health Care Organizations
  - Commission on Accreditation of Rehabilitation Facilities
  - Commission on Accreditation
  - National Correctional Health Care Commission
  - State of Missouri, Washington

# Methadone Related Deaths (% all Poisoning Deaths)

<b>Year</b>	<b>Percentage</b>
1999	4.0%
2000	4.9%
2001	6.5%
2002	8.9%
2003	10.4%
2004	12.7%
2005	13.6%

- Source: CDC/NCHS, National Vital Statistics System.

# Total Prescriptions Dispensed in U.S. Outpatient Retail Pharmacies for Methadone by Strength: 1997 – 2006

<b>Year</b>	<b>Total prescriptions</b>	<b>10 mg Methadone</b>	<b>5 mg Methadone</b>	<b>40 mg Methadone</b>
<b>1997</b>	348,343	237,880	105,446	5,017
<b>1998</b>	467,666	330,982	129,334	7,350
<b>1999</b>	640,943	446,056	162,116	12,711
<b>2000</b>	863,308	641,549	197,268	24,491
<b>2001</b>	1,200,566	882,325	269,786	48,455
<b>2002</b>	1,624,823	1,188,857	374,976	60,990
<b>2003</b>	2,171,996	1,603,371	453,234	115,391
<b>2004</b>	2,779,823	2,031,049	541,108	207,666
<b>2005</b>	3,420,595	2,446,449	645,424	328,722
<b>2006</b>	3,913,215	2,798,391	637,246	477,578

# 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

# Methadone-Associated Mortality Report

- In 2003, CSAT convened a multidisciplinary group of more than 70 experts to conduct a National Assessment of Methadone-Associated Mortality.
- The goal was to determine whether opioid treatment programs (OTPs) that use methadone in the treatment of opioid addiction and the revised Federal regulations governing the manner in which OTPs administer methadone could be contributing to methadone-associated mortality.

# Methadone-Associated Mortality Report: National Assessment Recommendations

- Uniform case definitions should be established
- Standards for toxicological testing are needed
- More useful data are needed
- Health professionals need better training in addressing pain and addiction
- Public misperceptions about methadone

# CSAT's Implementation of Recommendations

- Improve the accuracy of reporting
  - CSAT convened medical examiners, epidemiologists, and other experts to examine how methadone-associated deaths are classified and reported
  - Experts concluded the current system uses inconsistent classification methods
    - In response, they drafted new uniform case definitions, which are currently undergoing review and validation

# CSAT's Implementation of Recommendations

- Use Multiple Sources of Data to Monitor Methadone Trends
  - SAMHSA's OAS systematically collects and reports data on a variety of health indicators
  - CSAT commissioned independent epidemiologists to monitor data and perform special studies of methadone-associated morbidity and mortality
  - An information specialist systematically tracks and evaluates published reports related to methadone mortality and morbidity

# CSAT's Implementation of Recommendations

- Educate health care professionals in how to use methadone safely
  - CSAT has programs in place or in development to educate physicians and other health care professionals regarding the use of methadone for the treatment of addiction and for the management of pain
    - Publication of CSAT Treatment Improvement Protocol
    - CSAT-sponsored workshops and symposium on methadone
    - CSAT-hosted summit meetings for opioid treatment programs
    - Development of computerized patient intake questionnaire
    - Development of CME course on the use of methadone to treat pain

# Physician Education

## 4-8 Hours CME

- Problems we see with patients who are prescribed opioids for persistent pain
- Deciding whether or not to prescribe an opioid
- Pharmacology, emphasis on methadone
- Steps to take if you decide to use opioids in the treatment of persistent pain
- Steps to take if you decide NOT to use opioids in the treatment of persistent pain
- The practical side of patient monitoring – PMP, screening, lost Rx, etc.
- When, why and how to stop prescribing

# Opioid Prescribing CME

- Planned with State Medical Society
- Pilot tested in Ohio, Virginia
- Offered in West Virginia (2), Massachusetts, Connecticut, North Carolina
- Integrate with online – tie to registration renewal

# Office-Based Opioid Treatment (OBOT)

- As of July 2008, SAMHSA has certified 15,200 physicians to use Buprenorphine in office-based treatment of opioid abuse and dependence (more than twice the number 2 years ago)
- 8,600 (57 %) of these are listed on the Buprenorphine Physician Locator System.
- Almost 22,000 have been trained.
- 2500 physicians have indicated their intent to treat up to 100 patients.

# Total Number of Patients that Filled a Prescription for Suboxone and Subutex in U.S. Retail Pharmacies, 2003-2007

<b>Year</b>	<b>Suboxone</b>	<b>Subutex</b>
2003	15,000	5,000
2004	43,000	12,000
2005	79,000	16,000
2006	142,000	25,000
2007	266,000	39,000

- Source: Verispan Total Patient Tracker, Extracted Feb. 2008

# Buprenorphine Treatment Issues

- Training within medical school and residence
- Use in pain management and addiction
  - Managing patients with pain conditions and who are addicted to opioids
- Adverse events reported to emergency rooms and poison control centers
- Diversion
- New patient limits – 2500 physicians authorized to treat up to 100 patients each
- Prescription Drug Monitoring Programs
  - National All Schedules Prescription Electronic Reporting (NASPER)

# Resolving “False Positives”

- CSAT is actively involved in helping to resolve cases of concomitant medication interactions.
- Many programs have policies about patients on methadone and benzodiazepines
- Patients are often prescribed the medications for legitimate medical reasons.
- Considerable resources are devoted to resolving the “false positives” that result from the combination of drugs.

