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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 Medical Colleges is a not-for-profit association representing all 144 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and 93 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians. AAMC appreciates the opportunity to provide the FDA with comments.

AAMC strongly objects to any attempt to change international regulation of ketamine that would result in this drug being more difficult, or impossible, to obtain by licensed clinicians and medical researchers for authorized and appropriate use. 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). In order to provide sedation and analgesia to animals under their care, medical researchers 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.

Ketamine also has important clinical uses in pediatrics, psychiatry, anesthesiology, and emergency medicine.

According to a 2012 WHO report (WHO Critical Review Ketamine 2012), ketamine abuse rates in the United States and worldwide are low with less than 2% of the general population reporting that they had used ketamine at least once in their lifetime. Elevating ketamine to a Schedule I drug would result in serious repercussions to both biomedical research and the welfare of animals by removing a key component of essential anesthesia.

In the interest of protecting our Nation's ability to practice responsible medicine and to preserve the health and welfare of innumerable research animals, we urge the FDA to strongly oppose any changes to the schedule placement of ketamine such that it cannot efficiently be accessed by licensed clinicians and medical researchers.

AAMC 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).

Respectfully,

Atul Grover, MD, PhD
Chief Public Policy Officer