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October 13, 2017

Scott Gottlieb, MD

Acting Commissioner

US Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Re: FDA-2017-N-4977

Dear Dr. Gottlieb,

The American Society of Addiction Medicine (ASAM) is pleased to have the opportunity to comment on the new drug application (NDA) 209819, buprenorphine subcutaneous injection, submitted by Indivior Pharmaceuticals, Inc. for the proposed indication of maintenance treatment of opioid dependence.<sup>1</sup>

Foremost to ASAM's mission is a goal to increase access to and improve the quality of addiction treatment. The introduction of novel addiction pharmacotherapies supports this goal. Addiction patients, like all patients, should have available to them a robust and varied array of treatment options as no one treatment modality is appropriate or therapeutic for everyone.

Buprenorphine has been shown to be safe and effective for the treatment of opioid dependence. Unlike the oral buprenorphine formulations, this once- or twice-monthly subcutaneous injection formulation has the potential to decrease the risk of diversion. As with all medications for opioid addiction, treatment with buprenorphine subcutaneous injection, should include evidence-based psychosocial interventions and ongoing monitoring for relapse, drug interactions and overdose risk.

ASAM supports the development and manufacturing of medications that aid in the treatment of addiction and applauds the efforts of manufacturers to minimize the risks of diversion, accidental exposure and/or overdose associated with potentially addictive pharmaceuticals. Both are necessary to improve the care of people with addiction and to



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Addiction Medicine

advance the field of treatment but, independent of similar efforts to advance prevention, education, and recovery support services, not sufficient to fully address the causes and consequences of addiction.

ASAM looks forward to a continued collaboration with your agency to promote advances in and increased access to addiction treatment. Again, ASAM thanks the FDA for the opportunity to share our comments with the Psychopharmacologic Drugs Advisory Committee.

Sincerely,

Kelly Clark, MD, MBA, DFASAM  
President, American Society of Addiction Medicine

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<sup>1</sup> Disclosure Statement: The American Society of Addiction Medicine has received unrestricted grants from Indivior Pharmaceuticals, Inc.