EMERGING THERAPIES: BREAKTHROUGHS IN THE BATTLE AGAINST SUICIDE?

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

TUESDAY, NOVEMBER 14, 2023

Serial No. 118–39

Printed for the use of the Committee on Veterans' Affairs

Available via http://govinfo.gov

U.S. GOVERNMENT PUBLISHING OFFICE

54–362 WASHINGTON : 2024

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C O N T E N T S

TUESDAY, NOVEMBER 14, 2023

EMERGING THERAPIES: BREAKTHROUGHS IN THE BATTLE AGAINST SUICIDE?

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U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C.

The subcommittee met, pursuant to notice, at 2 p.m., in room 360, Cannon House Office Building, Hon. Mariannette Miller-Meek [chairwoman of the subcommittee] presiding.

Present: Representatives Miller-Meek, Bergman, Murphy, Luttrell, Kiggans, Brownley, Deluzio, Budzinski, and Landsman.

Also present: Representative Takano.

OPENING STATEMENT OF MARIANNETTE MILLER-MEEKS, CHAIRWOMAN

Ms. MILLER-MEEKS. Thank you. The Subcommittee on Health will now come to order. As a 24-year Army veteran, I have seen firsthand the struggles that many servicemembers and veterans face in light of their service, which is why I am excited about this first House Committee on Veterans' Affairs hearing on the potential for psychedelic assisted therapy treatments in the emerging battle against suicide, or, as we like to say, emerging therapies or breakthrough therapies. I would also like to say that as a physician who practices traditional medicine, I never thought I would enter Congress to be then advocating for emerging breakthrough therapy. I think the science is leading the way.

The VA dedicates a considerable amount of its budget and resources in pursuit of evidence-based treatments for veterans who suffer from post-traumatic stress disorder and other cognitive disorders. For many veterans, this treatment is lifesaving, but more work needs to be done. It is a sad reality that close to 17 veterans per day will lose their lives to suicide. One life lost to suicide is one too many, and our fight must continue.

Psychedelic assisted therapy is a groundbreaking clinical procedure that has the potential to transform the way we look at mental healthcare. A licensed clinician carefully examines a veteran prior to administering a dose of a compound such as 3-4,Methylenedioxymethamphetamine (MDMA) or psilocybin. A veteran must go through two or three sessions, during which intense psychotherapy is overseen by a licensed medical professional assisting the veteran throughout the experience. These sessions last about 8 hours, the full duration of the drug's effects. Based on the most recent clinical trials, patients experience positive therapeutic

responses resulting in reduction of their symptoms, if not remission, altogether.

The fight against suicide and substance abuse goes hand in hand, as substance use disorder can lead to higher suicide rates among veterans. Therefore, we cannot be afraid to explore new treatment methods, especially the ones that we will hear about today, that have proven to transform veterans' lives and are done in a clinical and a scientific manner. Still, we must argue and urge caution when speaking on this topic. We are not advocating for the legalization or the casual use of psychedelics. What we are discussing is the clinically administered dosage of these substances in combination with targeted therapy sessions in a clinical setting.

I look forward to hearing more about the process and progress that the VA and our private healthcare partners are making in advancing what could be a new way of treating the debilitating mental health conditions that affect our veteran community. I would like to hear what next steps are anticipated, as well as what challenges, including bureaucratic barriers, safety concerns, workforce, and others that should be addressed in moving forward. I am also looking forward to hearing from our second panel on the positive personal impact this therapy option has had on their lives and in successfully treating their Post-Traumatic Stress Disorder (PTSD).

I want to reiterate, we are not advocating for the legalization or casual use of psychedelics, but rather the advancement of science of their medicinal properties in a clinical setting with assisted therapy. Thank you all for being here, and I look forward to our discussion and hearing the multiple perspectives based on the incredible expertise present today on both panels to discuss this important topic. With that, I yield to Ranking Member Brownley for her opening statement.

OPENING STATEMENT OF JULIA BROWNLEY, RANKING MEMBER

Ms. BROWNLEY. Thank you, Madam Chair. I look forward to hearing more today about the potential therapeutic benefits of psychedelic assisted therapies for veterans. The landscape of psychedelics has evolved significantly in recent years, and we are at the brink of a new era in which these substances, once stigmatized and misunderstood, are being examined for their potential to address mental health and addiction challenges, and we need to make sure that the Department of Veteran Affairs is keeping up.

Veterans are continuing to die by suicide at rates higher than the general population. We know that pharmaceuticals and certain types of therapy are not enough for many veterans. Many post-traumatic stress patients do not respond to traditional medication-only treatments because traditional medications are only treating symptoms such as insomnia or anxiety. As our RAND witness points out in his testimony, up to 30 percent of patients drop out of evidence-based psychotherapy treatments, and more than half who do complete treatments still retain diagnoses of post-traumatic stress.

We need to look at all available treatment options, and one of them is the topic before us today. While the research in psychedelics has been limited, it has shown promise. However, as

the chairwoman said, it is our duty as Members of Congress to ensure that treatments offered to veterans are both effective and safe. We must weigh the risks and rewards carefully, recognizing the need for safeguards while also fostering innovation at VA and other Federal agencies and expanding treatment options. This is also an exciting topic because at a time when much of Congress is polarized and partisan, this is one area where many of us on this dais agree that more should be done to research psychedelic assisted therapy.

I look forward to the discussion today about what VA is already doing and whether Congress needs to take action to change existing statues, whether more can be done to bolster research, and whether there is opportunity for greater involvement by VA in this research. Some in this room today may be skeptical about the wider use of psychedelics. I would like us to remain committed to the principles of rigorous research, thoughtful policy, and patient centered care.

Veterans have given so much of themselves to our country. Our ultimate goal should be to promote the health and well-being of veterans and make sure that we are providing them with the very best care possible. They deserve nothing less. With that, Madam Chair, I yield back.

Ms. MILLER-MEEKS. Thank you, ranking member. Thank you, Ranking Member Brownley. On our first panel, we have Dr. Carolyn Clancy, Assistant Under Secretary for Health at the Office of Discovery, Education and Affiliate Networks, Department of Veterans Affairs, Dr. Ilse Wiechers, Deputy Executive Director at the Office of Mental Health and Suicide Prevention, Department of Veteran Affairs, Dr. Rachel Yehuda, Patient Care Director at the Bronx VA Medical Center, Department of Veterans Affairs. Dr. Clancy, you are recognized for 5 minutes to deliver your opening statement.

STATEMENT OF CAROLYN CLANCY

Dr. CLANCY. Good afternoon, Chairwoman Miller-Meeks, Ranking Member Brownley, and distinguished members of the subcommittee. Thank you for the opportunity to discuss VA's ongoing clinical trials involving emerging therapies and specifically, psychedelic assisted therapy. Accompanying me today, as you noted, are Dr. Ilse Wiechers and Dr. Rachel Yehuda.

The VA is committed to safely exploring all avenues that promote the health of our Nation's veterans. Veterans Health Administration (VHA) continues to effectively advance the health and well-being of veterans through the exploration of innovative, safe, and ethical emerging therapies. Every study in VA is conducted under stringent safety protocols. Our focus is not just on finding the best innovative treatments for our veterans, but on doing so safely. This is especially true for studies that test compounds such as MDMA and psilocybin as part of an intensive psychotherapy program to treat veterans with PTSD, depression, and other mental health conditions.

We have also been monitoring psychedelic research outside of the VA and will continue to evaluate the scientific evidence those investigations uncover for possible use in our future studies. There

is still much to learn about the potential benefits of psychedelic assisted therapy. VA researchers are conducting several studies on the use of psychedelic assisted therapy for the treatment of mental health conditions. To date, the studies underway have been funded by outside organizations or philanthropic foundations. VA ensures these treatments take place in a safe clinical environment and use pharmaceutical grade medications under carefully controlled conditions.

Potential participants undergo comprehensive medical and psychiatric screenings to make sure it is safe for them to participate. Furthermore, dosing of psychedelic medications is performed only by trained staff who know how to monitor for adverse events.

