VETERAN
MENTAL HEALTH
LEADERSHIP COALITION

Testimony of

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Co-Founder & President

Veteran Mental Health Leadership Coalition

Co-Founder & Chief Executive Officer

Reason for Hope

Before the
U.S. House Committee on Veterans' Affairs

Subcommittee on Health

October 19th, 2023

Testimony on "Emerging Therapies: Breakthroughs in the Battle Against Suicide?"

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The Honorable Mariannette Miller-Meeks
Chair
Subcommittee on Health
House Veterans' Affairs Committee
Washington, DC 20515

The Honorable Julia Brownley
Ranking Member
Subcommittee on Health
House Veterans' Affairs Committee
Washington, DC 20515

Chairwoman Miller-Meeks, Ranking Member Brownley, and distinguished Members of the Committee:

On behalf of the Veteran Mental Health Leadership Coalition (VMHLC), thank you for the opportunity to testify today on the tremendous potential of psychedelic-assisted therapy for America's veterans.

My name is Martin R. Steele, and I am a retired Lieutenant General in the U.S. Marine Corps. I had the privilege of wearing the uniform of a U.S. Marine for nearly 35 years, rising from an enlisted private in 1965 to three-star general, and retiring in 1999 as Deputy Chief of Staff for Plans, Policies, and Operations, which is the civilian equivalent of Chief Operating Officer of the Marine Corps.

Following my active-duty service, I served as CEO of the Intrepid Sea, Air, and Space Museum in New York City, including during the 9/11 terrorist attacks. Afterwards, I served as Associate Vice President for Veterans Research and the Executive Director of Military Partnerships at the University of South Florida in Tampa, working with scientists exploring the co-morbidities between traumatic brain injury (TBI) and PTSD.

My work resulted in Leader McConnell (R-KY) appointing me to the Commission on Care, which was established during the Obama Administration to make recommendations about the future of VA health care. Many of the Commission's recommendations to Congress were brought to life through various bills previously before this Committee.

Over the last two years, I've had the privilege of leading Reason for Hope and the Veteran Mental Health Leadership Coalition. These organizations are dedicated to policy and grassroots patient advocacy aimed at providing safe access to psychedelic therapies to combat the PTSD, suicide, and opioid crises. Our Coalition's founding members include several researchers and mental health providers within the VA healthcare system with expertise in psychedelic medicine.

Our members also include leaders from various Veteran Service Organizations that have either funded or supported veterans seeking psychedelic therapies in other countries. These therapies encompass substances like MDMA, psilocybin, DMT, ibogaine, and 5-MeO-DMT, amongst others. For the veterans who've sought these treatments abroad, it was never their initial choice, it was their last line of defense after exhausting available treatments at home.

I've been fortunate to work alongside many of these veterans who have undergone treatment abroad. Those recipients attribute psychedelic therapy not only to saving their lives, but also to instilling a renewed sense of purpose, meaning, and connection to themselves, their families, and their communities. However, with dozens of veterans succumbing to suicide daily, it is morally unacceptable that so many have been compelled to leave the country they served to access these life-saving therapies abroad.

One of our coalition advisors, formerly of the West Los Angeles VA, testified recently before the Kentucky Opioid Abatement Advisory Commission that the clinic where he now works in Mexico, The Mission Within, has treated over 1,000 United States military veterans in the past 6 years. Let that sink in. American veterans are traveling to other countries to receive better care than what's available in the United States, the very nation they risked their lives to defend. Frankly, this is unconscionable and unacceptable.

Some of these veterans have traveled abroad to access treatments designated as Breakthrough Therapies by the FDA, indicating they are sufficiently safe and potentially much more effective than existing treatments. The FDA has awarded this designation to MDMA-assisted therapy for PTSD and psilocybin for treatment-resistant depression and major depressive disorder. Veterans with co-morbid PTSD and major depressive disorder face a significantly increased risk of suicide, making accelerated access to these Breakthrough Therapies imperative.

While current treatments are life-saving tools for some, they fall far short for most patients. That is why we are here today. The time has come for the federal government to act. We must proactively work within the VA to safely and effectively deliver Breakthrough Therapies like MDMA and psilocybin. We must also fund research that reflects real-world settings and invest in educating and training providers in this innovative form of care delivery.

We also humbly request that this Committee support the Breakthrough Therapies Act (H.R. 1393/S. 689), which we collaborated with Senators Cory Booker (D-NJ) and Rand Paul (R-KY), along with Congresswomen Madeleine Dean (D-PA) and Nancy Mace (R-SC) to introduce in March. We are grateful for the strong bipartisan coalition that has championed both bills, including you, Chairwoman, as well as Congressman Luttrell.

