Prepared Statement
Transcript of Delivered Remarks Will Vary

Comment Before the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee on Behalf of the Center for Lawful Access and Abuse Deterrence

November 1, 2017

Good afternoon. I will be reading the public comment of the not-for-profit Center for Lawful Access and Abuse Deterrence (CLAAD). I am Dr. Andrea Barthwell, and I am a co-founder of CLAAD.

CLAAD is a tax-exempt, not-for-profit organization working to improve health and safety. We recommend consensus-based solutions to the nation's drug overdose epidemic. All such efforts must revolve around individualized health care. CLAAD's funders are disclosed at CLAAD.org.

Thank you for the opportunity to provide input on the proposed buprenorphine weekly and monthly injections for the treatment of opioid dependence.

In the midst of an opioid overdose epidemic, the weekly and monthly buprenorphine injections offer several benefits to individuals with opioid use disorder, the health care providers who treat them, and society as a whole.

First, the practitioner-administered, long-acting buprenorphine injections will provide greater peace of mind. They will deliver medication continuously over one week or one month. This delivery system will enable patients to receive their medication with greater confidence, confidentiality, and convenience. Patients may then focus on the psychosocial treatment necessary to achieve long-term recovery.

The injections will also enable practitioners to know that the primary dose is administered according to the treatment plan. In other words, the patient will receive exactly what the doctor ordered. For this reason, CLAAD considers practitioner-administered, long-acting buprenorphine injections to be adherence-enhancing.

Second, the weekly and monthly buprenorphine injections will provide practitioners with flexible dosing options. Practitioners may individualize treatment based on the specific needs of the patient. They may do so without deviating from the current standard of care, which calls for weekly or more frequent office visits early in treatment, and monthly visits after the patient is stabilized.

Third, given that the buprenorphine injection will not be dispensed to patients, it will not be susceptible to post-dispensing diversion. Replacing transmucosal buprenorphine with practitioner-administered forms means that there will be less oral buprenorphine available in medicine cabinets, drawers, and purses for diversion, medical misuse, intentional abuse, or unintentional exposure. For this reason, CLAAD considers practitioner-administered, long-acting buprenorphine injections to be post-dispensing-diversion-resistant. This quality benefits patients, practitioners, and the public at large.

Fourth and finally, time is of the essence, and we need flexible dosing options in practitioner-administered forms as soon as possible. If the advisory committee or agency determines that the clinical data is presently insufficient for an indication for long-term maintenance treatment for opioid use disorder, CLAAD recommends labeling the product for a use over a specific period of time. For example, the buprenorphine implant is presently approved for two six-month courses of treatment.

In conclusion, the weekly and monthly buprenorphine injections stand to provide the benefits of buprenorphine medications along with greater peace of mind and safety for patients, practitioners, and the public.

Thank you again for this opportunity. More information on CLAAD and our policy recommendations is available at CLAAD.org.