Last month, the VHA held a state-of-the-art conference on psychedelic treatments. This conference provided us a better understanding of the current state of scientific evidence, allowing us to create a strategic framework for future psychedelic treatment research. It also identified the necessary steps for potential system wide clinical implementation of treatments with Food and Drug Administration (FDA) approval.

This conference also determined a need for clinical trials that enroll a unique and diverse population of veterans. Rigorous studies of VA patients are important because they often have mental and physical health challenges that can reduce the effectiveness of a treatment. VHA trials would build confidence that the results accurately represent an expected clinical response in veteran patients.

Psychedelic treatments are far from the only emerging therapy the VA is researching for the battle against suicide. We are also leveraging technology to offer nonpharmaceutical approaches to help veterans address the day-to-day challenges related to anxiety, suicide prevention, and acute and chronic pain. For example, in March of this year, our researchers reported that transcranial magnetic stimulation is effective as a treatment for depression, even in veterans with traumatic brain injuries. We also have a study examining the use of a stellate ganglion block to reduce PTSD symptoms. This procedure could be a method that expands the range of evidence-based PTSD treatments available to veterans.

VHA also developed a 60-site clinical demonstration pilot to address suicide as it relates to pain, deploying 300 virtual reality headsets to VA providers across the country. That pilot will also test the use of positive environments to distract from negative stressors and build both coping mechanisms and resilience. We are really excited about the potential of these treatments. We are combining these innovations with strong research to evaluate and assess health outcomes. Even as we encourage new and effective interventions, the VA will continue to fully implement current evidence-based interventions that move mental health treatments forward.

We appreciate the committee's continued support in this shared mission, and my colleagues and I look forward to answering any questions you may have.

[THE PREPARED STATEMENT OF CAROLYN CLANCY APPEARS IN THE APPENDIX]

Ms. MILLER-MEEKS. Thank you, Dr. Clancy. We will now proceed to questioning. As has been my directive in the past, I will put my-

self at the end of the questions. I now recognize Ranking Member Brownley for any questions she may have.

Ms. BROWNLEY. Thank you, Madam Chair. My first question is to you, Dr. Clancy, good to see you again. It has been a while. Is it already possible for the VA to fund research on psychedelic assisted therapies, or are there statutory or regulatory barriers that Congress would first have to address?

Dr. CLANCY. There are no statutory barriers. This is a highly regulated environment. As Dr. Yehuda, my colleague from the Bronx, could describe in great detail, this requires that investigators invest a considerable amount of time in getting approval from the FDA and the Drug Enforcement Administration (DEA), down to the precise doses that will be used in the treatment. We have not done anything to discourage this, but I think the timeframe of getting all these approvals has been a bit of a disincentive to some researchers. Do you want to add anything to that, Dr. Yehuda?

Dr. YEHUDA. Thank you. The VA research program works on a peer review basis, so nothing precludes a VA investigator such as myself from writing a grant. Because of all the steps that are necessary to conduct this research, it is often difficult to get all of that work done in that kind of a framework. I think this is something that will become easier in the future.

Ms. BROWNLEY. Very good. Dr. Clancy, in your testimony, too, you talked about funding virtual reality research and demonstration projects. I am sort of curious to know how much funding has gone into that. Have you given any consideration to directing similar levels of funding toward research on psychedelics?

Dr. CLANCY. You know, those are the conversations that we are having right now. I will take for the record and be happy to get back to you about how much we have invested in virtual reality. These are not pure research studies. They really come out of our innovation portfolio. In some cases, we are buying headsets. In other cases, we are working under something called a cooperative research and development agreement with various companies that make these headsets. They are wildly popular, to put it mildly.

Ms. BROWNLEY. Thank you. Dr. Wiechers, am I pronouncing that name correctly? Are providers at VA permitted to discuss psychedelic assisted therapy with veterans if they have questions about it? I fully understand that we are still in the experimental stages here, but as word of the potential benefits of some of these therapies, veterans may have questions and they would like to discuss with a physician. Are there any limitations around discussing this at all?

Dr. WIECHERS. No. In fact, I would hope and I would encourage our veterans to actually openly have these conversations with their providers. We want to encourage our veterans to share any information that they have received or that they are considering about potential participation in one of the available research studies, or if they were thinking about using recreationally, we would hope they would have a conversation with their VA provider first so that we could help ensure that they have all the information that they need. There is nothing in policy that would prevent our providers from having those conversations with the veterans when they have questions.

Ms. BROWNLEY. Great. Thank you for that. This is a question for really, any of you, but are any of you aware of clinical trials focusing on the potential effectiveness of psychedelics for women veterans, particularly women veterans with post-traumatic stress? I am always advocating for, particularly when we talk about mental illness and so forth, that different therapies are going to work better for women than men, vice versa, and that we need to be thinking specifically about both genders as we approach this.

Dr. CLANCY. I do not believe that anyone is focusing exclusively on women with PTSD, but we totally agree with you about the urgency of the need. A much higher proportion of women veterans have PTSD than men. They are a smaller number, so absolute numbers are different. It is something of very high interest to us.

We have a number of studies ongoing now, not funded by VA, but funded by private foundations and so forth. We will get back to you about how many women are involved, but I am quite confident we are not at the place where we are going to have the statistical power to say anything conclusive.

Ms. BROWNLEY. Dr. Clancy, you talked about creating sort of the future framework of research around this area, so do you have a timeframe for that?

Dr. CLANCY. Not at this moment, but we will be following up with you. I can absolutely guarantee that.

Ms. BROWNLEY. Thank you. I yield back, Madam Chair.

Ms. MILLER-MEEKS. Thank you, Ranking Member Brownley. I am just going to add in that 50 percent of NYU or New York University trials involve women. The chair now recognizes Representative Bergman for 5 minutes.

Mr. BERGMAN. Thank you, Madam Chairwoman. First of all, I have a personal request for all three of you. That is, you know, the VA has the best hearing aids in the world. I have not gotten there yet to get mine, so if you would not mind, when you speak into the mic, pull it close. It will help me hear a little more clearly. I am sure my colleagues can hear just fine, except for Dr. Murphy, who keeps saying what? Anyway, Dr. Clancy, great to see you again. It has been a while. Dr. Yehuda, it is great to see you. Doctor, this is the first time we have met, so I am looking forward to hearing, you know, hearing more from you.

Dr. Clancy, in your testimony, you state that more research in the MDMA assisted therapy, especially research including more veterans, is needed before the VA can take any next steps. As you may be aware, Congressman Lou Correa from California, Lou and I came in together as freshmen back in 2017. We introduced an amendment to the MilCon VA Appropriations Bill directing VA to conduct a widescale study into this treatment, which was approved unanimously on the floor.

Now, having said that, just because something gets approved on the floor now the next steps falls, you know, into your bailiwick. Now that the House of Representatives has shown its support for these efforts, will VA commit to advancing large scale research into MDMA assisted therapy to treat PTSD in veterans?

Dr. CLANCY. There is no question that we are actually funding a number of studies, and I will commit right here that we will be

keeping all of you informed just as soon as those decisions are finalized.

Mr. BERGMAN. Is there any barriers right now that exist that you could foresee that you would be willing to share with us so that we can kind of be proactive here?

Dr. CLANCY. No. The barriers Dr. Yehuda and I described earlier all have to do with going through the requisite regulatory approvals from the FDA and the DEA. There is not a shortcut there. I think I know a number of our colleagues are excited about the possibility. Not that they think this is the answer, but they are inspired by hearing from veterans whose own experience has been very, very positive and want to be part of learning whether that is a generalizable finding for many veterans.

Mr. BERGMAN. Okay. Will the publication of phase three clinical trial results with that last month all signs point toward MDMA assisted therapy receiving FDA approval within the next year. What steps will the VA take before then to have therapists trained and ready and to prevent bottlenecks to ensure that the veterans in need do not have to wait years to actually receive the treatment? We know one of the limiting factors here is going to be to have those trained therapists ready to take that veteran through the experience.

