

The Peer Report

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Dedicated to quality, accessible prevention and intervention services in workplaces and communities, focusing on substance abuse and related issues.

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NIDA Responds to Changing Drug Abuse Patterns

By Nora D. Volkow, M.D. Director, National Institute on Drug Abuse National Institutes of Health Department of Health and Human Services, July 26, 2006

Efforts of the National Institute on Drug Abuse to Prevent and Treat Prescription Drug Abuse — Testimony Before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources Committee on Government Reform, United States House of Representatives

Statement for the Record

Mr. Chairman and Members of the Subcommittee: Thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services, to participate in this important hearing. Prescription drugs are powerful allies in our quest to alleviate human suffering. And psychotherapeutics - those drugs that target the central nervous system (CNS) — are responsible for remarkable advances in our ability to understand and reduce the burden of mental illness and physical pain.

However, as is often the case with beneficial technologies, there is a negative side, too. Because some of the psychotherapeutic drugs act, either directly or indirectly, upon the same brain systems affected by addictive drugs, their non-medical use carries a substantial abuse liability that NIDA's efforts are designed to assess, reduce, and make publicly known. I am pleased to have the opportunity today to share with you what we know and where we are relative to the issue of prescription drug abuse in this country.

What is the Scope of Prescription Drug Abuse in this Country?

Several indicators show that prescription drug abuse is a significant problem in the

United States and one that has been increasing recently.

- Approximately 6 million persons 12 and older used psychotherapeutic drugs for non-medical purposes in 2004, which represents 2.5 percent of the U.S. population. Most of them reported abusing opiate pain relievers in particular, with young adults (18-25) showing the greatest increases in lifetime use between 2002 and 2004 (National Survey on Drug Use and Health (NSDUH), conducted by HHS's Substance Abuse and Mental Health Services Administration).
- In 2004, 2.4 million persons ages 12 or older initiated non-medical use of prescription pain relievers during the past year, surpassing for the first time in the life of the survey, those who initiated abuse of marijuana (2.1 million) (National Survey on Drug Use and Health).
- Among 12th graders, in 2005, 9.5% reported past-year non-medical use of Vicodin, and 5.5% reported past-year non-medical use of OxyContin. Data show an increase in the abuse of OxyContin between 2002 and 2005 among 12th graders (NIDA's 2005 Monitoring the Future survey [MTF]).
- Past-year non-medical use of stimulant medications is also high, with 8.6% of 12th graders reporting abuse of amphetamine (a parent class of drugs that includes methamphetamine), and 4.4% reporting abuse of methylphenidate (Ritalin) (2005 MTF).

(Continued on page 2)

Prescription Drugs with Abuse Liability

The psychotropic prescription drugs that present abuse liability fall into three broad categories:

(1) stimulants, which are prescribed to treat attention-deficit hyperactivity disorder (ADHD) and narcolepsy and include drugs such as Ritalin and Adderall; (2) opioids, which are mostly prescribed to treat moderate to severe pain and include drugs such as OxyContin and Vicodin; and (3) CNS depressants, typically prescribed for the treatment of anxiety, panic, sleep disorders, acute stress reactions, and muscle spasms and include drugs such as Valium, Librium, and Xanax.

To understand how these drugs can have both beneficial effects in patients and serious abuse and health liabilities in people taking them for non-medical reasons requires knowledge of how drugs exert their effects in the brain. As noted above, there can be substantial overlap between the brain systems that mediate the therapeutic effects of psychotropic medications and those responsible for the reinforcing effects of drugs of abuse. However, while the molecular targets in the brain for some medications may be the same ones as those for some of the drugs of abuse, differences in how much of the drug gets into the brain and how fast it gets there determine whether desirable (therapeutic) or undesirable (abuse and addiction) effects will follow. Factors such as drug dosage, route of administration (which regulates the speed of drug delivery to the brain), and user expectations are crucial. For example, the stimulant methylphenidate (Ritalin) has much in common with cocaine — they bind to similar sites in the brain and they both increase the brain chemical dopamine through the same molecular targets. And when both drugs are administered intravenously, they cause a rapid and large increase in dopamine, which a person experiences as a rush or high. However, when methylphenidate is taken orally, as prescribed, it elicits a gradual and sustained increase in dopamine, which is not perceived as euphoria and instead produces the expected therapeutic effects seen in many patients.

