



ASSOCIATION OF AMERICAN UNIVERSITIES

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.

Boston University
Brandeis University
Brown University
California Institute of Technology
Carnegie Mellon University
Case Western Reserve University
Columbia University
Cornell University
Duke University
Emory University
Georgia Institute of Technology
Harvard University
Indiana University
Iowa State University
The Johns Hopkins University
Massachusetts Institute of Technology
McGill University
Michigan State University
New York University
Northwestern University
The Ohio State University
The Pennsylvania State University
Princeton University
Purdue University
Rice University
Rutgers, The State University
of New Jersey
Stanford University
Stony Brook University –
State University of New York
Texas A&M University
Tulane University
University at Buffalo –
State University of New York
The University of Arizona
University of California, Berkeley
University of California, Davis
University of California, Irvine
University of California, Los Angeles
University of California, San Diego
University of California, Santa
Barbara
The University of Chicago
University of Colorado, Boulder
University of Florida
University of Illinois, Urbana-
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University of Michigan
University of Minnesota, Twin Cities
University of Missouri, Columbia
The University of North Carolina at
Chapel Hill
University of Oregon
University of Pennsylvania
University of Pittsburgh
University of Rochester
University of Southern California
The University of Texas at Austin
University of Toronto
University of Virginia
University of Washington
University of Wisconsin - Madison
Vanderbilt University
Washington University in St. Louis
Yale University

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,

A handwritten signature in black ink that reads "Hunter R. Rawlings III". The signature is written in a cursive style with a prominent flourish at the end.

Hunter R. Rawlings III
President