SUBMITTED ELECTRONICALLY

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
August 25, 2023

RE: Docket No. FDA-2023-D-1987; Psychedelic Drugs: Considerations for Clinical Investigations – Draft Guidance for Industry

Reason for Hope, The Veteran Mental Health Leadership Coalition, BrainFutures, and the additional cosigners noted below ("the Organizations") appreciate the opportunity to comment on the draft guidance, *Psychedelic Drugs: Considerations for Clinical Investigations / Guidance For Industry* ("draft Guidance"), which the Food and Drug Administration ("FDA") announced in the Federal Register on June 26, 2023.

I. Introduction to Commenters

Reason for Hope is a national non-profit organization focused on advancing safe and affordable access to psychedelic therapies to prevent deaths of despair (including suicide and substance overdose) and improve quality of life. Reason for Hope's work includes educating government officials and various stakeholder groups on the scientific and legal landscape for psychedelic medicine, establishing pilot programs that focus on bridging the gap between research and access to treatment for those most in need, and collaborating with experts to develop and advocate for the policy and legal reforms needed to safely increase access to treatment. Reason for Hope's co-founders and multi-disciplinary leadership team includes Lieutenant General Martin Steele, USMC (ret), Lynnette Averill, PhD, and Brett Waters, Esq.

The Veteran Mental Health Leadership Coalition (the "Coalition") is a national member-based Veteran organization that advocates for increased research and safe, affordable access to psychedelic medicine and assisted therapies for Veterans and their family members. The Coalition's founding members include (but are not limited to) the leadership of various Veteran Service Organizations, researchers, and mental health providers with expertise in psychedelic medicine. The Coalition, alongside its 40+ partner organizations, has successfully advocated for over $12 million in state funding for Veteran-focused research and implementation of psychedelic therapies in the healthcare system. The Coalition is led by retired Marine Lieutenant General Martin Steele, the Chief Executive Officer of Reason for Hope, who in 2015-2016 served on the VA Commission on Care exploring the future of VA healthcare.

BrainFutures is a national non-profit that works to advance the practical application of promising brain health interventions and expand access to treatments and technologies. BrainFutures was launched in 2015 by the nation's second oldest mental health advocacy organization, the Mental Health Association of Maryland ("MHAMD"). For more than 100 years, MHAMD has addressed the mental health needs of Marylanders of all ages through programs that

educate the public, advance public policy, and monitor the quality of mental healthcare services. Building on this success and bolstered by a cross-disciplinary advisory board of leading experts, BrainFutures brings together diverse stakeholders, policymakers, funders, and influencers to support and accelerate the national adoption of effective practices in brain health. Our recent work includes a guide to youth executive function programs in schools, an issue brief on neurofeedback as a treatment for ADHD and anxiety, and a series of reports on psychedelics that have been widely utilized by policymakers, advocates, and business leaders in the field of medical psychedelics.

These comments are also supported by the following organizations: Mental Health Association of Maryland, Sunstone Therapies, Avesta Ketamine and Wellness, SoundMind Institute, Navy SEAL Foundation, Balanced Veteran Network, Doctors For Cannabis Regulation, Heroic Hearts Project, Hippie and a Veteran Foundation, Mental Joe, No Fallen Heroes, REID Foundation, Southeast Coalition of Psychedelic Practitioners, The Hope Project, Warrior Wellness Solutions, NONSTANDARD, Veterans Healing Farm, and American Legion Post 426.

These comments are supported by the following individuals: Heidi Allen, PhD, MSW, Associate Professor, Columbia School of Social Work; Lynnette Averill, PhD, Associate Professor of Psychiatry and Behavioral Sciences, Baylor College of Medicine; Frederick Barrett, PhD, Director of the Johns Hopkins Center for Psychedelic and Consciousness Research,; Austin Hearst, Co-Founder, Bridge Builders Collaborative; Justin Heesakker DAOM, M.S., L.Ac. Dipl. OM, CPTR, VHA Office of Patient Centered Care & Cultural Transformation (OPCC&CT); Karen Jumisko-Amidon, RD, CSG, HBPC/MOVE; Brian L. Losey, RADM, USN (ret); Carlene MacMillan, MD, Chief Medical Officer, Osmind & Co-Founder, Fermata; Andrew Penn, MS, PMHNP, Clinical Professor, UC San Francisco, School of Nursing, Co-Founder, Organization of Entheogenic and Psychedelic Nurses (OPENurses); Brian Richards, Psy.D., Clinical Psychologist, Sunstone Therapies; Tony Rousmaniere, PsyD, Clinical Faculty, University of Washington; Nathan Sackett, MD, MS, Assistant Professor of Psychiatry and Behavioral Sciences, Co-Director of the Center for Novel Therapeutics in Addiction Psychiatry, University of Washington; Jordan Sloshower, MD MSc, Clinical Instructor, Department of Psychiatry, Yale University, Co-Director, West Rock Wellness PLLC; Angela Terhune, MHA Senior Director, Elligo Health Research; and Eric Utecht, Ph.D. Licensed Clinical Psychologist.

