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An Invited Review

Evolution of The National All Schedules Prescription Electronic Reporting Act (NASPER): A Public Law for Balancing Treatment of Pain and Drug Abuse and Diversion

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In the United States, physicians are faced with two opposing dilemmas in the treatment of pain – the potential for drug abuse and diversion, and the possible undertreatment of pain. While controlled prescription drugs such as narcotic analgesics, anxiolytics, antidepressants, stimulants, and sedative-hypnotics, play a legitimate role in managing chronic pain and other conditions, the illicit use of prescribed medicines is increasing at epidemic proportions. Diversion and abuse of prescription drugs is costly in terms of addiction, overdose, death, and related criminal activities, but chronic pain carries significant economic, social, and health impact as well.

The American Society of Interventional Pain Physicians (ASIPP), as the introducing organization, was joined by several physician and nurse practitioner organizations in support of the National All Schedules Prescription Electronic Reporting (NASPER) Act of 2005, legislation that not only will give physicians an information tool to aid in prescribing controlled substances but also will help identify illicit use and abuse. NASPER is the law that provides for the establishment of a controlled substances monitoring program in each state.

The concept for NASPER originated with ASIPP and was modeled after the highly successful Kentucky All Schedules Prescription Electronic Reporting Program (KASPER). Legislation was introduced in the United States House of Representatives during three different Congresses, the 107th, 108th, and 109th, by Reps. Edward Whitfield (R-KY) and Frank Pallone (D-NJ). It was first introduced in the United States Senate in the 107th Congress by Sen. Tim Hutchinson (R-AK), and in the 108th and 109th by Sens. Jeff Sessions (R-AL) and Dick Durbin (D-IL), with multiple cosponsors in both chambers. NASPER passed the House on July 27, 2005, by voice vote and passed the Senate by unanimous consent on July 29, 2005. President George W. Bush signed NASPER on August 11, 2005, and it became Public Law 109-60.

Implementation of NASPER will improve patient care and reduce abuse and diversion of prescription controlled substances.

Keywords: NASPER, KASPER, chronic pain, National All Schedules Prescription Electronic Reporting Act, prescription monitoring, controlled substances, drug abuse, drug diversion

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. It amends the Public Health Service Act to require the United States (U.S.) Secretary of Health and Human Services to award 1-year grants to each state with an approved application to establish, or improve, a state controlled substance monitoring program.

NASPER requires the Secretary of Health and Human Services to develop minimum standards for states to ensure the security of information collected and to recommend penalties for the provision or use of information in violation of applicable laws or regulations.

NASPER requires each approved state to: (1) require dispensers to enter a report to their state within one week of dispensing a controlled substance to an ultimate user or research subject; and (2) establish and maintain an electronic searchable database containing the information reported. NASPER allows each state to provide information from their database in response to certain requests by practitioners, law enforcement, narcotics control, licensure, disciplinary, or program authorities, the controlled substance monitoring program of another state, and agents of the Department of Health and Human Services (HHS), state Medicaid programs, state health departments, or the Drug Enforcement Administration (DEA).

Evolution

The concept for the National All Schedules Prescription Electronic Reporting (NASPER) Act of 2005 was the brainchild of the American Society of Interventional Pain Physicians (ASIPP) whose members and leadership saw a need for the information exchange program.

Efforts that resulted in NASPER's approval were initiated with three major and important goals:

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

Modeled on the highly success-

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ful state monitoring program in Kentucky (Kentucky All Schedules Prescription Electronic Reporting Act – KASPER) (1), the proposed national legislation was introduced during the 107th Congress in the U.S. House of Representatives on September 30, 2002, as H.R.5503 by Reps. Ed Whitfield (R-KY), and Frank Pallone (D-NJ), with the bi-partisan co-sponsorship of Reps. Pete Sessions (R-TX), Jerry Kleczka (D-WI), Ernie Fletcher (R-KY), Bill Pascrell (D-NJ), and Bart Stupak (D-MI) (2). In October 2002, the bill was introduced in the U.S. Senate as S.3033 by Sen. Tim Hutchinson (R-AR) (3).

The bill called for development of an electronic monitoring system for prescribed Schedule II, III, and IV controlled substances under a program to be established by the U.S. Secretary of Health and Human Services. The House and Senate were unsuccessful in efforts to pass NASPER during the 107th Congress.

In 2004, following persistent promotion by ASIPP throughout 2003 and 2004, the bill to establish NASPER was reintroduced in the 108th Congress in the House of Representatives as H.R.3015 (4), again by Reps. Ed Whitfield and Frank Pallone, along with 56 bipartisan co-sponsors (Table 1). Hearings were held by the Health Subcommittee of the House Energy and Commerce Committee on October 8, 2004 (5). Witnesses included U.S. Rep. Harold Rogers (R-KY); James Holsinger, Jr., MD, Secretary of Health and Family Services for the Commonwealth of Kentucky; and Laxmaiah Manchikanti, MD, ASIPP President and founder. Following hearings and negotiations with congressional leaders, the bill was combined with another bill sponsored by Reps. Charles Norwood (R-GA) and Ted Strickland (D-OH) that supported state monitoring programs and communication between states. The new bill provided for development of state monitoring programs under a federal grant as opposed to the creation of a federal databank. Preserved in the bill were several issues of primary concern to ASIPP: physician access; monitoring of Schedule II, III, and IV controlled substances; and management by the U.S. Department of Health and Human Services. The modified version of NASPER was approved by the Energy and Commerce Committee and passed the House by voice vote on October 5, 2004 (5).

The Senate companion, S.3013, was sponsored by Sens. Jeff Sessions (R-AL), Dick Durbin (D-IL), Edward Kennedy (D-MA), and Christopher Dodd (D-CT)(5). Hearings were held by the Senate Health, Education, Labor and Pensions (HELP) Committee on September 23, 2004, with Kenneth Varley, MD, serving as a witness on behalf of ASIPP (6). However, due to the Congressional schedule, the Senate was unable to act on the House-passed bill prior to adjournment of the 108th Congress.

Finally, in 2005, after continued advocacy efforts by ASIPP, NASPER (H.R.1132) was again introduced in the U.S. House of Representatives by Reps. Ed Whitfield and Frank Pallone along with 34 bipartisan cosponsors (Table 2) (7). Simultaneously, the Senate companion, S.518, was introduced in the U.S. Senate by Sen. Jeff Sessions, with 7 co-sponsors including Christopher Dodd (D-CT), Richard Durbin (D-IL), David Vitter (R-LA), Edward Kennedy (D-MA), Jim Talent (R-MO), Richard Burr (R-NC), and Lamar Alexander (R-TN) (8).