Dr. CLANCY. Yes. For all of the studies that are ongoing right now in VA, all of the therapists have gone through that intensive kind of training. A few other people have sought this training from the organization Multidisciplinary Association for Psychedelic Studies (MAPS) on their own because they see this as part of the future and a skill set that they would very much need. I can assure you that our state-of-the-art conference, the whole question of what is the right research strategy and how do we plan right now for implementation would make sense. I am going to turn to Dr. Wiechers who will explain briefly that we have a pretty good track record here.

Dr. WIECHERS. Thank you, Dr. Clancy. I think there are a lot of unanswered questions that relate to what will actually come out of the FDA approval process and the steps that will need to be taken in terms of ensuring we have trained providers that we are following what we anticipate will be REMS, risk evaluation mitigation strategies, that will be prudent——

Mr. BERGMAN. I do not want to cut you short——

Dr. WIECHERS. Yes.

Mr. BERGMAN [continuing]. because I know you have got a lot of data to share.

Dr. WIECHERS. I see the time is ticking.

Mr. BERGMAN. You know, in war fighting, training and readiness is everything, and we train in advance knowing the fight is coming.

Dr. WIECHERS. Yes.

Mr. BERGMAN. You know the fight is coming. In this case, a good fight. The more proactive the VA can be we are here to help, to, you know, to knock down any barriers. My time is short.

Dr. Yehuda, I understand these patients are administered the medication onsite and are at no point given any kind of supply to take home. Do you feel there is any potential for recreational misuse through these therapies?

Dr. YEHUDA. Thank you, Congressman, for your question. In our experience thus far, I do not think that there is going to be opportunity for misuse. One of the most common things that veterans say after receiving MDMA assisted therapy and working hard processing traumatic memories is, I cannot believe they call this ecstasy. Most veterans have told us that they would not seek out recreational use of MDMA on their own. I think that veterans are very happy to have these treatments in the safety of a clinical setting that they have come to trust. It is not only the provision of the medication it is also the psychotherapy that allows them to open up about very difficult experiences——

Mr. BERGMAN. Okay.

Dr. YEHUDA [continuing]. so that the environment is really ripe for this.

Mr. BERGMAN. Well, we have seen your operation, and I appreciate you allowing me to go over a minute, because we have to make sure that the guardrails are up to not only minimize but eliminate abuse and misuse of these substances. With that, I yield back.

Ms. MILLER-MEEKS. Thank you, Representative Bergman. The chair now recognizes Representative Deluzio for 5 minutes.

Mr. DELUZIO. Thank you, Madam Chair. Good afternoon, everyone. I think one of the things you will hear across the dais here is we all want to make sure that my fellow veterans can receive the treatment that is safe and effective. I encourage that research. I want to see Federal law not be standing in the way of pursuing treatment that could be safe or that you are finding is safe and effective.

Dr. Clancy, I will start with you. In your testimony, you write that the VA complies with all applicable laws, rules around psychedelics and research. I know Ranking Member Brownley asked about funding. General Bergman asked a similar question. My question is, are there any statutory barriers for the VA to conduct research on psychedelics, cannabis, any other Schedule 1 substances?

Dr. CLANCY. There are no statutory barriers, no.

Mr. DELUZIO. That being the case, well, let us start with cannabis, is VA doing research into cannabis, and if so, what does that look like?

Dr. CLANCY. We have about 10 studies ongoing right now, and they range from basic science to what we call health services research, which is, how does it work in healthcare every day? Of the 10, two are clinical trials. One focuses on PTSD, and one is focused on reducing pain, or assessing whether it can reduce pain in a meaningful way.

Mr. DELUZIO. Ongoing research?

Dr. CLANCY. Yes.

Mr. DELUZIO. Okay. Do you have an expectation of timeline when you might see results?

Dr. CLANCY. I do not know that right at the moment. Again, happy to take it, for the record.

Mr. DELUZIO. Thank you. Dr. Clancy or Dr. Wiechers, if you are more appropriate to respond here, please feel free, shifting back to psychedelics. If research, if these studies show that any of these

treatments will be safe and effective for whatever conditions, does the law prevent the VA from ultimately pursuing a treatment? What stands in the way beyond FDA approval, should that ever come?

Dr. CLANCY. Well, I am just going to take a key from Dr. Wiechers a couple of minutes ago. FDA approval will almost certainly be accompanied by something called a REMS approach, risk evaluation and management strategy, which may be straightforward and it may be quite complicated. That will be something that we would obviously review very, very carefully. That is not a statutory process.

Mr. DELUZIO. Right.

Dr. CLANCY. This is all about effectiveness and safety.

Mr. DELUZIO. I guess then on both psychedelics and cannabis, is there anything Congress needs to change should your research and what happens at the FDA suggest these should be safe and effective treatments for veterans?

Dr. CLANCY. Not that I can see, no. We would be in touch if we thought otherwise.

Mr. DELUZIO. Okay. In terms of research and funding, are there funding issues? How can this body and the Congress help if there are?

Dr. CLANCY. I think you can help, and you are helping by having this hearing, the roundtable a few months ago. We have appreciated Congress's support, particularly this committee for our research budget. Again, I do not see anything else there, but thank you.

Mr. DELUZIO. Very good. Okay. Madam Chair, I yield back.

Ms. MILLER-MEEKS. Thank you, Representative Deluzio. The chair now recognizes Dr. Murphy, for 5 minutes.

Mr. MURPHY. Thank you, Madam Chairman. Thank you, guys. This is very, very intriguing. I just met with some folks actually a couple of times today and exploring this. Just being a scientist myself, I am going to probe this pretty hard. Do not take anything personally, but it is just like we were pimped in medical school and everything else. Can somebody give me a little bit of a historical scenario? Where did this start coming out? Were folks coming in and saying they use these stuff recreationally and they were helped by it, or how did all this—what was the genesis?

Dr. CLANCY. To the best of my knowledge, some of this work dates back to the 1960's, if not earlier. Then there was a hiatus. I am going to guess the Controlled Substance Act passed in the early 70's had something to do with that. I think the people from the organization MAPS, unless Dr. Yehuda knows more about the history, could actually give us a more recent timeline. It is not that there was suddenly a campaign. This has been growing for the past few years, witness—Congressman Bergman's, you know, insertion into law——

Mr. MURPHY. Sure, sure.

Dr. CLANCY [continuing]. a few years ago.

Mr. MURPHY. Does anybody really definitively know mechanism of action? I know it is serotonin, but anybody specifically know where that is going to hit or what it does?

Dr. YEHUDA. Thank you very much for that question. We do not specifically know the mechanism of action of psychedelic assisted therapy. One reason for that is that an active ingredient in the treatment, in the clinical efficacy, comes from the combination of administering a psychedelic plus the——

Mr. MURPHY. The therapy.

Dr. YEHUDA [continuing]. psychotherapy. We know how these compounds act in the brain. We know what receptors they target. We know that they maybe build avenues for brain plasticity. The real task ahead of us is to conduct research that will answer that question. Specifically, why taking psychedelic medicines in the context of a safe container with trained providers can facilitate, and insight, and introspection, and galvanize healing. This is very important work in the lifecycle.

Mr. MURPHY. Is this thought to be really therapeutic or maintenance? In other words, what is our schedule here? Are we thinking that two or three therapies are curative or is this something that we think our vet is going to have to take lifelong? Is there going to be subset of patients? All of the above?

Dr. CLANCY. I would say that is why we are continuing to do research. We have certainly met veterans for whom this appears to have been curative. The real test obviously will be for how long a period of time and so forth. I think it is too early to answer a very logical question like that.

Mr. MURPHY. Subsets of patients with preexisting, you know, cardiac disease, arrhythmias. There has to be some exclusionary criteria for some individuals just because these things are not like taking Tylenol and not like taking aspirin. I will just say one of these things. We had an occurrence, I guess it was 3 or 4 weeks ago, where a pilot who was sitting in a jump seat took some magic mushrooms recreationally, and he had taken those 3 days before. Then he tried to bring down a plane. Then he got restrained in the back and then tried to open the back of the door.

