The National Center on Addiction and Substance Abuse at Columbia University

Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.

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Accompanying Statement by
Joseph A. Califano, Jr., Chairman and President

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 percent, the number of people abusing controlled prescription drugs jumped 94 percent--twice the increase in the number of people abusing marijuana, five times in 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 substance in America behind only marijuana, alcohol and tobacco.

Particularly alarming is the 212 percent 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. New abuse of prescription opioids among teens is up an astounding 542 percent, more than four times the rate of increase among adults. The explosion in the prescription of addictive opioids, depressants and stimulants has, for many children, made the medicine cabinet a greater temptation and threat than the illegal street drug dealer, as some parents have become unwitting and passive pushers.

Teens who abuse controlled prescription drugs are twice as likely to use alcohol, five times likelier to use marijuana, 12 times likelier to use heroin, 15 times likelier to use Ecstasy, and 21 times likelier to use cocaine, compared to teens who do not abuse such drugs.

These are just a few of the deeply troubling findings of this report, three years in the making, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.*, the first comprehensive analysis of all aspects of controlled prescription drug abuse--from patient
scams to inadvertent addiction, from gaps in professional training to drug formulation and marketing, from parental carelessness to physician ignorance, from rogue Internet pharmacies to local, state and federal monitoring, regulation and enforcement. It represents three years of intense work by The National Center on Addiction and Substance Abuse (CASA) at Columbia University. The work includes landmark national surveys of physicians and pharmacists, more than 200 interviews, seven focus groups, a national conference on substance abuse and pain management, and a review of more than 2,000 publications. The findings presented in this report represent an extensive and unprecedented analysis of 15 national data sets by CASA’s Substance Abuse Data Analysis Center (SADAC™). SADAC™, created in 1995, has a unique capacity to analyze, compare and synthesize the wide variety of data sets necessary for this report.

The bottom line: our nation is in the throes of an epidemic of controlled prescription drug abuse and addiction. Today 15.1 million people admit abusing prescription drugs--more than the combined number who admit abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (.3 million) combined. For reasons set out in this report, that number underestimates significantly the extent of the epidemic.

Some key findings of this CASA analysis are:

- The number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003--by 94 percent--seven times faster than the increase in the U.S. population.

- Children are especially at risk. In 2003, 2.3 million teens between the ages of 12 and 17 (9.3 percent) admitted abusing a prescription drug in the past year; 83 percent of them admitted abusing opioids. Younger teens are likelier to abuse only prescription drugs and older teens are likelier also to abuse alcohol or illicit drugs, signaling a dangerous progression of use.

- Young people are abusing prescription steroids for purposes of body sculpting and athletic performance, following the examples of professional and elite athletes. Rates of lifetime steroid abuse among high school students have increased 126 percent between 1991 and 2003. Steroid abuse is a problem for girls and boys alike. However, while boys abuse steroids at higher rates than girls, the increase in abuse has been much sharper for girls than for boys (342 percent vs. 66 percent increase). In 2003, approximately 1.7 million teens admitted trying steroids.

- Most people who admit abusing prescription opioids, central nervous system depressants and stimulants (74.7 percent) are poly-substance abusers; they also admit excessive drinking or use of illicit drugs.

- 25.3 percent of controlled prescription drug abusers report abusing only prescription drugs. These individuals are more likely to be women, older, married, better educated and have higher incomes. Their mainstream profile increases the risk that the medical profession will overlook their substance abuse or even compound it by prescribing drugs that may exacerbate their problems. Women, for example, are 37 percent likelier than men to be prescribed psychoactive tranquilizers like Valium, even controlling for diagnosis.

America is in a perfect storm of abuse of mind altering prescription drugs including: opioids like OxyContin and Vicodin that relieve pain, central nervous system (CNS) depressants like Valium and Xanax that relieve anxiety, CNS stimulants like Ritalin, Adderall and Dextroamphetamine that boost attention and energy, and steroids like Anadrol and Equipoise that enhance athletic performance. The question is why?

One factor driving the increase in controlled prescription drug abuse is that these drugs can be found in abundance in family medicine cabinets in every town in America, and they are just a click away on the Internet. They can be acquired with relative ease from doctors, friends,
relatives and classmates. The fact that controlled prescription drugs are approved by the FDA and prescribed by a physician leads many to conclude that they are safe even when abused. Sadly, nothing could be further from the truth.

Controlled prescription drug abuse can lead to serious emotional, social and health problems, medical emergencies and death. In 2002, controlled prescription drugs accounted for 23 percent of all drug-related emergency department mentions in the U.S. Between 1994 and 2002, there was a 168 percent increase in emergency department opioid mentions, four times more than the increase in cocaine mentions, three and a half times the increase in heroin mentions and exceeded only marginally by marijuana mentions (198 percent increase). In 2002, controlled prescription drug abuse was implicated in one in five emergency room deaths. The concurrent abuse of alcohol and illicit drugs by three-quarters of controlled prescription drug abusers further raises their risk of dangerous consequences.

The abuse of controlled prescription drugs was foreshadowed by dramatic increases in their manufacture and distribution and in the number of prescriptions written and filled. Between 1992 and 2002, while the U.S. population increased 13 percent and the number of prescriptions written for non-controlled drugs increased by 57 percent, the number of prescriptions filled for controlled drugs increased by 154 percent. During this same period, there was a 90 percent increase (from 7.8 million to 14.8 million) in the number of people who admitted abusing controlled prescription drugs--a 203 percent increase among 12- to 17-year olds and a 78 percent increase among those 18 and older (by 2003, the comparable increases were 212 percent for teens and 81 percent for adults).

As the overdose death of basketball star Len Bias awakened the nation in 1986 to the danger of cocaine, so the explosion in OxyContin prescriptions written to treat non-cancer pain--from 670,000 in 1997 to some 6.2 million in 2002--and the resulting rampant abuse and addiction related to the drug sounded the prescription drug alarm for many and drew attention to gaps in prevention and control.

For example, the Internet is a wide-open highway for distribution of illegally acquired abusable prescription drugs. An investigation conducted for this report by Beau Dietl & Associates found hundreds of Web sites advertising and selling controlled prescription opioids, CNS depressants, CNS stimulants and steroids. Most could be purchased without a prescription and without regard to age, so teens and children could easily get them. A little Internet savvy and a credit card were the only requirements to have the drugs arrive at the designated address within a few days.

CASA’s unprecedented survey of physicians found that 57 percent of doctors believe that they bear primary responsibility for preventing prescription drug diversion and abuse. This survey also reveals, however, that only 19 percent received training in prescription drug diversion in medical school, 39 percent in residency, and 34 percent through continuing medical education. Other CASA surveys of physicians reveal that they are not well trained to spot the signs of substance abuse and addiction.

CASA’s survey of pharmacists found that since pharmacy school only 56 percent received instruction in dispensing controlled drugs; 50 percent received instruction in identifying prescription drug abuse/addiction, and 48 percent received instruction in preventing diversion.

Dentists, nurses and veterinarians also shoulder some responsibility to prevent diversion and abuse yet they appear to receive little or no training in this area.

Pharmaceutical companies may contribute to diversion and abuse by the way they formulate and market controlled drugs. The abuse potential of a drug is linked to the speed and intensity of the high it creates. Drugs like OxyContin and Dilaudid that can easily be altered to destroy their time-release mechanism
are premium on the abuse market. Yet, formulation of a drug to reduce its abuse potential is not a required consideration by either pharmaceutical companies or the Food and Drug Administration (FDA) in bringing a controlled drug to market. Nor are plans to manage the risk of diversion and abuse required for all controlled drugs prior to their release. Aggressive marketing of controlled drugs to physicians—as occurred with OxyContin for moderate as well as severe pain—is designed to increase profits with little regard for abuse potential. In recent years pharmaceutical companies have begun to market controlled prescription drugs directly to consumers in order to increase demand.

Controlled prescription drugs can be stolen anywhere along the pathway from manufacture to consumption and diverted for illicit use by individuals or criminal operations. CASA's surveys of physicians and pharmacists reveal that both believe the major source of diversion is patients through such techniques as doctor shopping, fraudulent or altered prescriptions, and deception and manipulation of doctors.

But parents also play a key role. Their easily accessible medicine cabinets containing these very drugs are an open invitation to children—fueling "pharming" parties where teens bring drugs from home and trade or share for purposes of getting high. Parental ignorance about the dangers of these drugs and failure to safeguard them (e.g., by locking their medicine cabinets) can yield inadvertent but devastating harm to their own children.

With the rapid pace of development of new mood-altering pharmaceuticals and with abuse and addiction climbing so sharply, controlled prescription drug abuse has the potential to rival alcohol and marijuana abuse. Avoiding such an outcome requires an all-fronts effort of prevention and control. The task of eliminating diversion and abuse cannot be left to law enforcement alone, for even the most well funded and staffed enforcement efforts cannot succeed on their own. Parents, physicians, pharmacists, pharmaceutical companies, schools and public health officials must sign up.

I hope this report will be a wake up call to Americans. It provides a roadmap for coming to terms with this problem—preventing children from dangerous experimentation, protecting adults from inadvertent abuse and addiction, and controlling willful diversion for purposes of abuse—while preserving the availability of these important drugs for those who can benefit from their use under a physician’s care. It is designed to reveal the complexity of the problem and to spark debate and action from parents, physicians and pharmacists to Congress, the FDA and pharmaceutical companies to protect our children and the public health. Dealing effectively with abuse of controlled prescription drugs is essential to preserve their availability for appropriate use to improve the lives of Americans who need them.

Many individuals and institutions made important contributions to this work. It began with an unrestricted grant from Purdue Pharma LP. All CASA research is conducted independently and with the oversight of an independent advisory commission. However, because Purdue Pharma manufactures OxyContin—one of the drugs discussed in this report—CASA received written confirmation from the company that the grant could be used in any way it saw fit and that Purdue Pharma would not be involved in the conduct or reporting of the research. To eliminate the possibility of real or perceived influence by the pharmaceutical industry, CASA restricted its Advisory Commission membership to leaders in the field with no financial ties to pharmaceutical manufacturers of controlled drugs that might in any way compromise their involvement. We are grateful to Purdue for its grant.

The CASA National Advisory Commission on the Diversion and Abuse of Controlled Prescription Drugs is chaired by Alan I. Leshner, PhD, Chief Executive Officer of the American Association for the Advancement of Science and former Director of the National Institute on Drug Abuse. His outstanding leadership, and his commitment and that of the Commission members, contributed significantly to the quality of this product.
As our work progressed, it became clear that there were no data about the practices, attitudes and perceptions of those on the front line—doctors, pharmacists, nurses, dentists and veterinarians. We appreciate the generosity of Leonard D. Schaeffer and WellPoint Health Networks Inc. for providing funds to conduct surveys of physicians and of pharmacists as well as intensive focus groups with other health professionals.

The issue of diversion and abuse of opioids is intricately tied to pain management. To better understand the relationship between pain, pain management and addiction, on February 27, 2003, CASA hosted a conference Feeling No Pain: Substance Abuse, Addiction and Pain Management that brought together physicians, pharmaceutical company executives, law enforcement officials, pain management and addiction treatment professionals, and recovering individuals. We thank Ortho-McNeil Pharmaceuticals, Inc., Endo Pharmaceuticals, Inc, the National Institute on Drug Abuse, and the National Development & Research Institutes, Inc. for funding this conference. Key issues raised at the conference are discussed in this report.

We extend special thanks to Beau Dietl and his professional colleagues at Beau Dietl & Associates, who volunteered their time and investigative talent to conduct a baseline analysis in February 2004, and a follow-up analysis a year later, of the availability of controlled prescription drugs on the Internet, and who conducted a special investigation of the online availability of steroids.

We would not have been able to analyze changes in prescribing abusable prescription drugs without the help of Intercontinental Marketing Services (IMS). IMS provided specific data analyses drawing on their database of the National Prescription Audit™ Plus. We thank Barrett A. Toan, former Chairman and Chief Executive Officer of Express Scripts, for the analyses he conducted of prescribing patterns for controlled prescription drugs. Richard Brown, MD, MPH of the University of Wisconsin Medical School, Department of Family Medicine, and Norman Wetterau, MD of the New York State Academy of Family Physicians, provided technical assistance for our physician focus groups and survey. David Albert, DDS of the Columbia School of Dental and Oral Surgery provided similar assistance for our focus groups and interviews of dentists, and Henri R. Manasse, Jr., PhD (a member of the Advisory Commission) and staff at the American Society of Health System Pharmacists (ASHP) helped design the pharmacist survey instrument.

We thank Survey Research Laboratory at the University of Illinois at Chicago for their work on the focus groups and surveys, and consultants Mary Beth Clarke, Hedi Nasheri, PhD and Bonnie Wilford. Seddon R. Savage, MD and Nathaniel P. Katz, MD appeared before the Commission and offered professional advice on a range of issues relevant to this project.

Susan E. Foster, MSW, CASA’s Vice President and Director of Policy Research and Analysis, directed this effort. Linda Richter, PhD, senior research manager, was the Project Manager. CASA’s Substance Abuse Data Analysis Center (SADAC™), headed by Roger Vaughan, DrPH, CASA Fellow and associate clinical professor of biostatistics at Columbia University, was responsible for the data analysis which was conducted by Hung-En Sung, PhD, research associate, with assistance from Elizabeth Peters. Other CASA staff who contributed to this effort are research associates Heather Horowitz, JD, MPH, and Carrie Sanders, MPH; research assistants Sally Mays, Rachel Adams and Chris Sexton, MSW; CASA librarian David Man, PhD, MLS, and his colleagues Ivy Truong and Barbara Kurzweil; and bibliographic database manager Jennie Hauser. Jane Carlson handled administrative responsibilities.

While many individuals and institutions contributed to this effort, the findings and opinions expressed herein are the sole responsibility of CASA.
Chapter I
Introduction and Executive Summary

For three years, The National Center on Addiction and Substance Abuse (CASA) at Columbia University has been conducting an exhaustive study of the diversion and abuse of controlled prescription drugs—medications with the potential for abuse and addiction—in America. This report, *Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.*, is a comprehensive analysis of how widely opioids, central nervous system depressants, stimulants and steroids are abused and by whom, the health and social consequences of such abuse, and how these drugs are diverted from their normal distribution channels. It describes efforts underway to reduce such diversion and abuse and explores the barriers and gaps that remain in prevention and control.

The good news is that the increase in invention, production and distribution of controlled prescription drugs has brought relief to millions of people. The bad news is the 94 percent increase in the number of people abusing these drugs between 1992 and 2003, and the 212 percent increase among teens, while the population increased by only 14 percent. The problem of abuse of controlled prescription drugs in America has grown under the counter and under the radar to the point where this abuse now eclipses abuse of all illicit drugs combined except marijuana. The supply often comes from our own medicine cabinets or speedy delivery by ordering over the Internet.

New abusers of controlled prescription drugs are growing at an even more alarming rate and children are especially at risk. For example, the number of teens abusing these drugs for the first time grew by 542 percent from 1992 to 2002—four times the rate of increase among those ages 18 and over. And the number of teens abusing steroids increased 126 percent from 1991 to 2003 with the rate of increase five times greater for girls than for boys.
The diversion and abuse of controlled prescription drugs in the U.S. dates back to morphine abuse during the Civil War and continues through OxyContin and Ritalin abuse today. The problem can be seen in every stage of life: rich and poor, old and young, teens partying or cramming for exams, stressed executives, women juggling the challenges of work and care-giving, seniors coping with illness and loss, the mentally ill searching for relief, movie stars, rock musicians and athletes.

Against the backdrop of a nation conditioned to medicate every ill, the abuse of controlled prescription drugs has gone unattended. Education, prevention, treatment and enforcement efforts have focused primarily on illicit drugs. Thanks to the Food and Drug Administration (FDA), the medical use of prescription drugs is considered relatively safe. Unfortunately and incorrectly, for too many, this perception extends to their abuse as well.

Just as the number of people abusing controlled prescription drugs has been on the rise, so has the resulting increase in harm. For example, controlled prescription drug-related visits to emergency departments have increased three and a half times more than heroin related visits and four times more than visits linked to cocaine abuse.

As a result of historic inattention to prescription drug diversion and abuse, data defining the extent and nature of the diversion and abuse of controlled prescription drugs are limited. CASA’s Substance Abuse Data Analysis Center (SADAC™)—the most sophisticated in the nation—conducted extensive analyses of 15 national data sets to understand the scope of the problem, document the populations most at risk and explore the consequences associated with prescription drug diversion and abuse in the United States. (See Appendix A) CASA reviewed more than 2,000 articles, reports, books and other reference materials related to controlled prescription drug diversion and abuse and analyzed the most relevant and current information from these sources for this report.

To go beyond the published information and to get a sense of how the problem is perceived, CASA conducted telephone interviews with more than 200 key professionals from government agencies and private organizations across the nation. In addition, we conducted extensive interviews and focus groups with those on the front lines of providing and receiving clinical care—physicians, dentists, veterinarians, pharmacists, and individuals abusing controlled prescription drugs and those addicted to them. (See Appendix B)

As CASA proceeded with this study, it became clear that there were no data on how healthcare professionals perceive and respond to this problem. To fill this gap in research, WellPoint Health Networks Inc. provided funds for CASA to conduct two landmark national surveys, one of physicians and the other of pharmacists to explore in depth how diversion occurs at the clinical level and to elicit their practices, perceptions and attitudes with regard to controlled prescription drug diversion and abuse. (See Appendices C and D)

As part of this study, CASA also collaborated with Beau Dietl & Associates (BDA) to investigate the availability of controlled prescription drugs on the Internet. BDA donated its services for an initial investigation in February of 2004 and for a follow-up one year later. In April of 2005, BDA conducted an additional investigation of the availability of prescription steroids on the Internet. (See Appendix E)

To guide its research, CASA assembled an exemplary panel of experts. The CASA National Advisory Commission on the Diversion and Abuse of Controlled Prescription Drugs is chaired by Alan I. Leshner, PhD, former director of the National Institute on Drug Abuse and currently the Chief Executive Officer of the American Association for the

* To avoid any conflicts of interest on the Advisory Commission, CASA recruited experts who do not receive funding from pharmaceutical companies that manufacture controlled prescription drugs that might compromise their involvement.
Advancement of Science. The Commission advised CASA as we conducted our research in an effort to measure the extent of the problem and shape recommendations.

**Key Findings**

The controlled prescription drugs most likely to be abused include: opioids or pain relievers like OxyContin or Vicodin; central nervous system (CNS) depressants like Valium or Xanax; stimulants like Ritalin or Adderall; and anabolic-androgenic steroids like Anadrol or Equipoise. Opioids, CNS depressants and stimulants are abused for their mind-altering properties; steroids are abused for purposes of athletic performance or body sculpting.

Abuse of prescription drugs is defined as using a prescription drug that was not prescribed for you or that was taken only for the experience or feeling it caused. When discussing prescription drugs, it is important to distinguish between physical dependence and addiction. One can become dependent on a drug--tolerant to its effects and suffer withdrawal when use is discontinued--without becoming addicted. Addiction is a chronic, relapsing disease characterized by compulsive drug seeking and use, craving and continued use despite harm. Because of the potential for abuse of these drugs, federal and state governments regulate their distribution and use.

Most controlled prescription drug abusers are poly-substance abusers (74.7 percent); they either drink excessively and/or use illicit drugs as well as abuse controlled prescription drugs.

Of controlled prescription drug abusers, 63.9 percent also abuse alcohol and 53.6 percent also abuse illicit drugs. But 25.3 percent abuse only prescription drugs.

**Increased Availability and Increased Abuse**

Between 1992 and 2002, the U.S. population increased by 13 percent and prescriptions written for non-controlled drugs rose 56.6 percent, but the number of prescriptions written for controlled drugs increased 154.3 percent--12 times faster than the population and almost three times faster than prescriptions for non-controlled drugs.

While this increase in prescriptions for controlled medications may signify improved treatment of pain, mental illness, anxiety and other ailments, it was accompanied by a sharp increase in diversion and abuse. The number of people who admit abusing controlled prescription drugs increased from 7.8 million in 1992 to 15.1 million in 2003--up 93.8 percent--seven times faster than the increase in the U.S. population. Approximately six percent of the U.S. population (15.1 million people) admitted abusing controlled prescription drugs in 2003, 23 percent more than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000).

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* Opioids include narcotic pain relievers, depressants include tranquilizers and sedatives that depress the central nervous system (CNS) and stimulants are drugs that stimulate the CNS. Benzodiazepines and barbiturates are types of CNS depressants.

† Among individuals ages 18 and older, 73.8 percent of controlled prescription drug abusers are poly-substance abusers and among teens ages 12 to 17, 79.8 percent of controlled prescription drugs abusers are poly-substance abusers.

‡ Excessive drinking is defined as drinking more than the National Institute on Alcohol Abuse and Alcoholism (NIAAA) recommended levels: for women two or more drinks per day and for men three or more drinks per day in the past 30 days. For teens, any use of alcohol in the past year is considered abuse. Illicit drug use, which includes the use of marijuana, cocaine, crack, heroin, hallucinogens and inhalants, is defined for both adults and teens as any use of these drugs in the past year. Those who abuse multiple prescription drugs but are not excessive drinkers or illicit drug users are not considered poly-substance abusers for purposes of this report.

§ Throughout this report, CASA has attempted to use the most recent available data; therefore, findings from different years may be reported for different analyses.

** Except where indicated, the following analyses refer to opioids, CNS depressants and stimulants. Limited national data on steroids precludes their inclusion in much of the discussion that follows.
Between 1992 and 2003, there has been a:

- 140.5 percent increase in the self-reported abuse of prescription opioids,
- 44.5 percent increase in the self-reported abuse of prescription CNS depressants, and
- 41.5 percent increase in the self-reported abuse of prescription CNS stimulants.

Between 1992 and 2003, abuse of controlled prescription drugs has been growing at a rate twice that of marijuana abuse, five times greater than cocaine abuse and 60 times greater than heroin abuse.

These estimates are based on self-reported data from the National Survey on Drug Use and Health (NSDUH) that is representative of the non-institutionalized U.S. population, ages 12 and older. While the definition of controlled prescription drug abuse is broad,* the NSDUH is known to underestimate considerably all forms of substance use in the U.S. Because it is administered in the home, respondents--particularly teens--tend to under-report their substance use. Moreover, the survey does not include high-risk institutionalized populations, such as prison inmates, hospital patients, nursing home residents, patients in drug abuse treatment and others who cannot be reached in a home (e.g., the homeless).

**Teens**

Teen prescription drug abusers represent an especially vulnerable group. Teens may view prescription drugs as relatively safe either when abused alone or in combination with alcohol or other drugs and, for them, prescription drugs may serve as gateway drugs to other substances of abuse. In addition to teen abuse of these drugs for purposes of partying or studying, some teens abuse controlled prescription drugs to self-medicate feelings of stress or depression, anxiety or other mental health problems that may go undetected or untreated by the adults around them.

In 2003, 2.3 million teens ages 12 to 17 (9.3 percent) reported abusing a controlled prescription drug in the past year; 83 percent of them reported abusing opioids. The rate of increase in controlled prescription drug abuse among teens has been growing at a faster pace than among adults. Between 1992 and 2003, the percent of teens ages 12 to 17 who admit abusing controlled prescription drugs increased by 212 percent--2.6 times that of individuals ages 18 and over (81 percent).

Compared to teens who do not abuse controlled prescription drugs, those who do are twice as likely to use alcohol, five times likelier to use marijuana, 12 times likelier to use heroin, 15 times likelier to use Ecstasy, and 21 times likelier to use cocaine.

Steroid abuse among teens is a growing problem. Between 1991 and 2003, reported rates of lifetime steroid abuse among high school students increased 126 percent. The rate of increase among girls (342 percent) is more than five times that of boys (66 percent). In 2004, 1.1 percent of eighth graders, 1.5 percent of tenth graders and 2.5 percent of twelfth graders admitted abusing steroids. Approximately 1.7 million teens between 12 and 17 have tried steroids at least once.

**Controlled Prescription Drug Only vs. Poly-Substance Abusers**

Those who abuse prescription drugs only (25.3 percent of controlled prescription drug abusers) differ considerably from those who abuse other substances. Among teens, prescription drug only abusers are likelier to be younger--ages 12 and 13--than those who are poly-substance abusers (36.7 percent vs. 8.7 percent).

Those ages 18 and older who abuse prescription drugs only are likelier than poly-substance-abusers to be women (60.9 percent of prescription drug only abusers are women vs. 45.1 percent of poly-substance abusers are women) and to be age 35 and older (63.7 percent

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* Used a drug that was not prescribed for you or that was taken only for the experience or feeling it caused.
of prescription drug only abusers are age 35 or older vs. 31.9 percent of poly-substance abusers who are age 35 or older.* Prescription drug only abusers also are likelier than poly-substance abusers to be married (59.3 percent vs. 25.8 percent), better educated (24.7 percent vs. 15.8 percent are college graduates) and have higher incomes (81.7 percent vs. 72.8 percent have family incomes of $20,000 or more).

Because the profile of a prescription drug only abuser differs so significantly from that of poly-substance abusers, prevention service and healthcare providers may be likelier to overlook them.

**New Abusers**

In 1992, the prescription drug abusing population was overwhelmingly composed of regular or experienced abusers. By 2000, about one-third of all abusers were abusing the drug for the first time. Between 1992 and 2000, the number of new opioid abusers grew by 224.8 percent, new tranquilizer abusers, by 149.5 percent, new sedative abusers, by 127.3 percent, and new stimulant abusers, by 171.2 percent. The increase in new teen abusers has grown at an even faster pace than the increase for those abusers ages 18 and over—more than four times faster for opioid abuse (530.4 vs. 130.1 percent), three times as fast for tranquilizers (329.9 vs. 105.1 percent) and sedatives (260.0 vs. 80.7 percent), and 2.6 times faster for stimulants (283.0 vs. 106.7 percent).

**The Consequences**

The growth in the abuse of controlled prescription drugs has been accompanied by increases in the consequences of such abuse. Abuse of controlled prescription drugs is implicated in at least 23 percent of drug-related emergency department admissions and 20.4 percent of all single drug-related emergency department deaths. Prescription opioids accounted for more drug mentions involved in multiple drug-related deaths (18.9 percent) than cocaine (15.2 percent), heroin (12.6 percent) and marijuana (2.6 percent). Between 1994 and 2002, there was a 78.9 percent increase in the total number of controlled prescription drug-related mentions in emergency department visits, with prescription opioids demonstrating the sharpest increase (168 percent) over this period. Seven percent of all controlled prescription drug abusers report experiencing emotional or mental health problems caused or worsened by their abuse of the drugs.

About 12 percent (1.9 million) of controlled prescription drug abusers (15.3 percent of teenage prescription drug abusers compared to 11.8 percent of adult abusers ages 18 and older) meet the stringent clinical (DSM-IV) diagnostic criteria for abuse or addiction to these drugs.

Individuals who are current abusers of alcohol or illicit drugs or have a history of such abuse are at increased risk for prescription drug abuse.

**Controlled Prescription Drug Abuse and Mental Illness**

A higher than average level of prescription drug abuse compared to the general population can be found among those who are mentally ill, due in part to the greater reliance of these individuals on psychotropic medications to address their ailments. While some individuals with a mental illness abuse prescription drugs to self-medicate their problems, others may have legitimate prescriptions for these medications but begin to abuse them over time.

**Controlled Prescription Drug Abuse and Crime**

Incarcerated criminal offenders are likelier than the general, non-institutionalized population to have abused controlled prescription drugs. Controlled prescription drug abusers are at greater risk than non-abusers of engaging in criminal behavior.
Controlled Prescription Drug Abuse and Healthcare Workers

Individuals working in the health profession who have relatively easy access to controlled prescription drugs, such as anesthesiologists, emergency medicine physicians, family/general practitioners and psychiatrists, are at particularly high risk of abusing them.

Regional Differences

Relative to their share of the population, the southern and western regions of the country account for a disproportionately large percent of the distribution of certain opioids, sedatives and stimulants from manufacturers. The western region of the country has disproportionately high levels of opioid and stimulant abuse; the southern region has a disproportionately high level of CNS depressant abuse.

Sources of Diversion

Drugs can be diverted or sidetracked from their lawful (medical) purpose to illicit use at any point in the pharmaceutical manufacturing and distribution process. Drugs can be stolen from the manufacturing facility, wholesale distributors, mid-level warehouses, pharmacies, hospitals, nursing homes or clinics; from physician, dentist or veterinarian offices; or from parents’ or friends’ medicine cabinets. On the clinical level, doctors, pharmacists, dentists, nurses and veterinarians may be involved intentionally or unintentionally in diverting controlled prescription medications, and patients may intentionally divert these drugs for purposes of abuse.

Healthcare professionals. CASA’s surveys of pharmacists and physicians reveal several ways that diversion may occur at the clinical level. One reason may relate to a lack of training. Only 19.1 percent of physicians receive training in identifying prescription drug abuse and addiction; 61.4 percent receive such training in residency and 45.6 percent through continuing medical education. About half of pharmacists have received training in identifying prescription drug abuse and addiction (49.6 percent) and in preventing diversion (48.1 percent) since pharmacy school. Only about one-third of physicians and half of pharmacists rated the training they received in preventing the abuse or diversion of controlled prescription drugs as good or excellent.

While most physicians (80.0 percent) feel qualified to diagnose prescription drug abuse and addiction and confident in their ability to know when a person is attempting to obtain controlled drugs for purposes of diversion or abuse (81.9 percent), other research calls this confidence into question. A survey of physicians conducted by CASA in 2000 found that 94 percent of physicians failed to identify the symptoms of alcohol abuse or addiction, even when given five diagnostic opportunities. An earlier CASA survey, in which physicians were presented with a hypothetical case of an older female patient with symptoms consistent with alcohol or prescription drug abuse, found that only one percent offered substance abuse as one of five possible diagnoses.

Almost half of physicians find it difficult to discuss prescription drug abuse with their patients, only about half (53.8 percent) ask about prescription drug abuse when taking a patient’s health history and only about half (54.5 percent) either always or most of the time call or obtain records from the patient’s previous (or other treating) physician before prescribing controlled drugs on a long-term basis.

A significant proportion of pharmacists (28.4 percent) do not regularly validate the prescribing physician’s DEA number when dispensing controlled drugs. Others admit to dispensing a controlled drug without a written prescription order (but in response to a phone order) or based on a prescription order that is missing information.
Steps that might help prevent controlled prescription drug diversion and abuse by patients include contacting a patient’s prior physicians to identify those with an abuse/diversion history; medication contracts to help ensure adherence to a prescribed regimen; drug testing to monitor whether a patient has taken a prescribed drug; pill counts to ensure that the patient has not used (or diverted) more than the indicated amount of a drug; prescribing limited doses of the drug at a time; and educating patients about the dangers of controlled prescription drug abuse. CASA’s survey of physicians found that when suspecting a patient of diversion or abuse, only 27.8 percent usually require urine tests, 23.1 percent usually conduct pill counts and 36.9 percent usually create a medication contract.

**Patients.** CASA’s surveys of physicians and pharmacists reveal that 59.1 percent of physicians and 51.8 percent of pharmacists believe that patients themselves account for the bulk of the drug diversion problem. Methods of patient diversion include providing fraudulent prescriptions, impersonating physicians, altering prescriptions, pressuring or deceiving physicians, dentists, nurses or veterinarians and doctor shopping.

**The Internet.** Rogue Internet pharmacies are emerging as an unmonitored and unregulated source of diversion for controlled prescription drugs. CASA’s investigation in cooperation with Beau Dietl & Associates (BDA) of the availability of controlled prescription drugs over the Internet found that only six percent of Web sites selling these drugs required a prescription prior to dispensing the drugs. Forty-one percent indicated that no prescription was needed; 49 percent offered an “online consultation;” four percent made no mention of prescriptions at all. A replication of this analysis one year later found that the landscape of illegal Internet drug availability has not improved. In fact, opioids were offered on considerably more sites in 2005 compared with 2004, and more sites advertised the U.S. as the country of origin for the drugs.

A similar analysis by BDA found that 95 percent of Web sites that sell steroid drugs do not require a prescription or ask only that a brief questionnaire be answered to receive the drugs. Only five percent of the sites require that a copy of a prescription be faxed or mailed or that the patient’s doctor be contacted for the prescription.

**Pharmaceutical companies.** The appeal of a prescription drug for abuse depends on the strength and immediacy of the high it can produce as well as on how easily the medication can be altered to achieve that high. Adding an antagonist to an opioid drug can counteract its morphine-like effects in the event that the tablets are altered for abuse. Pharmaceutical companies do not routinely include antagonists in the manufacture of abusable prescription drugs on grounds that patients may have negative physical reactions to the antagonist or it may reduce the drug’s efficacy. Marketing practices of pharmaceutical companies, such as Purdue Pharma’s aggressive promotion of OxyContin for moderate as well as severe pain, may increase the chances that these drugs will be abused. Direct advertising of controlled prescription drugs to patients in print and broadcast media runs the risk of creating an artificial demand for these powerful drugs.

**Regulation and Control**

The nation’s response to this silent public health menace has been primarily one of regulation and enforcement. The regulation and monitoring of controlled prescription drugs involves many governmental and nongovernmental agencies, with considerable variation in policy and practice across states. Because controlling prescription drug diversion and abuse is costly and labor intensive, however, there are gaps in monitoring and enforcement. At the federal level:

- The Controlled Substances Act (CSA) of 1970 created a system for classifying prescription drugs according to their medical use and potential for abuse.
The Drug Enforcement Administration (DEA), an agency of the U.S. Department of Justice, is the lead federal agency responsible for enforcing the CSA. In cooperation with state authorities and other federal agencies, the DEA is responsible for monitoring the distribution of controlled prescription drugs, preventing the diversion of controlled prescription drugs for illicit purposes and complying with international treaties in doing so. The extent to which the DEA can perform these functions is related to the resources allocated to them.

The Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services is responsible for providing approval to pharmaceutical companies to market new drugs and for ensuring that their marketing and promotional practices are accurate. The FDA requires specific drug labeling, tracks adverse events related to drugs and conducts risk assessments of potentially abusable drugs. The FDA does not require, however, that risk management plans be prepared for all controlled prescription drugs prior to their release to the market. Neither does it require that pharmaceutical companies demonstrate in their application materials for FDA approval of new drugs that they have made every effort to formulate the drug to avoid or minimize its potential for abuse.

Businesses that manufacture or distribute controlled prescription drugs, all health professionals who dispense, administer or prescribe controlled drugs and all pharmacies that fill prescriptions for controlled drugs must register with the DEA and comply with regulatory requirements relating to drug security, record keeping and adherence to standards.

Prescriptions written for controlled drugs must meet specific requirements, such as being signed and dated on the day they are issued and including the name, address and DEA registration number of the physician, the name and quantity of the drug prescribed, directions for use and refill information.

At the state level, professional practice acts administered by oversight institutions such as boards of medicine, pharmacy or nursing govern prescribing and dispensing of controlled drugs. Professional oversight boards have the authority to license and discipline members within each profession. Inspectors who report to the oversight boards monitor professional practice compliance with state laws and regulations. State bureaus of narcotics and local law enforcement play an active role in enforcement of diversion control.

Twenty states have enacted Prescription Drug Monitoring Programs in an effort to stem diversion and abuse; several more states have received grants to set up such programs. Medicaid reviews and state and local task force data also have been used for these purposes. Depending on state law, information obtained through these programs may be shared with law enforcement agencies, healthcare and regulatory agencies and, in some states, healthcare practitioners to help identify inappropriate or illegal activities involving controlled prescription drugs. The current system of monitoring programs, however, is spotty because not all states have programs and those that do have vastly different data-collection protocols. No standardized outcome measures have been established, and little empirical research has been conducted, to assess the effectiveness of these programs.

An overriding concern in attempts to control diversion and abuse of prescription drugs is the risk that such controls might interfere with their legitimate and beneficial use. As a result, healthcare professionals and law enforcement officials face the difficult operational challenge of controlling diversion and abuse without jeopardizing legitimate, medical use of these drugs.

**Prevention Programs**

School and community programs designed to prevent prescription drug abuse are few and far between. Those that exist have been launched primarily by pharmaceutical companies that manufacture drugs susceptible to diversion and
abuse. To date, no formal independent evaluations of the effectiveness of these programs are available.

*Treating Prescription Drug Abuse*

Nationwide only 16.6 percent of those in need receive any kind of substance abuse treatment and only 11.4 percent of underage youth in need receive such treatment. The two main types of treatment available for prescription drug abusers are behavioral therapies and pharmacological treatments. Behavioral treatments, including individual and group counseling and cognitive behavioral therapy (CBT), typically are not designed specifically for prescription drug abuse. Pharmacological treatments are used to help alleviate withdrawal symptoms, reduce drug cravings, or treat overdoses.

The main pharmacological treatments available for opioid addiction are methadone, levo-alpha-acetyl-methadol (LAAM), naltrexone and buprenorphine. The effectiveness of these treatments has been primarily investigated for illicit rather than prescription opioid addiction. Unlike treatment for opioid addiction, little progress has been made in treating addictions to prescription depressants and stimulants via pharmacological therapies.

**Recommendations**

Addressing the problems of controlled prescription drug diversion and abuse requires comprehensive action and concerted collaboration among health professionals, law enforcement, government, healthcare, regulatory and enforcement agencies, and parents. Below is a summary of CASA’s recommendations to prevent and reduce diversion and abuse while assuring availability of prescription drugs for medical purposes. A complete list of recommendations is presented in Chapter VIII.

**Train Healthcare Providers**

Associations of healthcare training institutions and medical training programs should require education and training in prescribing and administering controlled drugs; identifying diversion; identifying, diagnosing and treating substance abuse and addiction; and identifying, diagnosing and treating psychiatric disorders and pain in ways that minimize the risk of abuse and addiction.

The American Board of Medical Specialties and state professional boards should require that knowledge in identifying, diagnosing and treating substance abuse, addiction and the prescribing/administering of controlled drugs be part of its minimum standards of competency, and national professional boards should establish, publicize and enforce national standards of practice in these areas.

The DEA should require physician competence in prescribing and administering controlled prescription drugs as a condition of registration.

**Strengthen Efforts to Control Internet Diversion**

Congress should clarify federal law related to the sale or purchase of controlled prescription drugs on the Internet, and require Internet search engines to provide warnings about the illegal sale and purchase of controlled prescription drugs over the Internet and to block sites that fail to require a legitimate prescription for selling controlled prescription drugs.

The DEA and state attorneys general should encourage financial institutions to restrict purchases of controlled prescription drugs from non-licensed and accredited providers and encourage postal and shipping services to train counter and delivery personnel to recognize potential signs of pharmaceutical trafficking and to know how to respond in the event of suspicious activity.

**Strengthen Monitoring and Enforcement to Prevent and Detect Diversion**

The U.S. Department of Justice and the Food and Drug Administration should fund the development of model state legislation for state prescription drug monitoring programs (PDMPs).
and provide financial incentives for states to develop and operate PDMPs in accordance with national standards.

The DEA should work together with state medical boards to train law enforcement professionals (including state and local police and prosecutors) to better understand therapeutic uses of controlled prescription medications and conditions under which the medical community recommends their use in treating patients.

Federal and state governments should ensure adequate staffing of law enforcement and prosecutors to pursue cases of controlled prescription drug diversion.

**Strengthen FDA Regulation of Controlled Prescription Drugs**

The FDA should require pharmaceutical companies to include proactive risk management plans in all new applications for controlled drugs and to demonstrate that they have made every effort to formulate the drug in a way that avoids or at least minimizes the drug’s potential for abuse. The FDA should require all pharmaceutical companies to submit promotional materials for controlled drugs to the FDA for review and approval prior to their use.

**Safeguard Controlled Prescription Drugs From Children**

Parents should educate themselves about the dangers of controlled prescription drug abuse for themselves and their children, and take steps to keep controlled prescription drugs prescribed for them from the hands of children.

Parents should also take steps to make sure their children are not using the Internet to acquire controlled prescription drugs.

**Improve Treatment for Prescription Drug Abuse and Addiction**

Federal and state governments should assure access to appropriate treatment for prescription drug abuse, and require managed care and private health insurance companies to reimburse physicians and dentists for time spent screening patients for substance abuse and addiction, referring them to treatment if needed, and collaborating with pharmacists to prevent diversion and abuse.

Treatment programs should address co-occurring disorders and make comprehensive medical assessment a standard part of treatment for prescription drug abusers.

**Educate the Public on the Dangers of Prescription Drug Abuse**

Government-sponsored public awareness campaigns that focus on alcohol, marijuana and other illicit drugs should include the abuse of controlled prescription drugs and should inform parents of the need to safeguard their prescription drugs from children. Schools and communities should incorporate prescription drug abuse, including steroid abuse, into evidence-based substance use prevention programs.

**Improve Surveillance and Research**

To better inform policy, prevention and treatment initiatives, national surveys of drug use should refine their measures of prescription drug abuse and addiction and use consistent terminology. Federal agencies (e.g., National Institute on Drug Abuse, Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration) should fund systematic and well-designed studies to better understand prescription drug diversion and abuse.
Chapter II
Abuse of Prescription Drugs: America’s Long History

Enormous strides have been made in recent years in the development of beneficial and often life-saving pharmaceuticals. The vast majority of prescriptions written and medications dispensed provide great benefits to the patients who need them. Unfortunately, however, some medications, if used inappropriately or abused, have enormous potential to cause harm, illness, addiction and even death.

Thanks to rigorous standards of the U.S. Food and Drug Administration (FDA), the appropriate use of prescription drugs is relatively safe. However, against the backdrop of a nation conditioned to seek a pill for every ill, prescription drugs typically are viewed as safe even when used inappropriately, despite the highly addictive properties of certain ones and the dangers of using them this way. Unfortunately and incorrectly, this perception of safety too often extends to their abuse as well.

Commonly abused prescription medications are those that alter mental functioning and include opioids like OxyContin or Vicodin, central nervous system (CNS) depressants like Valium or Xanax and CNS stimulants like Ritalin, Adderall or Dexedrine. Also commonly abused—although for their physical rather than psychoactive effects—are anabolic-androgenic steroids like Anadrol or Equipoise. The diversion and abuse of controlled prescription drugs in the U.S. has a long history dating back to the abuse of morphine during the Civil War.

America’s Pill-Popping Culture

Dramatic increases in the use of prescription medications—fueled by unprecedented drug development, a societal appetite for medication, increases in insurance company prescription drug coverage and the ramp up of pharmaceutical advertising—have reshaped the practice of American medicine. Indeed, consumption of controlled prescription drugs in the United States by far exceeds that of other
nations worldwide. The average consumption of controlled opioid medications in the U.S. is almost double that of the next largest consumer, Denmark.  

Ninety-one percent of Americans have taken prescription drugs and more than half (54 percent) take them regularly. Americans used an average of 11.8 prescriptions a year in 2003, up from 7.8 a decade earlier. A recent study found that 55 percent of individuals age 18 and over reported taking a prescription drug in the past week; 11 percent took five or more different prescription medications. Older Americans account for the bulk of this use—80 percent of males and 85 percent of females age 65 and over report taking a prescription drug in the past week compared with 20 percent of teens age 12 to 17. From 1997 to 2003, spending on prescription drugs nearly tripled from $78.9 billion to $216.4 billion. Recent advances in gene therapy suggest that the greatest surge in pharmacological therapeutics remains to be seen.

The mid-1950s signaled the beginning of a new approach to mental health problems with the development of psychotropic drugs. The 1980s marked another turning point, with the emergence of SSRI antidepressants, such as Prozac, as even greater percentages of Americans came to believe that drugs can be used safely to control depression, emotional problems and other unwanted feelings. Controlled psychotropic drugs are increasingly being used to treat different forms of insomnia, anxiety, obesity and child hyperactivity, as well as various kinds of pain.

Improvements in diagnostic and screening practices and technology have identified larger numbers of patients that can benefit from medications. The increasing use of pharmaceuticals has extended to children as well, with a growing tendency to prescribe psychotropic drugs to address their mental health and behavioral problems.

A United Nations analysis of drug use observed that the pill-popping culture develops as people use drugs for wide-ranging purposes—even to change their image—with little regard for the fact that prolonged, excessive consumption of psychoactive drugs can result in dependence and addiction, as well as considerable physical and mental suffering.

Abused Prescription Drugs

The federal Controlled Substances Act (CSA) of 1970 created a system for classifying prescription drugs according to their medical value and their potential for abuse, as determined by the Department of Health and Human Services’ Food and Drug Administration (FDA). Drugs addressed in this Act are termed controlled substances and include illicit drugs as well as those prescribed for medical purposes but have varying degrees of abuse potential. By law, every drug under the purview of the CSA is assigned to one of five categories or schedules.

- Schedule I: No medical use, high abuse potential (e.g., heroin, Ecstasy);
- Schedule II: Accepted medical use, high abuse potential (e.g., OxyContin, Ritalin);
- Schedule III: Accepted medical use, less abuse potential than Schedules I and II (e.g., Vicodin, Anadrol);
- Schedule IV: Accepted medical use, abuse potential not significantly less than Schedule II;
- Schedule V: Low abuse potential (e.g., some over-the-counter medications).

* Controlled opioid medications include codeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, pethidine (all Schedule II drugs) and tilidine (a Schedule I drug). Average consumption is measured in defined daily doses per million inhabitants per day, excluding Schedule III and IV drugs, between 2000 and 2002. The U.S. had 22,524 daily doses/million inhabitants in the U.S. vs. 11,271 daily doses/million inhabitants in Denmark.
† Includes new prescriptions and refills. For example, a prescription written by a physician in January that permits refills throughout the year would constitute 12 prescriptions.
‡ Although 2003 data are not available on age differences in prescription drug use, data from 2000 indicated that of an overall average of about 10 prescriptions used per year, young people in their late twenties and thirties used an average of two prescriptions while people over age 75 used an average of 11.
§ Selective serotonin reuptake inhibitors.
- Schedule IV: Accepted medical use, lower abuse potential than Schedules I-III (e.g., Valium, Xanax); and

- Schedule V: Accepted medical use, lowest abuse potential of scheduled drugs (e.g., Robitussin AC).

In general, the pharmacological properties of rapid speed of onset and rapid termination of effects are associated with abuse and addiction. The primary prescription medications that are diverted and abused are psychotropic or psychoactive drugs--pharmacological agents capable of altering mental functioning, affecting the mind, emotion and behavior. Drugs that are most commonly diverted and abused fall into three classes: opioids, CNS depressants and CNS stimulants.

**Opioids**

Also referred to as narcotics, analgesics, painkillers or pain relievers, opioids commonly are taken to relieve pain, the most common complaint that physicians hear from their patients. Opioids are prescribed for three types of pain: acute or short-lived pain, chronic malignant (cancer) pain and chronic non-malignant pain. Opioid medications include morphine, codeine, oxycodone (e.g., OxyContin, Percocet), hydrocodone (e.g., Lortab, Vicodin), hydromorphone (e.g., Dilaudid), propoxyphene (e.g., Darvocet, Darvon), and meperidine (e.g., Demerol).

Opioids attach to opioid receptors in the brain, block the transmission of pain signals to the brain and, like illicit opioids (e.g., heroin), produce a sense of heightened pleasure. The use of opioids is an important component of pain management.

**Abuse potential.** Prescription opioids, like their illicit counterpart heroin, are addictive and usually classified as Schedules II and III drugs. Yet, determining the risk of addiction to opioids following prescribed use has stirred considerable debate among pain management and addiction specialists. Pain management specialists tend to emphasize the risk of under-treating pain, sometimes understating the risk of addiction; addiction specialists tend to emphasize the risk of abuse and addiction, sometimes understating the risk of under-treated pain.

We [addiction specialists] are like orthopedic surgeons at the bottom of the ski slope.