S.518 passed the HELP Committee on May 25, 2005, and H.R.1132 passed the House Energy and Commerce Committee on June 22, 2005. On July 27, 2005, NASPER passed the House by voice vote and the Senate approved it by unanimous consent on July 29, 2005. President George W. Bush signed H.R.1132 on August 11, 2005 and it became Public Law 109-60 (9).

NASPER achieves all the goals as initially presented for a federal databank and consequently received support from many organizations. Major support came from ASIPP as the introducing organization, followed by the American Society of Anesthesiologists (ASA), and the American Medical Association (AMA). Other organizations supporting the concept were the

Table 1. *Sponsorship list of NASPER (H.R.3015) in the 108th Congress in 2004.*

Sponsors: Ed Whitfield (R-KY) Frank Pallone Jr. (D-NJ)	
Co-Sponsors:	
Spencer Bachus (R-AL)	Nancy L. Johnson (R-CT)
Charles F. Bass (R-NH)	Dale E. Kildee (D-MI)
Judy Biggert (R-IL)	Gerald D. Kleczka (D-WI)
Roy Blunt (R-MO)	Ken Lucas (D-KY)
Mary Bono (R-CA)	Carolyn B. Maloney (D-NY)
John Boozman (R-AR)	Marilyn N. Musgrave (R-CO)
Henry E. Brown Jr. (R-SC)	Grace F. Napolitano (D-CA)
Sherrod Brown (D-OH)	George R. Nethercutt Jr. (R-WA)
Ben Chandler (D-KY)	Anne M. Northup (R-KY)
Donna M. Christensen (D-VI)	Bill Pascrell Jr. (D-NJ)
Danny K. Davis (D-IL)	Charles Pickering (R-MS)
Rosa L. DeLauro (D-CT)	Joseph R. Pitts (R-PA)
Jim DeMint (R-SC)	Jim Ramstad (R-MN)
Peter Deutsch (D-FL)	Bobby L. Rush (D-IL)
Norman D. Dicks (D-WA)	Max Sandlin (D-TX)
Rahm Emanuel (D-IL)	Janice D. Schakowsky (D-IL)
Eliot L. Engel (D-NY)	Pete Sessions (R-TX)
Lane Evans (D-IL)	Christopher Shays (R-CT)
Mike Ferguson (R-NJ)	John Shimkus (R-IL)
Ernie Fletcher (R-KY)	Mark E. Souder (R-IN)
Randy J. Forbes (R-VA)	Bart Stupak (D-MI)
Paul E. Gillmor (R-OH)	John Sullivan (R-OK)
Charles A. Gonzalez (D-TX)	Lee Terry (R-NE)
Gene Green (D-TX)	David Vitter (R-LA)
Ralph M. Hall (R-TX)	Dave Weldon (R-FL)
Peter Hoekstra (R-MI)	Robert Wexler (D-FL)
William J. Jefferson (D-LA)	Albert Wynn (D-MD)
Christopher John (D-LA)	

Table 2. *Sponsorship list of NASPER (H.R.1132) in the 109th Congress in 2005.*

Sponsors:	Ed Whitfield (R-KY) Frank Pallone Jr. (D-NJ)
Co-Sponsors:	
Spencer Bachus (R-AL)	Bart Stupak (D-MI)
Anna Eshoo (D-CA)	Dale Kildee (D-MI)
Mary Bono (R-CA)	Michael Rogers (R-AL)
Rosa DeLauro (D-CT)	Roy Blunt (R-MO)
Christopher Shays (R-CT)	Charles Pickering (R-MS)
Michael Bilirakis (R-FL)	Lee Terry (R-NE)
Robert Wexler (D-FL)	Michael Ferguson (R-NJ)
Charles Norwood (R-GA)	Bill Pascrell (D-NJ)
Bobby Rush (D-IL)	Eliot Engel (D-NY)
Rahm Emanuel (D-IL)	Ted Strickland (D-OH)
John Shimkus (R-IL)	Sherrod Brown (D-OH)
Mark Souder (R-IN)	Ralph Hall (D-TX)
Anne Northup (R-KY)	Sheila Jackson Lee (D-TX)
Ben Chandler (D-KY)	Charles Gonzalez (D-TX)
Bobby Jindal (R-LA)	Donna Christensen (D-VI)
Rodney Alexander (D-LA)	Norman Dicks (D-WA)
Albert Wynn (D-MD)	

American Association of Nurse Practitioners, the American Association of Physicians of Indian Origin, and the Kentucky Board of Medical Licensure.

A NASPER Primer

Purpose

The purpose of NASPER is to (7,9):

(1) Foster the establishment of state-administered controlled substance monitoring systems in order to ensure that health care 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.

Federal Grants

Each fiscal year, the U.S. Secretary of Health and Human Services shall award a grant to each state to establish and implement a state-controlled substance monitoring program or to make improvements to an existing state-controlled substance monitoring program.

Minimum Requirements

The Secretary also shall establish minimum requirements for criteria to be used by states including an application approval process, state legislation, interoperability, and minimum reporting requirements.

Database

Each state shall establish and maintain an electronic database containing information reported to the state on Schedule II, III and IV drugs, a database interoperable between the monitoring programs of various states.

Drug Diversion

In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a state receiving a grant shall establish a program to notify practitioners and dispensers of information that will help identify and prevent the unlawful diversion or misuse of controlled substances; and may, to the extent permitted under state law, notify the appropriate authorities responsible for carrying out drug diversion investigations if a state determines that information in the database maintained by the state indicates an unlawful diversion or abuse of controlled substances.

Privacy

In implementing or improving a controlled substance monitoring program, a state shall limit the information provided pursuant to a valid request to the minimum necessary to accomplish the intended purpose of the request; and small limit information requested for research of a non-investigative nature by state or federal agencies or law enforcement to non-identifiable information. Information is available in an electronic format for the reporting, sharing, and disclosure of information.

Studies and Reports

The Secretary, based on the review of existing state-controlled substance monitoring programs and other relevant information, shall determine whether the implementation of such programs has had a substantial negative impact on patient access to treatment, including therapy for pain or controlled substance abuse; pediatric patient access to treatment; or patient enrollment in research or clinical trials involving controlled substances.

