PUBLIC COMMENT

Considerations for Potential Future Therapeutic Use of Psychedelic Drugs

Submitted to	U.S. Food and Drug Administration
Docket	FDA-2026-N-7542
Submitted by	Center for Psychedelic Public Health
Date	Monday, October 5, 2026
Primary contact	Heather Kuiper Director, Center for Psychedelic Public Health (CPPH) heather@psychedelicpublichealth.org
Authorized signatories	Missi Wooldridge, MPH, CPPH Alex Tribo, MPH, Johns Hopkins Bloomberg School of Public Health Alia Lilienstein, MD, MPH, UC Berkeley Center for the Science of Psychedelics Anna Lill DSocSci, MS, CPPH Avi Kenny PhD, Duke University Jean Velez MS, Puerto Rico Institute for Psychedelic Science, Medicine, and Awareness Joey Nichols MD, MPH, Independent
Financial-interest disclosure	The submitting organization reports no financial relationships relevant to this comment.
Submission method	Regulations.gov

Considerations for Potential Future Therapeutic Use of Psychedelic Drugs

The Center for Psychedelic Public Health (CPPH) brings public health research, practice, and population health expertise to psychedelic policy and implementation. Our comments draw from studies we have conducted that are currently under review for publication. Should the FDA have further interest in our remarks, we will provide details or data upon request.

Scope of This Comment

This comment responds primarily to FDA's questions concerning (1) Considerations for Access, (2) Data Needs, and (3) Data Collection and Standardization. We do not address the safety or effectiveness of any particular product or pending application, substance scheduling, legalization or decriminalization, religious or personal use, or individual disputes involving practitioners.

Our recommendations (summarized on the next page and detailed in subsequent text) concern potential future therapeutic use in supervised and supportive settings.

Summary of Recommendations

Recommendation 1: Adopt a prevention framework for psychedelic interventions.

Enable early intervention for prevention of morbidity, mortality, injury, lost productivity, and diminished quality of life due to tobacco, alcohol, opioid, or stimulant use. Research should meet prevention's evidentiary standards for external validity, primary care implementation, early intervention, long-term follow-up, net benefit assessment, and equity.

Recommendation 2: Open insurance access: Engage US Preventive Services Task Force.

With sufficient evidence, a nomination to and A/B recommendation by the USPSTF can lead to insurance coverage without cost-sharing that significantly improves access.

Recommendation 3: Advance psychedelic service models compatible with primary care.

USPSTF requires primary care settings, where screening and prevention functions, co-located tiered workforce, and community-based cultural competency can improve psychedelic access and outcomes.

Recommendation 4: Prioritize implementation science, including primary care models.

Implementation science should understand and optimize varied delivery models and tiered workforce/collaborative-care strategies for preparation, dosing, session, and integration to maximize access. Primary care, FQHC, community-based, and rural health settings should be prioritized.

Recommendation 5: Improve external validity and population representation in research

Research should prioritize increased representation across age, sex, race, ethnicity, socioeconomic status, geography, rurality, comorbidity, insurance status, and disease stage. It should include participants with earlier stages of behavioral risk and disease progression.

Recommendation 6: Evaluate net health and economic effects.

Future psychedelic intervention research should estimate averted morbidity, mortality, emergency and in-patient utilization, disability, productivity loss, and healthcare costs. Economic analysis should account for longer-term cost savings and other benefits.

Recommendation 7: Elevate consideration of and investment in state-regulated programs / other registries, and observational and other study designs.

Supplementing trials evidence with data from state psychedelic programs and other registries, large observational studies, especially with prospective designs, and even platform studies as trial alternatives, can generate the large and diverse study populations needed to establish psychedelics' preventive efficacy.

Recommendation 8: Embed psychedelic data systems in existing public health infrastructure.

Psychedelic data should be developed and integrated into existing national, state, and local public health data infrastructure and align with State Health Improvement Plans (SHIPs), Healthy People 2030, CDC Chronic Disease Indicators, the Behavioral Risk Factor Surveillance System, and other public health monitoring and evaluation systems.

Recommendation 9: Establish common data elements

Psychedelic science and policy should standardize core prevention and health promotion reporting and measures, including social determinants of health, and establish a minimum common data architecture.

Considerations for Access

Adopt a prevention framework for psychedelic interventions. Incorporate a preventive care framework into future psychedelic research and implementation models in order to:

- **Improve personal and population health status** by delivering psychedelic interventions earlier in behavioral or disease trajectories, before disordered behavior, advanced or treatment-refractory disease, or even symptomatic disease develops.
- **Increase access** by opening policy options for coverage. For example, a Category A or B recommendation by the U.S. Preventive Services Task Force (USPSTF) for preventive interventions in primary care settings can lead to insurance coverage without cost sharing.

