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Considerations for Potential Future Therapeutic Use of Psychedelic Drugs; Public Hearing; Request for Comments

Presenter Information for Hearing Registration

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Topic Areas Addressed: Provider training and credentialing; promotion of patient safety; considerations for access; best practices for data collection and standardization.

Brief Presenter Biography

Julie Bangs is a psychiatric and critical-care registered nurse with more than 19 years of experience in inpatient psychiatry, crisis stabilization, emergency medicine, trauma care, and intensive care. Her clinical background includes trauma-informed psychiatric assessment, crisis intervention, behavioral emergency management, suicide-risk assessment, and patient and family education. She is completing a Post-Master's Certificate in Psychiatric Mental Health Nurse Practitioner practice, with a professional focus on child and adolescent trauma, crisis care, and evidence-based psychopharmacology. These comments reflect her individual professional perspective and experience caring for people with severe and treatment-refractory psychiatric illness.

Conflict-of-Interest Disclosure

I am submitting these comments in my individual professional capacity. **[Confirm and retain if accurate: I have no financial relationships, consulting arrangements, research funding, ownership interests, or other financial ties with entities developing, manufacturing, marketing, or expecting to provide psychedelic drug products or related clinical services.]** My views are my own and do not necessarily represent those of any employer, professional organization, or educational institution.

To Whom It May Concern,

I submit this comment in support of a carefully regulated, evidence-based pathway for therapeutic psychedelic drug products in supervised and supportive clinical settings. I support continued research and product-specific clinical development of psilocybin, 3,4-methylenedioxymethamphetamine (MDMA), N,N-dimethyltryptamine (DMT), 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), lysergic acid diethylamide (LSD), mescaline, ayahuasca-derived DMT formulations, and other investigational psychedelic compounds.

I urge FDA and its federal partners to recognize that, once an individual psychedelic product meets FDA standards for approval, its scheduling assessment should be evidence-based, product-specific, and no more restrictive than necessary to protect public health. I support **Schedule IV as the presumptive scheduling goal for FDA-approved psilocybin** and as a potential outcome for other FDA-approved psychedelic products, including MDMA and DMT, when their completed abuse-liability assessments support that designation.

I do not support blanket scheduling of an entire class of substances. Psilocybin, MDMA, DMT, 5-MeO-DMT, LSD, mescaline, ibogaine-derived products, and other compounds differ in pharmacology, duration, route of administration, therapeutic evidence, toxicity, interaction risk, and potential for misuse or diversion. Each should undergo an independent evaluation. Scheduling should not, however, be dictated by stigma, historical nonmedical use, or a presumption that a psychedelic product with accepted medical use must remain Schedule I.

I recognize that this docket does not seek comment on Controlled Substances Act scheduling. I raise Schedule IV because scheduling materially affects research, pharmacy operations, medication storage, clinical implementation, insurance coverage, and patient access to FDA-approved treatments.

Childhood Trauma and Lifelong Consequences

Too often, society and the broader community fail to keep children safe from emotional, verbal, physical, and sexual abuse. Child maltreatment includes physical, sexual, and emotional abuse, as well as neglect, and can have profound effects on a child's safety, development, and long-term health. [1]

Prevention of adverse childhood experiences must remain an urgent public-health priority. Safe, stable, nurturing environments for children require coordinated action across families, schools, healthcare, public health, social services, and government. [2] However, for adults who have already endured adverse childhood experiences and carried their effects throughout their lives, prevention alone cannot undo the harm already sustained.

Throughout my career in psychiatric and crisis care, I have seen the devastating effects of childhood trauma continue into adulthood. These experiences can affect emotional regulation, relationships, trust, self-worth, physical health, ability to work, substance use, and the ability to sustain recovery across the lifespan. Adults with trauma histories may present repeatedly with depression, anxiety, PTSD, addiction, chronic pain, suicidality, and recurrent psychiatric hospitalization.