Despite the ongoing tension between addiction specialists and pain management specialists surrounding this issue, compelling and reliable evidence-based research is not available. Virtually no studies have been published examining the experiences of pain patients who use opioids for extended periods of time.

Researchers who claim that the use of opioids as prescribed to treat chronic or acute pain--even over a long period of time--rarely results in abuse or addiction often base this claim on a small number of specific studies. In recent years, the validity, reliability, strength and relevance of many of these studies have been called into question.

One commonly cited study of this nature is a survey of approximately 12,000 hospital patients who took at least one opioid for pain. The results indicated that only four patients with no history of addiction demonstrated signs of addiction. These findings were published in 1980 in a one-paragraph letter to the editor of the *New England Journal of Medicine*. In this study, patients were treated for acute or short-term pain, posing little relevance to the risk of addiction from long-term use of opioids. The patients were not followed up over time, leaving open the question of whether symptoms of addiction may have emerged following their release from the hospital. Another study of 62 patients conducted in 1977 over an 11-month period in a headache clinic concluded that only several patients demonstrated signs of addiction.

*Not all analgesics/painkillers/pain relievers are opiate-based (e.g., acetaminophen, aspirin).
A separate set of research findings suggest the possibility that abuse or addiction resulting from therapeutic use of opioids may not be so minimal. However, these findings also derive from small studies and do not provide definitive results. One study in Lexington, Kentucky reviewed the charts of 258 patients who sought treatment for addiction at a psychiatric center, 162 of which primarily abused or were dependent on OxyContin. Sixty of these OxyContin-dependent patients reported chronic pain issues upon admission. No conclusive data, however, were collected on whether the use of the opioids—in this case OxyContin—to treat the chronic pain actually led to the addiction.

Perhaps because of the lack of concrete evidence supporting one or the other side of the debate, there is a basic disagreement among healthcare professionals about the danger of addiction resulting from opioid use. Some physicians and patients fear that using opioids therapeutically can result in addiction; such concern can affect physicians’ prescribing practices. In addition to the fear of causing addiction, some physicians fear being scrutinized by regulatory agents for too liberally prescribing controlled substances. Surveys of physicians, however, show that concerns about addiction tend to outweigh concerns about regulatory scrutiny. CASA’s survey of physicians found that 63.5 percent do not worry much or at all about the possibility of review of their prescribing practices by regulatory or enforcement agencies. About a quarter (24.2 percent) say they worry somewhat and 9.5 percent say they worry a great deal about this possibility.

Other physicians—particularly those who specialize in pain management—feel that opioids are under-utilized to treat pain. They argue that the under-treatment of pain can lead to health problems such as increased risk of pneumonia or respiratory problems and also can cause acute pain to develop into chronic pain.

The dearth of reliable data speaking to the issue of the addictive potential of pain medications when used to treat pain suggests a dire need for well-conducted research in this area. Until the necessary evidence is obtained, however, physicians must walk the delicate line of balancing appropriate pain management while avoiding over-prescribing and patient addiction.

**Consequences of abuse.** Long-term use of opioids can lead to physical dependence on the drugs. Physical dependence is characterized by tolerance to the drug and withdrawal symptoms when use of the drug is reduced or stopped. Opioid withdrawal symptoms include insomnia, bone and muscle pain, diarrhea and vomiting. These signs of physical dependence may occur even when opioids are used appropriately for medical purposes. Opioid abuse—particularly taking a large dose at one time can lead to severe respiratory depression and death.

**Central Nervous System (CNS) Depressants**

CNS depressants slow normal brain function by affecting the neurotransmitter gamma-aminobutyric acid (GABA), which decreases brain activity. Because of their sedating or

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* Tolerance involves a decreased physiological sensitivity to the action of a drug with continued use or the need to use increasing amounts of the drug in order to achieve the desired effect.

† Withdrawal is a physical syndrome with psychological manifestations that results from a marked reduction or abrupt cessation in the long-term use of a drug.

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calming effects, medications in this class commonly are used to treat anxiety and sleep disorders. Sedative-hypnotics, often referred to as tranquilizers, are the primary group of prescribed CNS depressant medications. Barbiturates and benzodiazepines are the two main types of sedative-hypnotics.

Benzodiazepines such as diazepam (e.g., Valium), alprazolam (e.g., Xanax), chlordiazepoxide HCl (e.g., Librium), clonazepam (e.g., Klonopin), and lorazepam (e.g., Ativan) are used to treat anxiety, acute stress reactions and panic disorder. Sleeping disorders commonly are treated with more sedating benzodiazepines, such as triazolam (e.g., Halcion) and estazolam (e.g., ProSom).

Barbiturates are prescribed to induce anesthesia or sleep, relieve anxiety or treat seizure disorders. These drugs work by depressing the activity of muscle tissues, the heart and the respiratory system. Examples of barbiturates are mephobarbital (e.g., Mebaral) and pentobarbital (e.g., Nembutal).

Benzodiazepines largely have replaced barbiturates in medical use because benzodiazepines are more effective and safer in that they have a lower risk of coma and fatal intoxication.

**Abuse potential.** CNS depressants can be addictive, resulting in their classification as Schedule II-IV drugs. Short-acting, high-potency benzodiazepines, such as alprazolam (e.g., Xanax), are likely to lead to addiction sooner than slower- and longer-acting benzodiazepines such as chlordiazepoxide (e.g., Librium).

**Consequences of abuse.** Long-term use of CNS depressants leads to tolerance to the drug. If drug cessation occurs abruptly rather than through a medically supervised tapering-off process, the individual may experience serious withdrawal symptoms, including a need for more of the drug to reclaim its calming effect, seizures, hallucinations and, in some cases, death. Barbiturates have a particularly high risk of inducing severe and potentially life-threatening withdrawal symptoms. In contrast to barbiturates, taking benzodiazepines rarely leads to death except when used in combination with alcohol or other drugs.

**Central Nervous System (CNS) Stimulants**

Stimulants enhance brain activity, resulting in an increase in alertness, attention and energy as well as elevated blood pressure and increased heart rate and respiration. The chemical structure of stimulants is similar to the neurotransmitters norepinephrine and dopamine; taking stimulants increases the amount of these chemicals in the brain. Like illicit stimulants (e.g., cocaine†), prescription stimulants produce euphoria. Traditionally used to treat asthma, other respiratory problems, obesity and neurological disorders, stimulant medications increasingly are being replaced by alternative drugs because of concerns about their abuse potential. Today, the clinical use of stimulants primarily is confined to the treatment of a few medical disorders, including narcolepsy, attention deficit hyperactivity disorder (ADHD) and, in some cases, depression. Some of the commonly prescribed stimulants include methylphenidate (e.g., Ritalin, Concerta) amphetamine-dextroamphetamine (e.g., Adderall), dextroamphetamine (e.g., Dexedrine) and sibutramine hydrochloride monohydrate (e.g., Meridia).

**Abuse potential.** Stimulants, like their illicit counterpart cocaine, can be addictive, resulting in their classification primarily as Schedule II drugs.

* Some researchers make a distinction between sedatives and tranquilizers. For example, the National Survey on Drug Use and Health (NSDUH), upon which much of the statistics presented in this report are based, provide data separately for the two categories of drugs.

† Considered an illicit drug except in rare instances when used in medical practice.

‡ A disorder marked by an uncontrollable desire for sleep.
Much research on the use and abuse of prescription stimulants focuses on medications such as Adderall and Ritalin, used to treat ADHD. Although there has been some debate in medical and research communities about whether the therapeutic use of stimulants such as Ritalin in youngsters may lead to later substance abuse, there is now some consensus among many experts in this area that this is not the case. Most people who abuse these drugs (to stay awake, study or party) do not obtain them through legitimate prescriptions.

I realized that taking drugs was fun so I wanted to experiment. Before that I was against it but this [Adderall] was a pill from a doctor that helped you take tests better...There couldn’t be anything bad about it.

--Addicted Prescription Drug Abuser, Age 21
CASA Interview

Consequences of abuse. The long-term use of prescription stimulants can lead to physical tolerance and withdrawal symptoms. Abuse of certain stimulants, such as amphetamines, can result in side effects including insomnia, irritability, dizziness, agitation, tremors, elevated body temperature, rapid or irregular heartbeat, hypertension, adverse mood reactions, loss of appetite and, in extreme cases, paranoia, hallucinations, heart failure or fatal seizures.

Stimulant abusers sometimes attempt to counter, increase or sustain the effects of the drugs by using them with alcohol or other drugs such as opioids or CNS depressants. As a result, individuals who continually use stimulants are at high risk of developing multiple drug dependencies.

It all started with Ritalin and Adderall. I started taking them every day [to get high] and pretty soon it didn’t work anymore and I needed something more. I needed a bigger, faster boost.

--Teenager interviewed for ABC News report

Anabolic-Androgenic Steroids

Anabolic-androgenic steroids are synthetic chemicals based on the structure and pharmacology of testosterone that promote the growth of skeletal muscle and the development of male sexual characteristics. Steroids are used to treat anemia, breast cancer and delayed puberty. Experimentally, steroids have been used to treat erectile dysfunction, osteoporosis, wasting as a result of AIDS, and other diseases. Steroids also are used in veterinary practice.

Steroids are used illicitly to promote muscle growth and strength by high school, college, professional and elite amateur athletes, and by body builders, fitness buffs and individuals in occupations requiring enhanced physical strength. Victims of physical and sexual assault have been found to use steroids to increase muscle size and strength as a means of self protection. Individuals with eating and body dysmorphic disorders are among the most recently identified groups more likely to abuse steroids.

Teens, particularly young athletes, are at increased risk of steroid abuse. Although steroid abuse is more common in boys, over the past decade the increase in abuse among girls has been five times greater than among boys. As boys have done historically, many girls abuse these drugs to enhance their muscle tone and have a more attractive physique. The doses of steroids taken by these individuals are 10 to 100 times higher than the doses used for medical purposes.

Commonly abused steroids include Nandrolone (e.g., Durabolin, Deca-Durabolin), Oxandrolone (e.g., Anvar, Oxandrin), Oxymetholone (e.g., Anadrol), Sanozolol (e.g., Winstrol), Boldenone (e.g., Equipose), Methandrostenolone (e.g., Dianabol) and Testosterone-Cypionate (e.g., Depo-Testosterone).

* Body dysmorphic disorder is a preoccupation with an imagined physical defect in appearance or a vastly exaggerated concern about a minimal defect.
Abuse potential. Although little is known about the extent to which steroid abuse can lead to addiction, some steroid abusers show signs of addiction by continuing to use the drugs even when suffering the physical, social or behavioral consequences, spending time and money trying to obtain the drugs, and experiencing withdrawal symptoms when discontinuing use.  

Consequences of abuse. Physical side effects of steroid abuse include elevated blood pressure and cholesterol levels, potentially fatal liver cysts and liver cancer, jaundice, severe acne, premature balding and reduced sexual function. In males, irreversible breast development, testicular atrophy and reduced sperm production can occur. In females, side effects may include an increase in body hair, a deeper voice, smaller breasts, an enlarged clitoris and fewer menstrual cycles. In adolescents, steroid abuse may prematurely stop the lengthening of bones, resulting in stunted growth. The abuse of steroids also is associated with psychiatric reactions, manic episodes, feelings of anger or hostility, aggression and violent behavior. Withdrawal symptoms include mood swings, fatigue, restlessness, loss of appetite, insomnia, reduced sex drive and depression. Injecting steroids may place an abuser at risk for hepatitis and HIV if needles are shared with an infected user.

A Brief History of Prescription Drug Diversion and Abuse

Although recent media reports have generated public attention, the diversion and abuse of controlled prescription medications is not a new problem.

America’s First Prescription Drug of Abuse: Morphine

Morphine is one of the most effective opioid pain relievers, but for centuries, the primary agent of morphine--opium--has been known to have addictive potential. Morphine-like drugs have a long history of being popular drugs of abuse. Public concern about morphine peaked after the Civil War when the drug was widely used to treat injury-related pain. Many soldiers became addicted, rendering chronic morphine use so common that it became known as “Soldiers’ Disease.”

Partially in response to morphine’s widespread abuse (and partially due to international political considerations), the Harrison Narcotic Act of 1914 was enacted. This Act called for the registration (or licensing) of any individual, including manufacturers, importers, pharmacists and physicians, involved in the production, importation, sale or distribution of opium or coca leaves and their derivatives. The Act required that registered physicians keep records of drugs dispensed or prescribed. It also stated that “nothing contained in this section shall apply…to the dispensing or distribution of any of the aforesaid drugs to a patient by a physician, dentist or veterinary surgeon registered under this Act in the course of his professional practice only.” This clause, originally meant to protect clinicians, was interpreted by law enforcement to indicate that physicians who prescribed opioids to addicts could be prosecuted, because such prescriptions were not considered part of “the course of professional practice.” Many physicians were arrested under this interpretation and some were convicted and imprisoned.

Today morphine continues to be used to relieve severe pain. It is used intravenously in hospitals and also can be prescribed in pill form. It continues to be widely abused. Particularly popular among today’s drug abusers is the morphine-like drug hydromorphone, marketed as Dilaudid, to treat pain. With two to eight times the analgesic potency of morphine, hydromorphone is shorter acting and more sedating.

Amphetamines

From the 1940s through the early 1970s, the rampant abuse of amphetamines, a group of stimulants also known as speed, became an international public health concern. Before their addictive properties were recognized and before CNS stimulant medications came under federal control, these drugs were used in the
treatment of obesity, fatigue and depression. In several countries, their widespread use was accompanied by epidemics of stimulant abuse. During World War II, the armed services used amphetamine-like stimulants to alleviate fatigue in pilots and other personnel. The reduction of fatigue continues to be a primary incentive for amphetamine abuse: college students in years past as well as today abuse amphetamines to stay alert when studying for exams and to stay awake for late-night parties. Amphetamines have been used and abused historically by those who want to lose weight rapidly. Amphetamine abuse also has become popular among gay men on the “circuit party” scene who use the drug to continue partying for several days.

**Ritalin and Adderall**

First marketed in 1954 by the CIBA-Geigy Pharmaceutical Company (now Novartis), Ritalin is a well-known brand name for the CNS stimulant methylphenidate hydrochloride. Originally prescribed to treat depression, chronic fatigue and narcolepsy, Ritalin began to be used in the 1960s to treat children diagnosed with attention deficit hyperactivity disorder (ADHD). Even though abuse of Ritalin can be dated to the 1960s, it is only in the last decade, with the surge in medical use of Ritalin to treat ADHD, that its abuse has become more common. The “high” produced by excessive, intranasal or intravenous use of Ritalin is similar to the euphoria produced by cocaine and other amphetamines. Taking high doses of the drug can lead to delirium, hallucinations and toxic psychosis.

Abuse of Ritalin, Adderall and other stimulants is increasingly prevalent among high school and college students. Some use the drugs at parties to get high; others to stay awake and focused when studying; still others to control their weight. Students who abuse prescription stimulants exhibit higher rates of alcohol and other drug use.

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**Miltown**

In 1955, Wallace Laboratories and Wyeth Laboratories introduced the anti-anxiety (CNS depressant) drug meprobamate (e.g., Miltown, Equanil) believed a safer alternative to previous anxiety treatments that involved sleep-inducing or potentially lethal sedatives and narcotics. Miltown was the first minor tranquilizer introduced on the market. One year after its release, five percent of Americans were taking tranquilizers and the popular comedian Milton Berle was referring to himself as “Miltown Berle.” Miltown is still used today as a muscle relaxant, but it lost its popularity when Hoffman-La Roche Pharmaceuticals introduced its own tranquilizer, Valium.

**Valium**

Valium, a benzodiazepine, was introduced in 1963 by Hoffman-La Roche and has since been used primarily to treat anxiety, certain skeletomuscular conditions and convulsive disorder, and to alleviate alcohol withdrawal symptoms. Although the drug has helped millions of patients, it has been one of the most commonly abused drugs in America. When it was released onto the market, it was not well regulated and was often prescribed for ailments that did not require the level of drug potency that Valium offers. The Rolling Stones’ hit song “Mother’s Little Helper” underscored the drug’s prominence in popular culture.

By the mid-1970s, more than 60 million Valium prescriptions were written annually. Until the emergence of Prozac in the 1980s, Valium was the highest-selling pharmaceutical drug in history, hitting its peak in 1978 when 20 percent of all American women and 14 percent of American men were taking the tranquilizer.
“Kids are different today,”
I hear every mother say.
“Mother needs something today to calm her down.”
And though she’s not really ill,
there’s a little yellow pill;
She goes running for the shelter
of her mother’s little helper.
And it helps her on her way,
Gets her through her busy day...

--Song Lyrics to
Mother's Little Helper
The Rolling Stones, 1966

Valium’s reputation as a magic pill began to fade in the wake of high profile stories of celebrities battling addiction to the drug. The dangers of mixing medications became all too apparent when Elvis Presley was reported to have used Valium with other prescription drugs shortly before his death; Elizabeth Taylor admitted to mixing Jack Daniels with her doses; and Betty Ford entered treatment for alcoholism and dependence on Valium which her doctors had prescribed for her arthritis.113

Because Valium is pharmacologically active at brain receptor sites sensitive to alcohol use, many physicians prescribed the medication for alcohol withdrawal, which inadvertently led some alcoholics to trade one addiction for another.114 Valium continues to be widely prescribed and widely abused.115

**Ketamine**

Ketamine, a CNS depressant, is an anesthetic that is used to sedate animals and in humans undergoing surgical procedures.116 Reports that Ketamine was being sold on the illicit drug market began to surface in the U.S. in the early 1970s.117 Ketamine, commonly abused by “ravers” to enhance their partying experience,118 can have hallucinogenic effects and produce “out of body experiences.” It often is taken in combination with illicit drugs such as Ecstasy and gamma-hydroxybutyrate (GHB).119 Ketamine commonly is diverted to the illicit market from veterinary clinics120 and pharmacies in Mexico.121 The drug can cause aggressive or violent behavior, affect motor skills and obstruct the sensation of pain, potentially leading to injuries.122 Although Ketamine overdose deaths are rare, the drug can lead to fatal accidents such as falls, burns or drowning.123

**Fentanyl: The Duragesic Patch and Narco-Pops**

Fentanyl, an opioid, was introduced on the U.S. market as an anesthetic by Janssen Pharmaceutica in the 1960s and continues to be used to treat pain.124 The first form of fentanyl, which was administered intravenously, was branded Sublimaze.125 Two variations of the drug followed and today there are many brand names and versions of this drug.126 A little more than a decade after the release of Sublimaze, reports of abuse surfaced, particularly among healthcare professionals.127 Fentanyl is an extremely potent drug and can lead to overdose and death if abused.128

The Duragesic patch is a slow release form of fentanyl that has been increasingly implicated in cases of abuse.130 Individuals seeking the drug often steal it from hospitals and clinics and then cut open the patches to extract the fentanyl.131 At least 12 different “street” forms of fentanyl are involved in the U.S. illegal drug traffic.132

> Spivey cut off a corner of the [Duragesic] patch, removed that gel with his finger and ate it... A half an hour later he was found on a couch, his skin blue, not breathing.129

--The Baltimore Sun

Recently, Cephalon, Inc. formulated fentanyl in a berry-flavored lollipop or lozenge version called Actiq. Although it is meant to provide fast-acting relief to cancer patients suffering from “breakthrough” pain,134 Actiq is being prescribed for non-cancer pain as well.135 It is starting to be seen in the illegal drug market with the nicknames “perc-a-pop” or “narco-pop.”

† Pain so severe it “breaks through” other pain medications.

* Raves are nightlong dance parties often held in large, empty warehouses.
The pleasing taste and ease of use--no pill taking, snorting or injection is needed--has made the drug so attractive to abusers that it is selling on the streets at twice its retail value.\textsuperscript{134}

**Talwin**

In 1967, the abuse of fentanyl led to the development of pentazocine (Talwin), another opioid medication,\textsuperscript{135} in hopes that Talwin would help to treat pain without being as addictive as fentanyl.\textsuperscript{136} However, the drug quickly became prevalent in the illicit trade. Typically used in combination with tripelennamine, an antihistamine, this combination was known as the “T’s and Blues.”\textsuperscript{137} In 1979, acknowledging the need for tighter controls, the FDA placed Talwin into Schedule IV of the Controlled Substances Act. In an attempt to reduce the abuse potential of the medication, manufacturers created Talwin Nx, which contains naloxone, an antagonist that counteracts the morphine-like effects of pentazocine if the tablets are dissolved and injected by someone seeking a high.\textsuperscript{138} As a result, abuse of Talwin diminished substantially.\textsuperscript{139}

**Vicodin**

Vicodin (hydrocodone and acetaminophen)--is an opioid that has become one of the most widely abused pain medications in the United States.\textsuperscript{140} Its primary ingredient, hydrocodone, was first developed in the 1920s by the Knoll pharmaceutical company in an attempt to create a form of codeine that would be less toxic and not as harsh on the stomach.\textsuperscript{141} In addition to its functions as a potent painkiller and cough suppressant,\textsuperscript{142} the drug produces a powerful euphoria and, like other opioids, is addictive.\textsuperscript{143} Compared to morphine or hydromorphone (e.g., Dilaudid), tolerance to the drug develops more slowly and withdrawal symptoms tend to be less pronounced.\textsuperscript{144} With the tremendous expansion of its prescriptions over the past decade, Vicodin abuse and addiction have increased.\textsuperscript{145}

**OxyContin**

Purdue Pharma LP introduced OxyContin in 1996\textsuperscript{146} and it is one of the most potent prescription opioids on the market today.\textsuperscript{147} OxyContin is a 12-hour time-release version of the molecular compound oxycodone, the same active ingredient found in Tylox, Percocet and Percodan, three other opioids.\textsuperscript{148} The advanced features of OxyContin allow patients to take fewer pills and enjoy relief three times longer than from earlier versions of oxycodone.\textsuperscript{149} By 2001, OxyContin had become the most frequently prescribed brand-name narcotic medication for treating moderate-to-severe pain in the U.S.\textsuperscript{150}

Reports of OxyContin diversion and abuse have received significant media attention in the past few years.\textsuperscript{151} Diversion and abuse of OxyContin have been reported primarily in the Appalachian states of Kentucky, Virginia and West Virginia.\textsuperscript{152} Some have called its abuse an epidemic in these areas.\textsuperscript{153} OxyContin abuse, however, has been spreading throughout the nation. The potential profitability of OxyContin--selling on the street for more than 10 times its legitimate value--has contributed to its widespread diversion.\textsuperscript{154}

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**From 50 percent to 90 percent of new patients in methadone programs in Kentucky, Virginia, Pennsylvania and West Virginia claim OxyContin as their primary drug of abuse.**

--Asa Hutchinson, former Administrator
Drug Enforcement Administration

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Purdue Pharma LP aggressively marketed OxyContin for treatment of both severe and moderate cancer and non-cancer pain.\textsuperscript{156} Prescriptions written to treat non-cancer pain grew from 670,000 in 1997 to approximately 6.2 million in 2002.\textsuperscript{157} The Drug Enforcement Administration (DEA) has criticized the company for using misleading and non-FDA approved marketing and promotional strategies\textsuperscript{158} and for neglecting to immediately (or even proactively) add an antagonist agent to
OxyContin to prevent its abuse, as was done successfully with Talwin decades ago.\textsuperscript{159}

Originally, the FDA permitted Purdue Pharma to imply in its labeling that OxyContin had a lower abuse potential than other opioids because of its 12-hour time release mechanism.\textsuperscript{160} This was the first time such labeling had been allowed for a Schedule II drug.\textsuperscript{161} Ironically, OxyContin appears to have greater, rather than less, abuse potential than other opioids, primarily because when crushed and then snorted or injected, OxyContin loses its time-release component and provides an immediate narcotic rush to the brain.\textsuperscript{162} In addition, the original safety warning on the label instructed users not to crush the pills because when crushed, toxic levels of the drug could be released.\textsuperscript{163} This labeling may have suggested to drug abusers how to abuse the drug; the label has since been rewritten in accordance with FDA requirements.\textsuperscript{164}

\begin{quote}
The disproportionate abuse of OxyContin is due, in part, to aggressive marketing and promotion of OxyContin by Purdue Pharma, who represented the product as having a lower abuse potential than other opioid pain relievers. Purdue Pharma accentuated the problem by suggesting that physicians prescribe OxyContin as a substitute for a variety of less addictive existing medications.

\textemdash\ Asa Hutchinson, former Administrator Drug Enforcement Administration
\end{quote}

The press coverage of the diversion and abuse of OxyContin has helped shape the public’s perception of the magnitude of the overall problem of controlled prescription drug diversion and abuse in the U.S. and has raised considerable awareness. In response to public outcry and pressure from the DEA and FDA, Purdue Pharma adjusted some of its marketing practices, launched an educational campaign and, together with the FDA, implemented a risk management plan--aimed at detecting and preventing diversion and abuse--for the drug.\textsuperscript{166}

The FDA recently has given approval to Teva Pharmaceuticals and Endo Pharmaceuticals to sell generic versions of OxyContin. The distribution of generic versions of the drug likely will increase its availability on the illegal drug market.\textsuperscript{167}

\textbf{Abuse of Over-the-Counter and Non-Controlled Prescription Drugs}

Over-the-counter (OTC) drugs and non-controlled prescription drugs may be abused and can be extremely dangerous. Some examples are:

- Over-the-counter cough suppressants containing dextromethorphan (DXM) are used in large doses by some young people to get high. Sometimes called “Robotripping,” because of the popular cough suppressant Robitussin, excessive use of DXM can produce hallucinogenic and other psychiatric effects and can lead to brain damage and death.\textsuperscript{168}

- Ephedra, an herbal supplement (and its principal active ingredient, ephedrine), is a stimulant found in asthma medications, dietary supplements, and energy and muscle enhancers\textsuperscript{169} that has been abused since the early 1980s.\textsuperscript{170} Adverse health effects ranging from dizziness to heart attacks have been linked to the drug. In 2004, the FDA completely banned sale of products containing ephedra.\textsuperscript{171}

- Viagra, a prescription drug used to treat erectile dysfunction,\textsuperscript{172} is often mixed with illicit drugs such as methamphetamine, amyl nitrate (“poppers”), Ketamine or Ecstasy.\textsuperscript{173} An overdose of the drug can lead to a painful prolonged erection and sexual performance problems\textsuperscript{174} and when combined with illicit drugs, loss of consciousness and possibly death.\textsuperscript{175}

\textsuperscript{* Risk management plans may include post-marketing surveillance, education and outreach programs to health professionals or consumers, informed consent agreements for patients, limitations on the supply or refills of the drug, and restrictions on individuals who may prescribe and dispense the drug.
Carisoprodol (SOMA), a prescription drug used to treat pain, muscle spasms and skeletomuscular illnesses, is increasingly being abused among individuals with a history of substance abuse and by long-term users of the drug. When abused, SOMA is commonly combined with opioid drugs such as hydrocodone or codeine. Some states have designated SOMA a controlled drug.
Chapter III
How Big is the Problem of Controlled Prescription Drug Abuse?

The good news is that the increase in invention, production and distribution of controlled prescription drugs has brought relief to millions of people. The bad news is the accompanying diversion and abuse of these drugs.

Between 1992 and 2002,* the U.S. population increased by 13 percent† and prescriptions filled for non-controlled drugs rose 56.6 percent,‡ but the number of prescriptions filled for controlled drugs climbed 154.3 percent--12 times faster than the population and almost three times faster than prescriptions for non-controlled drugs.

While this increase in prescriptions for controlled medications may signify improved treatment of pain, mental illness, anxiety and other ailments, it has been accompanied by an increase in diversion and abuse. The number of people who admitted abusing controlled prescription drugs † increased from 7.8 million in 1992 to 15.1 million in 2003--a 93.8 percent jump--seven times faster than the increase in the U.S. population.³

Between 1992 and 2003, there has been a:

• 140.5 percent increase in the self-reported abuse of prescription opioids,

• 44.5 percent increase in the self-reported abuse of prescription CNS depressants, and

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* Throughout this report, CASA has attempted to use the most recent available data; therefore, findings from different years may be reported for different analyses. For example, because more recent data are not available to estimate the increase in prescriptions filled for controlled and non-controlled prescription drugs, comparisons in this analysis are made between 1992 and 2002.

† Except where indicated, the following analyses refer to opioids, CNS depressants (tranquilizers and sedatives) and stimulants. Limited national data on steroids precludes their inclusion in much of the discussion that follows.
• 41.5 percent increase in the self-reported abuse of prescription CNS stimulants.

Approximately six percent of the U.S. population (15.1 million people) reported abusing controlled prescription drugs in 2003, higher than the combined number abusing cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000). Abuse of controlled prescription drugs has been increasing at a rate twice that of marijuana, five times greater than cocaine and 60 times greater than heroin.

These estimates are based on self-reported data from the National Survey on Drug Use and Health (NSDUH) which is representative of the non-institutionalized U.S. population, ages 12 and older. Because this survey is administered in the home, respondents tend to under-report substance use behaviors and because high-risk institutionalized populations (such as incarcerated individuals, hospital patients, nursing home residents, patients in drug abuse treatment) and those that cannot be reached in a home (the homeless) are excluded, the NSDUH is known to underestimate considerably all forms of substance use in the U.S.

Teen prescription drug abusers represent a particularly vulnerable group. They may view prescription drugs as relatively safe either when abused alone or in combination with alcohol or other drugs and, for them, prescription drugs may serve as gateway drugs to other substances of abuse. In addition, some teens who abuse prescription drugs may do so in an attempt to self-medicate feelings of stress or depression, anxiety or other mental health problems that may go undetected or untreated by the adults around them.

In 2003, 2.3 million teens ages 12 to 17 (9.3 percent) admitted abusing a controlled prescription drug in the past year; 88 percent of them admitted abusing opioids. The rate of increase in controlled prescription drug abuse among teens has been growing at a faster pace than among adults. For example, between 1992 and 2002, the number of new prescription opioid abusers ages 12 to 17 increased by 542 percent compared with a 124 percent increase in new abusers among those ages 18 and over. Teens who admit abusing controlled prescription drugs are twice as likely to have used alcohol, five times likelier to have used marijuana; 12 times likelier, heroin; 15 times likelier, Ecstasy; and 21 times likelier, cocaine.

Teens--both boys and girls--also are abusing prescription steroids at increasing rates. Between 1991 and 2003, reported rates of lifetime steroid abuse among high school students increased 126 percent. The rate of increase among girls (342 percent) is more than five times that of boys (66 percent).

Most controlled prescription drug abusers are poly-substance abusers (74.7 percent) who also abuse alcohol and/or illicit drugs; 63.9 percent also abuse alcohol and 53.6 percent also abuse illicit drugs.

* No comparable prevalence data on steroid abuse are available in the NSDUH. Therefore, analysis of steroid abuse is restricted to young people in the specific grades surveyed by the Monitoring the Future study (MTF) and the Youth Risk Behavior Survey (YRBS). Trend data are available from the YRBS from 1991.
† Among adults ages 18 and older, 73.8 percent of prescription drug abusers are poly-substance abusers and among teens ages 12 to 17, 79.8 percent of prescription drugs abusers are poly-substance abusers.
‡ Adult poly-substance abusers are those who abuse prescription drugs and either drink excessively and/or use illicit drugs. Excessive drinking is defined as drinking more than the National Institute on Alcohol Abuse and Alcoholism (NIAAA) recommended levels: for women two or more drinks per day and for men three or more drinks per day in the past 30 days. For teens, any use of alcohol in the past year is considered abuse. Illicit drug use, which includes the use of marijuana, cocaine, crack, heroin, hallucinogens and inhalants, is defined for both adults and teens as any use of these drugs in the past year. Those who abuse several prescription drugs but are not excessive drinkers (or for teens, do not drink alcohol) or illicit drug users are not considered poly-substance abusers.
Those who abuse controlled prescription drugs only (25.3 percent of prescription drug abusers) differ considerably from those who abuse other substances as well. Among teens, prescription drug only abusers are likelier to be younger—ages 12 and 13—than those who are poly-substance abusers (36.7 percent vs. 8.7 percent). Adults (ages 18 and older) who abuse prescription drugs only are likelier than poly-substance-abusing adults to be women, older,* better educated, married and have higher incomes. Because the profile of a prescription drug only abuser differs so significantly from that of poly-substance abusers, prevention services and healthcare providers may overlook them.

The tremendous growth in the abuse of controlled prescription drugs has serious consequences. In 2002, abuse of controlled prescription drugs was implicated in at least 23 percent of drug-related emergency department admissions and 20.4 percent of all single drug-related emergency department deaths. Prescription opioids accounted for more drug mentions involved in multiple drug-related deaths than cocaine, heroin and marijuana. Between 1994 and 2002, there was a 78.9 percent increase in the total number of controlled prescription drug-related mentions in emergency department visits, with prescription opioids demonstrating the greatest increase over this period.

**Increase in the Availability of Controlled Prescription Drugs**

The availability of prescription opioids and stimulants has increased substantially over the past few years. One way to measure increased availability of controlled prescription drugs is by changes in the amount of drugs manufactured and distributed to retail establishments and in the number of prescriptions filled. Other factors accounting for increased availability are Internet access and illegal distribution discussed in subsequent chapters. Considerable regional differences can be found in the availability of these drugs.

**Production and Distribution**

CASA’s analysis of data from the DEA’s Automation of Reports and Consolidated Orders System (ARCOS),† which presents the total volume of a drug produced and distributed (i.e., supply in grams),‡ indicates that the production and distribution of prescription opioids and stimulants have increased significantly over the past years.*** These increases can be attributed both to an increase in the legitimate and the illegitimate use of these medications.

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* The average age of prescription drug only abusing women is 38.5 years vs. 30.4 years for poly-substance abusing women. Men who abuse prescription drugs only also are, on average, older than men who abuse multiple substances (average age of 35.5 years vs. 29.1 years).

† CASA analyzed data from the Automation of Reports and Consolidated Orders System (ARCOS), managed by the DEA, and data from the National Prescription Audit (NPA) Plus, provided by the trade organization IMS Health, to track fluctuations in the production, distribution and consumption of controlled prescription drugs.

‡ ARCOS is an automated drug reporting system that monitors the lawful distribution of controlled substances—including all Schedule II drugs, Schedule III narcotics and Schedule III and IV psychotropics—from manufacture to distribution at the retail level, including hospitals, retail pharmacies and health practitioners. Approximately 1,100 distributors and manufacturers report to ARCOS. Although this is just a fraction of the more than one million distributors and manufacturers registered with the DEA, ARCOS is the primary data source for this type of information. Data are reported in terms of the volume in grams of the particular drug manufactured and distributed.

§ Volume of the drug shipped from manufacturers to retail distributors, measured in grams. Because the number and potency of grams in a dose of a drug differs from one drug to another, the values presented here cannot be combined to form one meaningful value for opioids and another for stimulants.

*** The most recent data available for these analyses are from 2001. Because ARCOS collects only limited data on Schedule III and IV drugs, many CNS depressants (e.g., tranquilizers) are not monitored by the system; therefore, findings are presented only for opioids, sedatives and stimulants.
Between 1997 and 2001* the supply of most opioids increased dramatically: oxycodone (e.g., OxyContin, Percocet) increased by 348 percent,† fentanyl (e.g., Duragesic) by 151 percent, hydromorphone (e.g., Dilaudid) by 80 percent and hydrocodone (e.g., Lortab, Vicodin) by 66 percent. For stimulants, the supply of methylphenidate (e.g., Ritalin, Concerta) increased by 20 percent during this time, the supply of DL-amphetamine-based drugs (e.g., Adderall) increased by 555 percent and the supply of D-amphetamine-based drugs (e.g., Dexedrine) increased by 130 percent.‡ The supply of most sedatives (in this case, primarily barbiturates) decreased during this time. For example amobarbital (e.g., Amytal) decreased by 65 percent, secobarbital (e.g., Seconal) by 59 percent and pentobarbital (e.g., Nembutal) by nine percent.§

Regional differences.§ Although the South represents 36 percent of the national population and the Western region, 22 percent, these regions accounted for a disproportionately large percentage of the distribution of certain opioids, sedatives and stimulants in the U.S. The Midwest, which accounts for 23 percent of the population, accounted for a disproportionately large percentage of the distribution of most stimulants. The Northeast, which accounts for 19 percent of the population, accounted for a disproportionately large percentage of the distribution of certain sedatives. (See Tables 3.1, 3.2 and 3.3)

The highest rates of opioid distribution from manufacturers to retailers (including pharmacies, hospitals and health practitioners) were in Arizona, Florida, Nevada, New Hampshire and Oregon; the highest rate of sedative distribution, in Florida; and the highest rates of stimulant distribution, in Delaware, Rhode Island, South Carolina and Wisconsin.§ Additional research is needed to determine the reasons for these regional differences.

Prescriptions Filled

Another way to examine changes in drug availability is to look at the number of prescriptions filled. In 2002, more than three billion prescriptions were filled for over 500,000 different drugs; 234 million for controlled prescription drugs. Of controlled drugs, opioids were the most widely prescribed (152.8 million prescriptions), followed by CNS depressants** (58.2 million) and stimulants (23.4 million).8

CASA’s analysis of data on the total number of prescriptions filled for controlled drugs between 1992 and 2002 (based on the National Prescription Audit (NPA) Plus†† provided by the trade organization IMS Health for the purposes of this study) reveals that the largest percent increase in prescriptions filled was for stimulants (368.5 percent), followed by opioids (221.9 percent) and CNS depressants (48.2 percent), for an overall increase of 154.3 percent.¹¹ (Figure 3.A)

---

* Available data limited to these years.
† Large increases in the production and distribution of OxyContin during this time are to be expected since the drug was introduced on the market in 1996.
‡ The supply of butalbital (e.g., Fioricet) remained largely the same.
§ The Northeast region includes CT, ME, MA, NH, NJ, NY, PA, RI and VT; the Midwest includes IL, IN, IA, KS, MI, MN, MO, ND, NE, OH, SD and WI; the South includes AL, AR, DE, DC, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA and WV; and the West includes AK, AZ, CA, CO, HI, ID, MT, NM, OR, NV, UT, WA and WY.
** Including barbiturates and benzodiazepines.
†† NPA Plus lists the top 200 drugs dispensed from retail pharmacies to patients, based on a nationwide survey of 22,000 retail pharmacies regarding approximately 36 million filled prescriptions. This sample of 22,000 pharmacies represents a random sample of more than 34,000 stores (accounting for more than half of all retail pharmacies in the U.S.) that report every new and refilled prescription to IMS Health.
Table 3.1

**Distribution of Opioids by Region (percent of volume in grams)**

<table>
<thead>
<tr>
<th>Region</th>
<th>Proportion of US Population</th>
<th>Meperidine (e.g., Demerol)</th>
<th>Morphine</th>
<th>Oxycodone (e.g., Percocet, OxyContin)</th>
<th>Codeine</th>
<th>Methadone (e.g., Lortab, Vicodin)</th>
<th>Hydrocodone (e.g., Lortab, Vicodin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>19</td>
<td>13</td>
<td>17</td>
<td>21</td>
<td>17</td>
<td>17</td>
<td>11</td>
</tr>
<tr>
<td>Midwest</td>
<td>23</td>
<td>17</td>
<td>22</td>
<td>20</td>
<td>26</td>
<td>14</td>
<td>19</td>
</tr>
<tr>
<td>South</td>
<td>36</td>
<td>50</td>
<td>33</td>
<td>39</td>
<td>27</td>
<td>42</td>
<td>46</td>
</tr>
<tr>
<td>West</td>
<td>22</td>
<td>18</td>
<td>28</td>
<td>20</td>
<td>30</td>
<td>27</td>
<td>24</td>
</tr>
</tbody>
</table>

Note: Data in bold indicates any proportionately higher volume of drug distribution relative to the proportion of the U.S. population in the region.

Table 3.2

**Distribution of Sedatives by Region (percent of volume in grams)**

<table>
<thead>
<tr>
<th>Region</th>
<th>Proportion of US Population</th>
<th>Amobarbital (e.g., Amytal)</th>
<th>Butalbital (e.g., Fioricet)</th>
<th>Pentobarbital (e.g., Nembutal)</th>
<th>Secobarbital (e.g., Seconal)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>19</td>
<td>48</td>
<td>14</td>
<td>12</td>
<td>24</td>
</tr>
<tr>
<td>Midwest</td>
<td>23</td>
<td>14</td>
<td>24</td>
<td>22</td>
<td>28</td>
</tr>
<tr>
<td>South</td>
<td>36</td>
<td>24</td>
<td>42</td>
<td>37</td>
<td>39</td>
</tr>
<tr>
<td>West</td>
<td>22</td>
<td>14</td>
<td>23</td>
<td>29</td>
<td>20</td>
</tr>
</tbody>
</table>

Note: Data in bold indicates any proportionately higher volume of drug distribution relative to the proportion of the U.S. population in the region.

Table 3.3

**Distribution of Stimulants by Region (percent of volume in grams)**

<table>
<thead>
<tr>
<th>Region</th>
<th>Proportion of US Population</th>
<th>DL-amphetamine (e.g., Adderall)</th>
<th>D-amphetamine (e.g., Dextedrine)</th>
<th>D-methamphetamine</th>
<th>Methylphenidate (e.g., Ritalin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>19</td>
<td>15</td>
<td>16</td>
<td>12</td>
<td>19</td>
</tr>
<tr>
<td>Midwest</td>
<td>23</td>
<td>25</td>
<td>25</td>
<td>24</td>
<td>28</td>
</tr>
<tr>
<td>South</td>
<td>36</td>
<td>44</td>
<td>40</td>
<td>24</td>
<td>37</td>
</tr>
<tr>
<td>West</td>
<td>22</td>
<td>15</td>
<td>19</td>
<td>41</td>
<td>16</td>
</tr>
</tbody>
</table>

Note: Data in bold indicates any proportionately higher volume of drug distribution relative to the proportion of the U.S. population in the region.

-27-
Opioids. Prescriptions filled for opioids increased by 222 percent between 1992 and 2002. The opioid hydrocodone (e.g., Lortab, Vicodin) is the most frequently prescribed drug in the U.S., accounting for 85.1 million out of the three billion prescriptions filled in 2003. In 2002, hydrocodone and oxycodone (e.g., Percocet, OxyContin) were by far the most widely prescribed opioid medications, with increases in prescriptions filled between 1992 and 2002 of 376 percent and 380 percent, respectively. Some opioids, such as fentanyl and methadone, demonstrated far greater increases in prescriptions filled over the past decade, yet the total number of prescriptions filled for these medications is low relative to hydrocodone and oxycodone. Increases in other opioids, such as codeine and meperdine, were substantially lower. (See Table 3.4)

<table>
<thead>
<tr>
<th>Opioid</th>
<th>1992</th>
<th>2002</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>codeine</td>
<td>9,120</td>
<td>10,169</td>
<td>+12</td>
</tr>
<tr>
<td>fentanyl (e.g., Sublimaze)</td>
<td>341</td>
<td>4,111</td>
<td>+1106</td>
</tr>
<tr>
<td>hydrocodone (e.g., Vicodin)</td>
<td>15,843</td>
<td>75,357</td>
<td>+376</td>
</tr>
<tr>
<td>hydromorphone (e.g., Dilaudid)</td>
<td>380</td>
<td>785</td>
<td>+107</td>
</tr>
<tr>
<td>meperdine (e.g., Demerol)</td>
<td>1,039</td>
<td>1,728</td>
<td>+66</td>
</tr>
<tr>
<td>methadone</td>
<td>107</td>
<td>1,816</td>
<td>+1,597</td>
</tr>
<tr>
<td>morphine</td>
<td>715</td>
<td>2,706</td>
<td>+279</td>
</tr>
<tr>
<td>oxycodone (e.g., OxyContin)</td>
<td>5,641</td>
<td>27,053</td>
<td>+380</td>
</tr>
<tr>
<td>Total</td>
<td>33,186</td>
<td>123,725</td>
<td>+222</td>
</tr>
</tbody>
</table>


CNS Depressants. Benzodiazepines account for one out of five prescriptions written for controlled substances. Prescriptions filled for benzodiazepines increased by 49.2 percent between 1992 and 2002. Clonazepam (e.g., Klonopin) showed the greatest increase in prescriptions filled between 1992 and 2002; however, lorazepam (e.g., Ativan) remained the most widely prescribed benzodiazepine throughout this period. (See Table 3.5)

<table>
<thead>
<tr>
<th>Benzodiazepine</th>
<th>1992</th>
<th>2002</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>clonazepam (e.g., Klonopin)</td>
<td>2,286</td>
<td>8,040</td>
<td>+252</td>
</tr>
<tr>
<td>diazepam (e.g., Valium)</td>
<td>8,358</td>
<td>8,265</td>
<td>-1</td>
</tr>
<tr>
<td>estazolam (e.g., ProSoma)</td>
<td>0</td>
<td>115</td>
<td>+115</td>
</tr>
<tr>
<td>lorazepam (e.g., Ativan)</td>
<td>7,449</td>
<td>12,068</td>
<td>+60</td>
</tr>
<tr>
<td>triazolam (e.g., Halcion)</td>
<td>2,091</td>
<td>760</td>
<td>-64</td>
</tr>
<tr>
<td>Total</td>
<td>20,184</td>
<td>29,248</td>
<td>+49</td>
</tr>
</tbody>
</table>


Between 1992 and 2002, the use of barbiturates declined significantly, largely replaced by benzodiazepines. Prescriptions filled for barbiturates increased by 38.1 percent between 1992 and 2002. Whereas pentobarbital (e.g., Nembutal) and butalbital (e.g., Fioricet) showed the largest increases in barbiturate prescriptions filled, prescriptions for other barbiturates (e.g., secobarbital, amobarbital) declined. Butalbital remained the most widely prescribed barbiturate throughout this period. (See Table 3.6)

<table>
<thead>
<tr>
<th>Barbiturate</th>
<th>1992</th>
<th>2002</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>amobarbital (e.g., Amytal)</td>
<td>18</td>
<td>5</td>
<td>-72</td>
</tr>
<tr>
<td>butalbital (e.g., Fioricet)</td>
<td>3,524</td>
<td>4,885</td>
<td>+39</td>
</tr>
<tr>
<td>pentobarbital (e.g., Nembutal)</td>
<td>0</td>
<td>147</td>
<td>+147</td>
</tr>
<tr>
<td>secobarbital (e.g., Seconal)</td>
<td>109</td>
<td>6</td>
<td>-95</td>
</tr>
<tr>
<td>Total</td>
<td>3,651</td>
<td>5,043</td>
<td>+38</td>
</tr>
</tbody>
</table>


Note: In NPA data, a “0” indicates that the volume of prescriptions filled was between 1 and 499.

* Of those assessed by NPA Plus.
Stimulants. Prescriptions filled for stimulants increased by 368.5 percent between 1992 and 2002. Whereas amphetamine-based drugs (e.g., Adderall) showed the largest increase in stimulant prescriptions filled between 1992 and 2002, methylphenidate (e.g., Ritalin) has been the most widely prescribed stimulant medication since the mid-1990s.\(^\text{17}\) (See Table 3.7)

<table>
<thead>
<tr>
<th>Stimulant</th>
<th>1992</th>
<th>2002</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>amphetamine (e.g., Adderall)</td>
<td>0</td>
<td>9,008</td>
<td>+9,008</td>
</tr>
<tr>
<td>dextroamphetamine (e.g., Dexedrine)</td>
<td>482</td>
<td>1,501</td>
<td>+211</td>
</tr>
<tr>
<td>methamphetamine</td>
<td>32</td>
<td>23</td>
<td>-28</td>
</tr>
<tr>
<td>methylphenidate (e.g., Ritalin)</td>
<td>4,483</td>
<td>12,881</td>
<td>+187</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>4,997</td>
<td>23,413</td>
<td>+369</td>
</tr>
</tbody>
</table>

Note: In NPA data, a “0” indicates that the volume of prescriptions filled was between 1 and 499.

