NASPER:
Why has the National All Schedules Prescription Electronic Reporting Not Been Implemented?

Statement of:

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Subcommittee on Oversight and Investigations

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Oral Testimony

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Distinguished Chairman, Ranking Member, Members of Congress and staff, my name is Dr. Andrea Trescot. I am very grateful for this invitation to speak before you about a critical issue, prescription drug abuse. I am an Interventional Pain Management physician with nearly 20 years of private practice experience. Earlier this year I left private practice to join the University of Florida Faculty as the Director of the Pain Fellowship Program. I am currently the President of the American Society of Interventional Pain Physicians, a professional society with over 4000 providers. It is in my role as a physician treating patients in agonizing pain that I come to you today requesting your help.

Opioid or narcotic use and misuse is a huge and growing problem in the United States. Americans make up only 4.6% of the worlds population, but they consume 80% of the global supply of pain medicines, 99% of the global supply of Hydrocodone (one of the most abused of our readily available pain medicines) and 2/3rds of the world's illegal drugs. Despite the billions of dollars thrown at this problem, we have not been able to reduce the nation's substance abuse and addiction.

The number of illegal drug users is rising. The number of teen illegal drug users has more than doubled, and the number of Americans abusing controlled prescription drugs has jumped from 6.2 to 15.2 million in the last ten years. Among the patients suffering with chronic pain and receiving opioids, 1 in 5 are abusing those prescription-controlled medications and approximately the same number of patients are also using illicit drugs.

The National Drug Control Strategy from the White House spent over 10 billion dollars a year since its enactment in 1988 with no demonstrable results in curbing drug abuse or addiction. And, specifically, there has been no change in prescription controlled substance abuse. Yet, almost a quarter of a trillion dollars of the nation's yearly healthcare bill is attributed to substance abuse and addiction.

Some of the increase in opioid abuse is occurring with teenagers, who view prescription medications as not only "safer," but also the "cool" drugs to use. Prescription medications are the most commonly used drugs to get high among teenagers, and teenagers represent almost a third of the prescription drugs abused in the country. These medicines have come from friends, from stealing the medications from their family members, and occasionally from the internet. Over 90% of drugs were obtained by legitimate prescriptions.

In addition, the highest use of pain relievers nonmedically was in the 18-25 year group. I was struck by an undercover surveillance video I viewed last week, which showed nearly a hundred people standing in a doctor's waiting room as they waited their turn to pickup their narcotic prescriptions. I was stunned by how much it looked like a "bar seen" and then realized it was because virtually every person in the waiting room was under the age of 30. This pill mill was catering to the young.

Unfortunately the elderly are also at risk, because of their multiple medications (and potential drug interactions), and their multiple degenerative joint changes (such as hip, knees and back). And yet, though this population may have significant and legitimate opioid needs, they are at risk for diversion of their medications, either actively (selling them for income supplementation) or passively (with their medications stolen by caregivers and family members).

Approximately 75-90% of drug abusers have obtained their medications legally, and most likely through a prescription. Doctor shopping is one of the most common methods of obtaining prescription drugs for personal and illegal use. We feel therefore strongly that the most effective way of controlling this epidemic is to control the "end of the pen" or, in other words, the way the medications are prescribed.

The White House Office of National Drug Control Policy, which focused on stopping use before it started, intervening and healing drug users, and disrupting the market, is pending approximately 13 billion dollars per year. Unfortunately, the ONDCP budget does not include funding for NASPER which is arguably the most effective program. To fight drug abuse before the drug is prescribed would require 10 million dollars, which is less than 1% of the budget. This 1% would provide as much as 30% reduction in prescription drug abuse. We feel strongly that the National All Schedules Prescription Electronic Act (NASPER), which was signed into law August 11, 2005, is a major weapon against prescription drug abuse.

NASPER was based on a successful program in Kentucky, KASPER, which has been effective but limited by the fact that Kentucky has 7 Border States and patients can therefore take their prescriptions across state lines and thwart the ability of Kentucky physicians to monitor that narcotic use. One of the most important features of NASPER was the information sharing across state lines, but that requires each state to have a monitoring program in place. However, in this day of unfunded mandates, the states have been slow

to enact legislation, most of which are inadequately funded, and are not designed to share information.

By identifying those patients who are doctor shopping, legitimate physician will be able to identify and intervene early with patients who are misusing and abusing their medications. In addition, the ability to identify legitimate pain patients will increase the access to care for those patients who truly need the medication and shut down the most obvious avenue for obtaining fraudulent prescriptions.

As an example, I live in North Florida, an hour away from the Georgia border. Although Florida passed a bill that was named FLASPER, suggesting that it was the state response to the NASPER bill, the eventual legislation, which was passed in July of this year was castrated onto a voluntary program of electronic prescribing.

We are convinced that had the funding for NASPER been in place, the law in Florida would have conformed to the national recommendations. This would have prevented Florida patients from visiting multiple doctors regardless of whether they were day laborers or national syndicated radio columnists.

It is clear the prescription monitoring programs are effective specifically when they are proactive. NASPER would allow communication among states. We in ASIPP also feel that since less than 40% of physicians receive any training regarding pain evaluation in medical school, the White House should organize events to facilitate the dissemination of pain and addiction information to the general medical community. I have provided to the committee a copy of such an education tool, published last year by the Florida Medical Association.

We also feel that controlled substance education must be mandated in medical schools, residency training programs and supported by continuing education every year. That training should be accredited and approved and could be monitored by the DEA or the State Boards of Medical Licensure.

There are a growing number of pain professionals who feel that pain management should be a separate residency. ASIPP is doing its part by providing a training program and examination leading to a clinical competency in controlled substance prescribing.

In closing, the White House has declared a global war on terrorism with a budget of $145 billion dollars. We are asking for a tiny fraction of that to battle an insidious and just as deadly internal threat to the welfare of this nation. Please help us in this battle by providing funding for NASPER, one of the major tools we have in this crucial battle.

Thank you.

I will be happy to answer any question you might have.

Written Testimony

National Drug Control Policy and Prescription Drug Abuse: Facts and Fallacies

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Joseph A. Califano, Jr., Chairman and President of the National Center on Addiction and Substance Abuse at Columbia University (CASA), on May 7, 2007 issued a press release on the state of the affairs of illicit drug use and the diversion and abuse of controlled prescription drugs in the United States (1). Califano, a former U.S. Secretary of Health, Education, and Welfare, called for a major shift in American attitudes about substance abuse and addiction and a top to bottom overhaul in the nation's healthcare, criminal justice, social service, and education systems, in awakening the power of parenting, to curtail the rise in illegal drug use and other substance abuse. He called substance abuse and addiction a chronic disease of epidemic proportions with physical, psychological, emotional, and spiritual elements that require continuing and holistic care (1,2).

Americans, constituting only 4% of the world's population, consume 80% of the global supply of opioids, 99% of the global supply of hydrocodone, and two-thirds of the world's illegal drugs (1-4). Consequently, the sum of all the measures on the current war on drugs has not been able to reduce the nation's substance abuse and addiction.

Califano, also in a July 2005 editorial on the diversion and abuse of controlled prescription drugs in the United States (5) noted the following:

"While America has been congratulating itself in recent years on curbing increases in alcohol and illicit drug abuse and in the decline in teen smoking, abuse and addiction of controlled prescription drugs - opioids, central nervous system depressants and stimulants - have been stealthily, but sharply, rising. Between 1992 and 2003, while the US population increased 14%, the number of people abusing controlled prescription drugs jumped 81% - twice the increase in the number of people abusing marijuana, 5 times the number abusing cocaine and 60 times the increase in the number abusing heroin. Controlled prescription drugs like OxyContin, Ritalin, and Valium are now the fourth most abused substances in America behind only marijuana, alcohol, and tobacco."

Consequently, as in prior years, multiple surveys of non-prescription drug abuse (6-10), emergency department visits for prescription controlled drugs (11-15) and unintentional deaths due to prescription controlled substances (16-20) have been steadily rising.

Further, the activities of the White House Office of National Drug Control Policy (21-23), numerous hearings held by Congress, the Administration, and various agencies at the federal and state levels (4,24,25) reiterate the growing problem of illicit drug use and prescription controlled substance abuse. Yet, the number of prescriptions for controlled substances continue to soar along with arguments for undertreatment of pain and education for increased prescription and availability of controlled substances with continued funding for numerous programs whose effectiveness have not been proven yet.

Figure 1 illustrates the increase of controlled substances abuse from 1992 to 2003, in comparison to US population and prescriptions written for controlled substances, but, newer statistics are even more impressive. From 1992 to 2005, the US population increased 15%, whereas, during this period adults abusing controlled substances increased 98%. The 2005 NSDUH Survey showed 6.4 million persons or 2.6% of the population 12 years or older in the United States used prescription type psychotherapeutic drugs nonmedically in the past month (6). Nonmedical use of psychotherapeutic drugs in the past year increased to 15.172 million or 6.2% of the US population of 12 years or older (6). Similarly, lifetime nonmedical use of psychotherapeutics increased to 48.709 million persons or 20% of the United States population of 12 years or older. Further, in the past year, initiation of substance use among persons aged 12 or older, nonmedical use of psychotherapeutics, was 2.526 million. The only silver lining is that nonmedical use of therapeutic drugs among 12-17 year olds decreased in 2005 compared to 2002 and 2003, whereas it significantly increased for 18-25 year olds from 2002 to 2005.

The National Institute on Drug Abuse (NIDA) on the eve of unveiling its first consumer publication to

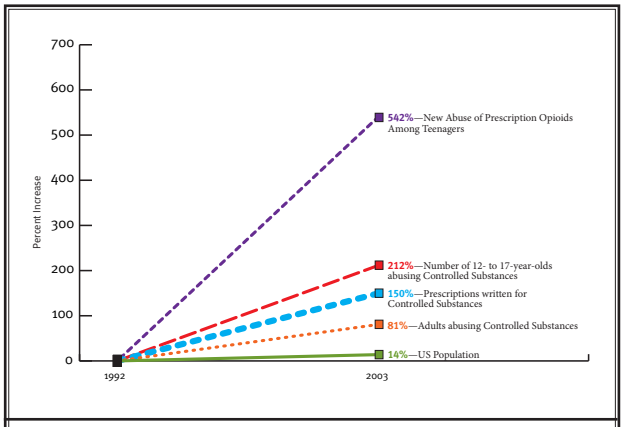


Fig. 1. *Increase of controlled substance abuse from 1992 to 2003, in comparison to US population and prescriptions written for controlled substances.*

explain the signs of addiction on March 5, 2007, reported that abuse and addiction to alcohol, nicotine, and illegal substances costs Americans upwards of half a trillion dollars a year (26).

The National Center on Addiction and Substance Abuse at Columbia University in an update published in 2006, its third report (27), concluded that prescription controlled drugs continue to be as easy to buy over the Internet as candy, and anyone, including children, can readily obtain, without a prescription, highly addictive controlled substances from Internet drug pushers as long as a person has a credit card. Califano once again reiterated that not surprisingly, controlled prescription drug abuse is on the rise, today, with more adults and teens having reported abusing these drugs than having abused all other illicit drugs combined except marijuana.

Even then pain is considered as undertreated by some, while opioid prescriptions are soaring (3). In recent medical news and perspectives of JAMA, it was shown that by far the most commonly used prescription analgesic in the United States is hydrocodone with acetaminophen which has been the most prescribed medication of any category for at least the past 5 years, with more than 100 million prescriptions in 2005, far exceeding the number of prescriptions for the second and third most prescribed medications-cholesterol-lowering atorvastatin with about 63 million prescriptions, and the antibiotic amoxicillin, with about 52 million prescriptions. In addition, in 2004, the United States used 99% of the global supply of the opioid hydrocodone, according to the 2005 report from the International Narcotics Control Board (3). Between 2000 and 2004, medical use of hydrocodone increased 60% domestically.