II. Comments on Draft Guidance

A. General Comments

As a general comment, the draft Guidance (at page one) appears to assume that psychedelic drugs will be investigated primarily for treating "psychiatric disorders [and] substance use disorders," and will do so through dosages sufficient to "cause intense perceptual disturbances and alterations in consciousness." That describes only some of the potential medical uses of psychedelics. A 2022 review of the clinicaltrials.gov database showed psilocybin was being investigated for use in treating numerous non-psychiatric conditions, including headaches, chronic pain, Parkinson's disease, and fibromyalgia.[1] There have been numerous investigations of the

[1] *See* Sky, J., *Psilocybin / At a Glance*, PSYCHEDELIC MEDICINE, at 29 (BrainFutures 2022) (*available at* https://www.brainfutures.org/wp-content/uploads/2022/05/BrainFutures-Psychedelic-Medicine-Report.pdf).

benefits of microdosing, both for chronic pain[2] and for mental health.[3] The Organizations would encourage the FDA to consider a broader range of conditions and dosage levels in preparing future drafts of this Guidance, particularly as such alternative usages would be expected to reduce the prevalence of safety concerns in clinical studies.

The organizations also note that there is immense interest in researching ibogaine, a non-classic psychedelic, for its potential to treat opioid use disorder (OUD) and traumatic brain injury (among other conditions, including stress- and trauma-related mental health concerns).[4] The state of Kentucky's Opioid Abatement Advisory Commission is currently considering an allocation of $42 million for research and development of ibogaine for OUD. The Organizations encourage FDA to clarify whether the draft Guidance applies to non-classic psychedelics such as ibogaine (a partial 5-HT2 agonist) and/or to consider ibogaine's inclusion in future guidance.

B. Comments on the Clinical Section of the Draft Guidance

(1) The FDA Should Not Require Sponsors to Report Expected and Likely Beneficial Reactions to Psychedelic Drugs as "Abuse-Related Adverse Events."

Page 7 of the draft Guidance states that "for psychedelic drugs, investigators and session monitors should be trained to record all abuse-related AEs [adverse events], including psychedelic ones" such as "euphoria, hallucinations, stimulation, and emotional lability," and to report them "as a safety concern even if they are hypothesized to be associated with the therapeutic response."

However, it is critical to distinguish between expected (and believed to be beneficial) psychedelic effects during the medication administration session versus similar effects of unexpected intensity or duration (*e.g.,* feelings of intense euphoria or experiencing hallucinations in the days following the medication administration session). Indeed, the regulation that the draft Guidance cites (21 C.F.R. § 312.32) does not require reporting of all "abuse-related adverse events." Rather, it only requires reporting "potential serious risks" (21 C.F.R. § 312.32(c)(1)),

---

[2] *See* Lyes, M., Yang, K., Castellanos, J., Furnish, T., *Microdosing psilocybin for chronic pain: a case series*, PAIN (2023) (*available at* https://pubmed.ncbi.nlm.nih.gov/36066961).

[3] *See* Rootman, J.M., Kiraga, M., Kryskow, P. et al., *Psilocybin microdosers demonstrate greater observed improvements in mood and mental health at one month relative to non-microdosing controls*, SCIENTIFIC REPORTS (June 30, 2022) (*available at* https://doi.org/10.1038/s41598-022-14512-3). *See also* Rootman, J.M., Kryskow, P., Harvey, K., *et al.*, *Adults who microdose psychedelics report health related motivations and lower levels of anxiety and depression compared to non-microdosers*, SCIENTIFIC REPORTS (Nov. 18, 2021) (*available at* https://pubmed.ncbi.nlm.nih.gov/34795334/); Kuypers, K. P. C., *The therapeutic potential of microdosing psychedelics in depression*, THERAPEUTIC ADVANCES IN PSYCHOPHARMACOLOGY (Aug. 27, 2020) (*available at* https://pubmed.ncbi.nlm.nih.gov/32922736/).