Advisory Council

A state may establish an advisory council to assist in the establishment, implementation, or improvement of a controlled substance monitoring program.

Authorization

Funding authorized under the law is $15 million for fiscal years 2006 and 2007, and $10 million for fiscal years 2008, 2009, and 2010.

Background

Drug abuse and diversion, along with potential undertreatment of pain, are prominent public health concerns in the U.S.. Controlled prescription drugs, including narcotic analgesics, anxiolytics, anti-depressants, stimulants, and sedative-hypnotics play a significant and legitimate role in managing chronic pain and other conditions; however, they do so with controversy. The illicit use of prescribed medicines continues to increase at epidemic proportions. Diversion and abuse of prescription drugs is associated with incalculable costs to society in terms of addiction, crime, overdose, and death. The DEA has stated that the diversion and abuse of

legitimately-produced controlled pharmaceuticals constitute a multi-billion dollar market nationwide (10-12).

Chronic pain is highly prevalent in the United States and is estimated at ranging from 2% to 40% of the populace, with a median point prevalence of 15% (13). Literature has overwhelmingly and consistently described the prevalence of chronic pain in children, adults, and the elderly. Studies evaluating chronic low back pain estimate the average age-related prevalence of persistent low back pain as 12% in children and adolescents, 15% in adults, and 27% in the elderly (13). Modern evidence also shows that chronic persistent low back and neck pain are seen in up to 60% of patients, 5 years or longer after the initial episode (13). Further, it has been demonstrated that patients suffer with pain involving multiple regions. Chronic pain has significant economic, social, and health impact (13). It is alleged that undertreatment of pain is a major public health issue in the U.S. (14-18); unfortunately, most descriptions are related to acute pain, cancer pain, and end of life care. Consequently, approximately one-third of state legislatures have passed intractable pain treatment acts in an attempt to improve pain management.

Combatting the illegal diversion of prescription drugs, while at the same time ensuring that pharmaceuticals remain available for those with legitimate medical needs, involves the efforts of federal and state government agencies. The Controlled Substances Act of 1970 (19) provided the legal framework for the federal government's current oversight of the manufacture and wholesale distribution of controlled substances; whereas individual states address these issues through regulation of the practice of medicine and pharmacy (10).

Controlled Substances Act

The Controlled Substances Act of 1970 established a classification structure for drugs and chemicals used in the manufacture of drugs designated as controlled substances (10,19). Controlled substances are classified into 5 schedules based on their medicinal value and potential for abuse, addiction, and dependence. With the exception of Schedule I drugs, all are legally available to the public with a prescription.

The DEA has the authority to regulate transactions involving the sale and distribution of controlled substances at manufacturer and wholesale distributor levels. The DEA's Office of Diversion Control (ODC) provides legitimate handlers of controlled substances – including manufacturers, distributors, hospitals, pharmacies, practitioners, and researchers – with registration numbers that are used in all transactions involving controlled substances. Through the maintenance of inventories and records, registrants must comply with a series of regulatory requirements relating to drug security and accountability.

State Regulation of Practice of Medicine and Pharmacy

State laws govern prescribing and dispensing of prescription drugs by licensed health care professionals (10). All states require that physicians practicing in that state be licensed, and state medical practice laws generally outline standards for the practice of medicine and delegate the responsibility of regulating physicians to state medical boards. State medical boards not only license physicians and grant them prescribing privileges (10), but also investigate complaints and impose sanctions for violations of state medical practice laws.

Similarly, every state requires resident pharmacists and pharmacies to be licensed. The regulation of the practice of pharmacy is based on state pharmacy practice acts and regulations enforced by state boards of pharmacy (10). These state pharmacy boards are also responsible for ensuring that pharmacists and pharmacies comply with applicable state and federal laws; they also investigate and discipline those failing to comply. Consequently, all state pharmacy laws require that records of prescription drugs dispensed to customers be maintained. In addition, state pharmacy laws also provide access by state pharmacy boards to prescription records.

Non-Medical Use of Prescription Drugs

Joseph A. Califano, Jr., Chairman and President of the National Center on Addiction and Substance Abuse at Columbia University (CASA), in a July 2005 editorial on the Diversion and Abuse of Controlled Prescription Drugs in the United States (20) noted as follows:

"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 U.S. population increased 14%, the number of people abusing controlled prescription drugs jumped 94% – 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."

The CASA report (20) presented alarming statistics including a 212% increase from 1992 to 2003 in the number of 12- to 17-year-olds abusing controlled prescription drugs, and the increasing number of teens trying these drugs for the first time. The report also illustrated that new abuse of prescription opioids among teens is up an astounding 542%, more than 4 times the rate of increase among adults. Further, additional disturbing statistics show that teens who abuse opioids are likely to use other drugs including alcohol, marijuana, heroin, ecstasy, and cocaine at rates 2, 5, 12, 15, and 21 times that of teens who do not abuse such drugs.

As per the CASA report (20), the bottom line is that the United States is in the throes of an epidemic of controlled prescription drug abuse and addiction with 15.1 million people admitting to abusing prescription drugs – more than the combined number of those who admit abusing cocaine (5.9 million), hallucinogens (4 million), inhalants (2.1 million), and heroin (0.3 million).

Abuse and diversion of prescription drugs "on the street" are serious problems. In 2001, prescription drug abuse and misuse was estimated to impose approximately $100 billion annually in health care costs (12,21,22). The abuse of prescription medications has increased steadily over the last 10 years, and every year more and more Americans try them for the first time. The abuse of controlled prescription drugs was foreshadowed by dramatic increases in their manufacture and distribution and the number of prescriptions written and filled (20). Between 1992 and 2002, while the population of the U.S. increased by 13% and the number of prescriptions written for non-

controlled drugs increased by 57%, the number of prescriptions filled for controlled drugs increased by 154%. During this same period, there was a 90% increase (from 7.8 million to 14.8 million) in the number of people who admitted abusing controlled prescription drugs.