Scientists and physicians are learning how to exploit such differences to develop formulations and dosage regimens for optimal therapeutic value and minimal abuse and addiction potential. Unfortunately, these strategies can sometimes be undermined by sophisticated abusers. Consider OxyContin, a pain medication originally marketed as having a low potential for abuse because it was formulated to ensure a slow and gradual release of the drug. Abusers quickly learned that the

pills could be crushed and their contents injected or snorted, releasing the entire dosage at once. What abusers do not realize is the great risk of overdose and other devastating consequences that may result from this practice. Now widespread in its abuse, OxyContin is the only commonly prescribed opioid analgesic that comes with a "black box" warning.

Why is this happening now?

The recent increase in the extent of prescription drug abuse in this country is likely the result of a confluence of factors, such as: significant increases in the number of prescriptions; significant increases in drug availability; aggressive marketing by the pharmaceutical industry the proliferation of illegal Internet pharmacies that dispense these medications without proper prescriptions and surveillance; and a greater social acceptability for medicating a growing number of conditions. The fact that doctors are prescribing these drugs legitimately and with increasing frequency to treat a variety of ailments leads to the misguided and dangerous conclusion that their non-medical use should be equally safe. This misperception of safety may contribute, for example, to the casual attitude of many college students towards abusing stimulants to improve cognitive function and academic performance.

Notably, between 1987 and 1996, a nearly four-fold increase occurred in the prevalence of stimulant prescriptions among youth; this increase has persisted, but has since remained near the 1996 levels. Similarly, the number of oxycodone and hydrocodone prescriptions has more than doubled between 1994 and 2001. While such increases in psychoactive drug prescriptions reflect improved diagnostic practices and treatment options, it would be naive not to also consider the contribution of market forces in the emergence of these trends. For example, sales of ADHD medications in the United States reached \$3.1 billion in 2004. But even at this robust level of sales, the number of prescriptions for ADHD medications is less than 20 percent when compared to the 120 million prescriptions written in 2005 for pain medications containing hydrocodone or oxycodone. Such high exposure rates suggest that we need to discover the potential abuse consequences for youth and other populations at risk for addiction.

Special populations, specific risks and consequences

Indeed, the growing problem of prescription drug abuse in this country, which affects individuals at all stages in life, is alarming. In adolescents, the increase in

prescription drug abuse reported over the past 5 years contrasts with the steady declines in overall illicit drug abuse that has been reported in this group over this same time period. These trends in adolescents are particularly problematic because adolescence is the period of greatest risk not only for drug experimentation, but also for developing addiction. Also at this stage the brain is still developing and exposure to drugs could interfere with these developmental changes.

Today we know that the last part of the brain to fully mature is the prefrontal cortex, a region that governs judgment and decision-making functions. This may help explain why teens are prone to risk-taking and why high rates of risky behaviors, including abuse of alcohol and other drugs, have been reported among those who abuse prescription drugs. The 2001 NSDUH survey reveals that youth who had used prescription drugs non-medically in the past year were almost four times more likely to have also used other illicit drugs.

We are also particularly concerned about older Americans, who currently make up only 13 percent of the population but who receive approximately one-third of all medications prescribed in the Nation. For practical reasons, older patients are sometimes prescribed long-term and multiple prescriptions, which could lead to abuse or unintentional misuse. These medications can interact with over-the-counter medicines and dietary supplements, which older adults tend to consume in significant quantities. Older adults also experience higher rates of other illnesses, normal changes in drug metabolism, and increased susceptibility to toxic effects. It is hardly surprising then that abuse or unintentional misuse of prescription drugs by elderly persons could lead to more severe health consequences. For example, elderly persons who take benzodiazepines such as Valium, Librium, and Xanax are at increased risk for cognitive impairment, leading to possible falls as well as vehicular accidents. Moreover, not all physicians know that prescribing benzodiazepines to elderly people is contraindicated for these reasons. Therefore, physician education is a necessary part of any effort to curb the abuse of prescription medications.

Prescription drug abuse must also be carefully tracked among women because of their combined vulnerabilities. First, women are more likely than men to suffer from depression, anxiety, trauma, and victimization, all of which frequently appear with substance abuse in the form of comorbidities. Second, girls and women report using drugs to cope with stressful situations in their lives. Third, studies suggest that women are significantly more likely than men to be prescribed an abusable drug, particularly in the form of narcotics and anti-anxiety

medications. These cumulative risks notwithstanding, adult men and women have roughly similar rates of non-medical use of prescription drugs; 12- to 17-year-old girls, however, are more likely than boys to abuse psychotherapeutic drugs, including stimulants.

