DEPARTMENT OF HEALTH & HUMAN SERVICES

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# CONGRESSIONAL TESTIMONY

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**U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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Mr. Chairman, I am grateful for the opportunity to address this Committee regarding the treatment of OxyContin® addiction and the prevention of further drug abuse through effective medical interventions for addiction to OxyContin and other prescription and non-prescription opioids. Before delivering my remarks on this very important and timely topic, I would like to thank the Committee for its attention to this issue, and for your recognition of the importance of addiction treatment in the drug abuse equation, that you demonstrate by today's invitation to the Substance Abuse and Mental Health Services Administration (SAMHSA).

As you know, SAMHSA is the lead federal agency for improving the quality and availability of substance abuse prevention, addiction treatment and mental health services in the United States. SAMHSA has both funding authority and certain key regulatory responsibilities that will play a central role in the national response to abuse of and addiction with OxyContin and the many other prescription analgesics which can be abused by Americans in the grip of opioid addiction. It must be recognized that the abuse of OxyContin is primarily by those who are not pain patients, but opioid addicts. In diverting and abusing prescription opioids, these addicted Americans hurt not only themselves, their families and those around them, but they also hurt the pain patients, who have ongoing needs for these medications, and for whom these medications sustain life and improve function, rather than endangering life and destroying function, as they do in the untreated disease of opioid addiction. I have worked as a physician for many years in this area of practice, and have published on the use of opioids in the treatment of chronic pain and on the assessment of addiction in that setting.

Most people who take OxyContin and other prescription opioids, as prescribed, do not become addicted. With prolonged use of opioids, however, pain patients often do become tolerant, that

is, require larger doses, although this does typically reach a plateau, which can vary markedly between different patients and different pain conditions. Chronic pain patients can also become physically dependent on their medications. However, most patients who receive opioids for pain, even those undergoing long-term therapy, do not become addicted to these drugs.

Addiction in the course of opioid treatment for pain should ideally be assessed after the pain has been brought under adequate control, though this is not always initially possible. Addiction is recognized by one or more of its characteristic features: impaired control, craving and compulsive use, and continued use despite negative physical, mental, and/or social consequences. Sometimes patient behaviors that might suggest addiction are simply a reflection of unrelieved pain. This has been called pseudo-addiction, and is an important misdiagnosis to be avoided in pain patients. Therefore, medical judgment must be used in determining whether a concerning pattern of behaviors in a pain patient signals the presence of addiction or whether it reflects a different medical problem.

In short, most individuals who take their prescribed OxyContin, or any other opioid such as hydrocodone or morphine, under medical treatment for pain, will not become addicted, although some may become physically dependent on the drug and may need to be carefully withdrawn after their pain problem is otherwise resolved. Patients who are taking these drugs as prescribed should continue to do so, as long as they and their physician agree that taking the drug is a medically appropriate way for them to manage pain.

For patients who do run into addictive problems with their medication, or for persons who didn't start with a pain problem at all, but who obtained diverted prescription opioids to further an existing syndrome of drug abuse and addiction, we have a range of very effective treatments, to be described in more detail below. However, the system that provides these treatments has historically been fragmented and underfunded. The Presidents' new budget addresses this important general problem by proposing an increase of $127 million for the next year of a five-year drug treatment initiative to help reduce this treatment gap in the United States, to reduce the difference between the number of Americans who need treatment for addictive disorders and the number that receive the treatment and services to manage their illness and rebuild their lives. The President's current proposal is for the second year of this five-year initiative. Secretary Thompson has confirmed that, "There continues to be a great need to expand our nation's capacity to treat people who are addicted." and that, "This administration is committed to supporting local programs that combat the personal despair and community disintegration brought by drug addiction." Our new fiscal year 2003 budget requests an increase of $60 million for the Substance Abuse Block Grants to the States and an additional $67 million for competitive drug treatment grants, which can be specifically targeted to urgent local needs such as those we are discussing today.

There is a particularly large treatment gap when it comes to treatment for opioid addiction, with estimates of over one million Americans addicted to licit or illicit opioids, and only about 200,000 patients enrolled in effective medical treatment programs. It is most difficult to find treatment for opioid addiction especially in the rural areas of our country. But that is exactly the

location of the most urgent new reports of abuse and addiction with prescription opioids. Many reports of abuse and addiction are occurring in rural areas that have labor-intensive industries, such as logging or coal mining. These industries are often located in economically depressed areas, as well. Therefore, people for whom the drug may have been legitimately prescribed may be tempted to sell their prescriptions for economic reasons. Substance abuse treatment providers tell us that the OxyContin addiction is so strong that people will go to great lengths to get the drug, including robbing pharmacies and writing false prescriptions. A recently opened methadone treatment facility in southwest Virginia began receiving telephone calls from people seeking treatment for OxyContin addiction before it was even open. Eighty percent of patients entering this now fully-functional outpatient treatment program name OxyContin as their primary drug of abuse. The new millennium's continuing news reports of a rural OxyContin crisis have brought this rural opioid treatment gap into even sharper contrast for those of us already familiar with the treatment gap as a whole.