[4] *See*, *e.g.*, Davis, A.K., Averill, L.A., Sepeda, N.D., Barsuglia, J.P., Amoroso, T., *Psychedelic Treatment for Trauma-Related Psychological and Cognitive Impairment Among US Special Operations Forces Veterans*, CHRONIC STRESS (THOUSAND OAKS) (July 8, 2020) (*available at* https://pubmed.ncbi.nlm.nih.gov/32704581/); Armstrong, S.B., Xin, Y., Sepeda, N.D., Polanco, M., Averill, L.A., & Davis, A.K., *Prospective associations of psychedelic treatment for co-occurring alcohol misuse and posttraumatic stress symptoms among United States Special Operations Forces Veterans*, MILITARY PSYCHOLOGY (2023) (*available at* https://www.tandfonline.com/doi/full/10.1080/08995605.2022.2156200).

which may include "serious and unexpected suspected adverse reactions" (21 C.F.R. § 312.32(c)(1)(i)). The regulations define these terms as follows:

- a "suspected adverse reaction" is an "adverse event for which there is a reasonable possibility that the drug caused the adverse event";
- a "suspected adverse reaction" is considered "serious" if its results in, among other things, "[d]eath, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, [or] a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions" and may also include "the development of drug dependency or drug abuse" if, "based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent" an "[i]mportant medical event that may … result in death, be life-threatening, or require hospitalization"; and
- an "unexpected suspected adverse reaction" is an adverse event that is "not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended."

According to prior FDA guidance, "if [an] adverse event does not" qualify as serious, unexpected and a "suspected adverse reaction," "it should not be submitted as an IND safety report."[5]

Thus, we suggest FDA clarify that sponsors do not need to report *all* instances of expected psychedelic effects such as euphoria, hallucinations, stimulation, or emotional lability as "abuse-related AEs." Rather, sponsors need only report when these symptoms meet the criteria under 21 C.F.R. § 312.32(c), for example, because the psychedelic effects appeared more severe or inconsistent with the expected risk described in an investigator brochure (an "unexpected suspected adverse reaction").

(2) The FDA Should Remove Language Suggesting Psychedelics Have High Abuse Potential.

Page 6 of the draft Guidance states that "[m]any psychedelic drugs are Schedule I substances under the Controlled Substances Act because they have high abuse potential and do not have a currently accepted medical use in the United States." The Organizations strongly urge FDA to remove this language, as most "classic psychedelics were placed in Schedule I at the time the CSA was enacted in 1970, and their abuse potential has not been systematically assessed using modern methodology."[6] Indeed, a CSA "8-factor analysis" of psilocybin conducted by Johns Hopkins found its "scope of use and associated harms are low compared to prototypical abused drugs, and the medical model addresses these concerns with dose control, patient screening,

[5] *Id.* at 9, § V.A..

[6] Calderon, S.N., Bonson, K.R., Reissig, C.J., Lloyd, J.M., Galati, S., Chiapperino, D., *Considerations in assessing the abuse potential of psychedelics during drug development*, NEUROPHARMACOLOGY (Feb. 15, 2023) (*available at* https://pubmed.ncbi.nlm.nih.gov/36455646/).

preparation and follow-up, and session supervision in a medical facility."[7] Accordingly, the paper concluded that "placement in Schedule IV may be appropriate if a psilocybin-containing medicine is approved."[8]

(3) The FDA Should Encourage Clinical Trials Assessing the Impact of Different Models of Therapy and Psychosocial Support.