You know, these things are not magic bullets. They are not without consequence. I applaud your work on trying to help this. This is amazing if it can be done. It would be naive to think, one, there are not repercussions, and two, there is not going to be abuse. People will find a way to abuse these medicines because it is a drug and it is one of these things that will be abused.

Putting guardrails up as stringently as possible is going to be critical because we are going to get doctors who are not the best doctors in the world that will go through a course and will become prescribing mills just like anything else. Keeping this well within guidelines is going to be absolutely critical from day one, not 5 years afterwards when we see people ruining the system, but from day one. There is, you know, to General Bergman's point, there is going to be an onrush of individuals.

I personally, and I will make a plug in. I still am a firm believer in hyperbaric oxygen. I know the studies are somewhat controversial on that one regard. Just in the same vein that you are saying you try to touch these individuals who cannot be touched, why would we not do anything that can be? One quick question. Is there any comparison to scopolamine with any of these things that are being done?

Dr. CLANCY. Not that I am aware of.

Mr. MURPHY. Okay. All right. Good luck on your work, be stringent, no predetermined outcomes, and let the evidence take you where the decision should be. Thank you very much.

Ms. MILLER-MEEKS. Thank you, Dr. Murphy. The chair now recognizes the Ranking Member of the Full Committee, Mr. Takano.

Mr. TAKANO. Thank you, Madam Chair. You know, a few months ago, Dr. Elnahal, the Under Secretary for Health, and I visited Loma Linda VA healthcare system, where we met with Dr. Shannon Remick. She is leading a phase two clinical trial examining MDMA assisted psychotherapy in veterans with combat related PTSD. She was quite likely the first VA researcher since the 1960's to administer a psychedelic as medicine to a VA patient. I am proud to have this groundbreaking research going on at the VA medical center that serves my constituents.

My question is to Dr. Clancy and Dr. Wiechers. I understand that there are currently five clinical trials involving psychedelic assisted therapy going on at VA medical facilities. To what extent is there interest from other VA researchers in getting involved in this research, and how is VA supporting it?

Dr. CLANCY. A big reason that we had the state-of-the-art conference in September was to actually bring together some of the best and brightest within VA, as well as across the Federal Government and from some of our affiliates, to really assess the answer to that question, because it is an important one. I will say that for people in our system who invest a fair amount of time in providing care to people with PTSD, they were inspired and very hopeful and hoping that more science like you have described at Loma Linda could get us to a place where we can know if this is a breakthrough for veterans, and which veterans, and how do we do that safely, and so forth. It would be hard for me to overstate their enthusiasm. As you and your colleagues have said, we have got to make sure that it is both effective and safe.

Mr. TAKANO. Dr. Wiechers.

Dr. WIECHERS. I would simply say, yes. To echo what Dr. Clancy said, we have actually a large and robust kind of de novo community of researchers and clinicians across VA who have interest in this work, who have taken it upon themselves, many of them, to seek out education and training in this space, and who are enthusiastically looking forward to becoming more involved, both in the research and anything beyond that, as the opportunities develop.

Mr. TAKANO. Well, thank you. Dr. Clancy, in your written testimony, you explained that VA and Department of Defense (DoD) determined the current evidence regarding MDMA was insufficient to include it as a recommended treatment in their latest clinical practice guidelines for the management of PTSD. I think I came in, as you were saying, maybe it is a little too early. Those guidelines were released in June 2023. How many clinical trials would you need to have published? Or how many veteran clinical trial participants would there need to be for DoD and VA to consider including MDMA in their clinical practice guideline?

Dr. CLANCY. I do not have a precise answer to the question because it depends both on the size and right now, there are not enough veterans that we would feel comfortable in terms of saying

that this works that well for veterans, notwithstanding the fact that there are two phase three trials that are showing promising results. It is also about the quality of the studies, how clearly and safely were they conducted? It is easy to say we are going randomize people or enroll people with these specific characters and have other exclusion criteria. The real question is, did they actually manage to come up with that? Ultimately, the FDA is going to decide in terms of whether they approve this.

Mr. TAKANO. Okay, so we have another agency then.

Dr. CLANCY. Yes.

Mr. TAKANO. How far away would you say we are from achieving that level of rigorous study and sufficient evidence, you know, if we have optimum support from Congress? My sense is that there is strong bipartisan interest in supporting VA and encouraging VA to move aggressively in this area.

Dr. CLANCY. Well, I have huge, deep respect for the FDA's process. I would say that evaluating a treatment that is a combination, as Dr. Yehuda so clearly described, of psychotherapy plus a drug, will challenge how they have been evaluating processes before. I am quite confident that they will but I would not be betting on a timeline.

Mr. TAKANO. Thank you. What barriers, if any, are there to conducting multisite studies of psychedelic assisted therapy, where researchers at multiple VA medical centers would partner to enroll participants, adhere to the same study protocols, and pool their data?

Dr. CLANCY. You know, one of the core strengths of our research program is multisite studies. Over the past few years, starting, interestingly enough, just a little before COVID came on the scene, but it turned out to be hugely helpful, was a way to make it easier and far more efficient and quicker for us to stand up multisite studies. I am not seeing a problem there at all.

Mr. TAKANO. All right. Well, thank you. I am over time. I yield back.

Ms. MILLER-MEEKS. Thank you, Representative Takano. The chair now recognizes Representative Lutrell for 5 minutes of questions.

Mr. LUTTRELL. Thank you, Madam Chairwoman. Dr. Wiechers, so, the Deputy Executive Director for Office of Mental Health and Suicide Prevention, you arguably carry the heaviest rucksack in the VA, and I applaud you for that. I can imagine the challenges.

In the past, we have had hearings where they are breaking out the numbers to us out of your department, and it is an exponential growth rate in the wrong direction. It is really hard to wrangle. My colleagues have stated, and Dr. Clancy, you can answer this one as well, but we are, I would say they may argue with it, but a united front behind the efforts and the well beings of our veterans. This seems like the next level proverbial tool you can put in a toolbox to save the lives, to increase the quality of life, and decrease the symptomatic issues.

The VA seems to be actively engaging with Congress and moving forward in the right direction. My concern is that it dies on the vine between the communications between the VA and possibly the FDA. In conversations that you are having, please be honest, in

conversations that you are having—can I even say be honest? I can say be honest, right? Please be honest. We need to know. The veterans behind you would love this answered, too. Does the FDA seem like they are playing ball with us in order to get this thing moved accordingly? Dr. Wiechers, you can go with that one, or Dr. Clancy. Dr. Clancy, you have kind of talked around it a little bit. I am not trying to get on you or anything, but I need the answer. It sounds like the FDA is not fully engaged on this.

Dr. CLANCY. First of all, I do not actually have a way to assess that, but I did——

Mr. LUTTRELL. You would not. Okay.

Dr. CLANCY. Yes.

Mr. LUTTRELL. Who does?

Dr. CLANCY. Right. Well, they are an independent body, and they have very, very serious responsibilities. I have no doubt whatsoever, because I have full confidence in the FDA Commissioner currently that there is any reason for them to be foot dragging here.

Mr. LUTTRELL. Yes, ma'am, I——

Dr. CLANCY. I think this is a tough challenge.

Mr. LUTTRELL [continuing]. I can appreciate the responsibility that the FDA has, but the members sitting on this dais right here, when we walk around our districts, we have to talk to the families that lost their veterans. There is no more serious a situation than that. Again, so if it seems like there is a friction point that this may stall, we want to engage.

Dr. CLANCY. Okay.

Mr. LUTTRELL. Dr. Yehuda, can you please share with the committee just some high-level results from your research so we can go home? One of the hardest—excuse me—one of the challenges, and if anybody in the room has a creative name besides the word psychedelics, we are eagerly awaiting that to hit. Can you share with us some results that we can share with our base and the rest of the Members of Congress that may be a little apprehensive on us pushing this forward?

