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**Testimony to the Food and Drug Administration's Public Hearing on Considerations for Potential Future Therapeutic Use of Psychedelic Drugs**

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I'm Dr. Marie Ezran, a family medicine physician and a fellow with Public Citizen. Public Citizen is a nonprofit consumer advocacy organization with over one million members. We have no financial conflicts of interest related to this topic.

Public Citizen supports research on potential psychedelic treatments for serious psychiatric conditions. There is a need for therapies that are more effective and provide faster relief for conditions such as treatment-resistant depression, post-traumatic stress disorder, and substance use disorders.

Public Citizen also appreciates the Food and Drug Administration's (FDA's) consideration of patient safety when studying the potential future therapeutic use of psychedelic drugs. **The most effective ways the FDA can protect patients are by requiring rigorous and well-designed clinical trials that enroll adequate numbers of participants and by conducting a thorough review of a new drug application prior to any potential approval.**

We are concerned about the use of the Commissioner's National Priority Voucher (CNPV) pilot program for three psychedelic drugs currently in clinical trial or under review. Public Citizen has previously outlined our concerns about the CNPV pilot in a public comment.[1] A 2017 study demonstrated that new drugs reviewed under accelerated pathways "are associated with increased safety related label changes after approval, particularly for the types of changes representing the highest risk warnings."[2] At the time of the study, the one- to two-month review timeline of the CNPV pathway had not been established. For a class of medications that remains relatively new to the FDA, there should be careful and complete review of the benefits and

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[1] Steinbrook R, Kowalik AM. Comments to the FDA about the Commissioner's National Priority Voucher Pilot Program. June 29, 2026. https://www.citizen.org/article/comments-to-the-fda-about-the-commissioners-national-priority-voucher-pilot-program/. Accessed September 17, 2026.

[2] Mostaghim SR, Gagne JJ, Kesselheim AS. Safety related label changes for new drugs after approval in the US through expedited regulatory pathways: retrospective cohort study. *BMJ*. 2017;358:j3837. Published 2017 Sep 7. doi:10.1136/bmj.j3837

harms of each therapeutic, which is impossible to accomplish within a one- to two-month review time frame.

In the July 2026 guidance for industry about psychedelic drugs, the FDA stated that careful consideration of the selection of placebo is important for determining the drug's efficacy.[3] Use of an inert placebo would create unfunctional blinding that can bias results. Thoughtful choice of placebos in clinical trials of psychedelics therapeutics is essential to ensure the efficacy of drugs that are eventually approved. Moreover, long-term studies, of at least 12 months duration, are also needed to evaluate the potential lasting effects of psychedelic therapeutics.

For any approved psychedelic therapeutics, we support the use of the Risk Evaluation and Mitigation Strategies (REMS) program with elements to assure safe use (ETASU).[4] Because psychedelics have serious dissociation and hallucinogenic potential as well as cardiovascular side effects, use of the REMS program would allow for appropriate administration and monitoring.[5] We support the following safety precautions, many of which are part of the REMS program for esketamine (SPRAVATO), a medication for treatment-resistant depression and a drug that raises similar safety concerns.[6]

- The psychedelic therapeutic should be prescribed by a licensed psychiatrist that provides ongoing treatment to the patient. The prescriber should receive REMS training and certification prior to prescribing and dispensing the medication.

- The patient should have a separate evaluation prior to medication administration to ensure there are no contraindications to treatment. Patients should give written consent after demonstrating an understanding of possible side effects in addition to the potential transformative and irreversible effects of these medications.

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[3] Food and Drug Administration. Psychedelic Drugs: Considerations for Clinical Investigations Guidance for Industry. July 2026. https://www.fda.gov/media/169694/download. Accessed September 17, 2026.
[4] U.S. Food & Drug Administration. What's in a REMS? January 26, 2018. https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems. Accessed September 17, 2026.
[5] Romeo B, Kervadec E, Fauvel B, et al. Safety and risk assessment of psychedelic psychotherapy: A meta-analysis and systematic review. *Psychiatry Res*. 2024;335:115880. doi:10.1016/j.psychres.2024.115880
[6] U.S Food & Drug Administration. Approved Risk Evaluation and Mitigation Strategies (REMS): Spravato (Esketamine). June 24, 2026. https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=386. Accessed September 17, 2026.

- The medication should be administered only at a REMS-certified outpatient or inpatient health care setting. There should not be doses to take home. Two licensed providers should monitor the patient during the entire treatment session: "a health care provider with graduate-level professional training and clinical experience in psychotherapy, licensed to practice independently, serving as the lead monitor" and "an assistant monitor with a nursing or bachelor's degree and at least 1 year of clinical experience in a licensed mental health care setting."[7] The session should also be video recorded for the safety of the patient. The patient should be monitored for a specified number of hours after treatment with vital sign checks to ensure return to a baseline state.

- Finally, to support safe use of the medication, patients taking this therapeutic should be enrolled in a registry to monitor clinical outcomes and adverse effects.

We recognize that needed safety measures to protect patients can also make a medication harder to access and increase administrative work for prescribers. Nonetheless, if or when the FDA approves psychedelic therapeutics, the agency must prioritize ensuring patient safety. Part of the approval of any new psychedelic therapeutic should be requirements for strong patient protection measures that can be promptly updated when new evidence develops.

The FDA can best serve and protect patients by upholding quality clinical trial standards; conducting thorough reviews of drug applications prior to approval, regardless of the approval pathway for the drug; and requiring robust post-market surveillance for adverse events, misuse, and abuse.

[7] Food and Drug Administration. Psychedelic Drugs: Considerations for Clinical Investigations Guidance for Industry. July 2026. https://www.fda.gov/media/169694/download. Accessed September 17, 2026.