Even before this grim news began to break, SAMHSA was already planning to pilot new ways of working with the medical community to provide exemplary models of medical treatment for opioid addiction in rural areas. In September of 2000, we initiated a small project with Dr. Seddon Savage, of the Dartmouth Medical School and the New Hampshire Medical Society. The New Hampshire Regional Medical Opioid Treatment and Education Project, (NH ReMOTE), was a groundbreaking treatment planning project. Its chief objectives were to assess addiction treatment needs and resources in various communities in New Hampshire, and to plan development of primary care office based management of addictive disease, including medical therapy of opioid addiction, at several sites around the State. NH ReMOTE was the first project

in the United States to target development of a statewide office-based treatment system for opioid addiction.

Primary care physicians, interested in expanding their care of individuals with addictions, are being drawn from 8-10 sites geographically distributed through the state. Physicians will be linked with addiction counselors and social and vocational services in their region to form integrated care teams for patients with addictive disorders. Hospital or other established local pharmacies will dispense opioid medications to patients requiring opioid addiction treatment under direction of the treating physician. The NH ReMOTE Project will develop regulatory and documentation systems to support effective medical treatment practices.

A central resource group of professionals, experienced in therapy of opioid addiction, will be available to provide consultation as needed to the regional care providers. This group will likely be drawn from existing free-standing specialty addiction treatment clinics. Patients requiring opioid therapy who cannot successfully be managed by the regional teams will receive care managed by this central group of experts.

All personnel involved in the regional care teams will receive training requisite to fulfilling their role on the care team. Physician training will include education in general addiction medicine and specific training in opioid therapies, including the use of methadone, LAAM, naltrexone, and buprenorphine. I will return later to describe these specific medication assisted therapies for opioid addiction.

The initial response of the medical community to New Hampshire ReMOTE was very promising. So, while we were publishing our first CSAT Advisory on OxyContin: Prescription Drug Abuse, in April of 2001 (which I have brought for the Committee), we were already working on an additional $500,000 to be allocated to the CSAT Action Grant Program for similar purposes. The purpose of that special announcement, for which applications were received in September 2001, was to provide leadership in developing consensus among key stakeholders in additional State and local communities toward the goal of developing opioid treatment services to meet the unique needs of rural communities, and to address new and emerging treatment needs related to the increased availability of heroin or prescription opioid medications, such as oxycodone or hydrocodone, and to support exemplary practice models for rural communities experiencing problems with opioid addiction. Proposed projects were intended to help treatment providers, including physicians, hospitals, community health centers and community mental health centers adopt exemplary practice models for opioid treatment into their communities. These exemplary practices will be targeted at delivering medication assisted therapy to rural populations where previous access to opioid treatment services has been limited or nonexistent. We anticipate that grants will be awarded this Spring under this special funding opportunity. While I cannot comment on specific grant proposals currently under review, I will say that some excellent and important projects are anticipated to start this fiscal year.

We have also worked with the State of Connecticut, since 1997, to fund pilot demonstrations of office-based opioid treatment (OBOT), which we believe may serve as one appropriate model of treatment that could be provided in the offices of rural physicians. Similar projects have been funded in New York by the National Institute on Drug Abuse (NIDA), and we have worked closely with NIDA, the Food and Drug Administration (FDA) and the New York State Office of

Alcoholism and Substance Abuse Services to develop models of opioid treatment based on community pharmacies, such as may also be found in rural communities.

Now that I have spoken specifically to what we are doing about rural opioid addiction treatment, I would like to speak more generally about the medical therapy of opioid addiction, and CSAT's programs to increase the quantity and availability, as well as the quality and effectiveness, of treatment for this potentially devastating illness.

Abuse of prescription pain medications is not new. However, two primary factors set apart OxyContin abuse from other prescription drug abuse:

First, OxyContin contains a much larger amount of the active opioid ingredient (oxycodone) than most other prescription pain medications. By crushing the tablet and either swallowing or snorting it, or by injecting the dissolved tablet, abusers feel the effects of the opioid in a short time, rather than over a 12-hour span. It is this high rate at which drug gets to the brain, as well as the overall dose taken, that makes for a greater effect on the brain's reward centers and the consequent chemical highjacking of those centers that we call addiction.

Secondly, great profits can be made from the illegal sale of OxyContin. A 40-milligram pill costs approximately $4 by prescription, yet it may sell for $20 to $40 on the street, depending on the area of the country. OxyContin is comparatively inexpensive when purchased legitimately, especially if its cost is covered by insurance. However, because heroin is usually less expensive than OxyContin purchased illegally, the National Drug Intelligence Center reports that

OxyContin abusers may often turn to heroin, if their insurance will no longer pay or they otherwise lose access to their OxyContin prescriptions.