Despite currently available psychotropic medication classes, psychotherapy, and other treatment modalities, many patients continue to experience severe symptoms and impaired quality of life. Psychedelic-assisted therapies may represent a meaningful new opportunity to mitigate ongoing suffering for this population. I see these therapies as a

potential light at the end of the tunnel for people who have lived for years, and sometimes decades, with the consequences of trauma.

This is not an argument for indiscriminate or unsupervised psychedelic use. It is an argument for providing access to rigorously studied, FDA-approved products within highly structured, trauma-informed, medically accountable settings.

Why Inpatient Psychiatric Hospitals Should Be Included in Future Access Models

Inpatient psychiatric hospitals should be eligible to provide FDA-approved psychedelic therapies under defined federal and state requirements. These facilities already care for patients with severe depression, anxiety, PTSD, trauma-related disorders, suicidality, and co-occurring substance-use disorders. They have established systems for psychiatric assessment, medication management, observation, multidisciplinary care, crisis intervention, safety planning, and discharge coordination.

A hospital-based model could provide safe access for clinically complex patients who may not be appropriate for an outpatient or minimally monitored environment. It could support comprehensive screening, preparation, medication-interaction review, observed administration, management of acute psychological or medical events, integration therapy, family education when appropriate, discharge planning, and coordinated follow-up.

If FDA-approved psychedelic therapies become available in properly credentialed inpatient psychiatric hospitals, they should be prospectively studied for their ability to improve remission of depression, anxiety, trauma-related symptoms, and PTSD; reduce substance-use relapse in selected populations; improve functioning and patient-reported well-being; and potentially reduce emergency utilization and recurrent psychiatric admissions. These outcomes are important hypotheses, not established conclusions, and should be measured directly in prospective studies and postmarketing registries.

Evidence to date supports cautious optimism. Short-term controlled trial data suggest that certain psychedelic therapies may benefit major depressive disorder, treatment-resistant depression, PTSD, and selected substance-use disorders, but critical questions remain regarding long-term safety, efficacy, the role of psychological support, and performance in diverse, real-world populations. [3]

Schedule IV Is a Balanced Regulatory Framework

Schedule IV does not mean unrestricted availability. Schedule IV medications remain controlled substances subject to prescribing requirements, secure storage, inventory management, documentation, dispensing controls, and enforcement against diversion.

For approved psychedelic products delivered in one or a limited number of observed clinical sessions, Schedule IV may provide a better balance than Schedule I. It would

preserve meaningful federal oversight while avoiding restrictions that can unnecessarily impede research, hospital implementation, and equitable access. Scheduling should reflect the actual evidence for a particular FDA-approved product's abuse potential, physical-dependence risk, psychological-dependence risk, and medical utility.

A Schedule IV framework could allow hospitals and outpatient specialty programs to develop responsible care models while maintaining strict conditions of use. It would also make it more feasible to conduct the large, diverse, longitudinal studies needed to understand which patients benefit, which patients are at risk, what level of psychotherapeutic support is needed, and whether treatment affects symptom burden, readmissions, substance-use relapse, function, and well-being.

Psilocybin and MDMA

Psilocybin has the most developed contemporary evidence base among classic serotonergic psychedelics, particularly for depression. It should be considered the strongest current candidate for Schedule IV after FDA approval, provided the final eight-factor analysis supports that designation.

MDMA should be assessed separately because it is pharmacologically distinct from classic serotonergic psychedelics and has been studied primarily as an adjunct to psychotherapy for PTSD. A phase 3 trial reported significant improvement in PTSD symptoms and functional impairment compared with placebo plus therapy. At the same time, the FDA did not approve the prior MDMA application, and additional rigorously designed research, transparent reporting, safety monitoring, and independent replication remain necessary. MDMA should not be presumed to belong in Schedule IV, but Schedule IV should remain available if future FDA approval and a product-specific abuse-liability review support that outcome.

DMT: A Strong Candidate for Hospital-Based Research and Future Clinical Use

I specifically support continued development of **DMT for administration in hospital-based settings**. DMT's rapid onset and rapid resolution of acute psychoactive effects may offer practical advantages for inpatient psychiatric care. Compared with longer-acting compounds, an intravenous DMT protocol may allow clinicians to induce, monitor, and conclude the psychedelic state within a shorter and more controllable clinical window.