The current psychedelic intervention paradigm has largely focused on treating mental health and substance use conditions after they reach diagnostic thresholds, limiting potential population health impact. In contrast, a primary and secondary prevention framework provides intervention earlier, when behavioral risk profiles may not meet diagnostic criteria, health consequences may be subclinical. For tobacco, alcohol, opioid, and stimulant use, earlier intervention could prevent progression to problematic or disordered use and downstream outcomes such as cardiovascular, pulmonary, and other inflammatory disease, cancer, cirrhosis and other chronic disease, overdose, suicide, injury, and disability. Public health research has established that early intervention improves personal and population health outcomes and is cost-effective. Prevention research should evaluate whether early psychedelic interventions can alter these trajectories before substantial morbidity develops. Investment should support studies designed to meet prevention evidentiary standards, emphasizing representative populations and external validity, primary care implementation, early intervention, long-term follow-up, net-benefit assessment, and equity.

Open insurance access: Engage the US Preventive Services Task Force (USPSTF). Development of the psychedelic evidence base from a prevention frame could expand insurance access. A nomination to and A/B recommendation by the USPSTF can lead to insurance coverage without cost-sharing that significantly improves access, through: (1) Evidence of preventive efficacy (2) USPSTF review based on certainty of the evidence for net benefits and net magnitude of benefit for asymptomatic primary care populations; (3) Grade A/B recommendation, if warranted; (4) applicable insurance coverage guidance; (5) increased access. Coverage policies should accordingly anticipate both treatment and prevention indications. Coverage models should not require advanced disease status or severe problematic behavior if there is evidence of net benefit from earlier intervention.

Advance psychedelic service models that are compatible with primary care. The USPSTF specifically addresses prevention within a primary care context, which may prove to be more equitable and scalable than psychiatry or mental health models as it lowers costs and has a track record in prevention (and primary care providers already serve as a mental health backstop). Primary care clinicians also perform screening and monitoring roles that are transferable to psychedelic care. Primary care's Screening, Brief Intervention, and Referral to Treatment (SBIRT) framework, for example, is already under consideration by the USPSTF for unhealthy alcohol use in adults and adolescents. The primary care setting also can support a tiered workforce model for psychedelic care as it frequently co-locates with behavioral and community health providers and peer support specialists suited to psychedelic preparation, administration, and integration functions. Staff and providers in primary care settings often reflect the demographics and culture of the communities they serve, which can improve outcomes.

Data Needs

Research should quantify preventative net benefits, determining for whom, under what circumstances, and at what stage of risk psychedelic interventions lead to averted adverse health outcomes.

Prioritize implementation science, including primary care models. Even if approved by the United States Food & Drug Administration (USFDA), implementation and economic models for psychedelic care require further development to guide their safe, scalable, and equitable integration into the U.S. healthcare system. Improving outcomes and access through a prevention framework calls for investment in implementation science. However, our research found that no tobacco or opioid and 38% of alcohol-related psychedelic trials addressed implementation factors, and only 2% assessed primary-care settings. Implementation science efforts should seek to understand and optimize factors related to delivery models, tiered workforce/collaborative-care strategies for preparation, dosing, session, and integration strategies to maximize access, and provider qualification/training. The role of primary care, FQHC, community-based, Tribal, and rural health settings for psychedelic care should be prioritized. Access should also be addressed through systems and workforce design. Research should examine collaborative care, team-based staffing, and task sharing.

Improve external validity and population representation in research Meeting the evidentiary standards of preventive care and the USPSTF requires greater heterogeneity in study populations and clinical circumstances. CPPH's research found substantial limitations with regard to external validity in the current evidence base: only 2% of psychedelics trials addressing smoking, alcohol, or opioid use recruited populations representative of community or primary-care populations; only 19% reported inclusion of participants of low socioeconomic status; average female participation was 29%; and average Indigenous, Black, Hispanic, Asian/Pacific Islander, North African/Middle Eastern participation was 21%. Future trials should therefore increase representation across age, sex, race, ethnicity, socioeconomic status, geography, rurality, comorbidity, insurance status, behavioral health severity, disease stage, and primary care versus specialty care settings. Research should also deliberately examine greater behavioral-health heterogeneity, moving beyond participants with established disorders to include earlier stages of behavioral risk and disease progression and longer follow-up periods to demonstrate preventive effectiveness. This should include indicated and secondary prevention and, where scientifically and ethically appropriate, investigation of primary prevention before problematic behavior or disease onset.