Dr. YEHUDA. Thank you very much for your question, Congressman, and thank you for your service. Yes, we are in the middle of a study. We have now randomized 17 combat veterans to receive MDMA assisted psychotherapy.

While we have not completed, except for 10 veterans, I can say that I am extremely encouraged by what we have seen, and there is every reason to be extremely optimistic that this is not only a therapy that can help veterans reduce their PTSD, but also give them a way to reconnect with their purpose and mission and find ways for them to be more integrated with their families and societies. We are very, very hopeful. I do not want to get ahead of the trial that is in process just to say that there is really every reason for optimism and investment.

Mr. LUTTRELL. Thank you. The committee, we are basing our kind of our right and left flank off of the science. I am a scientist by trade, a neuroscientist by trade before I became a Congressman, and we are looking for the empirical data. We are. I understand this space lives between science and spirituality.

I have often said, and maybe this committee may not know, but I have gone through these treatments, and it is something that I

would, for me, this is Morgan saying this, I would never, ever tell anybody to do it. It was such a challenging experience, but life changing.

I think, as the chairwoman said, given the proper guardrails for those who need it, not for those who want it, that is where the magic happens. I can use some scientific terminology, but I do not have one in my head right now. Mr. Murphy, left. There are no rules and regulations, Mr. Deluzio asked a great question, that prevents the VA from moving forward on this. I would like to see the VA leading this.

Our veterans are ready. Our veterans want to move away from the selective serotonin reuptake inhibitors (SSRIs) and all the other tools that seem to may not move the needle as much as they can and break this proverbial tool out to go, hey, you know what, if we are at this point now, let us make this a thing. Okay? My time is up. Thank you so much, chairwoman.

Ms. MILLER-MEEKS. Thank you, Representative Lutrell. The chair now recognizes Representative Landsman for 5 minutes.

Mr. LANDSMAN.

[Inaudible].

Ms. MILLER-MEEKS. Thank you very much. That is the most rapid set of questions we have had—and relevant. The chair now recognizes Representative Kiggans for 5 minutes.

Ms. KIGGANS. Thank you, Madam Chair. Just a couple of questions about the criteria. When we are talking about who is eligible for some of these clinical trials, are there any disqualifying factors, like addiction, criminal charges, or when we have to choose who is going to receive the initial treatments, what are we looking for?

Dr. YEHUDA. Thank you very much for the question, Congresswoman. Yes. Every clinical trial has exclusion criteria, but they are designed to protect the patient from potential adverse effects if they are vulnerable. For example, patients receive a cardiovascular workup, but we do not look at things like, if they are in the justice system, because it is not a medical reason to exclude someone.

Yes, the exclusions are designed to be protective. Currently, they are quite conservative. One of the reasons that we need to do more research is because, as we become comfortable with these treatment approaches, we can see who else can fit under the tent. This is a very important part of the kind of work that has to be ongoing so that we can make this really as generalizable as possible and as safe as possible.

Ms. KIGGANS. I know that with some other controlled substances, the VA does a great job with things like drug contracts and making sure that we are doing periodic drug screenings and pill countings and just really staying on top of people who are prescribed things like opioid medications. Will we have that same type of kind of safety tracking mechanisms in place with this type of treatment?

Dr. YEHUDA. In our clinical trial, the patient receives the medicine from a physician, and we watch the patient take the medicine. There is no opportunity for diversion. Again, this is as safe as it gets. Nobody is going home with anything. It is really happening under controlled conditions.

Also, the patient is being monitored in terms of biometrics. There is every opportunity to look at whether something may need an intervention for the patient's safety.

Ms. KIGGANS. Will you be doing randomized drug screenings? I wanted to, you know, if we are going to do a clinical trial, just making sure it is as pure as possible so they are not going home and using or taking maybe other substances. How are we ensuring that the results we are seeing are truly the result of the treatment that they are receiving in house?

Dr. YEHUDA. A lot of what we do before we administer MDMA therapy is we do preparation. We do a lot of talking about what to expect in a psychedelic experience, what it is for, what the person's intention is, and what are the kind of barriers or reactions that might be anticipated. All of these things are discussed.

If a person will then develop a craving for a substance, that will be discussed in the therapy. So far, in our experience, that is not what happens. I think people are not using the psychedelics to alter their state in the sense of getting high or avoiding. They are using this medication in the context of facilitating an insight, of allowing them to connect with traumatic material, to build empathy, to build self-compassion, and to be able to confront things that they just have not been able to confront before.

The idea is not let me feel good from a drug. It is let me put myself in a state that is most conducive to safely exploring material that is very difficult. It is a very different paradigm than the paradigm of drug seeking behavior in order to avoid and forget. This is seeking a medicine that helps you engage, and it is sometimes very difficult in the room, and that there is an opportunity to do that work with the veteran, especially if the workforce, as it is in the VA, is very well trained and well versed in what it means to talk about very difficult traumatic war related material.

Ms. KIGGANS. I hear you, and I can appreciate those things. I just want to make sure that we are, again, conducting a clinical trial that is very pure in its sense, and it does not have other factors, because I am sure that this is a group of people that is fragile. You know, I think of patients with mental health issues and there is a lot of sad stories out there that they have tried. I just want to make sure that we are being protective of this treatment so that we can have the most accurate results. That is my only concern.

Last question. I just want to know what, if any, if we know of any long-term side effects from these treatments.

Dr. YEHUDA. We have not encountered long-term effects yet, but that is one of the most important things that we have to do. It is often the endpoint of clinical trials is maybe a month or at the most, 3 months following treatment. Really, what is important here, and the VA affords the opportunity to do this, is to really look down the road and see if the gains are maintained. What else pops up? How the patient engages in healthcare and mental healthcare, and what else we can offer in a different way to the veteran?

Dr. CLANCY. I just wanted to add one brief point. Every clinical trial in VA and many, many other places has a data safety monitoring board. They are constantly, this is an independent group. For example, if the results were so stunningly positive that it would feel almost unethical to continue, for example, a placebo

group, the trial will be stopped. On the other hand, if some adverse effects emerge, that would also question whether we should continue this trial. This is all independent. That is part and parcel, and we will certainly be watching that very, very closely.

Ms. KIGGANS. Thank you. I yield back.

Ms. MILLER-MEEKS. Thank you. The chair now recognizes herself for 5 minutes. Certainly, whether we are talking about emerging breakthrough therapy or we are talking about standardized conventional care, does not every clinical trial, randomized controlled trial for a drug, go through a process by which patients are excluded from the trial, you are trying to get as pure results as possible, would that not be true for any type of therapy? Yes, no?

Dr. CLANCY. I would say yes. It is just that it is a little bit different. You know, there is not one single science like pharmacology or pharmacotherapeutics, right, to guide what would be inclusion and exclusion criteria. Clearly, studies like the one Dr. Yehuda is leading and others, I think, will be highly informative to us in the future.

Ms. MILLER-MEEKS. Yes, certainly, this is not only a chemical that is being administered. There is psychotherapy. That is a little bit different and a little more convoluted or difficult, I would think, for the FDA to seek approval. Dr. Yehuda, so the Bronx VA is not the only VA that is doing these types of studies, and there are also similar studies going on through other research institutions and medical facilities as well, is there not?

Dr. YEHUDA. Yes, I believe so.

Ms. MILLER-MEEKS. I think the evidence and the literature would confirm what you just said, that, yes, there is. Dr. Clancy, at the VA hosted psychedelic state-of-the-art conference, one of the key gaps in research identified was the need for more trials conducted with veterans. What is the VA's plan to address this obvious gap, i.e., are you setting out to do more trials or to expand the number of admissions into trials?

Dr. CLANCY. That is a topic that we are working through right now. Again, we look forward to sharing our conclusions when we have made those decisions.

Ms. MILLER-MEEKS. Is it not true, if there were, let me give an example, a drug for high blood pressure that was approved by the FDA, how long would it take for the VA to then prescribe that medication for individuals or a statin for cholesterol?