Abuse of Controlled Prescription Drugs

To assess the extent of the controlled prescription drug abuse problem in the United States, CASA analyzed data from the National Survey on Drug Use and Health (NSDUH),\(^*\) which provides information on the prevalence and associated problems of substance use and abuse in the non-institutionalized U.S. population ages 12 and older. CASA chose to rely on data from the NSDUH because it is the most comprehensive, nationally representative survey available that provides data on the topic of prescription drug abuse. Researchers agree, however, that data from the NSDUH—which is a survey conducted in households, potentially in the presence or earshot of parents or other family members—largely under-represent the extent of substance use, particularly among teens.\(^\text{18}\) It also should be noted that changes in the methodology of the NSDUH in 2002 and 2003 might affect trend data.\(^\text{†}\)

To assess the extent of steroid abuse among teens, CASA examined data from the Monitoring the Future study (MTF) which provides information on eighth, tenth and twelfth grade students and the Youth Risk Behavior Survey (YRBS) which provides information on ninth through twelfth grade students. MTF also under-represents the extent of abuse because it is administered in the classroom in the presence of teachers. The YRBS comes closest to providing accurate estimates since it is anonymous.

Clarifying the Terms

The use of various terms to describe problems associated with controlled prescription drug abuse (e.g., non-medical use, inappropriate use, misuse, problem use, abuse, addiction and dependence) pose problems in estimating the scope of the problem.

Prescription drug abuse. Because of limitations in available data for purposes of analyzing prevalence rates and trends, CASA has defined prescription drug abuse in accordance with the definition of the U.S. government’s NSDUH survey. The survey question asks respondents to indicate whether they had “used a drug that was not prescribed for you or that was taken only for the experience or feeling it caused.” This primarily includes individuals who take a medication that was not prescribed for them solely for the purpose of getting high; however, it also may include individuals who take a friend’s or family member’s medication for an actual physical or mental problem. Estimates drawn on the basis of this definition therefore may be slightly overstated; however, as noted above, the NSDUH is widely recognized to underestimate rates of substance use and abuse, particularly

\(^*\) This survey previously was called the National Household Survey on Drug Abuse (NHSDA).

\(^\text{†}\) For example, the five percent increase in overall reported drug use among teens from 2001 to 2003 may be, at least in part, a function of a monetary incentive offered to survey participants since 2002.
among youth.* 19 Despite the limitations of the NSDUH, it provides the best available national data on the extent of the prescription drug abuse problem.

**Clinical abuse, dependence and addiction.**

Clinical substance abuse and substance dependence are defined in accordance with the clinical diagnostic criteria presented in the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)—the main diagnostic reference of mental health professionals in the United States.† Substance dependence is a diagnosis that incorporates both the concepts of physical dependence and addiction.§ 20

Physical dependence is a physiological adaptation to the regular use of a drug and can result in tolerance to the drug and withdrawal symptoms when use of the drug is discontinued.21 Tolerance involves a decreased physiological sensitivity to the action of a drug with continued use or the need to take increasing amounts of the drug in order to achieve the desired effect.22 Withdrawal is a physical syndrome with psychological manifestations that results from a marked reduction or abrupt cessation in the long-term use of a drug.23 Tolerance and withdrawal symptoms can occur either in the presence of or absence of addiction.§ 24

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*R In several recent independent studies, researchers found that the NSDUH reported lower prevalence rates than other national surveys (MTF and YRBS).
† The questions on abuse ask about problems at work, home, and school; problems with family or friends; physical danger; and trouble with the law due to use of prescription drugs. The questions on substance dependence ask about health, emotional problems, attempts to cut down on use, tolerance, withdrawal and other symptoms associated with the use of prescription drugs. Dependence reflects a more severe substance problem than abuse, and persons are classified with abuse of a particular substance only if they are not dependent on that substance.
§ To meet clinical criteria for this diagnosis, a patient must evidence three or more of seven symptoms—two of which are symptoms of physical dependence (tolerance and withdrawal) and five of which are symptoms of addiction. To reduce confusion with the concept of physical dependence which is common among controlled prescription drug users, the term “addiction” is used later in this chapter in reference to the DSM-IV diagnosis of substance dependence.

**Physical dependency on drugs and tolerance to the effects of opioids are often confused with addiction. Physical dependency alone [on prescription opioids] doesn’t lead people to beat up elderly persons in the street to get money for drugs...to think about drugs constantly...to crave the drugs. Addiction is...loss of control...preoccupation and craving...and continuing to use [drugs] despite the fact that one’s life is unraveling as a result of them.**

--Seddon R. Savage, MD
Dartmouth Medical School
CASACONFERENCE, Feeling No Pain: Substance Abuse, Addiction and Pain Management February 27, 2003

**Drug addiction is a brain disease. Although initial drug use might be voluntary, once addiction develops this control is markedly disrupted.**

--Nora D. Volkow, MD
Director, National Institute on Drug Abuse

Drug addiction is a brain disease that develops over time as a result of the initially voluntary behavior of using drugs. The consequence is virtually uncontrollable compulsive drug craving, seeking and use that interferes with, if not destroys, an individual’s functioning in the family and in society.

--Alan I. Leshner, PhD
former Director, National Institute on Drug Abuse
Chief Executive Officer, American Association for the Advancement of Science

Addiction describes a pattern of drug use that extends beyond abusive use and exhibits a pervasive loss of control and persistent negative consequences directly or indirectly attributable to the use of the drug.27 It is a chronic, relapsing disease characterized by compulsive drug seeking and use, craving and continued use despite harm.28 Believed to have a neurochemical basis located in the limbic system.

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$ Tolerance and withdrawal symptoms can occur with non-addictive drugs as well, such as antidepressant, cardiac or hypertension medications.
of the brain, addiction is determined by a complex interplay of biological, psychological and environmental factors.

Many researchers, health professionals and policymakers do not draw specific distinctions between the concepts of dependence and addiction. Although perhaps not as crucial in considerations of alcohol or illicit drug use for which, with few exceptions, there is no legal therapeutic use, the distinction can be important when considering prescription drug use. For example, a cancer patient may become physically dependent on a prescription pain medication and demonstrate symptoms of tolerance and withdrawal after long-term use, but not exhibit the loss of control and adverse consequences typically associated with addiction. Therefore, an individual who is physically dependent on a prescription medication may or may not be addicted to it.

Some symptoms of substance dependence, beyond those of tolerance and withdrawal, also can describe a patient who legitimately is using certain prescription medications. For example, if pain is under-treated, a patient may become preoccupied with finding a pain medication or may take a pain medication for a longer time than was originally prescribed; these activities would fall under the DSM-IV’s criteria of substance dependence.

**Controlled Prescription Drug Abuse: Current Estimates**

In 2003, 6.4 percent of the population ages 12 or older (15.1 million people) abused controlled prescription opioids, tranquilizers, sedatives or stimulants at least once. (See Figure 3.B)

By comparison, 4.1 percent of the population ages 12 and older (9.7 million people) abused all illicit drugs other than marijuana in the past year. The number of people reporting controlled prescription drug abuse (15.1 million) is higher than the combined number reporting abuse of cocaine (5.9 million), hallucinogens (4.0 million), inhalants (2.1 million) and heroin (328,000). (See Figure 3.C) Overall, 56 percent more Americans abuse controlled prescription drugs than abuse cocaine, hallucinogens, inhalants and heroin combined.

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* The NSDUH presents data separately for tranquilizers and sedatives, both types of CNS depressants.
† The NSDUH includes methamphetamines in the stimulant category of prescription drugs. Although methamphetamines have some medical uses, these drugs are used largely for illegitimate purposes.
‡ Excludes all marijuana users: those who used marijuana only as well as those who used marijuana along with other illicit drugs.
§ Numbers add to more than 9.7 million because of overlap in illicit drugs used.
Opioids. The largest group of prescription drug abusers is comprised of individuals who abuse opioids. In 2003, an estimated 11.7 million people (4.9 percent of the population) abused prescription opioids. With the exception of marijuana, prescription opioids are the most widely abused controlled drug in the U.S.

CNS Depressants. In 2003, an estimated five million people (2.1 percent of the population) abused prescription tranquilizers and 894,000 (0.4 percent of the population) abused prescription sedatives.

Stimulants. In 2003, an estimated 2.8 million people (1.2 percent of the population) abused prescription stimulants.

Regional variations in controlled prescription drug abuse. Relative to population size, individuals living in the western region of the country report disproportionately high levels of opioid and stimulant abuse. Those living in the South report disproportionately high levels of CNS depressant abuse. (See Table 3.8)

<table>
<thead>
<tr>
<th>Region</th>
<th>Population</th>
<th>Opioids</th>
<th>Tranquilizers</th>
<th>Sedatives</th>
<th>Stimulants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Northeast</td>
<td>19</td>
<td>16</td>
<td>15</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Midwest</td>
<td>23</td>
<td>22</td>
<td>17</td>
<td>13</td>
<td>19</td>
</tr>
<tr>
<td>South</td>
<td>36</td>
<td>34</td>
<td>23</td>
<td>44</td>
<td>38</td>
</tr>
<tr>
<td>West</td>
<td>22</td>
<td>29</td>
<td>23</td>
<td>31</td>
<td>36</td>
</tr>
</tbody>
</table>


Between 1992 and 2003, the rate of prescription drug abuse among those ages 12 and over increased by 93.8 percent, from 7.8 million abusers in 1992 to 15.1 million in 2003. This significant increase in the abuse of controlled prescription drugs is greater than that found in the abuse of illicit drugs during this time period--five times greater than the increase in cocaine abuse and 60 times greater than the increase in heroin abuse.

The abuse of prescription medications has increased in all segments of the population, and in recent years the increase in abuse of prescription painkillers has been particularly sharp and worrisome....

--Nora D. Volkow, MD, Director, National Institute on Drug Abuse

* The NSDUH tracks 27 specific pain relievers and combinations which include Codeine, Darvocet, Darvon, Demerol, Dilaudid, Fioricet, Fiorinal, Hydrocodone, Lorcet/Lorcet Plus, Lortab, Methadone, Morphine, OxyContin, Percocet, Percodan, Phenaphen with Codeine, Propoxyphene, SK-65, Stadol, Talacen, Talwin, Talwin NX, Tramadol, Tylenol with Codeine, Vicodin. The NSDUH uses the term “pain relievers” rather than “opioids” because several opioid-type drugs addressed in the survey, such as SK-65, are not opioid-based even though they may act on opioid receptors in the brain.

† The NSDUH tracks 21 specific tranquilizers which include Ativan, Alprazolam, Atarax, Buspar, Clonazepam, Diazepam, Equanil, Flexeril, Klonopin, Librium, Limbitrol, Lorazepam, Meprobamate, Miltown, Rohypnol, Serax, Soma, Tranxene, Valium, Vistaril and Xanax. The NSDUH tracks 16 specific sedatives which include Amytal, Butalbital, Butisol, Chloral Hydrate, Dalmane, Halcion, Methaqualone, Nembutal, Pentobarbital, Phenobarbital, Placidyl, Restoril, Secobarbital, Seconal, Temazepam and Tuinal.

‡ The NSDUH tracks 21 specific stimulants which include Benzedrine, Biphetamine, Cylert, Desoxyxyn, Dexedrine, Dextroamphetamine, Didrex, Eskatrol, Fastin, Ionamin, Mazanor, Methamphetamine, Methedrine, Methylphenidate, Obedrin-LA, Phentermine, Plegine, Preludin, Ritalin, Sanorex and Tenuate.

§ Defined as having used an illicit drug in the past year.

1998 is the most recent year for which regional data are reported in the NSDUH.
Prescription opioid abuse increased by 140.5 percent; prescription CNS depressant abuse, by 44.5 percent; prescription stimulant abuse, by 41.5 percent. At the same time, there was a 47.1 percent increase in marijuana use; a 19.1 percent increase in cocaine use and a 1.5 percent increase in heroin use. (See Figure 3.D) This suggests that experimenting with controlled prescription drugs is becoming increasingly popular. While experimenters may not become chronic users, the healthcare and social consequences of this increase in experimentation, and the accompanying progression to abuse of other drugs, are likely to emerge in the coming years.

Opioid abuse increased seven times faster than cocaine use and 94 times faster than heroin use. One important emerging trend is the increasingly critical role of new users or experimenters in the controlled prescription drug-abusing population. In 1992, this population was overwhelmingly comprised of regular or experienced users, with new abusers representing a relatively small proportion of this population. Yet less than a decade later (in 2000), approximately one-third of all abusers were abusing controlled prescription drugs for the first time. Between 1992 and 2000, the number of new opioid abusers grew by 224.8 percent, new tranquilizer abusers, by 149.5 percent, new sedative abusers, by 127.3 percent, and new stimulant abusers, by 171.2 percent. (See Table 3.9)

Table 3.9

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>1992</th>
<th>2000*</th>
<th>Percent Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids</td>
<td>626</td>
<td>2,033</td>
<td>+224.8</td>
</tr>
<tr>
<td>Tranquilizers</td>
<td>390</td>
<td>973</td>
<td>+149.5</td>
</tr>
<tr>
<td>Sedatives</td>
<td>77</td>
<td>175</td>
<td>+127.3</td>
</tr>
<tr>
<td>Stimulants</td>
<td>257</td>
<td>697</td>
<td>+171.2</td>
</tr>
</tbody>
</table>

* Data on new abusers are available only through 2000, except for opioids for which there are data through 2002. Opioid data are presented here for 2000.

* Prescription tranquilizer abuse increased by 64.6 percent and prescription sedative abuse declined by 50.5 percent.
† Data on new abusers (initiators) of CNS depressants and stimulants only are available through 2000; therefore all data analyses related to new abusers span the years 1992-2000 rather than 1992-2003.
Clinical Abuse and Addiction:*
Current Estimates†

In 2003, 12.3 percent (1.9 million) of the 15.1 million individuals ages 12 and older who reported abusing controlled prescription drugs also reported symptoms consistent with clinical abuse of or addiction to these drugs. The rates of clinical abuse or addiction among prescription drug abusers (11.7 percent for opioids, 8.4 percent for tranquilizers, 16.1 percent for sedatives and 13.6 percent for stimulants) were lower than rates among marijuana users (16.7 percent), excessive drinkers‡ (19.6 percent) and other illicit drug users (24.8 percent for cocaine and 56.2 percent for heroin). (See Figure 3.E)

Teens: The Most Vulnerable Group of Controlled Prescription Drug Abusers

In 2003, 2.3 million teens between the ages of 12 and 17 (9.3 percent) admitted abusing a controlled prescription drug at least once in the past year, accounting for 15.4 percent of all prescription drug abusers. Of the teenage abusers, 83.4 percent abused opioids; 24.6 percent, tranquilizers; 5.6 percent, sedatives; and 25.1 percent, stimulants. Other recent research finds that to get high, one in five teens (18 percent) has abused the prescription opioid Vicodin; 10 percent, OxyContin; and 10 percent, the stimulants Ritalin and/or Adderall. Not all teens and young adults who abuse prescription drugs do so to get high. Some abuse these drugs to relieve stress, relax or to improve their academic performance.

Teens who report abusing controlled prescription drugs are twice as likely to use alcohol; five times likelier to use marijuana; 12 times likelier, heroin; 15 times likelier, Ecstasy; and 21 times likelier, cocaine.

Among 12- to 17-year olds, girls are likelier than boys to report the past year abuse of controlled prescription drugs (10.1 percent vs. 8.6 percent). The rate of controlled prescription drug abuse among teens is significantly higher than their rates of cocaine (1.7 percent), Ecstasy (1.2 percent) or heroin (0.1 percent) use, but lower than their rate of marijuana use (15.2 percent).

---

* To avoid confusion with the concept of physical dependence, the term “addiction” is used here to refer to controlled prescription drug abusers who meet the diagnostic criteria for “substance dependence.”

† Data on clinical abuse and dependence were introduced in the NSDUH in 2000; therefore, trend data are not presented.

‡ Individuals classified as excessive drinkers by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) are, for women, those who drink two or more drinks per day and, for men, those who drink three or more drinks per day in the past 30 days.
Between 1992 and 2003, the percent of teens ages 12 to 17 who admitted abusing controlled prescription drugs increased by 212 percent—2.6 times that of individuals ages 18 and over (81 percent). Despite modest declines or relatively steady rates between 2002 and 2003 in the NSDUH reported abuse of most illicit drugs, data from the MTF survey show increased abuse of certain prescription opioids among eighth, tenth and twelfth graders. For example, in 2003, 4.5 percent of twelfth graders reported using OxyContin “on your own—that is, without a doctor telling you to take them” (a 0.5 percent increase from 2002) and 10.5 percent reported using Vicodin (a 0.9 percent increase from 2002).57

**New Teen Abusers**

The high rate at which teenagers are beginning to experiment with abusing controlled prescription drugs is a relatively recent phenomenon. Between 1992 and 2002, the number of new (first time) teenage prescription opioid abusers increased by 542 percent (compared to a 124 percent increase among adults ages 18 and older).58 Between 1992 and 2000—the most recent year for which data are available on new abusers of CNS depressants and stimulants—the increases in teenagers’ abuse of these drugs were substantial as well. During this period, increases in new teen opioid abusers were four times greater than increases in new users ages 18 and over, three times the increase for tranquilizers and sedatives and 2.6 times the increase for stimulants.59 (See Table 3.10)

**Clinical Abuse and Addiction**

In 2003, an estimated 15.3 percent of teens (compared to 11.8 percent of abusers ages 18 and over) met the stringent clinical (DSM-IV) diagnostic criteria for abuse or addiction to controlled prescription drugs. Among teen controlled prescription drug abusers, 9.3 percent reported symptoms consistent with the DSM-IV criteria for addiction: 8.2 percent of teenage opioid abusers, 4.7 percent of teenage tranquilizer abusers, 23.8 percent of teenage sedative abusers and 10.0 percent of teenage stimulant abusers.60 Rates of addiction to controlled prescription drugs in the teenage population are generally comparable to rates of illicit drug addiction: in 2003, 10.5 percent of teen cocaine users and 22.2 percent of teen heroin users reported symptoms consistent with addiction.61

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids</td>
<td>148</td>
<td>933</td>
<td>+530.4</td>
<td>478</td>
<td>1,100</td>
<td>+130.1</td>
</tr>
<tr>
<td>Tranquilizers</td>
<td>77</td>
<td>331</td>
<td>+329.9</td>
<td>313</td>
<td>642</td>
<td>+105.1</td>
</tr>
<tr>
<td>Sedatives</td>
<td>20</td>
<td>72</td>
<td>+260.0</td>
<td>57</td>
<td>103</td>
<td>+80.7</td>
</tr>
<tr>
<td>Stimulants</td>
<td>94</td>
<td>360</td>
<td>+283.0</td>
<td>163</td>
<td>337</td>
<td>+106.7</td>
</tr>
</tbody>
</table>

Table 3.10
Percent Increase in New Abusers of Controlled Prescription Drugs by Age, 1992-2000

Steroid Abuse

In 2004, 1.1 percent of eighth graders, 1.5 percent of tenth graders and 2.5 percent of twelfth graders admitted abusing steroids in the past year.62 Most (69.7 percent) twelfth grade steroid abusers consumed the drugs orally; 19.6 percent by injection and 10.7 percent both orally and by injection.63

Between 1991 and 2004, steroid abuse increased sharply among older students: the proportion of twelfth grade steroid abusers increased by 78.6 percent (from 1.4 percent to 2.5 percent), the proportion of tenth grade abusers jumped by 36.4 percent (from 1.1 percent to 1.5 percent); and the proportion of eighth grade abusers, by 10 percent (from 1.0 percent to 1.1 percent).64 One aspect of this rise in abuse, particularly among twelfth graders, is the decreased proportion of students who report that they perceive steroid use to be harmful or to pose a
great risk (15.1 percent decline, from 65.6 percent in 1991 to 55.7 percent in 2004). Other research shows that rates of lifetime steroid abuse among high school students have increased 126 percent between 1991 and 2003. In 2003, approximately 1.7 million teens admitted trying steroids.

Steroid abuse is a problem for both girls and boys. But, while boys abuse steroids at higher rates than girls, the increase in abuse has been more precipitous for girls than for boys (342 percent vs. 66 percent increase). Other research finds that, among ninth graders, 7.3 percent of girls report abusing steroids compared to 6.9 percent of boys.

Characteristics of Teen Controlled Prescription Drug Abusers

Prescription drug-abusing teens are likelier than those who do not abuse prescription drugs to have been arrested, to have received drug or alcohol treatment, to have met with a school counselor for emotional problems, to feel that schoolwork is not important, to have poorer grades and to have unengaged parents.

Poly-substance abusers vs. controlled prescription drug only abusers. Most teen prescription drug abusers (79.8 percent) are poly-substance abusers; 74.3 percent also abuse alcohol and 59.9 percent also abuse illicit drugs. Teens who abuse controlled prescription drugs in combination with alcohol or illicit drugs often do so to accentuate a high or help bring them down from one.

Teens who abuse controlled prescription drugs only may do so because these drugs are more accessible to them than tobacco, alcohol or illicit drugs. Controlled prescription drugs can be found in parents’ medicine cabinets or gotten from friends who have a prescription for the drug. Teens also may believe prescription drugs to be safer and carry less stigma than other substances of abuse.

More younger teens (ages 12 and 13) abuse controlled prescription drugs only than abuse these drugs along with alcohol or illicit drugs (36.7 percent vs. 8.7 percent). This may suggest that prescription drugs serve as a gateway to the use of other substances of abuse.

Poly-substance-abusing teens are more likely than those who abuse prescription drugs only to experience emotional problems, problems with family, friends, school or work, and trouble with the law. (See Table 3.11)

Table 3.11

<table>
<thead>
<tr>
<th>Problem</th>
<th>Non-Users</th>
<th>PD Only Abusers</th>
<th>Poly-Substance Abusers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever arrested and booked for a crime</td>
<td>4.1</td>
<td>7.3</td>
<td>27.2</td>
</tr>
<tr>
<td>Ever received drug/alcohol treatment</td>
<td>0.3</td>
<td>3.5</td>
<td>11.8</td>
</tr>
<tr>
<td>Talked with school counselors in past year</td>
<td>8.7</td>
<td>15.5</td>
<td>15.0</td>
</tr>
<tr>
<td>Seldom/never felt schoolwork was important in past year</td>
<td>17.0</td>
<td>20.6</td>
<td>37.8</td>
</tr>
<tr>
<td>D or lower average grade for last grading period</td>
<td>4.8</td>
<td>6.6</td>
<td>12.7</td>
</tr>
<tr>
<td>Parents seldom/never checked homework in past year</td>
<td>16.1</td>
<td>21.0</td>
<td>39.0</td>
</tr>
<tr>
<td>Parents seldom/never told teen he/she had done a good job in past year</td>
<td>10.3</td>
<td>19.3</td>
<td>25.3</td>
</tr>
<tr>
<td>PD use caused emotional problems</td>
<td>N/A</td>
<td>6.2</td>
<td>12.5</td>
</tr>
<tr>
<td>PD use caused family/friendship problems</td>
<td>N/A</td>
<td>3.0</td>
<td>7.7</td>
</tr>
<tr>
<td>PD use caused serious problems at home/work/school</td>
<td>N/A</td>
<td>5.6</td>
<td>8.1</td>
</tr>
<tr>
<td>PD use caused troubles with law</td>
<td>N/A</td>
<td>1.1</td>
<td>3.1</td>
</tr>
<tr>
<td>PD use caused or worsened health problems</td>
<td>N/A</td>
<td>3.8</td>
<td>3.8</td>
</tr>
</tbody>
</table>


* Rates reflect lifetime abuse.
Individuals Ages 18 and Over Who Abuse Controlled Prescription Drugs Only

Most controlled prescription drug abusers ages 18 and over are poly-substance abusers (73.8 percent) who abuse prescription drugs as well as alcohol and/or illicit drugs; 62.0 percent also abuse alcohol and 52.5 percent also abuse illicit drugs.74

Individuals ages 18 and over who abuse controlled prescription drugs only are likelier than poly-substance abusers to be female (60.9 percent vs. 45.1 percent), ages 35 or older (63.7 percent vs. 31.9 percent), married (59.3 percent vs. 25.8 percent), better educated (24.7 percent vs. 15.8 percent are college graduates) and have higher incomes (81.7 percent vs. 72.8 percent have family incomes of $20,000 or more).75

Because the characteristics of prescription drug only abusers are different from those commonly associated with substance abusers, the abuse and addiction problems of these individuals may be overlooked by family, friends and healthcare professionals.

Controlled Prescription Drug Abusers and Mental Illness

People diagnosed with psychiatric disorders are likelier to engage in the abuse of controlled prescription drugs than those without a diagnosed mental illness. * 77 The mentally ill may seek out legitimate prescriptions for controlled psychiatric drugs and some turn to psychotropic prescription drugs to self-medicate their ailments. Over time, some may end up abusing them or becoming addicted to them. (See Table 3.12)

---

<table>
<thead>
<tr>
<th>Mental Health</th>
<th>Opioids</th>
<th>Tranquilizers</th>
<th>Sedatives</th>
<th>Stimulants</th>
</tr>
</thead>
<tbody>
<tr>
<td>No mental health problem</td>
<td>2.8</td>
<td>1.4</td>
<td>0.8</td>
<td>2.3</td>
</tr>
<tr>
<td>Mania</td>
<td>19.4</td>
<td>27.0</td>
<td>10.8</td>
<td>10.8</td>
</tr>
<tr>
<td>Antisocial personality disorder</td>
<td>12.8</td>
<td>10.3</td>
<td>8.2</td>
<td>15.3</td>
</tr>
<tr>
<td>Bipolar disorder</td>
<td>10.3</td>
<td>20.0</td>
<td>11.9</td>
<td>11.9</td>
</tr>
<tr>
<td>Non-affective psychosis</td>
<td>9.6</td>
<td>13.5</td>
<td>7.7</td>
<td>9.6</td>
</tr>
<tr>
<td>Post-traumatic stress disorder</td>
<td>8.6</td>
<td>7.9</td>
<td>4.7</td>
<td>5.6</td>
</tr>
<tr>
<td>Generalized anxiety disorder</td>
<td>7.9</td>
<td>7.0</td>
<td>4.1</td>
<td>5.5</td>
</tr>
<tr>
<td>Panic disorder</td>
<td>7.0</td>
<td>8.8</td>
<td>2.8</td>
<td>2.8</td>
</tr>
<tr>
<td>Major depression</td>
<td>6.7</td>
<td>7.6</td>
<td>4.6</td>
<td>5.1</td>
</tr>
<tr>
<td>Simple phobia</td>
<td>6.4</td>
<td>5.8</td>
<td>3.3</td>
<td>4.6</td>
</tr>
</tbody>
</table>


---

*I* Analyses of prescription drug abuse in the mentally ill are based on the most recent available data from the National Comorbidity Survey (NCS), 1990–1992, a nationally representative survey of more than 8,000 respondents designed to assess the prevalence and correlates of psychiatric disorders (based on DSM III-R criteria) and patterns and correlates of mental health services utilization. Nine diagnostic categories are analyzed in the NCS: generalized anxiety disorder, mania, panic disorder, simple phobia, post-traumatic stress disorder, major depression, antisocial personality disorder, bipolar disorder and non-affective psychosis.

---

*I call it the silent epidemic...many older people either do not realize or are ashamed to admit that they have a drug problem.*

--Ruth Sanchez-Way, PhD, former Director, Center for Substance Abuse Prevention
**Opioids**

Individuals diagnosed with major psychiatric disorders are up to seven times likelier than those who are not mentally ill to abuse prescription opioids. The highest rates of opioid abuse are found among those diagnosed with mania (19.4 percent), antisocial personality disorder (12.8 percent), bipolar disorder (10.3 percent) and non-affective psychosis (9.6 percent).78

**CNS Depressants**

Among individuals diagnosed with a psychiatric disorder, rates of CNS depressant abuse, particularly tranquilizers, are up to 19 times higher than among the non-mentally ill population. The highest rates of tranquilizer abuse are found among those diagnosed with mania (27.0 percent), bipolar disorder (20.0 percent), non-affective psychosis (13.5 percent) and antisocial personality disorder (10.3 percent). The highest rates of sedative abuse are found among those diagnosed with bipolar disorder (11.9 percent), mania (10.8 percent), antisocial personality disorder (8.2 percent) and non-affective psychosis (7.7 percent).79

**CNS Stimulants**

Stimulant abuse is up to seven times more prevalent among individuals diagnosed with psychiatric disorders compared to those without a psychiatric disorder. The highest rates are found among those diagnosed with antisocial personality disorder (15.3 percent), bipolar disorder (11.9 percent), mania (10.8 percent) and non-affective psychosis (9.6 percent).80

**Controlled Prescription Drug Abusers and Criminal History**

In addition to examining data from the NSDUH, CASA analyzed criminal justice data to explore the prevalence of prescription drug abuse in the criminal justice population.*

Prescription drug abusers are at greater risk of engaging in criminal behavior than non-abusers of prescription drugs. Prescription drug abusers are more than twice as likely as non-abusers to have been arrested for breaking the law (35.8 percent vs. 15.4 percent). Among prescription drug abusers, stimulant abusers are the likeliest to have a criminal record (47.2 percent).81

**Lifetime and Past Month Controlled Prescription Drug Abuse**

Incarcerated criminal offenders are likelier than the general, non-institutionalized population† to have abused controlled prescription drugs in their lifetimes. Local jail inmates had the highest rates of lifetime abuse of these drugs followed by state and federal prison inmates. (See Figure 3.F)

* Data for these analyses were derived from the most recent data available from three national surveys of federal and state prison inmates, local jail inmates and adults on probation (the 1997 Survey of Inmates in State and Federal Correctional Facilities, the 1996 Survey of Inmates of Local Jails and the 1995 Survey of Adults on Probation). These surveys were conducted by the Bureau of Justice Statistics between 1995 and 1997 and contain questions about lifetime and past month use of prescription drugs, and whether the inmates were under the influence of a drug at the time of the offense. Amphetamines and methamphetamines are included in the category of stimulants.

† Based on National Household Survey on Drug Abuse (NHSDA) data from 1996.
Compared to reports of past-month controlled prescription drug abuse in the general population, criminal offenders were likelier to have abused CNS depressants or stimulants in the month prior to their arrest.83 (See Table 3.13)

### Healthcare Professionals

Healthcare professionals may be vulnerable to controlled prescription drug abuse because of their ready access to these drugs and the high levels of stress often associated with their work.85 Members of certain medical specialties, including anesthesiologists, emergency medicine physicians, family/ general practitioners and psychiatrists are at particularly high risk of prescription drug abuse.86 One study found that pharmacists and nurses (and pharmacy and nursing students) admitted a higher rate of lifetime prescription drug abuse than that in the general population.87

Six percent of state prison inmates (64,581), five percent of federal prison inmates (4,445) and five percent of local jail inmates (23,771) were incarcerated for offenses committed while they were under the influence of abused controlled prescription drugs; 1.2 percent of adult probationers (15,753) were under the influence of abused controlled prescription drugs at the time of their offense. The majority of the prescription drug-abusing offenders were under the influence of stimulants at the time of their offense.84 (See Table 3.14)

### Consequences of Controlled Prescription Drug Diversion and Abuse

In addition to the risk of addiction and dependence described earlier, the abuse of controlled prescription drugs, primarily opioids, is implicated in increasing numbers of drug-related deaths as well as visits to the emergency department. Prescription drug abusers also report emotional, social, health and financial problems directly associated with their abuse of controlled prescription drugs.

---

**Table 3.13**

<table>
<thead>
<tr>
<th></th>
<th>Opioids</th>
<th>Tranquilizers</th>
<th>Sedatives</th>
<th>Stimulants</th>
</tr>
</thead>
<tbody>
<tr>
<td>General population</td>
<td>0.9</td>
<td>0.4</td>
<td>0.1</td>
<td>0.4</td>
</tr>
<tr>
<td>Federal prison</td>
<td>1.7</td>
<td>2.6</td>
<td>1.3</td>
<td>7.5</td>
</tr>
<tr>
<td>State prison</td>
<td>2.2</td>
<td>2.5</td>
<td>3.0</td>
<td>8.9</td>
</tr>
<tr>
<td>Local jail</td>
<td>0.9</td>
<td>2.4</td>
<td>2.6</td>
<td>6.5</td>
</tr>
<tr>
<td>Probationers</td>
<td>0.3</td>
<td>---</td>
<td>1.0</td>
<td>2.3</td>
</tr>
</tbody>
</table>


**Table 3.14**

<table>
<thead>
<tr>
<th></th>
<th>Opioids</th>
<th>Tranquilizers</th>
<th>Sedatives</th>
<th>Stimulants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal prison</td>
<td>0.2</td>
<td>0.8</td>
<td>0.4</td>
<td>4.0</td>
</tr>
<tr>
<td>State prison</td>
<td>0.6</td>
<td>1.1</td>
<td>0.8</td>
<td>4.2</td>
</tr>
<tr>
<td>Local jail</td>
<td>0.3</td>
<td>1.0</td>
<td>0.1</td>
<td>3.8</td>
</tr>
<tr>
<td>Probationers</td>
<td>0.2</td>
<td>---</td>
<td>0.1</td>
<td>0.9</td>
</tr>
</tbody>
</table>

Drug-Related Deaths

To determine the extent to which the abuse of controlled prescription drugs is involved in or responsible for drug-related deaths, CASA analyzed data from the Drug Abuse Warning Network (DAWN).* Controlled prescription drugs more frequently are included in multiple drug-involved deaths than in deaths linked to a single controlled prescription drug. Up to six drugs may be reported for each drug-related death in the DAWN system.

All drug deaths. In 2002,† controlled prescription drugs‡ were mentioned in 29.9 percent of all drug-related deaths, including single drug and multiple drug deaths. Prescription opioids were the most frequently mentioned controlled prescription drug in all drug-related deaths (18.9 percent vs. 7.5 percent for tranquilizers and 3.5 percent for stimulants).§ Prescription opioids accounted for more drug mentions involved in drug-related deaths than cocaine (15.2 percent), heroin (12.6 percent) and marijuana (2.6 percent).¶ (See Figure 3.G)

![Figure 3.G](image)

Mentions in All Drug Deaths in 31 Metropolitan Areas

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Percent Mentions</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Controlled Prescription Drugs</td>
<td>29.9</td>
</tr>
<tr>
<td>Opioids</td>
<td>18.9</td>
</tr>
<tr>
<td>Tranquilizers</td>
<td>7.5</td>
</tr>
<tr>
<td>Stimulants</td>
<td>3.5</td>
</tr>
<tr>
<td>Marijuana</td>
<td>2.6</td>
</tr>
<tr>
<td>Cocaine</td>
<td>15.2</td>
</tr>
<tr>
<td>Heroin</td>
<td>12.6</td>
</tr>
</tbody>
</table>

Source: CASA analysis of DAWN, 2002.

Single-drug deaths. In 2002, controlled prescription drugs were involved in 20.4 percent of all single-drug deaths in the DAWN system. Of controlled prescription drugs, opioids were involved in the largest number of single-drug deaths, representing 15.4 percent of all single-drug deaths (vs. 2.1 percent for tranquilizers and 2.9 percent for stimulants).∥

Relative to any class of controlled prescription drugs, cocaine and heroin were likelier to be mentioned in single-drug deaths, accounting for 37.4 percent and 17.0 percent, respectively, of all single-drug deaths.¶ (See Figure 3.H)

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* DAWN, operated by the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services, includes data on drug-related visits to emergency departments in a national sample of non-federal, short-stay hospitals. Data on drug-related deaths are drawn from 127 medical examiners and coroner jurisdictions in 38 metropolitan areas throughout the U.S. Because these data come from a sample of select locations, they are not necessarily nationally representative. Although similar, there is not a perfect correspondence between drugs covered by DAWN and those covered by the NSDUH.

† Current prescription drug-related deaths are reported for the year 2002; in that year, data reflect the number of drug-related deaths reviewed, identified and reported by participating medical examiners and coroners in 31 selected metropolitan areas that reported at least 30 drug abuse deaths and submitted data for at least 10 months of the year to DAWN in 2002 (seven of the 38 metropolitan areas were excluded based on these criteria).

‡ Excluding sedatives, for which mortality data are not available.
Regional differences. Consistent with their disproportionately higher levels of abuse, the western and southern regions of the country have the highest rates of prescription drug-related deaths.

In 2002, controlled prescription drugs accounted for at least 23 percent of all drug-related ED mentions in the U.S.; opioids accounted for the most and sedatives accounted for the fewest of all drug-related ED mentions.

Examining trends in this data from 1994 to 2002, the analyses reveal a 78.9 percent increase in the number of controlled prescription drug-related ED mentions, with prescription opioids demonstrating the greatest increase.

Although the total number of cocaine ED mentions surpassed that of each class of controlled prescription drugs, the total number of heroin mentions was fewer than those for prescription opioids and tranquilizers. In addition, while the rate of increase in marijuana ED mentions between 1994 and 2002 exceeds all other drugs, the rates of increase in cocaine and heroin mentions were much lower than the rates of increase in prescription opioid and sedative mentions during this time.

Drug-Related Emergency Department Visits

To determine the extent to which the abuse of controlled prescription drugs is involved in or responsible for emergency medical visits, CASA analyzed data from DAWN. The analyses assess the number of drug mentions associated with a drug-related Emergency Department (ED) visit; up to four drugs plus alcohol may be recorded for each drug-related visit to the ED.

Opioids. Opioids were implicated in the largest number of prescription drug-related ED mentions and showed the largest growth rate over time. In 2002, opioids were involved in more than 119,000 or 9.9 percent of all drug-related (including illicit drugs) ED mentions--as many as heroin or marijuana but less than alcohol or cocaine.

Oxycodone (e.g., OxyContin, Percocet) and hydrocodone (e.g., Lortab, Vicodin) were the most frequently named prescription opioids (19 percent and 21 percent, respectively), accounting for 40 percent (47,594) of prescription opioid mentions in these ED visits. Seventy-one percent of ED visits involving oxycodone and 78 percent of ED visits involving hydrocodone also involved other substances--most commonly alcohol and...
benzodiazepines. Between 1994 and 2002, the number of opioid-related ED mentions increased by 168 percent.

**CNS Depressants.** In 2002, tranquilizers accounted for 8.7 percent and sedatives accounted for 0.1 percent of all drug-related ED mentions. Alprazolam (e.g., Xanax) and clonazepam (e.g., Klonopin) were the most frequently reported benzodiazepine mentions in these ED visits (25 percent and 16 percent, respectively). Seventy-eight percent of ED visits involving benzodiazepines also involved other substances, commonly alcohol and marijuana. Nearly half of the drug abuse-related ED visits involving benzodiazepines were connected to suicide attempts. Between 1994 and 2002, the number of tranquilizer-related ED mentions increased by 42 percent and the number of sedative-related ED mentions increased by 66 percent.

**CNS Stimulants.** In 2002, stimulants accounted for 3.4 percent of all drug-related ED mentions. Between 1994 and 2002, the number of stimulant-related ED mentions increased by 41 percent.

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* CNS depressants include tranquilizers, which consist primarily of benzodiazepines, and sedatives which consist primarily of barbiturates in the DAWN dataset.

† Methamphetamine is included in the category of prescription stimulants. Because controlled prescription stimulants cannot be differentiated from illicit stimulants in the DAWN dataset, the level of detail provided above for opioids and CNS depressants is not provided here.

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Emotional and Social Consequences

CASA’s analysis of data from the 2003 NSDUH reveals that 7.4 percent of all prescription drug abusers experience emotional or mental health problems caused or worsened by their use of these drugs. Stimulant and sedative abusers were likeliest to report such problems (10.7 percent and 9.5 percent, respectively, vs. 6.6 percent of opioid abusers and 4.5 percent of tranquilizer abusers). Nearly half (46.1 percent) of those who meet diagnostic criteria for clinical abuse or addiction report emotional or mental health problems related to their prescription drug abuse--just about the same proportion as heroin abusers who report heroin-related emotional or mental health problems (46.2 percent).

Prescription drug abuse also causes problems with family and friends, school or work, health and the law. Controlled prescription drug abusers report experiencing emotional, mental health and social problems related to their prescription drug abuse at similar or higher rates as alcohol-induced problems among alcohol abusers, but at considerably lower rates than illicit drug-induced problems among illicit drug abusers. However, those prescription drug abusers who meet diagnostic criteria for abuse or addiction suffer from these problems at rates similar to heroin abusers and greater than cocaine abusers. (See Table 3.15)

† Alcohol abusers are defined as excessive drinkers. Illicit drug abuser analyses include cocaine and heroin only.
Table 3.15
Impact of Substance Abuse on Abusers (Percent)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Abusing</th>
<th>Using</th>
<th>Clinical Abuse or Addiction: All Controlled Prescription Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All</td>
<td>Opioids</td>
<td>Tranquilizers</td>
</tr>
<tr>
<td>Emotional or mental health problems</td>
<td>7.4</td>
<td>6.6</td>
<td>4.5</td>
</tr>
<tr>
<td>Family/friendship problems</td>
<td>5.1</td>
<td>4.6</td>
<td>3.9</td>
</tr>
<tr>
<td>Serious problems at home, work or school</td>
<td>4.6</td>
<td>3.9</td>
<td>3.8</td>
</tr>
<tr>
<td>Trouble with law</td>
<td>1.8</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>Worsened health problems</td>
<td>2.5</td>
<td>2.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Used drug while doing dangerous activities</td>
<td>5.4</td>
<td>4.7</td>
<td>4.7</td>
</tr>
</tbody>
</table>

Note: All questions were asked in relation to the specific substance (e.g., stimulant abuse worsening health problems, cocaine abuse causing trouble with the law.) Alcohol refers to excessive drinking for adults and any alcohol use for those underage.
Financial Consequences

No data are available on the total cost of controlled prescription drug diversion and abuse to society, but costs are linked to police and court costs, incarceration, health and mental health care, social services (e.g., child abuse, teen pregnancy), lost productivity and human suffering. Controlled prescription drug abuse is estimated to cost states alone approximately $100 billion annually just in healthcare expenses.\textsuperscript{111}

The \textit{Florida Sun-Sentinel} reports that, in Florida alone, Medicaid paid pharmacies $346.6 million for controlled drugs between 2000 and 2003. Most of these prescriptions were written by less than three percent of the state’s medical professionals, many of whom were linked to drug-related deaths. The newspaper also reports that Medicaid paid more than $63,000 to Florida pharmacies that filled prescriptions for controlled drugs issued by 108 physicians after they had died, lost their licenses or had been found guilty of crimes that would have barred them from treating Medicaid patients. It also paid $800,000 to pharmacies for filling prescriptions for controlled drugs from two Florida doctors who deny writing the prescription orders.\textsuperscript{112}

Costs to states also include those associated with running prescription drug monitoring programs, which are state-run programs that collect data on the prescribing and dispensing of controlled medications in order to assist law enforcement and regulatory agencies in identifying potential instances of diversion. The average start-up costs for these programs are approximately $300,000 per state and annual costs for running these programs can range from approximately $150,000 to $1 million dollars annually.\textsuperscript{113}
Chapter IV
The Mechanisms of Diversion

Prescription drugs typically are sold by pharmaceutical manufacturers to wholesalers who in turn sell them to pharmacies where they are purchased by patients with a valid prescription from a physician.¹ (See Figure 4.A) Diversion--any criminal act that causes controlled prescription drugs to be sidetracked from their lawful (medical) purpose to illicit use--can occur at any point in this manufacturing and distribution chain. Diversion can occur through theft, fraudulent prescriptions, patient scams, dishonest healthcare practitioners, prescription sharing and through criminal operatives. The risks of diversion can be increased by the way that drugs are formulated and marketed. A growing source of diversion is the Internet, discussed in Chapter V.

The CASA Surveys

To better understand the mechanisms of diversion and how physicians and pharmacists deal with this problem, CASA conducted two unprecedented surveys--one of 979 physicians and the other of 1,030 pharmacists--regarding their perceptions, attitudes and behaviors in relation to controlled prescription drug diversion and abuse. The margin of error for each survey was three percent. (See Appendix C for methodology and description of the sample, and Appendix D for survey instruments.) These surveys reveal that most physicians and pharmacists believe that patients account for the bulk of the diversion problem. Physicians and pharmacists also perceive the three main mechanisms of diversion to be doctor shopping (when patients obtain controlled prescription drugs from many doctors), patient deception or manipulation of doctors, and forged or altered prescriptions.

In addition, CASA conducted intensive focus groups with physicians, pharmacists, dentists and veterinarians to determine their perceptions and attitudes about diversion and abuse of controlled prescription drugs.
Drug Manufacture and Distribution: Potential Points of Diversion

Figure 4.A

Raw ingredients for the drug are manufactured and sold by a Supplier

Drug is manufactured and sold by a Pharmaceutical Company

Drug is dispensed by Retail Pharmacies (including mail-order, Internet and brick and mortar pharmacies), Hospitals, Clinics and Nursing Homes

Drug is sold by Drug Wholesalers

Drug is prescribed (and in some cases dispensed) by Licensed Clinician

Patient

Pharmaceutical Companies

In an effort to manufacture and sell products that benefit those with physical or psychological illnesses while at the same time maximize company profits, pharmaceutical company practices at times have contributed to the problems of prescription drug diversion and abuse.

Drug Formulations

Before a medication is released on the market, scientific tests are conducted by the manufacturer to assess its risk of abuse. The manufacturer submits evidence to the FDA demonstrating the safety and effectiveness of the drug, disclosing its abuse potential and comparing its effects (including potential for abuse) to existing drugs. This assessment provides useful information to help guide physician education about the best use of a drug and how to reduce the risk of abuse. The FDA and the DEA, the federal agencies responsible for regulating drugs in the U.S., also use this information to determine how best to classify and regulate the drug.

How pharmaceutical manufacturers formulate a particular drug can contribute to the drug’s potential for abuse. The appeal of a prescription drug for abuse depends on the strength and immediacy of the high it can produce, as well as on how easily the medication can be altered for purposes of abuse. For example, some controlled-release opioid formulations (e.g., Duragesic, MS Contin, OxyContin) can be altered through crushing or dissolving to release the full dose at once, producing an intense high.

Adding an antagonist to an opioid drug—such as was done with Talwin—can counteract its morphine-like effects in the event that the tablets are altered for abuse; however, the addition of an antagonist is not routinely done in the manufacture of prescription drugs with potential for abuse. Despite the benefits of reformulation, some patients may have negative physical reactions to the antagonist and may not be able to take the reformulated medication. In addition, an antagonist, such as naloxone, may reduce the pain-relieving effects of a drug, compromising its effectiveness.

Marketing to Physicians

Pharmaceutical company marketing may increase the risk that a drug will be diverted for illicit purposes and abused. Pharmaceutical detailing—company representatives promoting and providing information on new drugs and products to physicians—is designed to help educate physicians about medications. Although most detailing involves non-controlled drugs, some health professionals see it as dangerous in that it could lead to prescribing practices that may not be in the best interest of the patient. Some health professionals have called for placing limits on the
interactions between pharmaceutical company representatives and physicians as well as for increases in “counterdetailing” by well-trained physicians or pharmacists who are not promoting a particular drug.

The U.S. Court of Appeals in Washington, DC...upheld a lower-court ruling that Purdue had falsely claimed in its patent application to have clinical evidence that OxyContin was easier for doctors to use than other pain-relief drugs.

CASA’s survey of physicians and pharmacists found that only 30.1 percent physicians and 40.0 percent of pharmacists view the drug product information they receive from manufacturers as “very or somewhat” helpful in educating them about which controlled drugs are best to prescribe.

Attorneys General are now looking very carefully...about how the marketing practices of pharmaceutical drug companies in general inflate unnecessarily the use of certain drugs.