In a recent letter to Members of Congress titled "Prescriptions Drugs: An Emerging Threat," John P. Walters, Director of White House Office of National Drug Control Policy, expressed his deep concern that America's leadership be aware of this burgeoning problem so that they can inform their communities about the dangers of prescription drug abuse (28).

The National Drug Threat Assessment 2007 by the National Drug Intelligence Center US Department of Justice (29) reported that rates of pharmaceutical drug abuse exceeded that of all other drugs except marijuana resulting in a high number of pharmaceutical overdose deaths annually.

Despite the alleged undertreatment of pain, based on the present statistics, it appears that opioids are overprescribed. Widely quoted literature about the undertreatment of pain, pertains to terminal illness, malignancy, post-operative pain and AIDS. Opioid prescriptions have increased substantially from 1997 to 2005, with increases in methadone prescriptions of 933%, oxycodone prescriptions of 588%, and hydrocodone prescriptions of 198% (Table 1). The increase in the legitimate use of opioids has been paralleled by a rise in abuse of these drugs with a 62.5% increase in opioid deaths during the 5-year period from 1999 to 2004 (16,17). Further, in pain management settings, as many as 90% of patients have been reported to receive opioids for chronic pain management (30,31). Multiple investigators (32-49) have shown prevalence of drug abuse around 20% and as high as 58% in the patients receiving opioids for chronic pain. Unfortunately, a significant proportion of chronic pain patients also tend to use illicit drugs, with proportions increasing based on concurrent abuse of prescription controlled substances (32-49). The explosion of opioid use and abuse along with illicit drug use in chronic pain patients is sadly coupled with a lack of evidence of their long-term effectiveness in these patients.

Our national drug control strategy, with billions of dollars spent each year, is not working. As Califano stated, "All the huffing and puffing of the current war on drugs has not been able to blow down the nation's house of substance abuse and addiction." Note the following glaring and startling facts (1,2):

- The number of illegal drug users, which had dropped from a high of 25.4 million in 1979 to a quarter century low of 12 million in 1992, has risen to 20 million in 2005.

Table 1. *Retail sales of opioid medications (grams of medication 1997 –2005*

	1997	2005	% of Change
Methadone	518,737	**5,362,815**	933%
Oxycodone	4,449,562	**30,628,973**	588%
Fentanyl Base	74,086	**387,928**	423%
Hydromorphone	241,078	**781,287**	244%
Hydrocodone	8,669,311	**25,803,544**	198%
Morphine	5,922,872	**15,054,846**	154%
Meperidine	5,765,954	**4,272,520**	-26%
Codeine	25,071,410	**18,960,038**	-24%

Source: http:www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.htmo

- The number of teen illegal drug users, which had dropped from its 1979 high of 3.3 million to a low of 1.1 million in 1992, has more than doubled to 2.6 million in 2005.
- From 1995 to 2005 the number of Americans abusing controlled prescription drugs jumped from 6.2 to 15.2 million.
- One in 4 Americans will have an alcohol or drug problem at some point in their lives.
- Among the patients suffering with chronic pain and receiving opioids, 1 in 5 abuse prescription controlled substances and approximately the same number of patients also use illicit drugs.

Thus, the consequences of this epidemic are severe (1,2):

- Almost a quarter of a trillion dollars of the nation's yearly health care bill is attributable to substance abuse and addiction.
- The national drug control strategy from White House spent over $10 billion dollars a year since its enactment in 1988 with no demonstrable results in curbing drug abuse and addition, specifically prescription controlled substance abuse.
- The National All Schedules Prescription Reporting Act of 2005 signed into law by President Bush on August 11, 2005, has not been funded. Instead, an incoherent program by the DEA has been appropriated over the years.
- While education about the undertreatment of pain, prevalence of pain and increasing levels of comfort among physicians prescribing opioids has fueled increased prescriptions of opioids with parallel growth in the unintentional consequences of misuse, abuse and deaths, the education of physicians and the public with reference to deleterious effects of opioids, non-opioid management of chronic pain, abuse and addiction, hasnot been implemented.
- Majority of prescription controlled substances for nonmedical use are obtained for free from a friend or relative (60%), purchased from a friend or relative (8%), taken from a friend or relative without asking (4%) and from prescriptions from one doctor (17%).

Consequently, a mounting revolution is essential to control this problem. Changes are needed not only in the healthcare system, but also justice, social service, and education. This review will focus on the problem of prescription drug abuse and relevance of the National Drug Control Policy and will discuss multiple facts and fallacies, along with proposed solutions.

State of Illicit Drug Use

The 2005 National Survey on Drug Use and Health (NSDUH), an annual survey sponsored by the Substance Abuse and Mental Health Services Administration provided the following statistics about the state illicit drug use in the United States (6). The survey considered current use of an illicit drug during the month prior to the survey interview.

- In 2005, an estimated 19.7 million Americans aged 12 or older or 8.1% of the population were current illicit drug users.
  - Illicit drugs include marijuana/hashish, cocaine including crack, heroin, hallucinogens, inhalants, or prescription-type psychotherapeutics used nonmedically.
  - The rate of current illicit drug use in 2005 was slightly higher than the rate in 2004 (8.1% vs 7.9%), but similar to 2003 and 2002 (8.2% and 8.3%).
  - The rates of current illicit drug use among youths aged 12 to 17 in 2005 was 9.9% similar to the rate in 2004, but significantly lower than 2002 (11.6% in 2002, 11.2% in 2003, 10.6% in 2004).
  - There were no significant changes in past month use of any illicit drugs among adults aged 18 to 25 between 2004 and 2005, except for cocaine use which increased from 2.1% to 2.6%.
- Marijuana was the most commonly used illicit drug with 14.6 million past month users with a 6% population.
  - The rates remained same as in 2004 (6.1%), 2003 (6.2%) and 2002 (6.2%).
  - The rate of current marijuana use among youths aged 12 to 17 declined from 7.6% in 2004 to 6.8% in 2005.
- The current cocaine use was reported in 2.4 million Americans aged 12 and older or 1% of the population.
  - Current use of cocaine in 2005 was slightly higher than 2004 (1% vs 0.8%), however, was not statistically significant.
- The current use of hallucinogens was by 1.1 million or 0.4%.
  - This included 0.2% who had used ecstasy and the estimates were similar to the corresponding estimates for 2004.
- The current use of methamphetamine (0.2%) and past year use of 0.5%, did not change between 2004 and 2005, but the lifetime rate changed in 2005.
  - Even though, the lifetime rate declined from 4.9% in 2002 to 4.3% in 2005, the number of methamphetamine users who are dependent on or abused some illicit drug did rise significantly during this

Table 2. *Types of illicit drug use in past year among persons aged 12 or older from 1995 to 2005 (numbers in thousands).*

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Non-medical use of Psychotherapeutic drugs	6,166 (2.9%)	6,652 (3.1%)	6,111 (2.8%)	5,759 (2.6%)	9,220 (4.2%)	8,761 (3.9%)	11,102 (4.9%)	14,680 (6.2%)	14,986 (6.3%)	14,643 (6.1%)	15,172 (6.2%)
Marijuana	17,755 (8.4%)	18,398 (8.6%)	19,446 (9.0%)	18,710 (8.6%)	19,102 (8.6%)	18,589 (8.3%)	21,086 (9.3%)	25,755 (11.0%)	25,231 (10.6%)	25,451 (10.6%)	25,375 (10.4%)
Cocaine	3,664 (1.7%)	4,033 (1.9%)	4,169 (1.9%)	3,811 (1.7%)	3,742 (1.7%)	3,328 (1.5%)	4,186 (1.9%)	5,902 (2.5%)	5,908 (2.5%)	5,658 (2.4)	5,523 (2.3%)
Total or Any Illicit Drug usage	22,662 (10.7%)	23,182 (10.8%)	24,189 (11.2%)	23,115 (10.6%)	25,402 (11.5%)	24,535 (11.0%)	28,409 (12.6%)	35,132 (14.9%)	34,993 (14.7%)	34,807 (14.5%)	35,041 (14.4%)

Source: www.samhsa.gov

period from 164,000 in 2002 to 257,000 in 2005.

- There were 6.4 million (2.6%) persons who used prescription-type psychotherapeutic drugs non-medically in the past month.
- The estimates were similar to the corresponding estimate for 2004.

Epidemic of Non-medical Prescription Drug Abuse

The National Survey on Drug Use and Health (NSDUH) of 2005 (6) provided rather startling statistics as shown in Table 2. The type of illicit drugs used in past year among persons aged 12 or older from 1995 to 2005 increased for nonmedical use of psychotherapeutic drugs and overall use of any illicit drug, but decreased slightly for marijuana and cocaine (6).

In 2005, there were 6.4 million or 2.6% of persons aged 12 or older who used prescription-type psychotherapeutic drugs nonmedically in the past month. Of these 4.7 million used pain relievers, 1.8 million used tranquilizers, 1.1 million used stimulants including 512,000 using methamphetamine, and 272,000 used sedatives (Fig. 2). The current nonmedical use of prescription-type drugs among young adults aged 18 to 25 increased from 5.4% in 2002 to 6.3% in 2005 (6). The majority of the increase was seen in pain reliever use which was 4.1% in 2002 and 4.7% in 2003, 2004, and 2005.

In a report of patterns and trends in nonmedical prescription pain reliever use from 2002 to 2005 (50), NSDUH reported that nonmedical use of prescription pain relievers among persons aged 12 or older remained relatively stable between 2002 and 2005 (nonsignificant increases were seen), 4.8% of the

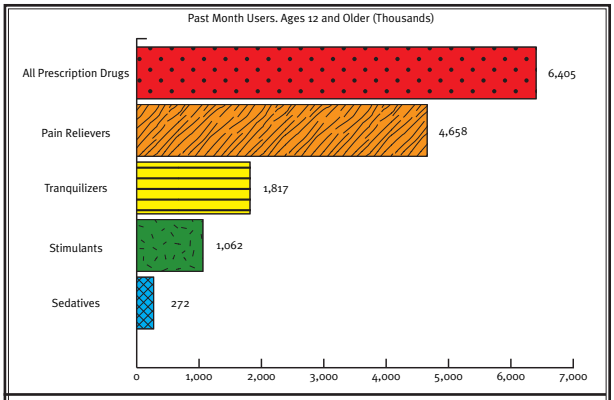


Fig. 2. *Pain relievers account for the largest portion of non-medical use of prescription drugs. Source: SAMHSA, 2005 National Survey on Drug Use and Health (Sept. 2006).*

population or 11.4 million persons used a prescription pain reliever nonmedically in the 12 months prior to the survey and 57.7% of persons who first used pain relievers nonmedically in the past year used hydrocodone products and 21.7% used oxycodone products.

As shown in Figure 3, the highest use of pain relievers nonmedically was in the 18 to 25 age group with males more likely than females to have used a prescription type pain reliever nonmedically in the past year (5.2% vs 4.4%). However among youths aged 12 to 17, females were more likely than males to have used pain relievers nonmedically in the past year (7.9% vs 6.8%) whereas males aged 18 to 25 and males aged 26 to 34 at higher rates than their female counterparts. Among adults aged 35 to 49 and those aged 50 or older, males and females had similar rates

of nonmedical use prescription pain relievers.

In another report released by the Office of National Drug Control Policy with an analysis of recent trends on the emerging drug threat among teens (51), the following was included:

- Next to marijuana, prescription medications are the most commonly used drugs among teens to get high.
  - Teens are turning away from street drugs and using prescription drugs to get high. Indeed, new users of prescription drugs have caught up with new users of marijuana.
- For the first time, there are just as many new abusers of prescription drugs as there are marijuana abusersamong teens (6).
- Among 12- to 17-year-olds, the gap between new marijuana users and new prescription drug users is shrinking (Fig. 4).

