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Testimony

Statement by

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on

Prescription Drug Abuse

before

The Subcommittee on Criminal Justice, Drug Policy, and Human Resources

Committee on Government Reform

U.S. House of Representatives

Wednesday, July 26, 2006

Mr. Chairman and Members of the Subcommittee:

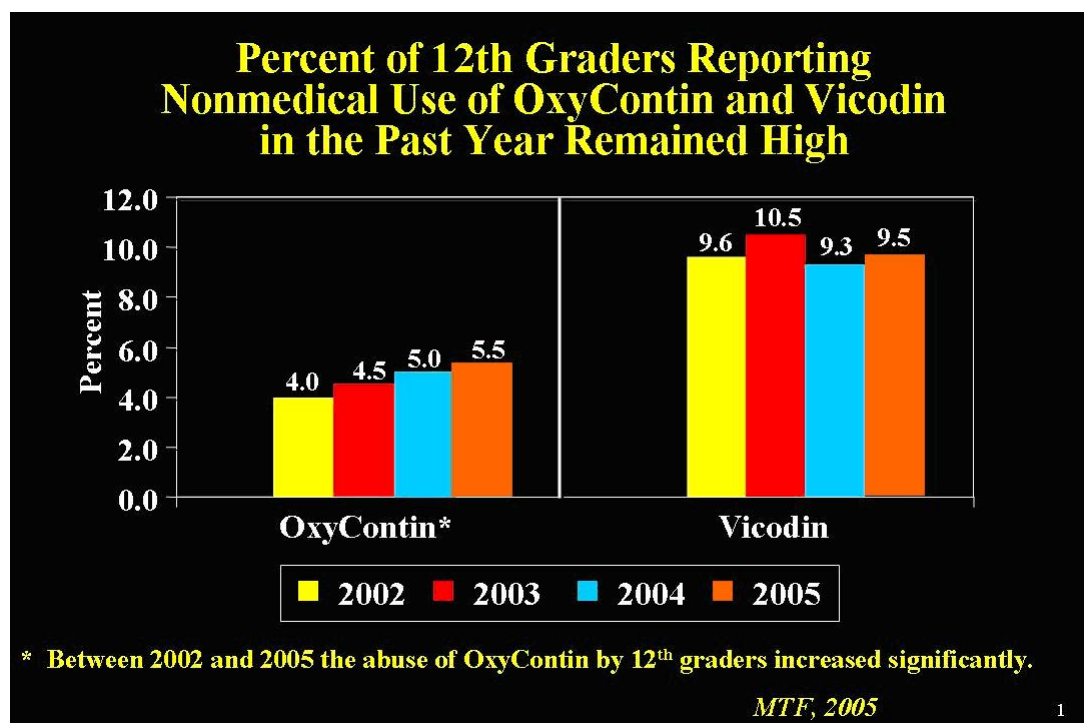
Thank you for inviting the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services, to participate in this important hearing. Prescription drugs are powerful allies in our quest to alleviate human suffering. 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).

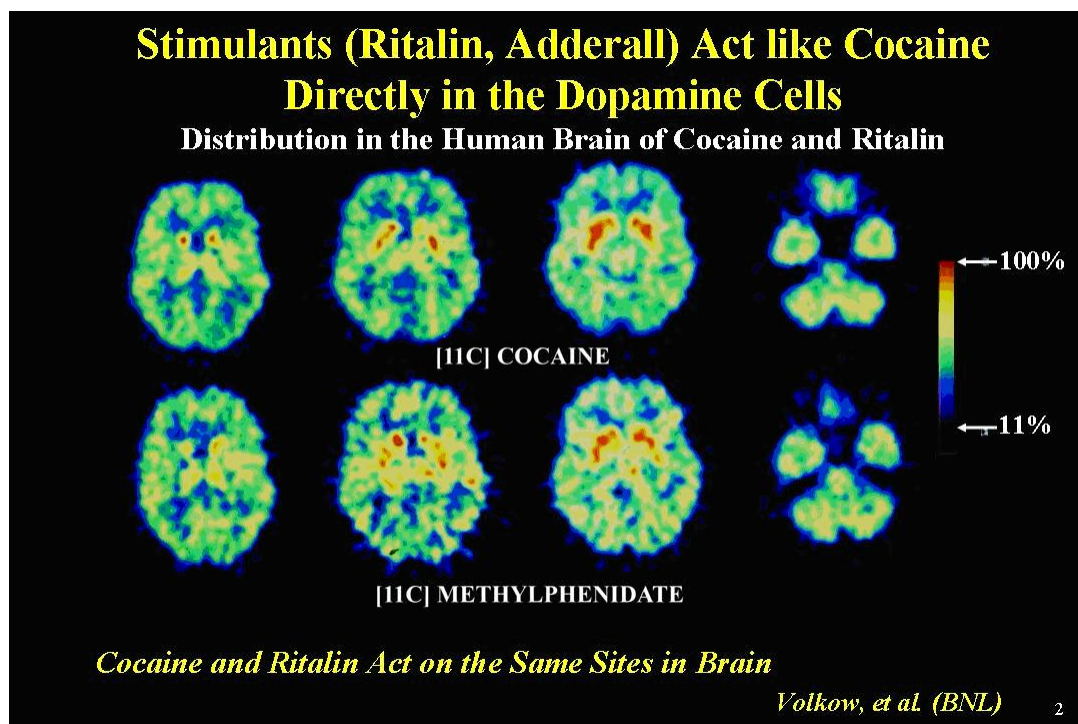
Prescription Drugs with Abuse Liability

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;¹ significant increases in drug availability;² aggressive marketing by the pharmaceutical industry;³ the proliferation of illegal Internet pharmacies that dispense these medications without proper prescriptions and surveillance;⁴ 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.

