September 10, 2026

The Honorable Terrance C. Cole
Administrator
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

Re: Docket No. DEA-1570 – Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold in Schedule I

Dear Administrator Cole:

The American Association of Psychiatric Pharmacists (AAPP) appreciates the opportunity to provide comments regarding the Drug Enforcement Administration's notice of intent to temporarily place 7-hydroxymitragynine (7-OH) above a specified threshold in Schedule I of the Controlled Substances Act.

About AAPP

AAPP is a professional association of nearly 3,000 members who envision a world where all individuals living with mental illness, including those with substance use disorders (SUDs), receive safe, appropriate, and effective treatment. Pharmacist members specialize in psychiatry, SUDs, and psychopharmacology, and most are residency trained and board-certified in psychiatric pharmacy holding the BCPP credential (Board Certified Psychiatric Pharmacist). Given the significant shortage of mental health care professionals, psychiatric pharmacists offer another resource to improve outcomes for patients with psychiatric disorders and SUDs.

Role of Psychiatric Pharmacists

Pharmacists graduate with a Doctor of Pharmacy degree, requiring six to eight years of higher education to complete, and have more training specific to medication use than any other health care professional. Psychiatric pharmacists (a specialty within clinical pharmacy) have specialized training in providing direct patient care and medication management for the complete range of psychiatric disorders and SUDs. Psychiatric pharmacists are not only integral to interprofessional treatment teams but also for decision-making and leadership roles in health care organizations, state and federal organizations, academia, and industry.

Psychiatric pharmacists are important members of the health care team working directly with patients and in collaboration with other health care providers including, but not limited to, psychiatrists, other physicians, therapists, social workers, and nurses (including advanced practice nurses). Psychiatric pharmacists provide expert, evidence-based Comprehensive Medication Management (CMM) services for the most complex patients with mental health disorders and SUDs. Psychiatric pharmacists increase the capacity of the health care team to provide care and psychopharmacology expertise, as well as improve patient outcomes and reduce overall health care costs. As medication experts, psychiatric pharmacists are uniquely positioned to facilitate medication access and adherence by identifying and helping to address potential treatment barriers, including prior authorizations and high out-of-pocket patient costs.

Psychiatric pharmacists have a deep understanding of Medications for Opioid Use Disorder (MOUD) and Medications for Alcohol Use Disorder (MAUD) that extends beyond that of most other health care providers. When included in the provision of MOUD services through a collaborative practice arrangement, psychiatric pharmacists' involvement demonstrates improved patient adherence and success with buprenorphine treatment for opioid use disorders; reduced per patient dosage of buprenorphine through improved medication management, improved monitoring and titration; and reduced overall costs. Psychiatric pharmacists with their education and advanced training are uniquely positioned to provide education to raise awareness, reduce stigma, and address SUD treatment barriers to mitigate the underuse of effective, evidence-based SUD pharmacotherapy. Furthermore, given the insufficient number of providers in addiction medicine, psychiatric pharmacists increase access to SUD treatment by providing systematic screening, medication initiation and management, monitoring, care coordination, and follow-up care.

AAPP Comments to DEA Proposed Rule

As DEA notes, concentrated 7-OH products are increasingly available through retail outlets and online vendors, often with limited information about their contents or risks. Additionally, these products can contain substantially higher concentrations of 7-OH than naturally occur in botanical kratom and have opioid-like effects that can lead to dependence, withdrawal, overdose, and other serious health consequences. DEA's notice also points to increasing reports of 7-OH exposures and adverse health outcomes.

Given these concerns, AAPP agrees that concentrated 7-OH is a substance of concern and supports stronger federal controls to limit its largely unregulated availability. At the same time, 7-OH remains an emerging substance, and significant questions remain about its use and health effects.

As such, AAPP supports DEA's goal of protecting the public from the risks associated with concentrated, readily available 7-OH products. At the same time, we encourage DEA to ensure that temporary Schedule I placement does not unnecessarily impede scientific and clinical research. Continued research is important to better understand patterns of use, health effects, and approaches to managing withdrawal, and should be used to inform any future permanent scheduling decisions.

Additionally, AAPP encourages DEA to continue monitoring kratom-derived products and other emerging substances for evidence of misuse and public health risk and to take appropriate regulatory action when warranted.

AAPP appreciates DEA's consideration of these comments. If you have any questions, please do not hesitate to contact me or our Health Policy Consultant, Deepti Loharikar at daloharikar@venable.com. We look forward to working with you.

Sincerely,

Brenda K. Schimenti
Executive Director