October 13, 2015

James R. Hunter
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2015-N-0045 for International Drug Scheduling

The American Society for Pharmacology and Experimental Therapeutics (ASPET) appreciates this opportunity to respond to the request for comments that appeared in the Federal Register on October 5, 2015 regarding international drug scheduling and ketamine, specifically.

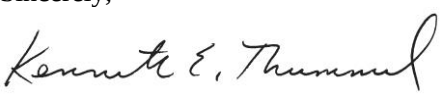
ASPET is a 5,000 member scientific society whose members conduct basic and clinical pharmacological research in academia, government, large pharmaceutical companies, small biotech companies, and non-profit organizations. The research efforts of our members help develop new medicines and therapeutic agents to fight existing and emerging diseases.

On behalf of our membership, we strongly object to any adoption of an international regulation of ketamine that might result in more restrictive regulation in the US, which would interfere with the use of the drug by licensed professionals for authorized and appropriate use.

Ketamine is currently a Schedule III drug under the Controlled Substance Act; a regulatory classification that is appropriate given its pharmacological effects and that provides the necessary mechanism to help prevent illegal use. ASPET is aware of proposals from China to tighten scheduling to the equivalent of Schedule I; a change so drastic that if implemented in the US could severely limit its availability to US practitioners. We believe that adopting a more restrictive classification of ketamine is unwarranted and unnecessary. ASPET asserts that ketamine does not meet the criteria for Schedule I because it has approved uses in humans and animals. Because its pharmacological effects are short-lived, ketamine is often the preferred drug in clinical and research settings for brief procedures in animals and for human pediatric surgeries, providing fast onset of action and positive recovery outcomes. Clinical trials also have shown ketamine to be effective in the treatment of refractory depression mitigating suicidal thoughts. Additionally, ketamine has been incorporated into the research protocols for many pre-clinical research studies. Reclassification of ketamine to a more restrictive schedule would create unnecessarily prohibitive barriers to accessing the drug for these appropriate uses.

In summary, changing the classification of ketamine is unwarranted, unnecessary, and would have a profound negative impact on biomedical research and the welfare of patients. **ASPET strongly urges the FDA to oppose any international regulation of ketamine use that might lead to a change to a change in its classification and use in the US.**

Sincerely,



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