In addition to the risk to women is the potential for harm to the developing fetus. Therefore, more research is needed on the extent and patterns of prescription drug abuse during pregnancy. National projections from survey data collected between 2002 and 2004 suggest that 109,000 pregnant women abused pain relievers in the past year. And past-year abuse of any stimulants (including methamphetamine) or sedatives/tranquilizers was reported by 32,000 and 56,000 pregnant women, respectively. However, there is overall less non-medical abuse of prescription psychotherapeutics among pregnant than among non-pregnant women (6% and 9.3%, respectively), although this is not the case in pregnant adolescent girls (15–17 years), in whom the rate of prescription drug abuse is higher than in those who are not pregnant.

What Abuse of Prescription Drugs Does to the Brain and Body?

When taken under the supervision of a physician, prescription drugs can be lifesaving, but when abused, they can be as life-threatening as illicit drugs. Stimulants can elevate blood pressure, increase heart rate and respiration, cause sleep deprivation, and elicit paranoia. Their continued abuse, or even one high dose, can cause irregular heartbeat, heart failure, and seizures. Painkillers and anti-anxiety medications can cause depressed respiration and even death, and CNS depressants can also induce seizures when a reduction in their chronic use triggers a sudden rebound in brain activity. Particularly dangerous is when young people indiscriminately mix and share prescription drugs, also combining them with alcohol or other drugs. In an environment where opiate analgesics are the most frequently prescribed medication, with over 100 million prescriptions written every year, this risky practice is likely to contribute to the growing trend of drug abuse-related emergency room visits involving prescribed narcotics. And again, these classes of psychotherapeutic drugs have a real potential for leading to addiction, especially if abused repeatedly, at high doses, and/or by susceptible individuals.

What is NIDA doing about it?

Recent research has revealed an increasing problem with prescription drug abuse, yet we still must get a better picture of the broader epidemiologic patterns of abuse. We need to

learn more about how specific drugs are abused and in what quantities and combinations, why they are abused and how often, as well as other associated medical and health consequences. We also need a better understanding of the regional and local variations in patterns of abuse, and the influence of age, gender, and race/ethnicity all of which can provide an essential foundation for developing effective and targeted interventions and services.

Another important initiative pertains to the development of new pain medications or formulations with minimum abuse potential. We have witnessed some remarkable advances in this area of research recently with the introduction of buprenorphine/naloxone, a combined formulation for the treatment of opiate addiction with dramatically reduced abuse liability. Compounds that act on a combination of two distinct opioid receptors (μ and δ), have been shown in preclinical studies to induced strong analgesia without producing tolerance or dependence.

Researchers are also getting closer to developing a new generation of non-opioid-based medications for severe pain that would circumvent the brain reward pathways, greatly reducing abuse potential. Included are compounds that work through a cannabinoid receptor subtype located primarily in the peripheral nervous system.

Treatment and Prevention

Treatment and prevention of drug abuse and addiction are key NIDA goals. Our efforts to identify effective treatments for prescription opioid abuse and addiction include conducting a multi-center study of more than 600 participants, employing our Clinical Trials Network (CTN) to evaluate treatment regimens using oral buprenorphine/naloxone. In addition, behavioral therapies, an integral part of all treatment strategies, continue to be a mainstay for treating stimulant addiction.

Although scientifically validated prevention programs have been shown to be effective in curbing the prevalence of substance abuse and addiction in general, non-medical use of prescription drugs in some ways presents a more difficult scenario than illicit drugs. Because prescription drugs are safe and effective when used properly and are broadly marketed to the public, the notion that they are also harmful and addictive when abused can be a difficult one to convey. Thus, we need focused research to discover targeted communication strategies that effectively address this problem. Reaching this goal may be significantly more complex and nuanced than developing and deploying effective programs for the prevention of abuse of illicit drugs, but good prevention messages based on scientific evidence will be hard to ignore and

will make their mark in time.

In the meantime, the centerpiece of our strategy to curtail the prevalence of prescription drug abuse must center around our efforts to disseminate accurate information about the serious health consequences involved, with particular focus on addiction potential. Our messages aim to reach not only the general public and populations at heightened risk, such as adolescents, but also physicians and other health care providers, whose training on proper diagnostic and monitoring practices is vitally important. We will continue our close collaborations with physicians' organizations, the Office of National Drug Control Policy (ONDCP), SAMHSA and other Federal agencies, as well as professional associations with a strong interest in preserving public health. We regard these preventive efforts an integral part of NIDA's mission.