The Organizations believe that additional research to better inform the optimal balance of safety, efficacy, and affordability/accessibility of psychedelic treatments is critical. As Dr. Nora Volkow, Director of the National Institute of Drug Abuse, and Dr. Josh Gordon, Director of the National Institute of Mental Health, recently wrote, much remains unknown about how to administer psychedelic compounds most effectively and safely.[9] Dr. Volkow and Dr. Gordon noted in a separate article that the "most immediate need is for research that focuses on how these rapid acting treatments can be used in the real world," as their "potential to significantly reduce morbidity and mortality and to improve care ... can only be realized if research answers key questions about how to use them effectively."[10]

While precise protocols and types of therapy are not yet consistently defined, psychedelic clinical trials for mental health conditions most often utilize a care model involving a continuum of support during preparation sessions, a medication administration session, and integration sessions, which is generally referred to as "psychedelic-assisted therapy" ("PAT").[11] The PAT model is based on developing trust and rapport between the patient/participant and the therapist during intake and preparation and then seeing the patient through the entire process, ensuring a consistent therapeutic presence.[12]

Although we recognize this model presents challenging confounding variables for determining the safety and efficacy of psychedelic drugs alone (as FDA outlined on page 9),[13] the Organizations believe that existing research supports, and future research will further validate that the PAT model produces the most consistently safe and effective patient outcomes. As such, we recommend FDA remove the draft Guidance language advising that sponsors need to "justify the inclusion of a psychotherapy component" to trial designs. We further suggest removing the Guidance's blanket preference for clinical trials where "the in-session monitor is not involved in

---

[7] Johnson, M.W., Griffiths, R.R., Hendricks, P.S., Henningfield, J.E., *The abuse potential of medical psilocybin according to the 8 factors of the Controlled Substances Act*, NEUROPHARMACOLOGY (Nov. 2018) (*available at* https://pubmed.ncbi.nlm.nih.gov/29753748/).

[8] *Id*.

[9] Volkow, N.D., Gordon, J.A., Wargo, E.M., *Psychedelics as Therapeutics—Potential and Challenges*, *JAMA PSYCHIATRY* (July 26, 2023) (*available at* https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2807608).

[10] Gordon, J.A., Volkow, N.D. & Koob, G.F., *No time to lose: the current state of research in rapid-acting psychotherapeutics*, NEUROPSYCHOPHARMACOL (2023) (*available at* https://doi.org/10.1038/s41386-023-01627-y).

[11] Sky, J., Esselman, D. and Glastra, J., *An Expert-Informed Introduction to the Elements of Psychedelic-Assisted Therapy* at 9 (2022) (*available at* https://www.brainfutures.org/wp-content/uploads/2022/10/An-Expert-Informed-Introduction-to-the-Elements-of-PAT_web.pdf).

[12] *Id.* at 14.

[13] Specifically, Page 9 of the Guidance states "[a]s of the publication date of this guidance, the contribution of the psychotherapy component to any efficacy observed with psychedelic treatment has not been characterized. [ ] Psychotherapeutic interventions have the potential to increase expectancy and performance biases. Sponsors should plan to justify the inclusion of a psychotherapy component and describe any trial designs intended to reduce potential bias or to quantify the contribution of psychotherapy to the overall treatment effect."

post-session psychotherapy[,]" as it could result in less effective care and worse patient outcomes for vulnerable patient populations, who benefit from the consistent therapeutic alliance. As explained above, therapeutic rapport and trust are vital to positive clinical outcomes, and having a different in session monitor defeats the primary purpose of the preparation sessions, which are to build rapport and trust, and thus, in turn, reduce anxiety and increase a sense of safety. An integration therapist's presence during administration also ensures awareness of specific content that came up in-session that could help the patient effectively integrate.

To better inform safe and effective real-world treatment, the Guidance should *encourage* sponsors to conduct clinical trials that control for and assess how various models of in-session and integration therapy and/or psychosocial support contribute to clinical outcomes. This could also include attempts to reduce expectancy and performance bias through studies of different informed consent and preparation processes, as well as the use of different individuals for in-session monitoring and post-session therapy or support (though, as noted above, we caution against this split).[14] Such studies will be useful to inform product labeling, potential Risk Evaluation and Mitigation Strategies, and clinical treatment delivery both on-label and off-label.

Unfortunately, the administrative hurdles presented when researching Schedule I drugs (and a historical lack of funding) create unique challenges to conducting clinical trials of psychedelics, particularly for real-world trials that would better inform treatment models.[15] Thus, we suggest FDA proactively take steps to reschedule psychedelics that have received FDA Breakthrough Therapy designations (in advance of full FDA approval) and work with stakeholders to develop large-scale pilot programs that will help inform the clinical roll-out, scaling-up, and reimbursement of these treatments.

