American Society of Addiction Medicine

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Treat Addiction ● Save Lives

October 22, 2012

Margaret A. Hamburg, MD
Commissioner
US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket ID "FDA-2012-P-1028"

Dear Dr. Hamburg,

The American Society of Addiction Medicine (ASAM) is pleased to have the opportunity to comment on the citizen's petition submitted by Reckitt Benckiser Pharmaceuticals, "Safety Concerns Regarding Buprenorphine for Opioid Dependence."

The recent increases in the diversion of prescription drugs from the person to whom they were originally prescribed and the non-medical, sometimes lethal use of these drugs, particularly by young children, are of special concern to ASAM physicians. While most generally ascribe drug diversion to narcotic pain relievers and sedative hypnotics, there are instances when even opioid replacement [pharmaceutical] therapies (ORT) are diverted for non-medical use. Reckitt Benckiser Pharmaceuticals (RBP) manufactures Suboxone and Subutex, two of the more widely used ORTs on the market. Suboxone tablets have been shown to be divertible. Furthermore, recent data has shown that its current packaging may contribute to the incidence of pediatric exposure. Consequently, RBP has asked the FDA to not approve any buprenorphine application for opioid dependence that does not include a risk evaluation management strategy that adequately safeguards against pediatric exposure.

ASAM applauds the efforts of manufacturers to minimize the risks of diversion, accidental exposure and/or overdose attributed to potentially addictive pharmaceuticals. Moreover, ASAM is grateful for the development and manufacturing of drugs that aid in the treatment of addiction. And, while we remain committed to working with manufacturers and regulators alike to ensure the safe use of these drugs, we are also committed to ensuring that access to opioid addiction treatment is not further restricted.

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Addiction remains a highly stigmatized disease and, as a consequence the treatment of addiction is stigmatized, too. Medication-assisted opioid therapies like buprenorphine are often subject to more restrictive prescriber limitations and lower reimbursement rates than their pain therapy analogs. And, payer formularies may only include one or two treatment modalities.

Given the restrictions already imposed on opioid maintenance therapies, we respectfully ask that the FDA considers equally the safeguarding of accidental exposures among children and the protection of a patient's access to these life-saving medications.

Again, ASAM thanks the FDA for the opportunity to submit comments regarding this important issue. We look forward to a continued collaboration with your agency and our pharmaceutical partners on advances in and increased access to alcohol and drug addiction treatment.

Sincerely,

Stuart Gitlow, MD, MBA, MPH, FAPA

Acting President, American Society of Addiction Medicine

Verification Statement

ASAM makes the following verification statement, pursuant to FDC Act §505(q)(1)(I):

I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about October 1, 2012. I do not expect to receive payments, including cash and other forms of consideration, to file this information or its contents. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.