

TO: Oversight Board

FROM: National Association of Boards of Pharmacy

DATE: June 8, 2023

RE: Request for Comment – “Promoting Ketamine for Non-FDA-Approved Treatments”

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We are writing on behalf of the National Association of Boards of Pharmacy (NABP), a US-based non-profit organization whose members include the 50 US state pharmacy boards, as well as pharmacy regulators in the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Bahamas, and ten Canadian provinces. NABP’s mission is to assist our member boards in protecting public health.

NABP appreciates the Oversight Board’s outreach to NABP regarding this case.

### **Background**

According to the [Case Description](#), in December 2022:

“[A] verified Instagram user posted a series of related images, including a colorful drawing of an office. The caption on the post explained that the user was given ketamine at the clinic depicted in the drawing as treatment for anxiety and depression, and another username for an account that appears to belong to a well-known ketamine therapy provider is at the top of the post. The user describes their experience with ketamine at the clinic as an entry ‘into another dimension,’ and refers to ketamine as ‘medicine.’ They also explained that they believe that ‘psychedelics’ (a category that includes ketamine, but also other substances) are an important emerging mental health medicine. Other images in the series have text overlaid on drawings, and they are all related to their experience at the clinic. They range from a drawing depicting a person wearing an eye mask and lying under a blanket who is preparing to receive ketamine treatment to a colourful drawing of a person with rainbows, planets, and other objects coming out of their head.”

The content was removed – and reinstated – three times under Meta’s [Restricted Goods and Services Community Standard](#). In its referral to the Oversight Board, Meta noted that “the increasing use of mind-altering drugs in the United States for purposes that blur the line between medical treatment, self-help, and recreation, makes it particularly difficult to ascertain whether this content should be treated as promoting pharmaceutical drugs, which is generally allowed on the platform, or as endorsing drugs for non-prescribed purposes or in order to achieve a high, which is generally not allowed.”

### **NABP's Analysis**

Based on the limited facts provided in the [Case Description](#), it appears that the verified Instagram user complies with Meta's Restricted Goods and Services Community Standard. Ketamine is an FDA-approved prescription-only drug. Although ketamine has not been FDA-approved as a treatment for anxiety and depression, physicians are permitted to prescribe FDA-approved drugs for "off-label" use.<sup>1</sup> In addition, esketamine (an isomer of ketamine) is *specifically* approved for treatment-resistant depression. Therefore, ketamine could reasonably be prescribed by medical professionals for depression. In short: The facts, as provided, do not clearly indicate violative behavior by the involved parties.

Please note: NABP is assuming that the "well-known therapy provider" referenced in the Case Description is a licensed practitioner operating within the parameters of the law. If this is not the case, NABP's analysis would be very different.

**Oversight Board's Question:** *In its request for public comments, the Oversight Board asked for an analysis of the "impact of Meta's Restricted Goods and Services policy on the ability of users to share relevant experience and information about new mental health treatments."*

**NABP's answer:** *As written, Meta's current policy should not implicate cases where users share relevant experience about new mental health treatments involving FDA-authorized drugs prescribed by licensed providers. However, unless Meta develops or leverages expertise in this space, it will be impossible for Meta to consistently apply a policy that distinguishes "drugs or substances that are not being used for an intended medical purposes" from "pharmaceutical drugs."*

### **Ketamine is: (1) an FDA-approved prescription-only drug; (2) a Schedule III controlled substance; and (3) a well-known substance of abuse**

It may be helpful to provide some background regarding the drug in question. Ketamine is made up of two mirror-image molecules: R-ketamine (also known as arketamine) and S-ketamine (also known as esketamine). For more than 50 years, ketamine has been approved by the FDA as an anesthetic. In 2019, esketamine was approved, in nasal form, for treatment-resistant depression.<sup>2</sup>

Not only is ketamine regulated as a prescription-only drug, it is also a [Schedule III controlled substance](#) in the United States. Under the Federal Controlled Substances Act, Schedule III drugs are defined as medicinal drugs with a potential for abuse less than the drugs or other substances in schedules I and II, with abuse potentially leading to moderate or low physical dependence or high psychological dependence. See [21 USC § 812\(b\)\(3\)](#). For context: In addition to ketamine, Schedule III controlled substances include anabolic steroids and buprenorphine.