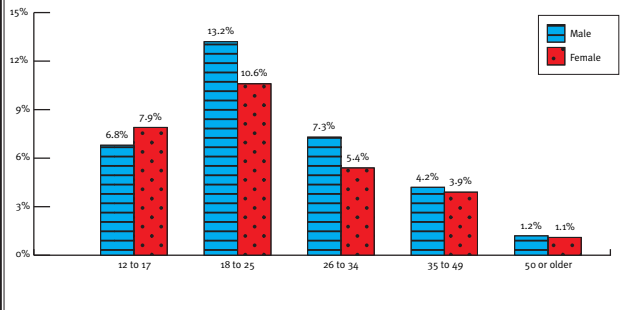


Fig. 3. *Percentages of past year nonmedical pain reliever use among persons aged 12 or older, by age group and gender: 2002-2005.*

- Between 2003 and 2005, the gap closed by 5.9%.
- In 2005, the estimated number of 12- to 17-year-olds who started using prescription drugs in the 12 months prior to the survey was 850,000, compared with 1,139,000 marijuana initiates.
- In 2003 the estimates were 913,000 for prescription drugs, compared to 1,219,000 marijuana initiates (6,7)
- Three percent, or 840,000, teens ages 12-17, reported current abuse of prescription drugs in 2005, making this illegal drug category the second most abused drug next to marijuana (7%) (6).
- In 2005, 2.1 million teens abused prescription drugs, almost one-third of prescription drugs abused in the country. Teens aged 12-17 have the second-highest annual rates of prescription drug abuse after young adults aged 18-25 (Fig. 5).
  - For young adults 18-25, past month nonmedical use of prescription-type drugs increased from 5.4% in 2002 to 6.3% in 2005, whereas, it decreased among the 12-17 age group (Fig. 5).
- Prescription drugs are the most commonly abused drug among 12- to 13-year-olds (6). Teens aged 12-17 and young adults aged 18-25 were more likely than older adults to start abusing prescription drugs in the past year (6).
- Teens (12-17) in western and southeastern states are more likely to abuse prescription pain relievers.
  - Arkansas (10.3%), Kentucky (9.8%), Montana (9.6%), Oregon (9.3%), Oklahoma (9.1%), Tennessee (8.9%), and West Virginia (8.9%).
- Teens are abusing prescription drugs because they

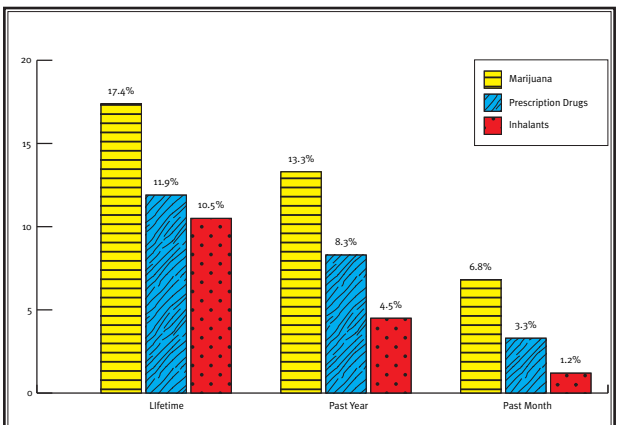


Fig.4. *Types of illicit drug use among teens aged 12-17 (percentage). Source: SAMHSA, 2005 National Survey on Drug Use and Health (Sept. 2006).*

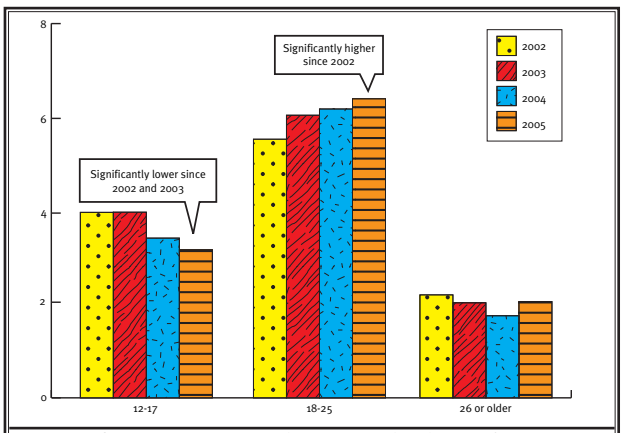


Fig. 5. *Current (past month) Nonmedical use of prescription drugs among various age groups (percentage). Source: SAMHSA, 2005 National Survey on Drug Use and Health (Sept. 2006).*

believe the myth that these drugs provide a medically safe high (51).

- Monitoring of the Future Study from the University of Michigan in 2006 (52) showed among 12th graders in the past year, marijuana was used by 31.5%, while a 2006 Partnership for a Drug America survey showed nearly 1 in 5 teens (19% or 4.5 million) report abusing prescription medications that were not prescribed to them (53).
- A dangerous trend is developing among the teens where they admit to abusing prescription medicine for reasons other than getting high, including to relieve pain or anxiety, to sleep better, to experiment, to help with concentration, or to increase alertness (54).
- Further, when teens abuse prescription drugs, they often characterize their use of the drugs as "responsible," "controlled," or "safe," with the perception that the prescription drugs are safer than street drugs (55).
- In addition, more than one-third of teens say the feel some pressure to abuse prescription drugs, and 9% say using prescription drugs to get high is an important part of fitting in with their friends.

♦ In its 17th Annual National Study of Teen Drug Abuse, the Partnership for a Drug-Free America reported that an alarming number of teenagers are abusing a variety of prescription and over-the-counter medications to get high and classified them as generation RX.

♦ Approximately 1 in 5 teenagers has abused a prescription painkiller to get high, and 1 in 11 has abused OTC products, like cough medicine.

- Figure 6 shows an emerging category of substance abuse: 18% of teens trying Vicodin, 10% OxyContin, and 10% Ritalin and Adderall. In contrast, crack cocaine was used by 9% and marijuana was used by 37%. Meth and ketamine were also used but to a lesser extent.
- Thus, 50% of teens tried psychotherapeutic drugs alone or in combination.

Epidemic of Medical Prescription Drug Abuse

Supply

In response to the alleged undertreatment of pain as a major health problem in the United States, numerous initiates were developed (3,4,25,30). Multiple patient advocacy groups, professional organizations, Federation of State Medical Boards and its constituent boards, and even DEA have fueled explosion in use of therapeutic opioids (4). Consequently, use of therapeutic opioids in the United States is responsible for over 80% of the global supply of all opioids and 99% of hydrocodone. In fact, sales of hydrocodone increased 198% from 1997 to 2005, whereas methadone usage increased 933% and oxycodone increased 588% (Table 1 and Fig. 7). Estimated number of prescriptions filled for controlled substances increased from 222 million in 1994 to 354 million in 2003.

Increasing Deaths

Paulozzi et al (16) reported unintentional drug poisoning morality rates increased on average 5.3% per year from 1979 to 1990 and 18.1% per year from 1990 to 2002 and at-

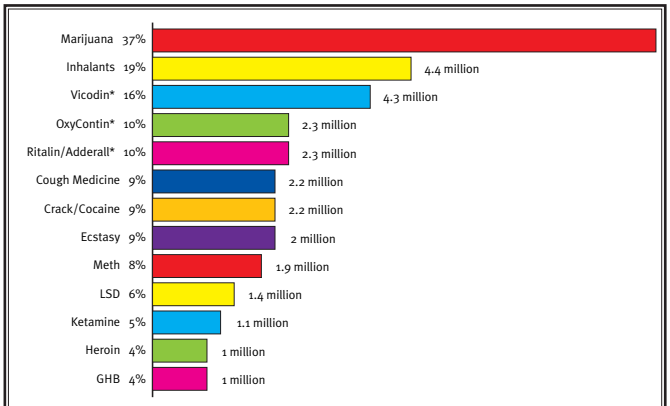


Fig. 6. *Generation Rx, emerging category of substance abuse among teens (percentage and number (in millions) of teens who have ever tried).*

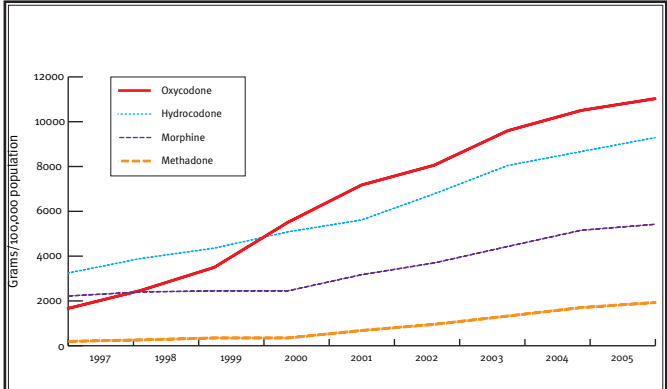


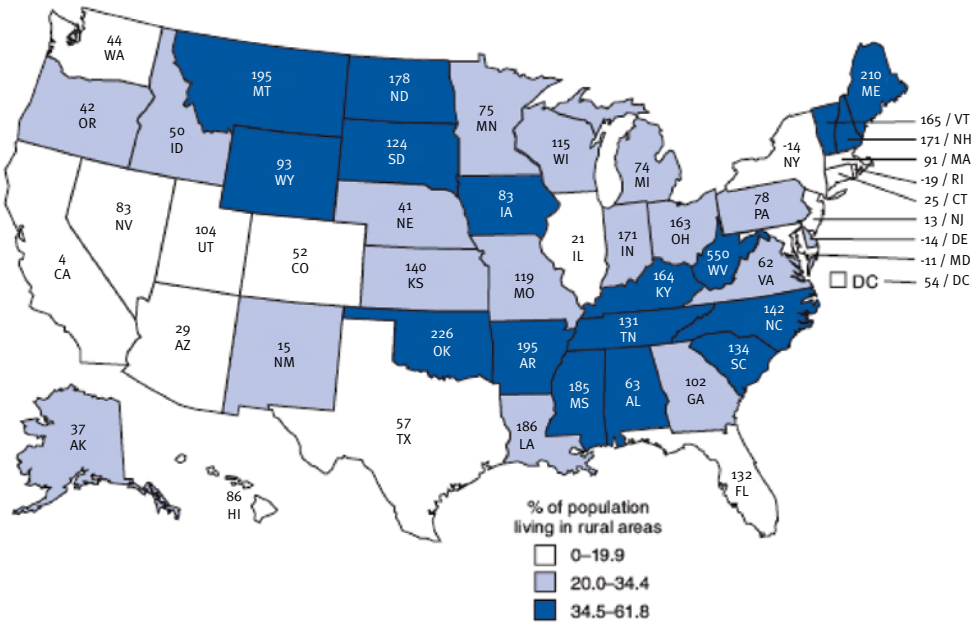
Fig. 7. *The increase in therapeutic opioids use in the United States (grams/100,000 population).*
Source: Based on data from US Drug Enforcement Administration. Automation of Reports and Consolidated Orders System (ARCOS); www.deadiversion.usdoj.gov/arcos/retail_drug_summary/index.html

tributed the rapid increase during the 1990s to narcotics and unspecified drugs. Between 1999 and 2002, the number of opioid analgesic poisonings on death certificates increased 91.2%, while heroin and cocaine poisonings increased 12.4% and 22.8%, respectively. By 2002, opioid analgesic poisoning was listed in 5,528 deaths – more than either heroin or cocaine. The increase in deaths generally matched the increase in sales for each type of opioid.

