

**For Immediate Release**

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**Bush Signs Law: More Patients May be Treated for Opioid  
Dependence/Addiction with Buprenorphine**

*-- For many patients on treatment waiting limits nationwide, higher prescribing limit  
expands access to FDA-approved, in-office medical treatment --*

**Richmond, VA (December 29, 2006)** – President Bush has signed into law an amendment to the Controlled Substances Act that will increase the availability of buprenorphine for the treatment of opioid dependence/addiction. The new law raises from 30 to 100 the number of patients a physician may treat with buprenorphine, the only FDA-approved, controlled medication indicated for treatment of opioid dependence that doctors may prescribe in private medical offices, as permitted under special legislation. The new law will ease restrictions on Suboxone<sup>®</sup> (buprenorphine HCl/naloxone HCl dihydrate) C-III Sublingual Tablets and Subutex<sup>®</sup> (buprenorphine HCl) C-III Sublingual Tablets.

“The President’s signature now makes it the law of the land -- medical treatment can now be available to more Americans across the country who are addicted to opioids,” said Edwin A. Salsitz, MD, of Beth Israel Medical Center in New York City. “Many of the estimated six million people in the United States who are dependent on opioids have been forced to wait for the medical treatment they so desperately need simply because of a mandated 30-patient ‘cap’ on how many people a doctor may treat. By increasing the number of patients each physician can treat with buprenorphine, this new law begins to address this inequity.”

Addiction to opioids is defined as a long-term brain disease by the World Health Organization (WHO) and the National Institute on Drug Abuse (NIDA). It is a treatable medical condition that is caused by changes in the chemistry of the brain. Opioid dependence can start with use of pain medication that a doctor appropriately prescribes for pain but that a person continues to use after the medical need for pain relief has passed. Or it may begin as recreational drug use that spins out of control.

“Millions of everyday Americans from all walks of life are burdened with dependence on such prescription painkillers as oxycodone, hydrocodone, fentanyl, morphine, or are battling heroin addiction.” continued Dr. Salsitz. “This chronic brain disease often has devastating consequences for individuals, their families, and their communities. Opioid dependence and addiction is a national public health crisis, and giving more patients access to an FDA-approved medical treatment that can be prescribed in the privacy of a

doctor's office, just as treatment for other serious diseases is offered, is a tremendously positive step forward.

“Whether patients suffer from drug dependence or any other disease, they are entitled to FDA-approved medicines that can treat their conditions. Physicians should be armed with as many medical options as possible as they tailor treatment plans to the needs of individual patients. Office-based treatment with Suboxone is one option in the physician's arsenal, and removing restrictions around its use surely will be beneficial to patients across the country. And, of course, the corollary to removing unnecessary restrictions on prescribing is that more doctors need to become active in treating this undertreated and often unrecognized but life-threatening disease.”

### **Physician Training to Prescribe Buprenorphine**

Any doctor may take the training to become certified to prescribe Suboxone and Subutex in his or her private office as a treatment for opioid dependence. Physicians interested in becoming certified may obtain more information from [docoptin.com](http://docoptin.com). Additionally, information about online and CD-ROM training may be obtained from 1-877-782-6966.

### **About the New Law**

The 30-patient prescribing limit on individual doctors was part of the original Drug Addiction Treatment Act of 2000 (DATA 2000) that allowed office-based treatment with Scheduled III-V drugs indicated for treatment of opioid dependence. To qualify for the higher prescribing limit now allowed by law, doctors must have been certified to treat opioid dependence with buprenorphine for at least a year. The legislation that underlies the new law was part of Senate Bill 2560, the Reauthorization of the Office of National Drug Control Policy, introduced by Sen. Arlen Specter (PA) and co-sponsored by Sens. Biden (DE), Dayton (MN), Grassley (IA), Hatch (IT) and Levin (MI). The corresponding Bill in the House of Representatives, HR 2829, was introduced by Rep. Mark Souder (IN) and co-sponsored by Rep. Tom Davis (VA). The bill the President has now signed raising the patient limit to 100 is HR 6344.