Dr. CLANCY. Well, in the case of pharmaceuticals, we have a very active pharmacy evaluation group, and I am mangling their official bureaucratic name, that meets almost immediately, and that has allowed us to do——

Ms. MILLER-MEEKS. Would it take 5 years? Would it take more clinical trials——

Dr. CLANCY. No, no, no, it would not take——

Ms. MILLER-MEEKS [continuing]. to both Representative Bergman——

Dr. CLANCY. Yes.

Ms. MILLER-MEEKS [continuing]. and Representative Lutrell's point, the concern that we have is that even after FDA approval of MDMA assisted therapy or breakthrough therapy, that there will be a long lag time until the VA starts instituting that. I guess

what we would like to convey, or some of us would like to convey, is that we think the VA should be preparing for that ahead of time.

Dr. CLANCY. Yes.

Ms. MILLER-MEEKS. We know that there will be workforce issues. We know that the types of veterans that will seek this therapy, and that utilizing both the research within the VA as well as the research outside of the VA that is being conducted be brought into that, because certainly the FDA is not looking only at the research the VAs are doing, but they are looking at the research that is occurring at other research institutions.

Dr. CLANCY. Yes. No, I think we agree with you completely. I would just like to ask Dr. Wiechers to, again, stress that we have a strong track record here. This was a very important theme at our conference.

Dr. WIECHERS. Thank you, Dr. Clancy. As an example, previous emerging therapy, intranasal esketamine, or Spravato, was FDA approved in March 2019. We treated our first veteran inside VA at the Boston VA in July 2019. It took about 4 months for our pharmacy benefits Management National Formulary Committee to go through its standard operating processes to review all of the information from FDA, and to make its own determination about the status within VA, and then for us to stand up with building upon some expertise at facilities that were already providing ketamine treatments, to then utilize the intranasal esketamine treatments. Then we expanded thereafter and now have 42 sites across VA providing either ketamine or esketamine treatment today.

Ms. MILLER-MEEKS. Well, we would hope if the FDA approves this, there would be the same rapidity of treatment. As we know, ketamine has a dosing issue and more addictive potential. When I think SSRIs were discussed, so when we are talking about medication that we currently utilize in addition to therapy and psychotherapy for veterans for depression. Whether it is anxiolytics, antidepressants, these medications have a side effect profile that is fairly significant. Whether it is foggy brain, whether it is multiple medications, alteration of medications, there is a side effect profile that so far, and I think Dr. Yehuda alluded to this, you have not seen that same side effect profile as you have in the studies that you are doing.

Dr. YEHUDA. Yes, because the drug is not administered continuously. The drug is taken just a few times. There are things that happen during the course of the day that are monitored very carefully. Then what we are on the lookout for is whether there are other kinds of changes in mood or physiologic states that occur over time. This is exactly the work that we have to do in the future to make sure that this is safe for everybody to take.

Ms. MILLER-MEEKS. Thank you. I yield. The chair now recognizes Representative Budzinski for 5 minutes.

Ms. BUDZINSKI. Thank you, Chairwoman, and thank you to the witnesses for joining us today. Addressing the behavioral health needs of our veterans has really been one of my top focuses and priorities as I am honored to serve on this committee. As we know, veterans face unique traumas while in the line of duty, and many face these struggles alone and without the care they need. I just hosted a veterans town hall when I was home over the Veterans

Day holiday, and I heard very much firsthand from the veterans in the district about access to more behavioral health treatments was critically and is critically important. I really want to be a part of the solution, but I also really want to ensure we are doing so in a way that builds off of a solid base of evidence. Psychedelics have shown promise in early clinical trials, especially when combined with therapy.

However, the scope of clinical trials and research into these psychedelics for veterans is still limited and in early stages, as I understand. For example, dropout rates in trials among veterans is relatively high. Co-occurring medical and psychiatric disorders need more research, and cultural diversity among trial participants has been very low, some of the concerns that I have.

I also want to make sure we are including women veterans in these trials. As we know they face very unique experiences in the line of duty as well. I have heard from many women veterans, including those on my Veterans Council, about military sexual assault trauma they have experienced. We need to ensure that we include in any clinical trials for psychedelic assistance that taking that into account, I think.

I want to be clear that I do support the use of psychedelic assisted therapy for our veterans, but I want to make sure we are not rushing the process and potentially putting veterans in danger. I support robust government funding at the VA directed toward more extensive research to fully examine the potential positive effects and consequences these therapies can have on our veterans' community.

With that, I do have a question. My first question, if you do not mind, Dr. Clancy, if psychedelic drugs receive FDA approval to treat psychiatric disorders and DEA reclassifies these drugs, what steps does the VA need to take to help scale these therapies and make them more broadly available?

Dr. CLANCY. When it is approved and when we have enough evidence with veterans for all the reasons you just so clearly described, one of the big steps would be making sure that we had appropriate training. There are some other issues that we would need to be exploring. For example, one-third of the veterans we serve live in rural areas. For those veterans who live in rural areas and have broadband, you know, can this be done virtually? That is not happening in this country. I learned at the conference that in Europe, some studies are pursuing this and so forth. It would be a whole process of scaling very similar to what Dr. Wiechers just described in terms of starting the first treatment for veterans with ketamine or inhaled ketamine, and then building out from there. We know how to do this, and we take enormous pride and care about making sure that it is safe and well done.

Ms. BUDZINSKI. Yes, I appreciate what you have shared specifically about rural communities. That definitely reflects concerns I have within my district and those unique challenges, especially when you are looking at trials. I do not know if anyone would like to add anything beyond that, beyond what Dr. Clancy shared.

Okay, I just had one other quick question with the time I have. How can researchers encourage veterans from various racial and ethnic backgrounds, and women in particular, as I mentioned, to

participate in clinical trials to help ensure that trials are representative of the veteran population?

Dr. CLANCY. I am really happy you asked this because, again, for all the reasons that you stated a few moments ago. The population of veterans we serve now is far more diverse, gender, racial, and ethnic background and so forth. That is very high in our minds. We have got a group in our Office of research and development very much focused on both enrolling more diverse patient populations, but also, quite honestly, identifying and encouraging future scientists from multiple backgrounds.

Ms. BUDZINSKI. Okay.

Dr. CLANCY. That will be a challenge for sure, but important.

Ms. BUDZINSKI. Okay, great. Thank you. I will yield back. Thank you, chairwoman.

Ms. MILLER-MEEKS. Thank you. On behalf the subcommittee, I want to thank you for the testimony and for joining us today. I am sure that we could have many more questions, some of which we may submit for answers later. You are now excused, and we will wait for a moment as the second panel comes to the witness table.

[Recess]

Ms. MILLER-MEEKS. Welcome, everyone, and thank you for your participation in today's hearing. Joining us today is Sergeant Jonathan Lubecky, U.S. Army retired and a psychedelic therapy clinical trial participant, Dr. Frederick Barrett, Associate Professor of Psychiatry and Behavior Sciences at Johns Hopkins Center for Psychedelic and Consciousness Research, Mr. Mike Mullette, Chief Operating Officer at the Multidisciplinary Association for Psychedelic Studies Public Benefit Corporation (MAPS PBC), Dr. Rajeev Ramchand, Co-Director at the RAND Epstein Family Veterans Policy Research Institute, Mr. Brett Waters, Co-Founder and Executive Director at Reason for Hope and Co-Founder of the Veteran Mental Health Leadership Coalition, Mrs. Juliana Mercer, Director of Veteran Advocacy and Public Policy at Healing Breakthrough. Sergeant Lubecky, you are now recognized for 3 minutes to deliver your opening statement.

STATEMENT OF JONATHAN LUBECKY

Mr. LUBECKY. My name is Jonathan Lubecky, and I am an American veteran. I served 4 years in the Marines, and upon seeing the towers fall, I joined the North Carolina Army National Guard, and I served in Iraq 2005–2006, with 172 members of Bravo Battery, 5th/113th. I was medically retired in 2009 after a total of 12 years' service.

As a veteran, I have the privilege to have my trauma be socially acceptable, unlike so many others, because it is easily understood why a veteran who deployed, whose base was shelled almost daily, would have PTSD. As someone who frequently shares their story publicly, I fully understand why so many chose not to share such intimately personal details of their trauma.