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<sup>1</sup> According to the Federal Agency for Healthcare Research and Quality: "Off-label prescribing is when a physician gives [a patient] a drug that the U.S. Food and Drug Administration (FDA) has approved to treat a condition different than [the patient's] condition. **This practice is legal and common.** In fact, one in five prescriptions written today are for off-label use." <https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drug-usage.html> (Emphasis added).

<sup>2</sup> See FDA Approves New Nasal Spray Medication for Treatment-Resistant Depression; Available Only at a Certified Doctor's Office or Clinic, *available at* <https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified>

Finally, ketamine is a well-known substance of abuse. Its recreational effects (and side effects of legitimate use) include hallucinations and distorted perceptions of sight and sound. When sold as a street drug, ketamine is referred to by various slang names, including “Special K,” “Cat Tranquilizer,” and “Vitamin K.” Misuse of ketamine poses [potential health risks](#), including agitation, depression, cognitive difficulties, unconsciousness, dangerously slowed breathing, and prolonged visual disturbances.

**Oversight Board’s Question:** *In its request for public comments, the Oversight Board asked “[w]hether ketamine and other psychedelic drugs should be considered as ‘pharmaceutical drugs’ in the context of discussions about new treatments for mental health issues.”*

**NABP’s answer:** *Ketamine is, in fact, an FDA-approved pharmaceutical drug and should be considered as such in the context of treatments provided by licensed providers. However, drugs that are not FDA-approved, and drugs that are promoted for use without the involvement of a licensed provider, should be treated as “drugs or substances that are not being used for an intended medical purposes” under Meta’s policy.*

### **Ketamine, clearly marketed for recreational use, remains widely available for sale on Instagram**

While the case presented to the Oversight Board is an edge case, NABP notes that ketamine remains widely available for sale on Instagram. With only a cursory search (less than 1 minute), NABP found the following examples of recreational ketamine sales on Instagram:

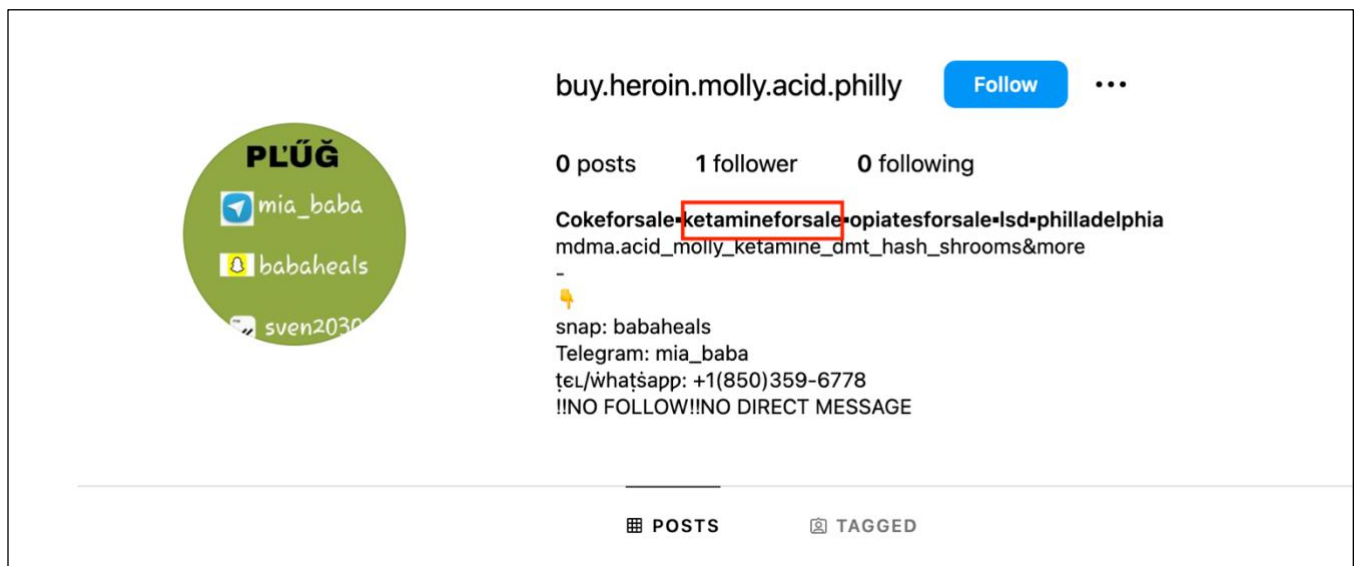


Fig. 1: <https://www.instagram.com/buy.heroin.molly.acid.philly/>

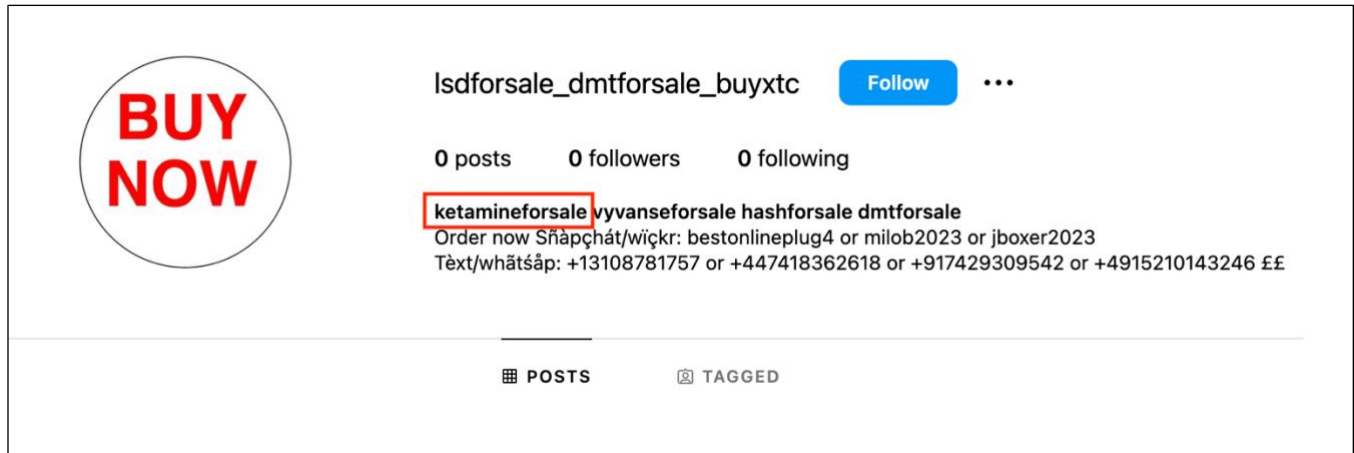


Fig. 2: [https://www.instagram.com/lsdforsale\\_dmtforsale\\_buyxtc/](https://www.instagram.com/lsdforsale_dmtforsale_buyxtc/)

These pages *clearly* violate Meta's [Restricted Goods and Services](#) Community Standard. Multiple times during the past ten years, NABP staff (in their individual capacities) have reported similar profiles to Meta. In each case, NABP staff was informed that the post in question did not violate Meta's Community Standards. NABP recommends that Meta leverage experts to ensure the prompt removal of users and posts that promote the sale of recreational drugs on its platforms.

**Oversight Board's Question:** *In its request for public comments, the Oversight Board asked commenters to address "[t]ransparency considerations related to the level of automation of Meta's appeal systems and information provided to users in this regard."*

**NABP's Answer:** *Automation must be coupled with expertise. In NABP's experience, Meta has failed to take action on the clear-cut illegal promotion of recreational drugs. NABP recommends that Meta prioritize taking action on bright-line cases, rather than spending resources on edge cases.*

## **Conclusion**

NABP appreciates the Oversight Board's request to submit comments on this issue. If the Oversight Board has any questions, please contact Senior Digital Health & Policy Expert, Niamh Lewis, at [nlewis@nabp.pharmacy](mailto:nlewis@nabp.pharmacy).