This legislation would reduce the barriers to research and enable compassionate medical use of Breakthrough Therapies like MDMA and psilocybin, including under the bipartisan Right to Try law. The Breakthrough Therapies Act does not add costs to taxpayers and does not change criminal penalties for misuse or diversion of these substances. It's an essential step to accelerate access to potentially life-saving treatments, particularly for veterans with complex comorbidities, who often don't qualify for clinical trials in the United States. Put simply: our nation's heroes should not be forced to travel abroad in an attempt to save their lives.

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Thank you for your time today, and I look forward to answering your questions.

Additional attachments to this testimony include:

- Veteran Mental Health Leadership Coalition Psychedelic Science One-Pager
- Gen. Steele Letter to Congress regarding the reintroduction of the Breakthrough Therapies Act (March 7th, 2023)
- Letters of Support for the Breakthrough Therapies Act (March 7th, 2023)
- Veteran Mental Health Leadership Coalition & Reason for Hope Response to FDA Request for Public Comment on FDA-2023-D-1987 titled "Psychedelic Drugs: Considerations for Clinical Investigations (August 25th, 2023)
- New York State Assembly Committee on Health Letter to SAMHSA on Psychedelic-Assisted Therapy Task Force (February 11th, 2022)
    - Response from SAMHSA (May 13th, 2022)

Breakthrough Therapies for Veteran Mental Health and Suicide Prevention

When it comes to Veteran mental health and suicide prevention, our nation has fallen woefully short of its moral obligation to care for those who selflessly served in our military. We lose around **40 Veterans** every day to suicide or other forms of self-injury. Combat Veterans are not only more likely to have suicidal ideation, often associated with post-traumatic stress disorder (PTSD) and depression, but they are more likely to act on a suicidal plan. Further, Veterans with comorbid major depressive disorder and PTSD are more than twice as likely as those with PTSD only to have attempted suicide.

Fortunately, in recent years, studies from premier academic institutions across the globe have found that MDMA (an entactogen) and psilocybin (a classic psychedelic) – used as an adjunct to psychotherapy – offer rapid and robust improvement in treating these serious psychiatric conditions. Indeed, due to the incredible results achieved in well-controlled clinical trials, **the U.S. Food and Drug Administration (FDA) granted a Breakthrough Therapy Designation** to MDMA for the treatment of PTSD (2017) and to ***two different*** psilocybin therapies, one for treatment-resistant depression in 2018, and a second for major depressive disorder in 2019. The Breakthrough Therapy designation is a process designed to expedite the development and review of drugs where *preliminary clinical evidence has indicated that the drug may demonstrate substantial improvement over available therapies.*

Research Findings

MDMA-Assisted Therapy ("MDMA-AT")

- The first FDA Phase 3 trial using MDMA to treat PTSD found that after three MDMA-AT sessions, **67% of participants no longer qualified for a PTSD diagnosis, and 88% experienced a clinically significant reduction in symptoms**. A second Phase 3 trial, soon to be published, reportedly found similarly impressive results.
- Long-term follow-up (LTFU) outcomes of trials investigating MDMA-AT for treating PTSD showed that the percentage of **participants that no longer qualified for PTSD diagnoses increased from 56% to 67%** between treatment exit and follow-up over a year later, suggesting this therapy has not only persistent but compounding effects.
- As conducted in the Phase 3 trial, compared to the standard of care for 1,000 patients, MDMA-AT generates discounted net healthcare savings **of $132.9 million over 30 years**, accruing 4,856 quality-adjusted life years, and averting 61.4 premature deaths.

Psilocybin-AT

- A Phase 2 trial assessing the effect of psilocybin therapy for patients with cancer and major depression disorder (MDD) found a **sustained reduction in 80% of patients and full remission in 50% of patients** with depressive symptoms.
- Multiple studies found **at least 70% of participants** with cancer-related psychiatric distress showed clinically significant reductions in symptoms following two psilocybin-AT sessions.
- A Phase 2 trial found psilocybin was efficacious in treating MDD, with a **clinically significant response in 71% of participants and remission from depression in 54%** at four weeks post treatment.