In a morbidity and mortality weekly report by Paulozzi in February 2007 (17), in 2004, unintentional drug poisoning was second only to motor-vehicle crashes as the cause of death from unintentional injury in the United States. The number of unintentional poisoning deaths increased from 12,186 in 1999 to 20,950 in 2004. The annual age-adjusted rate increased 62.5%, from 4.4 per 100,000 population in 1999 to 7.1 in 2004. The highest rates in 2004 were among persons aged 35-54 years, who accounted for 59.6% of all poisoning deaths. Rates also varied based on the states from 1999 to 2004, rates increased by less than one-third in the Northeast and West but more than doubled in the South and nearly doubled in the Midwest. States with the largest relative increase were West Virginia (550%), Oklahoma (226%), Maine (210%), Montana (195%), and Arkansas (195%). Increases of 100% or more occurred in 23 states (Fig. 8).

Fingerhut (19) from the Office of Analysis and Epidemiology evaluated methadone-related deaths from 1999 to 2004. She reported that the number of all poisoning deaths increased 54% to 30,308 over the 1999-2004 period, while the number of poisoning deaths mentioning methadone increased 390% to 3,849. Poisoning deaths mentioning methadone increased from 4% of all poisoning deaths to 13% of all poisoning deaths. Most recently, it was also shown that all poisoning deaths increased 6% from 2003 to 2004, whereas those mentioning methadone increased 29%. The absolute number of poisoning deaths mentioning methadone was less than the number of deaths mentioning heroin, cocaine or other opioids (Table 3). Age specific rates of methadone death were higher for persons aged 35-44 and 45-54 years than for those younger or older. The largest increase, however, was noted for young persons 15-24 years; the rate in 2004 was 11 times that in 1999.

Methadone-related unintentional poisoning deaths from 1999 to 2004 and ratio of deaths in 2004 to deaths in 1994 by state-by-state showed greater than ratio of 15 in West Virginia (24.8), Ohio (17.4),



* Age-adjusted rates per 100,000 population
† Defined as the percentage of the population living in census blocks below a certain population density, based on U.S. Census data for 2000.

Fig. 8. *Percentage change in unintentional poisoning mortality rates *by rural status of state † United States, 1999 - 2004 (17).*

Table 3. *Number of poisoning deaths in which specific narcotic substances are mentioned, 1999 to 2004.*

Substance	1999	2000	2001	2002	2003	2004	1999-2004	2003-2004
							Percent change	
Poisoning by narcotics and psychodysleptics, all	9,955	10,173	11,480	14,247	15,731	16,735	68.1	6.4
Opium	4	2	5	3	4	1	-75.0	-75.0
Heroin	1,964	1,846	1,782	2,091	2,080	1,881	-4.2	-9.6
Other opioids	2,757	2,932	3,484	4,431	4,877	5,242	90.1	7.5
Methadone	786	988	1,456	2,360	2,974	3,849	389.7	29.4
Other synthetic narcotics	732	784	962	1,301	1,406	1,668	127.9	18.6
Cocaine	3,832	3,565	3,840	4,612	5,212	5,461	42.5	4.8
Other narcotics	2,902	2,880	2,881	3,143	3,117	2,761	-4.9	-11.4
Cannabis	37	41	37	50	61	99	167.6	62.3
LSD	3	3	2	0	1	1	--66.7	0.0
Other	9	8	7	5	6	5	-44.4	-16.7

Note: Substance-specific data are not addictive because a death certificate could have multiple drugs listed.
Source: National Center for Health Statistics, National Vital Statistics System Ref. (19)

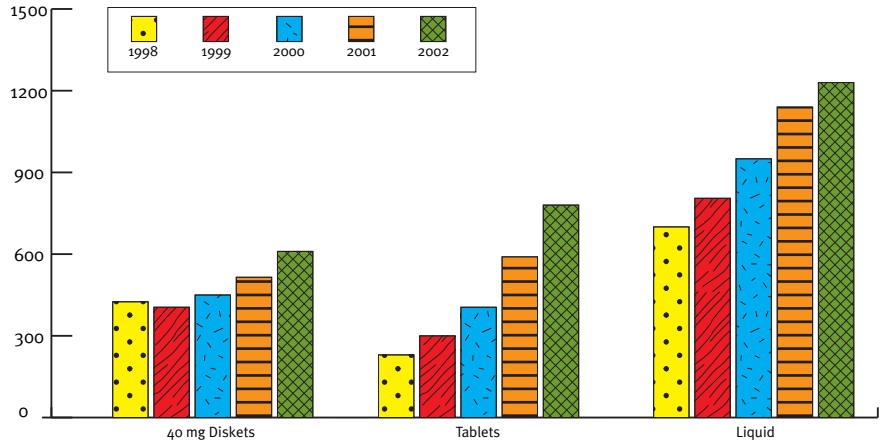


Fig. 9. *Methadone distribution by formulation (grams per 100,000 population)*
Source: Adapted from DEA ARCOS-2 data provided by June E. Howard, Methadone-associated mortality from a report of a national assessment.

Louisiana (16.0), Kentucky (15.1) and New Hampshire (14.5); whereas ratios between 10 and 14 were seen in Florida (13.8), Oregon (13.6), Pennsylvania (12.6), Tennessee (12.4), Wisconsin (10.5) and Maine (10.4).

As shown in Figure 9, the available data for methadone by formulation from 1998 to 2002, grams per 100,000 population, shows consumption of liquid has increased substantially and was higher than diskettes and tablets. However, for prescription availability, tablets are the only source for physicians and rarely liquid. Diskettes and liquids are prescribed by methadone clinics. Thus, the combined dispersion of diskettes and liquids was higher when compared to tablets. If this is combined with methadone tablet seizures, which increased 133% between 2001 and 2002, it appears that illegally obtained methadone and methadone

clinics have contributed more to methadone deaths than prescription methadone by physicians, contrary to popular opinion (18).

Emergency Department Visits

The Drug Abuse Warning Network (11) showed in 2005, there were 816,696 emergency department visits involving an illicit drug. Nonmedical use of pharmaceuticals contributed to 598,542 visits involving nonmedical use of prescription or over-the-counter pharmaceuticals or dietary supplements, with majority of these visits (55%) involving multiple drugs. Central nervous system agents (51%) and psychotherapeutic agents (46%) were the most frequent drugs reported in the nonmedical-use category of emergency department visits. Among the CNS agents the most frequent drugs were opiate/opioid analgesics (33%). Methadone, oxycodone, and hydrocodone were the most frequent opioids.

- Hydrocodone/combinations in 51,225 ED visits (CI: 37,416 to 65,033),
- Oxycodone/combinations in 42,810 ED visits (CI: 30,672 to 54,948), and
- Methadone in 41,216 ED visits (CI: 29,249 to 53,184).

Overall narcotic analgesic emergency department visits were 160,363 in 2005 compared to 42,857 in 1995. Among the psychotherapeutic agents, the anxiolytics (anti-anxiety agents, sedatives, and hypnotics) were the most frequent, occurring in 34% of visits associated with the nonmedical use of pharmaceuticals. DAWN estimated that 172,388 ED visits were associated with the nonmedical use of pharmaceuticals involving benzodiazepines in 2005, compared to 71,609 in 1995. Figure 10 illustrates emergency department visits resulting from narcotic analgesics and benzodiazepines from 1995 to 2005.

Is Pain Undertreated?

Considerable controversy exists about the use of opioids for the treatment of chronic pain of a non-cancer origin (30). Inadequate treatment of pain has been attributed to a lack of knowledge about pain and pain management options, inadequate understanding of addiction, or fears of investigation or sanction by Federal, State and local regulatory agencies. It has been alleged that pain is undertreated and it is a major problem in the United States. Consequently, multiple initiatives have been developed to address the alleged barriers responsible for the undertreatment of pain however, widely quoted literature pertains to pain management in terminal illness, malignancy, post operative pain, and AIDS. Thus far, there is no single, reliable objective report of the undertreatment of chronic, non-cancer pain.

The prevalence of pain also has been over-reported. The prevalence of chronic pain in the adult population ranges from 2% to 40%, with a median point prevalence of 15% (30). However, persistent pain was reported with an overall prevalence of 20% of primary care patients, with approximately 48% reporting back pain (56). Thus, chronic persistent pain may be much less than advocacy organizations report which is as high as 50-60% of Americans. It is stated

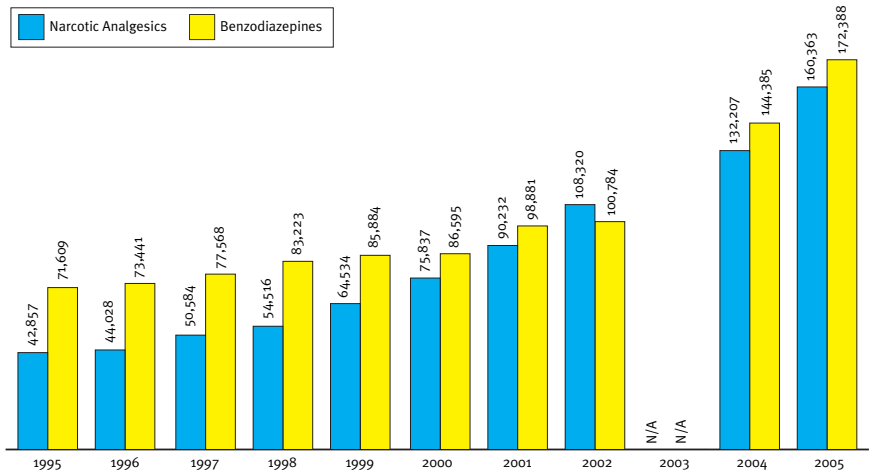


Fig. 10. *Drug abuse related emergency department visits involving narcotic analgesics and benzodiazepines (data from 2003 not available). Source: DAWN data (11-13).*

that alleged undertreatment and prevalence of pain has been expected to worsen as the population ages, with increasing rates of arthritis, cancer, back pain, and other conditions. Thus, both the undertreatment of pain and high prevalence of pain represent inflated statistics from patient self reports which are unreliable and may even indicate drug abuse rather than undertreatment.

Are Opioids Overprescribed?

As shown in Table 1 between 1997 and 2005 methadone prescriptions increased 933% whereas oxycodone prescriptions increased 588% compared to increase of hydrocodone prescriptions of 198%. Kuehn (3) wrote that in addition to an increased awareness of the importance of pain control, pain experts attribute the overall increases in prescription pain medication use to a variety of factors, including support and requirements for appropriate pain control from state medical boards and advances in the science of pain control. In spite of lingering concerns surrounding prescription pain medications, which are overblown, many physicians have become more comfortable using these drugs as they have learned more about them (3).

State and national organizations also are emphasizing the importance of managing pain. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued unproven, mandatory standards for pain management in January 2001. Many state health care licensing organizations have followed JCAHO. While these widely applied policies are meant only for acute pain and postoperative pain, they have been argued for application in all settings including chronic non-cancer pain.

In many states, medical, pharmacy, and nursing boards are issuing joint statements emphasizing the need to use these drugs in appropriate circumstances while taking steps to avoid abuse and diversion (3). The Federation of State Medical Boards has crafted a model policy, adopted by many states, regulating the use of controlled substances, which emphasizes adequate pain control and that physicians should periodically monitor patients to prevent abuse (3,57).

In pain management settings, as many as 90% of patients have been reported to receive opioids for chronic pain management (30,31). In addition to promotion of undertreatment, promotion of breakthrough pain will also increase or explode the use of opioids in managing chronic non-cancer pain (58).

Are Controlled Substances Abused by Chronic Pain Patients?