This new law is the second amendment to the Controlled Substances Act to increase patient access to buprenorphine treatment. Last July, Congress lifted a provision of DATA 2000 that had limited to 30 the number of opioid-dependent patients able to be treated at any one time in a group medical practice, even if multiple doctors within the practice were certified to treat with buprenorphine. As an example of the impact this restriction had imposed, all group medical practices, including large institutions such as hospitals and entire health maintenance organizations, could only treat 30 patients at a time.

### **Resources for Opioid Dependence and Its Treatment**

Individuals who need more information about opioid dependence and its treatment, either for themselves or for someone they are concerned about, have several options. Educational materials on opioid dependence are available to answer questions about this often-misunderstood disease and the treatments that are available for it. Free educational Resource Kits on this topic can be obtained from [turntohelp.com](http://turntohelp.com) or by calling **1-866-**

**455-TURN**, both provided by Reckitt Benckiser Pharmaceuticals. **Turntohelp.com** also offers a physician locator designed to help individuals find an area doctor available to prescribe buprenorphine.

Additionally, the non-profit patient advocacy group NAABT – National Alliance of Advocates for Buprenorphine Treatment – is dedicated to helping educate the public on opioid dependence and treatment in a private doctor’s office. NAABT now offers a nationwide confidential matching service to pair individuals seeking buprenorphine treatment with available doctors. This matching service is an important corollary to the new law, in that it provides a mechanism for the additional patients to find treatment that the law now allows. For information on physicians who can prescribe buprenorphine to treat opioid dependence in a private medical office, visit **naabt.org**. SAMHSA’s Web site also provides a physician locator and other valuable information at **buprenorphine.samhsa.gov**.

#### **About Reckitt Benckiser Pharmaceuticals Inc.**

Reckitt Benckiser Pharmaceuticals Inc. is a specialty pharmaceutical company that markets Suboxone<sup>®</sup> (buprenorphine HCl/naloxone HCl dihydrate [2 mg/0.5 mg and 8 mg/2 mg]) C-III Sublingual Tablets and Subutex<sup>®</sup> (buprenorphine HCl [2 mg and 8 mg]) C-III Sublingual Tablets, formulations of buprenorphine used to treat opioid dependence in a medical office-based setting. Suboxone and Subutex, manufactured by Reckitt Benckiser Healthcare Ltd., are the only controlled medications under the Drug Addiction Treatment Act of 2000 approved by the FDA for office-based treatment of opioid dependence. Reckitt Benckiser Pharmaceuticals Inc. is committed to expanding access to medical therapies for patients suffering from the chronic, relapsing brain disease of opioid dependence. For more information, visit **suboxone.com** or **opioiddependence.com**. Reckitt Benckiser Pharmaceuticals Inc. is a wholly owned subsidiary of Reckitt Benckiser PLC, a publicly traded UK firm.

#### **Important Safety Information**

Intravenous use of buprenorphine, usually in combination with benzodiazepines or other CNS depressants has been associated with significant respiratory depression and death. Suboxone<sup>®</sup> and Subutex<sup>®</sup> have potential for abuse and produces dependence of the opioid type with a milder withdrawal syndrome than full agonists. Cytolytic hepatitis and hepatitis with jaundice have been observed in the addicted population receiving buprenorphine. There are no adequate and well-controlled studies of Suboxone or Subutex (a pregnancy category C medication) in pregnancy. Due caution should be exercised when driving cars or operating machinery. The most commonly reported adverse events with Suboxone have included headache (36%, placebo 22%), withdrawal syndrome (25%, placebo 37%), pain (22%, placebo 19%), nausea (15%, placebo 11%), insomnia (14%, placebo 16%), sweating (14%, placebo 10%). See full prescribing information for complete information at **suboxone.com**.

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