The 2003 survey of drug abuse (23) revealed that 6.3% of the U.S. populace over 12 years of age (14,986,000 Americans) used psychotherapeutic drugs for non-medical purposes; of these, 4.9% of the U.S. population (11,671,000 Americans) over 12 years of age used pain relievers for non-medical purposes (Table 3). The number of individuals abusing pain medications for the first time grew from 628,000 in 1990 to nearly 3 million in 2000 (Fig. 1). First-time use of stimulants and tranquilizers is also on the rise. Statistics showing trends in drug-related emergency department visits also reveal that prescription drug abuse is on the rise (Fig. 2) (24,25). Increases for specific opioids are illustrated in Table 4, with the highest increase that of oxycodone at 345%. From 1994 to 2002, mentions of pain medications during emergency department visits increased by 168%, whereas, mentions of benzodiazepines increased by 42%.

During the same time period, the percentage of increase mentioned by the Drug Abuse Warning Network (DAWN) for prescription pain relievers has been greater than the increase for marijuana, cocaine, and heroin.

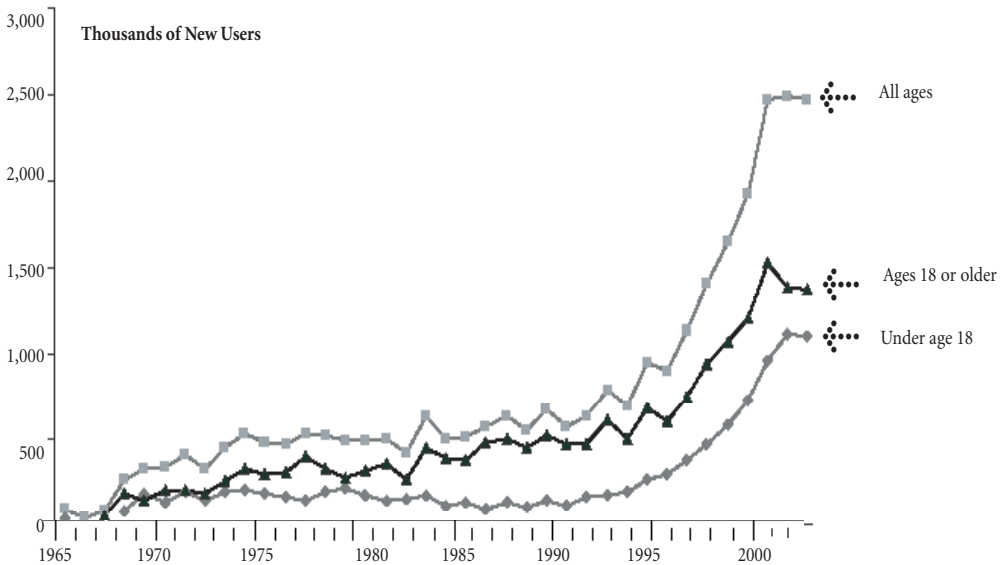
Table 3. *Use of illicit drugs and illicit pain relievers among persons age 12 or older; 2003.*

	Number (Percentage)			
	12-17 years of age	**18-25 years of age**	**>26 years of age**	**Total >=12 years**
U.S. population	24,995,000	31,728,000	180,958,000	237,682,000
Any illicit drug	5, 448,000.9 (21.8%)	10,977,000.8 (34.6%)	18,638,000.7 10.3%	34,993,000 (14.7%)
Nonmedical use of any psychotherapeutic drug	2,229,000.5 (9.2%)	4,600,000.6 (14.5%)	8,143,000 (4.5%)	14,986,000 (6.3%)
Nonmedical use of pain relievers	1,924,000.6 (7.7%)	3,807,000.4 (12.0%)	5,971,000.6 (3.3%)	11,671,000 (4.9%)

Source: 2003 SAMHSA Survey (23)

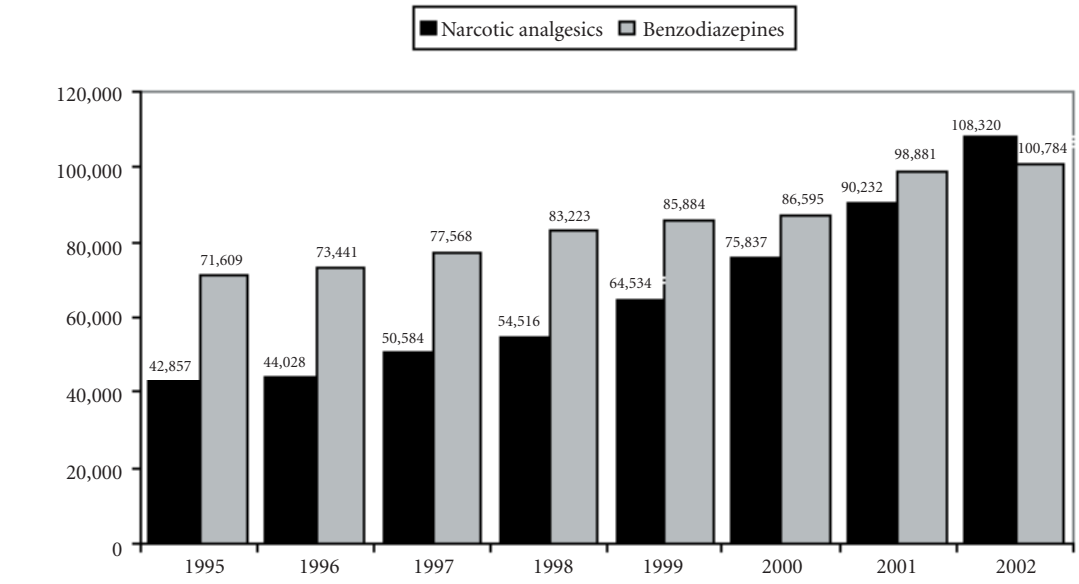
Substance Abuse in Chronic Pain

It is well known that chronic pain is a prevalent problem. However, due to the inability to provide most chronic pain patients with a precise pathoanatomic diagnosis, a multitude of pharmacologic agents are commonly used for symptom relief. Opioids are the most potent and effective analgesics available and are one of the most widely prescribed and abused medications for chronic pain. While opioids are by far the most abused drugs, other controlled substances such as benzodiazepams, sedative hypnotics, and central nervous system stimulants, though described as having less potential for abuse, are also of major concern to interventional pain specialists as they appear to be widely used for non-medical purposes as well (23,26). This is exemplified by the



Annual Numbers of New Nonmedical Users of Pain Relievers: 1965–2002
Adapted from ref. 23.