Conclusion

In conclusion, we should not be surprised that the availability of more, new, and better psychotherapeutics has been followed more recently by an upswing in the prevalence of their non-medical use by varied populations. However, we should be seriously concerned: prescription drugs can be powerfully addictive and their abuse accompanied by toxic and sometimes fatal consequences.

Perhaps one of the most challenging aspects of this trend is that prescription drug abuse affects individuals of all ages. On the other hand, we are fortunate to have in place an efficient warning system that has helped us to spot this problem at a relatively early stage and to quickly implement activities designed to keep it in check.

Consistent with one of NIDA's most important goals, our response has been framed by our commitment to translate what we know from research to help the public better understand drug abuse and addiction, and to develop more effective strategies for their prevention and treatment.

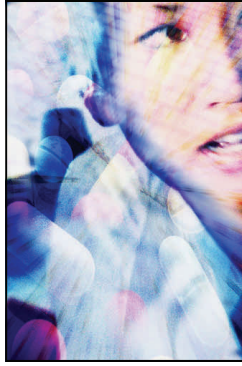
The emerging nature of the prescription drug abuse problem, combined with our substantial but still growing knowledge of its underlying causes and resulting consequences, make us optimistic about our chances to rationally and successfully address this challenge.

About the speaker

Dr. Volkow brings to NIDA a long record of accomplishment in drug addiction research. She is a recognized expert on the brain's dopamine system with her research focusing on the brains of addicted, obese, and aging individuals.

News Worthies

September is the 17th annual celebration of **National Alcohol and Drug Addiction Recovery Month (Recovery Month)**. This year, the initiative of the U.S. Department of Health and Human Services' Substance Abuse and Mental Health Services Administration (SAMHSA), through its Center for Substance Abuse Treatment (CSAT) asks you to **"Join the Voices for Recovery: Build a Stronger, Healthier Community"** and celebrate people and families in recovery from substance use disorders who have overcome stigma, discrimination, and other barriers to treatment and recovery support services.
www.recoverymonth.gov



HIV, Hepatitis and Substance Abuse Prevention Grant Funded through The U.S. Department of Health and Human Services Public Health Service (SAMHSA) (CSAP)

The estimated prevalence of human immunodeficiency virus (HIV) infection is nearly five times higher for incarcerated populations (2.0%) than for the general U.S. population (0.43%) (CDC-MMWR April 21st 2006). HepC Connection, a network and support system based in Denver, estimates that there are about 77,000 people infected with hepatitis C in Colorado and that over half of them are unaware of it. HIV, hepatitis, and substance abuse continue to be a problem for the U.S. population as a whole and for minorities with a history of incarceration in particular.

In an effort to combat these problems in the metro Denver region, Peer Assistance Service and Andrés Guerrero, HIV, Hepatitis and Substance Abuse Prevention Program Coordinator will soon implement a prevention program that will deal with these problems in an innovative way. The program will be based at Mile High and Southeast TASC offices and will focus on minorities on parole. This program will attempt to address the three issues of HIV, hepatitis, and substance abuse in a way that is effective and the basis of the program will be the Holistic Health Recovery Program (HHRP). This is a twelve-session, manual guided, group-level program to promote health and improve quality of life. HHRP takes a holistic approach to substance abuse and HIV prevention in the context of living a more healthful and rewarding life.

With the help of HepC Connection and the Colorado Department of Public Health and Environment, hepatitis information will be integrated into the sessions so that all three areas of concern, HIV, hepatitis and substance abuse, will be addressed. In order to ensure that the program is culturally relevant to the clients, the Voices prevention program will also be integrated into HHRP. Voices is a condom education and safer sex program that utilizes culturally-specific videos to show how to negotiate condom use with partners and how to properly use condoms. Finally, referrals for HIV and hepatitis testing will be made to those who wish to be tested.

The prevention program for minority parolees will be designed using techniques and prevention programs that have been proven to be effective. It is our expectation that this program will significantly reduce the incidence of HIV and hepatitis as well as substance abuse in those who participate.

Welcome New Peer Assistance Services Board Member, Gail Boyd

Gail Boyd, RDH, BS, BA, manager of Delta Dental of Colorado, recently joined the Peer Assistance Services Board of Directors.

Gail's professional experience included three years as a dental assistant, 11 years as a clinical dental hygienist, and 17 years at Delta Dental of Colorado in the capacity of professional services. For the past six years she has served as a department manager.