Most of my story is shared by hundreds of thousands of veterans. I am but one voice of many. I grew up in a house where my siblings were abused, where one of my siblings suffered from addiction. Like so many, I left for boot camp because I wanted to help people and to escape.

After all I saw and experienced in Iraq, it cracked my mental health. I returned home to find my house empty, my dog gone, and my wife living with someone else. In the early hours of Christmas morning, 2006, less than 2 months after returning home, after going to Sacred Heart Church in Raleigh and being turned away because they were full, going to Womack Army Medical Center and being told to come back after the holidays, and I was sent home, I did what 136 Americans do, including veterans, I tried to end my life. I put a gun to my head and I pulled the trigger. I forever remember the peace I felt as a hammer fell because it would all be over at last. I heard the pop. I thought I was dead, but the pain was still there. It was then that I realized that the ammunition malfunctioned.

That was the first of five suicide attempts that should have been successful. That does not include the daily ideation, the hundreds of times I stood on a bridge. Following my last attempt, I was passed a note from a The Medical University of South Carolina (MUSC) intern that said Google MDMA PTSD, and I did. I discovered that MAPS PBC was conducting a clinical trial in Mount Pleasant, South Carolina, just across the bridge.

I was the 26th person in a 25-person study of veterans and first responders. I went through a clinical trial lasting about 4 months. I took MDMA and sat with trained therapists for 8 hours only three times. To be clear, I have only taken MDMA three times in my life, 9 years ago.

The MDMA does not fix anything like anaesthesia, it puts the mind, body, and spirit in the place it needs to be so the therapy can work. Much like when I was given fentanyl prior to my back surgery, the anaesthesia did not fix my back, the surgeon did. For the first time, I was able to freely talk about my demons without my body betraying me. With the help of Michael and Annie Mithoefer, I not only worked through my trauma from Iraq, but my whole life, and excised those demons for good.

The VA in their formulary currently has exceptionally powerful drugs such as ketamine, fentanyl, and a long list used as anaesthesia that the VA has been able to properly handle and use in a medical environment. MDMA assisted therapy is the same and objectively safer than many of those drugs.

Through a guiding hand, I have been placed in circumstances where, if I was not healed, I would have cracked. For example, attempting to rescue a drowning victim in my backyard, attempting to save a gunshot victim in Charleston, and most recently, providing humanitarian aid on the front lines of the Ukraine-Russia war.

I am not special. My story is the same as every other veteran suffering with PTSD. My story changes because I went through MDMA assisted therapy. I was blessed by being able to participate in a clinical trial. Most veterans face the choice of leaving the country that sent them to war. The country they love, they have shown they will die for so they can heal, because otherwise they will sacrifice their life for this great country, far from a battlefield, at home, alone in the dark.

The only entity that can ensure that all veterans have access to the same treatment I went through in a safe and effective manner

with trained therapists and medical grade substances is the VA. I measure my failures by the list of people I know who have committed suicide. It hangs on my fridge. We, as a Nation, have left these veterans to suffer. We have left them behind. It is beyond time for this country to mean it when they say we do not leave anyone behind and ensure that there are more sons and daughters, mothers and fathers, and fewer loved ones left with nothing but a folded flag because I know that the sole reason my son has a father instead of a folded flag is because I went through MDMA assisted therapy.

Every veteran who is suffering from PTSD and is at risk of suicide should have access to the treatment I received by going to the VA. I vehemently oppose the idea that you can achieve the same results that I did by removing the therapeutic component and using untested and potentially lethally tainted drugs. Veterans have earned the right to heal by doing what this august body asked them to do. It is unconscionable to prohibit research, given where the science and evidence currently sits.

Every time I made the choice to end my life, it was because I had lost all hope of a better day. Hope of a day like I now have every day. Because I share my story publicly, I often have veterans reach out, begging for help for access to the treatment I went through that saved my life. I am now begging the veterans on this committee and for the whole of Congress to please give them hope of a better day. We all know it would not be tomorrow, but I beg for you to give them the hope of someday. I thank you for this opportunity, and I stand ready to answer questions.

[THE PREPARED STATEMENT OF JONATHAN LUBECKY APPEARS IN THE APPENDIX]

Ms. MILLER-MEEKS. Thank you, Sergeant Lubecky. Dr. Barrett, you are now recognized for 3 minutes to deliver your opening statement.

STATEMENT OF FREDERICK BARRETT

Mr. BARRETT. Chairwoman Miller-Meeks, Ranking Member Brownley, and members of the subcommittee, I thank you for the opportunity to testify today. I am Dr. Frederick Barrett, Associate Professor of Psychiatry and Behavioral Sciences at Johns Hopkins University School of Medicine, and I am the Director of the Center for Psychedelic and Consciousness Research at Johns Hopkins. I am providing testimony as an individual and not as a representative of any institution. The following are my own views and not necessarily those of Johns Hopkins University, Johns Hopkins Medicine, or the Psychedelic Research Center.

I have been conducting human research with psychedelic drugs in healthy individuals and patients with mood and substance use disorders at Johns Hopkins for 10 years. This program of research was initiated by my mentor, Dr. Roland Griffiths, who published the first psilocybin administration study in the modern era in 2006. The study is widely recognized as the study that reignited and catalyzed academic and medical interest in psilocybin. Since then, dozens of peer reviewed empirical reports of clinical trials have been published testing the safety and potential efficacy of psilocybin and closely related compounds to treat patients with a

wide range of psychiatric disorders, including mood, substance use, anxiety, obsessive compulsive, and other disorders. Notably, two FDA regulated multisite phase three registration trials are currently underway to determine whether psilocybin can be approved as a medicine to treat patients with depression.

We also come at a time when FDA is also considering whether to approve the related compound, MDMA, for the treatment of patients with posttraumatic stress disorder.

Depression, substance use, PTSD, and trauma writ large are leading causes of disability that plague our veterans as well as citizens at large in this country and around the world. I urge the committee to do everything in their power to facilitate the careful and thoughtful evaluation and implementation of these therapies, and importantly, the expansion of access to these therapies to as many veterans as possible in the event that they receive FDA approval. Evidence to date demonstrates the relative safety of psychedelic drugs to appropriately screen individuals in controlled settings, but these drugs do have known risks. These risks are well managed and mitigated for properly screened individuals when under the care of trained therapists. Within these procedures, we have safely administered nearly 1,000 doses of psilocybin to well over 400 individuals at Johns Hopkins since 1999.

While incredibly promising, psychedelic science is still underfunded, hidden behind some restrictive regulatory barriers, and not well understood by clinicians, policymakers, and the general public. I am grateful for you all for doing your due diligence and hosting these panels. I think there are clear next steps that can be taken to address these deficits. I urge the representatives of this committee to support programs that will allow the education of at least stakeholders, if not the general public, about the risks and the potential therapeutic benefits of psychedelics. These will be incredibly important, especially in the context of local ballot initiatives and state legislation that seek to kind of circumvent the FDA and the Federal processes.

I also urge the representatives of this committee to consider funding initiatives that will not only foster a greater level of investment in psychedelic therapy in the VA and research in the VA, but also more broadly within academic medicine, law, and public policy. Finally, I would like to urge the representatives of this committee and the House to support the bipartisan and bicameral Breakthrough Therapies Act, introduced by Representatives Mace and Dean, as well as Senators Paul and Booker. This act proposes the Schedule 1 compounds that are granted breakthrough therapy designation by the FDA be automatically rescheduled to Schedule 2, which would substantially ease the burden of academic research into these compounds, while not substantially increasing risk to the public, especially in the case of psilocybin and MDMA. Thank you for this opportunity to speak on this topic that I believe has such great import at this time. Thank you.

[THE PREPARED STATEMENT OF FREDERICK BARRETT APPEARS IN THE APPENDIX]

Ms. MILLER-MEEKS. Thank you, Dr. Barrett. Mr. Mullette, you are now recognized for 3 minutes to deliver your opening statement.