A randomized placebo-controlled study found that intravenous DMT produced rapid, intense, short-lasting, and moderately well-tolerated psychedelic effects. Infusion administration enabled a stable psychedelic state that could be closely controlled and ended promptly. This pharmacokinetic profile makes DMT a particularly compelling candidate for study in hospitals, where continuous observation, medical oversight, crisis intervention, and post-session assessment are immediately available.

DMT's rapid onset and resolution should not reduce safeguards. Rather, those characteristics make it appropriate for research within a highly structured hospital protocol that includes psychiatric and medical screening, preparation, continuous monitoring, integration, and follow-up. Larger, more diverse, longer-term studies are needed before routine clinical use, including studies of durability, optimal dosing, psychotherapeutic support, safety in clinically complex populations, and effects on hospitalization and substance-use outcomes.

Other Studied Psychedelics and Potential Indications

Other psychedelic compounds warrant continued research but require separate regulatory evaluation:

- **LSD** has a prolonged duration of action and would require staffing, observation, discharge, and clinical-capacity standards appropriate to longer treatment sessions.
- **Ayahuasca-derived DMT formulations** require special attention to monoamine oxidase-inhibiting components, medication interactions, and dietary considerations.
- **5-MeO-DMT** is short acting but has a less mature evidence base and should remain investigational until its safety, efficacy, and abuse potential are more fully characterized.
- **Mescaline** has limited modern clinical evidence and should continue in research settings.
- **Ibogaine and ibogaine-derived products** require separate, heightened cardiac-safety standards and should not be presumed eligible for a Schedule IV framework without robust product-specific evidence.
- **Psychedelic-assisted therapies for chronic pain** are an important area of active research. Current evidence is insufficient to establish routine care, but ongoing studies of psilocybin, LSD, DMT, and mescaline may clarify whether these treatments have a role alongside established pain-management approaches. [4]
- **End-of-life distress** is another important area for continued clinical research. Psychedelic-assisted therapy may have potential to reduce depression, anxiety, and existential distress in carefully selected patients with serious or life-limiting illness, but it should be delivered as a structured, time-limited intervention with psychological support and cultural humility. [5]

Alzheimer's Disease and Assisted-Living Research

I also support the inclusion of Alzheimer's disease and memory-care assisted-living facilities in properly approved prospective research. People living with Alzheimer's disease, mild cognitive impairment, and related neurocognitive disorders frequently experience depression, anxiety, demoralization, social isolation, chronic pain, existential distress, and significant caregiver burden. They are often excluded from clinical research despite substantial unmet need.

Psychedelic therapies should not be offered routinely to patients with Alzheimer's disease outside an approved research protocol. However, Alzheimer's disease assisted-living and memory-care facilities that meet rigorous clinical-research standards should be eligible to participate in prospective studies. Such research must include careful capacity assessment, legally appropriate informed consent or surrogate consent, medical and psychiatric screening, medication-interaction review, safeguards for delirium and behavioral disturbance, staff training, caregiver involvement, and longitudinal monitoring of cognition, mood, function, safety, and quality of life.

Older adults remain markedly underrepresented in psychedelic trials. A systematic review found that adults age 65 years and older accounted for fewer than 1.4% of study participants, demonstrating an urgent need for carefully designed research in this population. [6]

A Unified National Psychedelic Research Database

FDA and federal partners should establish a unified national psychedelic research database, registry, or coordinated registry network. This system should allow qualified private practices, inpatient psychiatric hospitals, outpatient specialty programs, academic centers, hospice and palliative-care programs, and approved assisted-living or memory-care research facilities to contribute **de-identified data** using common data elements.