--The Honorable Richard Blumenthal
Attorney General, State of Connecticut
CASACONFERENCE, Feeling No Pain: Substance Abuse, Addiction and Pain Management
February 27, 2003

The American Medical Association and the Department of Health and Human Services’ Office of Inspector General have urged pharmaceutical companies to refrain from offering elaborate gifts to physicians and the Pharmaceutical Research and Manufacturers of America (PhRMA) have adopted voluntary guidelines for detailing activities.

Marketing to Patients

Direct marketing of controlled prescription drugs to patients is designed to increase the demand for a particular medication among those seeking it for legitimate (i.e., medical) purposes. Unfortunately, it may increase demand among those seeking drugs for abusive (i.e., diversion) purposes as well. There are no federal prohibitions against direct-to-consumer (DTC) advertising of controlled prescription drugs. DTC advertising of any controlled prescription drug, however, is prohibited by Article 10 of the 1971 International Convention on Psychotropic Substances which states “Each Party [to the treaty] shall, with due regard to its constitutional provisions, prohibit the advertisement of such substances [controlled psychotropic substances] to the general public.” Because DTC advertising in general has to date been deemed protected by a Constitutional First Amendment right to commercial speech, the U.S. government has not prohibited drug manufacturers from advertising their drugs to consumers. However, this protection has not been tested in the courts specifically for controlled prescription drugs.

Unfortunately, the pharmaceutical industry has begun to advertise a number of controlled substances—including a schedule II stimulant and several schedule IV products—through public advertisements. This practice is contrary to DEA’s long-standing policy against such advertising....Consequently, DEA will continue to work through available avenues to communicate to the pharmaceutical industry the belief that direct to consumer advertising of controlled substances is contrary to the public interest.

--Asa Hutchinson, former Administrator
Drug Enforcement Administration

I find [direct-to-consumer advertising] extremely annoying...When my patients come in and say ‘Gee, Doctor, I’ve seen drug X on the tube and I want that.’ and I say, ‘Well, I’m sorry you’ve got the wrong diagnosis’ or ‘There’s a better drug out there’ and they say, ‘No Doctor, I want that.’ Then we get into a non-therapeutic and contentious situation.

--R. Norman Harden, MD
Director, Center for Pain Studies
Rehabilitation Institute of Chicago
CASACONFERENCE, Feeling No Pain: Substance Abuse, Addiction and Pain Management
February 27, 2003
While pharmaceutical companies have largely refrained from advertising controlled prescription drugs directly to consumers, companies such as Sanofi-Synthelabo and Celltech Pharma initiated DTC ad campaigns for drugs including Ambien (a Schedule IV sedative) and Metadate CD (a Schedule II stimulant). Other drugs, including Sonata (a Schedule IV sedative) and Meridia (a Schedule IV stimulant), were advertised by King Pharmaceuticals, Inc. and Abbott Laboratories, respectively, but the makers of these drugs chose to discontinue the ads in the face of DEA objections.19

Theft From Wholesalers

There are three main pharmaceutical wholesalers in the United States* and thousands of smaller wholesalers that sell pharmaceuticals to retail pharmacies, hospital pharmacies and doctors’ offices.20 Drugs may be stolen from wholesalers--to divert for illegal sale. Sometimes they are replaced with counterfeit drugs.21 Counterfeit drugs (those without the active ingredient, with an insufficient quantity of the active ingredient or with the wrong active ingredient) can enter the distribution chain through secondary wholesalers or unlicensed pharmacies that distribute products that cannot be traced back to a legitimate manufacturer.22 The extent to which counterfeiting is a problem in the distribution of controlled prescription drugs is unknown.

Pharmaceutical products can change hands several times among wholesalers before reaching an end user.23 The three main wholesalers, which account for 90 percent of prescription drugs distributed in the U.S., currently are not required to document the sales history of a drug (known as a drug’s pedigree).24 Because a pedigree can help to prevent counterfeiting and track stolen drugs, the FDA plans to impose and enforce a pedigree requirement on wholesalers by December 2006.25 The FDA is monitoring projects such as the Massachusetts Institute of Technology’s Auto-ID Center, which aims to use methods of identification that help to differentiate counterfeit drugs from legitimate drugs and ultimately may be helpful in identifying stolen drugs.26

Pharmacists

Pharmacists, as the “gatekeepers” of large supplies of potent psychoactive drugs, are targets of prescription drug diversion.

Ever since prescription painkillers such as OxyContin became the drug of choice among dealers and addicts in Appalachia, the days of small-town pharmacists dispensing medicines from behind an ordinary counter have become a quaint memory. Now, many pharmacies have turned into virtual fortresses. Some now have bars over the windows. The most sought-after drugs are stored in vaults. The pharmacist often works behind safety glass, and some have even armed themselves. Surveillance cameras and alarm systems monitor every spot. Pharmaceutical companies also have adopted practices from the banking industry, delivering prescription pills in armored trucks protected by armed guards and tracked by satellites on carefully chosen routes.27

For decades, most pharmacists practiced in independent pharmacies where they came to know the local physicians (and their prescribing patterns) and customers. Today, retail pharmacy is dominated by large chains that tend to rotate personnel through various stores and set benchmarks for the number of prescriptions to be filled each day.28 In such an environment, it is more difficult for a pharmacist to be attuned to a particular physician’s prescribing patterns or patient’s medication use patterns, reducing the likelihood of detection of diversion activities.

CASA’s national survey of pharmacists found that 28.9 percent have experienced a theft or robbery of controlled drugs at their pharmacy within the last five years and 20.9 percent do not stock

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* AmerisourceBergen, Cardinal Health and McKesson.
certain controlled prescription drugs in order to prevent diversion.*

When asked to identify the source of most of the diversion problem, 51.8 percent of the pharmacists said patients, while 15.4 percent said Internet pharmacies, 9.8 percent said other pharmacies (retail, hospital/clinic), and 9.7 percent said physicians/clinicians. Fewer than one percent cited drug wholesalers (0.9 percent), manufacturers (0.7 percent) or pharmaceutical companies (0.5 percent) as accounting for most of the diversion problem.

The top three methods of diversion reported by pharmacists in CASA’s survey are doctor shopping--where patients obtain controlled drugs from several doctors (89.2 percent), forged or altered prescriptions (75.2 percent) and patient deception or manipulation of doctors (65.4 percent). Other methods of diversion reported by pharmacists are theft of prescription pads from doctors’ offices (35.0 percent) and doctors who knowingly divert controlled prescription drugs (16.4 percent). Fewer than five percent of pharmacists thought that theft of controlled prescription drugs from pharmacies (4.2 percent), pharmacy employees (other than pharmacists) who knowingly divert controlled drugs (3.4 percent), pharmacists who knowingly divert controlled drugs (1.3 percent) or theft of controlled drugs from doctors’ offices (0.9 percent) were primary methods of diversion. Other mentioned methods of diversion were “pharmacy shopping” (attempting to obtain the same medication from several pharmacies), theft from family or friends, and diversion by nurses.

**Patient Diversion from Pharmacies**

When a patient presents with a request for a controlled drug, 26.5 percent of pharmacists in CASA’s survey “somewhat or very often” think it is for purposes of abuse or diversion. Pharmacists who received training/instruction in prescription drug abuse and/or diversion were significantly less likely to suspect abuse or diversion.

Although patients with certain medical conditions—particularly those treated for chronic pain or repeated episodes of acute pain—are likely to know the brand name of a medication that they have found to be most effective, more than three-quarters (78.4 percent) of the pharmacists said that they become somewhat or very concerned about abuse or diversion when a patient asks for a controlled prescription drug by its brand name.

Other characteristics of the customer that might raise suspicions and lead a pharmacist to determine the validity of a prescription include: the prescription appears to have irregularities, unfamiliarity with the prescribing physician, the customer and/or the prescribing physician is from out of town, the demeanor of the customer is overly friendly, nervous or aberrant, or the customer tries to pay in cash rather than using his or her insurance. Some pharmacists rely on their “gut instinct.” (See Table 4.1)

<table>
<thead>
<tr>
<th>Suspicious Prescription Characteristic</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finding mistakes or irregularities in written prescription</td>
<td>88.6</td>
</tr>
<tr>
<td>Verifying with prescribing physician</td>
<td>83.1</td>
</tr>
<tr>
<td>Noting patient’s nervous or unusual behavior</td>
<td>78.0</td>
</tr>
<tr>
<td>Noting patient’s payment method (cash vs. insurance)</td>
<td>53.2</td>
</tr>
<tr>
<td>Checking if dosage is medically appropriate</td>
<td>48.7</td>
</tr>
<tr>
<td>Checking if number of refills is medically appropriate</td>
<td>48.4</td>
</tr>
<tr>
<td>Checking if prescription has correct provider number</td>
<td>42.4</td>
</tr>
<tr>
<td>Noting a refill request that is too early</td>
<td>41.4</td>
</tr>
</tbody>
</table>

When asked what they would do if they suspected a patient of abusing or diverting a controlled prescription drug, most reported calling the prescribing physician (92.8 percent), refusing to fill the prescription (76.6 percent) or documenting the incident (71.3 percent). (See Table 4.2)

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* The most common drugs that are not kept in stock for this reason are OxyContin, Dilaudid, Percocet and Percodan.
I give the prescriptions to the people that need the prescriptions. I'm not law enforcement...it isn't my job to enforce the law or rehabilitate them...

--Pharmacist
CASA Focus Group

Fraudulent prescriptions. The pharmacist’s responsibility is to dispense a controlled drug only upon presentation of a valid prescription. A pharmacist who fills a prescription knowing or having reason to know that it was not issued by a licensed practitioner in a legitimate physician-patient relationship and for a therapeutic purpose, violates the law.\(^{29}\)

However, this determination can be very difficult to make, particularly because high-quality photocopiers make professional-looking prescriptions relatively simple to create. In addition to the use of stolen or counterfeit prescription forms, valid prescription orders may be altered to increase the potency or amount of drugs or refills. Finally, drug-seeking individuals may impersonate a physician or a member of a physician’s staff to obtain drugs illegitimately from pharmacies.\(^{30}\)

Table 4.2

<table>
<thead>
<tr>
<th>Action</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call prescribing physician</td>
<td>92.8</td>
</tr>
<tr>
<td>Refuse to fill prescription</td>
<td>76.6</td>
</tr>
<tr>
<td>Document it</td>
<td>71.3</td>
</tr>
<tr>
<td>Contact police</td>
<td>47.6</td>
</tr>
<tr>
<td>Counsel patient on dangers</td>
<td>33.5</td>
</tr>
<tr>
<td>Confront patient with suspicions</td>
<td>32.3</td>
</tr>
<tr>
<td>Ask opinion of another pharmacist</td>
<td>26.4</td>
</tr>
<tr>
<td>Tell patient to leave pharmacy</td>
<td>16.3</td>
</tr>
<tr>
<td>Offer educational materials</td>
<td>6.4</td>
</tr>
<tr>
<td>Take no action</td>
<td>1.7</td>
</tr>
</tbody>
</table>

The overwhelming majority of pharmacists (83.1 percent) report that they have withheld dispensing a controlled prescription drug in the past year because of suspicions of diversion or abuse. Male pharmacists were significantly likelier than female pharmacists to say that they would confront the patient with their suspicions (35.6 percent vs. 26.1 percent).

Other actions reported by some pharmacists in response to their suspicion of a customer include contacting the DEA or state investigators or saying that the drugs the customer is seeking are out of stock.

Those pharmacists who explicitly said they would take no action at all (1.7 percent) explained their response by saying that they would be fearful to report cases of suspicion because the customer might seek revenge or harm them in some way. Others claimed that they would not take action because their employers would not want them to (fear of losing business, lawsuits for false accusations) or because the process of prosecuting cases of suspected diversion is too burdensome and time consuming.

Pharmacists face pressure from employers to “look the other way” and fill all prescriptions presented in order to increase revenue.

Chain drug stores would not permit intense monitoring; dispensing [controlled drugs] has become a cash cow.

--Pharmacists responding to CASA’s survey
(comments written on survey instrument)

When they want a brand name, you know they’re selling it on the black market because they can get more money for it.

And of course they pay with cash, never a check.

They’re very talkative because they’re trying to distract you versus someone who’s in real pain really just doesn’t have much to say to you because they just really want to go home...

The hardest thing, working on Saturday nights…is the call-in scripts. You have no way of knowing if it is a real doctor.

--Pharmacists
CASA Focus Group
CASA’s survey of pharmacists revealed that half (50.1 percent) at least sometimes would dispense a limited quantity of a controlled drug without a written prescription on the basis of a prescription received over the telephone; more than one in four (28.4 percent) usually or always do so. Only about half (53.8 percent) would always decline to dispense a controlled drug if the written prescription order lacks complete information (and they are unable to obtain clarification from the prescribing physician); 10.4 percent rarely or never decline to dispense the drug under these conditions.

When dispensing a controlled prescription drug, the vast majority (92.4 percent) of pharmacists say that they “usually or always” check the quantity and dose on the prescription to make sure it is in accordance with regulations. Pharmacists who report having received training/instruction in dispensing controlled drugs, identifying prescription drug addiction and/or preventing diversion were significantly more likely to check the quantity and dose than those who did not receive such training.

Types of Fraudulent Prescriptions

- Legitimate prescription pads are stolen from physicians’ offices and prescriptions are written for fictitious patients.
- The physician’s prescription is altered.
- Prescription pads from a physician are printed with a different call-back number that is answered by an accomplice who verifies the prescription.
- Drug abusers call in their own prescriptions and give their own telephone number for confirmation.
- Computers are used to create prescriptions for non-existent physicians or to copy legitimate prescriptions.

While 91.9 percent of pharmacists check for the number of refills requested, one-third (34.3 percent) do not typically have the time to review in detail all the prescription medications that a patient is taking when filling a new prescription order. Twenty-eight percent (28.4) do not regularly validate the prescriber’s DEA number; one in 10 (10.5 percent) rarely or never do so. Three-fifths (61.0 percent) do not regularly ask if the patient is taking any other controlled drugs when dispensing a controlled medication; one-quarter (25.8 percent) rarely or never do so.

Potential Signs to Pharmacists of Diversion

- Prescription looks “too good”--prescriber’s handwriting is too legible.
- Quantities, directions or dosages on prescription order differ from usual medical usage.
- Prescription does not comply with acceptable standard abbreviations or appears to be textbook presentations.
- Prescription appears photocopied.
- Directions on prescription order written in full with no abbreviations.
- Prescription written in different color inks or different handwriting.
- Prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from same physician.
- Prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. (Drug abusers often request prescriptions for "uppers and downers" at the same time.)
- Patient presents prescriptions written in names of other people.
- Patient appears to be returning too frequently for refills.

Provider Diversion

If a pharmacist suspects that a physician either is the victim or perpetrator of drug diversion

* In an emergency, a practitioner may provide a prescription order for a Schedule II medication to a pharmacist via fax or phone; however, this must be followed within seven days by a written, signed order. Prescription orders for Schedules III-V medications may be given over the telephone.

† Females were significantly likelier than males to take the time to perform this type of review (70.0 percent vs. 61.9 percent “always or usually” did).
‡ Always or most of the time.
activities, most states require that such suspicions be filed with the pharmacy board. However, some pharmacists may be reluctant to do so if they lack clear-cut proof, for fear of unjustly maligning a physician’s reputation or provoking retaliation. Two in five pharmacists (42.3 percent) in CASA’s survey said they are somewhat or very reluctant to report a physician for controlled-drug prescribing practices that they consider illegitimate. Pharmacists who received training/instruction in the areas of prescription drug abuse and/or diversion were significantly less likely to be reluctant to make such reports.

CASA’s survey found that a significant proportion of pharmacists would fail to take basic steps to address the problem of a professional colleague’s suspected diversion activities. While 62.9 percent would document the problem, only half would confront the colleague or report it to a professional association. (See Table 4.3)

<table>
<thead>
<tr>
<th>Action</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document it</td>
<td>62.9</td>
</tr>
<tr>
<td>Confront colleague</td>
<td>50.1</td>
</tr>
<tr>
<td>Report colleague to professional association</td>
<td>49.5</td>
</tr>
<tr>
<td>Ask opinion of another pharmacist</td>
<td>35.7</td>
</tr>
<tr>
<td>Contact police</td>
<td>11.7</td>
</tr>
<tr>
<td>Take no action</td>
<td>0.7</td>
</tr>
</tbody>
</table>

**Diversion by Pharmacy Staff**

Pharmacists or pharmacy employees may themselves divert controlled substances by forging prescriptions for drugs they sell illegally or making prescriptions seem legitimate by copying prescriber and patient information from their database of physicians and customers. If one pharmacist suspected another of diversion activities, some indicated that they would notify a supervisor, security or the loss prevention department of the pharmacy. Male pharmacists were significantly likelier than female pharmacists to say that they would confront a colleague with their suspicions of diversion (54.1 percent vs. 42.8 percent). Males were significantly less likely than females to say that they would ask the opinion of another pharmacist in deciding how to respond (32.2 percent vs. 42.2 percent).

Over one-third (34.2 percent) of pharmacists in CASA’s survey said they had been investigated or audited by a regulatory agency in regard to handling or dispensing controlled drugs (including routine, random audits).

**Opportunities for Diversion Control**

Three of five (62.1 percent) pharmacists think that physicians bear the primary responsibility for preventing prescription drug abuse and addiction; 16.2 percent placed primary responsibility on patients, 10.5 percent on pharmacists, 1.7 percent on law enforcement, and 0.7 percent on schools/educators. Others cited parents and “society as a whole” as primarily responsible.

However, when asked, about half of pharmacists (48.4 percent) said they have a great deal of responsibility in helping to prevent prescription drug diversion and abuse. They indicated that their ability to do so would be enhanced if they had increased cooperation with physicians (84.2 percent agreed), more time to attend to each prescription (61.7 percent agreed) and more training (42.6 percent agreed).

*I think pharmacists are still somewhat intimidated by physicians. If a better rapport was established and there was better communication between physicians and pharmacists, greater prevention would be possible.*

--Pharmacist

(comment written on survey instrument)

Some cited better law enforcement, stricter laws or fewer regulatory restrictions protecting patient confidentiality as essential for more effective prevention of diversion and abuse. Others said that a database of the prescription history of customers and/or of physicians would help them prevent prescription drug diversion and abuse.
Clinical Practice

Physicians, dentists, veterinarians and other healthcare workers who have access to controlled prescription drugs have a professional responsibility to learn and abide by the relevant requirements of state and federal laws governing such drugs. Healthcare providers also are professionally responsible for using controlled substances appropriately, guarding against abuse while assuring that patients receive needed medications. Nevertheless, healthcare providers may become involved in diversion in a number of ways. They may be deceived by patients, ill informed, careless or dishonest, suffer from addiction themselves, or succumb to patient pressure to prescribe inappropriately.

Physicians

CASA’s national survey of physicians asked them to indicate who or what they think accounts for most of the diversion problem. Responses were similar to those of pharmacists: 59.1 percent said patients; 11.8 percent, physicians/clinicians; 8.6 percent, Internet pharmacies; and 3.7 percent, other pharmacies (retail, hospital, clinic). Less than one percent cited manufacturers (0.8 percent), pharmaceutical companies (0.6 percent) or drug wholesalers (0.5 percent). Most physicians believe that diversion is not much of a problem in their own offices or clinics.

When asked to indicate what they consider the three most common methods of diversion, physicians’ responses also were similar to those of pharmacists: 96.4 percent said doctor shopping; 87.8 percent, patient deception or manipulation of doctors; 69.4 percent, forged or altered prescriptions. Other methods mentioned included: theft of prescription pads from doctors’ offices (17.1 percent); doctors who knowingly divert controlled drugs (8.5 percent); theft of controlled drugs from pharmacies (3.3 percent); pharmacy employees (other than pharmacists) who knowingly divert controlled drugs (2.8 percent); pharmacists who knowingly divert controlled drugs (2.0 percent); or theft of controlled drugs from doctors’ offices (1.7 percent).

CASA’s survey found that 68.5 percent of physicians have their patients complete a health history at their first visit. Less than one-quarter do so at every visit (21.1 percent), when conducting a physical exam (23.5 percent) or annually (18.7 percent). Although the vast majority said that the health histories ask questions about tobacco use (93.6 percent), alcohol use (93.1 percent) and alcohol or drug abuse history (77.6 percent), only about half (53.8 percent) had questions on prescription drug abuse. Physicians with more instruction/training in prescription drug abuse and addiction and in pain management were likelier to get this information.
When prescribing controlled drugs, most physicians (81.8 percent) say that they regularly counsel each patient on the risk of physical dependence; 17.3 percent do so only sometimes or never. They are likelier to counsel patients on the risk of physical dependence when prescribing benzodiazepines (83.8 percent) or opioids (78.5 percent) than when prescribing stimulants (41.3 percent) or barbiturates (31.4 percent). Three-quarters (75.1 percent) of physicians report that, when first prescribing a controlled medication, they regularly counsel each patient on the risks of addiction associated with it. Those who do not discuss addiction on a regular basis said that addiction is not a big risk for short-term prescriptions (55.1 percent), that patients already know about the risk of addiction (33.1 percent), or that they do not have enough time to do so (23.6 percent). Several physicians stated that the risks are explained in written information that accompanies a medication dispensed by a pharmacist. Female physicians are somewhat likelier than male physicians to regularly explain the risks of addiction when first prescribing controlled medications (79.9 percent vs. 72.5 percent).

When prescribing controlled drugs, the vast majority of physicians (88.1 percent) say they regularly ask their patients about their present use of other controlled prescription drugs; 46.2 percent said that their likelihood of doing so depends on the drug they are prescribing (89.4 percent do so for opioids, 79.3 percent for benzodiazepines, 43.2 percent for stimulants and 29.9 for barbiturates). Most physicians (81.2 percent) report regularly asking about their patients’ use of alcohol and/or illicit drugs when prescribing controlled medications. Asked what they would do if they did not have complete information on a patient’s current or prior medication history and/or drug abuse history when prescribing a controlled drug, 32.1 percent would be most likely to prescribe one week’s worth of the drug; 25.9 percent, one to three days worth; 8.1 percent, the usual amount; and 21.1 percent would refuse to prescribe until they obtained the information they needed.

Patient diversion. Patients share with healthcare providers the responsibility for sound drug therapy by providing the physician with accurate information and complying with the treatment plan.\(^{37}\) While some patients deviate from the therapeutic program through miscommunication or misunderstanding, others deliberately abuse controlled prescription drugs or seek to obtain such drugs for illegal sale to others.\(^{38}\)

Nearly half (47.1 percent) of the physicians surveyed said patients commonly try to pressure them into prescribing a controlled drug. Younger physicians (age 50 or younger) experienced this pressure significantly more often than older physicians (over age 50). Two in 10 (20.1 percent) say that pharmacists frequently call them to discuss suspicions of patient fraud or abuse.

Some physicians are deceived by their patients into providing them with controlled prescription medications that are not needed for medical purposes. Certain physician characteristics may contribute to this ease of deception. For example, some physicians try to do anything within their professional capabilities to help patients achieve a higher level of functioning.\(^{39}\) While this instinct often contributes to heroic efforts to help patients overcome disease, such physicians are easy prey for manipulation by drug-seeking patients.\(^{40}\)

You do get a sense every once in a while that you’re being used.

--Physician
CASA Focus Group

Another phenomenon that may contribute to problematic prescribing is described as “confrontation phobia.”\(^{41}\) Today, medical school curricula and residency training stress skills in patient interviewing and relationship building. Such skills involve active listening strategies, empathy and achievement of rapport with the patient.\(^{42}\) They do not typically involve teaching physicians how to say no to patients. Fear and avoidance of setting limits may make the physician an easy target for manipulation.\(^{43}\)
Manipulative approaches employed by patients to obtain controlled prescription drugs include:

- **Feigning physical problems.** Fake physical symptoms to convince a physician to prescribe opioid medications, for example, bleeding induced by using anticoagulants, self-inflicted skin lesions, or claimed gastrointestinal or musculoskeletal problems. The general public has ready access to medical information via the Internet or other sources and can learn easily which symptoms will induce a physician to prescribe a desired medication. A recent report described a prescription drug-abusing patient who consulted the Physicians’ Desk Reference for a medication she wanted, learned the indications for that drug and then reported those symptoms to physicians.

- **Feigning psychological problems.** Most drug seekers who feign psychological problems are attempting to obtain stimulants or depressants rather than opioids. The psychological symptoms most often presented include anxiety, insomnia, fatigue and depression.

- **Other deceptions.** Other patient techniques used to deceive physicians into prescribing controlled medications include concealing or pretending to take medications and requesting refills sooner than indicated by the prescription.

As asked what they would do if they suspected a patient of abusing or diverting a controlled prescription drug, physicians gave a variety of responses, including documenting it (89.9 percent); confronting the patient (80.0 percent); counseling the patient (72.0 percent); contacting a family member (14 percent); contacting the police (10.7 percent); or taking no action at all (0.4 percent). (See Table 4.4)

<table>
<thead>
<tr>
<th>Action</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document it</td>
<td>89.9</td>
</tr>
<tr>
<td>Confront patient with suspicions</td>
<td>80.0</td>
</tr>
<tr>
<td>Counsel patient on dangers</td>
<td>72.0</td>
</tr>
<tr>
<td>Provide prescription without refills</td>
<td>68.5</td>
</tr>
<tr>
<td>Refer patient to a specialist, such as a pain specialist</td>
<td>62.0</td>
</tr>
<tr>
<td>Refer patient to substance abuse treatment</td>
<td>51.2</td>
</tr>
<tr>
<td>Prescribe patient non-controlled drugs only</td>
<td>50.6</td>
</tr>
<tr>
<td>Create medication contract/agreement with patient</td>
<td>36.9</td>
</tr>
<tr>
<td>Require urine tests</td>
<td>27.8</td>
</tr>
<tr>
<td>Consult with another physician for second opinion</td>
<td>26.4</td>
</tr>
<tr>
<td>Do pill counts</td>
<td>23.1</td>
</tr>
<tr>
<td>Discharge patient from practice</td>
<td>20.5</td>
</tr>
<tr>
<td>Refer patient to another doctor</td>
<td>19.1</td>
</tr>
<tr>
<td>Offer educational materials</td>
<td>19.0</td>
</tr>
<tr>
<td>Contact family member</td>
<td>14.0</td>
</tr>
<tr>
<td>Contact police</td>
<td>10.7</td>
</tr>
<tr>
<td>Take no action</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Similar to the findings from the pharmacist survey, some interesting gender differences emerged in response to this question. Males were likelier than females to confront a patient with suspicions of diversion (81.9 percent vs. 75.3 percent) and less...
likely than females to create a drug contract/agreement with the patient (34.2 percent vs. 43.2 percent) or to refer the patient to substance abuse treatment (47.6 percent vs. 58.4 percent).

Most physicians (87.0 percent) reported having had a patient with a history of substance abuse who was legitimately in need of a controlled drug. Two-thirds (66.3 percent) diagnosed an adult patient with a prescription drug abuse problem in the past 12 months; 14.5 percent diagnosed such an adolescent patient. When they last encountered such a patient, about half treated the patient with a controlled drug but monitored the patient more closely than other patients (54.7 percent) or treated the patient with medications other than controlled drugs (48.7 percent). About one-quarter (26.1 percent) of physicians referred the patient to a specialist and

\[\begin{array}{|l|}
\hline
\textbf{Potential Signs to Physicians of a Drug Abuser or Diverter}\* \\
\hline
\hline
- Shows unusual knowledge of controlled substances, gives medical history with textbook symptoms, or gives evasive or vague answers to questions regarding medical history.
- Reluctant or unwilling to provide reference information. Usually has no regular doctor and often no health insurance.
- Requests a specific controlled drug and is reluctant to try a different drug.
- Generally has no interest in diagnosis--fails to keep appointments for further diagnostic tests or refuses to see another practitioner for consultation.
- Exaggerates medical problems and/or simulates symptoms.
- Exhibits mood disturbances, suicidal thoughts, lack of impulse control, thought disorders, sexual dysfunction.
- Cutaneous signs of drug abuse--skin tracks and related scars on the neck, axilla, forearm, wrist, foot or ankle.
\hline
\end{array}\]

Uninformed and careless practitioners. Some practitioners fail to keep up-to-date with current knowledge of pharmacology, differential diagnosis\† and management of conditions such as chronic pain, anxiety, insomnia and addiction.\textsuperscript{50} The very areas of knowledge required for skillful management of controlled prescription drugs are those areas in which many physicians are deficient.\textsuperscript{51} Many medical school programs do not adequately teach students about opioids and other psychoactive drugs.\textsuperscript{52} (See Chapter VII)

Because most patients who abuse controlled prescription drugs also abuse other substances,\textsuperscript{53} if physicians were more knowledgeable about identifying alcohol and drug use problems in their patients they would be less likely to contribute to patient abuse of prescription drugs.\textsuperscript{54}

Unfortunately, research by CASA and others indicates that physicians rarely screen for or accurately diagnose substance abuse in patients presenting clear substance abuse-related symptoms.\textsuperscript{55}

Uninformed physicians typically prescribe drugs in excessive quantities, for excessive periods, for conditions that do not warrant medication therapy, or for conditions better treated by other means.\textsuperscript{56}

Health professionals may contribute to the diversion of controlled prescription drugs through careless prescription writing or dispensing or through inadequate safeguarding of blank prescriptions and drug supplies.\textsuperscript{57} Only about half (54.5 percent) of the physicians in CASA’s survey regularly call or obtain records from the patient’s previous (or other treating) physician before prescribing long-term controlled drugs, such as narcotics for chronic pain. Younger physicians (those age 50 or younger) request these records more often than older physicians (those over age

\[\begin{array}{|l|}
\hline
\textsuperscript{\*} Complicating the accurate detection of an abuser or diverter is the fact that some legitimate patients may display a number of these signs or apparent deceptions, such as knowing a lot about controlled medications, asking for a specific brand name of a drug or needing to be seen right away.
\hline
\textsuperscript{\†} Evaluating whether the presentation of symptoms represent one disease/disorder vs. another.
\hline
\end{array}\]
Physicians with more instruction/training in identifying prescription drug addiction and/or preventing diversion were likelier to request a patient’s prior records.

I’m concerned that many physicians who start prescribing long-acting opioids don’t know how to follow these patients. Some patients will develop difficulty; some perhaps abuse and addiction. So physicians who are prescribing need to be able to follow patients, recognize issues, and as appropriate, enforce referrals for addiction treatment, and stop prescribing.

--Richard L. Brown, MD, MPH
Department of Family Medicine
University of Wisconsin

CASACONFERENCE, Feeling No Pain:
Substance Abuse, Addiction and Pain Management
February 27, 2003

We’ve gone from a point within the medical profession when there was a reluctance, probably too much, to prescribe painkillers, to a permissive attitude, whereby anybody who says they’re in pain can get a narcotic.

--Joel R. Saper, MD, Founder and Director
Michigan Head Pain & Neurological Institute

Impaired practitioner. Practitioners’ mental health problems, such as depression, dementia or a personality disorder, may affect their clinical and prescribing practices. Impaired practitioners may themselves abuse controlled prescription drugs, illicit drugs or alcohol. The extent to which substance-involved practitioners divert drugs to others, however, may not differ substantially from non-impaired physicians. An anonymous survey of physicians enrolled in a recovery program found that they reported prescribing controlled drugs while actively addicted and while in recovery at rates that were equal to—and in some cases lower than—the rates at which other physicians prescribed controlled drugs.

Dishonest practitioner. Dishonest physicians, also known as “script doctors,” intentionally prescribe controlled drugs to patients who they know will abuse them or sell controlled drugs in exchange for monetary compensation, sexual favors or other considerations. Such physicians are not practicing “good faith” medicine; rather, they are using their medical license to deal drugs illegally. Typically, these physicians are prosecuted rather than being eligible for rehabilitation or educational interventions.

Pressure to prescribe. Some physicians believe that patients deserve a prescription at each visit or for each symptom offered. The tendency to give into patient pressure to prescribe a drug is characteristic of many physicians who engage in inappropriate prescribing practices.

I’m not going to sit there and police it. That’s not my job….I’m not going to follow and try to figure out what’s going on. I don’t have time for that.

I don’t find myself being the drug police…I have enough things I have to do. If I prescribe an adequate amount, and if someone loses it or whatever, then obviously I’ll see them again and if they need more medication, I’ll give it to them.

If someone comes in and tells me that they’re in pain, well I have to accept that they’re in pain. Whether I believe them or not…I mean you get in trouble for it if you don’t.

--Three Physicians
CASA Focus Group

Provider diversion. CASA’s survey found that reports of physicians’ reactions to a professional colleague’s diversion activities centered primarily on confronting the colleague with their suspicions (59.2 percent) and reporting it to a professional association (55.2 percent). (See Table 4.5) Males were likelier than females to document their suspicions of their colleague (18.7 percent vs. 10.7 percent), but less likely to ask the opinion of another physician (38.9 percent vs. 52.3 percent). Older physicians (over age 50) were less likely than their younger counterparts to confront their colleague with suspicions of diversion (54.9 percent vs. 63.2 percent), but more likely to document their suspicions (21.1 percent vs. 11.9 percent).
Opportunities for Diversion Control

Similar to pharmacists’ responses, 57.2 percent of physicians indicated that physicians bear the primary responsibility for preventing prescription drug abuse and addiction; 27.4 percent placed the primary responsibility on patients; 23 percent, on pharmacists; 2.3 percent, on law enforcement; and 0.9 percent, on schools/educators. However, asked how much responsibility physicians have in helping to prevent prescription drug diversion and abuse, nearly all physicians (97.5 percent) believe they have some responsibility. Most indicated that their ability to do so would be increased if they had more training (75.5 percent), increased cooperation with pharmacists (73.5 percent) and more time to attend to each patient (58.5 percent).

A little over half of the physicians in CASA’s survey (59.6 percent) said that preventing prescription drug abuse and addiction in patients is very much a priority; however, fewer than half (48.8 percent) think that available methods for treating prescription drug abuse are effective.

### Table 4.5

<table>
<thead>
<tr>
<th>Action</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confront colleague with suspicions</td>
<td>59.2</td>
</tr>
<tr>
<td>Report it to professional association or health committee</td>
<td>55.2</td>
</tr>
<tr>
<td>Ask opinion of another physician</td>
<td>43.1</td>
</tr>
<tr>
<td>Document it</td>
<td>16.0</td>
</tr>
<tr>
<td>Take no action</td>
<td>3.4</td>
</tr>
<tr>
<td>Contact police</td>
<td>1.7</td>
</tr>
</tbody>
</table>

**Deceptions that May be Used by Drug Abusers or Diverters**

- Must be seen “right away.”
- States he/she is traveling through town, visiting friends or relatives (not a permanent resident).
- Feigns physical problems, such as abdominal or back pain, kidney stone or migraine headache in an effort to obtain narcotic drugs.
- Feigns psychological problems, such as anxiety, insomnia, fatigue or depression in an effort to obtain stimulants or depressants.
- States that specific non-narcotic analgesics do not work or that he/she is allergic to them.
- Contends to be a patient of a practitioner who is currently unavailable or will not give the name of a primary or reference physician.
- States that a prescription has been lost or stolen and needs replacing.
- Requests refills more often than originally prescribed.
- Pressures the practitioner by eliciting sympathy or guilt or by direct threats.
- Uses a child or an elderly person when seeking methylphenidate (a controlled stimulant) or pain medication.

**Dentists**

Dentists are susceptible to many of the same problem prescribing practices as physicians. Dentists may be more vulnerable to diversion because most are not aware that they are targets. Although dentists routinely prescribe opioid and other analgesics for pain that accompanies certain dental problems or procedures, many are not aware that some patients create or exacerbate such problems in order to obtain these medications. Moreover, because dentists store supplies of drugs and anesthetics in their offices, they are susceptible to drug theft (often by employees), burglary and robbery.

**Key Themes From Dentist Focus Group and Individual Interviews**

- Most common signs of patient abuse/diversion are when patients call in for medication rather than visit the office and when patients request a specific medication by name.
- When prescribing controlled drugs, risks of addiction are rarely discussed with patients.
- Dentist training in controlled prescription drug abuse, diversion, addiction and pain management is very limited.
- Dentists are not knowledgeable about laws and regulations on what actions to take if a patient or colleague is suspected of diversion.

The risk of diversion and abuse varies by dental specialty. For example, general dentists and certain specialists (endodontists, periodontists)
typically prescribe non-controlled drugs or only small doses of controlled drugs for short periods of time and require follow-up office visits if patients experience pain. In contrast, oral surgeons are likelier to have chronic pain patients in their practice and to face diversion-related challenges similar to those of many physicians.

**Veterinarians**

Veterinarians routinely administer, dispense and store large quantities of sedatives, stimulants and opioids that can be diverted for resale and human use. Drug thefts, burglaries and robberies in veterinary clinics are not uncommon. With ready access to controlled drugs, veterinarians themselves may engage in diversion by writing themselves prescriptions for such drugs. Drug-seeking individuals have employed various scams to obtain controlled substances from veterinarians, including pretending that one’s dog needs stimulants in order to perform better in dog shows or pretending that one’s animal is sick or in pain in order to receive controlled opioids.

One notable case was a young man who had a very small dog named Dolly. He visited local veterinarians in our area and told them that Dolly had ‘a lot of anxiety.’ He further explained that Dolly’s past bouts with anxiety had always been solved with doses of diazepam, which, of course, was the reason for his visit that day. Five veterinarians were visited each month with Dolly, each one providing ‘anxiety-ridden’ Dolly her tranquilizers.

--John Burke, Commander Warren County Ohio Drug Task Force

Veterinarian shopping as a means of diverting drugs is not a common practice because veterinarians use controlled drugs primarily for procedures conducted in the office and rarely write prescriptions. They also tend to prescribe few controlled drugs and most do not accept insurance, making it expensive for drug-seeking pet owners to take advantage of them.

**Other Healthcare Practitioners**

Until recently, most state professional practice laws prevented non-physician practitioners, such as nurse practitioners, physician assistants and chiropractors, from prescribing, dispensing or administering controlled prescription drugs, except under the direct supervision of a physician. Today, more non-physician practitioners have prescribing authority, although there is much variability between states. Organizations that represent such practitioners are lobbying state legislatures across the country to expand their members’ scope of practice to include prescriptive authority. While advocates argue that expanding the scope of practice increases the pool of badly needed caregivers in underserved areas, it also increases the risk that these practitioners will be potential sources of prescription drug diversion.

As changing patterns of healthcare delivery require that more care be delivered in outpatient settings, more controlled prescription drugs are being used outside the relatively structured confines of the hospital. For example, certain opioids used for patients with AIDS and cancer are prescribed for use at home and in hospice settings. Thus, more healthcare professionals (and non-healthcare professionals) are placed in proximity to potent drugs that have a significant potential for diversion and abuse.

Just as the training of physicians in how to identify and resist the tactics of drug-seeking patients is deficient, the training of other healthcare practitioners in such topics is negligible.

**Retail Theft**

Controlled prescription drugs may be stolen from pharmacies, medical, dental and veterinary offices and clinics, nursing homes, or from individual patients. Theft includes shoplifting, robbery and burglary.

To deter theft and diversion of controlled prescription drugs, the federal Controlled Substances Act stipulates that all such drugs stored in a physician’s office, clinic or pharmacy be securely locked in a substantially constructed
cabinet or safe. Pharmacies also have the option of dispersing their stock of controlled drugs throughout the non-controlled drug stock to make the controlled drugs more difficult to find and steal. For physicians, the stock of controlled substances should be minimal and access to the area where the controlled substances are stored should be restricted to a minimum number of employees. If a theft (or substantial loss) of controlled drugs is discovered, physicians and pharmacists are required immediately to notify the nearest regional DEA office, file a formal written report with the DEA, and notify the local police department.\textsuperscript{81}

To help prevent theft of controlled substances, Purdue Pharma LP created a program called \textit{Rx Patrol}, an online clearinghouse for reporting pharmacy theft, robbery and burglary.\textsuperscript{82} One goal of \textit{Rx Patrol} is to collect data directly from pharmacies on thefts and burglaries in order to provide information on the extent of the problem and to furnish law enforcement with information it can use to take action.\textsuperscript{83}

The theft of controlled prescription drugs from pharmacies is a growing concern.\textsuperscript{84} In recent years, OxyContin has been the target of the majority of pharmacy robberies across the United States.\textsuperscript{85} In 2001, nearly all states had documented OxyContin-related robberies.\textsuperscript{86} Preventative actions that are being taken by pharmacies themselves include installing surveillance cameras, alarms and panic buttons in pharmacies and employing security guards.\textsuperscript{89} Some pharmacies choose not to stock certain drugs that are the target of robberies.\textsuperscript{90}

### Friends and Family

One increasingly common method of diversion is the use of a friend’s or family member’s prescribed medication. For example, although no hard data exist, reports by clinicians in

\textsuperscript{*} CASA thanks the Caron Foundation for providing us access to interview recovering prescription drug addicts to gather insight into how individuals gain access to abusable prescription drugs.

\begin{itemize}
  \item stealing from medicine cabinets of family/ friends.
  \item Feigning illness (e.g., sports injuries, anxiety, depression)/doctor shopping.
  \item Dishonest doctors and pharmacists who act as drug dealers.
  \item Forged prescriptions.
  \item Pharmacy theft.
  \item Buying from drug dealers.
  \item Buying from patients who leave clinics with prescriptions.
\end{itemize}

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Addicted Prescription Drug Abusers in Treatment\textsuperscript{*}

CASA Personal Interviews

Prescription drugs are sold and traded, sometimes for other prescriptions, for beer, for test answers, for cocaine.\textsuperscript{87}

--David Amsden
New York Magazine

Some kids say it’s easy to get a prescription after a brief consultation with a doctor. One [college] student said all he had to do was fill out a true-false questionnaire of five to 10 questions: “Marked all 10 of them true and was prescribed.”\textsuperscript{88}

--ABC News
CASA’s focus groups reveal that controlled prescription drugs used by terminal patients or those left over by someone who had recently died are sometimes diverted from their homes by family, friends or health attendants.

"People with terminal illness...they’re laying in bed and conscious just a few hours of the day and every time they look at their bottle, five or six more of their pills are gone and they only took one.

--Physician
CASA Focus Group

Criminals

Some patients participate in organized criminal operations created to obtain drugs for resale. For example, in Missouri, amputees were employed to procure large amounts of controlled prescription pain medication. Groups of amputees were driven around the state in a van that would drop them off at doctors’ offices to obtain powerful pain medications for their “recently injured” limbs. To ensure doctors would be duly impressed by the need for medication, sandpaper was applied to the skin before the amputees entered the office to present their damaged appendage.94

The New Jersey Department of Law and Public Safety acted to quash a sophisticated scheme in which physicians all over the state received official-looking forms “requiring” them to provide their DEA and medical license numbers, two copies of their signatures, driver’s license and social security numbers and a host of other identifying information.98 Armed with such data, it would have been possible for criminals to create prescriptions for controlled drugs that would have eluded detection as forgeries.99

Some cases of diversion involve drug trafficking organizations.95 For example, criminal gangs operating in southern Maine and New Hampshire illegally obtained controlled substances—primarily OxyContin—from local pharmacies by using forged, stolen and altered prescriptions and then sold the drugs throughout the Northeast.96 In December of 2001, armed robbers stole more than 30,000 bottles of OxyContin (900,000 20-mg. tablets) from a pharmaceutical distributor in Mexico City in what appears to have been an organized crime operation.97 Other criminal operations involve the Internet. (See Chapter V).
In recent years, Internet sites not adhering to state licensing requirements, medical board standards or federal law have enabled consumers to obtain controlled prescription drugs without a valid prescription or physician supervision and without regard to age. These sites present significant challenges to law enforcement and public health officials, regulators, policymakers and parents.1

**Growth in Internet Pharmacies**

Consumers increasingly use the Internet for health information and to purchase medical products and prescription medications, including controlled drugs. Because the Internet offers a convenient and often more affordable means of purchasing their prescription drugs, online sales have grown rapidly since the first Internet pharmacies began in 1999.

The growth of online drug sales by state-licensed, legitimate and reputable Internet pharmacies has provided significant benefits to consumers.2 Legitimate online pharmacies operate much like traditional drugstores where drugs are dispensed only on receipt by the pharmacy of a valid prescription from the consumer or directly from the consumer’s physician.3

However, illegal Internet pharmacies have introduced a new avenue through which unscrupulous buyers and users can purchase controlled substances for unlawful purposes. There pharmacies--many of them based outside the U.S.--sell a variety of prescription medications including controlled drugs.

Some of these pharmacies provide consumers with prescription drugs without a physical examination by a physician. The consumer fills out an online questionnaire that is reportedly evaluated by a physician affiliated with the online pharmacy. Without ever meeting the
patient face-to-face, the physician approves the questionnaire and then authorizes the Internet pharmacy to send the drug to the patient. Tens of thousands of “prescriptions” are written each year for controlled and non-controlled prescription drugs through such Internet pharmacies, none of which require medical records, examinations, lab tests or follow-ups. Some of these “rogue” Internet pharmacies provide such online consultations free of charge; others refer customers to “script” doctors who are willing to write prescriptions for cash. Finally, some Internet pharmacies dispense prescription drugs without even the pretense of having a physician’s prescription.

### Indicators of Illegitimate Internet Pharmacies

The site:
- Does not require a prescription issued by your physician.
- Is not a participant in any insurance plan and requires all payment by credit card or money order.
- Advises you about the law, indicating that it is permissible to obtain controlled prescription drugs from foreign countries via the Internet.
- Does not ask how to contact your current physician.
- Advises you to have the drugs sent to post office boxes or other locations to avoid detection by U.S. authorities.

While estimates of the number of Internet pharmacies have reached as high as 1,400, it is virtually impossible to identify the precise number of Internet pharmacies selling prescription drugs--especially controlled substances--directly to consumers. Web sites easily can be created or removed, or change their names or Web addresses; they also may offer no identifying information that can assist in tracking them to a particular location or source. Many large Internet pharmacies have multiple portal sites where numerous independent Web sites all connect to one online anchor pharmacy.

A recent investigative report by the Washington Post describes an Internet pharmacy that, in one month, filled 1,105 prescriptions for opioids and other controlled drugs. In 2002, the pharmacy shipped nearly five million dosage units of controlled drugs to all parts of the U.S. In Nevada alone, the pharmacy accounted for 10 percent of all the hydrocodone that was sold in that state. Nevada Board of Pharmacy investigators discovered that the Internet pharmacy was owned by a 23-year old former restaurant hostess, but was run by her father who was a convicted felon. After a yearlong investigation, Post reporters concluded that the Internet has become a pipeline for all kinds of addictive drugs.

The Post report is supported by other emerging research on Internet pharmacies. One survey found 53 Web sites (identified through a Google search) that offered to sell opioid medications without a prescription—in violation of federal law. Of the 53 sites, 35 claimed to sell other abusable drugs as well, including stimulants, benzodiazepines and barbiturates. Twenty-three of the 53 sites were registered to owners outside of the United States.

Prevention magazine also carried out an investigation of online pharmacies. The magazine’s four month investigation of the Internet pharmacy trade revealed that many sites do not require a prescription and that drugs are sent from all over the world and arrive in a variety of different packages.

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For young people in particular, online pharmacies seem to be especially seductive, says University of Pennsylvania researcher Robert Forman. For this generation, the Internet is a familiar medium where friends hang out, and it feels safe...

...The new trade in controlled substances has raised another, more disturbing prospect: that of a generation hooked on drugs with the ease of logging onto a computer.