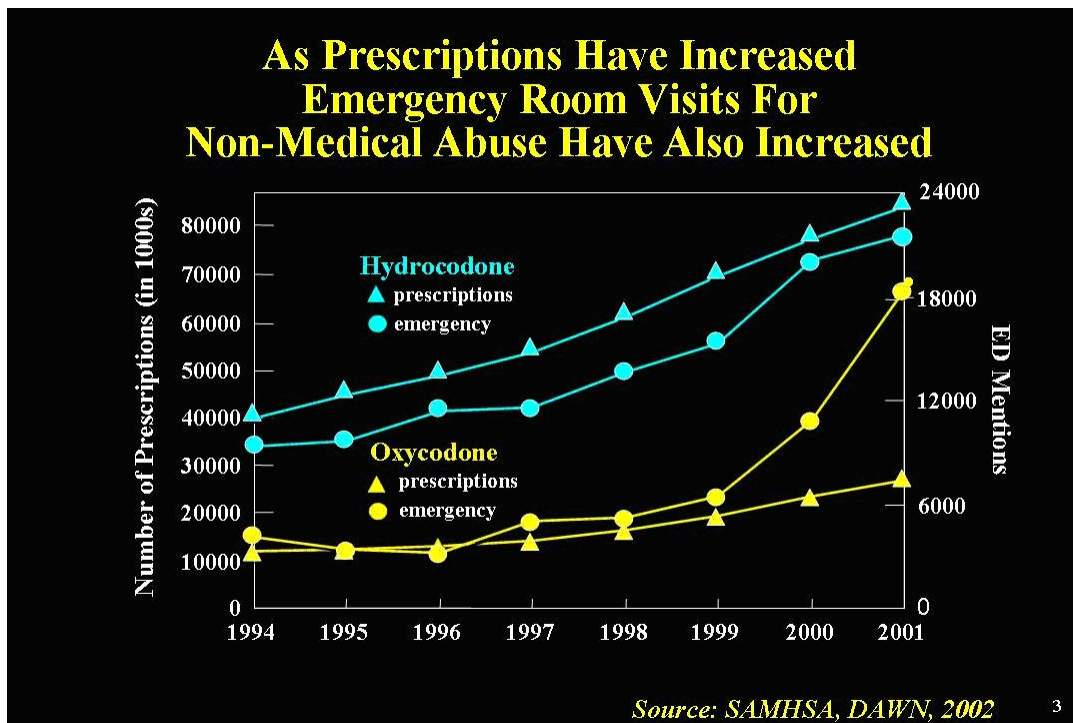
Prescription drug abuse must also be carefully tracked among women because of their combined vulnerabilities. First, women are more likely than men to suffer from depression, anxiety, trauma, and victimization, all of which frequently appear with substance abuse in the form of comorbidities. Second, 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; 12-17-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.

Epidemiology and surveillance

We have at our disposal a series of surveillance instruments, which we use to continuously monitor trends in all forms of drug abuse, including the abuse of prescribed medications. For example, 21 Community Epidemiology Work Group (CEWG) sentinel sites across the Nation provide ongoing community-level surveillance of drug abuse profiles through analysis of quantitative and qualitative research data. At its 56th semiannual meeting, CEWG representatives held a special conference on patterns and trends in the abuse of prescription drugs, information later disseminated to drug abuse prevention and treatment agencies, public health officials, researchers, and policymakers. The application of this and other tools have allowed NIDA to stay ahead of the curve and to identify potentially troublesome trends as soon as they begin to surface in the population, such as those that have

prompted NIDA-supported researchers to investigate the patterns and sources of illicit use of prescription medications in high school and college students.

Research initiatives

In response to the mounting evidence of increased abuse of prescribed medications, NIDA has orchestrated a multi-pronged strategy intended to complement and expand our already robust portfolio of basic, preclinical, and clinical research aimed at better understanding the prescription drug phenomenon. An important item on this agenda is our latest initiative on "Prescription Opioid Use and Abuse in the Treatment of Pain," which encourages a multidisciplinary approach using both human and animal studies from across the sciences to examine factors (including pain itself) that predispose or protect against opioid abuse and addiction. Particularly important is to assess how genetic influences affect the vulnerability of an individual exposed to pain medication to become addicted. This type of information will help develop screening and diagnostic tools that primary care physicians can use to assess the potential for prescription drug abuse in their patients. Because opioid medications are prescribed for all age groups, NIDA is also encouraging research that assesses the effects of their chronic use over the entire lifespan.

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.

Thank you for allowing me to share this information with you. I will be happy to answer any questions you may have.

Footnotes:

¹ See, e.g., Zacny et. al., *College on Problems of Drug Dependence taskforce on Prescription Opioid Non-Medical Use and Abuse: Position Statements*, Drug and Alcohol Dependence 69 (2003) 25-232; and Compton and Volkow, *Major Increases in Opioid Analgesic Abuse in the U.S.: Concerns and Strategies*, Drug and Alcohol Dependence 81 (2006) 103-107. These citations include information from IMS Health's National Prescription Audit.

² See, e.g., McCabe et al, *Medical Use, Illicit Use, and Diversion of Abusable Prescription Drugs*, Journal of American College Health 54 (2006) 269-278.

³ See, e.g., United States General Accounting Office, *Prescription Drugs - Oxycontin Abuse and Diversion and Efforts to Address the Problem*, GAO-04-110, 12/2003

⁴ See, e.g., Forman et al, *The Availability of Web Sites Offering to Sell Opioid Medications Without Prescriptions*, American Journal of Psychiatry 163 (2006) 1233-1238.

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