

March 6, 2013

Dr. Minh Doan
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 31, rm. 2417
Silver Spring, MD 20993-0002

RE: FDA Docket Number FDA-2013-N-0001

Dear Dr. Minh Doan:

The Partnership at Drugfree.org is pleased to submit this letter to the FDA's Pschyopharmacologic Drugs Advisory Committee to discuss Probuphine, a new formulation for delivery of buprenorphine hydrochloride in the treatment of opioid addiction. The FDA docket number for this Advisory Committee meeting, to be held March 21, 2013, is FDA-2013-N-0001.

The Partnership strongly supports the development and availability of tested medications that can help significantly in the treatment of opioid addiction, and are resistant to diversion and abuse.

The Partnership

From its beginnings in 1987 as a public service advertising campaign aimed at preventing illegal drug use, especially among young people, the Partnership has evolved into the premiere online and offline resource for parents and other youth influencers as they seek to prevent or get help for a child's alcohol and other drug abuse. We work closely with leading researchers in the field, including those at the Treatment Research Institute, as well as experienced parents of drug-involved teens to develop science-based, accessible content and messaging that addresses multiple aspects of youth substance abuse: parent education modules on the vulnerability of the teen brain and better parenting practices; extensive how-to guides on early intervention and identifying appropriate treatment; in-depth information on a range of evidence-based paths to recovery for young people.

This content is delivered via our website at www.drugfree.org, through an extensive community education program (PACT360) funded by the U.S. Department of Justice / Bureau of Justice Assistance, and over a toll-free telephone helpline (1-855-DRUGFREE) staffed Monday through Friday by trained counselors. The Partnership relies upon its longstanding relationships with leading marketing communications and media companies to promote all these resources, receiving over \$100 million annually in pro bono advertising support.

In September, 2012, the Partnership launched **The Medicine Abuse Project**, which brings together federal agencies (FDA, NIDA, ONDCP, CDC, DEA, DOJ/Bureau of Justice Assistance and US Attorneys), private sector partners, medical societies and many relevant nonprofits in an effort to drive down abuse of prescription and over-the-counter medications by teens and young adults. This is by far the largest and most comprehensive public / private effort to date to address this still emerging and harmful form of drug abuse. Its dedicated website at www.medicineabuseproject.org includes resources for multiple constituencies, including parents / caregivers, educators, communities and healthcare professionals. The Partnership is currently working with support from FDA to build out and evaluate the content we are offering to prescribers as part of the Medicine Abuse Project campaign.

Medication Assisted Treatment

The Partnership is dedicated to helping parents and other youth influencers find effective help for their teen and young adult children who are struggling with alcohol and other drug abuse. Prescription drug abuse in general, and abuse of long acting prescription opioids in particular, continues among teens and young adults at unacceptably high levels. The 2012 University of Michigan “Monitoring the Future” survey showed 7.9% of 12th graders reporting past year misuse or abuse of “narcotics other than heroin”, 7.5% reporting misuse or abuse of Vicodin, and 4.3% reporting misuse or abuse of Oxycontin. The Partnership’s own annual Attitude and Tracking Study (or “PATS”, supported by MetLife Foundation) shows that in 2012 over one quarter (27%) of teens in grades 9-12 agreed that prescription drugs are “safer to use than illegal drugs”, while 56% agreed that they are “easy to get from parent’s medicine cabinet” – suggesting that relatively low perceptions of risk and easy availability are major contributors to this continuing problem among teenagers.

The 2011 National Survey on Drug Use and Health (NSDUH) reported declines in prescription drug abuse overall in the population 12 years and older, but noted increases in use of heroin, which has nearly doubled since 2007. These findings prompted the American Society of Addiction Medicine (ASAM) to state on September 25, 2012, that, “Opioid addiction is an ongoing, serious problem in this country. Increasing access to all forms of treatment for opioid addiction, including medication-assisted therapies, must remain a priority for our nation’s policy makers at both the federal and state legislative levels.”

To this end, the Partnership is nearing completion of a parent / caregiver education module focusing on medication assisted treatment. We have consulted with numerous researchers and clinicians in the development of this resource, including Dr Herbert Kleber (Columbia University and Partnership board member) and Dr Edward Salsitz (Beth Israel Hospital, New York), and made every effort to be accurate, comprehensive and understandable to parents who are seeking help for their teen or young adult child’s opioid addiction – and may not even be aware of the *existence* of medication that can assist in treatment. The education module will address methadone, buprenorphine and naltrexone – the characteristics specific to each and the appropriateness of each in treatment of older adolescents and young adults, as well as first hand doctor, patient and parent accounts of their experiences with medication assisted treatment.

In development of this educational module, we have been mindful of:

- The (anecdotally) low parent / caregiver awareness of medication assisted treatment as an option for older teens and young adults with opioid dependence;
- The resistance in general of opioid addiction to treatment, and high rate of relapse;
- The importance of a comprehensive approach that includes therapy;
- The benefits that many patients have derived from medication assisted treatment, including the achievement of stability in their lives, families and work;
- The stigma that still attaches to addiction and treatment, and the importance of raising awareness of available treatment opportunities in the positive context of accessible and evidence-based healthcare;
- The frequent abuse of methadone and buprenorphine, and desirability of abuse-resistant forms of medication;
- The desirability of medications and forms of medication that impose minimal barriers to those who are committed to recovery and eager to live and function fully, at work and at home;
- The importance of expanding in a responsible way the “toolbox” that can be used by healthcare providers, their patients and their patients’ families as they work towards the goal of stable recovery.

These factors that have governed our work on medication assisted treatment are essentially the same factors that lead us to encourage and applaud new, innovative and evidence-based medications and forms of medication that can add materially to that “toolbox” referenced above.

From all that we know to date about Probuphine, it is responsive to several of the factors listed above, including resistance to abuse and a lowering of barriers to patients who are committed to recovery and intent on improving their ability to function fully at work and at home. It appears to further a welcome expansion of the toolbox that providers can now offer to patients struggling with addiction to opioids, and to their families, friends and employers. We would also welcome future research to establish this as an option for adolescents and their families, and efforts to insure these treatments are easily accessible to all who can benefit from them.

Respectfully,

A handwritten signature in black ink, appearing to read "Stephen J. Pasierb". The signature is fluid and cursive, with the first letter of the first name being a large, stylized 'S'.

Stephen J. Pasierb
President and Chief Executive Officer