Two types of treatment have been documented as effective for opioid addiction. One is a long-term, residential, therapeutic community type of treatment and the other is long-term, medication-assisted outpatient treatment. Medication-assisted opioid treatment can utilize medications that are agonists, antagonists, or partial agonists. An agonist medication is one that has the same basic effect at the brain cell membrane as the drug of abuse. However, there may be crucial differences in how fast it creates this effect and how long the effect lasts. An antagonist drug simply blocks the effect of agonist drugs, including the drug of abuse. A partial agonist drug has less effect at the brain cell membrane as the "full" agonist, but it also serves to block the full agonist, so the partial agonist medication, such as buprenorphine, may combine certain treatment advantages of both other kinds of medication.

Some opioid-addicted patients with very good social supports may occasionally be able to benefit from antagonist maintenance with naltrexone. This treatment works best if the patient is highly motivated to participate in treatment, has strong social support, and has been adequately detoxified from the opioid of abuse. Most opioid-addicted patients in outpatient therapy, however, will do best with medication that is either an agonist or a partial agonist. methadone and levo alpha acetyl-methadol (LAAM) are the two agonist medications currently approved for addiction treatment in this country. Prior to May of 2001, providers of this treatment were regulated by the Food and Drug Administration (FDA). In May 2001, SAMHSA took over the regulation of opioid agonist treatment (OAT) providers under the new 42 CFR Part 8. We now

have major initiatives underway to modernize, improve, mainstream and expand this treatment modality. These include our use of an accreditation based system, similar to that used in most other kinds of medical facilities and along the lines that have previously been recommended by the 1995 Institute of Medicine (IOM) Report on Federal Regulation of Methadone Treatment (available at: http://www.nap.edu/books/0309052408/html/) and the 1997 NIH Consensus Conference Report on Effective Medical Treatment of Opiate Addiction, (available at: http://odp.od.nih.gov/consensus/cons/108/108_intro.htm).

The guidelines for treating OxyContin addiction are basically no different than the medical guidelines for treating addiction to any opioid. There is one important thing to remember, however: because OxyContin contains higher dose levels of opioid than are typically found in other oxycodone-containing pain medications, higher dosages of methadone or other medications may be needed to adequately treat patients who are addicted to OxyContin.

Methadone or LAAM may be used for OxyContin addiction treatment or, for that matter, treatment for addiction to any other opioid, including the other prescription opioids. This is not a new treatment approach. Rural States have been seeing abuse and addiction with prescription opioids for some time. For instance, Alaska has reported there are about 15,000 prescription opioid abusers in the State and that most methadone patients are not heroin-addicted, but addicted to those prescription opioids. Even back when Arkansas opened its first methadone maintenance clinic in December of 1993, the vast majority of its new patients were not admitted for heroin addiction, but for addiction to prescription opioids. When seeking treatment previously, these patients had to travel to other States because methadone treatment had not been

available in Arkansas. This continues to be the case, for example, in the State of Mississippi. Our colleagues at the American Association for the Treatment of Opioid Dependence (AATOD) report that they have documented at least 500 Mississippi residents needing opioid agonist treatment that must travel to one of the adjacent States who do allow for this life-saving medical therapy.

Some persons in the few States that still don't allow the full spectrum of medical therapies for opioid addiction may believe their remaining problems will be solved by the advent of buprenorphine, the new partial agonist opioid treatment. This kind of medication shares certain properties with the antagonist medication naltrexone as well as the full opioid agonists, and is safer than, although not as therapeutically powerful as, Methadone or LAAM.

Partial agonist opioid medication will be an important new tool in the medical arsenal against addiction, but it certainly won't be able to replace the current medications. Presently there is no partial agonist approved by the Food and Drug Administration (FDA) for use in addiction treatment, although a form of buprenorphine, researched by the National Institute on Drug Abuse (NIDA) and its partners in academia and industry, holds great promise. This medication, in conjunction with new authority provided to DHHS and redelegated to SAMHSA under the Drug Addiction Treatment Act of 2000 (Title XXXV of P.L. 106-310), which amends section 303(g) [21 U.S.C. 823(g)] of the Controlled Substances Act, is expected to make significant gains possible in expanding access to opioid addiction treatment in rural and other under-served areas of the country.

