October 9, 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; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ketamine; Phenazepam; Etizolam; 1-cyclohexyl-4-(1,2-diphenylethyl)-piperazine (MT-45); N-(1-Phenethylpiperidin-4-yl)-N-phenylacetamide (Acetylfentanyl); α-Pyrrolidinovalerophenone (α-PVP); 4-Fluoroamphetamine (4-FA); para-Methyl-4-methylaminorex (4,4’-DMAR); para-Methoxymethylamphetamine (PMMA); 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexanone (Methoxetamine or MXE); Request for Comments

Dear Mr. Hunter:

This letter is in response to the Food and Drug Administration’s request for comments that appeared in the Federal Register on October 5, 2015, concerning International Drug Scheduling. The Association of American Universities (AAU) represents 62 leading research universities, 60 in the United States and two in Canada. Our membership consists of both public and private universities, many with medical and veterinary schools and teaching hospitals. AAU appreciates the opportunity to provide the FDA with these comments ahead of the November 16-20 meeting of the World Health Organization’s 36th Expert Committee on Drug Dependence (ECDD).

AAU and many of our institutional members strongly object to any attempt to change international regulation of ketamine that would result in this drug being more difficult, or impossible, to obtain by biomedical researchers, health care providers, and licensed veterinarians for authorized and appropriate treatment of animals. In the United States, ketamine is currently a Schedule III drug under the Controlled Substances Act, and strict regulations and safeguards are already in place to prevent its illegal use.

Schedule I drugs are defined as drugs with no currently acceptable medical use and a high potential for abuse. Ketamine does not meet that definition in that it has important approved anesthetic uses in humans and animals and is appropriately and effectively regulated by the Controlled Substances Act (CSA). Biomedical research with ketamine is exploring ways to use the drug to develop alternatives to opioid pain medication. In order to provide sedation and analgesia to animals under their care, research veterinarians regularly administer ketamine in accordance with applicable regulations and laws.
Without adequate access to this drug, countless pre-clinical research studies, including many that are federally funded, may grind to a halt in the United States. According to a 2012 WHO report (WHO Critical Review Ketamine 2012), ketamine abuse rates in the United States and worldwide are low – less than 2% of the general population reported that they had used ketamine at least once in their lifetime. The potential elevation of ketamine to a Schedule I drug is not warranted and would result in serious repercussions to patient treatment, biomedical research, and the welfare of animals by removing a key component of essential anesthesia.

AAU urges the FDA to strongly oppose any changes to the schedule placement of ketamine such that it cannot efficiently and appropriately be accessed by researchers, health care providers, and veterinarians.

Sincerely,

[Signature]

Hunter R. Rawlings III
President