Fig. 1. *Number of individuals abusing pain medications for the first time*



Source: The Office of Applied Studies, SAMHSA, DAWN, 2003 (24, 25)

Fig. 2. *Drug abuse related emergency department visits involving narcotic analgesics and benzodiazepines*

Table 4. *Retail sales of opioid medications (grams of medication) 1997-2002*

	1997	2002	% change
Morphine	5,922,872	10,264,264	73.3
Hydrocodone	8,669,311	18,822,618	117.1
Oxycodone	4,449,562	22,376,891	402.9
Methadone	518,737	2,649,559	410.8

fact that benzodiazepam-related emergency department visits increased from 71,609 in 1995 to 100,784 in 2002 (24). Further, it has been reported that 77.3% of suicide attempts involved benzodiazepams (27).

Overall, it has been reported that the principal drug of abuse for nearly 10% of youths in drug treatment programs is a prescription drug (28). In a comprehensive review, Fishbain et al (29) concluded that between 3.2% and 18.9% of patients have been diagnosed with a substance abuse disorder. In addition, they also concluded that diagnoses of abuse, drug dependency, and drug addiction occur in a significant proportion of chronic pain patients. Polatin et al (30) showed current substance abuse among patients with chronic low back pain at 19% and a lifetime prevalence at 36%. Murata et al (31) determined that among the patients on opioids, 24% were drug dependent and 41% were drug abusers, whereas only 35% were non-abusers. Hoffman et al (32) found that 12.6% of studied patients showed current analgesic dependency, followed by 7% with sedative dependency, and 9.7% with alcohol dependency. Chabal et al (33) showed that 27.6% of patients met 3 or more criteria for drug abuse. In another study, Jinks and Raschko (34) reported that approximately 5% of patients were referred for treatment because of prescription drug abuse whereas 9.6% were referred because of alcohol abuse. Katz et al (35) reported that among the patients receiving long-term opioid therapy, 43% presented with either a positive urine toxicology or one or more aberrant drug-taking behaviors. Manchikanti et al (36,37) showed an 18% to 24% incidence of controlled substance abuse among patients in interventional pain management practice settings.

Kell (38) used urine drug testing to monitor compliance with OxyContin® prescriptions in 14,712 patients treated in 127 outpatient pain centers. The results showed that 20.1% of the patients tested negative for oxycodone, whereas 53.6% failed to be within expected ranges for urine concentration dose curves. In addition, 13.7% of patients prescribed medications other than OxyContin or oxycodone IR also tested positive for oxycodone. This monitoring has demonstrated that many patients prescribed OxyContin are not compliant with their prescriptions, in percentages ranging from 20% to 73.7%.

Sikirica et al (39) in comparing the prevalence, comorbidities, and utilization of an opioid abuse "cohort of managed care patients with matched controls reported that prevalence of opioid abuse rose from 2000 to 2002." They also concluded that opioid abuse was 6.7 per 10,000 patients in 2002. Opioid abusers also presented with higher prevalence of opioid prescriptions and comorbidities compared with controls. Illicit drug use also is a common phenomenon in chronic pain patients. Table 5 illustrates the prevalence of prescription drug abuse in a typical interventional pain management practice setting in western Kentucky (37).

Manchikanti et al (40,41) also identified illicit drug use in patients without controlled substance abuse in 14% to 16% of patients, and illicit drug use in patients with controlled substance abuse in 34% of the patients. Manchikanti et al (42) evaluated the prevalence of illicit drug use among individuals with chronic pain based on their type of insurance coverage. It was shown that abuse was high in patients on Medicaid (Table 6). Atluri et al also showed significant illicit drug use in

patients with chronic non-malignant pain treated with opioids (43,44).

Abuse is not limited to opioids. Extensive use of other psychotherapeutic agents including benzodiazepines has been described. In fact, it has been stated that except for cardiac glycosides, benzodiazepines are the most frequently prescribed drugs all over the world; 4 out of 5 of all psychological drugs are benzodiazepines or hypnotics (45). In fact, in some countries benzodiazepines are the leading drugs of abuse, followed by analgesics, opioids, and barbiturates. It has also been reported that 77.2% of suicide attempts involve benzodiazepines.

Patterns of opioid use and abuse among chronic pain patients have been evaluated. Luo et al (46) showed that the frequency of overall opioid use among individuals with back pain was approximately 12%. Turk et al (47,48) found that rheumatologists, family practitioners, and internists were much more likely to prescribe opioids for patients with chronic pain than were surgeons and neurologists. Vogt et al (49), in a cross sectional analysis of analgesic use by patients with low back pain, showed that in 2001 55.5% of insurance plan members with low back pain had insurance claims for analgesics, with 68% of claimants receiving an opioid. Pembrook (50) also reported that Medicaid patients were more likely to receive prescription drugs, particularly opioids, for 30 days or longer and to visit the emergency room. The majority of Medicaid patients (73%) received an opioid, as compared with 40% of commercial insurance members.

In pain management settings, more than 90% of patients have received opioids for chronic pain management (51-56). Manchikanti et al (51) showed that 90% of the patients were on opioids and 42% were on benzodiazepines prior to presenting to an interventional pain management setting. Many of the patients also received more than one type of opioid for breakthrough pain. Similar illicit drug use and dose escalations have been demonstrated in patients on long-acting and short-acting opioids (55,56). Finally, the increasing retail sale of opioid medications is the proof that opioids are used much more frequently. As illustrated in Table 7, retail sales of opioid medications shown as grams of medication from 1997 to 2002 increased 73.3% for morphine, 117.1% for hydrocodone, 402.9% for oxy-

Table 5. *Prevalence of controlled prescription drug abuse in Western Kentucky*

	Number	Proportion
Grade '0' – No abuse	444	72.2%
Grade I – Low grade abuse	47	9.4%
Grade II – Moderate abuse		
II-A – 3 or more physicians	17	3.4%
II-B - Receiving Schedule II drugs	6	1.2%
II-C - Abusing of Schedule II drugs	7	1.4%
Total Grade II	30	6%
Grade III – High grade		
Category A - Trafficking	10	2%
Category B - Overdose	2	0.4%
Total Grade III	12	2.4%
Total Abuse	89	17.8%
Total	500	100%

Adapted from Manchikanti et al (37)