While opioids are by far the most abused drugs other controlled substances such as benzodiazepines, sedative-hypnotics, and central nervous system stimulants, though described as having less potential for abuse, are also of major concern. Multiple investigators (30-49,59,60) have shown a prevalence of drug abuse in 18% to 41% in patients receiving opioids for chronic pain. In a recent systematic review (49) of opioid treatment for chronic back pain, the prevalence of lifetime substance use disorders ranged from 36% to 56%, and the estimates of the prevalence of current substance use disorders were as high as 43%. Aberrant medication-taking behaviors ranged from 5% to 24%.

Are Illicit Drugs Used by Chronic Pain Patients?

It has been shown that patient's in chronic pain on prescription controlled substances also use illicit drugs. Prospective evaluations (34,43) have shown illicit drug use in 22% of the patients which reduced to 16% with enhanced adherence monitoring.

What Is the Evidence of Effectiveness?

Multiple reviews have been published to evaluate the effectiveness of opioid therapy in chronic pain (49,61-66). Short-term trials provide favorable results where treatment lasts for 32 weeks and moderate doses of opioids were administered with 180mg of morphine or morphine equivalent per day.

The real question, however, when embarking on a course of opioid treatment for chronic pain is whether analgesic efficacy is maintained over time (66). A review of the open-label follow-up studies has shown that 56% of patients abandon the treatment because of a lack of effectiveness or side effects (62). One meta-analysis directly comparing the effectiveness of efficacy of different opioids demonstrated a non-significant reduction in pain from baseline (66). In another systematic review (61) it was concluded that there was insufficient and poor evidence to prove the safety or effectiveness of any opioids. In another systematic review of effectiveness and safety (62), the mean decrease in pain intensity in most studies was at least 30% and only 44% of the patients continued treatment between 7 and 24 months. In an analysis of effectiveness and side effects (65), it was concluded that strong opioids were more effective with pain relief and functional outcomes, however, drop-out rates averaged 33%. Ballantyne and Mao (63) and Ballan-

tyne (66) concluded that a cautious approach must be used in using opioids.

A recent epidemiological study from Denmark (67), where opioids are prescribed liberally for chronic pain, demonstrated worse pain, higher healthcare utilization, and lower activity levels in opioid treated patients compared to a match cohort of chronic pain patients not using opioids, suggesting that even if some patients benefit, the overall population does not when opioids are prescribed liberally.

Overall the evidence supporting the long-term analgesic efficacy is weak based on the present evidence. Epidemiological studies are less positive with regards to function and quality of life and report failure of opioids to improve quality of life in chronic pain patients.

What Are Side Effects?

Common and well known side effects are related to nausea, sedation, euphoria or dysphoria, constipation, depression, and itching. However long-term opioid therapy results in hyperalgesia or increased pain, negative hormonal and immune effects, addiction and abuse.

Where Do These Drugs Come From?

Most of diversion of prescription drugs from their lawful purpose to illicit use can happen at any point from the pharmaceutical manufacturing to distribution and consumption by the intended lawful individual. The diversion of prescription drugs among adults is typically one or more of the following: doctor shopping, illegal Internet pharmacies, drug theft, prescription forgery, or illicit prescriptions by physicians.

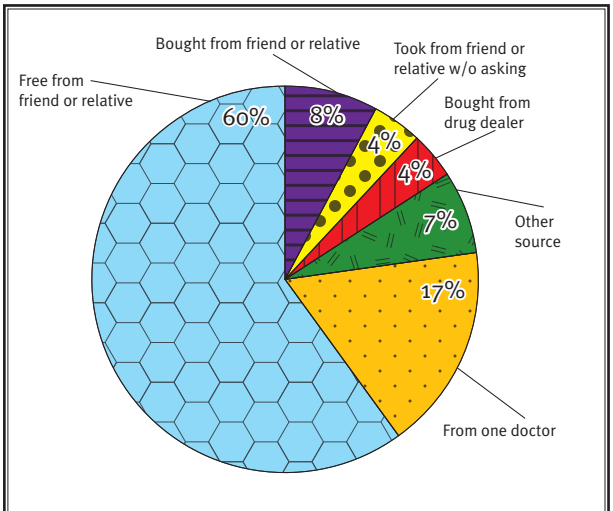


Fig. 11. *Source of pain relievers for most recent non-medical use among past year users. Source: Ref (6)*

In contrast, youths typically acquire drugs by stealing them from parents or relatives, buying them from classmates who are selling legitimate prescriptions, or buying them from illegal Internet pharmacies or vendors.

Based on a 2005 NSDUH survey (6), nearly 60% of non-medical prescription drug users say that they received the prescription drug from a friend or a relative for free (Fig. 11). This study also showed that other methods of acquiring prescription drugs for non-medical use include doctor shopping, traditional drug dealing, theft from pharmacies or homes, and illicitly acquiring the prescription drugs over the internet. Among these, 17% reported that they received it from one doctor, 8% reported that they bought from friend or relative, 7% from other sources, 4% took from a friend or relative without asking, with another 4% buying from a drug dealer.

Thus, approximately 77% to 89% obtained the drugs legally, most likely through a prescription. Consequently, providing a controlled substance prescription drug to a person who is not the intended recipient of the prescription, whether freely given, shared, or offered for sale, is not only dangerous but also illegal.

A report of National Drug Threat Assessment 2007 from the National Drug Intelligence Center US Department of Justice (29) concluded that the availability of diverted pharmaceutical drugs is high and increasing, fueled by increases in both the number of illegal online pharmacies and commercial disbursements within the legitimate pharmaceutical distribution chain. The rates of past year use for pharmaceuticals are stable even though at very high levels. The report also found that demand for prescription narcotics may decline as some users switch to heroin, particularly in areas where law enforcement efforts curb the diversion and availability of prescription drugs.

Doctor Shopping

Doctor shopping is one of the most common methods of obtaining prescription drugs for legal and illegal use (4). The majority of physicians perceive "doctor shopping" as the major mechanism of diversion (5). The persons practicing doctor shopping may be targeting physicians who readily dispense prescription without a thorough examination or screening (68-70). It has been reported that individuals may collect thousands of pills during a one-year period and sell on the street (70). Further, some individuals collect pills and give them to others to whom they perceive need the pills whereas some supplement Social Secu-

rity check income by selling part or all of their prescriptions (71).

Since 1999, illegal Internet pharmacies have provided a convenient alternative for individuals wishing to fill their prescriptions (25,27,72-76). In a June 2006 CASA report (27), the Internet was found as a growing source of drugs with increased prescription drug abuse. They also found that an emergent trend was "online consultation" whereas there were no controls blocking sale to children and substantial shipments were from within the United States. Table 4 illustrates Internet availability of controlled prescription drugs by class whereas Table 5 illustrates Internet sites advertising or selling controlled prescription drugs. The startling fact is that a staggering 89% of sites selling controlled prescription drugs have no prescription requirements, down slightly from 94% in 2004. However, the total number of sites selling drugs that do not require a prescription has increased each year with 147 in 2004 compared to 152 in 2005 and 165 in 2006. Of the 11% of the sites stating that they require a prescription, 70% only require that a prescription be faxed-allowing a customer to easily forge prescription or fax the same prescription to several Internet pharmacies. Table 6 illustrates Internet pharmacy prescription requirements.

Drug Theft

Drug theft is another problem which is on the rise, largely due to vast increases in prescription drug abuse and high street prices (55,75,77-83). In addition, prescription forgery is also fairly common, either by altering the prescriptions, stealing blank prescription pads in order to write fake prescriptions, or calling pharmacies for prescriptions without authorization from the physician.

Improper Prescribing and Sharing

Similarly improper prescribing and sharing among family and friends is also very common (Fig. 11). Diversion and abuse of methadone is a special issue (Fig. 9).

Thus, multiple causes and reasons leading to abuse include increasing supply and demand, advertising and advocacy availability, Internet availability, Internet sales, increasing street value, motivation for use, perceived safety, lack of perception of risks, lack of knowledge of prescription drug abuse liability, lack of knowledge about non-opioid techniques, lack of eduction, wasted efforts on war on drugs, non-evidence based practice guidelines, and finally incoherent and ineffective prescription drug monitoring programs.

Table 4. *Internet availability of controlled prescription drugs by class*

	2004	2005	2006
Benzodiazepines	92% (144)	146 (91%)	84% (155)
Opioids	66% (103)	74% (118)	68% (126)
Stimulants	30% (47)	21% (34)	8% (14)
Barbiturates	1% (2)	3% (4)	1% (2)
Total sites	157	160	185

Source: The National Center on Addiction and Substance Abuse. (27) www.casacolumbia.org/pdshopprov/files/you_ve_got_drugs.pdf

Table 5. *Internet sites advertising or selling controlled prescription drugs*

	2004	2005	2006
Sites selling drugs (anchor sites)	32% (157)	40% (160)	54% (185)
Sites advertising drugs (portal sites)	68% (338)	60% (242)	46% (159)
Total sites	498	402	344

Source: The National Center on Addiction and Substance Abuse. (27) www.casacolumbia.org/pdshopprov/files/you_ve_got_drugs.pdf

Table 6. *Internet pharmacy prescription requirements*

	2004	2005	2006
Sites not requiring prescription	94% (147)	95% (152)	89% (165)
No prescription needed	44%* (64)	36%* (55)	30%* (50)
Online consultation	52%* (77)	57%* (87)	60%* (99)
No mention of prescription	4%* (6)	7%* (10)	10%* (16)
Sites requiring prescription	6% (10)	5% (8)	11% (20)
Patient faces	70%# (7)	12%# (1)	70%# (14)
Patients mails	30%# (3)	63%# (5)	15%# (3)
Doctor contacted	0	25%# (2)	15%# (3)

*of sites not requiring prescription
# of sites requiring prescription

Source: The National Center on Addiction and Substance Abuse. (27) www.casacolumbia.org/pdshopprov/files/you_ve_got_drugs.pdf

National Drug Control Strategy

The White House Office of National Drug Control Policy (ONDCP), a component of the Executive Office of the President, was established by the Anti-drug Abuse Act of 1988. The principle purpose of ONDCP is to establish policies, priorities, and objectives of the nation's drug control program. The goals of the program are to reduce illicit drug use, manufacturing, trafficking, drug-related crime and violence, and drug-related health consequences. The national drug control strategy directs the nation's anti-drug efforts and establishes a program, a budget, and guidelines for cooperation among Federal, State and local entities.

The National Drug Control Strategies focus around 3 issues: 1) stopping use before it starts, 2) intervening and healing drug users, 3) disrupting the market. The budget for fiscal year 2007 was $13.128 billion, an increase of $0.129 billion over the FY 2006 enacted level of $12.999 billion (Fig. 12). For fiscal year 2008 the proposed budget totals $12.961 billion, which is a decrease of $0.167, or 1%. However, for fiscal year 2008 the administration is also separately requesting $266.1 million in additional spending for emergency designations associated with drug-related operations, principally in Afghanistan.

Stopping Use Before It Starts

The fiscal year 2008 budget includes federal resources totaling $1.6 billion or 12% (Fig. 13) supporting a variety of education and outreach programs aimed at preventing the initiation of drug use. The Department of Health and Human Services (HHS) contributes a 60% share of these resources ($937.4 million) to fund prevention activities through its Programs of Regional and National Significance. As shown in Figure 13, $17.9 million is spent on Student Drug Testing, $59.0 million is spent on Research-Based Grant assistance to local educational agencies, $100.0 million is spent on Safe and Drug-Free Schools and Communities State Grants, $90.0 million is spent on Drug-Free Communities through Office of National Drug Control Policy and $130.0 million is spent on National Anti-Drug Youth Media Campaign again through the Office of National Drug Control Policy.

