

Congress of the United States

Washington, DC 20515

September 30, 2024

Director Rahul Gupta
Office of National Drug Control Policy
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Director Gupta,

Thank you for your commitment and leadership in coordinating the nation's drug policy to improve the health and lives of the American people. We are writing to you to better understand the Administration's overall efforts to combat the rise of illicit sales and use of oral and at-home ketamine. There is rapidly increasing evidence, given by health care providers, law enforcement and substance abuse experts that the same early warning signs that were present at the start of the opioid crisis are present for illicit ketamine use.

As you are aware, ketamine is a Schedule III controlled substance that is U.S. Food and Drug Administration (FDA)-approved for the induction and maintenance of general anesthesia.¹ While ketamine has not been approved for the treatment of depression, anxiety, or chronic pain, it has been successfully prescribed off-label to treat these conditions for decades. Notably, ketamine derivative, esketamine, was approved by the FDA in 2019, in the form of a nasal spray under the name Spravato for treatment-resistant depression.² Due to the risk of serious adverse outcomes and the potential for abuse and misuse of the drug, Spravato is only available to be administered at a certified doctor's office or clinic.

Several online pharmacies began operation during the pandemic and used newly promulgated telemedicine rules to prescribe ketamine for a variety of mental health conditions. For example, one such pharmacy, called Mindbloom, allows patients to click through a brief questionnaire, meet once with a practitioner, who is unlikely to be expertly trained on the use of ketamine and who often is located far from the patient's domicile, and are then mailed compounded ketamine to administer themselves.³ In October 2023, FDA issued a warning stating "[Ketamine] presents a risk to patients and should only be used under the care of a health care provider."⁴ Hundreds of similar online "clinics" are opening up at a staggering rate across the country. This includes clinics like BetterU, Joyous, NueLife, Wondermed, Innerwell, Anywhere Clinic, and Choose Your Horizon to name just a few. To be clear, intravenous ketamine infusions administered by trained medical

¹ Food and Drug Administration. "Understanding Current Use of Ketamine for Emerging Areas of Therapeutic Interest" (2024) Online at: <https://www.fda.gov/drugs/news-events-human-drugs/understanding-current-use-ketamine-emerging-areas-therapeutic-interest-06272024>

² Food and Drug Administration. "FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic" (2019) Online at: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified>

³ Id.

⁴ FDA, "FDA warns patients and health care providers about potential risks associated with compounded ketamine products, including oral formulations, for the treatment of psychiatric disorders" (2024) Online at: <https://www.fda.gov/drugs/human-drug-compounding/fda-warns-patients-and-health-care-providers-about-potential-risks-associated-compounded-ketamine>

professionals are not the focus of our concern. Reputable clinics are different than the online pharmacies that prescribe unmonitored compounded ketamine and are likely run and managed by non-physicians.

We are deeply concerned about unscrupulous for-profit companies and untrained providers coming together to make access to self-injectable and oral ketamine effortless for vulnerable patients. Trained doctors who provide ketamine have said mailing people a fast-acting version of the drug raise the risks of substance misuse and of diversion into the illicit market.⁵ Ketamine is an anesthetic and should never be taken at home in an unsupervised setting.

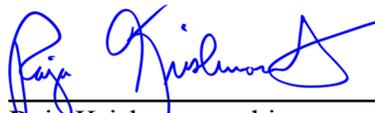
Actor Matthew Perry, who had a history of addiction, fell victim to ketamine abuse after inappropriately obtaining large quantities of oral and injectable ketamine at home. Perry had been seeking out unsupervised doses of the controlled substance and had developed an “out of control” dependence on it.⁶ Perry took 6 to 8 shots a day of ketamine and accidentally overdosed on the drug after he was injected by his assistant at home. Five people were charged in his death.

Considering the ominous nature of these facts and conditions, we ask that you provide answers to the following questions:

1. Does the Administration have a strategy to combat the distribution and sale of illicit self-administered oral and IV ketamine?
2. Which agencies are involved in combatting illicit use of ketamine?
3. How are federal, state and local law enforcement agencies coordinating enforcement?
4. Are there rules and guidelines for providers prescribing self-administered ketamine?
5. How are you tracking the use/misuse of ketamine and what agencies are involved?
6. What are the rules, laws, and penalties for non-physicians prescribing, monitoring, or administering oral and IV ketamine, both at home and in office?

We request that you provide answers to these questions by October 31st, 2024. In the interim, we request that you provide a staff-level briefing on this issue for the undersigned offices. Advancing treatment for mental health disorders is critical in combatting the mental health crisis in the United States, but we must do so responsibly and with evidence-based solutions. Thank you for your attention to this important matter.

Sincerely,



Raja Krishnamoorthi
Member of Congress

⁵ Wall Street Journal “People Are Injecting Ketamine at Home” (2024) Online at: https://www.wsj.com/health/wellness/ketamine-shots-at-home-test-limits-of-unproven-treatment-60346d10?mod=article_inline

⁶ NBC News “The depths of Matthew Perry's addiction: 6 to 8 shots a day and \$55K for a month of ketamine” (2024) Online at: <https://www.nbcnews.com/news/us-news/depths-matthew-perrys-addiction-6-8-shots-day-55k-month-ketamine-rcna166806>