Policy considerations such as monitor-to-patient ratio and the necessary qualifications of monitors would directly benefit from this additional, real-world research. However, we highlight below specific areas of concern with FDA's baseline position on these issues and some suggested revisions.

(a) The FDA Should Reconsider its Recommended 2-to-1 Monitor-to-Patient Ratio.

Pages 9 to 10 of the draft Guidance state that safety monitoring during the treatment session should include "[o]bservation by two monitors": one, "[a] healthcare provider with graduate-level professional training and clinical experience in psychotherapy, licensed to practice independently, serving as the *lead* monitor[,]" and two, "[a]n *assistant* monitor with a bachelor's degree and at least 1 year of clinical experience in a licensed mental healthcare setting." The Organizations have several concerns with this portion of the draft Guidance.

First, while the Organizations want to ensure safety, we are concerned about the equity implications of a two-monitor requirement. Requiring two monitors to be present will create access

[14] *See, e.g.*, Kamilar-Britt, P., Gordis, E.B., and Earleywine, M., *The Therapeutic Alliance in Psychedelic-Assisted Psychotherapy: A Novel Target for Research and Interventions,* PSYCHEDELIC MEDICINE (Aug. 18, 2023) (*available at* https://www.liebertpub.com/doi/full/10.1089/psymed.2023.0020) (discussing the need for additional research on therapeutic alliance).

[15] *See* Volkow, N.D., *et al.*, *Psychedelics as Therapeutics—Potential and Challenges*, *supra*.

barriers by not only increasing costs but reducing the availability of qualified providers. Moreover, a second monitor may not be warranted for a patient in a microdose research trial or being treated for a pain disorder such as cluster headache, rather than for a mental health or substance use disorder.

A more cost-effective approach to ensuring safety would be a default requirement that all psychedelic administration sessions (in research and clinical practice) be video-recorded, unless explicitly objected to by a patient in writing. Recordings will help protect patients by discouraging and providing accountability against abuse from providers,[16] while protecting providers against false or mistaken accusations from patients (*e.g.*, false memories induced by the psychedelic experience).[17]

For patients and circumstances in which two monitors are necessary, the Organizations would encourage the FDA to accept roving and remote monitoring for at least one of the monitors. Late last year, Sunstone Therapies announced that it had received FDA authorization for a clinical trial to test the safety of MDMA-assisted therapy for patients with treatment-resistant post-traumatic stress disorder, where therapy sessions were to be "monitored onsite by a combination of therapists, medical doctors and research personnel through live audio and video feeds."[18] The FDA should confirm that safety monitoring through live audio and video feeds is an acceptable alternative.

The FDA's Guidance should also encourage further research into whether group administration of psychedelics is permissible and suggest a monitor-to-patient ratio for group treatment. The Organizations believe PAT can be successfully administered in group settings, as it has been traditionally used in many cultures and is often utilized by Veterans' groups in naturalistic settings. Critically, group administration of PAT can be more cost-effective, making it more accessible to low-income and marginalized communities. In April of this year, Elliot Marseille, founding director of the Global Initiative for Psychedelic Science Economics at University of California Berkeley, presented research at the Breaking Convention conference in Exeter, United Kingdom, demonstrating that "group [MDMA-assisted] therapy can save over 50% of clinician costs and would allow thousands fewer clinicians to treat the same number of eligible PTSD patients.[19] We suggest that the Guidance clarify that two monitors are sufficient per group *treatment session* of up to 6 people.

---

[16] *See* Mattha Busby, *MDMA trials under review in Canada over alleged abuse of study participants*, THE GUARDIAN (June 20, 2022) (*available at* https://www.theguardian.com/world/2022/jun/20/mdma-trials-canada-review-alleged-abuse).

[17] *See* Doss, M.K., Samaha, J., Barrett, F.S., Griffiths, R.R., de Wit, H., Gallo, D.A., & Koen, J.D., *Unique Effects of Sedatives, Dissociatives, Psychedelics, Stimulants, and Cannabinoids on Episodic Memory: A Review and Reanalysis of Acute Drug Effects on Recollection, Familiarity, and Metamemory* (May 24, 2022) (preprint) (*available at* https://www.biorxiv.org/content/10.1101/2022.05.20.492842v1.full).