Healing America's Users

The second item involves intervening and healing America's drug users with a budget of $3 billion or 29% (Fig. 14) in federal funds to drug abuse intervention and treatment efforts in the fiscal year 2008 representing an increase of nearly $100 million over fiscal year 2007 level. The majority of the budget of 82% ($2,498.4 million) goes to HHS which supports the majority of Federal Government's efforts to help drug users in need. Others include the Justice Department with $136.7 million or 5%, Veterans Administration $392 million or 13%, and others 15.7 million or 1%.

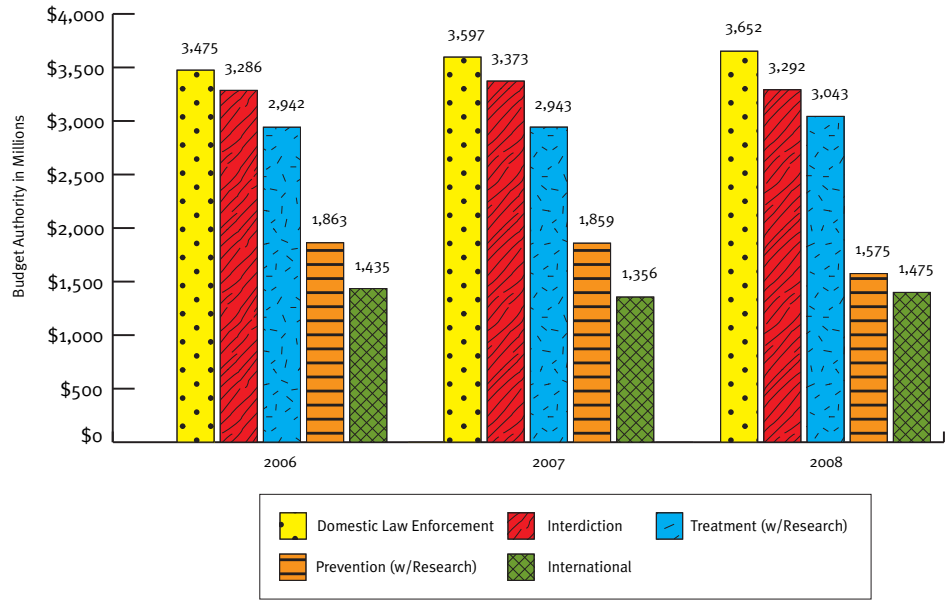


Fig. 12. *Drug resources by function.*

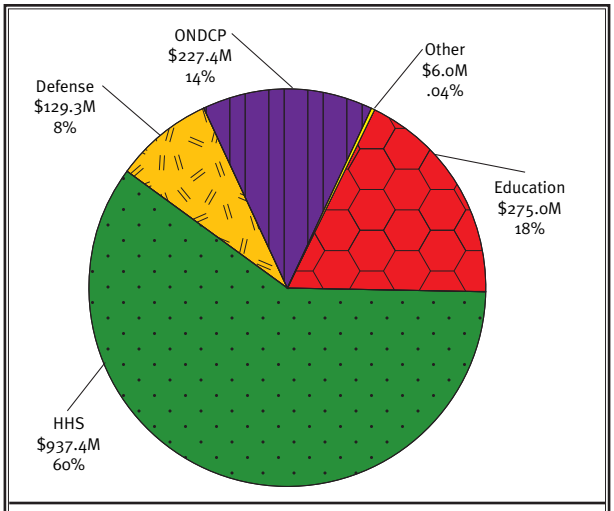


Fig. 13. *Stopping use before it starts ($1.6 billion).*

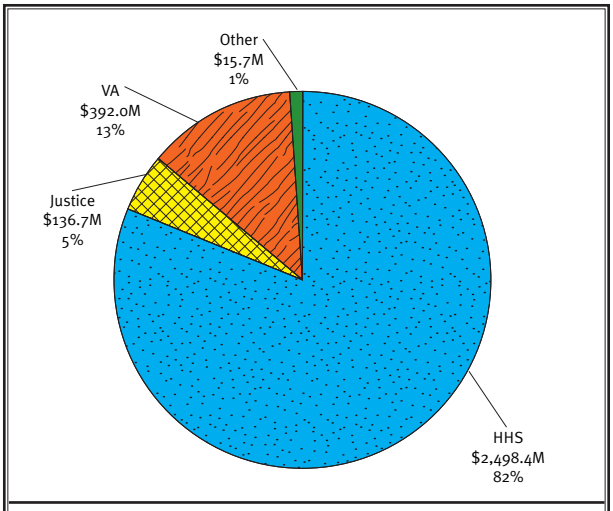


Fig. 14. *Healing America's Users ($3.0 billion).*

Disrupting the Market

The third activity of the National Drug Control Policy is composed of $8.3 billion or 63% of the National Drug Control Policy federal spending with 42% of this allocated to the Department of Homeland Security, 10% to Defense, 1% to Treasury, 13% to State, 32% to Justice and 3% to the ONDCP (Fig. 15).

Distribution of Funds

The total budget is approximately $13 billion, of which the Department of Defense receives approximately $936.8 million, the Department of Education receives $275 million, the Department of Health and Human Services receives $3,435.7 billion, $3,493.7 to the Department of Homeland Security, $2,797.0 billion to the Department of Justice, $473.4 million to the ONDCP, $1,096.8 billion to the Department of State, $2.7 million to the Department of Transportation, $57.3 million to the Department of Treasury, and $392 million to the Department of Veterans Affairs.

The Department of Defense, with a budget of $936.822, is the lead federal agency in efforts to detect and monitor the aerial and maritime transit of illegal drugs towards the United States. Defense also collects, analyzes, and disseminates intelligence on drug activity; provides training for US and foreign drug law enforcement agencies and foreign military forces with drug enforcement responsibility; and, approves and funds Governor's State Plans for National Guard use, when not in federal service, to support drug interdiction and other counter-narcotics activities, as authorized by state laws.

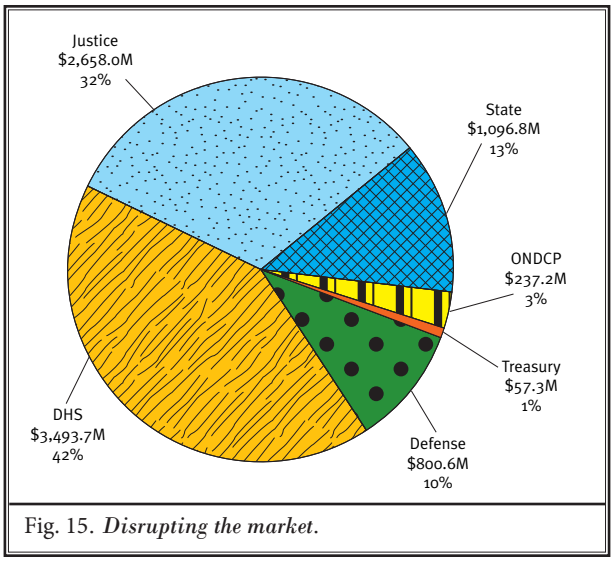


Fig. 15. *Disrupting the market.*

The Department of Education, with a budget of $275 million, administers programs to help ensure that all students can meet challenging standards and improve elementary and secondary education, including: special eduction and early intervention programs for children with disabilities; English language acquisition for limited English proficient and immigrant children; career, technical, and adult education; and higher eduction. Further, the Department of Education also carries out research, data collection, and civil rights enforcement activities.

For the Department of Health and Human Services, a large portion of the funding on federal drug control includes $75 million for Centers for Medicare and

Medicaid Services, $1,000.365 million for the National Institute on Drug Abuse and a large portion to the Substance Abuse And Mental Health Services Administration (SAMHSA) with $2,360.361 million in fiscal year 2008. SAMHSA requested a total of $2,360.4 million for drug control activities, which is a reduction of $82.1 million from 2007 level. The resources of SAMHSA are directed to activities that have demonstrated improved health outcomes and increased capacity and terminations or reduce less effective or redundant activities. SAMHSA has four major drug-related decision units: Substance Abuse Prevention Programs of Regional and National Significance (PRNS), Substance Abuse Treatment PRNS, the Substance Abuse Treatment Prevention and Treatment Block Grant, and Program Management.

The Department of Homeland Security, with various departments including Customs and Border Protection, with a budget of $1,970.345 billion, immigration and customs enforcement with a budget of $450.198 million, and the United States Coast Guard with a budget of $1,073.193.

The Department of Justice includes the Bureau of Prisons with $67.156 million, the Drug Enforcement Administration with a budget of $2,041.818 million and the Interagency Crime and Drug Enforcement with a budget of $509.154 million, and the Office of Justice program $178.869 million.

The Office of National Control Policy with Counterdrug Technology Assessment Center has a budget of $5 million. The High Intensity Drug Trafficking Areas has a budget of $220.0 million and other federal drug control programs have a budget of $224.485 million.

Prevention Of Prescription Drug Abuse

Multiple actions taken to prevent or address theprescription drug abuse epidemic include the activities of Drug Enforcement Agency (DEA), prescription drug monitoring programs, multiple state regulations, education of all concerned, Synthetic Drug Control Strategy, the Food and Drug Administration's ability to classify and approve drugs, various prevention and treatment efforts, and proposed changes to controlled substance formulations.

DEA

In 2005, Congress emphasized its concern regarding the diversion of controlled pharmaceuticals (84). The House report on the Justice Department's fiscal year 2005 appropriations stated . . . "DEA has demonstrated a lack of effort to address this problem." Consequently the DEA increased the amount of resources and manpower dedicated to investigating the diversion of controlled pharmaceuticals (78). However, in a July 2006 Justice Department OIG's report, it was shown that while the DEA has taken important steps to improve its ability to control the diversion of controlled pharmaceuticals, especially pharmaceutical diversion using the internet, several shortcomings in the DEA's diversion control efforts that were identified and reported in 2002 still exist (84).

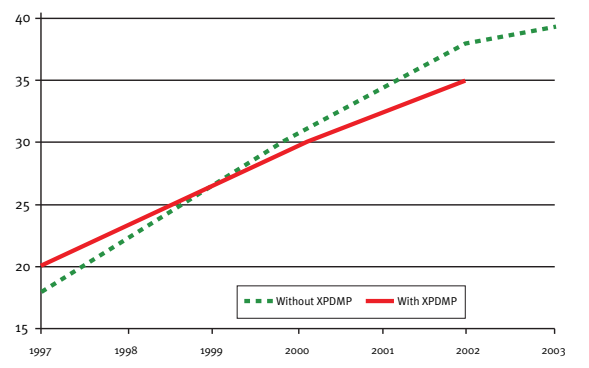


Fig. 16. *Pain reliever admissions in XPDMP states. Source: Ref (86).*

NASPER

The second major weapon against prescription drug abuse is the National All Schedules Prescription Electronic Reporting (NASPER) Act, signed into law on August 11, 2005 (25). It authorized the spending of $60 million from fiscal year 2006 to 2010 to create federal grants at the US Department of Health and Human Services to help establish or improve state-run prescription drug monitoring programs. Unfortunately NASPER has not moved as no funding has been committed either in 2006 or in 2007, in addition, there is no proposed funding in 2008.

DOJ PDMPs

The NASPER has been afflicted by the DEA and Harold Rogers sponsored, state monitoring programs that were initiated by the Department of Justice (DOJ) in 2003 to promote the development of prescription drug monitoring programs (PDMPs) by states. That commitment continues as part of the administration's National Drug Control Strategy for 2008, though incoherent and largely ineffective. PDMPs have the poten-

tial to help cut down on prescription fraud and doctor shopping by giving physicians and pharmacists more complete information about a patient's prescriptions for controlled substances as a goal. However, while these state programs have been useful, predominantly for law enforcement, their numerous deficiencies have not been corrected.