--Melissa Healy (2003)

Los Angeles Times
No data are available on the percent of prescription drug abusers who get their drugs online. However, researchers at the Caron Foundation, a residential treatment center in eastern Pennsylvania, found that six percent of adult drug-dependent patients in recovery reported having used the Internet to access controlled prescription drugs and six percent reported using it to locate a dealer or a medical professional who would write a prescription for them.17

According to one study, 17.4 million people visited an online pharmacy in the fourth quarter of 2004 (up 14 percent over the previous quarter); approximately 63 percent of these visited sites did not require a prior prescription. Sixty-one percent of the customers reported that they did not inform their physician of their last online purchase of a prescription drug. Customers said they went online to save time (57 percent) and money (64 percent), to be assured of confidentiality (24 percent), to find the most competitive prices (18 percent) and to have the convenience of filling several prescriptions at the same time (13 percent). Nine percent shopped online because a prescription was not necessary.18

### Availability of Controlled Prescription Drugs on the Internet

In 2003, Beau Dietl & Associates (BDA) released a report on the availability of all forms of prescription drugs on the Internet, describing the ease with which one can set up an online pharmacy and the ease with which customers can acquire a full range of prescription drugs--frequently without a prescription. The report also documented the involvement of convicted felons in the ownership and promotion of online pharmacies.19

In February 2004, CASA partnered with BDA to explore the availability of controlled prescription drugs on the Internet.20 This analysis documented the number of Internet sites that dispense opioids, CNS depressants and stimulants, and identified which sites dispense controlled drugs with a valid prescription, with an online “doctor consultation,” or without any consultation or prescription.” The findings from this analysis is presented in detail in CASA’s 2004 publication, “You’ve Got Drugs!” Prescription Drug Pushers on the Internet, and its methodology is presented in Appendix E of this report.

The analysis identified 495 Web sites offering Schedules II-V controlled prescription drugs during the course of a one-week period. Seventy-three percent of the drugs examined in the analysis were Schedules II and III; 41 percent were those with the highest potential for abuse (Schedule II).

Of the sites advertising these controlled prescription drugs:

- Sixty-eight percent were portal sites. Portal sites do not sell drugs; they simply act as a conduit to another Web site--an anchor site--which sells the drugs.
- Thirty-two percent were anchor sites. At an anchor site, the customer places an order and pays; the online pharmacy fills the order and ships the drugs. The pharmacy itself may operate the Web site or the Web site may send the order to the pharmacy. Often, different Web sites use the same pharmacy to fill prescriptions. The operator of the anchor Web site may not be located in the same geographic region as the pharmacy.

The availability of controlled drugs over the Internet varied by the class of drug:

- Benzodiazepines are the most frequently offered controlled prescription drugs; 144 Web sites sold these drugs. Of the

* The issue of counterfeit drugs was not addressed in this analysis.
benzodiazepines, the most frequently offered were alprazolam (generic), diazepam (generic), Xanax and Valium.

- The second most frequently offered class of controlled prescription drug was the opioids. A total of 103 sites sold drugs like fentanyl, hydrocodone and oxycodone.

- Forty-seven sites sold stimulants such as Ritalin and Adderall, and two sites sold barbiturates.

Few sites selling controlled drugs required a valid prescription:

- Of the 157 anchor sites investigated, only 10 required a prescription prior to dispensing the drugs. Ninety-four percent did not require a prescription; 41 percent indicated that no prescription was needed, 49 percent offered an “online consultation” and four percent made no mention of prescriptions at all.

- Four percent (seven sites) asked for a faxed prescription from the patient rather than the physician. Only two percent (three sites) required that a prescription be mailed.

**Q: Do I need a prescription?**

A: Instead of a traditional physical exam by the physician, the patient is allowed to decide for himself depending on the symptoms what’s right for him.

--pharmacourt.biz

Prescription-free access. Keep your prescription with you when you order from AmericasMedicine.com Online Pharmacy Drugstore. Though we do recommend you consult a physician before placing your order...

--americasmedicine.com

The age of the customer appears not to be an issue for Internet pharmacies. The BDA analysis found no mechanisms in place to block children from purchasing controlled drugs over the Internet.

The physical location of the anchor sites that sell controlled prescription drugs often is difficult to discern.

- Twenty-eight percent (44) of the anchor sites indicated that the drugs would be shipped from a U.S. pharmacy.

- Twenty-five percent (40) gave no indication where the drugs would originate.

- The remaining 47 percent (73) indicated drugs would come from outside the U.S. Twenty-six percent (41) simply stated that they would come from an international location while others listed specific locations including Mexico, Australia, Central America, Sweden, Canada, Peru, South America, India, British Virgin Islands, Europe, Latin America, New Zealand and Asia.

**Q: Is it legal to import drug into the USA?**

A: Importation of prescription medication is legal in most countries (including the US, France, Spain, Hong Kong, Japan, South Korea and India) provided the medication is for personal use.

--prescriptionwales.com

One year later, during the last week of January 2005, BDA replicated this study for CASA to determine the changes, if any, in the availability of controlled prescription drugs on the Internet. The findings indicate few changes, despite stepped-up efforts by the government to control Internet diversion of controlled pharmaceuticals.
In 2005, the analysis identified 402 Web sites (vs. 495 in 2004) offering controlled prescription drugs. Of these 402 sites:

- Proportionately more were anchor sites (sites selling drugs) (160 or 40 percent in 2005 vs. 157 or 32 percent in 2004).
- Proportionately fewer were portal sites (sites advertising drugs) (242 or 60 percent in 2005 vs. 338 or 68 percent in 2004).
- Approximately the same proportion of anchor sites did not require or made no mention of a prescription (95 percent in 2005 vs. 94 percent in 2004).
- Proportionately more anchor sites advertised the U.S. as the country of origin for the drugs (37 percent in 2005 vs. 28 percent in 2004).
- Opioid medications were offered on considerably more of the identified sites in 2005 than on those identified in 2004.

In its 2005 investigation, BDA identified a growing phenomenon--35 portal sites that require membership fees. These membership sites keep track of anchor sites selling specific controlled drugs and make them available to the subscriber--thus doing the Web searches for members.

In March 2005, BDA conducted a similar investigation of the availability of controlled steroids on the Internet. The analysis was designed to document the number of Internet sites that dispense steroids with a valid prescription, with an online “doctor consultation” or without any consultation or prescription. (See Appendix E)

In a week, the analysis identified 118 Web sites offering select controlled steroids:

- Thirty-six percent (43) were portal sites.
- Sixty-four percent (75) were anchor sites.

- Of the anchor sites investigated, 95 percent (71) did not require a prescription or asked simply that a questionnaire be answered to receive the drugs. Only five percent (4 sites) required that a copy of a prescription be faxed or mailed or that the patient’s doctor be contacted for the prescription.

- Only nine percent (seven) of the anchor sites indicated that the drugs would be shipped from a U.S. pharmacy. Twenty-two percent (17 sites) gave no indication of the country of origin of the drugs.

This extensive availability of controlled prescription drugs online poses a silent menace to our nation’s health and a challenge for law enforcement.

Although, for purposes of these analyses, orders for drugs were not placed, other evidence suggests that once a credit card number is entered, the order will be processed. To illustrate this point and to track specific online pharmacies, DEA task forces and police departments have purchased controlled substances over the Internet. For example, as part of an investigation, the Orlando DEA Task Force purchased OxyContin over the Internet without a prescription. The Web site in question required the purchaser to check a box saying that medical records would be sent, but charged the credit card and sent the order of OxyContin without receiving the records. One month later this online pharmacy automatically charged the same credit card and sent a refill order without a request. Similarly, the Lake Mary Florida Police Department purchased and received Vicodin after simply filling out an online questionnaire; no request for a prescription or medical records was made by the online pharmacy.21

**Regulation of Internet Pharmacies**

Access to controlled prescription substances over the Internet is a fairly new phenomenon and laws and regulations have yet to catch up. Computer technology allows Web sites to go up, move or be taken down in a short period of time, making it difficult to track, monitor or shut
down sites that are operating illegally. For example, two weeks after CASA’s initial analysis of the availability of controlled prescription drugs on the Internet was conducted, it was replicated with a select number of controlled prescription drugs and found that new sites had been created and that others had posted notices that they were no longer offering the same drugs.

**Federal Regulation**

The DEA and the National Association of Boards of Pharmacy have begun to identify mechanisms to prevent the illegal online sale of controlled prescription drugs.22 By law, Internet pharmacy sales must comply with federal regulations that dictate when and how controlled substances may be prescribed and dispensed.23 Internet pharmacies, like any pharmacy, must be registered with the DEA and licensed to dispense controlled substances by the state in which they operate.24 Pharmaceutical companies may sell controlled drugs only to DEA-registered wholesalers and must maintain records of the amount distributed and the identifying information--including registration number--of any recipient of the product. Therefore, only DEA-registered Internet pharmacies can legally sell controlled prescription drugs.25 The Internet pharmacy must have a license from the state in which the controlled substances are stored.26 The physical location of a pharmacy that purchases, stores and dispenses controlled substances pursuant to prescription orders processed by an Internet site must be registered with the DEA.27

Internet pharmacies are authorized to sell controlled substances only when there is a valid prescription from a DEA-registered practitioner issued in the usual course of professional practice. Valid prescriptions for Schedule II controlled substances can be filled only if the patient or prescriber provides the Internet pharmacy (or any pharmacy) with a signed original prescription. An original signed prescription, a facsimile of the original signed prescription or an oral prescription immediately reduced to writing is permissible for Schedules III through V controlled substance orders, provided that the pharmacy confirms that the prescription and the practitioner are legitimate.28 The DEA considers unlawful Internet pharmacies that dispense controlled substances based on an online health questionnaire and Internet pharmacies that sell controlled substances without any prescription.29

According to the DEA, completing an online questionnaire that is then reviewed by a doctor who is hired by the Internet pharmacy cannot be considered the basis for a legitimate doctor-patient relationship, particularly because a consumer can more easily provide false information in a questionnaire than in a face-to-face consultation with a physician.30

The Controlled Substances Act prohibits importation of controlled substances without a valid, current DEA authorization.31 Only pharmacies registered as controlled substance importers with the DEA and in compliance with DEA requirements may import controlled substances from a foreign country for sale in the U.S.32 Despite these rules, many foreign Internet pharmacies either claim that they can legally sell controlled substances without a prescription or advise consumers how to avoid having controlled substance packages seized by U.S. Customs.33 Federal regulations allow a “personal use exemption”--under which an individual is permitted to cross the U.S. border with a limited quantity of a controlled substance intended only for personal use but this exemption does not apply to controlled substances purchased on the Internet and then shipped into the United States.34 Any such shipments from foreign Internet pharmacies are illegal.35

**National Responses**

The President’s National Drug Control Strategy for fiscal 2005 calls for federal agencies to encourage businesses that support the work of online companies--such as credit card companies, shippers and Internet Service Providers (ISP)--to alert law enforcement officials to suspicious Internet activities regarding prescription drug sales and to ask credit card companies and ISPs to require that
Internet pharmacies display the address of their primary business locations on their Web sites.\textsuperscript{36} Although these recommendations are part of the federal strategy, the extent to which they have been implemented is unknown.

The National Association of Boards of Pharmacy (NABP) developed Verified Internet Pharmacy Practice Sites (VIPPS) in 1999.\textsuperscript{37} To be VIPPS certified, a pharmacy must comply with the licensing and inspection requirements of its state and each state to which it dispenses pharmaceuticals. In addition, pharmacies displaying the VIPPS seal are believed to have demonstrated to the NABP compliance with VIPPS criteria, including patient rights to privacy, authentication and security of prescription orders, adherence to recognized quality assurance policy and provision of meaningful consultation between patients and pharmacists. The NABP provides information on whether an Internet pharmacy is licensed and in good standing. Despite the hundreds of online pharmacies that currently are found on the Internet, as of June 2005, only 15 have VIPPS certification.\textsuperscript{38}

\begin{table}[h]
\centering
\begin{tabular}{|l|}
\hline
15 VIPPS Certified Internet Pharmacies \\
\hline
  \textbullet{} www.accuratepharmacy.com  \\
  \textbullet{} www.AdvanceRx.com  \\
  \textbullet{} www.anthemprescription.com  \\
  \textbullet{} www.careforlife.com  \\
  \textbullet{} www.caremark.com  \\
  \textbullet{} www.clickpharmacy.com  \\
  \textbullet{} www.cvs.com  \\
  \textbullet{} www.drugstore.com  \\
  \textbullet{} www.drugsourcinc.com  \\
  \textbullet{} www.familymeds.com  \\
  \textbullet{} www.medcohealth.com  \\
  \textbullet{} www.rxsolution.com  \\
  \textbullet{} www.rxwest.com  \\
  \textbullet{} www.teldrug.com  \\
  \textbullet{} www.walgreens.com  \\
\hline
\end{tabular}
\caption{15 VIPPS Certified Internet Pharmacies}
\end{table}

In February 2003, the FDA hosted a nationwide call with 38 state boards of pharmacy, other state regulatory agencies and consumer groups to discuss current Internet prescription drug sale practices.\textsuperscript{39} As of March 2003, the FDA had initiated 372 criminal investigations, 90 of which involved domestic Internet pharmacies; made 150 Internet-related drug arrests, 60 of which involved domestic Internet pharmacies; and obtained 92 convictions, 26 of which involved domestic Internet pharmacies.\textsuperscript{40} The FDA sent nearly 200 cyber warning letters\textsuperscript{1} to domestic and foreign Internet pharmacies.\textsuperscript{41} The DEA likewise has initiated numerous investigations into the use of the Internet for the unlawful sale of controlled substances.\textsuperscript{42}

The U.S. Customs and Border Protection (CBP) has increased its seizures of prescription drug shipments from overseas -- the majority of which involved controlled substances; the number of seizures increased approximately 450 percent between 1998 and 1999 alone.\textsuperscript{43} While it is impossible to determine how many of these seizures involved drugs purchased from Internet pharmacies, CBP officials believe that the Internet plays a significant role in the increase of illegal drug importation.\textsuperscript{44}

One significant example of inter-governmental agency collaboration in enforcing laws against rogue Internet pharmacies is Operation Cyber Chase-- a year-long Organized Crime Drug Enforcement Task Force investigation into Internet pharmaceutical traffickers who operated in the U.S., India, Asia, Europe and the Caribbean. This investigation targeted an international drug ring trafficking pharmaceuticals over the Internet that were smuggled into the U.S. from overseas manufacturers. Using more than 200 illegitimate Web sites, the drug traffickers shipped controlled drugs to buyers without a

\footnotesize{\textsuperscript{1} In 2000, the FDA began issuing “cyber” letters (letters sent electronically via the Internet) to potentially illegal Internet sites that offer to sell prescription drugs online. The letters warn site operators that they may be engaged in illegal activities and inform them of laws that govern prescription drug sales in the U.S., specifically the Food, Drug and Cosmetic Act and the Controlled Substances Act. In each of these cases, the FDA sent letters electronically to the domain holders for sites that it had determined may be engaged in illegal activity such as offering to sell prescription drugs to U.S. customers without valid or without any prescriptions.}
valid prescription and without proof of age. Since July 2003, the drug ring allegedly repackaged pharmaceuticals manufactured overseas, smuggled them into the U.S. and distributed approximately 2.5 million doses per month of controlled prescription drugs. The investigation involved the DEA, FDA, Federal Bureau of Investigation (FBI), U.S. Immigration and Customs Enforcement (ICE), U.S. Postal Inspections Service (USPIS), Internal Revenue Service (IRS), U.S. Attorneys for districts in Pennsylvania and New York, state and local law enforcement, and law enforcement in four foreign countries.

The DEA recently has begun efforts to enhance public awareness of illegitimate Internet pharmacies. One attempt is aimed at consumers searching the Internet for pharmaceuticals in which warnings from the DEA will appear during the search alerting the consumer to the possibility that the search may be yielding illegitimate Web sites. The following is an example of such a warning:

---Karen P. Tandy, Administrator Drug Enforcement Administration

Several bills were introduced in the Senate and House of Representatives during the 108th Congress from July 2003 through June 2004 that directly address the sale of prescription drugs over the Internet; many of these were reintroduced in 2005:

- The Safe Importation of Medical Products and Other Rx Therapies (IMPORT) Act would establish licensing, identification and professional services requirements for all Internet pharmacies. Providers of interactive computer and advertising services would violate this Act by accepting advertising for a prescription drug from an unlicensed Internet pharmacy or one stating that no prescription is needed to obtain a prescription drug.

- The Safe Online Drug Act would establish a uniform standard for Internet pharmacy certification, prohibit certain advertising practices on Internet pharmacies and the use of certain bank instruments, including extending credit and electronically transferring funds, for purchases associated with illegal Internet pharmacies.
• The Prescription Drug Abuse Elimination Act would require the Secretary of Health and Human Services to provide grants to states to develop or enhance prescription drug monitoring programs, to convene a working group to study and report on pharmaceutical counterfeiting, to impose requirements for Internet pharmacies and to conduct research and report on issues related to prescription drug abuse. It would require the Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA) to maintain a comprehensive, national database on deaths as a result of prescription drug abuse.51

• Other bills introduced in Congress related to Internet sales of prescription drugs include the Ryan Haight Internet Pharmacy Consumer Protection Act52 and the Pharmaceutical Market Access and Drug Safety Act.53

To date, none of these bills has been passed. Other than referrals to Senate and House Committees and Subcommittees, no further action has been taken.54

State regulation. The licensing and regulation of pharmacists and clinicians have traditionally taken place at the state level.55 With the advent of Internet pharmacies, pharmacists and clinicians are able to essentially cross state borders to prescribe and dispense controlled prescription drugs without abiding by state law.56 In March of 2005, the Kentucky House of Representatives passed a bill which attempts to control Internet pharmacy drug sales to state residents by requiring Internet pharmacies to register with the state pharmacy board and be monitored by the Kentucky All Schedule Prescription Electronic Reporting (KASPER) system that tracks prescription drug purchases in Kentucky.57 While several states have taken action against unlawful Internet pharmacies (see Appendix F), most have found it difficult not only to identify online pharmacies but also to take action against those that are engaging in illegal practices.58

Using consumer protection statutes, the Connecticut Attorney General’s office filed suit against Web “pharmacies” and physicians working for them that were not licensed in the state. The complication they found in obtaining convictions was the lack of clear standards of care for physicians related to Internet-based assessment, diagnosis and prescription writing.59
Federal, state and local governments, as well as professional associations and pharmaceutical companies share responsibility for preventing diversion and abuse of controlled prescription drugs. Their efforts have been hampered by limited resources available for addressing this labor-intensive and costly endeavor, insufficient awareness of the scope of the problem, competing priorities and lack of collaboration.

The challenge to policymakers, health professionals and law enforcement officials is to eliminate diversion and abuse of controlled prescription drugs while assuring proper treatment of patients who can be helped by these medications.

What Are the Laws?

International Law

Since 1912, international treaties have required governments to control the production, trade and consumption of psychoactive drugs. The principal treaties in force today are:\(^1\)


- The Convention on Psychotropic Substances of 1971 which establishes an international control system for psychotropic substances;\(^\dagger\)

- The United Nations (UN) Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (adopted in 1988) which presents legislative and administrative measures against drug trafficking, including

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\(^*\) 177 countries are parties to the treaty.
\(^\dagger\) 177 countries are parties to the treaty.
provisions against money laundering and
diversion of precursor chemicals.*

The provisions of these treaties are binding only
to the extent that they do not conflict with an
individual signatory’s constitutional principles
“and the basic concepts of its legal system.”2
While these treaties obligate governments to
create stringent control mechanisms, they
contain provisions to ensure that the restrictions
are not so rigid as to adversely affect patients’
access to needed medications.3

The International Narcotics Control Board
(INCB) is the independent and quasi-judicial
control body for the implementation of the UN
drug conventions. It seeks to assure that
adequate supplies of legal drugs are available for
medical and scientific purposes and to prevent
illicit trafficking.4 The INCB identifies and
helps to correct weaknesses in drug control
systems, determines which chemicals used to
illicitly manufacture drugs should be under
international control5 and issues annual reports
on the worldwide drug situation.

The UN has several other offices charged with
addressing issues related to international drug
control, including the UN Office for Drug
Control and Crime Prevention (ODCCP) which
consists of the UN International Drug Control
Programme (UNDCP) and the UN Centre for
International Crime Prevention (CICP).6 The
Commission on Narcotic Drugs (CND) is the
central policy-making body within the UN
system and is responsible for “analyzing the
world drug abuse situation and developing
proposals to strengthen international drug
control.”7 The World Health Organization
(WHO), which is a specialized agency of the
Economic and Social Council of the UN, is
responsible for reviewing psychoactive

substances for medical, scientific and control
purposes.8

Despite these various international arrangements,
every day controlled prescription drugs enter U.S.
borders illegally through personal transport,
cargo and mail services.

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.9

--William K. Hubbard
Associate Commissioner for Policy
Food and Drug Administration

Federal Laws and Regulations

Despite multiple laws, regulations and federal
regulatory agencies devoted, at least in part, to
the control of prescription drug diversion and
abuse, the problem is one that reaches beyond
U.S. borders and often beyond U.S. control.
Furthermore, the time, effort and costs associated
with addressing diversion effectively--
particularly with the advent of Internet
pharmacies--make it an extremely data-intensive
and arduous task that requires the cooperation
and collaboration of several regulatory and law
enforcement agencies.

The first federal law enacted on prescription drug
distribution, the Harrison Narcotics Act, was
adopted in 1914.10 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

* 162 countries are parties to this treaty.
† The UNDCP is charged with educating the world
about the dangers of drug abuse and the CICP works
with member states to strengthen the rule of law,
promote stable and viable criminal justice systems
and combat the growing threat of transnational
organized crime.

‡ Only WHO can submit scheduling recommendations
to the UN Commission on Narcotic Drugs (CND).
The CND in turn reports these recommendations to the
U.S. Secretary of State who passes them along to the
Secretary of the Department of Health and Human
Services (DHHS). The Secretary of the DHHS
evaluates the proposal and makes a binding
recommendation to the Secretary of State regarding
whether or not to support the recommendation [21
U.S.C. § 811].
consolidated more than 50 federal drug laws. The federal Controlled Substances Act (CSA) of 1970 created a system for classifying prescription drugs according to their medical value and potential for abuse. Drugs addressed in this Act are termed controlled substances and include illicit drugs, as well as abusable drugs prescribed or sold over-the-counter for medical purposes.

(See Table 6.1)

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Drug Schedule</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule I</td>
<td>Have no currently accepted medical use and high potential for abuse, addiction or physical dependence (e.g., marijuana, heroin).</td>
<td></td>
</tr>
<tr>
<td>Schedule II</td>
<td>Have accepted medical use and high potential for abuse, addiction or physical dependence. Examples include morphine, oxycodone (e.g., OxyContin) and hydromorphone (e.g., Dilaudid).</td>
<td></td>
</tr>
<tr>
<td>Schedule III</td>
<td>Have accepted medical use and potential for abuse, addiction or physical dependence less than drugs in Schedules I and II. Examples include methylphenidate (e.g., Ritalin), hydrocodone (e.g., Vicodin, Lortab) and anabolic steroids (e.g., Anadrol).</td>
<td></td>
</tr>
<tr>
<td>Schedule IV</td>
<td>Have accepted medical use and potential for abuse, addiction or physical dependence less than drugs in Schedules I-III. Examples include benzodiazepines such as Diazepam (e.g., Valium) and Alprazolam (e.g., Xanax).</td>
<td></td>
</tr>
<tr>
<td>Schedule V</td>
<td>Have accepted medical use and potential for abuse, addiction or physical dependence less than drugs in Schedules I-IV. Examples include medications containing limited quantities of opioids combined with other substances (e.g., codeine-containing analgesics, cough and cold preparations).*</td>
<td></td>
</tr>
</tbody>
</table>

* Some Schedule V drugs such as Cophene (an antihistamine and decongestant) are over-the-counter medications, while others such as Lomotil (an antiperistaltic and anticholinergic combination used to treat diarrhea) and Robitussin AC (a cough suppressant with codeine) require a prescription.

**Drug Enforcement Administration (DEA).**

The DEA, an agency in the U.S. Department of Justice, is the lead federal law enforcement agency responsible for enforcing the CSA. In cooperation with state authorities and other federal agencies (e.g., the FDA), the DEA is responsible for preventing the diversion of controlled substances for illicit purposes. In carrying out its mission, the DEA must comply with international treaties to the extent that they are not in conflict with Constitutional provisions† and work closely with foreign, state and local governments.

Under the CSA, businesses that manufacture or distribute controlled prescription drugs, health professionals entitled to dispense, administer or prescribe controlled drugs and pharmacies entitled to fill prescriptions for controlled drugs must register with the DEA. Registrants must comply with a series of regulatory requirements relating to drug security, record keeping and reporting loss or theft of these drugs immediately to the DEA and state licensing authorities.

There are 500 of us across the country that work on prescription drug abuse, that’s it. That’s all there is for DEA--compared to 4,500 for cocaine and other illicit drugs.

--Laura Nagel

former Deputy Assistant Administrator
Office of Diversion Control, DEA
CASACONFERENCE, Feeling No Pain:
Substance Abuse, Addiction and Pain Management
February 27, 2003

† The International Convention on Psychotropic Substances of 1971 prohibits direct-to-consumer (DTC) marketing of controlled drugs; however, in recent years there has been an explosion in DTC advertising of various pharmaceuticals, including controlled prescription drugs. The pharmaceutical industry has taken the view that the First Amendment right to commercial speech protects such advertising. The scope of Constitutional protection for DTC advertising of controlled drugs is uncertain.
In recent years, abuse of controlled medications has caused the DEA to devote more attention to issues of prescription drug diversion. For example, the DEA created an action plan to prevent the diversion and abuse of OxyContin through:

- Enhanced enforcement and intelligence (e.g., identifying large-volume purchasers of OxyContin for referral to field offices for appropriate action and scrutinizing all exports of OxyContin to detect diversion trends);

- Regulatory and administrative efforts (e.g., urging the reformulation of OxyContin to reduce its abuse potential, working with the Federation of State Medical Boards to encourage physician education on treatment of pain and recognition of addiction);

- Seeking industry cooperation (e.g., encouraging Purdue Pharma to develop a balanced marketing strategy that ensures appropriate use of OxyContin and to support public education and awareness programs highlighting the dangers of abusing the drug); and

- Awareness/education/outreach initiatives (e.g., creating and enhancing public awareness campaigns as well as outreach and education programs for the healthcare industry).19

The DEA’s investigation, enforcement and intelligence programs have begun to work more closely with other federal (e.g., FDA, U.S. Customs and Border Protection Service, Federal Trade Commission), state and local agencies to target individuals and organizations involved in diversion and abuse of controlled prescription drugs.20 The DEA has increased its monitoring of Internet prescription drug sales.21 (See Chapter V)

**Food and Drug Administration.** To reach the market in the U.S., all prescription drugs must first be approved by the FDA as safe and efficacious.22 An agency of the U.S. Department of Health and Human Services, the FDA was established by the Food, Drug and Cosmetic Act (FDCA) to assure the safety, efficacy and security of the nation’s food and drug supply (as well as that of other products such as medical devices and cosmetics).23

To obtain approval to market a drug, a manufacturer must submit a New Drug Application with detailed safety and efficacy data, as well as proposed labeling for the new drug. 24 Once approved, the manufacturer may introduce the drug into interstate commerce; however, the FDA still has broad powers to monitor marketing and adverse effects.25 The FDA monitors and evaluates pharmaceutical companies’ promotional materials but does not require them to submit promotional materials for any medications, including controlled prescription drugs, for approval prior to their use.26 It is within the FDA’s jurisdiction to place precautionary warnings on drugs to alert and educate healthcare practitioners and the public regarding the abuse potential of a particular medication.27

Because all opioids have some abuse potential, the FDA recommends that pharmaceutical companies voluntarily include a warning in their labeling of the risks of misusing the drug.28 The strongest labeling warning that the FDA requires is the “black box warning.”29 This labeling is intended to influence prescribing practices as well as increase clinicians’ awareness of the potential for diversion and abuse of the drug.30 Despite the intended purpose of this labeling, some argue that a “black box warning” on a drug label does not deter abuse, but instead becomes “a recipe for abuse,” alerting abusers and addicts to the high abuse potential of the drug.31

In light of the widespread abuse of controlled prescription drugs, the FDA calls for pre-market risk assessment and implementation of risk

*While the drug’s label is required to indicate approved uses for the drug, the label also must reveal all medically relevant information regarding the appropriate use of the drug such as dosage, directions for administration, known precautions, warnings and contraindications.*
management plans for all new controlled prescription drugs.32 Some pharmaceutical companies have initiated risk management plans to assess the risk associated with marketing a new drug. Recently the FDA’s Anesthetic and Life Support Drugs Advisory Committee recommended that Purdue Pharma LP, take such precautions in its upcoming release of Palladone, a new controlled-release form of hydromorphone, in addition to requiring a black box warning about the medication’s potential for abuse.33 This plan includes a statement in the package that the drug should not be crushed, dissolved or chewed, a hotline for information on adverse effects and a yearlong phased launch of the drug.* 34

This proactive approach, which can effectively preempt unexpected and widespread instances of abuse of new prescription drugs, is a recommended but not mandatory feature of new drug applications to the FDA for controlled substances.35

While the FDA determines safe and effective uses of particular drugs, it does not regulate medical practice. Physicians are free to use their judgment regarding the best interest of the patient in making prescribing decisions, even if the prescribing decision does not conform to the drug’s labeled indications or recommended doses.36 Although such “off-label” prescribing is accepted medical practice and typically serves the patient’s medical interests, it may allow for instances of intentional or unintentional diversion.

One action being taken by the FDA to tackle the problem of controlled prescription drug theft and counterfeiting is an initiative for drug companies to affix tiny radio antennas to the labels of frequently-abused or counterfeited drugs to track their path within the supply chain. The radio-frequency devices, which are read by special scanners, provide a unique identifier that allows the distribution history and authenticity of the medications to be tracked from the factory through the distribution chain to consumers. These devices are almost impossible to copy, thwarting the efforts of criminals to introduce counterfeit medications into the supply system. Affixing these radio labels will be voluntary until 2007 when the FDA may require them.37

Scheduling drugs. Substances may be added to a schedule, removed or transferred from one to another.38 The Controlled Substance Staff within the FDA’s Center for Drug Evaluation and Research (CDER) makes drug-scheduling recommendations.39 Although the FDA makes scheduling recommendations, the DEA makes the final determination.† 40

The DEA is considering rescheduling hydrocodone compounds—opioids that contain the pain reliever acetaminophen (e.g., Vicodin)—from a Schedule III drug to a Schedule II drug in order to better control its high rate of abuse.41 Yet, hydrocodone is the most widely prescribed type of prescription drug.42 Opponents to rescheduling hydrocodone argue that it will make the drug less accessible to patients because they will be required to visit their physician more frequently to obtain a new prescription rather than simply refilling their existing prescription. They argue that doctors will be overloaded with patient visits, increasing pain-related healthcare costs,43 and that greater penalties associated with violating prescribing regulations related to Schedule II drugs may result in doctors prescribing drugs from higher numbered schedules (e.g., III or IV) that may be less effective for patients.44

* During this introductory period, the company will focus its sales on pain management specialists and begin collecting data about the drug’s abuse through its new Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS) system—a system designed to monitor the diversion and abuse of prescription opioid medications with recognized abuse potential.

† In determining whether a drug should be controlled and to which schedule it should be assigned, several factors are considered including the drug’s potential for abuse, pharmacological effects, historical and current pattern of abuse, risks to the public health, dependence liability, and whether the drug is an immediate precursor of a substance already controlled.
Drug refills. The CSA indicates the refill policy for the drugs in the various schedules. For example, Schedule II drugs—those prescription drugs with the highest abuse potential—cannot be refilled; a new prescription is required. Schedules III and IV drugs are permitted refills; however, unless the order is renewed by the physician, prescriptions for these drugs may not be filled or refilled more than six months after the date on the prescription order and may not be refilled more than five times after the date on the prescription order. Limiting the number of refills allows the physician to monitor the patient’s course of illness periodically, which is particularly important during long-term therapy to detect tolerance, drug interactions and compliance.

Regulation of prescribing practices. A licensed physician or other healthcare professional entitled to prescribe, dispense or administer controlled drugs must register with the DEA (and usually with the state medical licensing board as well). The DEA registration must be renewed every three years. If a physician administers controlled drugs at more than one office, he or she must register with the DEA at each location. Any change of practice location must be reported to the DEA (and usually to the state medical licensing board as well).

A prescription for a controlled drug is considered legal only if a healthcare practitioner prescribes it for a legitimate medical purpose. Commonly accepted guidelines for compliance with the requirement of “legitimate medical purpose” include the following:

- The patient must desire treatment for an illness or medical condition;
- The physician must establish a legitimate need for the prescription through assessment of the patient and pertinent diagnosis; and
- There must be a reasonable relationship between the patient’s medical problem and the drug prescribed.

Prescription orders for controlled drugs must be signed and dated on the day issued and must include (at least) the name and address of the patient; the name, address and DEA registration number of the physician; the physician’s signature; the name, quantity, strength and dosage of the drug prescribed; directions for use; and refill information. Currently, the majority of Internet pharmacies fail to follow these basic rules. (See Chapter V)

Regulation of drug samples. The federal Prescription Drug Marketing Act (PDMA) of 1988 regulates drug samples that pharmaceutical company representatives give physicians. The PDMA prohibits knowingly selling, purchasing or trading a prescription drug sample, or offering to do so. These acts are punishable by up to 10 years imprisonment. Physicians are allowed to receive drug samples from pharmaceutical companies and to dispense those samples to patients. Pharmaceutical companies may distribute samples of controlled substances to clinicians only if they have a prior written request from a healthcare professional who is registered with the DEA to prescribe, administer or dispense controlled substances; if the controlled drug is to

*The written request must include the practitioner’s name, address, registration number and the name and quantity of the specific controlled substance that is requested.
be used for legitimate medical purposes; and if
reasonable quantities are requested.56

**Controlling steroid abuse.** Concerns over a
growing illicit market, abuse by teenagers and
harmful effects of long-term use of steroids led
Congress to pass the Anabolic Steroid Control
Act of 1990 and place anabolic steroids into
Schedule III of the CSA. The CSA defines
anabolic steroids as any drug or hormonal
substance chemically and pharmacologically
related to testosterone that promotes muscle
growth. However, because the scientific
community had yet to agree upon an accepted
methodology for accurately quantifying the
promotion of muscle growth, drug traffickers
have been able to market substances that were
chemically and pharmacologically related to
testosterone such as dietary supplements.57 In
addition, some steroid abusers consume steroid
precursors that do not themselves cause muscle
growth but get converted by the body into
anabolic steroids.58

The use of steroid supplements and other
performance-enhancing drugs by professional
athletes over the past decade has made steroid
use more appealing to teens seeking to emulate
their idols. President Bush signed into law the
Anabolic Steroid Control Act of 2004 which
redefines anabolic steroids as any drug or
hormonal substance chemically and
pharmacologically related to testosterone (other
than estrogens, progestins, corticosteroids, and
dehydropiandrosterone), regardless of the
ability of a given substance to promote muscle
growth.59 This Act added a number of anabolic
steroid precursors to the DEA’s list of Schedule
III controlled drugs including andro
(androstenedione)--the dietary supplement that
became popular in 1998 after major league
baseball player Mark McGwire admitted to
using it during his home run record-winning
season.60 A recent bill introduced in the Senate
seeks to add the popular anti-aging supplement
DHEA (dehydropiandrosterone) to that list as
well.61

**State Laws and Regulations**

States regulate professional standards of medical
practice.62 Virtually every step in prescribing or
dispensing controlled drugs is governed by state
professional practice laws and regulations.63
State bureaus of narcotics and local law
enforcement also play an active role in diversion
control.

Every state legislature has granted statutory
authority to professional oversight boards to
license and discipline members within each
profession.64 The governor typically appoints
board members who represent both practitioners
and the general public.

The licensing boards for each healthcare
profession have a designated national
organization: the Federation of State Medical
Boards of the United States (FSMB), the National
Association of Boards of Pharmacy (NABP), the
National Council of State Boards of Nursing
(NCSBN), the American Association of
Veterinary State Boards (AAVSB) and the
American Dental Association (ADA). These
organizations support a variety of activities,
including hosting annual meetings, conducting
research, providing technical assistance and
training, developing policy and creating and
disseminating model laws and regulations to
guide states in crafting their own laws.65

Many of these associations have not been
proactive in addressing the problems of
prescription drug diversion and abuse. However,
some have improved their handling of physicians
who prescribe large quantities of opioids; specific
and clearer criteria have been developed to guide
boards in determining when to investigate and
discipline these physicians without encroaching
on appropriate pain management practices. Yet
one study found that boards are likelier to
perceive over-prescribing of opioids as a
violation of standard of care than they are to
perceive the under-treatment of pain as such a
violation.66
In addition to statutes governing professional practice, most states have adopted some version of the federal CSA.Normally, these laws are based on the Uniform Controlled Substances Act (UCSA) created by the National Conference of Commissioners on Uniform State Laws. The UCSA was created to maintain consistency between the federal CSA and states’ acts to ensure effective control of drug abuse. State CSAs must include all the federal CSA requirements; however, states have the liberty to add a drug not scheduled by the federal CSA, change the schedule level of a drug to a lower numbered schedule (e.g., move a Schedule IV drug to Schedule III) or add registration requirements.

Compliance with the state laws and regulations is monitored--through routine audits and special investigations--by inspectors who report to the professional oversight boards. The extent to which this monitoring is thorough and effective varies by state and may depend, in part, on available resources and state priorities.

**Professional Guidelines**

To help physicians, pharmacists and other healthcare professionals meet their professional responsibility to prevent the abuse of controlled prescription drugs, several professional organizations have developed practice guidelines that, while lacking the force of law, nevertheless define the conduct that is considered to be within the boundaries of acceptable professional practice.

In 1998, the FSMB adopted Model Guidelines for the Use of Controlled Substances for the Treatment of Pain as a cooperative effort with representatives of state medical boards, the American Pain Society, the American Academy of Pain Medicine and the American Society of Law, Medicine and Ethics. The FSMB disseminated the Model Guidelines to each state medical board with a request that they be considered and adopted as policy.

The Model Guidelines recommend treatment parameters for the use of controlled prescription drugs for pain management. However, they recognize the need for flexibility, stating that a physician may deviate from the guidelines for good cause. The Guidelines do not exclude pain patients with substance use disorders from being treated with opioid medications; instead, they recognize that the decision to prescribe controlled substances to a patient should be determined on an individual basis. The Guidelines, however, do advise clinicians to be “diligent in preventing the diversion of drugs for illegitimate purposes.”

In April 2003, the FSMB membership called for an update to its Model Guidelines to assure currency and adequate attention to the undertreatment of pain. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The Model Policy (the updated version of the Guidelines) was designed to communicate to licensees that the state medical board views pain management to be important and integral to the practice of medicine; that physicians have a responsibility to minimize the potential for the diversion and abuse of controlled prescription substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes.

As of January 2004, 22 of 70 state medical boards have adopted policies based on the Model Guidelines. An evaluation of these guidelines found that almost 80 percent contain

* They involve seven steps: (1) medical history and physical examination, (2) treatment plan with identified objectives, (3) informed consent to treatment, (4) periodic review of treatment, (5) consultation as necessary, (6) accurate and complete medical records and (7) compliance with both federal and state controlled substances laws and regulations.

† A state may have more than one medical board and there are medical boards in U.S. territories, such as Puerto Rico, Guam and the Virgin Islands. These boards have policies, rules, regulations or statutes reflecting the Federation’s Model Guidelines and two states have formally endorsed the Guidelines. The full text of each state’s policies can be found at www.medsch.wisc.edu/painpolicy.
recommendations or specific requirements regarding prescribing opioids to patients with a history of addiction.80

In April 2002, the FSMB developed Model Policy Guidelines for Opioid Addiction Treatment in the Medical Office to encourage state medical boards to provide appropriate treatment for opioid-addicted patients and educate regulatory and healthcare professionals on new treatment options for opioid addiction.81

Monitoring Diversion and Abuse

Various federal, state and local data collection systems monitor prescription drug diversion and abuse and help gauge the scope of the problem.82 Data collection methods have included programs designed specifically to monitor prescription drug diversion, federal datasets such as Medicaid and data from law enforcement and state and local task forces.

Prescription Abuse Data Synthesis (PADS)

In 1980, the American Medical Association (AMA) co-sponsored the White House Working Conference on prescription drug diversion and abuse83 which resulted in the development of the Prescription Abuse Data Synthesis (PADS), a prescription drug diversion monitoring and prevention program.84 By 1989, 27 states and the District of Columbia had adopted the PADS program.85 The purpose of PADS was to help states use available data† to identify inappropriate prescribing patterns, enhance information-sharing and enforcement capability and develop interventions for inappropriate prescribers and dispensers.86 After the program’s fourth year, reports in some states reflected potential signs of the program’s success, documenting a 30 to 70 percent reduction in the use of commonly abused prescription drugs‡ and fewer emergency department visits and deaths attributed to these drugs. The American Medical Association (AMA) discontinued support of PADS programs at the end of 1990 due to a lack of resources.87

Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMPs) capture information that may be shared with law enforcement agencies, healthcare and regulatory agencies§ and, in some states, healthcare practitioners to help identify inappropriate or illegal activities involving controlled prescription drugs.88 PDMPs can be designed to educate healthcare and law enforcement professionals, produce data on the quantity of drugs prescribed or dispensed and help identify the most frequently diverted drugs.89 An important aim of these programs is to use the data collected to permit the enforcement of federal and state laws in a manner that is least disruptive to medical and pharmacy practice.90

There is ongoing debate regarding the effectiveness of the various monitoring mechanisms, the usefulness of the information that is gathered and the impact these programs have on access to quality patient care. All PDMPs focus on individual targets (i.e., individual patterns of physician prescribing, pharmacist dispensing, or patient usage) and, as such, they only are effective to the extent that they are part of a larger, systematic and long-term strategy for reducing prescription drug diversion and abuse. Only some states have programs and those that do have vastly different data collection methods.91

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* These practice parameters include: (1) evaluating each patient for a history of addiction or for current addiction, (2) consulting another physician about the diagnosis, (3) providing extra care and special attention, (4) establishing treatment plans that reflect the possibility of drug abuse and (5) being vigilant with regard to drug-seeking behaviors.
† From databases such as Drug Abuse Warning Network (DAWN), Automation of Reports and Consolidated Orders System (ARCOS) and Medicaid.
‡ Whether reductions in use signified less inappropriate use and not less appropriate use of the drugs could not be determined.
§ There is no automatic requirement that data be shared with any agency.
History of PDMPs. The nation’s first PDMP operated in New York from 1913 to 1915. In 1940, California’s Triplicate Prescription Program (TRIPS), which regulated and monitored the distribution of Schedule II controlled drugs, became the oldest, longest-running multiple copy prescription monitoring program in the nation. In 1943, Hawaii passed legislation requiring prescriptions for narcotics and other habit-forming drugs to be prepared by the prescriber in duplicate. The Illinois Triplicate Prescription Control Program has been in existence since 1961. Idaho’s triplicate prescription program for all Schedule II drugs began in 1967 with the passage and implementation of the state’s first comprehensive narcotics and dangerous drug law. In 1991, the Oklahoma Bureau of Narcotics instituted the first electronic monitoring system, Oklahoma Schedule Two Abuse Reduction (OSTAR).92

As of November 2004, 20 states have implemented a PDMP; several more states have received grants to set up a program.93 For illustrative purposes, Appendix G provides information about the PDMPs of four selected states.

Multiple Copy Prescription Programs (MCPP). MCPPs, also referred to as triplicate (copy) programs, require physicians and other prescribers to use special state-issued prescription order forms when prescribing certain scheduled drugs as designated by the state.94 Typically, forms are in triplicate, with one copy retained by the physician, another by the pharmacist and the third sent to a designated state agency.95 The agency that receives the copy varies: in some states it may be a law enforcement agency; in others, a healthcare agency such as the Board of Pharmacy. Multiple copy forms help prevent forgery and counterfeit prescriptions, thereby potentially limiting abuse.96 Yet some research indicates that MCPPs may affect prescribing practices, discouraging some physicians from prescribing controlled drugs.97 The AMA opposes MCPPs as ineffective in reducing controlled prescription drug abuse and having adverse effects on the availability of prescription medications for therapeutic use.98

Electronic Data Transfer (EDT). With EDT, pharmacies electronically transmit information on prescription medications that are dispensed and covered under the PDMP to a central databank or processor.99 The information collected may then be reported to appropriate state agencies.100 The pharmacist retains a copy of the physician’s prescription for two to five years.101 EDT programs avoid the time-consuming and labor-intensive data-entry step required by paper-based systems, yield data for analysis in a more timely fashion, are less expensive to administer and make searching for pertinent information easier.102 However, information might be reported or entered into the system incorrectly or patients might share certain identifying information with other patients, potentially creating confusion.103 The primary administrative responsibility for EDT programs lies with pharmacists, so clinicians often are less aware that their prescribing practices are being monitored than they would be with paper-based programs.104 Finally, an electronic system cannot identify forged prescriptions or track false identifications.105 Most states that have a PDMP or are starting one are implementing EDT programs rather than MCPP programs.106

Serialized single copy forms. Serialized single-copy prescription forms are imprinted with unique features to help prevent forgeries and prescription thefts.107 They reduce the amount of paperwork created by MCPP forms and, like MCPP, may help serve as a reminder to physicians that their prescribing practices are being monitored.108 As such, they may adversely impact physicians’ prescribing practice in much the same way that multiple copy forms do.

Drugs covered under PDMPs. Individual states determine which drugs are monitored by the program.109 Increased reporting increases program costs, limiting some states to monitor only certain drugs or certain drug schedules.110 If a state does not have a reported problem with a certain drug schedule (typically, Schedule III
drugs), that state may choose not to include drugs belonging to that schedule in their monitoring program. However, some experts believe that PDMPs should cover all Schedules II through IV prescription drugs because doing so makes it more difficult for abusers to switch to drugs in schedules that are not monitored by the state PDMP.111

**PDMP data.** Some states use the information they collect through PDMPs to generate reports of unusual prescribing or usage patterns that may point to diversion or abuse.112 Depending on the state, information may be offered to healthcare providers113 or to designated law enforcement agencies.114

Because proactive operations are more costly, most states use the data they collect only in response to requests from law enforcement or healthcare practitioners. * 115 Typically, a certain level of probable cause† is required before information is provided to a practitioner or law enforcement official.116

**Administrative responsibility for the PDMP.** The state agency that administers the PDMP differs by state. A law enforcement agency, the Board of Pharmacy or a public health agency typically oversees the PDMP.‡ 117

**Patient privacy/confidentiality.** A main concern of opponents to PDMPs is that they might violate patient privacy and confidentiality. Florida lawmakers recently rejected a bill calling for a state PDMP because of privacy concerns.119 Proponents of PDMPs, including the DEA and some state law enforcement officials, argue that each program has safeguards to protect patient confidentiality and that, to date, no evidence of breaches of patient confidentiality has emerged. In addition, proponents argue that the majority of controlled substance data collected for PDMPs already are available to state authorities through other means (e.g., pharmacies, Medicaid).120 Proponents of PDMPs contend that such programs help deter doctor shopping and decrease the time it takes to complete an investigation into suspected cases of abuse or diversion.121

The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA)—which is designed to provide uniform federal protection of patients’ privacy regarding their medical records and other health information given to health insurance plans and healthcare providers—may appear to be in conflict with state PDMPs that require prescription drug providers and dispensers to disclose patient information. However, although HIPAA preempts any contrary provisions of state law, there are exceptions under which state PDMPs are able to operate, such as a determination by the Department of Health and Human Services that the state law (i.e., related to the PDMP) is necessary “to prevent fraud and abuse related to the provision of…health care or for the purposes of serving a compelling need related to public health” or if the state law’s main purpose is to regulate controlled substances.123

**Effectiveness of PDMPs.** Determining the effectiveness of PDMPs in reducing prescription drug diversion and abuse is difficult since no clear standards or outcomes for measuring effectiveness have been established.