Table 6. *Prevalence of illicit drug use*

	Group I (100) Third party	Group II (100) Medicare with or without third party	Group III (100) Medicare & Medicaid	Group IV (100) Medicaid	P Value
Cocaine	7%	4%	6%	8%	0.684
95% CI	2% -12%	0% - 8%	1% - 11%	3% - 13%	
Marijuana (THC)	11%	8%	20%[b]	34%[a,b,c]	0.0000
95% CI	5% - 17%	3% - 13%	12% - 28%	25% - 43%	
Methamphetamine/Amphetamine	3%	2%	4%	3%	0.876
95% CI	0% - 6%	0% - 5%	0% - 8%	0% - 6%	
Combined use of cocaine and marijuana	1%	2%	2%	3%	0.888
95% CI	0% - 3%	0% - 5%	0% - 5%	0% - 6%	
Total	17%	10%	24%[b]	39%[a,b,c]	0.0000
95% CI	10% - 24%	4% - 6%	16% - 32%	29% - 49%	

Totals may not correlate as some patients were included in more than one category CI – Confidence Interval
a: Indicates significant difference from Group I b: Indicates significant difference from Group II
c: Indicates significant difference from Group IIII
Adapted from Manchikanti et al (41)

codone, and 410.8% for methadone.

Overall use and abuse of opioids and other controlled substances in conjunction with illicit drug use appears to be prevalent in pain management settings (55-58); however, using opioids for non-cancer pain has been questioned repeatedly as to whether it is effective and appropriate (59-63). Essentially, advocacy and unproven Joint Commission standards may be leading to overuse of narcotics and subsequent abuse. At the same time Americans continue to be dissatisfied with their pain relief options.

Drug Diversion

Drugs can be diverted from their lawful purpose to illicit use at any point in the pharmaceutical manufacturing and distribution process. The diversion of prescription drugs among adults is typically described to occur through one of the following: doctor shopping, illegal Internet pharmacies, drug theft, prescription forgery, and illicit prescriptions by physicians. Youth typically acquire drugs by stealing from their relatives or buying from classmates who sell their legitimate prescriptions.

"Doctor shopping" is one of the most popular methods of obtaining prescription drugs for legal and illegal use (10,58,64,65). Since 1999, illegal Internet pharmacies have provided a convenient alternative for individuals wishing to fill their prescriptions (66-68). In 2003, the Federal Drug Administration (FDA) estimated the number of Internet pharmacies selling drugs illegally to be about 400, with approximately 50% of these pharmacies located outside the U.S. (67).

Prescription drug theft can occur at any point from manufacturer to patient. Thefts are on the rise, largely due to drastic increases in prescription drug abuse and high street prices (Table 7) (67-74). All drugs ranging from OxyContin® to Soma® have been implicated. Prescription forgery is also fairly common, either by altering the prescription or stealing blank prescription pads to write fake prescriptions (65,71,75). Finally, illicit prescriptions written by physicians, though rare, are reality.

To lawfully prescribe a controlled substance, the prescription must be issued for a legitimate purpose, the physician must be acting in the usual course of his or her practice, and the patient's medical record must be complete and point to the prescribed drug as a reasonable treatment choice. Often making headlines are criminal cases involving physicians who become involved in diverting prescription drugs for huge profits (65,76-79). However, malprescribing, either due to lack of knowledge or prescribing illegally through "pill mills," is more common (65, 77-83). Malprescribing often represents a lack of knowledge rather than a deliberate attempt to profit from writing these transactions. DEA actions against physicians are decreasing (Fig. 3), while actions by state boards of medical licensure are increasing (Fig. 4).

Controlling Diversion and Abuse

Federal, state, and local governments, as well as professional associations and pharmaceutical companies, share responsibility for preventing diversion and abuse of controlled prescription drugs (20). However, the challenge is to eliminate or significantly curtail diversion and abuse of controlled prescription drugs while assuring proper treatment of patients who can be helped by these medications. Gaps exist between current efforts to control diversion and efforts to maintain access to patient care. These gaps involve international law, federal laws and regulations, activities of the DEA and FDA, scheduling drugs, drug refills, state laws and regulations, and existing prescription drug monitoring programs.

Table 7. *Street value of drugs*

Generic Name	Brand Name	Brand Cost per 100	Street Value Per 100
Acetaminophen w/ Codeine 30 mg	Tylenol #3	$56.49	$800
Diazepam 10 mg	Valium 10 mg	$298.04	$1,000
Fentanyl Patch	Duragesic Patches	$243.59	$400
Hydromorphone	Dilaudid 4 mg	$88.94	$10,000
Methylphenidate	Ritalin	$88.24	$1,500
Oxycodone	OxyContin 80 mg	$1,081.36	$8,000

Adapted from ref. 76

International Law

Since 1912, international treaties have required governments to control the production, trade, and consumption of psychoactive drugs (20). However, the provisions of these treaties are binding only to the extent that they do not conflict with an individual signatory nation's constitutional principles and the basic concepts of its legal system. These treaties obligate governments to create stringent control mechanisms. However, they also contain provisions to ensure that the restrictions are not so rigid as to adversely influence patient access to needed medications. William K. Hubbard, U.S. Food and Drug Administration Associate Commissioner for Policy, stated: "Evidence strongly suggests that the volume of these foreign drug importations is rising steadily, presenting an even more difficult challenge for agency field personnel at port of entry, mail facilities, and international courier hubs."

Federal Laws and Regulations

Despite numerous laws, regulations, and federal regulatory agencies that are devoted, at least in part, to the control of prescription drug diversion and abuse, the problem is one that reaches beyond the U.S. borders and its control. Known as the Harrison Narcotics Act, the first federal law enacted on prescription drug distribution was adopted in 1914. Since then, Congress has enacted many statutes to regulate the manufacture, importation, distribution, and use of pharmaceutical products. The comprehensive Drug Abuse Prevention and Control Act of 1970 consolidated more than 50 federal drug laws.

