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Congress Passes Legislation to Lift Restriction on Medical Groups that Prescribe Buprenorphine for Opioid Dependence/Addiction

- Patients may benefit from wider access to only FDA-approved medication for use in doctors' offices -

Richmond, VA (27 July 2005) – Today Congress passed legislation that amends the Controlled Substances Act by removing a restriction on medical groups that prescribe an office-based medical treatment for opioid dependence. The restriction had limited group medical practices to treating only 30 opioid-dependent patients at any given time with Suboxone® (buprenorphine / naloxone), the only FDA-approved medication to treat opioid dependence in the privacy of doctors' offices. The cap on group practices was part of the original Drug Addiction Treatment Act of 2000 (DATA) that allowed office-based treatment. Reckitt Benckiser Pharmaceuticals, Inc. is a specialty pharmaceutical company that manufactures and markets Suboxone.

“Today’s legislative action to amend DATA is a significant step forward for patients and their doctors,” said Edwin A. Salsitz, MD, of Beth Israel Medical Center in New York City. “The 30-patient group practice limit, though well intentioned, proved to be a safeguard that carried the unintended consequence of limiting patient access to treatment. Today’s milestone reflects some very positive developments. It underscores the value of treatment with Suboxone for patients with the disease of opioid dependence, and highlights the need for office-based medical treatment options in this disease state.”

Every year, millions of ordinary Americans become dependent on prescription opioid painkillers. Drug dependence, whether on prescription opioid medication or on heroin, is a chronic brain disease that can have devastating consequences. Medical treatments for

addiction are available, and with the provisions of DATA that allow office-based intervention, physicians now can provide the same type of care for opioid dependence as they do for other chronic diseases, such as diabetes or hypertension.

By lifting DATA's limitation on how many opioid-dependent patients may be treated at any one time in a medical group, today's change in the law will allow every qualified doctor within a group medical practice to prescribe Suboxone up to his or her individual physician limit of 30 patients. Group medical practices, defined by tax reporting ID numbers, include very large institutions such as hospitals and health maintenance organizations, many of which have numerous doctors certified to treat opioid dependence. Today's action will enable those physicians to offer a private and discrete office-based treatment option to many more patients than currently can receive treatment with Suboxone.

The bills to amend the Controlled Substances Act were filed in the Senate by Sen. Carl Levin (MI) and in the House by Rep. Mark Souder (IN). Both bills had significant co-sponsorships, including Senators Orrin Hatch, Joseph Biden, Hillary Rodham Clinton, Chuck Grassley, and Richard Durbin, and broad support from 44 co-sponsors in the House.

“There are an estimated six million people in the United States who are dependent on opioids,” said Mark L. Kraus, MD, Assistant Clinical Professor of Medicine at Yale University School of Medicine. “Allowing more doctors to treat opioid-dependent patients in their offices, coupled with more doctors becoming qualified to do so, will bring treatment to a much wider patient population. To create treatment plans that are properly tailored to the needs of individual patients, physicians should have access to as many medical treatment options as possible. Office-based treatment with Suboxone is one option in the physician's arsenal, and removing unnecessary restrictions around its use surely will be beneficial to patients across the country.”

About Reckitt Benckiser Pharmaceuticals, Inc.

Reckitt Benckiser Pharmaceuticals is a specialty pharmaceutical company that manufactures and markets Suboxone® and Subutex®, formulations of buprenorphine used to treat opioid dependence in a medical office-based setting. Suboxone and Subutex are the only products approved by the FDA for office-based treatment of opioid dependence. Reckitt Benckiser Pharmaceuticals is committed to expanding access to medical therapies for patients suffering from the chronic, relapsing brain disease of drug dependence. For more information, visit www.opioiddependence.com. Reckitt Benckiser Pharmaceuticals, Inc. is a wholly owned subsidiary of Reckitt Benckiser PLC, a publicly traded UK firm.

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Intravenous misuse of buprenorphine, usually in combination with benzodiazepines or other CNS depressants has been associated with significant respiratory depression and death. Suboxone has 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 (a category C medication) in pregnancy. Due caution should be exercised when driving cars or operating machinery.

The most commonly reported adverse events with Suboxone include 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%).

Suboxone is a registered trademark of Reckitt Benckiser Pharmaceuticals, Inc.

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