



October 15, 2015

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061, Rockville, MD 20852

Re: Comments Submission; Docket No. FDA-2015-N-0045 for International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ketamine

To Whom It May Concern:

The College of Psychiatric and Neurologic Pharmacists (CPNP) is submitting comments that are in opposition of any action by the FDA or DEA that would reschedule Ketamine as a Schedule I controlled substance. CPNP strongly urges the FDA and DEA not to increase restrictions or reduce the availability of ketamine, a potentially lifesaving medication for patients with treatment resistant Major Depressive Disorder (MDD).

There is a growing body of scientific evidence that Ketamine is highly effective in rapidly improving or remitting symptoms of MDD in some patients with life-threatening, treatment-resistant MDD (1). To date, over four controlled trials, ten open-label investigations, and ten case studies have been published in support of ketamine use in MDD or Bipolar Disorder (2). Response rates at 24 hours following infusion of ketamine in patients with treatment-resistant MDD have ranged from 25% to 85% in published literature (2).

About CPNP

We at CPNP envision a world where every individual with a psychiatric or neurologic disorder has a care team that includes a neuropsychiatric pharmacist accountable for optimal medication therapy. As the voice of the specialty, our mission is to advance the reach and practice of neuropsychiatric pharmacists. CPNP is a professional association of over 1600 members who work directly with patients and caregivers to apply specialized clinical knowledge and skills, educate and train healthcare professionals and develop new knowledge in order to improve health outcomes for those individuals with psychiatric and neurologic disorders. Members apply evidence-based, cost-efficient best practices as a member of a treatment team to achieve patient recovery and improved quality of life.

Respectfully submitted,

Raymond C. Love, PharmD, BCPP, CPNP President

References:

- (1) Murrough JW et al. Am J Psychiatry 2013;170:1134-42.
- (2) Aan het Rot et al. Biol Psychiatry 2012;72:537-547.

8055 O Street, Ste S113 ■ Lincoln, NE 68510
www.cnpn.org ■ info@cnpn.org
402-476-1677 (phone)
888-551-7617 (fax)