The medical community has mixed feelings about prescription monitoring. Some physicians fear it hampers the treatment of pain, while others believe that doctors who have nothing to hide have nothing to fear from such a program.118

Typically, PDMP effectiveness is evaluated by the number of cases referred for investigative purposes or by the extent to which a reduction in drug utilization is seen.124 The very existence of a PDMP can affect the number of prescriptions written for controlled substances, particularly opioids.125 Reductions in prescriptions for abusable drugs or increases in referred cases for investigative purposes may be suggestive of a...
reduction in diversion or abuse; however, these outcomes may indicate that physicians are prescribing medications not covered by the state PDMP in order to avoid legal scrutiny or protect patient privacy, or they may indicate a reduction in appropriate use of the covered medication through a chilling effect. For example, one study of New York’s inclusion of benzodiazepines in its triplicate prescription program (a MCPP) found that introduction of that regulation reduced benzodiazepine use by more than 50 percent (compared to no change in use in a comparison state during the period of the study). Although there was some reduction in use among those who may have been abusing the drugs, most reduction was found among non-abusive users. Related research found that inclusion of benzodiazepines in the program reduced use among chronically ill patients for whom the medications were effective.

In 2002, in an effort to create some uniformity across state PDMPs, the Alliance of States with Prescription Monitoring Programs (ASPMP) and the National Association of State Controlled Substances Authorities (NASCSA) proposed legislation to guide states in designing PDMPs that control diversion but do not interfere with the legitimate use of these drugs. (See Table 6.2)

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<thead>
<tr>
<th>Table 6.2</th>
<th>Elements of Model Legislation Proposed by ASPMP and NASCSA</th>
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<tr>
<td>• Collect information on all Schedules II-IV controlled substances, with the possibility of including Schedule V drugs and any other drug that might be abused.</td>
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<tr>
<td>• Specify data that should be submitted in each state while providing states with the option of requesting additional information.</td>
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<tr>
<td>• Require pharmacies to submit data electronically. States should utilize a serialized single copy form to accompany the EDT system.</td>
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<tr>
<td>• Ensure patient confidentiality by specifying which agencies or individuals (including patients who request their own prescription monitoring information) can access data and indicate what information is available to each of these parties.</td>
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<tr>
<td>• Examine data to determine what legal actions should be taken and which agency is responsible for carrying out such actions.</td>
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<tr>
<td>• Allow state agencies to remain up-to-date by providing authority to implement new regulations, as needed, related to the monitoring program.</td>
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<tr>
<td>• Allow inter-agency collaboration within the confines of confidentiality; any breach of confidentiality should be penalized.</td>
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<tr>
<td>• Impose penalties on individuals or agencies that knowingly fail to submit information to the monitoring program.</td>
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To measure their effectiveness, PDMPs must demonstrate a reduction in the abuse of controlled substances and a decrease in diversion without interfering with legitimate access to prescription medications or infringing on patient privacy. More research clearly is needed before any definitive conclusions regarding the effectiveness of PDMPs can be determined.

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* ASPMP is a national organization of states with prescription drug monitoring programs and states that have an interest in developing a program. The organization provides a forum for and exchange of information and ideas between states and state and federal agencies.

† NASCA was created to offer state and federal agencies a platform to work collaboratively to build on state and national efforts to prevent controlled prescription drug diversion and abuse.

‡ The Act does not provide assistance for educational or treatment programs. This responsibility is left to the states.
Only about one-third of pharmacists and physicians in CASA’s survey believe that PDMPs help “somewhat or very well” to prevent drug abuse (36.7 percent of pharmacists and 33.2 percent of physicians) or diversion (34.2 percent of pharmacists and 29.2 percent of physicians). More than one-quarter (28.3 percent of pharmacists and 31.2 percent of physicians) believe that PDMPs compromise patient confidentiality and 33.9 percent of pharmacists and 43.6 percent of physicians believe that they instill in physicians a fear of legal scrutiny. Nevertheless, approximately three-quarters of the respondents (71.6 percent of pharmacists and 75.2 percent of physicians) said that the information recorded in PDMPs is useful to them in preventing drug diversion and abuse.

Expanding and Improving Prescription Drug Monitoring

In FY 2004, Congress appropriated $6.9 million to the U.S. Department of Justice to support the Harold Rogers Prescription Drug Monitoring Program designed to assist states in establishing PDMPs and to provide resources to states with existing programs.

In 2002, the National All Schedules Prescription Electronic Reporting Act (NASPER) was introduced in the House of Representatives. This Act would require pharmacies or physicians to report information† on drugs dispensed to the Secretary of Health and Human Services. The proposed national program was to cover all 50 states and include Schedules II through IV controlled substances.

Reactions to this proposed national monitoring program were mixed. Proponents argued that a national program would be the only real option for monitoring the full extent of interstate diversion. The sheer volume of data collected in a national system could provide useful information on national drug use trends and prescribing practices.

Those opposing a national monitoring program argued that the federal government does not have a good track record in managing large databases, there is little information regarding how the data would be used (such as to identify trends before a prescription drug abuse problem arises) and patient and provider confidentiality may not be well protected.

In 2004, a revised version of NASPER legislation was introduced which replaced the proposed single national system with federal grants for individual states to establish and implement their own PDMPs that specifically address their individual needs while adhering to national standards. Similar legislation was introduced in 2005. Concerns remain about privacy and confidentiality.

In place of or in addition to state PDMPs, some states have developed prescription drug task forces or special units to tackle the problems of diversion and abuse. Some examples of such state actions are provided in Appendix G.

The Medicaid system is a largely untapped resource for monitoring and identifying cases of diversion and abuse. Several components of the system make it possible to track potentially problematic instances of diversion, including Medicaid fraud control units, drug utilization reviews and prior authorization requirements. Appendix H provides more information on these possibilities. Monitoring efforts focused on Medicaid data run the risk of bias against Medicaid patients, potentially creating a disincentive for physicians to accept Medicaid

† Information that would be required includes the drug dispensed, date and quantity dispensed, number of permitted refills and number ordered, as well as name of the individual dispensing the drugs.
patients for fear of patient drug abuse and legal scrutiny.

**Balancing Diversion Control With Appropriate Medical Care**

The scrutiny of professional boards and monitoring programs such as PDMPs has, in some cases, created a fear that legal actions will be taken against physicians and pharmacists regarding their prescribing and dispensing practices. As a result, practitioners may under-treat patients or use less appropriate medications that are not covered by a monitoring program.

The area in which this chilling effect has raised the most controversy is in the field of pain management. Some argue that a fear of legal scrutiny has resulted in the widespread under-treatment of pain. The undertreatment of pain can lead to health problems including increased risk of pneumonia or respiratory problems, relapse into alcohol or drug abuse, progression of acute pain into chronic pain, loss of job and depression.

Many pain management advocacy organizations have been formed in response to the problem of under-treatment of pain and have teamed up with pain management physicians and pharmaceutical companies to help advocate for the use of opioids in the treatment of pain. These groups argue that proper treatment of pain is a public health necessity since more than 70 million people in this country suffer from pain.

* The under-treatment of pain has been attributed to other factors as well, including inadequate pain management education and practitioners’ fears of inducing addiction in their patients.

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*We are facing a major problem because on one hand we believe that we are under-treating pain and we should be more generous and give it to the patients...No one should suffer--ever. And on the other hand we have to think, are we making them drug users by giving them the medicine?*

--Physician
CASA Focus Group

In August 2004, the DEA released a consensus document with major pain experts and advocacy groups, *Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals and Law Enforcement Personnel*, regarding balancing the appropriate treatment of pain with the prevention of diversion and abuse of prescription pain medications. Yet, in October 2004, the DEA rescinded its endorsement of the guidelines and took them off its Web site, claiming that the document contained misstatements. A revised statement, published by the DEA in November 2004, presents a tougher approach to the issue of prescribing controlled prescription drugs and was greeted with concern from pain management specialists.

*Combating prescription drug addiction is much more difficult than combating the abuse of cocaine, marijuana or even alcohol. This is because there is a need for a balance between restricting access to the abuser and maintaining availability to those who legitimately need them. This is not an easy task.*

--Daniel B. Dong, PharmD, Director
Department of Pharmaceutical Services
University of California, San Francisco
The DEA argues that very few physicians have gotten into trouble with the law and that those who have were “prescribing drugs outside medical norms in a manner that amounted to trafficking.” Pain doctors, in contrast, argue that “established medical use of opium-based drugs for pain is becoming criminalized by aggressive drug agents and zealous prosecutors.”

---Nathaniel Paul Katz, MD  
Director, Pain Trials Center  
Brigham and Women’s Center and  
Tufts University School of Medicine  
CASACONFERENCE, Feeling No Pain:  
Substance Abuse, Addiction and Pain Management  
February 27, 2003

Increasing prescription drug abuse has been a wakeup call to the medical community and must be addressed through a balanced approach.160

---Russell K. Portenoy, MD, Chairman  
Dept. of Pain Medicine and Palliative Care  
Beth Israel Medical Center, NY

Since 1989, Intractable Pain Treatment Acts (IPTAs) have been enacted in a number of states.158 These acts set forth pain treatment guidelines and are intended to provide protection for physicians against disciplinary actions from state medical boards.159
CASA’s unprecedented surveys indicate that healthcare practitioners are poorly trained in recognizing and managing addiction and treating pain in patients, that they routinely fail to recognize the signs and symptoms of substance abuse, and that many are uninformed about the laws and regulations surrounding the administration of controlled substances. This may be because many prescriptions for pain and psychiatric medications are written by primary care physicians who typically do not have the specialized training needed for treating pain and psychiatric conditions with controlled drugs. Prevention efforts aimed at the public rarely focus specifically on prescription drug abuse, and few treatment options exist that are designed specifically for prescription drug abusers.

**Education and Training**

**Medical School**

According to CASA’s survey of physicians regarding their medical school training:

- 19.1 percent received instruction in identifying diversion of controlled prescription drugs. Of these 56.4 percent had received only a few hours or less; 35.6 percent had more than a few hours but less than an entire course, and 7.4 percent had an entire course.

- 39.6 percent received instruction in identifying prescription drug abuse/addiction; however, half of them (51.9 percent) received only a few hours or less, 39 percent had more than a few hours but less than an entire course, and only 7.5 percent had an entire course.

- 55.4 percent received instruction in prescribing controlled drugs, but 57.6 percent received only a few hours or less; 34.8 percent had more than a few hours but...
less than an entire course, and 5.5 percent had an entire course.

- 47.5 percent received instruction in pain management; however, half (51.5 percent) received only a few hours of instruction or less, 42.1 percent had more than a few hours but less than an entire course, and 5.2 percent had an entire course.

**Residency**

Physicians’ knowledge about psychoactive drugs comes largely from their medical internship and varies greatly according to the resident or attending physician to whom they report.\(^1\) CASA’s survey of physicians found that during residency:

- 39.2 percent received instruction in identifying diversion, but of these 47.5 percent had a few hours or less, 40.3 percent had more than a few hours but less than an entire course, and 10.9 percent had an entire course.

- 61.4 percent received instruction in identifying prescription drug abuse/addiction, but 40.7 percent had a few hours or less, 44 percent had more than a few hours but less than an entire course, and 13.3 percent had an entire course.

- 69.9 percent received instruction in prescribing controlled drugs, but 42.4 percent had received only a few hours or less, 45.3 percent had more than a few hours but less than an entire course, and 10.3 percent had an entire course.

- 61.7 percent received some instruction in pain management, but 38.1 percent had a few hours or less, 51 percent had more than a few hours but less than an entire course, and 9.6 percent had an entire course.

Much of physicians’ knowledge about new drugs and prescribing trends comes from the *Physicians’ Desk Reference (PDR)* and drug package inserts, which contain information written by pharmaceutical companies about the drugs they manufacture.\(^2\)

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The appropriate use of analgesics and other mood-altering drugs is a subject that unfortunately receives too little attention in medical school and residency training. As a physician moves farther away from basic pharmacology—where most of the information concerning drug action is taught—an increasing unfamiliarity with the specific actions of analgesics and other mood-altering agents develops.\(^3\)

--Barry Stimmel, MD
Professor, Mount Sinai School of Medicine

**Pharmacist Training**

Pharmacists responding to CASA’s survey were asked whether they had received instruction since graduating pharmacy school in dispensing controlled drugs, identifying prescription drug abuse/addiction or preventing prescription drug diversion. The findings indicate that only about half received instruction in these areas:

- 55.9 percent received instruction in dispensing controlled drugs.
- 49.6 percent received instruction in identifying prescription drug abuse/addiction.
- 48.1 percent received instruction in preventing diversion.

**Continuing Medical Education (CME)**

Most healthcare practitioners are required to take continuing education courses to help keep them current and informed about new developments in their fields; those geared to physicians (Continuing Medical Education, or CME, courses) that address prescription drug abuse issues commonly focus on opioids and pain management. CME courses related to prescribing controlled substances or pain management are offered in some states as an option to fulfill mandatory CME credit requirements. California is the first state to require physicians to take a CME course on pain management.\(^4\) Some states offer or require such courses as a disciplinary action.
According to CASA’s survey of physicians:

- 34.2 percent received CME instruction in identifying diversion; 36.1 percent had a few hours or less, 37 percent had more than a few hours but less than an entire course, and 26 percent had an entire course.

- 45.6 percent received CME instruction in identifying prescription drug abuse/addiction; 35.2 percent had a few hours or less, 39.9 percent had more than a few hours but less than an entire course, and 24 percent had an entire course.

- 44.5 percent received CME instruction in prescribing controlled drugs; 32.3 percent had a few hours or less, 39.9 percent had more than a few hours but less than an entire course, and 26.4 percent had an entire course.

- 59.3 percent of physicians received CME instruction in pain management; 31.3 percent had a few hours or less, 36.8 percent had more than a few hours but less than an entire course, and 30.6 percent had an entire course.

In Tennessee, physicians who are deemed “over-prescribers” must take a CME course on proper prescribing practices. The Robert Wood Johnson Foundation teamed with Vanderbilt University to create a program specifically focusing on physicians who are reportedly misprescribing controlled substances. The course allows practitioners (physicians and dentists) to discuss their prescribing practices and learn how to avoid future problems.

CASA’s survey of pharmacists found that, since attending pharmacy school, approximately one-third received information from continuing education courses or seminars on dispensing prescription controlled drugs, identifying abuse or diversion or preventing diversion. Other sources from which pharmacists received information include state boards of pharmacy, state DEAs or law enforcement, professional associations, professional journals, employers, pharmaceutical companies and colleagues.

Mandatory re-licensure, which would include both passing an exam and looking at some doctors’ records, really would force physicians to actually learn as opposed to the passive thing [CME credits].

--Sidney M. Wolfe, MD
Director, Public Citizen’s Health Research Group
CASACONFERENCE, Feeling No Pain: Substance Abuse, Addiction and Pain Management
February 27, 2003

Adequacy of Training

Only about one-third of physicians (37.5 percent) and half (50.7 percent) of pharmacists rated the education/training they received in preventing the abuse and/or diversion of controlled prescription drugs as good or excellent. Older pharmacists (those over age 50) were significantly likelier to rate their training as better than younger pharmacists (those age 50 and younger).

Two-thirds of physicians (67.6 percent) and 97 percent of pharmacists think that they are somewhat or very knowledgeable about controlled substances laws and regulations. However, less than a third of physicians believe that federal (31.0 percent) and state (30.3 percent) laws are “very or somewhat” clear and six in 10 pharmacists believe that federal (59.0 percent) and state (62.4 percent) laws are “very or somewhat” clear on what actions they should take if they believe a patient is diverting or abusing controlled prescription drugs.

When asked what were their most valuable sources of information about controlled
prescription drugs, most physicians (83.7 percent) and pharmacists (90.0 percent) cited work experience and about half of physicians (50.6 percent) and pharmacists (46.6 percent) cited colleagues. (See Table 7.1 for additional responses.)

<table>
<thead>
<tr>
<th>Source of Knowledge</th>
<th>Physicians</th>
<th>Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work experience</td>
<td>83.7</td>
<td>90.0</td>
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<tr>
<td>Colleagues</td>
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<td>46.6</td>
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<tr>
<td>Internship/Residency/Fellowship</td>
<td>43.1</td>
<td>11.5</td>
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<tr>
<td>Journal articles</td>
<td>42.6</td>
<td>39.6</td>
</tr>
<tr>
<td>Continuing education courses</td>
<td>39.1</td>
<td>66.8</td>
</tr>
<tr>
<td>Pharmacology course</td>
<td>27.5</td>
<td>36.3</td>
</tr>
<tr>
<td>Reference books</td>
<td>17.0</td>
<td>20.2</td>
</tr>
<tr>
<td>Information from drug product manufacturers</td>
<td>16.6</td>
<td>19.8</td>
</tr>
</tbody>
</table>

Although 71.5 percent of physicians and 71.7 percent of pharmacists agree that it is lawful to prescribe opioids to patients with chronic pain who have a history of substance abuse, 5.8 percent of physicians and 9.0 percent of pharmacists inaccurately thought it was not lawful; 18.4 percent of physicians and 16.5 percent of pharmacists did not know whether it was lawful. Three in five physicians (64.8 percent) and pharmacists (61.7 percent) thought that patients with chronic pain who have a history of substance abuse should be discouraged from taking opioids.

One-third of the physicians (35.9 percent) and half of the pharmacists (50.4 percent) believe that, when taken as prescribed, opioids carry a high risk of addiction; 47.1 percent of physicians and 41.8 percent of pharmacists believe that CNS depressants put a patient at high risk of addiction and 19.0 percent of physicians and 24.9 percent of pharmacists believe that stimulants do so. Overwhelmingly, respondents (61.6 percent of physicians and 79.3 percent of pharmacists) believe that opioids are the most frequently abused controlled prescription drug.

Most physicians (80.0 percent) feel qualified to diagnose prescription drug abuse and addiction and most physicians (81.9 percent) and pharmacists (86.6 percent) are confident of their ability to know when a person is seeking controlled prescription drugs for purposes of abuse and/or diversion. Those who had received training/instruction in dispensing controlled drugs, identifying prescription drug addiction and/or preventing diversion were significantly more likely than those without such training/instruction to be confident of their ability to detect diversion and abuse.

Despite these physician reports of confidence in their ability to address these issues, CASA’s 2000 study, *Missed Opportunity: National Survey of Primary Care Physicians and Patients on Substance Abuse*, found that only 6.2 percent of primary care physicians identified substance abuse as one of their five diagnoses when presented with a hypothetical patient with clear early symptoms of alcohol abuse. A similar survey of physicians was conducted for CASA’s 1998 report, *Under the Rug: Substance Abuse and The Mature Woman*, in which physicians were presented with a hypothetical case of a 68-year old female patient with symptoms consistent with alcohol or prescription drug abuse and asked to offer five possible diagnoses. In this case, only one percent of the physicians surveyed offered substance abuse as a possible diagnosis.

In a study conducted at the University of Wisconsin Medical School in Madison, 2,000 physicians were asked how they would treat a set of hypothetical patients who suffered from anxiety disorders, pain associated with cancer or back pain. The researchers gave the physicians detailed profiles of the hypothetical patients, including a treatment history, current alcohol use and a history of substance abuse. The physicians’ responses were compared to a treatment plan developed by a panel of experts. Compared to the experts, the physicians who participated in the study were more reluctant to provide opioids and less cautious about prescribing sedatives.
CASA’s *Missed Opportunity* study found that 46.6 percent of primary care physicians find it difficult to discuss prescription drug abuse with patients for whom they prescribe the medications. Such lack of patient education may lead to under- or over-use of potentially addictive medications.

Medical school education provides students with pharmacology information but often does not adequately address issues of pharmacotherapy, such as the use of combination drugs, drug interactions, compliance issues, dosage reductions in the elderly and how to appropriately prescribe psychoactive drugs.

A comparison of surveys of medical board members in 1991 and 1997 reveals that medical board members have become more open to the notion of prescribing opioids, even to patients with non-cancer pain and to patients with pain who have a history of abusing opioids. This may be due to the increased efforts during the mid-1990s of pharmaceutical companies and pain management advocacy groups to encourage physicians to treat patients suffering from non-cancer chronic pain with prescription opioids.

Most physicians and pharmacists in CASA’s survey would be interested in receiving additional education or training in prescribing controlled substances (61.2 percent of physicians, 67.6 percent of pharmacists), in identifying prescription drug abuse/addiction (69.4 percent of physicians, 79.9 percent of pharmacists), and in identifying prescription drug diversion (70.9 percent of physicians, 81.0 percent of pharmacists).

Health Professional Students for Substance Abuse Training (HPSSAT)

HPSSAT is a project of the Physician Leadership on National Drug Policy (PLNDP). The goal of HPSSAT is that all graduating health professional students have the skills to appropriately screen, diagnose and provide intervention for patients with substance abuse problems...HPSSAT aims to impact the education of students throughout the array of health professions and to increase and improve health professional student training and education in substance abuse prevention and treatment. Members help to identify and understand the core requirements for adequate substance abuse prevention and treatment training and serve as advocates for local and national educational reform.

A journal article written more than 10 years ago denounced the lack of attention paid to prescribing practices by medical school curricula. The article concluded with a call for action within the next decade by the Association for Medical Education and Research in Substance Abuse (AMERSA), American Society of Addiction Medicine (ASAM) and American Academy of Psychiatrists in Alcohol and Addiction (AAPAA) to work with medical schools to create teaching standards. Still today, more than 10 years after the publication of this article, the need for improved education on prescribing controlled substances in medical schools is largely unmet.

Health Professional Education and Training About Diversion and Abuse of Controlled Prescription Drugs

The only thing I got was our third year of school...it was one day, it was a video.

They tell you about it but don’t make a big deal out of it.

--Veterinarians

I can’t recall any on the job training.

--Pharmacist

When I went to medical school, there was no education about any of this.

When I went to medical school, there wasn’t any formal education...but if you had an interest, you pursued it.

--Physicians

CASA Focus Groups
Educational Resources

Other than continuing education courses, much of the professional education on diversion, abuse and pain management relies on a few isolated efforts across the nation, including outreach programs facilitated by state or local community programs, education campaigns by federal organizations such as the National Institute on Drug Abuse (NIDA), newsletters from state medical boards, pamphlets and informational brochures.

State and local community efforts. A few states and local communities have initiated prescription drug abuse educational programs.23 For example, Commander John Burke, director of the Warren County Ohio Drug Task Force and architect of the Police Division’s Pharmaceutical Diversion Squad, created Pharmaceutical Diversion Education (PDE), based in Ohio. This program was designed to educate healthcare practitioners and law enforcement officials to better understand, identify and prevent diversion and abuse of controlled prescription substances.24

In Hawaii, pharmacy interns are recruited from local universities to work directly with the Hawaii Narcotic Enforcement Division to learn about diversion and abuse of controlled prescription substances and how to prevent diversion.25 In Virginia, a paid course in drug diversion is offered (on a voluntary basis) to law enforcement officials, teaching them how to carry out investigations on the diversion of controlled prescription drugs.26 Aside from a few notable exceptions, community-based efforts to address prescription drug diversion and abuse are rare.

Pamphlets, fact sheets and tips. Various pamphlets, fact sheets and tips have been developed for practitioners and law enforcement officials to help educate them about how to prevent and identify prescription drug diversion and abuse. For example, the DEA created a guide in 2000 for pharmacists to help them spot fraudulent prescriptions27 and has created a list of characteristics to help practitioners identify patients who are abusing prescription drugs.28 The American College of Physicians devised 10 questions to help practitioners identify patients who may be diverting or abusing prescription drugs.29 NIDA presents four simple questions for patients and providers to help identify if someone has a problem with prescription drugs.30 Although potentially useful, the extent to which these informational resources reach practitioners is unknown.

The few, isolated efforts to educate healthcare providers about prescription drug diversion and abuse through continuing education courses, community efforts and regulatory agencies’ and associations’ guidelines have had only a limited reach and their efficacy is unknown.

Prevention

Despite evidence of the magnitude of controlled prescription drug diversion and abuse in the U.S., current preventive measures remain sparse. Prevention efforts have been launched primarily by the federal government and pharmaceutical companies that manufacture abused and diverted drugs.

In April 2001, NIDA mounted a public education initiative on prescription drug abuse in response to reports of increased abuse of prescription opioids and concern over the abuse of other controlled prescription drugs.31 As part of the initiative, NIDA distributed 400,000 postcards containing messages about the dangers of prescription drug abuse to restaurants, bookstores, clubs, record stores, coffee shops, gyms and other locations in several major cities.32 The Substance Abuse and Mental Health Services Administration (SAMHSA), in conjunction with the FDA released an educational campaign, “Misuse of Prescription Pain Relievers: The Buzz Takes Your Breath Away--Permanently” which targets youth and warns them of the consequences of abusing prescription pain relievers.33

Novartis, the pharmaceutical company that manufactures the stimulant Ritalin has created a prescription drug abuse prevention program.34 S.T.A.R.T (Straight Talk About Responsible
Treatment), a public education campaign, focuses on the safe use of stimulants for the treatment of attention deficit hyperactivity disorder (ADHD). 35 Their brochures and educational Web site are aimed at children, parents and school officials.36

In response to the abuse of OxyContin, the DEA called on Purdue Pharma LP to create a marketing strategy to educate practitioners and the public about the correct usage for this medication and to warn the public about dangers of abusing it.37 The company outlined and has begun implementing a 10-point plan to address the diversion and abuse of OxyContin.38

As part of the plan, Purdue Pharma also created the Painfully Obvious program, a public service campaign aimed at middle and high school students to raise awareness and educate parents, teachers and students about the dangers of abusing prescription medicines.39

No formal independent evaluations of the effectiveness of these programs in preventing prescription drug abuse are available.

**Clinical Prevention Methods**

Before prescribing medications, healthcare providers should consider a patient’s substance abuse and medication history, work with patients to help ensure adherence to the drugs they prescribe for maximum effectiveness and abide by the laws that govern the administration of controlled substances. To meet these requirements, a clinician may employ a variety of tools that can be used to help make certain that patients receive the medications they need and that those who are diverting or abusing drugs are identified.

### Insurance Company’s Suggested Guidelines

Some insurance companies provide educational materials to healthcare practitioners and to patients. Unfortunately, in some cases, their efforts miss the mark. For example, one large insurer in New York State produced a packet of material on pain control for physicians. A sample initial patient evaluation form is provided, yet no questions about prior or current substance use are included.41

### Medication contracts/agreements

Medication contracts or agreements are written agreements between a doctor and patient, and are used to help the doctor obtain informed consent from the patient, to provide education to the patient regarding the medication, and to help ensure adherence to the prescribed drug regimen.42 Contracts or agreements most often are used when opioids (as opposed to other controlled substances) are prescribed. These agreements are intended to outline how much of a medication should be taken and when, and the associated side effects and risks.43 A broken agreement can provide information to physicians that may be helpful in identifying and diagnosing substance abuse problems.44 There is some controversy and a lack of research on the usefulness of these contracts.45 CASA’s survey of physicians found that 36.9 percent usually create medication contracts when they suspect a patient of abusing or diverting controlled prescription drugs.

### Urine drug testing

Urine drug testing is used to monitor whether a patient has taken a prescribed or illegal drug. There are two main purposes of urine tests: (1) to detect abuse—whether or not a patient is complying with the prescribed dosage regimen; and (2) to detect
diversion—if the patient claims to be taking the drug but it does not appear in the urine test. CASA’s survey of physicians found that only 27.8 percent usually require urine tests when they suspect a patient of abusing or diverting controlled prescription drugs.

**Pill counts.** Pill counts sometimes are used when addiction or abuse is suspected. Patients are instructed to return to the physician or visit a nearby pharmacy after a given number of days with the prescribed bottle of pills to ensure that the correct number of pills remains and that abuse or diversion has not occurred. CASA’s survey of physicians found that only 23.1 percent usually conduct pill counts when they suspect a patient of abusing or diverting controlled prescription drugs.

**Protecting prescriptions.** There are various actions a physician can take to prevent drug seekers from altering prescriptions. One such method is using tamper free prescription pads that are designed to help prevent forgery. Physicians can write prescriptions so that it is difficult to change or alter the prescribed drug dosage (e.g., write out the dose in words instead of numbers—for example it is easier to add a zero to the number “10” to make it “100” than to modify the word “ten” into the word “hundred”) and to keep their prescription pads in a safe place where patients do not have access.

**Additional approaches.** A number of other tactics can be employed to address diversion and abuse such as asking for a second opinion from another clinician, calling other physicians that the patient visits, providing the patient with educational materials about abuse and addiction, and paying close attention to easing patients off the drug. While much medical attention is paid to prescribing drugs to treat health problems and reduce symptoms, physicians may be less likely to attend to the process of helping patients recognize signs that they may be becoming addicted to a drug or helping them to taper off a medication as conditions improve.

Unfortunately, the number of clinicians who use these approaches is limited. Some do not do so because they are uninformed and others choose not to make these issues a priority in their practices.

**Treatment**

No data exist that document how many of those who need treatment for prescription drug addiction receive it. However, nationwide only 16.6 percent of those in need receive any kind of substance abuse treatment and only 11.4 percent of underage youth in need receive such treatment. It is likely that the proportion of prescription drug abusers who receive treatment is even lower.

Treatment options for prescription drug abuse and addiction are similar to those available for illicit drugs; however, the effectiveness of these treatments has been investigated primarily for illicit drugs, not for prescription drugs. The two main types of treatment available are behavioral and pharmacological, and can be administered in either inpatient or outpatient settings. Pharmacological and behavioral techniques can be used separately, but often are combined for a more effective approach to treatment. Self-help interventions, such as twelve-step programs, also are used to help patients cope with prescription drug-related problems.

**Behavioral Treatments**

Behavioral treatments include individual and group counseling and cognitive behavioral therapy (CBT). Inpatient programs tend to cater to middle-class patients and those with a co-occurring psychiatric problem. Typically, inpatient programs last up to 12 weeks, beginning with detoxification followed by various types of group or individual therapy. Some opioid abusers—including those who abuse prescription opioids—receive longer-term treatment in residential therapeutic communities (TCs).

**Pharmacological Treatments**

Pharmacological or medication treatments—used most commonly for opioid addiction—help to
alleviate withdrawal symptoms and reduce drug cravings. Before becoming involved in long-term treatment, those addicted to opioids often undergo detoxification. Detoxification helps individuals withdraw from a drug under the supervision of a medical professional. Once withdrawal symptoms subside, the patient undergoes pharmacological or behavioral treatment or both. Four pharmacological treatments for opioid addiction are used today: methadone, levo-alpha-acetyl-methadol (LAAM), naltrexone and buprenorphine.

**Methadone.** The most common pharmacological opioid addiction treatment is methadone maintenance. Methadone is a long-acting synthetic opioid that blocks the effects of the prescription or illicit opioid to which the patient is addicted, eliminates withdrawal symptoms and helps reduce drug cravings. Methadone is taken orally once a day and its effects last between 24 and 36 hours. Methadone maintenance requires frequent visits to certified clinics that administer the drug. Methadone is a Schedule II controlled drug and, as such, patients on methadone may become physically dependent on it (need to keep taking it) and experience cognitive difficulties and depression.

**LAAM.** Although methadone traditionally has been the most common pharmacological treatment administered to patients addicted to opioids, levo-alpha-acetyl-methadol (LAAM) also can be used and, like methadone, must be dispensed through certified clinics. LAAM is a long-acting synthetic opioid; whereas methadone must be administered daily, LAAM is administered only about three times per week. Like methadone, LAAM is a Schedule II controlled substance that blocks the euphoric effects of opioids and controls drug cravings. Yet, because of its slower onset and sustained action properties, LAAM is less likely than methadone to cause feelings of sedation, putting it at lower risk for abuse.

**Naltrexone.** Naltrexone, a non-controlled drug, blocks the opioid receptors in the brain and, consequently, the euphoric effect caused by the opioid. Naltrexone does not produce a high or symptoms of tolerance, nor is it psychologically addicting. Naltrexone is used to maintain abstinence approximately two weeks after a person has been detoxified. Any physician can prescribe the medication. Because it must be taken daily, it typically requires close supervision to maintain the regimen. Those who relapse while on naltrexone are at increased risk for overdose death. Naltrexone works best when used in a treatment program that requires complete abstinence from the drug to which the patient is addicted.

**Buprenorphine.** Buprenorphine, a Schedule III drug, is an opioid much like morphine but does not produce a high and has lower risk of abuse, physical dependence (fewer withdrawal symptoms) and overdose death. Compared to naltrexone, buprenorphine is more effective in reducing drug cravings and there is a lower risk of abuse and overdose than with methadone or LAAM.

The FDA approved two formulations of buprenorphine for treatment of opioid dependence. These formulations, Subutex and Suboxone, differ from each other in that Suboxone contains added naloxone which can result in intense withdrawal symptoms if abused intravenously and then stopped, helping reduce abuse of the drug by intravenous injection. Subutex is used in the first few days of treatment and Suboxone is used for maintenance therapy.

Trained physicians, who receive a special license from the DEA, may prescribe and administer buprenorphine in an office setting rather than in specially licensed narcotic treatment clinics. Physicians certified as addiction specialists are exempt from the training requirements. The Drug Addiction Treatment Act (DATA) of 2000 requires that physicians treat no more than 30 patients at a time with this medication and that prescribing physicians refer patients to counseling and other psychosocial treatment.
Although more research is needed, some proponents argue that buprenorphine will lead to better access to treatment for those with an opioid addiction because the medication regimen that patients must follow with buprenorphine is more convenient than with other treatments in terms of method and frequency of administration.\textsuperscript{79}

Although buprenorphine appears to have many advantages,\textsuperscript{80} further analysis is needed to determine its effectiveness.\textsuperscript{81} NIDA is taking steps to study the potential therapeutic use of buprenorphine in the treatment of patients with prescription opioid abuse and dependence, some of whom also may suffer from chronic pain.\textsuperscript{82}

**Treatment for CNS Depressant or Stimulant Addiction**

Little to no progress has been made in treating addictions to prescription CNS depressants or stimulants via pharmacological therapies.\textsuperscript{83} Treatment for CNS depressant or stimulant addiction consists primarily of behavioral therapies. Professional treatment is important to help individuals taper off the drug safely, deal with withdrawal symptoms and prevent relapse. Counseling and CBT are used to help recovering individuals cope with the effects of quitting and with life stress that may lead to relapse.\textsuperscript{84}

**Self-Help Programs**

Self-help (typically twelve-step) programs require total abstinence from drugs.\textsuperscript{85} Patients work through the 12 steps of these programs to reach and maintain sobriety. Examples of twelve-step programs designed specifically for prescription drug abuse include Prescription Drugs Anonymous, Narcotics Anonymous, Pills Anonymous and Benzodiazepine Anonymous. Research regarding the effectiveness of these programs--although limited--suggests that self-help approaches in combination with science-based therapy typically produces better outcomes than either approach used alone.\textsuperscript{86}

\textit{A qualified physician will be able, for the first time, to prescribe an anti-addiction medication in an office setting and treat opiate addiction as any other chronic disease.}\textsuperscript{78}

--Charles G. Curie, MA, ACSW, Administrator
Substance Abuse and Mental Health Services Administration
Chapter VIII
Recommendations for Change

While rates of illicit drug use for the most part have been stable or declining, the abuse of controlled prescription drugs has been increasing sharply. The greatest increases can be seen in abuse rates among teens and young adults. In spite of public misperceptions that abuse of prescription drugs is comparatively safe, increases in such abuse are reflected in more emergency room visits and the high number of controlled prescription drug-related deaths. Prescription drug abuse has become a major public health problem, affecting more people than the abuse of cocaine, hallucinogens, inhalants and heroin combined.

Despite the health consequences of this trend, America’s response to date has focused primarily on law enforcement. If we are to curb this growing problem and its disastrous consequences, we must train doctors, pharmacists and other healthcare professionals to spot the problem and know how to respond; educate the public about risks; tailor prevention and intervention to the unique characteristics of abusers; and assure appropriate and accessible treatment.

At the same time we must reduce availability by stopping the sale of controlled prescription drugs on the Internet, improving our ability to monitor diversion, cracking down on criminals and script doctors, enforcing drug importation laws, regulating advertising and marketing practices and reformulating drugs where possible to reduce their abuse potential. And parents who are using controlled prescription drugs must take steps to keep them out of the reach of their children.

CASA recommends the following actions to prevent and reduce diversion and abuse while assuring availability of controlled prescription drugs for medical purposes. A complete list of recommendations by responsible party is included as Appendix I.
**Train Healthcare Providers**

- The associations of healthcare training institutions should require education and training—including medical school and residency training, post-graduate fellowships and continuing medical education—in prescribing and administering controlled drugs; identifying diversion; identifying, diagnosing and treating substance abuse and addiction; and identifying, diagnosing and treating psychiatric disorders and pain in ways that minimize the risk of abuse and addiction. These associations include: The Association of American Medical Colleges (AAMC), the American Dental Education Association (ADEA), the Association of American Veterinary Medical Colleges (AAVMC), the American Association of Colleges of Nursing (AACN) and the American Association of Colleges of Pharmacy (AACP).

- The American Board of Medical Specialties should require that knowledge in identifying, diagnosing and treating substance abuse, addiction and the prescribing/administering of controlled drugs be part of its minimum standards of competency.

- State professional boards should require that, as a condition of licensure, license renewal or registration, healthcare professionals complete training in substance abuse, addiction, pain management and the legal regulations and responsibilities related to the prescribing and dispensing of controlled drugs.

- The DEA should require that as a condition of becoming registered to prescribe or administer controlled drugs, physicians demonstrate competence in prescribing controlled substances and physicians and pharmacists demonstrate knowledge of the Controlled Substances Act, how to recognize the signs and signals of diversion and abuse and how to respond in the event of suspicion of a patient or professional colleague.

- The DEA should include relevant educational material in correspondence with healthcare professionals, including the mailing of licenses or prescription pads.

- National professional boards (medical, dental, nursing, pharmacy, veterinary) should establish, publicize and enforce national standards of practice related to substance abuse, addiction and the prescribing, administering and monitoring of controlled prescription drugs. Standards should include: use of screening and diagnostic tools; assessing patients’ past use of controlled medications; prescribing and administering controlled substances; monitoring patients’ drug use and routine reevaluation of the medication’s efficacy and need for continued use; identifying complications of care including signs of diversion or abuse; safeguarding controlled prescription drugs; and preventing prescription fraud. Healthcare providers also should be trained to employ techniques such as patient contracts, urine tests and pill counts, as indicated, to limit diversion. At the same time, professional boards should establish, publicize and enforce standards related to pain management and assure that physicians provide quality care to their patients in a way that reduces the risk of addiction to pain medications.

**Strengthen Efforts to Control Internet Diversion**

- Congress should clarify federal law to prohibit sale or purchase of controlled prescription drugs on the Internet without an original copy of a prescription issued by a licensed, DEA-certified physician, licensed in the state of purchase, based on a physical examination and evaluation, and to impose higher penalties for illegal sale to minors.

- Congress should require Internet search engines to provide warnings that sale and purchase of controlled prescription drugs over the Internet from unlicensed pharmacies and physicians and without
prescriptions are illegal and to block sites that fail to require a legitimate prescription for selling controlled prescription drugs.

- The DEA and state Attorneys General should encourage financial institutions (credit card and money order issuers) to restrict purchases of controlled prescription drugs from non-licensed and accredited providers.

- The DEA and state Attorneys General should encourage postal and shipping services to train counter and delivery personnel to recognize potential signs of pharmaceutical trafficking and to know how to respond in the event of suspicious activity.

- The Office of National Drug Control Policy (ONDCP), DEA and FDA should carry out their intention to develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making online purchases of controlled substances.

- The State Department should encourage and assist foreign governments to crack down on Internet sites illegally selling controlled prescription drugs to U.S. citizens.

**Strengthen Monitoring and Enforcement to Prevent and Detect Diversion**

- The U.S. Department of Justice and the FDA should fund the development of model state legislation for state prescription drug monitoring programs (PDMPs), and provide financial incentives for states to develop and operate PDMPs in accordance with national standards. Such legislation would protect patient privacy, assure physicians and pharmacists access to patient data, provide law enforcement officials with access based on probable cause, provide for interstate data sharing and stipulate specific outcome measures to determine the efficacy of state PDMPs.

- The DEA should work with state medical boards to train law enforcement professionals (including state and local police and prosecutors) to better understand therapeutic uses of controlled prescription medications and conditions under which the medical community recommends their use in treating patients. Law enforcement should work closely with medical professional groups to develop diversion control strategies that would not produce an unnecessary chilling effect on physicians who treat patients in need of controlled prescription drugs.

- Federal, state and local law enforcement authorities should simplify the process of reporting suspected cases of diversion in order to encourage health professionals and pharmacists to do so.

- Federal and state governments should ensure adequate staffing of law enforcement and prosecutors to pursue cases of controlled prescription drug diversion and enact significant sanctions on clinicians and pharmacists who intentionally divert controlled prescription drugs.

- Federal agencies should step up enforcement of drug importation laws related to the sale of controlled prescription drugs and enforce international conventions.

- Congress should enact legislation prohibiting direct-to-consumer advertising of controlled prescription drugs on the grounds that it poses a danger to the public health and is contrary to the spirit of the Controlled Substances Act.

**Strengthen FDA Regulation of Controlled Prescription Drugs**

- The FDA should require pharmaceutical companies manufacturing controlled drugs to formulate or reformulate the drugs where possible to minimize the risk of abuse. Pharmaceutical companies should be required to demonstrate in their application
materials for FDA approval of new drugs that they have made every effort to formulate the drug in such a way that avoids or at least minimizes the drug’s potential for abuse.

- The FDA should require pharmaceutical companies to include proactive risk management plans in all new applications for controlled drugs, demonstrating strong evidence of a prescription drug’s safety and incremental benefits relative to existing drugs, as well as concrete steps that will be taken to prevent the abuse of the drug while maintaining its maximum therapeutic effectiveness.

- The FDA should require all pharmaceutical companies to submit promotional materials for controlled prescription drugs to the FDA for review and approval prior to their use.

- The FDA should require that a pedigree (the documented sales history of a drug) accompany all controlled prescription drugs sold by wholesalers and retailers in order to help prevent counterfeiting and track stolen drugs.

**Safeguard Controlled Prescription Drugs From Children**

- Parents should safeguard their prescription medications from their children, refrain from conveying through words or actions messages that condone casual use of prescription drugs, and be vigilant about their children's use of controlled medications prescribed to them to ensure that their children are taking the drugs appropriately and not selling or sharing them.

- Parents also should take steps to make sure their children are not using the Internet to acquire controlled prescription drugs.

**Improve Treatment for Prescription Drug Abuse and Addiction**

- Assure access to appropriate treatment for: teenagers for whom prescription drug abuse often is part of a larger drug problem; adults for whom prescription drugs is their main drug problem and who may have become addicted to these drugs inadvertently as a result of using or misusing prescribed medications; and adult poly-substance abusers who more closely resemble the larger drug-abusing population and who need treatment options that address their abuse of prescription drugs in addition to their abuse of other substances, while not compounding their addiction.

- Treatment programs should make medical assessment a standard part of treatment for prescription drug abusers so that any underlying medical condition (e.g., pain, ADHD, insomnia) that might compromise treatment for abuse can be addressed.

- Treatment programs should address co-occurring disorders and, where appropriate, combine evidence-based behavioral therapy with available pharmacological interventions.

- Federal and state mandated benefit laws should require managed care and private health insurance companies to reimburse physicians and dentists for time spent screening patients for substance abuse and addiction, referring them to treatment if needed and costs of treatment, and collaborating with pharmacists to prevent diversion and abuse.

**Educate the Public on the Dangers of Prescription Drug Abuse**

- Government-sponsored public awareness campaigns that focus on alcohol, marijuana and other illicit drugs should include the abuse of controlled prescription drugs as well as the dangers of poly-substance abuse.
• Government-sponsored public awareness campaigns should inform parents to safeguard their prescription drugs from their children, and advise individuals and families to dispose properly of unused controlled medications.

• Schools and communities should incorporate prescription drug abuse, including steroid abuse, into evidence-based substance use prevention programs, beginning with elementary school and continuing through college.

**Improve Surveillance and Research**

• To better inform policy, prevention and treatment initiatives, national surveys of drug use (e.g., the National Survey on Drug Use and Health, the Monitoring the Future study) should refine their measures of prescription drug abuse and addiction, use a consistent terminology in referring to these problems and add questions asking respondents how they obtained the prescription medications that they abused.

• The DSM-IV diagnostic categories for substance-related problems should be amended to take into consideration the unique aspects of prescription drug abuse and addiction, distinguishing between physical dependence and addiction.

• Federal agencies (e.g., National Institute on Drug Abuse, Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration) should fund systematic and well-designed studies to better understand prescription drug diversion and abuse. Such research might include studies examining:
  - The conditions under which legitimate medical use of controlled prescription drugs leads to abuse or addiction, the timing of prescription drug abuse relative to the abuse of other substances and the relationship between the abuse of controlled prescription drugs and illicit drugs;
  - Risk and protective factors for prescription drug abuse;
  - The relationship between the availability/supply of controlled prescription drugs and their likelihood of abuse;
  - The effectiveness of current programs aimed at tracking, preventing or reducing prescription drug abuse and diversion;
  - The impact of diversion prevention programs on the therapeutic use of controlled medications;
  - The development of validated screening tools for identifying and/or diagnosing prescription drug abuse.
  - The development of new pharmacological and psychosocial treatments for prescription drug abuse.
Appendix A  
National Data Sets Analyzed

Arrestee Drug Abuse Monitoring Program (National Institute of Justice)

Automation of Reports and Consolidated Orders Systems (Drug Enforcement Agency)

Community Epidemiology Work Group (National Institute on Drug Abuse)

Drug Abuse Warning Network (Substance Abuse and Mental Health Services Administration)

Express Scripts Drug Trends (Express Scripts)

Monitoring the Future Study (National Institute on Drug Abuse)

National Comorbiditity Survey (Harvard Medical School)

National Prescription Audit Plus (Intercontinental Marketing Services)

National Survey of Alcohol, Drug and Mental Health Problems (RAND Corporation)

National Survey on Drug Use and Health (Substance Abuse and Mental Health Services Administration)

Survey of Adults on Probation (Bureau of Justice Statistics)

Survey of Inmates in State and Federal Correctional Facilities (Bureau of Justice Statistics)

Survey of Inmates of Local Jails (Bureau of Justice Statistics)

Treatment Episode Data Set (Substance Abuse and Mental Health Services Administration)

Youth Risk Behavior Surveillance (Centers for Disease Control and Prevention)
Appendix B
Interviews and Focus Groups Methodology

To inform the report and the development of CASA’s national surveys of pharmacists and physicians, interviews and focus groups were conducted with those on the front lines of providing and receiving clinical care--physicians, pharmacists, veterinarians and dentists, as well as individuals suffering from an addiction to controlled prescription drugs.

CASA sub-contracted with the Survey Research Laboratory (SRL) of the University of Illinois at Chicago (UIC) to conduct two focus groups with 14 physicians (May 19 and May 20, 2004), two with 16 pharmacists (May 12 and May 13, 2004) and one with six veterinarians (May 3, 2004). Physicians and pharmacists were recruited from a list purchased from Medical Marketing Services, Inc. An attempt was made to recruit a mix of different types of physicians, such as primary care doctors and psychiatrists. In addition, different types of pharmacists were recruited (e.g., chain drug store pharmacists, independent pharmacists). Veterinarians were recruited from a list purchased from the Illinois Department of Regulation. Each of the focus groups was conducted in Chicago and led by a professional moderator.