A recent evaluation (85) showed a modest 10% decrease in prescription drug use on a per capita basis (Fig. 16). Historically, from 1940 to 1999, states have been able to establish only 15 functioning programs. The number of states with prescription drug monitoring programs has grown only slightly over the past decade from 10 in 1992 to 15 in 2002 and 27 in 2006 (Table 7). With increased funding and resources, these programs have been able to improve the statistics of the DEA, however, have been a major failure in providing assistance to the prevention of drug abuse, educating physicians, or preventing doctor shopping and drug diversion. The fundamental flaw with these programs is that they are created to help law enforcement identify and prevent prescription drug diversion after the fact. The secondary objective of this program, to educate and provide information to physicians, pharmacies and the public has been neglected. Very few programs are proactive to the extent that physicians can access the necessary information to reduce or prevent abuse and diversion. Program design is highly variable across the states. Eighteen of the 27 state programs monitor Schedule IV drugs and 20 of the 27 monitor Schedule III drugs which are the subject of major controlled substance abuse. Of all the available programs, only 3 programs are physician friendly and work proactively.

Synthetic Drug Control Strategy

Among the proposed mechanisms to reduce prescription drug abuse, the Synthetic Drug Control Strategy has taken center stage for the Administration (86). The Administration touts that the Synthetic Drug Control Strategy aims to reduce prescription drug abuse in America by 15% over 3 years from 2005 to 2008. The Synthetic Drug Control Strategy seeks to address each specific method of diversion including doctor shopping or other prescription fraud, shipping illegal prescriptions from online pharmacies, over-prescribing, theft and burglary, selling pills to others, receiving pills at little or no cost from friends or family.

The illicit diversion and theft of pharmaceuticals-currently at very high levels nationally, from legitimate supplies has been curbed somewhat in some areas, such as Kentucky, Michigan, Nevada, and Utah, through education, sustained law enforcement pressure, reduced access in pharmacies and the implementation of prescription monitoring programs in 3 of the 4 states with proactive physician-friendly programs (29).

In addition, part of the Synthetic Drug Control Strategy includes changing controlled substance formulations. The use of newer pharmaceutical technology can help combat the problem of prescription drug abuse by using chemical advances to develop a tamper resistant capsule that provides long-acting effective pain relief when used properly, while also resisting degradations under conditions of abuse (87). Two new pain medications or formulations were developed; however, the issues related to the usefulness of new formulations is the cost of development and the ability to purchase these drugs in the market and coverage by insurers.

NIDA Strategies

National Institute on Drug Abuse (NIDA) (88) has orchestrated a multi-pronged strategy intending to complement and expand the portfolio of basic, preclinical, and clinical research aimed at better understanding prescription drug abuse. Consequently, the NIDA started an initiative on prescription opioid use and abuse in the "treatment of pain," which encourages a multidisciplinary approach using both human and animal studies from across the sciences to examine factors (including pain itself) that predispose or protect again opioid abuse and addiction. Particularly important, NIDA believes, is to assess how genetic influence affects the vulnerability of an individual exposed to pain medication to become addicted. In fact, the NIDA has conducted a seminar on prescription drug abuse, inviting predominantly supporters of opioids, without a balanced presentation, and the next day, released a program on addiction management rather than control of psychotherapeutic substance abuse.

The National Institute on Drug Abuse (26) published a study revealing a new cellular adaptation which contributes to opioid tolerance, another study testing URB597 which relieves pain in rats without cannabinoid-associated side effects, and the use of antidepressants in managing pain. While these are noble investigations and scientific advances that may help some day, in today's environment it will take years to achieve any benefit from this research.

Thus, this entire strategy has been suboptimal for the past 3 years at an expense of $38.77 billion for

Table 7. The Bureau of Justice Assistance Prescription Drug Monitoring programs at a glance

State	Agency Housing the PDMP	Schedules of Drugs Monitored	Federal Award Amounts		
			FY03	FY04	FY05
Alabama	Department of Public Health	II, III, IV, V	$300,000	$350,000	$350,000
Arizona	Board of Pharmacy	**			$50,000
California	Department of Justice, Bureau of Narcotic Enforcement	II,III	$297,745		$350,000
Colorado	Department of Regulatory Agencies	II, III, IV, V		$50,000	
Connecticut	Department of Consumer Protection	**		$50,000	
Florida	Florida Office of Drug Control	**	$300,000		
Hawaii	Hawaii Department of Public Safety	II, III, IV, V		$349,350	$349,954
Idaho	Board of Pharmacy	II, III, IV	$97,320		
Illinois	Department of Health and Human Services	II			$349,994
Indiana	Indiana Professional Licensing Agency	II, III, IV, V		$281,876	$216,796
Iowa	Department of Public Health	**		$350,000	$292,963
Kansas	Board of Pharmacy	**		$50,000	
Kentucky	Cabinet for Health & Family Services, Office of the Inspector General	II, III, IV, V		$350,000	$350,000
Louisiana	Board of Pharmacy	**			$50,000
Maine	Office of Substance Abuse	II, III, IV	$300,000	$109,650	$339,164
Massachusetts	Massachusetts Department of Public Health	II		$350,000	$350,000
Michigan	Bureau of Health Professions	II, III, IV, V			$350,000
Mississippi	Board of Pharmacy	II, III, IV, V		$349,915	$350,000
Missouri	Department of Health and Senior Services	**			$350,000
Nevada	Board of Pharmacy	II, III, IV	$149,474	$344,581	$340,298
New Hampshire	Department of Justice	**			$49,836
New Jersey	Department of Law and Public Safety	**		$350,000	
New Mexico	Board of Pharmacy	II, III, IV	$245,650		
New York	New York Bureau of Narcotic Enforcement	II, III, IV, V	$300,000	$350,000	$350,000
North Carolina	Department of Health and Human Services	II, III, IV, V		$50,000	
Ohio	Board of Pharmacy	II, III, IV, V			$350,000
Oklahoma	Bureau of Narcotics and Dangerous Drugs	II		$350,000	$350,000
Oregon	Board of Pharmacy	**		$350,000	
Pennsylvania	Office of Attorney General	II		$350,000	
Rhode Island	Board of Pharmacy	II, III			
South Carolina	Department of Health and Environmental Control	**		$350,000	
Tennessee	Board of Pharmacy	II, III, IV, V		$50,000	$350,000
Texas	Department of Public Safety	II			
Utah	Department of Commerce, Division of Occupational & Provisional Licensing	II, III, IV, V			
Vermont	Department of Health	**			$350,000
Virginia	Board of Pharmacy	II		$82,300	$350,000
Washington	Disciplinary Board	Determined by disciplinary authority		$50,000	
West Virginia	Board of Pharmacy	II, III, IV		$350,000	$124,459
Wyoming	Board of Pharmacy	II, III, IV	$214,529		

***These states do not currently have legislation or regulation to establish a PDMP in place.*
Source: Ref (86)

2005-2006 and 2007 with a proposed expenditure of 12.961 billion for 2008. The failure of this strategy is illustrated by the staggering statistics of drug abuse, misuse, illicit drug use, emergency department visits, and deaths in face of escalating costs.

Education

Education is lacking at all levels primarily for physicians, pharmacists, and the public at large (5,89) and compounded by misinformation. Of 979 physicians surveyed regarding the diversion and abuse of controlled prescription drugs showed the following (5):

Physicians

- Physicians perceive the 3 main mechanisms of diversion to be:
  - Doctor shopping (when patients obtain controlled drugs from multiple doctors) (96%)
  - Patient deception or manipulation of doctors (88%)
  - Forged or altered prescriptions (69%).
- 59% believe that patients account for the bulk of the diversion problem.
- 47% said that patients often try to pressure them into prescribing a controlled drug.
- Only 19% of surveyed physicians received any medical school training in identifying prescription drug diversion.
- Only 40% of surveyed physicians received any training in medical school in identifying prescription drug abuse and addiction.
- 43% of physicians do not ask about prescription drug abuse when taking a patient's health history.
- One-third of physicians do not regularly call or obtain records from the patient's previous (or other treating) physician before prescribing controlled drugs on a long-term basis. HIPAA regulations have made this step much more difficult.
- 74% have refrained from prescribing controlled drugs during the past 12 months because of concern that a patient might become addicted to them.

In a recent study (89) based on questionnaire responses from 248 primary care physicians, published results showed that the most common concerns about prescribing opioids for chronic pain were prescription drug abuse and addiction. Other concerns included: adverse effects, tolerance, interaction with other medications, not knowing enough about which narcotic to prescribe, not knowing enough about dosage requirements, and having partners who prefer not to use opioids for treating chronic pain. The majority of the physicians were comfortable in prescribing narcotics to someone with terminal cancer but less confident in prescribing for patients with back pain. They were even less comfortable with prescribing narcotics to patients with a past history of drug or alcohol abuse. The survey also noted that only a small percentage of physicians are conducting urine toxicology screens on their patients either before or during opioid therapy, and that this was dependent on whether or not they had a system to track patients on opioids.

In two prospective evaluations of 500 patients in each study (34,43) with enhanced monitoring, it was shown that overall prescription controlled drug abuse reduced from 18% to 9%; whereas illicit drug use reduced from 22% to 16%. Significant decreases were observed in Medicaid patients.

Van Rooyan (90) described physician education as follows:

- The majority of physicians do not know that the long-term safety and effectiveness of opioids for management of non-malignant pain have *not* been substantiated.
- The majority of physicians do not know that patients seeking pain relief for chronic, non-malignant pain often have underlying psycho-social problems and need psychological or rehabilitation services or would respond well to other non-drug interventions.
- In busy medical practices, particularly primary care and family practice office settings, often, pain therapy is based not on science, but on intuition or hearsay, and ends up aggravating rather than ameliorating prescription pain medication abuse and addiction.
- Expansion of opioid therapy for patients who might benefit more from non-drug interventions or alternate drugs, without consideration of the accompanying risks of opioids, is based on pharmaceutical promotion.

Pharmacists fear of being labeled opiophobic by opioid and advocacy lobby.

The CASA survey (5) of 1,303 pharmacists regarding diversion and abuse of controlled prescription drugs showed the following:

- When a patient presents a prescription for a controlled drug:
  - 78% of pharmacists become "somewhat or very" concerned about diversion or abuse when a patient asks for a controlled drug by its brand name;
  - 27% "somewhat or very often" think it is for purposes of diversion or abuse.

- 52% believe that patients account for the bulk of the diversion problem.
- Only about half of the pharmacists surveyed received any training in identifying prescription drug diversion (48%) or abuse or addiction (50%) since pharmacy school.
- 61% do not regularly ask if the patient is taking any other controlled drugs when dispensing a controlled medication; 25.8% rarely or never do so.
- 29% have experienced a theft or robbery of controlled drugs at their pharmacy within the last 5 years; 20.9% do not stock certain controlled drugs in order to prevent diversion.
- 25% do not regularly validate the prescribing physician's DEA number when dispensing controlled drugs; 1 in 10 (10.5%) rarely or never do so.
- 83% have refused to dispense a controlled drug in the past year because of suspicions of diversion or abuse.

Pharmacists may be involved in prescription drug diversion, first by selling the controlled substances and then, using their database of physicians and patients to write and forge prescriptions to cover their illegal sale.

Patients

Patients also have many concerns about the lack of eduction. The problem list is long and extensive. A non-inclusive list is a follows:

- Undertreatment of pain.
- All patients are under suspicion.
- The interest in receiving opioids for chronic pain, fueled by advertising by pharmaceutical companies.
- Unproven, misunderstood regulations of JCAHO and other organizations mandating monitoring and appropriate treatment of pain.
- Media coverage of undertreatment of pain.
- Numerous organizations providing advocacy guidelines and standards.
- Patient advocacy groups advising them to demand more opioids.
- Very little or no effort on educating the public about non-opioid management.
- Access to Internet and a daily bombardment of the easy availability of drugs.
- Patient beliefs that they have the right to total pain relief.
- The lack of interest on behalf of the patients to understand deleterious effects of opioids and benefits of non-opioid techniques.