# Potential for Buprenorphine Abuse

- More than one-third of buprenorphine abusers reported that they took the drug in an effort to self-medicate and ease heroin withdrawal.<sup>1</sup>
- A majority of buprenorphine abusers are young white males with extensive histories of substance abuse.<sup>1</sup>
- When asked in a NASADAD study, **33%** of physicians considered Subutex to be a significant abuse and/or diversion threat in their states.<sup>2</sup>
- In the same study, only **6%** of physicians considered Suboxone to pose a significant abuse threat, and only **8%** considered it to be a significant diversion threat in their states.<sup>2</sup>

<sup>1</sup> Cicero, T & Inciardi, J, Potential for Abuse of Buprenorphine in Office-Based Treatment of Opioid Dependence, *The New England Journal of Medicine*, October 2005

<sup>2</sup> States' Perspectives on Buprenorphine and office Based Medication Assisted Opioid Dependency Treatment, NASADAD study prepared for CSAT, June 2004.

# Buprenorphine, Health Disparities and Diversion

- Lack of access to physician services may be contributing to the diversion and abuse of buprenorphine.
  - Financial barriers keep some patients from being able to get their own prescription from a physician.
  - Limited number of prescribers may also be a factor.
- Patients selling their buprenorphine to others dependent on opioids may not hesitate to sell their drugs to non-opioid dependent users.

# Surveillance Report Conducted by CRS Associates LLC

- 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.
- Source: *Surveillance Report*, July 1 thru September 30, 2007, CRS Associates LLC.<sup>38</sup>

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

<b>Year</b>	<b>Percentage</b>
2003	44.3%
2004	32.9%
2005	37.1%
2006	35.4%
2007	33.4%

- Average size: An average number of extended units dispensed per prescription. The calculation is extended units divided by prescriptions.
- Source: Verispan Vector One®: National 2003-2007, extracted 3/5/08

# Buprenorphine Patient Outcomes: Number of Days Drugs Were Acquired on the Street

- “In the past 30 days, how many days did you get drugs “on the street”?”

<b>Timeframe</b>	<b>Days</b>
Baseline	13.16
30 Day follow-up	0.10
6 Month follow-up	1.72

- Source: SAMHSA Patient Longitudinal Study, November 2005

# Buprenorphine Patient Outcomes: Percent of Patients Acquiring Drugs on the Street

<b>Timeframe</b>	<b>Percentage</b>
Baseline	67%
30 Day follow-up	4%
6 Month follow-up	20%

- Source: SAMHSA Patient Longitudinal Study, November 2005

# Buprenorphine Patient Outcomes: Specific Criminal Activities

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

<b>Activity</b>	<b>Baseline, %</b>	<b>30 day, %</b>	<b>6 month, %</b>
<b>Drug dealing</b>	16.1%	0.8%	2.9%
<b>Prescription fraud</b>	10.0%	1.3%	1.1%
<b>Other crimes</b>	10.3%	0.8%	2.1%

- Source: SAMHSA Patient Longitudinal Study, November 2005

# Risk Management for Buprenorphine

- Key elements of the FDA risk management program for monitoring the abuse and diversion of buprenorphine include:
  - Physician Surveys
  - Patients reporting to SA Treatment centers
  - Internet News groups
  - Poison Control
  - DAWN
  - Ethnographic studies

# SAMHSA's Smart Rx Disposal

- The abuse prevention information sheets address the following issues:
  - 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.

# SAMHSA's Smart Rx Disposal

- Preliminary results from the pilot indicate:
  - The system is effective in getting information to consumers
  - Approximately **6 Million** information sheets have been transmitted
  - **80%** of the recipients indicated that the material was useful
  - **48%** reported that they were keeping the information
  - **26%** were sharing the information with friends and family

# 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: <http://www.nida.nih.gov/Blending/><sup>46</sup>

# 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 via telephone, email, and/or at the place of clinical practice.
- Web site: <http://www.pcssmentor.org/>

# SAMHSA Prescription Drug Initiatives

- We're Developing Strategies on the Therapeutic and Non-therapeutic use of Prescription Drugs of Abuse...
  - CSAT Advisory: Oxycontin: Prescription Drug Abuse, April 2004, Volume 1, Issue 1

## **Treatment Improvement Protocols**

- SAMHSA has played a major role in educating physicians and other healthcare providers on treatments for opioid addiction
  - Clinical Guidelines for the Use of Buprenorphine in

# SAMHSA/CSAT Information

- SAMHSA website: <http://www.samhsa.gov/>
- Information web site:  
<http://buprenorphine.samhsa.gov/>
- Medication-Assisted Treatment information:  
<http://www.dpt.samhsa.gov/patients/mat.aspx>
- SHIN 1-800-729-6686 for publication ordering or information on funding opportunities  
  
1-800-487-4889 – TDD line
- 1-800-662-HELP – SAMHSA's National Helpline  
(average # of tx calls per mo: 24,000)