August 4, 2026

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

Re: DEA Proposed Rule – Tianeptine to Schedule I

Dear Administrator Cole:

The American Association of Psychiatric Pharmacists (AAPP) appreciates the opportunity to comment on the Drug Enforcement Administration's (DEA) proposed rule to place tianeptine 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

Psychiatric pharmacists have become increasingly concerned by the growing misuse of tianeptine and the significant risks it poses to patients. Based on the available scientific and clinical evidence, AAPP agrees that tianeptine should be a controlled substance. The drug has demonstrated substantial abuse potential, produces opioid-like effects at higher doses, and should not remain readily available through gas stations, convenience stores, smoke shops, and online retailers, where consumers may purchase it without appropriate medical oversight.

While tianeptine is approved as an antidepressant internationally, it is not approved by the Food and Drug Administration (FDA) for any indication in the United States. Nevertheless, it remains readily available through convenience stores, gas stations, and online vendors, where it is often marketed as a dietary supplement or nootropic. This widespread availability has given the false impression of safety and has contributed to increasing misuse, allowing consumers to access a substance with opioid-like effects outside the safeguards of the regulated pharmaceutical supply chain.[1]

From a clinical perspective, tianeptine presents significant public health concerns. Tianeptine is a full mu-opioid receptor agonist and, at the supratherapeutic doses commonly consumed in misuse, it produces euphoria, tolerance, physical dependence, withdrawal, and overdose, with symptoms that closely resemble those associated with traditional opioids. People who use tianeptine recreationally often consume doses many times higher than therapeutic doses, substantially increasing the risk of serious adverse events, including overdose and death.[2] Importantly, tianeptine overdose may respond

[1] U.S. Food and Drug Administration. FDA warns consumers not to purchase or use any tianeptine product due to serious risks. Published May 8, 2025. Accessed May 26, 2026. Available at: https://www.fda.gov/drugs/drug-alerts-and-statements/fda-warns-consumers-not-purchase-or-use-any-tianeptine-product-due-serious-risks

[2] El Zahran T, Schier J, Glidden E, Kieszak S, Law R, Bottei E, et al. Characteristics of Tianeptine Exposures Reported to the National Poison Data System - United States, 2000-2017. Mmwr Morb. Mortal. Wkly. Rep. 2018;67(30):815-818. DOI: 10.15585/mmwr.mm6730a2. PubMed PMID: 30070980; PubMed Central PMCID: PMC6072055.

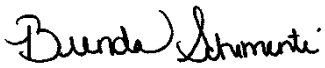
to naloxone.[3] In addition, products marketed as dietary supplements may contain inconsistent amounts of tianeptine or other undeclared ingredients, further increasing the risks to patients.[4]

Psychiatric pharmacists are increasingly recognizing tianeptine misuse in clinical practice. Patients may present with opioid-like intoxication or withdrawal despite negative routine opioid drug screens, making diagnosis particularly challenging for clinicians unfamiliar with the substance.[5] Chronic misuse is associated with clinically significant withdrawal that resembles opioid withdrawal and often requires treatment using established opioid use disorder management strategies, including buprenorphine and methadone[6]

While AAPP supports stronger federal controls on tianeptine, we also recognize an important consideration associated with placement in Schedule I. The substance is not yet completely understood, and additional research is needed to better identify patterns of use, risk factors for misuse, clinical management, and effective treatment strategies. We recognize that Schedule I status may increase the administrative burdens associated with conducting this research. As the DEA moves forward with this proposal, we encourage the DEA to continue to support and facilitate legitimate scientific and clinical research on tianeptine so that health care professionals can better understand its public health impact and develop evidence-based approaches to prevention and treatment.

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, Laura Hanen at lahanen@venable.com. We look forward to working with you.

Sincerely,



Brenda K. Schimenti
Executive Director

---

[3] Edinoff AN, Sall S, Beckman SP, Koepnick AD, et al. Tianeptine, an Antidepressant with Opioid Agonist Effects: Pharmacology and Abuse Potential, a Narrative Review. *Pain Ther*. 2023 Oct;12(5):1121-1134.

[4] White CM. Continued Risk of Dietary Supplements Adulterated With Approved and Unapproved Drugs: Assessment of the US Food and Drug Administration's Tainted Supplements Database 2007 Through 2021. J Clin Pharma. 2022;62(8):928- 934. DOI: 10.1002/jcph.2046. PubMed PMID: 35285963.

[5] http://dx.doi.org/10.1007/s00213-022-06093-whttp://www.ncbi.nlm.nih.gov/pubmed/35211768http://www.ncbi.nlm.nih.gov/pmc/articles/PMC10055856 Dempsey SK, Poklis JL, Sweat K, Cumpston K, Wolf CE. Acute Toxicity From Intravenous Use of the Tricyclic Antidepressant Tianeptine. J Anal Toxicol. 2017 Jul 1;41(6):547-550. doi: 10.1093/jat/bkx034. PMID: 28541419; PMCID: PMC6075028.

[6] Anand A, Alessi MR, Toussi RA, Tian J, Raffoul JJ, Pratt N, Nero N, Weleff J. Tianeptine misuse and addiction: A systematic review of withdrawal, toxicity, and clinical management. Drug Alcohol Depend. 2026 Aug 1;285:113196. doi: 10.1016/j.drugalcdep.2026.113196. Epub 2026 May 12. PMID: 42177839.