19 Annual Meeting of the Southwest Pharmacist Recovery Network—September 15–17, 2006

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“You’ve Got Drugs!” Prescription Drug Users on the Internet: 2006 Update

A Summary of CASA’s White Paper

The National Center on Addiction and Substance Abuse (CASA) at Columbia University and Beau Dietl & Associates has been following the availability of controlled prescription drugs on the Internet. *You’ve Got Drugs! Prescription Drug Pushers on the Internet* was published in 2004. The second report was CASA’s landmark study *Under the Counter: Diversion and Abuse of Controlled Prescription Drugs in the U.S., July, 2005*. This summarizes the third report in the series. It includes the most recent data from analysis done in February 2006 and compares the findings with the previous two reports.

- Despite the CASA reports, congressional hearings and increased media attention, prescription drugs are still easy to buy on the Internet. Anyone can readily obtain highly addictive controlled substances without a prescription.
- Controlled prescription drug abuse is still on the rise. More teens and adults report abusing these drugs than the number abusing all illicit drugs, except marijuana.
- The number of people who admit to abusing controlled prescription drugs increased from 7.8 million

in 1992 to 15.1 million in 2003 (94 percent) seven times faster than the increase in the U.S. population.

- In 2003, 15.1 million people in the U.S. admitted to 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.
- 344 sites were identified either advertising or selling controlled prescription drugs during a one week period in February 2006. For the third year, the number of sites selling drugs has increased.
 - 157 sites in 2004
 - 160 sites in 2005
 - 185 sites in 2006
- 89% of the sites selling controlled prescription drugs have no prescription requirements.
- Of the 11 percent (20) of the sites stating they require a prescription, 70 percent (14) require that the prescription be faxed (allowing forgery or faxing to several different Internet pharmacies).
- There has been a trend in Websites using “online” consultation instead of a prescription.
- In 2006, 99 sites selling drugs offered such consultations. Generally, the purchaser fills out an online questionnaire These consultations are intended to give the appearance of medical involvement rather than the criteria generally accepted to indicate a legitimate doctor-patient relationship exists.
- In 2003, 2.3 million teens between the ages of 12 and 17 (9.3 percent) admitted using a prescription drug within the last year, 83 percent of them, admitted to abusing opioids.
- Estimates of Internet pharmacies have reached as high as 1,400. It is difficult to get an accurate number due to Web sites being removed, changing names or addresses. Some sites are difficult to track due to multiple portal sites that connect to one online anchor pharmacy.

	2004	2005	2006
Sites selling drugs (anchor sites)	157 (32%)	160 (40%)	185 (54%)
Sites advertising drugs (portal sites)	338 (68%)	242 (60%)	159 (46%)
Total sites	495	402	344

Continued on page 7

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

- Of the 185 sites that directly sell controlled prescription drugs on the Internet, 89 percent did not require a prescription. Of those sites not requiring prescriptions:
 - 30 percent clearly stated, “no prescription required”
 - 60 percent offered an “on-line”

consultation

- 10 percent made no mention of a prescription
- Only 11 percent of the sites selling controlled prescription drugs required that a prescription be faxed or mailed or that the patient’s doctor is contacted for the prescription.
- Of the sites that required a prescription:
 - 7 percent asked for a faxed prescription (allowing forgery or faxing to multiple sites)
 - 15 percent asked that a prescription be mailed
 - 15 percent indicated that a doctor would be contacted prior to dispensing the drug
- No mechanisms exist to block children from purchasing addictive prescription drugs on-line. With access to a credit card, children may obtain dangerous, addictive and potentially lethal medication.
- Physical location of the anchor sites is difficult to determine. Of the 185 sites identified selling drugs in 2006:
 - 38 percent indicated they would be shipped from a U.S. pharmacy
 - 31 percent indicated they would be shipped from outside the U.S.
 - 31 percent gave no indication of where the drugs would originate

Next steps:

CASA recommends the following to address the problem of illegal Internet access to controlled prescription drugs:

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

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

The Office of National Drug Control Policy (ONDCP), DEA and FDA develop public service announcements that appear automatically during Internet drug searching to alert consumers of the potential dangers and illegality for making on-line purchases of controlled substances.

The DEA and financial institutions (credit card and money order issues) collaborate to restrict purchases of controlled prescription drugs from non-licensed and accredited providers.

Train postal and shipping services counter and delivery personnel to recognize potential signs of pharmaceutical trafficking and know how to respond in the event of suspicious activity.

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

The federal government, Internet search providers, shippers, financial institutions and non-profit organizations concerned with prescription drug abuse cooperate in creating a national non-profit clearinghouse to identify and shut down illegal Internet pharmacies.

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