CASA research staff conducted a focus group with eight family physicians in Lake Placid, NY at the annual New York State Academy of Family Physicians Winter Weekend Scientific Assembly on January 30, 2004.

CASA research staff conducted a focus group in New York City on May 5, 2004 with five dental specialists--endodontists, periodontists and oral surgeons. In addition, six individual phone interviews were conducted with general dentists and oral surgeons between April and August of 2004. These general dentists and dental specialists were recruited from lists of the Columbia Dental Plan, which consists of a network of faculty and alumni from the Columbia University School of Dental and Oral Surgery.
CASA research staff conducted a series of 19 one-on-one, in-person interviews with individuals receiving inpatient treatment for a primary prescription drug abuse problem at the Caron Foundation in Wernersville, PA. Caron is an addiction, co-dependency and chemical dependency treatment center. Male and female participants ranged in age from 21 to 52.

CASA’s Institutional Review Board (IRB) granted approval to conduct the focus groups and interviews. Additional IRB approval was granted by the University of Illinois for the focus groups conducted by SRL. In all cases, participants provided informed consent prior to taking part in the focus groups and interviews. All participants were adults.
Appendix C
National Survey of Physicians and Pharmacists Methodology

To learn about the perceptions and experiences of health professionals regarding prescription drug diversion and abuse on the clinical level, CASA conducted two national mail surveys of physicians and pharmacists. CASA sub-contracted with the Survey Research Laboratory (SRL) of the University of Illinois at Chicago (UIC) to recruit the samples and collect the data. CASA staff designed the surveys and conducted the data analyses.

Sampling Plan

The study design included a stratified, random sample of physicians and pharmacists throughout the U.S. Physicians were eligible only if currently in practice. Those who only conduct research were omitted. The physician sample covers a variety of specialties, including psychiatry, family practice, emergency medicine and internal medicine. The sample was purchased from Medical Marketing Services (MMS), a sample vendor specializing in medical industry lists.

Questionnaire Development

Two separate questionnaires were drafted for physicians and pharmacists, in order to reflect the differences in their professional practices and their interactions with prescription drugs. The questions were derived (either in whole or conceptually) from prior surveys of physicians and pharmacists (e.g., surveys from the Pain and Policy Studies Group, University of Wisconsin, Madison; Joranson and Gilson), suggestions from experts in medicine and pharmacy concerned with the topic of prescription drug diversion and abuse and input from physicians and pharmacists participating in CASA’s focus groups. Both questionnaires addressed the following elements:
• Awareness of prescription drug diversion and abuse;

• Perception of prescription drug diversion and abuse;

• Training in diversion control;

• Knowledge of prescription drug abuse and the effects of controlled medications on patients, including their abuse potential;

• Perceptions of prescription drug monitoring programs;

• Knowledge of laws and regulations regarding prescribing and dispensing controlled substances; and

• Demographic information.

Physicians were asked questions related to prescribing controlled substances and pharmacists were asked about their dispensing practices.

SRL’s Questionnaire Review Committee (QRC) reviewed both questionnaires. QRC, which consists of SRL staff members appointed by the Director, examines all questionnaires administered by SRL to ensure they follow ethical practices and basic principles of questionnaire construction.

Data Collection Protocol

The first questionnaire mailing was sent to all physicians and pharmacists in the sample. The mailing included the following: a cover letter from SRL explaining the purpose of the study, a copy of the appropriate questionnaire and a postage-paid return envelope. Also included in the mailing was a consent form which explained in further detail the reason for the research, as well as information on the potential risks, discomforts and benefits, privacy and confidentiality, and the telephone numbers for both the study project coordinator and the UIC Office for the Protection of Research Subjects.

CASA’s Institutional Review Board (IRB) approved the surveys and the associated consent forms. Respondents were asked to sign and date the consent form and return it along with their completed questionnaire. To maximize response rates, a cash incentive of $5 was included in the mailing. Pharmacists also received letters of support from the National Association of Chain Drug Stores Foundation and the American Society of Health-System Pharmacists. Approximately one week after the initial mailing, the entire sample received a postcard reminding them to complete the survey and thanking those who already had. Two weeks after that, a second packet was mailed to all remaining non-respondents. This packet included a cover letter from SRL, a copy of the questionnaire, a consent form and a postage-paid return envelope. The cover letter was revised to acknowledge that SRL had not yet received a completed questionnaire from the respondent. About three weeks after the initial mailing, one final letter was mailed to all remaining non-respondents.

Pretest

Seventy-five cases were included in the pretest: 25 physicians, 25 psychiatrists and 25 pharmacists. The pretest mailing was sent out on June 17, 2004 and included a cover letter explaining the study, a consent form, a $5 cash incentive, a questionnaire and a postage-paid return envelope. The packet sent to pharmacists also contained a letter of support from the National Association of Chain Drug Stores Foundation and the American Society of Health-System Pharmacists. A reminder postcard was sent to non-respondents one week later. The pretest yielded 22 completes. After reviewing the pretest completes, the instrument was modified to include unanticipated response categories.

Dates of Data Collection

Physicians and pharmacists were mailed the first packet on July 21-22, 2004 and a thank you/reminder postcard was sent approximately one week later, on July 30,
2004. The second mailing was sent on August 16, 2004 to those who had not yet responded and a third and final mailing was sent on August 27, 2004.

**Data Processing**

The SRL Office of Survey Systems checked and cleaned the data to ensure that any answers that did not fit into the response option parameters were caught and corrected. A final dataset and SPSS setup file were then created for the study.

**Response Rates**

The total response rate is 34.2 percent. The response rates for the physicians survey and pharmacists survey are 31.3 percent and 49.0 percent, respectively.

**Data Analyses**

All analyses were conducted using SPSS version 12.0 for Windows software.

**Sample Characteristics**

**Physicians**

The final sample included 979 physicians. Sixty-seven percent of the sample was male and 53.3 percent was age 50 or younger. The majority (75.3 percent) was white; 10.8 percent, Asian/Pacific Islander, 4.1 percent, African-American and 4.0 percent, Hispanic/Latino. Thirty-seven percent worked in an urban area; 30 percent in a suburban area, 16 percent in a small town and 8.3 percent in a rural area. Respondents from various medical specialties participated in the survey, including general psychiatry (22.3 percent), family practice (18.9 percent), internal medicine (16.5 percent), emergency medicine (9.2 percent), obstetrics/gynecology (8.9 percent) and orthopedic surgery (4.0 percent). Respondents worked in various types of practices, including group practices (22.6 percent), public hospitals (9.2 percent) and private hospitals (7.5 percent).

**Pharmacists**

The final sample included 1,030 pharmacists. Sixty-five percent of the sample was male and 52.7 percent was age 50 or younger. The majority (83 percent) was white; 7.8 percent, Asian/Pacific Islander, 2.8 percent, African-American and 2.5 percent, Hispanic/Latino. Approximately one-third (34 percent) worked in a small town, 30.5 percent in a suburban area, 28 percent in an urban area and five percent in a rural area. Respondents worked in various types of pharmacies, including chain pharmacies (51.1 percent), independent pharmacies (28.5 percent), hospital pharmacies (6.5 percent) and nursing home pharmacies (0.8 percent). Most (74.2 percent) were employees in a pharmacy; 21.2 percent were owners.
Appendix D
Survey of Pharmacists and Survey of Physicians:
Instruments and Summary Data
Survey of Pharmacists

Prescription Drug Diversion Study

The National Center on Addiction and Substance Abuse at Columbia University
DEFINITIONS FOR REFERENCE

**Diversion:** Any criminal act that causes legitimately manufactured controlled drugs to be sidetracked from their lawful purpose to illicit use (i.e., for personal use or distribution to others for purposes of abuse).

**Abuse:** Intentional use of a prescription drug for non-medical purposes, including intentional use in excess of a prescribed dose to get high or for the feeling it causes.

**Controlled Drugs:** The Controlled Substances Act assigns all drugs that are regulated under existing federal law to one of five categories, or “schedules,” depending on the drug’s medical usefulness, its potential for abuse and the degree of dependence that may result from abuse. In this questionnaire we refer to legal controlled drugs in schedules II–V. Drugs in lower-numbered schedules (e.g., II) are considered to have a higher potential for abuse and dependence than those in higher-numbered schedules (e.g., V).

The controlled drugs that we are most interested in for the purposes of this survey are (1) opioids (pain relievers or narcotics, such as OxyContin, Vicodin, Percocet, Dilaudid); (2) CNS depressants (benzodiazepines or barbiturates that function as tranquilizers or sedatives, such as Valium, Xanax, Nembutal); and (3) stimulants (such as Ritalin, Adderall, Dexedrine).

Please circle one code number for each question unless otherwise specified. Please add notes in the margins when your response only applies to specific drugs or specific classes of controlled drugs. In those cases, please indicate the name or class of the drug for which your response applies.

1. How comfortable do you feel talking to patients about how to take their medications?
   - Very comfortable ............................................................. 1 85.7%
   - Somewhat comfortable ................................................... 2 12.7%
   - Not too comfortable .................................................... 3 0.6%
   - Not at all comfortable .................................................... 4 0.1%

2. How often do you have time to review in detail all the prescriptions that a patient is taking, and potential interactions when filling a new prescription?
   - Always .............................................................................. 1 18.7%
   - Usually ........................................................................... 2 46.0%
   - Sometimes ....................................................................... 3 25.7%
   - Rarely ............................................................................. 4 8.0%
   - Never ............................................................................. 5 0.6%

3. How much would knowing the therapeutic purpose intended by the prescriber help you to improve patient care?
   - Very much ........................................................................ 1 74.0%
   - Somewhat ........................................................................ 2 23.0%
   - A little ............................................................................ 3 1.9%
   - Not at all ......................................................................... 4 0.2%
4. How can you tell if a prescription is forged? (CIRCLE ALL THAT APPLY)

- The patient’s nervous or unusual behavior ........................................ 1  78.0%
- The patient’s payment method (cash vs. insurance)........................... 2  53.2%
- A refill request that is too early ....................................................... 3  41.4%
- Mistakes or irregularities in the written prescription ......................... 4  88.6%
- Check to make sure it has the correct provider number ..................... 5  42.4%
- Check to make sure that the dosage for the drug is medically appropriate .......................................................... 6  48.7%
- Check to make sure that the number of refills for the drug is medically appropriate ................................................... 7  48.4%
- Verify with the prescribing physician ........................................... 8  83.1%
- There is no way to tell ............................................................. 9  1.7%
- Other (Please specify) .......................................................... 10  13.7%

5. Do you believe that tamper free prescription pads help to prevent diversion?

- Yes ..................................................................................... 1  64.4%
- No ..................................................................................... 2  14.7%
- Don’t know ........................................................................ 8  18.5%

6. In your opinion, how big of a risk is addiction when a person takes the following drugs as prescribed?

<table>
<thead>
<tr>
<th>Drug</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids</td>
<td>50.4%</td>
<td>29.1%</td>
<td>17.4%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>25.4%</td>
<td>48.3%</td>
<td>22.7%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>16.4%</td>
<td>42.8%</td>
<td>36.1%</td>
<td>1.7%</td>
</tr>
<tr>
<td>Stimulants</td>
<td>24.9%</td>
<td>42.7%</td>
<td>27.5%</td>
<td>2.1%</td>
</tr>
</tbody>
</table>

7. Which type of controlled drug do you think is most frequently abused?

- Opioids .......................................................... 1  79.3%
- CNS Depressants ................................................. 2  9.8%
- Stimulants .................................................... 3  3.2%
- Don’t know ....................................................... 8  3.9%

8. In your opinion, on a scale of 1 to 5, where 1 is not at all a problem and 5 is a big problem, how big of a problem is prescription drug diversion in your pharmacy?

<table>
<thead>
<tr>
<th>Not at all a problem</th>
<th>A big problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>26.3%</td>
<td>42.3%</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>21.3%</td>
<td>6.3%</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>1.5%</td>
<td></td>
</tr>
</tbody>
</table>
9. When you are dispensing a controlled prescription drug, how often do you perform the following tasks?

<table>
<thead>
<tr>
<th>Task</th>
<th>Always</th>
<th>Usually</th>
<th>Sometimes</th>
<th>Rarely</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Consult patient records that you have access to before dispensing the drug</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>52.1%</td>
<td>32.0%</td>
<td>12.0%</td>
<td>1.5%</td>
<td>0.2%</td>
</tr>
<tr>
<td>b. Check the quantity and dose on the prescription to make sure it is in accordance with regulations</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>72.2%</td>
<td>20.2%</td>
<td>3.4%</td>
<td>0.5%</td>
<td>0.4%</td>
</tr>
<tr>
<td>c. Provide patients with instructions on taking the medication</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>59.3%</td>
<td>27.4%</td>
<td>8.9%</td>
<td>1.3%</td>
<td>0.4%</td>
</tr>
<tr>
<td>d. Check for the number of refills</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>79.3%</td>
<td>12.6%</td>
<td>3.2%</td>
<td>1.4%</td>
<td>0.7%</td>
</tr>
<tr>
<td>e. Validate the prescriber’s DEA number</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>51.1%</td>
<td>17.1%</td>
<td>17.9%</td>
<td>8.8%</td>
<td>1.7%</td>
</tr>
<tr>
<td>f. Check for contraindications</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>57.0%</td>
<td>29.1%</td>
<td>9.8%</td>
<td>1.2%</td>
<td></td>
</tr>
<tr>
<td>g. Ask if the patient is taking any other controlled drugs</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>11.7%</td>
<td>24.4%</td>
<td>35.2%</td>
<td>22.1%</td>
<td>3.7%</td>
</tr>
<tr>
<td>h. Ask if the patient has any questions</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>53.3%</td>
<td>31.1%</td>
<td>10.6%</td>
<td>1.8%</td>
<td>0.6%</td>
</tr>
</tbody>
</table>

10. How often do you dispense a limited quantity of a controlled drug without a written prescription order, on the basis of a prescription order received from a practitioner by telephone?

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>8.9%</td>
</tr>
<tr>
<td>Usually</td>
<td>19.4%</td>
</tr>
<tr>
<td>Sometimes</td>
<td>21.8%</td>
</tr>
<tr>
<td>Rarely</td>
<td>24.3%</td>
</tr>
<tr>
<td>Never</td>
<td>20.6%</td>
</tr>
</tbody>
</table>

11. If the original written prescription order for a controlled drug lacks complete information, how often would you decline to dispense the drug, assuming you are unable to obtain clarification from the prescriber?

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
<td>53.8%</td>
</tr>
<tr>
<td>Usually</td>
<td>24.6%</td>
</tr>
<tr>
<td>Sometimes</td>
<td>8.6%</td>
</tr>
<tr>
<td>Rarely</td>
<td>6.2%</td>
</tr>
<tr>
<td>Never</td>
<td>4.2%</td>
</tr>
</tbody>
</table>

12. When a patient presents at your pharmacy with a request for a controlled drug, how often do you think it is for purposes of abuse or diversion?

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very often</td>
<td>3.6%</td>
</tr>
<tr>
<td>Somewhat often</td>
<td>22.9%</td>
</tr>
<tr>
<td>Not too often</td>
<td>68.1%</td>
</tr>
<tr>
<td>Never</td>
<td>2.4%</td>
</tr>
</tbody>
</table>
13. Suppose a new patient comes to your pharmacy with a prescription for a controlled substance. Please list up to three ways that you distinguish between a patient who is falsely seeking a controlled drug and someone who is legitimately in need of a controlled drug.

1) _________________________________________________________________________________
2) _________________________________________________________________________________
3) _________________________________________________________________________________

14. How confident are you in your ability to know when a person is attempting to obtain controlled drugs from a pharmacy for purposes of abuse and/or diversion?

<table>
<thead>
<tr>
<th>Confidence Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very confident</td>
<td>1 24.4%</td>
</tr>
<tr>
<td>Somewhat confident</td>
<td>2 62.2%</td>
</tr>
<tr>
<td>Not too confident</td>
<td>3 10.6%</td>
</tr>
<tr>
<td>Not at all confident</td>
<td>4 0.2%</td>
</tr>
</tbody>
</table>

15. How concerned are you about abuse or diversion when a patient requests a brand name controlled drug?

<table>
<thead>
<tr>
<th>Concern Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very concerned</td>
<td>1 35.1%</td>
</tr>
<tr>
<td>Somewhat concerned</td>
<td>2 43.3%</td>
</tr>
<tr>
<td>Not too concerned</td>
<td>3 15.7%</td>
</tr>
<tr>
<td>Not at all concerned</td>
<td>4 3.0%</td>
</tr>
</tbody>
</table>

16. In the past 12 months, have you withheld dispensing a controlled drug because of suspicions of abuse or diversion?

<table>
<thead>
<tr>
<th>Action</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1 83.1%</td>
</tr>
<tr>
<td>No</td>
<td>2 13.6%</td>
</tr>
</tbody>
</table>

17. In your opinion, what are the three most common methods of diversion? (CIRCLE THREE).

<table>
<thead>
<tr>
<th>Method</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor shopping (when patients obtain drugs from multiple doctors)</td>
<td>1 89.2%</td>
</tr>
<tr>
<td>Patient deception or manipulation of doctors</td>
<td>2 65.4%</td>
</tr>
<tr>
<td>Doctors who knowingly divert controlled drugs</td>
<td>3 16.4%</td>
</tr>
<tr>
<td>Pharmacists who knowingly divert controlled drugs</td>
<td>4 1.3%</td>
</tr>
<tr>
<td>Pharmacy employees (other than pharmacists) who knowingly divert controlled drugs</td>
<td>5 3.4%</td>
</tr>
<tr>
<td>Theft of prescription pads from doctors’ offices</td>
<td>6 35.0%</td>
</tr>
<tr>
<td>Theft of controlled drugs from doctors’ offices</td>
<td>7 0.9%</td>
</tr>
<tr>
<td>Theft of controlled drugs from pharmacies</td>
<td>8 4.2%</td>
</tr>
<tr>
<td>Forged or altered prescriptions</td>
<td>9 75.2%</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>10 2.7%</td>
</tr>
</tbody>
</table>

18. Which of the following sources do you think accounts for most of the diversion problem? (CIRCLE ONE)

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>1 0.7%</td>
</tr>
<tr>
<td>Pharmaceutical company</td>
<td>2 0.5%</td>
</tr>
<tr>
<td>Drug wholesaler</td>
<td>3 0.9%</td>
</tr>
<tr>
<td>Internet pharmacies</td>
<td>4 15.4%</td>
</tr>
<tr>
<td>Retail pharmacies</td>
<td>5 8.5%</td>
</tr>
<tr>
<td>Hospital/clinic pharmacies</td>
<td>6 1.3%</td>
</tr>
</tbody>
</table>
Physicians/clinicians ...................................................... 7 9.7%
Patients.............................................................................. 8 51.8%
Other (Please specify) ..................................................... 9 6.1%

19. In your opinion, who bears primary responsibility for preventing prescription drug abuse and addiction? (CIRCLE ONE)

Patients.............................................................................. 1 16.2%
Physicians......................................................................... 2 62.1%
Pharmacists ...................................................................... 3 10.5%
Schools/Educators .......................................................... 4 0.7%
Law enforcement............................................................. 5 1.7%
Other (Please specify) ..................................................... 6 5.0%

20a. What actions do you take or would you take if you suspected a patient of abusing or diverting controlled drugs? (CIRCLE ALL THAT APPLY.)

Document it...................................................................... 1 71.3%
Confront the patient with my suspicions ..................... 2 32.3%
Counsel the patient on the dangers .............................. 3 33.5%
Offer educational materials............................................ 4 6.4%
Ask for the opinion of another pharmacist.................. 5 26.4%
Call the prescribing physician ................................. 6 92.8%
Refuse to fill the prescription....................................... 7 76.6%
Tell the patient to leave the pharmacy ......................... 8 16.3%
Contact the police............................................................ 9 47.6%
No actions taken .............................................................. 10 1.7%
Other (Please specify) ..................................................... 11 3.1%

20b. If you answered ‘no actions taken’ to Q20a, please describe the main reason for your decision not to take action.

_______________________________________________________________________________________
_______________________________________________________________________________________

21a. What actions have you taken or would you take if you suspected a professional colleague of abusing or diverting controlled prescription drugs? (CIRCLE ALL THAT APPLY.)

Document it................................................................. 1 62.9%
Confront the colleague with my suspicions .............. 2 50.1%
Ask for the opinion of another pharmacist............. 3 35.7%
Report it to a professional association or committee.. 4 49.5%
Contact the police ............................................................ 5 11.7%
No actions taken .............................................................. 6 0.7%
Other (Please specify) ..................................................... 7 18.8%
21b. If you answered ‘no actions taken’ to Q21a, please describe the main reason for your decision not to take action.

_______________________________________________________________________________________

22. In your opinion, how much responsibility do pharmacists have in helping to prevent prescription drug abuse and diversion?

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>A great deal</td>
<td>1</td>
<td>48.4%</td>
</tr>
<tr>
<td>Quite a bit</td>
<td>2</td>
<td>35.2%</td>
</tr>
<tr>
<td>A moderate amount</td>
<td>3</td>
<td>12.7%</td>
</tr>
<tr>
<td>A little</td>
<td>4</td>
<td>1.7%</td>
</tr>
<tr>
<td>None at all</td>
<td>5</td>
<td>0.1%</td>
</tr>
</tbody>
</table>

23. Would your ability to prevent prescription drug abuse and diversion be increased if you were given...

<table>
<thead>
<tr>
<th>Option</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. More time to attend to each patient/prescription?</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>61.7%</td>
<td>33.6%</td>
</tr>
<tr>
<td>b. More training?</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>42.6%</td>
<td>51.3%</td>
</tr>
<tr>
<td>c. Increased cooperation with physicians?</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>84.2%</td>
<td>11.3%</td>
</tr>
<tr>
<td>d. Increased legal authority? (Please specify type)</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>17.1%</td>
<td>68.1%</td>
</tr>
<tr>
<td>e. Other? (Please specify)</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

24a. To your knowledge, is it lawful to prescribe opioids to patients with chronic pain who have a history of substance abuse?

<table>
<thead>
<tr>
<th>Lawfulness</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
<td>71.8%</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>9.0%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>8</td>
<td>16.5%</td>
</tr>
</tbody>
</table>

24b. Should prescribing opioids to patients with chronic pain who have a history of substance abuse be discouraged?

<table>
<thead>
<tr>
<th>Discouragement</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
<td>61.7%</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>32.9%</td>
</tr>
</tbody>
</table>

25. Has any pharmacy where you worked in the last five years had a theft or robbery of controlled drugs?

<table>
<thead>
<tr>
<th>Theft or robbery</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
<td>28.9%</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>66.4%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>8</td>
<td>2.6%</td>
</tr>
</tbody>
</table>
26a. At the pharmacy where you work, are there any controlled drugs that are not stocked for the sole purpose of preventing diversion?

Yes ............................................................. 1  20.9%
No .............................................................. 2 74.1%  (SKIP TO Q.27)
Don’t know .................................................... 8  2.3%  (SKIP TO Q.27)

26b. Please name the controlled drugs that are not stocked at your pharmacy in order to prevent drug diversion.

________________________________________________________________________
________________________________________________________________________

27. In the past 12 months, have you been asked to dispense a controlled drug that your pharmacy does not keep in stock?

Yes ............................................................. 1  78.4%
No .............................................................. 2 18.8%

28. If a controlled drug is not kept in stock, what is the main reason? (CIRCLE ONE)

Lack of prescriptions .................................................. 1  76.9%
Medication costs .......................................................... 2  4.0%
Fear of robbery/pilfering ............................................. 3  3.1%
Concern about investigation from a regulatory agency .... 4  0.2%
Potential for drug addiction ......................................... 5  1.9%
Other (Please specify) .................................................. 6

29. How reluctant are you to contact the prescribing physician when you have questions about dispensing a controlled drug to a particular patient?

Very reluctant .................................................. 1  1.3%
Somewhat reluctant ........................................... 2  6.3%
Not too reluctant .............................................. 3 20.4%
Not at all reluctant ............................................. 4  69.7%

30. How reluctant are you to report a physician for controlled-drug prescribing practices that you believe may be illegitimate?

Very reluctant .................................................. 1  11.4%
Somewhat reluctant ........................................... 2  30.9%
Not too reluctant .............................................. 3 26.8%
Not at all reluctant ............................................. 4  28.4%

31. If the records for handling, accounting for, and dispensing controlled drugs in the pharmacy where you work were scrutinized today by a regulatory agency, how certain are you that your pharmacy would pass this scrutiny?

Very sure ..................................................... 1  77.3%
Somewhat sure .................................................. 2  18.4%
Not too sure ..................................................... 3  1.1%
Not at all sure .................................................. 4  0.5%
Don’t know ..................................................... 8  0.3%
32. How clear are the procedures for record keeping of controlled drugs at your pharmacy?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very clear</td>
<td>1</td>
<td>88.9%</td>
</tr>
<tr>
<td>Somewhat clear</td>
<td>2</td>
<td>8.5%</td>
</tr>
<tr>
<td>Not too clear</td>
<td>3</td>
<td>0.4%</td>
</tr>
<tr>
<td>Not at all clear</td>
<td>4</td>
<td>0.1%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>8</td>
<td>0.1%</td>
</tr>
</tbody>
</table>

33. How clear are the federal laws on what actions you should take if you believe a patient is diverting or abusing controlled prescription drugs?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very clear</td>
<td>1</td>
<td>18.9%</td>
</tr>
<tr>
<td>Somewhat clear</td>
<td>2</td>
<td>40.1%</td>
</tr>
<tr>
<td>Not too clear</td>
<td>3</td>
<td>24.7%</td>
</tr>
<tr>
<td>Not at all clear</td>
<td>4</td>
<td>6.1%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>8</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

34. How clear are the state laws on what actions you should take if you believe a patient is diverting or abusing controlled prescription drugs?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very clear</td>
<td>1</td>
<td>22.2%</td>
</tr>
<tr>
<td>Somewhat clear</td>
<td>2</td>
<td>40.2%</td>
</tr>
<tr>
<td>Not too clear</td>
<td>3</td>
<td>22.5%</td>
</tr>
<tr>
<td>Not at all clear</td>
<td>4</td>
<td>6.1%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>8</td>
<td>5.7%</td>
</tr>
</tbody>
</table>

35. Have you ever been investigated or audited by a regulatory agency in regard to handling or dispensing controlled drugs (including routine, random audits)?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
<td>34.2%</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>63.0%</td>
</tr>
</tbody>
</table>

36. Some states have prescription drug monitoring programs. Prescription drug monitoring programs are state run electronic databases that track dispensed drugs to help detect, control and prevent prescription drug abuse and diversion. In your opinion…

a. How well do these programs help to prevent drug abuse?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very well</td>
<td>1</td>
<td>8.1%</td>
</tr>
<tr>
<td>Somewhat well</td>
<td>2</td>
<td>28.6%</td>
</tr>
<tr>
<td>Not very well</td>
<td>3</td>
<td>14.9%</td>
</tr>
<tr>
<td>Not at all well</td>
<td>4</td>
<td>5.0%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>8</td>
<td>39.8%</td>
</tr>
</tbody>
</table>

b. How well do these programs help to prevent diversion?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very well</td>
<td>1</td>
<td>6.4%</td>
</tr>
<tr>
<td>Somewhat well</td>
<td>2</td>
<td>27.8%</td>
</tr>
<tr>
<td>Not too well</td>
<td>3</td>
<td>16.9%</td>
</tr>
<tr>
<td>Not at all well</td>
<td>4</td>
<td>5.0%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>8</td>
<td>40.3%</td>
</tr>
</tbody>
</table>

c. To what extent do these programs compromise patient confidentiality?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very much</td>
<td>1</td>
<td>6.0%</td>
</tr>
<tr>
<td>Somewhat</td>
<td>2</td>
<td>22.2%</td>
</tr>
<tr>
<td>Not too much</td>
<td>3</td>
<td>17.0%</td>
</tr>
<tr>
<td>Not at all</td>
<td>4</td>
<td>12.7%</td>
</tr>
</tbody>
</table>
d. To what extent do these programs instill fear of legal scrutiny?

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very much</td>
<td>7.6%</td>
</tr>
<tr>
<td>Somewhat</td>
<td>26.3%</td>
</tr>
<tr>
<td>Not too much</td>
<td>18.0%</td>
</tr>
<tr>
<td>Not at all</td>
<td>8.6%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>35.9%</td>
</tr>
</tbody>
</table>

e. To what extent do these programs affect which drugs physicians prescribe?

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very much</td>
<td>5.6%</td>
</tr>
<tr>
<td>Somewhat</td>
<td>24.9%</td>
</tr>
<tr>
<td>Not too much</td>
<td>18.2%</td>
</tr>
<tr>
<td>Not at all</td>
<td>9.0%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>38.6%</td>
</tr>
</tbody>
</table>

f. How useful would the information recorded in prescription drug monitoring programs be to pharmacists and physicians in preventing drug abuse and diversion?

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very useful</td>
<td>34.6%</td>
</tr>
<tr>
<td>Somewhat useful</td>
<td>37.0%</td>
</tr>
<tr>
<td>Not too useful</td>
<td>5.2%</td>
</tr>
<tr>
<td>Not at all useful</td>
<td>0.8%</td>
</tr>
<tr>
<td>Don’t know</td>
<td>18.8%</td>
</tr>
</tbody>
</table>

37. In column A, please indicate whether you have received instruction on the topics listed since pharmacy school. For all of the “yes” responses in Column A, please note in Column B the means through which you received the instruction, such as continuing education courses, professional conference, pharmacy association mailings, professional journals.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Dispensing controlled drugs?</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>b. Identifying prescription drug</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>abuse/addiction?</td>
<td>49.6%</td>
<td>46.7%</td>
</tr>
<tr>
<td>c. Preventing prescription drug</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>diversion?</td>
<td>48.1%</td>
<td>48.1%</td>
</tr>
</tbody>
</table>

38. What have been your most valuable sources of knowledge about controlled prescription drugs? (CIRCLE ALL THAT APPLY)

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacology course</td>
<td>36.3%</td>
</tr>
<tr>
<td>Internship/Residency/Fellowship</td>
<td>11.5%</td>
</tr>
<tr>
<td>Work experience</td>
<td>90.0%</td>
</tr>
<tr>
<td>Journal articles</td>
<td>39.6%</td>
</tr>
<tr>
<td>Reference Books</td>
<td>20.2%</td>
</tr>
<tr>
<td>Continuing education courses</td>
<td>66.8%</td>
</tr>
<tr>
<td>Information from drug product manufacturers</td>
<td>19.8%</td>
</tr>
<tr>
<td>Colleagues</td>
<td>46.6%</td>
</tr>
<tr>
<td>The Internet</td>
<td>7.7%</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td></td>
</tr>
</tbody>
</table>
39. Would you be interested in receiving additional education/training in any of the following areas?

<table>
<thead>
<tr>
<th>Area</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispensing controlled drugs</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Identifying prescription drug abuse/addiction</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Identifying prescription drug diversion</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Area</th>
<th>Yes (%)</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispensing controlled drugs</td>
<td>67.6%</td>
<td>28.2%</td>
</tr>
<tr>
<td>Identifying prescription drug abuse/addiction</td>
<td>79.9%</td>
<td>16.7%</td>
</tr>
<tr>
<td>Identifying prescription drug diversion</td>
<td>81.0%</td>
<td>15.4%</td>
</tr>
</tbody>
</table>

40. How would you rate the education/training you have received in preventing the abuse and/or diversion of controlled prescription drugs?

<table>
<thead>
<tr>
<th>Rating</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>1</td>
<td>6.6%</td>
</tr>
<tr>
<td>Good</td>
<td>2</td>
<td>44.1%</td>
</tr>
<tr>
<td>Fair</td>
<td>3</td>
<td>37.6%</td>
</tr>
<tr>
<td>Poor</td>
<td>4</td>
<td>10.2%</td>
</tr>
</tbody>
</table>

41. In your opinion, how helpful is the information you receive from drug product manufacturers in educating pharmacists about which controlled drugs are best to prescribe?

<table>
<thead>
<tr>
<th>Rating</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very helpful</td>
<td>1</td>
<td>4.3%</td>
</tr>
<tr>
<td>Somewhat helpful</td>
<td>2</td>
<td>35.7%</td>
</tr>
<tr>
<td>Not too helpful</td>
<td>3</td>
<td>44.7%</td>
</tr>
<tr>
<td>Not at all helpful</td>
<td>4</td>
<td>14.0%</td>
</tr>
</tbody>
</table>

42. How knowledgeable are you about controlled substances laws and regulations

<table>
<thead>
<tr>
<th>Rating</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very knowledgeable</td>
<td>1</td>
<td>42.6%</td>
</tr>
<tr>
<td>Somewhat knowledgeable</td>
<td>2</td>
<td>54.4%</td>
</tr>
<tr>
<td>Not too knowledgeable</td>
<td>3</td>
<td>2.1%</td>
</tr>
<tr>
<td>Not at all knowledgeable</td>
<td>4</td>
<td>-</td>
</tr>
</tbody>
</table>

Finally, we have some background questions for you that will help us assess the representativeness of our respondents.

43. Are you male or female?

<table>
<thead>
<tr>
<th>Gender</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>1</td>
<td>65.0%</td>
</tr>
<tr>
<td>Female</td>
<td>2</td>
<td>34.3%</td>
</tr>
</tbody>
</table>

44. In what year were you born?

______________________________

45. With what racial or ethnic group do you identify yourself?

<table>
<thead>
<tr>
<th>Group</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>African American or Black, but not of Hispanic origin</td>
<td>1</td>
<td>2.8%</td>
</tr>
<tr>
<td>White, but not of Hispanic origin</td>
<td>2</td>
<td>83.0%</td>
</tr>
<tr>
<td>Hispanic or Latino</td>
<td>3</td>
<td>2.5%</td>
</tr>
<tr>
<td>Asian or Pacific Islander</td>
<td>4</td>
<td>7.8%</td>
</tr>
<tr>
<td>Native American or Aleut</td>
<td>5</td>
<td>0.2%</td>
</tr>
<tr>
<td>Multiracial or Biracial</td>
<td>6</td>
<td>0.7%</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>7</td>
<td>-</td>
</tr>
</tbody>
</table>
46. In what year did you complete your highest pharmacy degree?

47. What degrees do you hold? (CIRCLE ALL THAT APPLY)

- BS ............................................................. 1 88.5%
- MS ............................................................. 2 4.3%
- Pharm D ...................................................... 3 13.0%
- Other (please specify) .............................. 4 4.7%

48. Are you an employee, temporary worker, or owner of a pharmacy?

- Employee ............................................... 1 74.2%
- Temporary worker .................................. 2 0.9%
- Owner ..................................................... 3 21.2%
- Other (Please specify) ............................. 4 2.8%

49. How long have you been employed at the pharmacy where you currently work?

- Less than six months .............................. 1 1.4%
- 6 months–1 year .................................... 2 1.7%
- More than 1 year ................................. 3 95.7%

50. In what type of pharmacy do you work?

- Hospital Pharmacy ............................... 1 6.5%
- Chain Pharmacy .................................... 2 51.1%
- Independent Pharmacy .......................... 3 28.5%
- Nursing Home Pharmacy ....................... 4 0.8%
- Outpatient Clinic Pharmacy ................... 5 3.8%
- Other (Please specify): ......................... 6 7.8%

51. In which state do you work?

52. Would you say you practice primarily in an...

- Urban area ............................................. 1 28.0%
- Suburban area ........................................ 2 30.5%
- Small town ............................................ 3 34.0%
- Rural area (other than small town) ........... 4 5.0%
- Other (Please specify) ........................... 5 1.4%

Do you have any additional comments on prescription drug diversion and abuse?

________________________________________________________________________________________________

________________________________________________________________________________________________

________________________________________________________________________________________________

________________________________________________________________________________________________

________________________________________________________________________________________________

-126-
Thank you for taking time to complete this questionnaire!

Please return it in the enclosed postage-paid envelope provided to:

The University of Illinois at Chicago Survey Research Laboratory (M/C 336) Box 6905 Chicago, IL 60608
Survey of Physicians

Prescription Drug Diversion Study

The National Center on Addiction and Substance Abuse at Columbia University
DEFINITIONS FOR REFERENCE

**Diversion:** Any criminal act that causes legitimately manufactured controlled drugs to be sidetracked from their lawful purpose to illicit use (i.e., for personal use or distribution to others for purposes of abuse).

**Abuse:** Intentional use of a prescription drug for non-medical purposes, including intentional use in excess of a prescribed dose to get high or for the feeling it causes.

**Controlled Drugs:** The Controlled Substances Act assigns all drugs that are regulated under existing federal law to one of five categories, or “schedules,” depending on the drug’s medical usefulness, its potential for abuse and the degree of dependence that may result from abuse. In this questionnaire we refer to legal controlled drugs in schedules II–V. Drugs in lower-numbered schedules (e.g., II) are considered to have a higher potential for abuse and dependence than those in higher-numbered schedules (e.g., V).

The controlled drugs that we are most interested in for the purposes of this survey are (1) opioids (pain relievers or narcotics, such as OxyContin, Vicodin, Percocet, Dilaudid); (2) CNS depressants (benzodiazepines or barbiturates that function as tranquilizers or sedatives, such as Valium, Xanax, Nembutal); and (3) stimulants (such as Ritalin, Adderall, Dexedrine).

Please circle one code number for each question unless otherwise specified. Please add notes in the margins when your response only applies to specific drugs or specific classes of controlled drugs. In those cases, please indicate the name or class of the drug for which your response applies.

1. How often do your patients complete a written or oral health history? (CIRCLE ALL THAT APPLY)
   - At the first visit .................................................. 1 68.5%
   - At every visit .................................................... 2 21.1%
   - When receiving a physical exam .......................... 3 23.5%
   - Annually ............................................................. 4 18.7%
   - Never ................................................................. 5 3.8%
   - Something else (Please specify) ........................... 6

2. Does the written or oral health history that you take on your patients include the following information?

<table>
<thead>
<tr>
<th>Information</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current medications</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>97.7%</td>
<td>0.4%</td>
</tr>
<tr>
<td>Recent medications</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>83.2%</td>
<td>13.7%</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>93.6%</td>
<td>4.4%</td>
</tr>
<tr>
<td>Alcohol use</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>93.1%</td>
<td>4.8%</td>
</tr>
</tbody>
</table>
Illegal drug use .................................................................1 2 83.8% 13.4%
Previous history of alcohol or drug abuse .....................1 2 77.6% 19.6%
Prescription drug abuse...................................................1 2 53.8% 43.3%
Treatment for alcohol or drug abuse .............................1 2 59.3% 37.6%

3. Which of the following controlled drugs do you prescribe in your practice? (CIRCLE ALL THAT APPLY.)
   Opioids (narcotics) .......................................................1 72.6%
   Stimulants .....................................................................2 52.6%
   Benzodiazepines ............................................................3 87.1%
   Barbiturates ...................................................................4 28.5%
   I don’t prescribe any controlled drugs ...........................5 3.3% → (SKIP TO Q.13a)

4a. How often do you counsel each patient on the risks of physical dependence associated with taking controlled drugs when you first prescribe the medication?
   Always ...........................................................................1 52.7%
   Most of the time ............................................................2 29.1%
   Some of the time ...........................................................3 15.0%
   Never .............................................................................4 2.3% → (SKIP TO Q.5a)

4b. Does your likelihood of counseling patients on the risks of physical dependence vary according to which drug you are prescribing?
   Yes ...................................................................................1 72.5%
   No ....................................................................................2 25.5% → (SKIP TO Q.5a)

4c. For which drugs are you likely to counsel a patient on risks of physical dependence? (CIRCLE ALL THAT APPLY.)
   Opioids (narcotics) .......................................................1 78.5%
   Stimulants .....................................................................2 41.3%
   Benzodiazepines ............................................................3 83.8%
   Barbiturates ...................................................................4 31.4%

5a. How often do you explain to each patient the risks of addiction associated with taking controlled drugs when you first prescribe the medication?
   Always ...........................................................................1 45.9% → (SKIP TO Q.6)
   Most of the time ............................................................2 29.1%
   Some of the time ...........................................................3 18.6%
   Never .............................................................................4 3.5%

5b. What is the reason(s) you don’t always explain the risks associated with taking controlled drugs to patients? (CIRCLE ALL THAT APPLY.)
   Patients already know this information .......................1 33.1%
   Not enough time ...........................................................2 23.6%
   Patients will not understand .........................................3 6.4%
   Patients will not pay attention .......................................4 4.8%
   The information will scare my patients .......................5 13.2%
I am not clear about the risks myself .................. 6 2.7%
It is not my responsibility .................................... 7 0.2%
It is not necessary for short-term prescriptions ........ 8 55.1%
Other (Please specify) ......................................... 9 18.0%

6. How common is it for patients to try to pressure you into prescribing a controlled drug?
   Very common ................................................... 1 15.8%
   Somewhat common ............................................ 2 31.3%
   Not too common ................................................ 3 37.0%
   Not at all common ............................................. 4 13.3%

7a. How often do you ask your patients about their present use of other controlled prescription drugs when prescribing a new controlled drug?
   Always ................................................................. 1 60.7%
   Most of the time ............................................... 2 27.3%
   Some of the time ............................................... 3 8.8%
   Never ................................................................ 4 1.1% (SKIP TO Q.8)

7b. Does the likelihood of asking your patients about their use of other controlled prescription drugs vary according to which drug you are prescribing?
   Yes .................................................................. 1 46.2%
   No ...................................................................... 2 48.3% (SKIP TO Q.8)

7c. For which drugs are you likely to ask your patient about their use of other controlled prescription drugs? (CIRCLE ALL THAT APPLY.)
   Opioids (narcotics) .............................................. 1 89.4%
   Stimulants ......................................................... 2 43.2%
   Benzodiazepines ............................................... 3 79.3%
   Barbiturates ....................................................... 4 29.9%

8. How often do you ask your patients about their use of alcohol and/or illicit drugs when prescribing controlled drugs?
   Almost always ..................................................... 1 59.5%
   Most of the time ................................................. 2 21.8%
   Some of the time ............................................... 3 11.7%
   Almost never ..................................................... 4 3.5%

9. Before prescribing long-term controlled drugs, such as narcotics for chronic pain, how often do you call or obtain records from the patient’s previous or other treating physicians?
   Almost always ..................................................... 1 31.5%
   Most of the time ................................................. 2 23.0%
   Some of the time ............................................... 3 20.1%
   Almost never ..................................................... 4 12.9%
10a. If you do not have complete information on a patient’s current or prior medication history and/or drug abuse history, which of the following are you most likely to do with regard to prescribing a controlled drug?

Refuse to prescribe until I obtain the information ..... 1 21.2%
Prescribe 1-3 days worth of the drug ......................... 2 25.9%
Prescribe one week’s worth of the drug ..................... 3 32.1%
Prescribe the usual amount ....................................... 4 8.1%
Other (Please specify) ............................................. 5 9.7%

10b. Does the action you indicated in your answer to Q.10a vary according to the type of controlled drug you are prescribing?

Yes................................................................. 1 62.5%
No ............................................................... 2 32.8%

11. Please list up to three ways that you distinguish between a patient who is falsely seeking a controlled drug and someone who is legitimately in need of a controlled drug.

1) __________________________________________________________________________________
2) __________________________________________________________________________________
3) __________________________________________________________________________________

12. To what extent is your continued prescription of controlled opioids dependent on your assessment of how your chronic pain patients are responding to the medication? Assessment includes evaluating whether the drug has improved their ability to function; such as their ability to go to work, perform household tasks, care for children, go to school, etc.

A great deal .............................................. 1 46.7%
Somewhat ................................................. 2 14.1%
Not too much ............................................ 3 2.2%
Not at all ...................................................... 4 1.2%
No chronic pain patients in my practice................. 5 28.3%

13a. Have you ever been presented with a patient with a history of substance abuse who is in need of a controlled drug?

Yes................................................................. 1 87.0%
No ............................................................... 2 9.6% (SKIP TO Q.14a)

13b. The last time this happened, what did you do? (CIRCLE ALL THAT APPLY)

Treated them like any other patient....................... 1 15.3%
Referred them to a specialist............................... 2 26.1%
Treated them with a controlled drug but monitored them more closely than other patients............... 3 54.7%
Treated them with medications other than controlled drugs........................................ 4 48.7%
Other (Please specify) ..................................... 5 8.1%
14a. In the past 12 months, have you diagnosed any of your adult patients with a prescription drug abuse problem?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes...................................................................................... 1 66.3%</td>
<td></td>
</tr>
<tr>
<td>No ...................................................................................... 2 28.6% → (SKIP TO Q.15a)</td>
<td></td>
</tr>
<tr>
<td>I do not treat adult patients.................... 3 1.3% → (SKIP TO Q.15a)</td>
<td></td>
</tr>
</tbody>
</table>

14b. In the past 12 months, approximately how many of your adult patients have you diagnosed with a prescription drug abuse problem?

______________ Diagnosed adult patients

15a. In the past 12 months, have you diagnosed any of your adolescent patients with a prescription drug abuse problem?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes...................................................................................... 1 14.5%</td>
<td></td>
</tr>
<tr>
<td>No ...................................................................................... 2 57.3% → (SKIP TO Q.16)</td>
<td></td>
</tr>
<tr>
<td>I do not treat adolescent patients........... 3 24.1% → (SKIP TO Q.16)</td>
<td></td>
</tr>
</tbody>
</table>

15b. In the past 12 months, approximately how many of your adolescent patients have you diagnosed with a prescription drug abuse problem?

______________ Diagnosed adolescent patients

16. During the past 12 months, have you ever refrained from prescribing controlled drugs to any of your patients because of concern that they might become addicted to them?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes...................................................................................... 1 74.1%</td>
<td></td>
</tr>
<tr>
<td>No ...................................................................................... 2 19.2%</td>
<td></td>
</tr>
<tr>
<td>I do not prescribe controlled drugs.......... 3 2.8%</td>
<td></td>
</tr>
</tbody>
</table>

17. In the past 12 months, how many times have you tried to refer any of your patients to a substance abuse treatment or counseling program because of a suspected prescription drug abuse problem?

______________

18. How confident are you in your ability to recognize when a person is attempting to obtain controlled drugs from a physician for purposes of abuse and/or diversion?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very confident............................................... 1 25.3%</td>
<td></td>
</tr>
<tr>
<td>Somewhat confident................................... 2 56.6%</td>
<td></td>
</tr>
<tr>
<td>Not too confident................................... 3 12.9%</td>
<td></td>
</tr>
<tr>
<td>Not at all confident............................... 4 1.6%</td>
<td></td>
</tr>
</tbody>
</table>

19a. What actions do you usually take if you suspect a patient is abusing or diverting controlled drugs?

(CIRCLE ALL THAT APPLY.)

<table>
<thead>
<tr>
<th>Action</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Document it .............................................. 1 89.9%</td>
<td></td>
</tr>
<tr>
<td>Confront the patient with my suspicions........... 2 80.0%</td>
<td></td>
</tr>
<tr>
<td>Counsel the patient on the dangers.................. 3 72.0%</td>
<td></td>
</tr>
<tr>
<td>Offer educational materials........................... 4 19.0%</td>
<td></td>
</tr>
<tr>
<td>Contact a family member ................................ 5 14.0%</td>
<td></td>
</tr>
<tr>
<td>Require urine tests....................................... 6 27.8%</td>
<td></td>
</tr>
<tr>
<td>Do pill counts ............................................ 7 23.1%</td>
<td></td>
</tr>
<tr>
<td>Create a drug contract/agreement with the patient 8 36.9%</td>
<td></td>
</tr>
<tr>
<td>Provide prescriptions without refills............... 9 68.5%</td>
<td></td>
</tr>
<tr>
<td>Prescribe the patient non-controlled drugs only... 10 50.6%</td>
<td></td>
</tr>
<tr>
<td>Consult with another physician for a second opinion 11 26.4%</td>
<td></td>
</tr>
<tr>
<td>Refer the patient to another doctor ................. 12 19.1%</td>
<td></td>
</tr>
</tbody>
</table>
Discharge the patient from my practice ....................... 13 20.5%
Refer the patient to treatment ................................. 14 51.2%
Refer patient to a specialist, such as a pain specialist .15 62.0%
Contact the police ................................................. 16 10.7%
I have not suspected anyone of abusing or
diverting controlled drugs ............................................. 17 2.0%
No actions taken ....................................................... 18 0.4%
OTHER (Please specify).............................................. 19 5.4%

19b. If you answered ‘no actions taken’ to Q19.a, please describe the main reason for your decision not to take action.