[18] Press release, Sunstone Therapies, *Sunstone Therapies Collaborates with MAPS to Conduct Clinical Trial of MDMA-Assisted Therapy for PTSD* (Sept. 14, 2022) (*available at* https://www.prnewswire.com/news-releases/sunstone-therapies-collaborates-with-maps-to-conduct-clinical-trial-of-mdma-assisted-therapy-for-ptsd-301624200.html).

[19] Marseille, E., Stauffer, C. S., Agrawal, M., Thambi, P., Roddy, K., Mithoefer, M., Bertozzi, S., & Kahn, J.. *Group psychedelic therapy: Empirical estimates of cost-savings and improved access* (2023) (Unpublished Manuscript).

(b) The FDA Should Take a More Expansive View of Monitor Qualifications.

Given the significant shortage of mental health professionals in the United States,[20] the Organizations believe FDA should take an expansive and flexible approach to the qualifications of monitors in clinical trials.

For example, licensed professionals with advanced non-psychotherapy training such as palliative care doctors, clinical pharmacists, and advanced practice registered nurses (among others) should be eligible to serve as lead monitors. Moreover, it is unclear why an assistant monitor should need at least 1 year of clinical experience in a licensed mental healthcare setting, particularly if the lead monitor is required to have clinical experience in psychotherapy (and when the two monitor per patient design is framed around safety, not efficacy). To ensure a broader pool of assistant monitors, we suggest expanding the range of qualifications to include either a bachelor's degree, 1-year experience in *any* healthcare setting, a specialized peer support certification, or other equivalent experience.

Peer support, which offers a critical opportunity to reduce the burden on licensed providers, is already part of the care model utilized by the Veterans' Health Administration.[21] Veteran peer support specialists often have years of experience in the healthcare setting, often in PTSD, substance use, and/or TBI clinics, and other specialty services, and yet may not have a bachelor's degree. The peers are a vital part of care in many VA settings and are very much on the forefront of recovery-oriented care. Leveraging individuals like the Veteran Peer Support Specialists could be very important both for patient outcomes and for issues around accessibility and availability of providers/monitors.

(4) Broader Stakeholder Consideration is Needed to Address Gaps in the Healthcare System and Public Health Effects

The draft Guidance concludes on Pages 10-11 by advising that sponsors address "if gaps exist in the health care system regarding safe use" and whether the healthcare system would be able to prevent nonmedical use. Further, it notes that "FDA may consider whether a risk evaluation and mitigation strategy may be necessary to ensure that the benefits of the drug outweigh its risks." Finally, the draft Guidance states that "FDA may consider the public health effects of the drug as part of the overall benefit-risk assessment[,]" including "potential effect[s] on risks that are related to non-medical use … ."

The Organizations believe there are unique regulatory and public health complexities to the clinical roll-out of psychedelics that are common to nearly all sponsors, but that will require

---

[20] *See*, *e.g.*, *BEHAVIORAL HEALTH, Available Workforce Information and Federal Actions to Help Recruit and Retain Providers*, U.S. GOVT. ACCOUNTABILITY OFFICE, at 2 (Oct. 2022) ("There have been longstanding concerns about the availability of qualified behavioral health providers in the United States.") (*available at* https://www.gao.gov/assets/gao-23-105250.pdf).

[21] U.S. Department of Veterans Affairs, Peer Support Services in VA, https://www.veteranshealthlibrary.va.gov/142,41684_VA; *see also* Letter from Reason for Hope to Reps. Mark Takano and Mike Bost (Sept. 26, 2022) (*available at* https://docs.house.gov/meetings/VR/VR00/20220929/115166/HHRG-117-VR00-20220929-SD013.pdf).

broad stakeholder engagement to address. These issues are summarized in the excerpt below of a bipartisan Congressional letter led by Rep. Madeleine Dean (D-PA) to Secretary of Health and Human Services, Hon. Xavier Becerra, requesting the establishment of an inter-agency task force and public private partnership with stakeholders to address the proper use and deployment of psychedelic medicine and therapy:

> It is apparent that psychedelic medicines represent not just a new wave of psychiatry, but a significant shift in the delivery of mental health care, which does not neatly fit within our current system. The time intensive treatment process, including preparation, an administration session lasting several hours, and integration therapy (generally referred to as "psychedelic-assisted therapy"), will require an interdisciplinary approach with specialized training for session facilitators, and vastly different cost, insurance coverage, and infrastructure considerations. …
>
> Nevertheless, while FDA approval will likely be tied to a Risk Evaluation Mitigation Strategy (REMS) that determines the parameters of safe use, we know that psychedelic medicines, and particularly psilocybin, can and will be broadly acquired from other non-FDA approved sources – whether before or after the particular substance is rescheduled – which will not be subject to those same REMS protocols. This will be particularly true should FDA-approved therapies prove unaffordable or inaccessible to large segments of the population, which will rapidly fuel underground use or the establishment of a patchwork system of state decriminalization and/or legalization efforts. Indeed, psilocybin and other psychedelic compounds can be cultivated at home relatively easily, and several states have already passed or proposed measures for decriminalization or the creation of intrastate regulatory systems authorizing cultivation, production, distribution, research, and supervised or therapeutic use of non-FDA approved formulations of psilocybin or psilocybin mushrooms.
>
> Further, unlike the already complex state regulatory patchwork created by marijuana, psychedelic treatments require the regulation of both a drug *and* a therapy, the latter of which is traditionally a matter of state authority. ….
>
> Thus, we find it clear that REMS protocols alone are insufficient to ensure any broad-based harm reduction efforts, including safe supply, safe and ethical use, and accountability of session facilitators for psychedelic therapies, which would be more appropriately addressed through the proposed task force and public-private partnership with stakeholders.[22]

The Organizations worked with state legislators to send a similar letter to Secretary Becerra advocating for the establishment of this task force.[23] In response, the Assistant Secretary for Mental Health and Substance Use, Miriam Delphin Rittmon, wrote that:

---

[22] Letter from Reps. Madeleine Dean *et al.*to Xavier Becerra, Sec. of Health and Human Services re: Establishing an Inter-agency Taskforce on Psychedelic Medicines and Therapies (Feb. 11, 2022) (*available at* https://www.booker.senate.gov/imo/media/doc/vmhlc.pdf (attached to Reason for Hope letter as Exhibit 1).

[23] *See* Letter from Richard N. Gottfried, Chair, Committee on Health, New York State Assembly, *et al.*, to Xavier Becerra, Sec. of Health and Human Services re: Establishing an Inter-agency Taskforce on Psychedelic Medicines and Therapies (Feb. 11, 2022) (*available at* https://www.booker.senate.gov/imo/media/doc/vmhlc.pdf (attached to Reason for Hope letter as Exhibit 2).

> SAMHSA also agrees that the use of psychedelic medicines will require a broad-spectrum interdisciplinary stakeholder approach to effectively tackle the complexity of issues that stakeholders anticipate will arise with their introduction.
>
> SAMHSA, in collaboration with the Assistant Secretary for Health, is exploring the prospect of establishing a Federal Task Force to monitor and address the numerous complex issues associated with emerging substances. The Task Force may establish and oversee the functions of a public-private partnership that can broadly focus on addressing numerous complex issues associated with psychedelic (psilocybin) and entactogenic (MDMA) medicines but whose risks to public health may require harm reduction, risk mitigation, and safety monitoring. Collaboration across federal agencies with outside stakeholders will be the most effective way to ensure we are thoughtfully coordinating work on emerging substances such as MDMA and psilocybin.[24]

The Organizations strongly recommend FDA take steps to expedite the timeline of formally initiating this task force.

III. Conclusion

Again, Reason for Hope, The Veteran Mental Health Leadership Coalition, BrainFutures, and the additional cosigners listed below thank the FDA for the opportunity to comment on the draft guidance, *Psychedelic Drugs: Considerations for Clinical Investigations / Guidance For Industry*, and invite the FDA to reach out to them for further discussions on any of the issues discussed above. The Organizations would encourage the FDA to post any revised drafts of the Guidance for further public input and comment.

