



**Comment on the Interim Report of the  
President's Commission on Combating Drug Addiction and the Opioid Crisis  
August 25, 2017**

The Interim Report released by the President's Commission on Combating Drug Addiction and the Opioid Crisis is groundbreaking and outlines important steps to end the opioid epidemic. Having carefully studied the findings and recommendations in the Commission's Interim Report, we offer our support of the recommendations and are confident that their implementation will enable our country to bring an end to the current opioid crisis.

Alkermes is a global biopharmaceutical company that is committed to developing innovative medicines for the treatment of central nervous system diseases, including opioid and alcohol dependence. We manufacture VIVITROL<sup>®</sup> (naltrexone for extended-release injectable suspension), a once-monthly injectable medication for the treatment of alcohol dependence and the prevention of relapse to opioid dependence, following opioid detoxification. We work closely with addiction treatment professionals, organizations and those who have been directly impacted by opioid and alcohol addiction.

We thank the Commission for the invitation to offer our comments, and we welcome future opportunities where we may be able to assist.

**Authorized Providers of Medications to Treat Opioid Addiction** - We strongly agree with the Commission's statement that "all FDA-approved MAT should be offered by authorized providers, not just one or two of these approved options. These decisions of which (if any) MAT to be used must be based upon what is best for the patient, not what is best for the provider. This can be mandated by the Executive Branch."

On July 22, 2016 the Comprehensive Addiction and Recovery Act (CARA) was passed overwhelmingly by Congress, laying the groundwork for reforming the current opioid addiction treatment system. Section 303 of CARA amends the federal laws governing office-based opioid addiction treatment providers (OBOTs) and now requires all OBOTs to have the capacity to offer (either directly or by referral) all FDA-approved medications for the treatment of opioid use disorder, along with counseling and other appropriate ancillary services.

The current HHS/SAMHSA-regulated training course for waived treatment providers of Schedule III-V opioid addiction medicines must be updated to comply with the current requirements under Section 303 to educate on multiple forms of treatment including, but not limited to: opioid maintenance and detoxification, appropriate clinical use of all FDA-approved medications for the treatment of opioid use disorder, and individualized treatment planning.

As the Commission noted, patients are often provided medicines based on the setting of care and not based on a clinical assessment and informed discussion with the patient regarding all FDA-approved treatment options. We strongly encourage SAMHSA to immediately issue a notification to all existing OBOTs outlining the requirement to offer (either directly or by referral) all FDA-approved medications.

We also ask the Commission to consider incorporating the utilization of an Informed Consent document as a mechanism to ensure patients are aware of their treatment options. The Informed Consent protocol

should include the possible risks and benefits of the FDA-approved medications, and should objectively present both opioid agonists and antagonists.

Similarly, opioid treatment programs (OTPs) (sometimes referred to as “methadone clinics”) are also cited in the Commission’s Interim Report as needing to offer all approved MAT. We applaud the Commission’s acknowledgement that OTPs should provide patients the same access to all FDA-approved treatment options that must also exist in OBOTs. Based on HHS data, very few OTPs offer the full range of FDA-approved opioid addiction treatment medications<sup>1</sup> despite all being addressed within current federal guidelines.<sup>2</sup> To support OTPs in offering all treatment options, we encourage the Commission to consider applying the same Informed Consent policy as that which we propose for use in OBOT settings.

Current federal regulations governing certification of OTPs also include the requirement that every OTP maintain current protocols for detoxification off of all opioid medicines. We encourage the Commission to call for the enforcement of these regulations. Likewise, continuing medical education should ensure appropriate training in current detoxification protocols as well as the prescribing of medications approved by the FDA.

**Federally-Qualified Health Centers** –We agree with the Commission that federally-qualified health centers (FQHCs) play an important role in the health care continuum and are frontline providers of substance abuse treatment, including MAT. The role of FQHCs in providing access to high quality and affordable patient-centered care ensures those seeking treatment for opioid addiction will have access to treatment options that best fit their individual needs. FQHCs should adhere to the principles of §303 of CARA, including access to *all* forms of FDA-approved MAT.

**Criminal Justice Settings** - The Interim Report also includes the recommendation that “[t]he DOJ, in consultation with HHS and ONDCP, should be directed to increase the use of MAT for OUDs in these correctional settings.” Providing medications - plus counseling and other recovery supports - to opioid-dependent individuals in reentry programs presents a major opportunity to support successful reintegration back into the community. The Bureau of Prisons provides a positive example of the voluntary use of relapse prevention medications, counseling and recovery supports in this unique patient population oftentimes at high risk of overdose after release from jails or prisons. Expanded access to MAT for individuals addicted to opioids in this setting can provide an enormous benefit not just to the opioid-addicted individual, but also the families and communities to whom he or she returns following incarceration.

**Prescriber Education** – We also strongly agree with the Commission’s finding “that many medical providers are not well-versed on how to screen for addiction, and what to do if a patient has become dependent on substances or presents with an SUD.” Many medical providers have received little or no training on modern approaches to opioid addiction treatment. Given the high prevalence of opioid addiction, training on all FDA-approved treatment options for opioid use disorder should be included as part of prescriber education.

**Naloxone** - We agree with the Commission’s recommendation to increase access to naloxone through both public health and public safety initiatives. In addition, we urge the Commission to consider policies and initiatives that would encourage overdose survivors to enter into treatment for opioid addiction, when clinically indicated. For opioid-addicted overdose survivors, the compulsion to return quickly to using is extraordinarily high. Consequently, the Commission should consider policies and initiatives that break the cycle of “rescue, release and relapse” and instead provide the opportunity for such individuals to be presented with available treatment options, including MAT, detoxification, or inpatient rehabilitation.

Alkermes appreciates the work done by the President's Commission on Combating Drug Addiction and the Opioid Crisis and its focus on what may be the greatest public health and safety threat of our time. With the leadership of the President and this Commission, and the thoughtful and results-oriented steps outlined in the Interim Report, we can put an end to the current opioid crisis. We stand ready to assist you in this endeavor.

## References

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<sup>1</sup> Substance Abuse and Mental Health Services Administration, *National Survey of Substance Abuse Treatment Services (N-SSATS): 2014. Data on Substance Abuse Treatment Facilities*. BHSIS Series S-79, HHS Publication No. (SMA) 16-4963. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015. For example, see Table 2.4, on page 27.

<sup>2</sup> See Substance Abuse and Mental Health Services Administration. *Federal Guidelines for Opioid Treatment Programs*. HHS Publication No. (SMA) PEP15-FEDGUIDEOTP. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.