________________________________________________________________________________________
________________________________________________________________________________________

20a. What actions have you taken or would you take if you suspected a professional colleague is abusing or diverting controlled prescription drugs? (CIRCLE ALL THAT APPLY)

Confront the colleague with my suspicions.................... 1 59.2%
Call the police ......................................................... 2 1.7%
Document it (in my files or a computer system) ............ 3 16.0%
Ask for the opinion of another physician ................... 4 43.1%
Report it to a professional association or health committee .5 55.2%
No actions taken ....................................................... 6 3.4%
Other (Please specify) ............................................. 7 6.8%

20b. If you answered ‘no actions taken’ to Q20.a, please describe the main reason for your decision not to take action.

_____________________________________________________________________________________

21a. Do you require urine tests for patients for whom you prescribe controlled drugs to ensure that they are actually taking the drug?

Yes ........................................................................ 1 14.1%
No ........................................................................... 2 82.1% → (SKIP TO Q.22)

21b. Do you require urine tests for all of your patients for whom you prescribe controlled drugs or only for certain patients?

All of my patients .................................................. 1 23.7%
Only certain patients ............................................. 2 71.2%

22. In your opinion, on a scale of 1 to 5 (1 being not at all and 5 being a big problem) how big of a problem is prescription drug diversion in your office/clinic?

<table>
<thead>
<tr>
<th>Not at all a problem</th>
<th>A big problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 2 3 4 5</td>
<td>22.6% 42.9% 17.8% 7.4% 4.0%</td>
</tr>
</tbody>
</table>
23. Which type of controlled drug do you think is most frequently abused?

Opioids.................................................................1 61.6%
Benzodiazepines ..................................................2 21.8%
Barbiturates ..........................................................3 0.8%
Stimulants ............................................................4 3.7%
Other (Please specify)..............................................5 8.7%

24. How much is preventing prescription drug abuse and addiction in your patients a priority for you?

Very much .............................................................1 59.6%
Somewhat .............................................................2 29.5%
Not too much .........................................................3 7.3%
Not at all ...............................................................4 1.9%

25. In your opinion, how effective are available methods for treating prescription drug abuse?

Very effective ........................................................1 6.2%
Somewhat effective .................................................2 42.6%
Not too effective .....................................................3 37.9%
Not at all effective ..................................................4 5.7%
Don’t know ............................................................8 6.0%

26. In your opinion, how big of a risk is addiction when a person takes the following drugs as prescribed?

<table>
<thead>
<tr>
<th>Drug</th>
<th>High</th>
<th>Medium</th>
<th>Low</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioids</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Stimulants</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>8</td>
</tr>
</tbody>
</table>

27. How frequently do pharmacists call you to discuss suspicions of patient fraud or abuse?

Very frequently .................................................1 3.5%
Somewhat frequently .........................................2 16.7%
Not too frequently ..........................................3 60.1%
Not at all .......................................................4 17.8%

28. In your opinion, what are the three most common methods of diversion? (PLEASE CIRCLE THREE.)

Doctor shopping (when patients obtain controlled drugs from multiple doctors)........1 96.4%
Patient deception or manipulation of doctors ..........2 87.8%
Doctors who knowingly divert controlled drugs........3 8.5%
Pharmacists who knowingly divert controlled drugs 4 2.0%
Pharmacy employees (other than pharmacists) who knowingly divert controlled drugs .................. 5  2.8%
Theft of prescription pads from doctors’ offices ........ 6  17.1%
Theft of controlled drugs from doctors’ offices .......... 7  1.7%
Theft of controlled drugs from pharmacies .............. 8  3.3%
Forged or altered prescriptions ............................. 9  69.4%
Other (Please specify) ........................................... 10  4.5%

29. Which of the following sources do you think accounts for most of the diversion problem? (CIRCLE ONE)

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>0.8%</td>
</tr>
<tr>
<td>Pharmaceutical companies</td>
<td>0.6%</td>
</tr>
<tr>
<td>Drug wholesalers</td>
<td>0.5%</td>
</tr>
<tr>
<td>Internet pharmacies</td>
<td>8.6%</td>
</tr>
<tr>
<td>Retail pharmacies</td>
<td>3.1%</td>
</tr>
<tr>
<td>Hospital/clinic pharmacies</td>
<td>0.6%</td>
</tr>
<tr>
<td>Physicians/clinicians</td>
<td>11.8%</td>
</tr>
<tr>
<td>Patients</td>
<td>59.1%</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>10.5%</td>
</tr>
</tbody>
</table>

30. In your opinion, who bears primary responsibility for preventing prescription drug abuse and addiction? (CIRCLE ONE)

<table>
<thead>
<tr>
<th>Role</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>27.4%</td>
</tr>
<tr>
<td>Physicians</td>
<td>57.2%</td>
</tr>
<tr>
<td>Pharmacists</td>
<td>2.3%</td>
</tr>
<tr>
<td>Schools/Educators</td>
<td>0.9%</td>
</tr>
<tr>
<td>Law enforcement</td>
<td>2.3%</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>7.0%</td>
</tr>
</tbody>
</table>

31. How concerned are physicians in your specialty about patients abusing controlled prescription drugs, compared with physicians overall?

<table>
<thead>
<tr>
<th>Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>More concerned</td>
<td>58.0%</td>
</tr>
<tr>
<td>Less concerned</td>
<td>10.2%</td>
</tr>
<tr>
<td>About equally concerned</td>
<td>27.7%</td>
</tr>
</tbody>
</table>

32. How concerned are physicians in your specialty about patients abusing alcohol, compared with physicians overall?

<table>
<thead>
<tr>
<th>Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>More concerned</td>
<td>64.5%</td>
</tr>
<tr>
<td>Less concerned</td>
<td>9.0%</td>
</tr>
<tr>
<td>About equally concerned</td>
<td>22.5%</td>
</tr>
</tbody>
</table>
33a. To your knowledge, is it lawful to prescribe opioids to patients with chronic pain who have a history of substance abuse?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>8</td>
</tr>
</tbody>
</table>

-171.5%
-5.8%
-18.4%

33b. Should prescribing opioids to patients with chronic pain who have a history of substance abuse be discouraged?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

-64.8%
-27.7%

34. In column A, please indicate whether you received instruction in the areas listed while in medical school. For all of the “yes” responses in Column A, please note in Column B how much instruction you received.

<table>
<thead>
<tr>
<th>A. During medical school, did you receive instruction in …</th>
<th>B. How much instruction did you receive?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>An entire course or more</td>
</tr>
<tr>
<td>1. Pain management? ...........................................</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2. Prescribing controlled drugs?........................................</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3. Identifying prescription drug abuse/addiction? ...........</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4. Identifying prescription drug diversion?.......................</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

35. In column A, please indicate whether you received instruction in the areas listed during your residency training. For all of the “yes” responses in Column A, please note in Column B how much instruction you received.

<table>
<thead>
<tr>
<th>A. During your residency training, did you receive instruction in …</th>
<th>B. How much instruction did you receive?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>An entire course or more</td>
</tr>
<tr>
<td>1. Pain management? ...........................................</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2. Prescribing controlled drugs?........................................</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3. Identifying prescription drug abuse/addiction? ...........</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4. Identifying prescription drug diversion?.......................</td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
36. In column A, please indicate whether you received instruction in any CME courses you have taken in the areas listed. For all of the “yes” responses in Column A, please note in Column B how much instruction you received.

| A. In any CME courses you have taken, did you receive any specific instruction in… | B. If yes, how much instruction did you receive? |
|---|---|---|
| | Yes | No | An entire course or more | More than a few hours but less than an entire course | A few hours or less |
| 1. Pain management? | 1 | 2 | 1 | 2 | 3 |
| | 59.3% | 34.9% | 30.6% | 36.8% | 31.3% |
| 2. Prescribing controlled drugs? | 1 | 2 | 1 | 2 | 3 |
| | 44.5% | 49.2% | 26.4% | 39.9% | 32.3% |
| 3. Identifying prescription drug abuse/addiction? | 1 | 2 | 1 | 2 | 3 |
| | 45.6% | 47.8% | 24.0% | 39.9% | 35.2% |
| 4. Identifying prescription drug diversion? | 1 | 2 | 1 | 2 | 3 |
| | 34.2% | 58.9% | 26.0% | 37.0% | 36.1% |

37. What have been your most valuable sources of knowledge about controlled prescription drugs? (CIRCLE ALL THAT APPLY)

- Pharmacology course ...................................................... 1 27.5%
- Internship/Residency/Fellowship ............................... 2 43.1%
- Work experience .............................................................. 3 83.7%
- Journal articles ................................................................. 4 42.6%
- Reference Books ............................................................... 5 17.0%
- Continuing education courses ....................................... 6 39.1%
- Information from drug product manufacturers ............ 7 16.6%
- Colleagues ........................................................................ 8 50.6%
- The Internet ...................................................................... 9 7.0%
- Other (Please specify)...................................................... 10 5.7%

38. Would you be interested in receiving additional education/training in any of the following areas?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Prescribing controlled drugs</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>61.2%</td>
<td>35.7%</td>
</tr>
<tr>
<td>b. Identifying prescription drug abuse/addiction</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>69.4%</td>
<td>27.6%</td>
</tr>
<tr>
<td>c. Identifying prescription drug diversion</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>70.9%</td>
<td>26.0%</td>
</tr>
</tbody>
</table>

39. How do you perceive the adequacy of the education/training you have received in preventing the abuse and/or diversion of controlled prescription drugs?

- Excellent ................................................................. 1 6.2%
- Good ........................................................................... 2 31.3%
- Fair .............................................................................. 3 36.7%
- Poor ............................................................................... 4 22.4%
40. In your opinion, how helpful is the information you receive from drug product manufacturers in educating physicians about which controlled drugs are best to prescribe?

- Very helpful................................................................. 1 6.0%
- Somewhat helpful......................................................... 2 24.1%
- Not too helpful............................................................... 3 41.1%
- Not at all helpful............................................................ 4 25.5%

41. How knowledgeable are you about controlled substances laws and regulations?

- Very knowledgeable ..................................................... 1 11.5%
- Somewhat knowledgeable ............................................ 2 56.1%
- Not too knowledgeable.................................................. 3 26.0%
- Not at all knowledgeable............................................... 4 3.7%

42. How qualified do you feel you are to treat patients with chronic non-malignant pain?

- Very qualified............................................................... 1 11.2%
- Somewhat qualified....................................................... 2 41.1%
- Not too qualified........................................................... 3 29.9%
- Not at all qualified......................................................... 4 14.4%

43. How qualified do you feel you are to diagnose prescription drug abuse and addiction in your patients?

- Very qualified............................................................... 1 24.3%
- Somewhat qualified....................................................... 2 55.7%
- Not too qualified........................................................... 3 14.5%
- Not at all qualified......................................................... 4 2.7%

44a. How clear are the federal laws on what actions you should take if you believe a patient is diverting or abusing controlled prescription drugs?

- Very clear................................................................. 1 7.9%
- Somewhat clear.......................................................... 2 23.1%
- Not too clear............................................................... 3 30.6%
- Not at all clear........................................................... 4 12.9%
- Don’t know................................................................. 8 22.7%

44b. How clear are the state laws on what actions you should take if you believe a patient is diverting or abusing controlled prescription drugs?

- Very clear................................................................. 1 7.4%
- Somewhat clear.......................................................... 2 22.9%
- Not too clear............................................................... 3 27.9%
- Not at all clear........................................................... 4 13.8%
- Don’t know................................................................. 8 25.4%

45. To what extent do you worry about review of your prescribing practices by regulatory or enforcement agencies?

- A great deal................................................................. 1 9.5%
- Somewhat................................................................. 2 24.2%
- Not too much............................................................. 3 36.5%
- Not at all................................................................. 4 27.0%
46. Have you ever been investigated or audited by a regulatory agency in regard to prescribing controlled drugs?
   Yes...................................................................................... 1   5.1%
   No ...................................................................................... 2 92.1%

47. Some states have prescription drug monitoring programs. Prescription drug monitoring programs are state run electronic databases that track dispensed drugs to help detect, control and prevent prescription drug abuse and diversion. In your opinion...
   a. How well do these programs help to prevent prescription drug abuse?
      Very well................................................................. 1 7.5%
      Somewhat well...................................................... 2 25.7%
      Not too well......................................................... 3 16.1%
      Not at all well............................................... 4 6.0%
      Don’t know......................................................... 8 41.7%
   b. How well do these programs help to prevent prescription drug diversion?
      Very well................................................................. 1 5.4%
      Somewhat well...................................................... 2 23.8%
      Not very well....................................................... 3 17.4%
      Not at all well............................................... 4 6.4%
      Don’t know......................................................... 8 44.0%
   c. To what extent do these programs compromise patient confidentiality?
      Very much ............................................................... 1 6.5%
      Somewhat ............................................................. 2 24.6%
      Not too much ...................................................... 3 16.4%
      Not at all ............................................................. 4 8.9%
      Don’t know......................................................... 8 40.4%
   d. To what extent do these programs instill in physicians a fear of legal scrutiny?
      Very much ............................................................... 1 14.2%
      Somewhat ............................................................. 2 29.4%
      Not too much ...................................................... 3 15.5%
      Not at all ............................................................. 4 4.9%
      Don’t know......................................................... 8 33.0%
   e. To what extent do these programs affect which drugs physicians prescribe?
      Very much ............................................................... 1 9.4%
      Somewhat ............................................................. 2 34.2%
      Not too much ...................................................... 3 16.2%
      Not at all ............................................................. 4 5.7%
      Don’t know......................................................... 8 32.5%
   f. How useful would the information recorded in prescription drug monitoring programs be to physicians and pharmacists in preventing drug abuse and diversion?
      Very useful ............................................................. 1 36.5%
      Somewhat useful .................................................. 2 38.7%
      Not too useful ...................................................... 3 5.9%
      Not at all ............................................................. 4 0.7%
      Don’t know......................................................... 8 16.6%
48. In your opinion, do physicians have any responsibility for helping to prevent prescription drug abuse and diversion?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>97.5%</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

49. Would your ability to prevent prescription drug abuse and diversion be increased if you were given...

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>More time to attend to each patient?</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>58.5%</td>
<td>38.7%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>More training?</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>75.5%</td>
<td>21.4%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Increased cooperation with pharmacists?</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>73.5%</td>
<td>23.0%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Increased legal authority? (Please specify type)</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.8%</td>
<td>67.7%</td>
<td></td>
</tr>
</tbody>
</table>

Other (Please specify)................................................................. 1 2

Finally, we have some background questions for you that will help us assess the representativeness of our respondents.

50. Are you male or female?

<table>
<thead>
<tr>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>67.3%</td>
<td>31.5%</td>
</tr>
</tbody>
</table>

51. In what year were you born?

____________

52. With which racial or ethnic group do you identify yourself?

| African American or Black, but not of Hispanic origin | 1 | 4.1% |
| White, but not of Hispanic origin | 2 | 75.3% |
| Hispanic or Latino | 3 | 4.0% |
| Asian or Pacific Islander | 4 | 10.8% |
| Native American or Aleut | 5 | 0.2% |
| Multiracial or Biracial | 6 | 0.9% |
| Other (Please specify) | 7 | 2.0% |

53. In what year did you graduate medical school?

____________
54. What is your medical specialty?

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family Practice</td>
<td>1</td>
<td>18.9%</td>
</tr>
<tr>
<td>General Practice</td>
<td>2</td>
<td>1.7%</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>3</td>
<td>16.5%</td>
</tr>
<tr>
<td>Gynecology</td>
<td>4</td>
<td>1.2%</td>
</tr>
<tr>
<td>Ob-Gyn</td>
<td>5</td>
<td>8.9%</td>
</tr>
<tr>
<td>Emergency medicine</td>
<td>6</td>
<td>9.2%</td>
</tr>
<tr>
<td>Osteopathic medicine</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Sports medicine</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Infectious disease</td>
<td>9</td>
<td>0.4%</td>
</tr>
<tr>
<td>Addiction medicine</td>
<td>10</td>
<td>0.3%</td>
</tr>
<tr>
<td>Pain medicine</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Palliative medicine</td>
<td>12</td>
<td>0.1%</td>
</tr>
<tr>
<td>Sleep medicine</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>Orthopedic surgery</td>
<td>14</td>
<td>4.0%</td>
</tr>
<tr>
<td>General Psychiatry</td>
<td>15</td>
<td>22.3%</td>
</tr>
<tr>
<td>Addiction psychiatry</td>
<td>16</td>
<td>0.6%</td>
</tr>
<tr>
<td>Child &amp; Adolescent Psychiatry</td>
<td>17</td>
<td>3.4%</td>
</tr>
<tr>
<td>Geriatric Psychiatry</td>
<td>18</td>
<td>1.0%</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>19</td>
<td>9.8%</td>
</tr>
</tbody>
</table>

55. Approximately how large is your medical practice?

_________________ (Number of active patients)

56. What percentage of your time do you spend in direct patient care?

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>1</td>
<td>1.9%</td>
</tr>
<tr>
<td>1 - 20%</td>
<td>2</td>
<td>3.3%</td>
</tr>
<tr>
<td>21 - 40%</td>
<td>3</td>
<td>4.8%</td>
</tr>
<tr>
<td>41 - 60%</td>
<td>4</td>
<td>6.3%</td>
</tr>
<tr>
<td>61 - 80%</td>
<td>5</td>
<td>16.4%</td>
</tr>
<tr>
<td>81 - 100%</td>
<td>6</td>
<td>65.4%</td>
</tr>
</tbody>
</table>

57. In what type of setting do you practice medicine?

<table>
<thead>
<tr>
<th>Setting</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solo private practice</td>
<td>1</td>
<td>22.6%</td>
</tr>
<tr>
<td>Two-physician private practice</td>
<td>2</td>
<td>4.7%</td>
</tr>
<tr>
<td>Group practice (more than two other physicians)</td>
<td>3</td>
<td>28.6%</td>
</tr>
<tr>
<td>Community based organization</td>
<td>4</td>
<td>4.1%</td>
</tr>
<tr>
<td>Private hospital</td>
<td>5</td>
<td>7.5%</td>
</tr>
<tr>
<td>Public hospital</td>
<td>6</td>
<td>9.2%</td>
</tr>
<tr>
<td>Other (Please specify)</td>
<td>7</td>
<td>20.1%</td>
</tr>
</tbody>
</table>

58. In which state do you practice medicine?

_________________
59. Would you say you practice primarily in an...

Urban area .................................................................1 36.9%
Suburban area ...........................................................2 30.1%
Small town.................................................................3 16.1%
Rural Area.................................................................4  8.3%
Other (Please specify)....................................................5  4.8%

60. Are you certified to administer buprenorphine?

Yes.................................................................1  8.9%
No .................................................................2 57.9%
Don’t know.........................................................8 29.0%

Do you have any additional comments on prescription drug diversion or abuse?

____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________
____________________________________________________________________________________________

Thank you for taking time to complete this questionnaire!

Please return it in the enclosed postage-paid envelope provided to:

The University of Illinois at Chicago Survey Research Laboratory (M/C 336)

Box 6905 Chicago, IL 60608
Beau Dietl & Associates (BDA) conducted a comprehensive investigation of the availability of controlled prescription drugs (opioids, CNS depressants and stimulants) on the Internet over the course of one week in February 2004. The exact study was replicated one year later in January 2005 to determine whether and to what extent the landscape had changed. In March 2005, BDA was asked by CASA to conduct the same type of investigation of Web sites selling controlled steroid drugs. In each case, the following methodology was followed:

**Database Information**

A database was created containing detailed records for the Web sites uncovered during the week of each investigation. Each record contained the following information: distinction between anchor and portal sites, prescription requirements, advertised country of origin and the drugs offered by the Web site.

**Target Drugs**

The list of target drugs included Schedules II through V controlled substances, with an emphasis on Schedules II and III. Specifically, the drugs that were searched in the initial investigation and the replication included:

- **Opioids:** Codeine (Schedule II or III versions), diphenoxylate (e.g., Lomotil), dentanyl (e.g., Duragesic), hydrocodone (e.g., Vicodin), hydromorphone (e.g., Dilaudid), meperidine (e.g., Demerol), oxycodone (e.g., OxyContin, Percocet), and propoxyphene (e.g., Darvon)

- **CNS Depressants:** Benzodiazepines including alprazolam (e.g., Xanax), chlor Diazepoxide hydrochloride (e.g., Librium), diazepam (e.g., Valium), estazolam (e.g., ProXom), lorazepam
(e.g., Ativan), and triazolam (e.g., Halcion); and barbiturates including mephobarbital (e.g., Mebaral), pentobarbital sodium (e.g., Nembutal), and secobarbital (e.g., Seconal)

- **Stimulants:** Amphetamine-dextroamphetamine (e.g., Adderall), dextroamphetamine (e.g., Dexedrine), dexamphetamine HCl (e.g., Focalin), and methylphenidate (e.g., Ritalin)

The drugs that were searched in the steroid investigation included:

- **Oral tablets:** Oxymetholone (e.g., Anadrol), oxandrolone (e.g., Oxandrin), methandrostenolone (e.g., Dianabol) and stanozolol (e.g., Winstrol)

- **Injection drugs:** Nandrolone decanoate (e.g., Deca-Durabolin), nandrolone phenpropionate (e.g., Durabolin), testosterone cypionate (e.g., Depo-Testosterone) and boldenone undecylenate (e.g., Equipoise)

**Web Site Discovery**

The goal of the investigation was to uncover as many Web sites as possible that sell target drugs.

**Internet Search**

The Internet was searched using several popular search engines such as google.com as well as “meta” search engines (i.e., engines that search several search engines at once, such as dogpile.com, hotbot.com), combining the word “buy” with the drug being investigated (e.g., “buy Valium”). The number of hits obtained was then narrowed down and potential informational pages were excluded. The domain names from the resulting hits were added to the master database that was created for this purpose unless they were of no interest to this investigation, such as news articles or technical or academic papers.

Web sites from any e-mail advertisements (a.k.a. spam) that were received by the investigators also were investigated and included in the database if appropriate.

**Web Site Investigation**

Once a Web site was identified as a seller of a target drug, the investigators looked for the following information:

**Portal vs. Anchor Site**

Based on prior research, BDA realized that it is important to consider the relationship between what users see on the screen when a Web site is accessed and which Web servers actually are being accessed.

For example, Internet searchers may think they are visiting only one site when in fact they are being forwarded to a separate site. Or the page they are visiting might appear to be selling pharmaceuticals when actually it does not but is linked to other Web sites that do. Bearing those distinctions in mind, Web sites were categorized either as anchor sites or portal sites. An anchor site is one that sells the drugs directly to the potential buyer while a portal site only refers the potential buyer to the anchor site.

**Advertised Country of Origin**

Web sites exist in cyberspace and not in the real world. Therefore, when discussing the “location” of a Web site selling drugs one can mean the location the Web site advertises is the origin of the drugs it sells, the physical location of the computers holding the Web site data, the location of the business or individual running the Web site or the location from where the drugs actually are shipped.

The second definition provides little information because data in the Internet can be transmitted from anywhere in the world. The third presents a host of problems because registration information for a Web site can intentionally or unintentionally be inaccurate. And even if accurate, the Web site operator can exist anywhere in the world separate from the location from where the drugs are shipped. The fourth
definition would by far be the most accurate since the postage and return address would provide all the information one requires. However, that information is available only when the drugs are ordered--something the investigators did not do.

Thus, the information provided by the Web site as to the country from where the drugs originated was counted as the “advertised country of origin.”

Determinants of the advertised country of origin included:

- Text in the body of the Web page that stated outright the source of the drug(s);

- Graphics, such as a country’s flag, that might lead a visitor to believe the drugs were from a certain location; or

- The title of the site itself that would lead a visitor to believe the drugs were from a certain location.

**Dispensing Pattern**

Given the information provided by each Web site, investigators were able to determine each site’s prescription requirements. This was determined either by browsing through each site looking for such sections as “FAQs” or “How to Order” or by beginning the ordering process and noting if and when a prescription requirement was requested. The dispensing patterns of all the Web sites fell into these categories:

- **Pre-written prescription.** Some Web sites required that the patient submit a prescription already written by a doctor. In most cases, this was to be sent via fax (thus allowing an individual to use the same prescription at several sites). Occasionally, a site required the original prescription to be mailed. Both cases were noted in the master database.

- **Online consultation.** Other Web sites did not require a prescription. However, they required answers to a questionnaire that often was referred to as an “online consultation.” These sites asked the patient to fill out some form of medical questionnaire. Occasionally, a consultation fee was charged for this service.

- **No prescription.** Several sites made no mention of any type of prescription requirements nor did they include a medical questionnaire. Other sites advertised that no prescription was needed.

**Available Drugs**

Investigators noted any target drugs that were available at the Web site. If an investigator discovered a Web site selling a target drug, he or she recorded the drug in the database.
Appendix F
State Initiatives to Regulate Internet Pharmacies

New Hampshire enacted legislation in 2000 requiring registration of mail-order and Internet pharmacies and receipt of a permit to do business in the state.

Indiana enacted a law in 1999 requiring online pharmacies to comply with licensure laws of the state in which the Internet pharmacy resides.

Virginia enacted a law in 1999 requiring the Board of Pharmacy and the Board of Medicine to study the online sale of prescription drugs.

At least 12 states have taken action against physicians for Internet prescribing violations, including California, Colorado, Florida, Hawaii, Illinois, Michigan, Missouri, Nevada, Ohio, Washington, Wisconsin and Wyoming.

At least nine states have adopted rules or statements that clarify standards for Internet prescriptions and distribution of drugs, including Alabama, California, Florida, Maryland, Missouri, Nevada, North Carolina, Ohio and Texas.

In January 2000, the Michigan Department of Consumer and Industry Services established an Internet Prescribing Task Force to review rules and statutes regarding Internet prescribing, telemedicine and mail order pharmacies.

In March 2005, the Kentucky House of Representatives passed an anti-methamphetamine bill that was approved by the Senate in February 2005. The House amended the bill to tack on a bill that attempts to control Internet pharmacy drug sales to state residents by requiring Internet pharmacies to register with the state pharmacy board and be monitored by the KASPER system (the system that tracks prescription drug purchases in Kentucky). The bill was signed into law in March 2005 and became effective in June 2005.
Appendix G
Examples of State Actions to Address Controlled Prescription Drug Diversion and Abuse

State Prescription Drug Monitoring Programs

Four states have been selected, based on their unique characteristics, to serve as examples of state prescription drug monitoring programs (PDMPs). This information was obtained from key informants who directed the state PDMP or worked on the program in a managerial capacity.

Kentucky

In 1997, the Governor of Kentucky created a task force on prescription drug abuse and soon after recommended legislation for an electronic prescription drug monitoring program. Estimates gathered in advance predicted a cost savings of over $250,000 per year for law enforcement and healthcare regulatory agencies combined.\(^1\) Legislation for the EDT was passed in 1998\(^2\) and the program was implemented in 1999. As a result of the Governor’s interest in prescription drug diversion and abuse, he allotted funds for the program in the state budget in 1998. Therefore, the money already was in place when legislation was passed.\(^3\)

The Kentucky All-Schedule Prescription Electronic Reporting system (KASPER) monitors Schedules II through V controlled substances and requires dispensers (including physician dispensers) to report their prescription data twice monthly. Reports from the KASPER program are made available to physicians, pharmacists and law enforcement when diversion or abuse is suspected. The KASPER program receives 500 requests on average per day. KASPER averages a four-hour turnaround time for requests. KASPER generates reports by request and does not monitor the data to detect any abnormalities in prescribing practices, trends or patient behaviors. KASPER also includes an educational component for healthcare practitioners and professional
associations that addresses the scope of the diversion and abuse problems, the function of KASPER and lessons on proper prescribing and dispensing practices.  

**Washington**

Washington remains the only state to solely utilize triplicate prescription forms. The PDMP is used only to monitor specific prescribers suspected of overprescribing. Once the licensing board confirms that overprescribing has occurred via the information gathered from the PDMP, it may require the prescriber to submit to the board for its review a copy of each controlled substance prescription that had been issued. At any given time, there may be five to 10 prescribers monitored in this way. The physician is responsible for sending the third copy of the prescription (one is given to the patient to give the pharmacist and the other is kept by the physician) to the board.

**Virginia**

Abuse of controlled prescription drugs, particularly OxyContin, has received significant press attention in Virginia. In response to prescription drug diversion and abuse, a Governor’s task force was established and police diversion units now are stationed throughout the state. Originally, the task force proposed a comprehensive PDMP that would cover Schedule II through IV substances and would allow for retrospective and prospective investigations and monitoring. A dual bill was proposed in 2002 and legislators in favor of the bill tried to push it through quickly. Education for lobbyists was planned to ensure the bills would pass. However, the education campaign never took place and the bill was watered down; a PDMP bill was passed, but it was much different than the one originally proposed. The PDMP that passed was to be implemented only in a certain region of the state, would cover only Schedule II drugs and would be used only in the course of retrospective investigations.

Physicians and law enforcement can request information contingent on presenting a probable cause and physicians must have the patient’s consent to request the information. While some feel that this approach is better than nothing, others in the state fear that this limited program may only exacerbate the problem if illegitimate drug seekers begin to move to different regions and look to Schedules III and IV drugs that are not covered under the program.

**New York**

New York’s PDMP uses a single copy serialized form and Electronic Data Transfer (EDT) to monitor Schedule II drugs. The Department of Health’s Bureau of Controlled Substances operates the PDMP and has the authority of law enforcement. Historically, forgery and counterfeit prescriptions were the biggest methods of diversion in New York State.

Triplicate, and now serialized single copy forms have been an effective means of eliminating counterfeit and forged prescriptions. Any healthcare practitioner with a designated DEA number can purchase serialized forms. Once a licensed practitioner fills out the prescription, the patient takes the prescription to the pharmacy where it is logged electronically. When the Bureau receives a tip regarding a case of possible diversion or abuse, a report is run from the Bureau’s office and cases are prioritized based on their perceived likelihood of diversion and the degree of risk to the public’s health. Information is released only by subpoena to boards for disciplinary cases. Many doctors in New York are opposed to this system, especially because physicians cannot request information from the PDMP.

**Other State Actions**

Some states have developed task forces or special units to tackle the problems of prescription drug diversion and abuse. Several examples of such efforts are provided.

**Colorado**

Colorado has not yet passed PDMP legislation. In the meantime, they have a prescription drug
task force whose primary focus is on education. The Colorado Prescription Drug Task Force has initiated an educational campaign in medical schools, health fairs and in elementary, middle and high schools across the state. A main objective of the task force is to teach healthcare practitioners and law enforcement officials how to address effectively pain management, how to avoid getting scammed by patients and how to investigate fraud. The task force also teaches children how to talk to their doctors, when to throw away medications and the harms of misusing prescription drugs. They have implemented a DEA hotline available for anyone to call and report incidents of diversion or abuse. This information is sent directly to pharmacies for follow-up. There are over 600 individuals volunteering with the task force from all different professions, including healthcare and law enforcement. Some of these volunteers also deliver educational presentations. The task force extends its educational programs to seniors, teaching them how to talk to their doctors about proper prescription drug use. The Department of Health and Human Services provides $50,000 each year to support the task force.

Connecticut

Connecticut, like Colorado, does not yet have a PDMP although there have been numerous attempts to pass such legislation. The Drug Control Division of the Department of Consumer Protection is responsible for monitoring all prescription drugs in Connecticut. This division deals solely with prescription drug diversion and has helped to contain the problems of diversion and abuse of prescription drugs in Connecticut, despite the lack of a PDMP.

Connecticut also has various educational programs aimed at medical and nursing schools across the state. In addition, newsletters are sent out to practitioners and pharmacists to help them identify scammers, individuals forging prescriptions and doctor shoppers.

Kentucky

Kentucky has both a task force and a prescription PDMP. The task force focuses solely on the diversion and abuse of OxyContin. Governor Paul Patton created the OxyContin Task Force in 2001 in response to a significant problem with the drug throughout the state. Law enforcement agencies from across the state were selected to serve on this task force. Its goals are to create educational programs and implement law enforcement and legislative actions to help address the problem.
Appendix H
Diversion Control Through Medicaid

In 1983, Medicaid initiated its first effort to control prescription drug diversion and abuse. It conducted an audit in the District of Columbia to survey the current systems in place to monitor prescription drug diversion. A second audit conducted by the Office of Inspector General (OIG) in 1990 revealed that available systems for monitoring and controlling prescription drug diversion remained inadequate. The OIG deemed Medicaid an important target for diversion control since 15 of the top 20 abused drugs at the time were prescription drugs covered by Medicaid. The OIG worked with the DEA to create a computer software system, geared toward identifying practitioners, pharmacists and patients involved in drug diversion. Once the system was piloted in the District of Columbia, its use expanded to other states across the country.

On the street, the Medicaid card is called the “Gold Card” because those who have one seldom have their identities verified.

PDMPs and Medicaid Fraud Units

The Medicaid system has various mechanisms in place that are well-suited for helping to monitor or identify cases of diversion, despite the fact that these are not the main objectives of those mechanisms. For example, patients who are suspected of diverting or abusing drugs can be locked into one provider or pharmacy.* In Missouri, from January 2000 to August 2001, 400 Medicaid recipients were restricted to a single provider or pharmacy due to suspected abuse of prescription drugs. Another mechanism for monitoring diversion through the Medicaid system involves the Medicaid Fraud Control Units. These state-run units investigate fraudulent activity related to Medicaid that

* This mechanism allows Medicaid to control costs by preventing patients from obtaining duplicate medications. For diversion control purposes, it also can help to prevent doctor shopping.
includes but is not limited to investigations related to prescription drug diversion. In states with a PMDP, relevant information is fed to the Medicaid Fraud Unit for further investigation. For example, in Texas, the Medicaid Fraud Control Unit would respond to cases such as a healthcare worker who sells a patient’s medication or keeps it for personal use, a physician who sells prescriptions illegally or a nurse who orders a prescription for a patient without a doctor’s approval.

**Drug Utilization Review (DUR)**

Medicaid prescriptions also are tracked through the Medicaid Drug Utilization Review (DUR) program. DUR was a term originally intended to describe the review of a patient’s medication trajectory in order to ensure quality patient care. After 1990, these reviews became a federal requirement under the Omnibus Budget Reconciliation Act of 1990. DUR requirement mandates that states conduct reviews of outpatient drug utilization to make sure that prescriptions written and dispensed are appropriate, medically necessary and will not result in adverse medical consequences. These reviews are aimed at educating practitioners and pharmacists about how to identify and prevent adverse drug reactions, abuse, inappropriate use, overuse and fraud. The DUR also requires that states establish educational interventions aimed at helping physicians and pharmacists address drug therapy and problem patients identified through retrospective reviews. For example, Idaho Medicaid distributes educational pamphlets on how to prevent drug-related problems that commonly occur.

Two types of DUR are mandated. The retrospective DUR takes place after the point of sale and tracks physicians’ and pharmacists’ patterns to ensure that they are in accordance with drug standards. The retrospective review compares drug use against practice standards in an effort to identify cases of under- and over-utilization of medications by a patient. This review has the potential to identify inappropriate use of a drug, abuse and fraud, although it is not efficient for monitoring larger-scale diversion. The prospective DUR examines individual level drug use at the point of purchase. All pharmacies have a software package that records the various drugs that a patient is taking to ensure quality patient care (e.g., avoid adverse drug reactions when a patient is taking more than one medication). A second software package screens for early and late refill requests to help ensure that patients are obtaining their medications as prescribed.

**Prior Authorization**

State Medicaid plans may require prescribers to obtain approval from their state Medicaid agency (or a subcontractor) prior to the dispensing of a particular drug by a pharmacist. States may impose such prior authorization requirements on one or more individual drugs or on all drugs in one or more therapeutic classes. Some states require prior authorization for drugs that are not commonly indicated and also have a high likelihood for abuse. For example, Florida, Maine, Ohio, South Carolina and West Virginia all require prior authorization for dispensing OxyContin. Also, if a state elects to establish its own formulary, prior authorization is required for any drug excluded from the formulary.

**Audits**

Some states have implemented an auditing system for Medicaid patients. For example, in Missouri, the auditing system is very similar to the commercial software used by most pharmacies to communicate with various pharmacy benefit managers and health insurers and is used to identify individuals who are potentially abusing or diverting prescription drugs. These programs notify pharmacies when a recipient requests a medication in the same class or time period as an earlier request. In states such as Kentucky and Illinois, the pharmacist is required to check with the prescribing physician when a prescription is flagged as suspicious.

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* A list of drugs covered by Medicaid.
Appendix I
Suggested Responsible Parties for Carrying Out CASA’s Recommendations

The Federal Government

Congress

- Clarify federal law to prohibit sale or purchase of controlled prescription drugs on the Internet without an original copy of a prescription issued by a DEA-certified physician, licensed in the state of purchase, based on a physical examination and evaluation, and to impose higher penalties for illegal sale to minors.

- Require Internet search engines to provide warnings that sale and purchase of controlled prescription drugs over the Internet from unlicensed pharmacies and physicians and without prescriptions are illegal and to block sites that fail to require a legitimate prescription for selling controlled prescription drugs.

- Assure access to appropriate treatment for: teenagers for whom prescription drug abuse often is part of a larger drug problem; adults for whom prescription drugs is their main drug problem and who may have become addicted to these drugs inadvertently as a result of using or misusing prescribed medications; and adult poly-substance abusers who more closely resemble the larger drug-abusing population and who need treatment options that address their abuse of prescription drugs in addition to their abuse of other substances, while not compounding their addiction.

- Enact legislation prohibiting direct-to-consumer advertising of controlled prescription drugs on the grounds that it poses a danger to the public health and is contrary to the spirit of the Controlled Substances Act.
**Department of Justice**

- The U.S. Department of Justice and the FDA should fund the development of model state legislation for state prescription drug monitoring programs (PDMPs), and provide financial incentives for states to develop and operate PDMPs in accordance with national standards. Such legislation would protect patient privacy, assure physicians and pharmacists access to patient data, provide law enforcement officials with access based on probable cause, provide for interstate data sharing and stipulate specific outcome measures to determine the efficacy state PDMPs.

- The DEA and state Attorneys General should encourage financial institutions (credit card and money order issuers) to restrict purchases of controlled prescription drugs from non-licensed and accredited providers.

- The DEA and state Attorneys General should encourage postal and shipping services to train counter and delivery personnel to recognize potential signs of pharmaceutical trafficking and to know how to respond in the event of suspicious activity.

- Step up enforcement of drug importation laws related to the sale of controlled prescription drugs and enforce international conventions.

- Ensure that there is adequate staffing of law enforcement and federal prosecutors to pursue cases of controlled prescription drug diversion and enact significant sanctions on clinicians and pharmacists who intentionally divert controlled prescription drugs.

- ONDCP, DEA and FDA should carry out their intention to develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making online purchases of controlled substances.

- The DEA should require that as a condition of becoming registered to prescribe or administer controlled drugs, physicians demonstrate competence in prescribing controlled substances and physicians and pharmacists demonstrate knowledge of the Controlled Substances Act, how to recognize the signs and signals of diversion and abuse and how to respond in the event of suspicion of a patient or professional colleague.

- The DEA should include relevant educational material in correspondence with healthcare professionals, including the mailing of licenses or prescription pads.

**Department of State**

- The State Department should encourage and assist foreign governments to crack down on Internet sites illegally selling controlled prescription drugs to U.S. citizens.

**Department of Health and Human Services**

- The U.S. Department of Justice and the FDA should fund the development of model state legislation for state prescription drug monitoring programs (PDMPs), and provide financial incentives for states to develop and operate PDMPs in accordance with national standards. Such legislation would protect patient privacy, assure physicians and pharmacists access to patient data, provide law enforcement officials with access based on probable cause, provide for interstate data sharing and stipulate specific outcome measures to determine the efficacy state PDMPs.

- To better inform policy, prevention and treatment initiatives, national surveys of drug use (e.g., the National Survey on Drug Use and Health, the Monitoring the Future study) should refine their measures of prescription drug abuse and addiction, use a consistent terminology in referring to these...
problems and add questions asking respondents how they obtained the prescription medications that they abused.

- Assure access to appropriate treatment for: teenagers for whom prescription drug abuse often is part of a larger drug problem; adults for whom prescription drugs is their main drug problem and who may have become addicted to these drugs inadvertently as a result of using or misusing prescribed medications; and adult poly-substance abusers who more closely resemble the larger drug-abusing population and who need treatment options that address their abuse of prescription drugs in addition to their abuse of other substances, while not compounding their addiction.

- Federal and state mandated benefit laws should require managed care and private health insurance companies to reimburse physicians and dentists for time spent screening patients for substance abuse and addiction, for referring them to treatment if needed and costs of treatment, and collaborating with pharmacists to prevent diversion and abuse.

- The FDA should require pharmaceutical companies to include proactive risk management plans in all new applications for controlled drugs, demonstrating strong evidence of a prescription drug’s safety and incremental benefits relative to existing drugs, as well as concrete steps that will be taken to prevent the abuse of the drug while maintaining its maximum therapeutic effectiveness.

- The FDA should require all pharmaceutical companies to submit promotional materials for controlled prescription drugs to the FDA for review and approval prior to their use.

- The FDA should require that a pedigree (the documented sales history of a drug) accompany all controlled prescription drugs sold by wholesalers and retailers in order to help prevent counterfeiting and track stolen drugs.

- The FDA should require pharmaceutical companies manufacturing controlled drugs to formulate or reformulate the drugs where possible to minimize the risk of abuse. Pharmaceutical companies should be required to demonstrate in their application materials for FDA approval of new drugs that they have made every effort to formulate the drug in such a way that avoids or at least minimizes the drug’s potential for abuse.

- ONDCP, DEA and FDA should carry out their intention to develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and illegality of making online purchases of controlled substances.

- Federal agencies (e.g., National Institute on Drug Abuse, Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration) should fund systematic and well-designed studies to better understand prescription drug diversion and abuse. (See “Researchers” for examples.)

Office of National Drug Control Policy

- Government-sponsored public awareness campaigns that focus on alcohol, marijuana and other illicit drugs should be broadened to include the abuse of controlled prescription drugs as well as the dangers of poly-substance abuse. They should inform parents to safeguard their prescription drugs from their children, and advise individuals and families to dispose properly of unused controlled medications.

- ONDCP, DEA and FDA should carry out their intention to develop public service announcements that appear automatically during Internet drug searching to alert consumers to the potential danger and
illegality of making online purchases of controlled substances.

**States and Localities**

- Train law enforcement professionals (including state and local police and prosecutors) to better understand the therapeutic uses of controlled prescription medications and conditions under which the medical community recommends their use in treating patients. Law enforcement should work closely with medical professional groups to develop diversion control strategies that would not produce an unnecessary chilling effect on physicians who treat patients in need of controlled prescription drugs.

- Simplify the process of reporting suspected cases of diversion to law enforcement authorities in order to encourage health professionals and pharmacists to do so.

- Ensure that there is adequate staffing of law enforcement and federal prosecutors to pursue cases of controlled prescription drug diversion and enact significant sanctions on clinicians and pharmacists who intentionally divert controlled prescription drugs.

- Schools and communities should incorporate prescription drug abuse, including steroid abuse, into evidence-based substance use prevention programs, beginning with elementary school and continuing through college.

**Healthcare Industry**

- The Association of American Medical Colleges (AAMC), the American Dental Education Association (ADEA), the Association of American Veterinary Medical Colleges (AAVMC), the American Association of Colleges of Nursing (AACN) and the American Association of Colleges of Pharmacy (AACP) should require education and training—including medical school and residency training, post-graduate fellowships and continuing medical education—in prescribing and administering controlled drugs; identifying diversion; identifying, diagnosing and treating substance abuse and addiction; and identifying, diagnosing and treating psychiatric disorders and pain in ways that minimize the risk of abuse and addiction.

- The American Board of Medical Specialties should require that knowledge in identifying, diagnosing and treating substance abuse, addiction and the prescribing/administering of controlled drugs be part of its minimum standards of competency.

- State professional boards should require that, as a condition of licensure, license renewal or registration, healthcare professionals should complete training in substance abuse, addiction, pain management and the legal regulations and responsibilities related to the prescribing and dispensing of controlled drugs.

- National professional boards (medical, dental, nursing, pharmacy, veterinary) should establish, publicize and enforce national standards of practice related to substance abuse, addiction and the prescribing, administering and monitoring of controlled prescription drugs. Standards should include: use of screening and diagnostic tools; assessing patients’ past use of controlled medications; prescribing and administering controlled substances; monitoring patients’ drug use and routine reevaluation of the medication’s efficacy and need for continued use; identifying complications of care including signs of diversion or abuse; safeguarding controlled prescription drugs; and preventing prescription fraud. Healthcare providers also should be trained to employ techniques such as patient contracts, urine tests and pill counts, as indicated, to limit diversion. At the same time, professional boards should establish, publicize and enforce standards related to pain management and assure that physicians provide quality care to their
patients in a way that reduces the risk of addiction to pain medications.

- The DSM-IV diagnostic categories for substance-related problems should be amended to take into consideration the unique aspects of prescription drug abuse and addiction, distinguishing between physical dependence and addiction.

- Assure access to appropriate treatment for: teenagers for whom prescription drug abuse often is part of a larger drug problem; adults for whom prescription drugs is their main drug problem and who may have become addicted to these drugs inadvertently as a result of using or misusing prescribed medications; and adult poly-substance abusers who more closely resemble the larger drug-abusing population and who need treatment options that address their abuse of prescription drugs in addition to their abuse of other substances, while not compounding their addiction.

- Treatment programs should make medical assessment a standard part of treatment for prescription drug abusers so that any underlying medical condition (e.g., pain, ADHD, insomnia) that might compromise treatment for abuse can be addressed.

- Treatment programs should address co-occurring disorders and, where appropriate, combine evidence-based behavioral therapy with available pharmacological interventions.

Parents

- Parents should safeguard their prescription medications from their children, refrain from conveying through words or actions messages that condone casual use of prescription drugs, and be vigilant about their children's use of controlled medications prescribed to them to ensure that their children are taking the drugs appropriately and not selling or sharing them.

- Parents also should take steps to make sure their children are not using the Internet to acquire controlled prescription drugs.

Researchers

- Federal agencies (e.g., National Institute on Drug Abuse, Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration) should fund systematic and well-designed studies to better understand prescription drug diversion and abuse. Such research might include studies examining:
  - The conditions under which legitimate medical use of controlled prescription drugs leads to abuse or addiction, the timing of prescription drug abuse relative to the abuse of other substances and the relationship between the abuse of controlled prescription drugs and illicit drugs;
  - Risk and protective factors for prescription drug abuse;
  - The relationship between the availability/supply of controlled prescription drugs and their likelihood of abuse;
  - The effectiveness of current programs aimed at tracking, preventing or reducing prescription drug abuse and diversion;
  - The impact of diversion prevention programs on the therapeutic use of controlled medications;
  - The development of validated screening tools for identifying and/or diagnosing prescription drug abuse.
  - The development of new pharmacological and psychosocial treatments for prescription drug abuse.
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