Why These Therapies Have Unique Potential to Combat Mental Health Disorders and Prevent Suicide

- **Addressing the "Root Cause" and Breaking Rigid Patterns:** MDMA and psilocybin are often described as triggering a "rewiring of the brain," which is believed to occur by inducing neuroplasticity at the cellular and network levels, allowing the brain to form and reorganize or repair neuronal connections. This "rewiring," particularly when paired with psychotherapy, can help produce durable changes in symptoms, behavior, and functioning which may occur via reductions in experiential avoidance and heightened psychological flexibility.
- **Rapid Acting Effects:** Unlike SSRIs, which are slow-acting antidepressants that can take weeks to months for any potential (and uncertain) benefit, MDMA and psilocybin are rapid acting antidepressants that can produce both an immediate and durable clinical reduction in symptoms.
- **Transdiagnostic Treatment Potential:** MDMA and psilocybin show preliminary efficacy in treating numerous psychiatric conditions, including PTSD for Veterans, major depression and anxiety, treatment-resistant depression, substance use disorders, and eating disorders.

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

March 7, 2023

Dear Members of Congress:

The Veteran Mental Health Leadership Coalition (the "Coalition") and undersigned partner organizations strongly support the Breakthrough Therapies Act introduced by Senators Cory Booker and Rand Paul and Congresswomen Madeleine Dean and Nancy Mace.

My name is Martin R. Steele, and I am a retired Lieutenant General in the United States Marine Corps, retiring in August 1999 as Deputy Chief of Staff for Plans, Policies and Operations at Headquarters Marine Corps. I served on the VA Commission on Care from 2015-2016, which explored the future of VA healthcare, and I recently completed my term as Vice Chairman of the Board of Veterans Florida. I am now honored to be the CEO of Reason for Hope and co-founder and President of the Coalition, whose founding members include leadership from over 25 Veteran service and other mission-aligned partner organizations, as well as Veteran researchers, clinicians, and providers.

I experienced combat from all angles during my 34 years on active duty, beginning as an enlisted Marine on the battlefields of Vietnam and retiring as a three-star General. Since retiring, I have dedicated myself to various causes within the Veteran community, particularly Veteran mental health care. Thus, I have spent much of my life around active-duty combat soldiers and Veterans who unfortunately suffered from a mix of post-traumatic stress, traumatic brain injury, anxiety, depression, substance use disorder, sexual trauma, and suicidal ideation.

I firmly believe that as a nation, we have a moral responsibility to provide those who have selflessly served their fellow Americans with the best care possible to live meaningful and fulfilling lives. By failing to take care of our wounded warriors – particularly those who suffer from the invisible wounds of war – we should not expect others to step forward and serve our nation's military in the future.

In some areas of healthcare, we have done a great job upholding our moral obligation to those who served. However, when it comes to mental health care and suicide prevention, we have fallen woefully short. Indeed, we lose around 40 Veterans every day to suicide or other forms of self-injury. Male Veterans are two-to-three times as likely to die by suicide than their civilian counterparts, and female Veterans six times as likely. Combat veterans are not only more likely to have suicidal ideation, often associated with post-traumatic stress disorder (PTSD) and depression, but they are more likely to act on a suicidal plan.

Further, Veterans with comorbid major depressive disorder and PTSD are more than twice as likely as those with PTSD only to have attempted suicide. Currently available medications and talk therapies for these conditions fall woefully short for most Veterans, leaving many even worse off than when they started treatment. Yet, we have somehow made little progress with new forms of treatment.

Significantly, however, in recent years the FDA granted "Breakthrough Therapy Designations" to MDMA-assisted therapy to treat PTSD and to two psilocybin therapies for life-threatening forms of depression. This means that based on initial clinical trials, these therapies may be a substantial improvement over currently available treatments for these conditions. The Breakthrough Therapy Designation is meant to help patients access these potentially lifesaving treatments on an accelerated timeline.

However, because MDMA and psilocybin are listed as Schedule I compounds under Controlled Substances Act, they are subjected to unnecessarily burdensome regulatory hurdles that hinder research and access to treatment even for patients with life-threatening conditions who have exhausted other options. Thus, thousands of Veterans have been forced to leave the country or risk criminal prosecution in search of healing with MDMA, psilocybin, and other psychedelic-assisted therapies. For many, this includes treatment from underground providers who may lack the safety and oversight of a clinical setting with proper screening and medical supervision. It is unconscionable that Veterans are forced to take these drastic measures to obtain treatment for psychological injuries resulting from service to their country, particularly when such treatments – including MDMA- and psilocybin-assisted therapies – have demonstrated acceptable safety for use under medical supervision.