The Drug Addiction Treatment Act (DATA) amended the Controlled Substances Act to permit physicians to seek and obtain waivers to prescribe approved narcotic treatment drugs for the treatment of opiate addiction. The waivers will permit qualified physicians to prescribe schedule III, IV, or V opioid medications, when approved by FDA for the treatment of opioid addiction. These physicians would be required to refer the patients for appropriate counseling and limit his or her practice of this treatment to 30 patients. However, they would otherwise be exempted from the requirements of the Narcotic Addict Treatment Act (NATA) which otherwise governs the use of scheduled opioids for addiction treatment under 42 CFR Part 8, which as I mentioned before, is now also administered by SAMHSA. The NATA remains in place for schedule II opioids approved for addiction treatment (Methadone and LAAM). Once there is a form of buprenorphine approved by the FDA, and the new product is scheduled by the Drug Enforcement Administration (DEA) in Schedule III, IV, or V, then most of the provisions of the DATA will go into effect and SAMHSA will be accepting applications for waivers from qualified physicians.

The DATA contained a limited Federal preemption, to allow for rapid implementation of this new office-based treatment approach across all of the States. However, States can still opt out by passing new legislation. In states that do not opt out legislatively, use of buprenorphine under the DATA will immediately become part of the medical practice of the physicians who obtain the waiver from SAMHSA and a corresponding number from DEA, related to their existing controlled drug registration number. SAMHSA staff have been working with the State Medical Boards and their Federation of State Medical Boards (FSMB) to develop guidelines to help the Boards fulfill their responsibilities for oversight of this new and unfamiliar area of medical

practice.

SAMHSA has also been working with the American Society of Addiction Medicine (ASAM) the American Osteopathic Academy of Addiction Medicine (AOAAM), the American Academy of Addiction Psychiatry (AAAP), the American Psychiatric Association (APA) and other medical organizations to create a standardized medical curriculum, a Treatment Improvement Protocol (TIP) with guidelines for best medical practices, and a number of continuing medical education (CME) courses which have trained 1500 physicians from across the country, including many rural physicians who have been especially eager to prepare for this new opportunity to provide effective medical treatment for opioid addicted patients in their communities.

The 1500 physicians that SAMHSA and our partners have trained are in addition to those who may be already qualified by virtue of having been previously certified as addiction treatment specialists by one or more of the organizations specified in the DATA. Although many physicians qualified by previous certification in addiction have also sought the additional eight hours mandated under the DATA for physicians who do not already have such recognized certification.

In addition to our partners in the States and in the medical organizations, we continue to work on these issues with our Federal partners, in a variety of ways. For instance, the Interagency Narcotics Treatment Policy Review Board (INTPRB), which I currently chair, has created a special working group on the problem of OxyContin and other prescription drug diversion. The organizations participating in the INTPRB and our work group are as follows:

1. Department of Justice (DOJ)

   1.1 Drug Enforcement Administration (DEA)

   1.2 National Drug Intelligence Center (NDIC)

   1.3 National Institute of Justice (NIJ)

2. Food and Drug Administration (FDA)

   2.1 Center for Drug Evaluation and Research (CDER)

3. Substance Abuse and Mental Health Services Administration (SAMHSA)

   3.1 Center for substance Abuse Treatment (CSAT)

   3.2 Office of Applied Studies (OAS)

4. National Institute on Drug Abuse (NIDA)

5. Office of National Drug Control Policy (ONDCP)

6. DHHS Office of the Secretary, Office of Public health and Science (OPHS).

7. Centers for Disease Control and Prevention (CDC)

8. Health Resources and Services Administration (HRSA)

9. Centers for Medicare & Medicaid Services (CMS), and

10. Veterans Health Administration (VHA).

I want to conclude by pointing out to the Committee that although physical dependence in a pain patient on opioids is differentiable from opioid addiction, pain does not necessarily protect the patient who may be otherwise at risk for addictive disorders. Pain patients with addictive histories may well require additional safeguards when opioids are required for management of their pain. Withholding opioid analgesics from these patients is not necessarily a safe course at

all, as they may know all too well where they can obtain what they need for pain relief, but from a much more dangerous source that would significantly increase their risk of relapse. Patients with both chronic pain and opioid addiction may require very careful management, but they can and should be managed for both disorders concurrently. Medical experience in this area grows slowly and is not yet well defined. However, a notable case series reported in the Journal of Pain and Symptom Management (1996) by Dunbar and Katz, described 20 patients with both chronic pain and substance abuse problems, on chronic opioid therapy for intractable pain. Nine out of 20 did have at least some abuse of their medications, but the majority did not. Of the eleven who did not abuse their medications, all were active in drug abuse recovery programs with good family support. This small but important study illustrates not only that some pain patients with histories of drug problems can benefit from, may require, and can handle opioid pain management, but it also demonstrates the central importance of an active recovery program and good family support in the long-term management of opioid addiction, and for that matter, in the successful management of most addictions.

Mr. Chairman, I thank you again for this opportunity to appear before the Committee today. I would be happy to answer any questions that you or any other members of the Committee may have at the appropriate time.

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