Drug Enforcement Administration

The DEA, as an agency within the United States Department of Justice, is the lead federal law enforcement agency responsible for enforcing the Controlled Substance Act. In cooperation with state authorities and other federal agencies, the DEA is responsible for preventing the diversion of controlled substances for illicit purposes. However, the DEA must

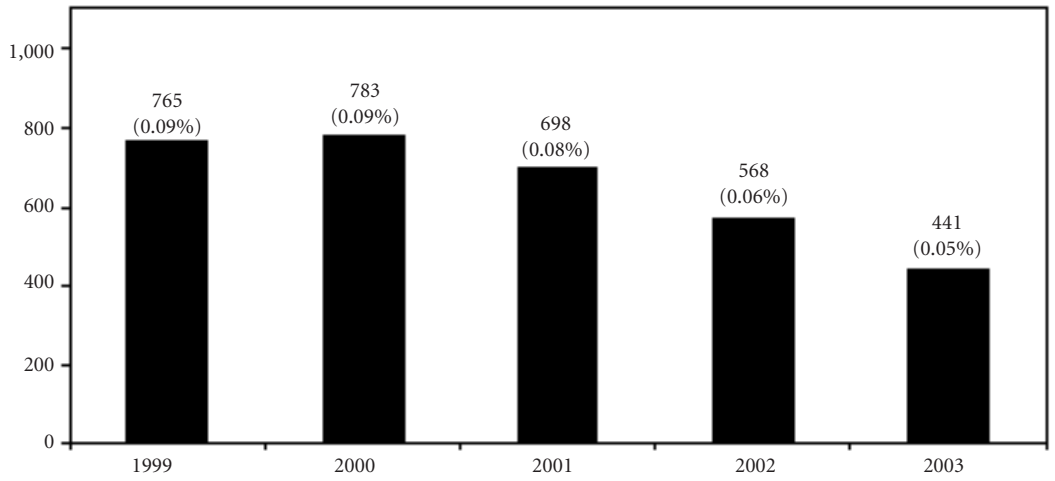
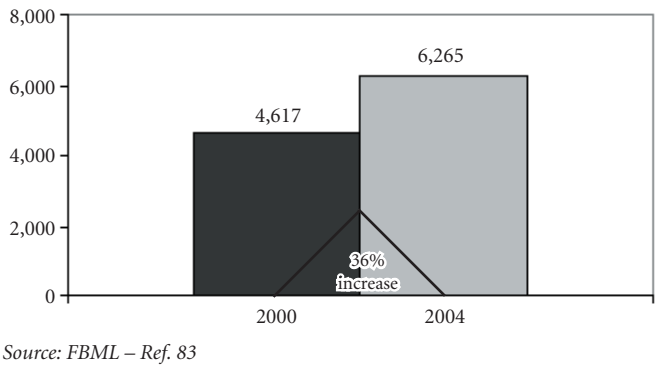


Fig. 3. *Drug Enforcement Administration (DEA) actions against physicians.*



Source: FBML – Ref. 83

Fig. 4. *Actions by state boards of medical licensure.*

comply with international treaties to the extent that they are not in conflict with constitutional provisions; it must also work closely with foreign, state, and local governments. Lora Nagel, former Deputy Assistant Administrator, Office of Diversion Control, said, "There are 500 DEA agents across the country that work on prescription drug abuse, compared to 4,500 for cocaine and other illicit drugs." Adverse actions taken by the DEA against drug providers has, in fact, decreased from 0.9% in 1999 to 0.05% in 2003 (Fig. 3). The DEA has increased its monitoring of Internet prescription drug sales. DEA investigations, enforcement, and intelligence programs have started to work more closely with other federal, state, and local agencies to target individuals and organizations involved in diversion and abuse of controlled prescription drugs.

The Food and Drug Administration

To reach the market in the United States, all prescription drugs must first be approved by the FDA as being safe and efficacious. It is within the FDA's jurisdiction to place precautionary warnings on drugs to alert and educate health care practitioners and the public regarding the abuse potential of particular medications. Because all opioids have some abuse potential, the FDA recommends that pharmaceutical companies voluntarily include a warning in the labeling as to the risks of misusing the drug. The strongest labeling warning that the FDA requires is the "black box" warning. This labeling is intended to influence prescribing practices, as well as to increase a clinician's awareness of the potential for diversion and abuse of the drug.

Scheduling Drugs

Substances may be added to a schedule, removed, or transferred from one to another. Even though scheduling recommendations are made by the FDA, final determinations are up to the DEA. One such recommendation being considered is the rescheduling of hydrocodone compounds from a Schedule III drug to a Schedule II drug.

Drug Refills

Presumably, limiting the number of refills allows the physician to periodically monitor the patient's course of illness, something that is particularly important during long-term therapy to aid in detecting tolerance, drug interactions, and compliance. In addition, it may also provide an avenue to reduced diversion.

State Laws and Regulations

Every state has professional oversight boards that license and discipline members within each profession. Further, the licensing boards for each health care profession have a designated national organization. However, many of these associations have not been proactive in addressing the problems of prescription drug diversion and abuse (20).

Prescription Drug Monitoring Programs

Prescription drug monitoring programs capture information that may be shared with law enforcement agencies, health care and regulatory agencies, and in some states, health care practitio-

ners, to help identify inappropriate or illegal activities involving controlled prescription drugs. It has been stated that the scrutiny of professional boards and monitoring programs has, in some cases, created fear that legal action will be taken against physicians and pharmacists regarding their prescribing and dispensing practices (5,14-16,20,83,84). As a result, practitioners may undertreat patients or use less appropriate medications that are not covered by a monitoring program.

In response to the problem of under-treatment of pain, many pain management advocacy organizations have been formed and have teamed with pain management physicians and pharmaceutical companies to advocate for the use of opioids in the treatment of pain (20). However, many of the assumptions on which these alliances are based may be incorrect. For example, one of the major assumptions of such groups is that pain physicians are well-educated in controlled substance use, whereas other physicians are not. Consequently, one would believe that if we educate the other physicians, pain will be well treated. However, there is no evidence that long-term opioid use is beneficial to patients with chronic pain. Further, the medical community does not clearly understand the consequences of diversion, abuse, and addiction (20).

The United States Government Accountability Office (GAO) conducted a study on state monitoring programs of prescription drugs (10). They concluded that state monitoring programs provide a useful tool to reduce diversion.

The first prescription drug monitoring program (PDMP) was established in California in 1940. The number of states with PDMPs has grown only slightly over the past decade, from 10 in 1992 to 15 in 2002 (Table 8). These 15 programs cover 47% of the nation's population and DEA-registered practitioners, and about 45% of the nation's pharmacies. Since the GAO report on state monitoring systems was published, PDMPs have been increasing gradually (5).