The Breakthrough Therapies Act can change this immoral and inappropriate policy by rescheduling current and any future breakthrough therapies from Schedule I to Schedule II in advance of final FDA approval. This would not only remove unnecessary barriers to research, but it would mitigate the government's role in a treatment decision that Veterans – in consultation with their doctors – should be able to make with informed consent of the risks and benefits based on the existing evidence. We urge Congress to swiftly pass this common-sense legislation.

Martin Steele

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


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SŌHEI BIOTECH

Brett M. Waters, Esq.
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March 7, 2023

Dear Members of Congress:

Reason for Hope and the undersigned organizations are proud to support the Breakthrough Therapies Act introduced by Senators Cory Booker and Rand Paul and Congresswomen Madeleine Dean and Nancy Macy. This legislation is a simple and straightforward solution to an obvious problem. It will reduce the regulatory red tape hindering research of urgently needed breakthrough mental health treatments and access to these treatments for patients with terminal or life-threatening conditions.

Our nation's continuously escalating mental health crisis – while complex – highlights the limitations of effective pharmacologic treatments and therapies in our toolbox for stress and trauma-related concerns such as PTSD, depression, and suicidality. Currently available medications prescribed for these conditions fail to work for many people, do not work well enough for most, and often have significant side effects. Moreover, as Tom Insel, our former Director of the National Institutes for Mental Health, noted: "It's a pretty safe bet in most of medicine that if you treat more people, death and disability drop. But when it comes to mental illness, there are more people getting more treatment than ever, yet death and disability continue to rise."

Indeed, the average number of suicides rose from 81-per-day in 2001 to 121-per-day in 2020. Overall, a reported 45,979 Americans died by suicide in 2020; there were an estimated 1.2 million suicide attempts; and 54% of Americans had been affected by suicide in some way, with suicide causing a devastating ripple effect on loved ones left behind. Overdose deaths have increased even more dramatically, with over 100,000 lives lost during the 12-month period ending April 2021.

The federal government should thus not stand in the way of urgently needed investigation of novel therapeutics with potential to offer relief and healing to individuals who have been failed by current treatments, especially those which can offer rapid and robust improvements. Mounting evidence suggests fast-acting therapeutics like MDMA and psilocybin – currently classified as Schedule I drugs under the Controlled Substances Act – have great potential to offer this level of healing to individuals suffering from a variety of mental health conditions.

Significantly, initial clinical trial results have been so promising that the Food and Drug Administration granted Breakthrough Therapy Designations to both MDMA-assisted therapy for PTSD and *two* psilocybin therapies for life-threatening forms of depression (treatment-resistant

depression and major depressive disorder). This means that the FDA hopes to accelerate the approval timeline for these potentially lifesaving therapies, as they demonstrated a substantial improvement over currently available treatments for these serious conditions. Yet, paradoxically, the Schedule I status of MDMA and psilocybin impedes access to these substances, both for clinical research and compassionate use.

Given existing evidence showing these therapies can be safely administered in medical settings and may be substantially more effective than any other available treatment, terminal cancer patients with end-of-life anxiety should not have to wait for full FDA approval to access them. Nor should Veterans with severe PTSD and depression who have exhausted available treatments (and do not qualify for clinical trials due to their complex conditions).

The Breakthrough Therapies Act offers a simple solution by rescheduling these and any future breakthrough therapies from Schedule I to Schedule II on an expedited basis, which would reduce the red tape hindering research and access to treatment. Ultimately, rescheduling could allow a cautious, phased roll-out of these potentially life-saving treatments, with little risk to the public health or safety. This would not only offer critical opportunities for patient access to those with more "complex" comorbid conditions who are ineligible for clinical trials—as is often the case with Veterans—but also provide valuable real-world training opportunities that providers need to be prepared to deliver this highly specialized form of care. Further, it could enable infrastructure development and real-world data collection to inform safety policies and best practices, as well as inform payors on insurance coverage.

The United States should be leading the charge for innovative solutions to the mental health crisis. Yet, we are already falling behind. On February 3, 2023, the Australian government announced it would reschedule MDMA and psilocybin to permit authorized psychiatrists to prescribe them for PTSD and treatment-resistant depression, respectively, subject to strict controls on prescribing and treatment protocols. Australia's decision acknowledged the current lack of options for patients with these specific conditions.