Very truly yours,

Shane Pennington
Porter Wright Morris & Arthur LLP
2020 K Street, NW
Suite 600
Washington, D.C. 20006
(T): 832.914.2985
spennington@porterwright.com

[24] Letter from Miriam E. Delphin-Rittmon, Assistant Sec. for Mental Health and Substance Use, Substance Abuse and Mental Health Servs. Admin., to Rep. Madeleine Dean (May 13, 2022) (*available at* https://www.documentcloud.org/documents/22121426-exhibit-3-response-to-rep-dean-et-al).

Martin R. Steele
Lieutenant General, US Marine Corps (Retired)
Founder and President
Veteran Mental Health Leadership Coalition

Brett M. Waters, Esq.
Co-Founder and Executive Director
Reason for Hope

David Esselman, MBA
Executive Director
BrainFutures

Additional Supporting Organizations

s/ *Manish Agrawal*
Manish Agrawal, MD, Co-Founder and CEO
Sunstone Therapies

Linda Raines
Chief Executive Officer
Mental Health Association of Maryland

Ladan Eshkevari, PhD, CRNA, FAAN
Professor Emeritus-Georgetown University
Editor in Chief-AANA Journal
CEO & Co-Founder
Avesta Ketamine and Wellness

Robin King
Chief Executive Officer
Navy SEAL Foundation

Hannah McLane MD, MA, MPH
Founder and Director
SoundMind Institute

Bryon Adinoff, MD,
President
Doctors for Cannabis Regulation

Jennifer Baxter
Executive Director
Balanced Veteran Network

Matthew "Whiz" Buckley
Matthew "Whiz" Buckley
Co-Founder
No Fallen Heroes Foundation

Rex Elsass
Founder and Chairman
REID Foundation

Lauren Feringa, US Army Retired
Founder
Hippie and a Veteran Foundation

Jesse Gould, US Army Retired
Founder
Heroic Hearts Project

Chad McLean
Founder
Mental Joe

Elijah Sacra, USMC (ret)
Founder
Warrior Wellness Solutions

s/ *Allison Wilson*
Allison Wilson
Founder
The Hope Project

Tracey Wyatt, M.A., LPC
Founder
Southeast Coalition of Psychedelic Practitioners

Alan J. Yeck
Executive Director
Veterans Healing Farm

s/ *Adam Bardwell*
Adam Bardwell
President/Founder
NONSTANDARD

Kendric Speagle
Commander
American Legion Blue Sky Post 426

Additional Supporting Individuals

s/ Heidi Allen
Heidi Allen, PhD, MSW, Associate Professor, Columbia School of Social Work

s/ *Lynnette A. Averill*
Lynnette A. Averill, PhD, Associate Professor of Psychiatry and Behavioral Sciences, Baylor College of Medicine

Frederick Barrett, PhD, Director of the Johns Hopkins Center for Psychedelic and Consciousness Research

Austin Hearst, Co-Founder, Bridge Builders Collaborative

Justin Heesakker
Justin Heesakker DAOM, M.S., L.Ac. Dipl. OM, CPTR, VHA Office of Patient Centered Care & Cultural Transformation (OPCC&CT)

s/ *Karen Jumisko-Amidon*
Karen Jumisko-Amidon, RD, CSG, HBPC/MOVE

Brian L. Losey, RADM, USN (ret)

Carlene MacMillan, MD
Chief Medical Officer, Osmind & Co-Founder, Fermata

Andrew Penn, MS, PMHNP
Clinical Professor, UC San Francisco, School of Nursing
Co-Founder, Organization of Entheogenic and Psychedelic Nurses (OPENurses)

s/ Brian Richards

Brian Richards, Psy.D.
Clinical Psychologist, Sunstone Therapies

Tony Rousmaniere, PsyD
Clinical Faculty, University of Washington

Nathan Sackett, MD, MS
Assistant Professor of Psychiatry and Behavioral Sciences, Co-director of the Center for Novel Therapeutics in Addiction Psychiatry University of Washington

Jordan Sloshower

Jordan Sloshower, MD MSc
Clinical Instructor, Department of Psychiatry, Yale University
Co-Director, West Rock Wellness PLLC

Deborah Tan

Deborah Tan, **MBA**
Co-Chief Executive Officer
Avesta Ketamine and Wellness

s/ Angela Terhune

Angela Terhune, MHA
Senior Director, Elligo Health Research

Eric Utecht

Eric Utecht, **Ph.D.** Licensed Clinical Psychologist