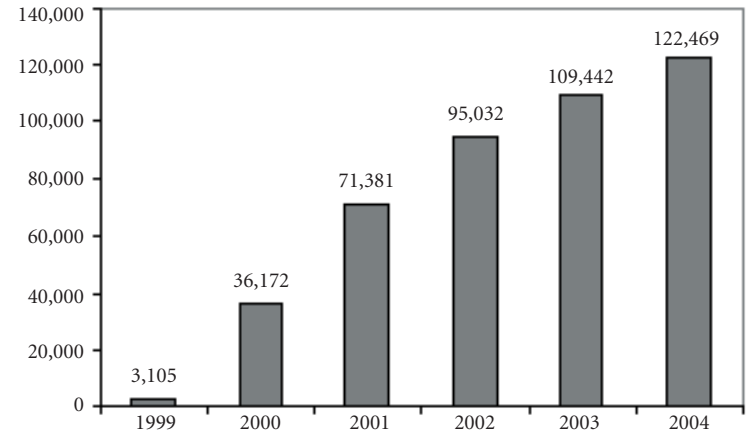
The National Alliance for Model State Drug Laws, established in 1993, has served as a resource center for states interested in identifying legislative and program improvements in drug abuse reduction and prevention. Each year since fiscal year 1995, the alliance has received a $1 million grant from the U.S. Department of Justice. The funds are used to identify legislative, policy, and program initiatives to address the supply of, abuse of, and addiction to, alcohol and other drugs. However, prescription drug monitoring programs vary as to objectives, design, and operation, even though the primary objective of PDMPs is to assist law enforcement in detecting and preventing drug diversion. In addition to helping law enforcement identify and prevent prescription drug diversion, state programs may include education objectives to provide information to physicians, pharmacies, and the public. The programs are also highly variable with regards to monitoring scheduled substances from Schedule II to Schedule IV. Only 4 states – Utah, Nevada, Kentucky, and Idaho – monitor Schedule II to IV drugs; the majority monitor only Schedule II drugs. Also, the majority of these programs are retroactive with after-the-fact identification of abuse as reported by public health departments, pharmacy boards, and law enforcement. The major disadvantage of the programs is lack of communication among the state programs. Consequently, 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 3 states provide this information proactively to physicians. The GAO report cited many advantages, as well as disadvantages, to PDMPs. 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

Table 8. *Prescription monitoring programs*

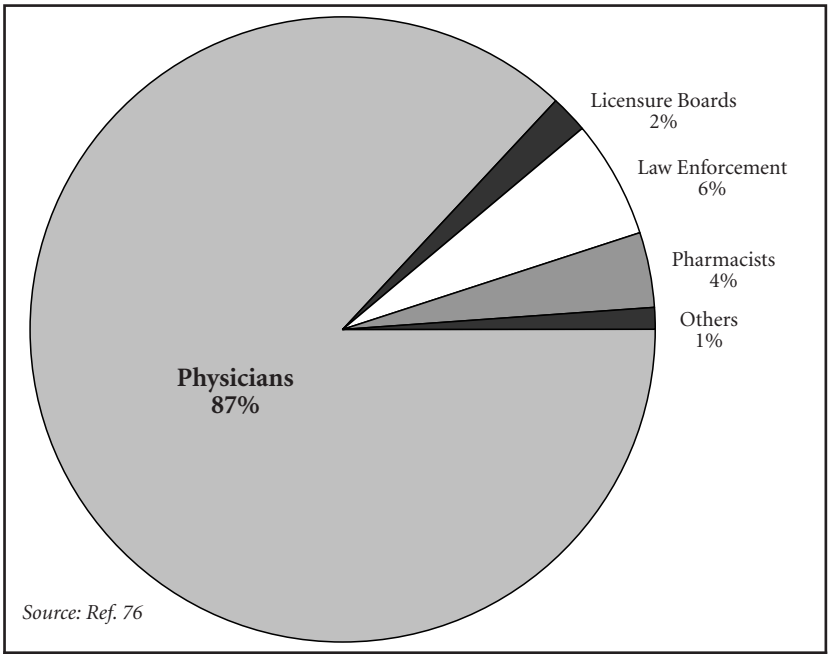
State	Year implemented	Controlled substance schedule(s)monitored	Type of monitoring system	Administrative agency
California	1940	II	Electronic and triplicate form	Pharmacy and law enforcement
Hawaii	1943	II	Electronic	Law enforcement
Idaho	1967	II, III and IV	Electronic	Pharmacy board
Illinois	1961	II	Electronic	Public health
Indiana	1995	II	Electronic	Law enforcement
Kentucky	1999	II, III, IV and V	Electronic	Public health
Massachusetts	1992	II	Electronic	Public health
Michigan	1989	II	Single form	Commerce
Nevada	1997	II, III, and IV	Electronic	Pharmacy board and law enforcement
New York	1977	II	Electronic	Public health
Oklahoma	1991	II	Electronic	Law enforcement
Rhode Island	1979	II, III	Electronic	Public health
Texas	1982	II	Electronic	Law enforcement
Utah	1997	II, III, IV, and V	Electronic	Commerce's Licensing Division
Washington	1987	Determined by disciplinary authority	Triplicate form	Public health

Source: National Alliance for Model State Drug Laws. Information current through February 4, 2002.
Adapted from Ref. 11



Source: Ref. 76

Fig 5. *KASPER use increases in Kentucky*



Source: Ref. 76

Fig. 6. *Physician use of Kentucky's KASPER program*

of a PDMP may help one state reduce its illegal drug diversion, diversion activities may actually increase in contiguous states without PDMPs. All three of the states providing access to physicians – Kentucky, Nevada, and Utah – have helped reduce the unwarranted prescribing and subsequent diversion of abused drugs in their states. In both Kentucky and Nevada, an increasing number of PDMP 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 (Figs. 5 and 6).

The success of a prescription drug monitoring program is demonstrated by its use by physicians and other professionals in Kentucky. Kentucky's KASPER system was designed to produce 2,000 reports per year at its inception in 1999; in 2004, however, it produced more than 2,500 reports per week (74). Even then, it is estimated that only 50% of the physicians who prescribe controlled substances in the Commonwealth of Kentucky are using the KASPER system.

Conclusion

Prescription controlled substance abuse and diversion is a major issue in the United States. It is a public health issue affecting patient access to appropriate interventions, due to a fear of sanctions on the part of providers. The implementation of the National All Schedules Prescription Electronic Reporting Act will improve patient care and reduce abuse and diversion of prescription controlled substances.

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