Given this reality, it should be unsurprising that for many patients, MDMA- and psilocybin-assisted therapies – amongst several other psychedelic medicines currently under clinical investigation – represent a reason for hope for a new era of mental health care. Personally, an experience with psilocybin helped treat an eating disorder for which no currently approved medications or therapies exist. Unfortunately, however, I failed to make the connection between the life changing effects I experienced and the broader potential for these substances to help people like my mom struggling with depression and suicidality. By the time I discovered the groundbreaking research, it was too late.

This week marks the five-year anniversary since I lost my mom – Sherrie Hope Waters – to suicide. Reason for Hope is named in her memory. Reflecting on the several notes my mom left behind (written over the course of many years that she was struggling to varying degrees), I cannot help but think she would have benefitted immensely from psilocybin-assisted therapy. This is one

of the many lingering questions I live with for which I will never know the answer. However, I do know that based on the existing evidence, this is the treatment that my sister and I would have worked with my mom to pursue if it were available. And there are many others currently struggling, who fully aware of the evidence of the risks versus the benefits this treatment may offer, would make the same decision. For these individuals, it is not too late, and they deserve the opportunity to pursue this potentially lifesaving treatment in advance of full FDA approval.

Thus, we urge members of Congress to support the Breakthrough Therapies Act, which offers a responsible path forward to usher in this new paradigm of mental health care by reducing barriers to research and limited compassionate use access to breakthrough mental health treatments.

Brett Waters

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Endorsing Organizations

BrainFutures • Law Enforcement Action Partnership • Affinity Healthcare Futures
Be Herd Foundation • Black Therapist Rock • SoundMind Project
Reaching Everyone in Distress (REID) Foundation • Vilomah Foundation • Chacruna Institute
Texas Emerging Therapies Association • Texans for Greater Mental Health
Revitalist • Wesana • PsiloHealth • Calyx Law • SNAP Lab • Sequoia Center
Wake Network • Reconsider • Fireside Project • Entheo IL • Beckley Retreats
Segal Trials • Fluence • Nushama • PharmAla Biotech

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)),

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[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.

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[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

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[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:

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[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,

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[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).

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February 11, 2022

The Honorable Xavier Becerra
Secretary of Health and Human Services
US Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Re: Establishing an Inter-agency Task Force on Psychedelic Medicines and Therapies

Dear Secretary Becerra:

Thank you for your persistence in addressing the many health care issues challenging our nation as we continue to battle the COVID-19 pandemic.

We have been informed by Reason for Hope, a non-profit policy and advocacy organization, that in advance of anticipated Food and Drug Administration (FDA) approval of MDMA for the treatment of Post-Traumatic Stress Disorder (PTSD) and psilocybin for the treatment of depression (expected within approximately 24 months), the Biden Administration is considering authorization of an inter-agency strategic task force to prepare for the real-world deployment of psychedelic medicine and therapy. We understand that the strategic task force would lead a public-private partnership with various groups of stakeholders, including relevant state agencies, to address the myriad complex regulatory and public policy issues necessary to ensure a framework for the safe and responsible use of psychedelic therapies for mental health care.

Whether through the FDA or state law, it seems clear that legalizing psychedelic medicine is far more complex than a typical drug approval; rather, it represents perhaps the most significant shift in the delivery of mental health care in modern history. The time intensive treatment process, generally including preparation, administration, and integration sessions ("psychedelic-assisted therapy"), does not fit neatly within our current mental health care system. Indeed, we must carefully consider issues of cost, access, infrastructure, and insurance coverage within this new paradigm of care.

We thus fully support the Biden Administration taking an active role in helping states to navigate this landscape. Reason for Hope, who helped prepare the October briefing for HHS and SAMHSA leadership, explained that the intended result of the inter-agency strategic task force would be to publish national guidelines in the federal register pertaining to issues such as provider training, credentialing, state licensure, dispensing, monitoring, instituting good standards of safe and ethical practice, etc. We are encouraged to learn that states would then receive block grant funding and support from SAHMSA to implement or tailor the guidelines to meet their individual needs.

After reviewing the October briefing materials, we are confident that the task force will significantly ease the burden on each state to develop its own novel regulatory system, and enable a scaled-up force of trained, credentialed, licensed, and accountable psychedelic-assisted therapy

session facilitators. Critically, this will also help ensure a cohesive system for safety and ethical monitoring and reporting nationwide. However, while we view this collaborative process as a clearly beneficial starting point, we believe that each state must also retain flexibility to adapt its regulations to meet the needs of its citizens as we learn new information in this emerging space.