A national database would allow the field to move beyond small, homogeneous clinical trials and create a more complete understanding of real-world safety, effectiveness, access, and implementation. It should capture:

- Product, formulation, dose, route, indication, and treatment protocol.
- Patient demographics and relevant social determinants of health.
- Trauma history and psychiatric, substance-use, neurologic, medical, and pain-related comorbidities.
- Medication interactions and concurrent treatments.
- Preparation, administration, monitoring, and integration practices.
- Acute and delayed adverse events.
- Depression, anxiety, PTSD, substance-use, pain, functional, cognitive, quality-of-life, and patient-reported well-being outcomes.
- Emergency department visits, psychiatric hospitalization, readmissions, and other healthcare utilization.
- Treatment response, remission, relapse, durability of benefit, and reasons for discontinuation.
- Equity measures, including access, reimbursement, geography, and representation of underserved populations.

Centralized registries and harmonized data collection can generate the large sample sizes needed to identify predictors of response, detect uncommon adverse events, compare protocols across sites, and tailor care more safely to individual patients. [7] A

unified system would permit private practices, hospitals, and other qualified facilities to contribute to the ongoing scientific evidence while protecting patient privacy.

Required Safeguards for Any Hospital-Based Psychedelic Program

Any Schedule IV framework for an FDA-approved psychedelic product should be paired with product-specific safety requirements, including:

- **FDA-approved, standardized products only**, with no reliance on unregulated or nonstandardized formulations.
- **Credentialed treatment sites**, including inpatient psychiatric hospitals and specialty programs meeting defined standards for secure storage, chain of custody, inventory reconciliation, and emergency response.
- **Specialized multidisciplinary training** for prescribers, nurses, therapists, counselors, pharmacists, and other staff in screening, preparation, monitoring, de-escalation, trauma-informed care, ethics, professional boundaries, and integration.
- **Comprehensive medical and psychiatric screening** for psychosis-spectrum disorders, bipolar-spectrum illness or mania risk, active suicidality, cardiovascular disease, seizure risk, substance-use risk, medication interactions, pregnancy considerations, and product-specific contraindications.
- **Enhanced informed consent** addressing acute psychological distress, altered perception and judgment, uncertain long-term risks, possible symptom worsening, professional boundaries, therapeutic-touch policies, alternatives to treatment, and discharge requirements.
- **Observed administration without routine take-home dosing**, unless future evidence and FDA labeling specifically support another model.
- **Continuous monitoring and emergency protocols**, including vital-sign monitoring when indicated, behavioral observation, immediate access to medical and psychiatric emergency response, and safe transportation and discharge planning.
- **Mandatory integration and longitudinal follow-up**, including measurement-based care, reassessment of suicide risk, coordination with outpatient clinicians, and evaluation of functional recovery.
- **National data collection standards** that track diagnosis, product, dose, route, patient characteristics, concurrent medications, acute and delayed adverse events, remission, relapse, readmissions, emergency utilization, substance-use outcomes, functional outcomes, cognitive outcomes where relevant, and patient-reported well-being.
- **Equitable access and reimbursement planning** to prevent these therapies from becoming available only to patients able to self-pay.

Conclusion

The appropriate federal response to psychedelic therapeutics is neither unrestricted access nor indefinite prohibition. It is a regulated medical model that distinguishes FDA-

approved, standardized, professionally administered therapies from unregulated nonmedical products.

For FDA-approved psilocybin, Schedule IV should be the presumptive scheduling goal when the evidence supports it. For MDMA and DMT, Schedule IV should remain a possible, evidence-dependent outcome following FDA approval and a complete product-specific abuse-liability assessment. DMT is especially promising for inpatient psychiatric research and potential future hospital-based treatment because its rapid onset and rapid resolution may allow closely monitored therapeutic sessions within a practical clinical timeframe.

Adults who have endured childhood trauma and its lifelong psychiatric, physical, and social consequences deserve access to innovative treatments when conventional approaches have not been enough. With rigorous standards, inpatient psychiatric hospitals could provide a safe, trauma-informed, and accountable setting for psychedelic therapies. With carefully designed prospective studies, including research in appropriately equipped Alzheimer's and memory-care facilities, we can determine where these therapies improve remission, reduce relapse and recurrent hospitalization, relieve suffering, and promote long-term well-being.

Respectfully submitted,

Julie Bangs

Sources:

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