Solutions to Drug Abuse Epidemic

A revised national drug control strategy with a 3-pronged approach is essential in combating the epidemic of prescription drug abuse with immediate implementation of NASPER with enhancements; widespread educational programs for physicians, pharmacists, and the general public emphasizing the deleterious effects of controlled substance use and abuse; and implementation of Synthetic Drug Control Strategy along with multiple other programs.

NASPER

The National All Schedules Prescription Electronic Reporting (NASPER) Act of 2005 is a law that provides for the establishment of a controlled substance monitoring program in each state, with communication between state programs (25). The concept for the NASPER was provided by the American Society of Interventional Pain Physicians (ASIPP) whose members and leadership saw such a need for the information exchange program. NASPER was formulator with 3 important goals including:

1) Physicians' and pharmacists' access to monitoring programs
2) Monitoring of Schedule II to IV drugs
3) Information sharing across state lines

Consequently, the purpose of NASPER is to: 1) foster the establishment of state-administered controlled substance monitoring systems in order to ensure that healthcare providers have timely access to accurate prescription history information for use in the early identification of patients at risk of addiction or diversion in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and (2) Establish, based on the experience of existing state-controlled substance monitoring programs, a set of best practices to guide the establishment of new state programs and the improvement of existing programs. NASPER is modeled after a highly successful states monitoring program in Kentucky (Kentucky All Schedules Prescription Electronic Reporting Action - KASPER). In fact, the US Government Accountability Office (GAO) conducted a study on state monitoring programs of prescription drugs (91). They concluded that state monitoring programs provide a useful tool to reduce diversion while most state programs have their major goal to assist law enforcement in identifying and preventing prescription drug diversion. State programs may include educational objectives to pro-

vide information to physicians, pharmacies, and the public. The programs are highly variable not only with monitoring of scheduled substances but with regulations and finally access to providers which is only available in 4 states – Utah, Nevada, Kentucky and Idaho. Thus, only a few programs operate proactively, while most operate reactively. A few states routinely analyze prescription data collected by PDMPs to identify individuals, physicians, or pharmacies that have unusual use, prescribing, or dispensing patterns that may suggest potential drug diversion, abuse, or doctor shopping. However, only three states provide this information proactively to physicians.

The GAO report (91) cited many advantages, as well as disadvantages of these programs. States with PDMPs experience considerable reductions in the time and effort required by law enforcement and regulatory investigators to explore leads and the merits of possible drug diversion cases. However, while the presence of a PDMP may help one state reduce its illegal drug diversion, diversion activities may actually increase in contiguous states without PDMPs. All 3 of the states providing access to physicians – Kentucky, Nevada, and Utah – help reduce the unwarranted prescribing and subsequent diversion of abused drugs in their states. In both Kentucky and Nevada, an increasing number of PDMPs reports are being used by physicians to check the prescription drug utilization history of current and prospective patients to determine whether it is necessary to prescribe certain drugs that are subject to abuse. As expected, most of the reports were requested by prescribers with 87%, followed by law enforcement 6%, pharmacists 4%, life insurer boards 2%, by subpoena, ARNPs, and court orders with 1% or less each (Fig. 17).

In fact, prospective evaluations (34,43) in interventional pain management settings have shown a significant reduction in drug abuse and illicit drug use in chronic pain patients when appropriately monitored and educated (Table 8). The reductions were seen across all patient groups, specifically Medicaid patients.

Further, an evaluation of prescription drug monitoring programs performed on September 1, 2006 (86) showed that PDMPs reduce the per capita supply of prescription pain relievers and stimulants and in so doing reduce the probability of abuse of these drugs. Evidence also suggested that states which are proactive in the approach to regulation are more effective in reducing the per capita supply of prescription pain relievers and stimulants than states which are reactive in their approach to regulation.

The illicit diversion and theft of pharmaceuticals-currently at very high levels nationally, from legitimate supplies have been curbed somewhat in some areas, such as Kentucky, Michigan, Nevada, and Utah, through education, sustained law enforcement pressure, reduced access in pharmacies, and the implementation of prescription monitoring programs, in 3 of the 4 states with proactive physician friendly programs (29).

In conclusion, prescription monitoring programs are effective specifically when they are proactive. Thus, a national program with communication among the states that is also proactive assisting physicians to prevent abuse of drugs in conjunction with education

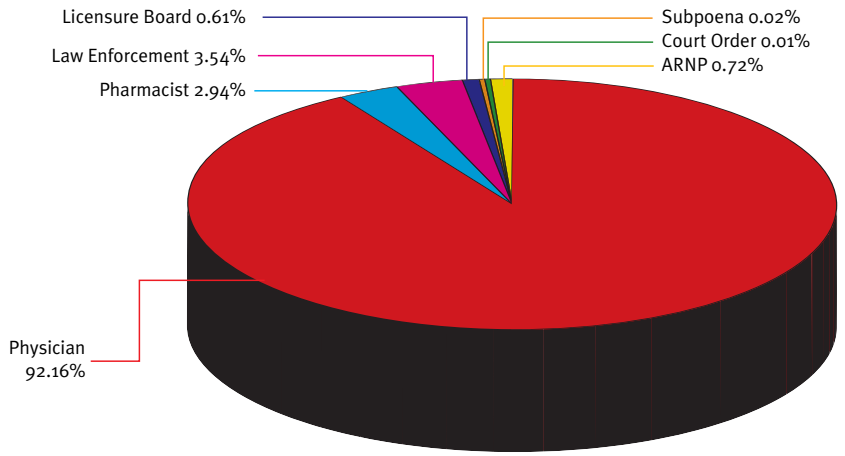


Fig. 17. *KASPER report requests 2005.*

Table 8. *Comparative evaluation of illicit drug use*

	Third party		Medicare w/wo third party		Medicare & Medicaid		Medicaid		Total	
	Present study (192)	Previous study (100)	Present study (154)	Previous study (100)	Present study (85)	Previous study (100)	Present study (69)	Previous study (100)	Present study (500)	Previous study (400)
Marijuana	14%* (26)	11% (11)	5% (7)	8% (8)	12%* (10)	20% (20)	16%*# (11)	34% (34)	11% # (54)	18% (73)
95% CI	9% - 12%	5% - 17%	2% - 9%	3% - 11%	5% - 21%	12% - 28%	8% - 27%	25% - 43%	8% - 14%	14% - 22%
Cocaine	6%* (11)	7% (7)	1% (2)	4% (4)	8%* (7)	6% (6)	6% (4)	8% (8)	5% (24)	6% (25)
95% CI	2% - 10%	2% - 12%	0% - 5%	0% - 8%	3% - 16%	1% - 11%	1% -15%	3% - 13%	3% - 7%	4% - 9%
Methamphetamine/ Amphetamines	4% (8)	3% (3)	1% (1)	2% (2)	1% (1)	4% (4)	1% (2)	3% (3)	2% (11)	3% (12)
95% CI	1% - 8%	0% - 6%	0% - 4%	0% - 5%	0% - 6%	0% - 8%	0% - 8%	0% - 6%	1% -4%	1% - 5%
Total Abuse	20%* (38)	17% (17)	6% (9)	10% (10)	21%* (18)	24% (24)	22%*# (15)	39% (39)	16% # (80)	22% (90)
95% CI	14% - 26%	10% - 24%	2% - 11%	4% - 6%	13% - 31%	16% - 32%	12% - 33%	29% - 49%	13% - 20%	18% - 27%

( ) Number of patients
* Indicates significant difference with Medicare with or without third party insurance
# Indicates significant difference with previous study (within the same insurance group)
Reproduced with permission from: Manchikanti et al (34, 43).

will probably reduce per capita prescription controlled substance use and abuse by 20%.

Enhanced NASPER should also include prescription controlled drug committees at State Health and Human Services Departments, Boards of Medical Licensures, and local Drug Enforcement Agencies. Further, each committees should be represented by at least one or more of interventional pain physicians well versed with opioid abuse.

Thus, funding and implementation of NASPER is a fundamental requirement for controlling the prescription drug abuse epidemic.

Education

Education is required at all levels including physicians, pharmacists, and public. Education is important to understand the functions and the role of the DEA, the functions and role of monitoring programs, the appropriate prescription of opioids, deleterious effects of opioid use and abuse, and the management of chronic pain with non-opioid techniques.

Physicians

Surveys have shown that less than 40% of physicians have received any training in medical school in identifying prescription drug abuse or drug diversion. The ONDCP as planned should organize several events to facilitate the dissemination of pain and addiction information to the general medical community (85). Representatives of the medical and pharmaceutical communities should be called together to develop concerted and effective strategy of change to address this public health problem. This should encourage medical professionals, pharmacists, and pharmaceutical companies to take a leading role in educating physicians and patients as to the importance of retaining control of prescription medications with abuse liability. The educational efforts should reach not only the people who are preaching to the community, resulting in increases in drug abuse, but also to all the physicians in every corner of the United States, specifically persons with balanced approach.

Consequently, controlled substance education must be mandated in medical schools, residency training programs, and supported by continuing education each year, variable from 20 hours in the first year and 10 hours in subsequent years. The training must be accredited and approved and may be monitored mainly by the DEA or state boards of medical licensures. Finally, a separate residency program is needed and must

be instituted in the near future in interventional pain management, which will not only train the physicians about comprehensive programs and other modalities of treatments than narcotics, but also will provide appropriate safety training and guidelines. In addition, an ABMS-approved specialty board certification for interventional pain management will facilitate long-term solutions to the problems of escalating use of controlled substance use and abuse.

Pharmacists

Controlled substance education must be mandated in pharmacy schools and training programs, which also should be supported by continuing education each year, variable from 20 hours in the first year and 10 hours in subsequent years. The training must be accredited and approved and may be monitored mainly by the DEA or State Boards of Pharmacy.

Education for pharmacists is also extremely crucial. Based on the CASA survey (5), only 50% of pharmacists receive any training in identifying prescription drug diversion, abuse, or addiction.

Public

The most important aspect of the training is for the public. The public must be educated on non-opiate techniques of chronic pain management. In addition, the public should be educated about the overall ineffectiveness of opioid use, prevalence of misuse and adverse effects, even if used properly. Further, public education should include youth and family education, prevention strategies specific for people with access to controlled prescription drugs with media campaigns, community coalitions, drug-free America, prescription drug tracking, prevention and intervention by biometric identification at various levels, students and employees, etc.; screening, brief intervention, referral and treatment.

Synthetic Drug Control Strategy and Coordination

Finally, the third prong relates to synthetic drug control strategy and coordination of efforts by agencies. There are more than 10 federal agencies and approximately 5 to 6 agencies in each state, followed by local agencies attempting to curb the drug epidemic. Each organization functions in its own way coupling or tripling the efforts and sometimes interfering with each other.

In summary, Congress and the Administration must proceed in a direction which is not only effective but well coordinated without hindering access. These efforts include the understanding of the monitoring programs, education, a proactive DEA, elimination of Internet pharmacies, development of abuse resistant prescriptions, monitoring of methadone clinics, improved labeling, and evidence-based prescribing guidelines. The major efforts should be directed to uncontrolled methadone clinics, limiting them to treat and manage only heroin addicts, with an emphasis on prevention addiction by substituting high dose methadone for low dose hydrocodone with the addition of reporting requirements. The next step is addiction management and availability of these treatment modalities on an outpatient basis to as many patients as possible such as wide spread training for buprenorphine administration.

The federal government must take a lead in preventing this epidemic by useful and effective programs rather than ineffective and incoordinated programs.

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