Evaluate net health and economic effects. Earlier intervention can improve population health outcomes and reduce downstream costs. Psychedelic research should measure and model behavioral outcomes against established disease trajectories to estimate averted morbidity, mortality, emergency and inpatient utilization, disability, productivity loss, and healthcare costs. Follow-up should encompass relevant relapse periods to assess durability and optimize when supportive care or additional intervention may be warranted. Economic analyses should capture longer-term costs and benefits. Safety should be evaluated within a net-benefit framework. Measurement should distinguish expected acute drug effects, challenging experiences, clinically significant and serious adverse events, persistent or delayed effects, and downstream functional or healthcare consequences. Positive acute effects classification, such as for euphoria or perceptual changes, should be disaggregated according to their functional consequences, treating them as harms only when there is functional impairment or other health and safety risk.

Long-term surveillance should assess suicidality, overdose, other substance use-related morbidity and mortality, chronic disease, healthcare utilization, quality of life, and functional outcomes.

Best Practices for Data Collection and Standardization

The psychedelic evidence base should incorporate large population data systems and observational studies to better assess net population health benefits. Ppsychedelic measures should be integrated into existing public health data infrastructure when possible.

Elevate consideration of and investment in state-regulated programs and other registries, and observational and other study designs. Evidence from clinical trials should be complemented by data from state psychedelic programs and registries, large prospective observational studies, and innovative trial designs such as panel studies. These approaches can generate the large and diverse populations needed to assess preventive efficacy, external validity, net benefits, and equity under real-world conditions. State psychedelic programs offer an important opportunity to evaluate safety, health outcomes, and healthcare utilization. State–academic partnerships, including the OPEN (Open Psychedelic Evaluation Nexus) and ORCHID (Oregon-Colorado Regulated Psychedelic Care: Healthcare Impacts & Decisions) projects, demonstrate the potential to link state-regulated services with healthcare utilization, costs, and outcomes. Such evidence could help accelerate development of the evidence base needed for USPSTF evaluation and inform coverage decisions by Medicaid programs, state employee health plans, and private insurers. Government agencies, researchers, healthcare systems, health information technology providers, and insurers should collaborate to develop interoperable data systems.

Embed psychedelic data systems in existing public health architecture. Psychedelic data systems, standardized codes, and common data elements should be developed and integrated into existing national, state, and local public health infrastructure. Where appropriate, measures should align with State Health Improvement Plans (SHIPs) and established state and local health indicators. National psychedelic surveillance measures should likewise be harmonized with established systems, including Healthy People 2030, CDC Chronic Disease Indicators, the Behavioral Risk Factor Surveillance System, and other validated population health measures. Integration with existing public health data infrastructure would enable psychedelic-related outcomes to be assessed against established population health baselines and benchmarks, facilitate comparisons across jurisdictions and populations, and reduce duplication of data collection resources.

Establish common data elements. Psychedelic science and policy should standardize core prevention and health promotion measures, including social determinants of health, and establish a minimum common set of data elements for registries, including state programs, aligned where feasible with established metrics. Common data elements should include:

- Population and demographics: age, sex/gender, race and ethnicity, socioeconomic and insurance status, geography, rurality, and comorbidities.
- Intervention and context: substance, dosing metrics, number of administrations, indication or prevention target, support model, setting, and workforce configuration.
- Behavioral health: substance use patterns (from initiation, escalation,problematic-use, overdose, patterns to reduction, cessation, relapse); diet, exercise, and sleep behaviors.

- Mental health, intermediate and chronic disease, and social outcomes, including: depression, anxiety, suicidality, hypertension, cardiovascular disease, pulmonary diseases (COPD, asthma), cancer, hepatic disease (e.g., cirrhosis), chronic pain, suicide, injury, disability, productivity, earlier cardiovascular, pulmonary, hepatic, inflammatory changes, well-being, quality of life, relational health, and social functioning.
- Healthcare utilization: emergency care, hospitalization, crisis services, transport, primary care, and specialty care.
- Implementation outcomes: feasibility, fidelity, reach, adoption, sustainability, cultural accessibility, equity, patient experience, and safety.

It would be valuable to establish a national set of core common elements with condition-specific modules, using validated public health indicators wherever possible. In particular, harmonizing these measures to SHIPs, Healthy People objectives, CDC chronic disease indicators, BRFSS, and local population health measures would allow comparison with existing state and national benchmarks and strengthen assessment of external validity, equity, effectiveness, safety, and net benefit.

Summary

Science and policy should emphasize preventive psychedelic interventions to improve public health and expand access, potentially through a USPSTF A/B Recommendation. **This calls for increased investment in trials and implementation studies that**:

- take place in primary care and community health settings
- include participation representative of the general and at-risk populations
- include greater heterogeneity in behavior and disease stages
- apply earlier intervention and longer follow-up periods
- assess net health and economic effects, including averted morbidity, mortality, injury, disability, and gained health and wellness
- incorporate observational and state and local registry evidence
- embed psychedelic data systems in existing public health architecture
- establish common data elements that harmonize with established public health indicators