Finally, given the ongoing mental health and substance abuse crises exacerbated by COVID, several states have already passed or proposed intrastate regulatory systems for research and supervised use of psilocybin, opting not to wait for FDA approval. Indeed, as NIDA Director Nora Volkow recently stated, "the train has left the station" regarding use of psychedelics as a mental health treatment.[1] And we need not look far to see that without proactive federal leadership and guidance, the result will be a confusing and administratively burdensome patchwork of state laws. However, this state patchwork will prove far more complex than with marijuana, as psychedelic-assisted therapy involves regulation of both a drug *and* the practice of medicine, which is traditionally a matter of state authority.

Thus, we reiterate the urgency to authorize the psychedelic task force and begin the process of federal and state government officials and stakeholders working together to create a cohesive regulatory system, through which states retain control over the practice of medicine.

Please reach out to Brett Waters, Co-Founder and Executive Director of Reason for Hope, or Kayleigh Zaloga, Legislative Associate to New York State Assemblyman Richard Gottfried, if you have any questions that you would like to discuss: brett@reason-for-hope.org; zalogak@nyassembly.gov. We appreciate your vision and leadership on this issue.

Sincerely,

Richard N. Gottfried
Chair, Committee on Health
New York State Assembly

Patrick B. Burke
New York State Assemblyman
Lead Sponsor, Medical Psilocybin Services Act

[1] https://darik.news/southdakota/top-federal-drug-official-says-train-has-left-station-on-psychedelics-as-reform-movement-spreads/202201474253.html.

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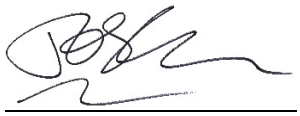

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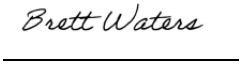
Lead Sponsor, Texas HB 1802



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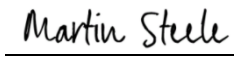

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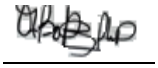

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Board Member SEAL Future Foundation
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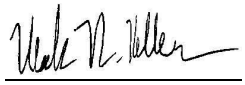
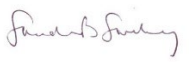


Mark R. Keller, LCDR, USN (Ret)
No Fallen Heroes

E. Matthew 'Whiz' Buckley
Founder & Chairman TOPGUN Fighter Foundation
Executive Producer *No Fallen Heroes*
U.S. Navy F/A-18 Hornet Pilot, TOPGUN Graduate



Sandra Samberg
Nurse Practitioner
The Joe & Sandy Samberg Foundation, President
Penn Nursing *A Journey Through the Psychedelic Revival Learning Series*, Co-Chair

Susan Ousterman
Vilomah Memorial Foundation, President

cc:

Admiral Rachel L. Levine, MD
Assistant Secretary for Health
U.S. Department of Health and Human Services

Miriam E. Delphin-Rittmon, Ph.D.
Assistant Secretary for Mental Health and Substance Use
U.S. Department of Health and Human Services

SAMHSA
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane • Rockville, MD 20857
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May 13, 2022

Richard N. Gottfried
Chair, Committee on Health
New York State Assembly
LOB 823
Albany, NY 12248

Dear Chairman Gottfried:

Thank you for your letter to Secretary Becerra in which you recommend the establishment of an interagency Federal Task Force to develop and lead a public-private partnership that can address the myriad of complex issues associated with the anticipated approval by the Food and Drug Administration (FDA) of 3,4-methylenedioxymethamphetamine (MDMA) for the treatment of Post-Traumatic Stress Disorder and psilocybin for the treatment of depression within approximately 24 months. The Substance Abuse and Mental Health Services Administration (SAMHSA) was asked to respond on the Secretary's behalf.

SAMHSA agrees that too many Americans are suffering from mental health and substance use issues, which have been exacerbated by the ongoing COVID-19 pandemic, and that we must explore the potential of psychedelic-assisted therapies to address this crisis. 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.

Thank you for taking the time to elevate this important issue.

Sincerely,

Miriam Delphin-Rittmon

Miriam E. Delphin-Rittmon
Assistant Secretary for Mental Health
and Substance Use

CC:
ADM Rachel Levine
Patrick Burke
Tracy Pennycuick
Jennifer O'Mara
Michelle Loness Cook
Josh Elliot
Alex Dominguez
Brett Waters
Lt. Gen. Martin Steele
Lynnette Averill
Rear Adm. Mark Leavitt
Jesse MacLachlar
Denise Bottiglieri
Mark Keller
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Sandra Samberg
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Brigadier Gen. Stephen Xenakis