STATEMENT OF MIKE MULLETTE

Mr. MULLETTE. Chairwoman, ranking member, and subcommittee members, thank you for your leadership in holding this first in kind hearing on emerging therapies and their potential for treating veterans suffering from PTSD and other mental health conditions. On behalf of MAPS Public Benefit Corporation, it is a privilege to be here. My name is Mike Mullette, and I am the Chief Operating Officer of MAPS Public Benefit Corporation, a public benefit company working to change the way mental health conditions are treated.

The mission is personal for me. For the past two decades, I have seen my wife, who is a therapist, struggle to find effective solutions for her patients with PTSD. I joined this company with the goal to help my wife, healthcare providers, and patients ultimately have access to new treatment options.

PTSD is a mental health condition affecting approximately 13 million Americans each year. However, currently available treatments only provide modest efficacy. Disproportionately impacting veterans, seven out of every 100 veterans will have PTSD at some point in their life. Despite growing mental health needs, there has not been significant innovation in decades. At MAPS PBC, we have made significant progress at researching a new investigational treatment for PTSD known as MDMA assisted therapy. It is an acute treatment that entails a unique combination of talk therapy and medicine.

In our clinical studies, the participants received either MDMA in therapy or a placebo and therapy three times over a 12-week period, with three therapy sessions in between each medication session. In 2017, the FDA granted MDMA assisted therapy breakthrough designation, which is a process designed to expedite the development of drugs intended to treat serious conditions with preliminary clinical evidence that indicates a potential improvement over available therapies.

Both of our phase three clinical trials, which were designed under a special protocol assessment with the FDA, met their prespecified primary and secondary endpoints and were published in Nature Medicine. In these studies, participants in the MDMA assisted therapy group experienced significant reduction in PTSD symptoms versus participants receiving placebo and therapy. MDMA assisted therapy also offered significantly reduced clinician rated functional impairment, which is measured by the change in baseline in the Modified Sheehan Disability Scale. This scale measures impairment in functions in three areas: work, social and family life. No serious adverse events were reported in either the MDMA group or the control group.

We are pulling together all of the data and preparing to submit our new drug application to the FDA by this year's end. If successful, we anticipate MDMA assisted therapy for the treatment of PTSD could be approved by the FDA next year, making it the first emerging therapy of its kind available to patients suffering from PTSD. The Veterans Administration has the opportunity to create innovative care models to ensure treatment for PTSD are scalable, accessible, and, importantly, covered in a timely manner for veterans in need. Thank you again for your leadership on this issue

and your continued commitment to the health and safety of veterans.

[THE PREPARED STATEMENT OF MIKE MULLETTE APPEARS IN THE APPENDIX]

Ms. MILLER-MEEKS. Thank you, Mr. Mullette. Dr. Ramchand, you are now recognized for 3 minutes to deliver your opening statement.

STATEMENT OF RAJEEV RAMCHAND

Mr. RAMCHAND. Chairwoman Miller-Meeks, Ranking Member Brownley, and members of the subcommittee, thank you for the invitation to testify. My name is Dr. Rajeev Ramchand. I am a senior policy researcher at the non-profit, nonpartisan RAND Corporation, where I co-direct the RAND Epstein Family Veterans Policy Research Institute. I will focus on two critical areas for policymakers to consider as we learn about the benefits and risks associated with psychedelic assisted therapies.

First, continued investment in research is critical. There currently are good treatments available for conditions like PTSD, but they do not work for everyone. There is a need to invest in research to develop new treatments. This includes adequate funding for the National Institutes of Health and research programs within VA and DoD. Federal investment is necessary because private funding for novel therapies for mental health conditions is waning.

Congress can also make the process for conducting research on psychedelic compounds more efficient. Relaxing the notoriously time consuming, confusing, and expensive processes required to conduct research on Schedule 1 drugs would expedite research into psychedelic assisted therapy and help get novel treatments to veterans more quickly.

Second, policy solutions are needed to address potential barriers to veterans' ability to access psychedelic treatments if and when these treatments become available. The first potential barrier is cost. If and when available, MDMA assisted therapy will not be cheap, especially in the early years. Evidence from Oregon and Australia suggests that the price of these therapies will be high enough to be a barrier for many veterans, particularly those who want care outside VA. Veterans who cannot afford MDMA assisted therapy may try to access it in illegal markets where a dose is cheaper but could include dangerous adulterants like methamphetamine.

A second access factor will be whether VA has the workforce and resources to provide MDMA assisted therapies within its behavioral health infrastructure. VA would need to determine who should deliver this treatment and how to accommodate a more time and labor-intensive protocol while simultaneously meeting expectations to provide care to veterans in a timely manner. If VA considers paying for this care through its community care network or new partnerships, it will need to consider which firms in an emerging market have lasting power, as well as how to assess whether veterans are able to access this care in a timely manner.

The final issue related to access is quality. If VA providers deliver this care, VA must decide how closely to adhere to the FDA approved protocol and how to monitor its own providers' adherence

to it. VA currently has no process for monitoring quality of care veterans receive in the community, creating yet another hurdle to outsourcing this care. Regardless of whether it provides or pays for it, psychedelic assisted therapy is becoming increasingly available. VA should prepare its providers to talk to patients about and encourage veterans to speak with their providers about their interest in these treatments without fear of losing VA benefits.

In conclusion, psychedelic assisted therapy holds great promise, but their full benefits will be realized only with continued investments in research, improvements in access to these compounds for research purposes, and careful planning for how this care can be offered to ensure that all veterans who need and want these treatments can benefit from them.

[THE PREPARED STATEMENT OF RAJEEV RAMCHAND APPEARS IN THE APPENDIX]

Ms. MILLER-MEEKS. Thank you, Dr. Ramchand. Mr. Waters, you are now recognized for 3 minutes to deliver your opening statement.

STATEMENT OF BRETT WATERS

Mr. WATERS. Chairwoman Miller-Meeks, Ranking Member Brownley, and distinguished members of the subcommittee, thank you for the opportunity to testify today on behalf of Reason for Hope and the Veteran Mental Health Leadership Coalition. My name is Brett Waters, and I am the co-founder and executive director of both organizations, which are led by retired Marine Lieutenant General Martin Steele. I am also a multi generation survivor of suicide loss, having lost my grandfather, a World War II veteran, when I was young, and my mom, Sherry Hope Waters, 5 years ago. Reason for Hope is named in her memory.

We are here today because a growing body of evidence suggests that psychedelic therapies can provide rapid, robust, and durable relief and healing to individuals suffering from a variety of mental health conditions, particularly those who have not benefited from existing options. Significantly, the Food and Drug Administration granted breakthrough therapy designations both to MDMA assisted therapy for PTSD and to two psilocybin therapies for 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 have demonstrated a substantial improvement over currently available treatments for these conditions.

However, the Schedule 1 status of MDMA and psilocybin under the Controlled Substances Act slows down the necessary clinical research and has resulted in a lack of public funding needed for such large-scale trials. Schedule 1 also blocks compassionate use under the Right to Try Act, including for veterans who do not qualify for clinical trials in the United States due to their complex conditions. A tragic result of this flaw in our regulatory system is that veterans have been forced to either leave the country or risk criminal penalties at home to access these potentially lifesaving treatments. This is morally unacceptable, and we can absolutely do better.

That is why we urge the committee to support the Breakthrough Therapies Act introduced by Senators Booker and Paul and Con-

gresswomen Dean and Mace. We are grateful for the strong bipartisan coalition that has championed both bills, including you, chairwoman, as well as Congressman Lutrell.

The Breakthrough Therapies Act is simple. It moves Schedule 1 drugs that the FDA designates as breakthrough therapies or approves for expanded access from Schedule 1 to Schedule 2 on an expedited timeline. At no cost to taxpayers, this bill reduces onerous barriers to innovative research and enables compassionate medical use of breakthrough therapies, including under the bipartisan Right to Try law. It is an essential step to accelerate access to potentially lifesaving treatments, particularly for veterans who do not qualify for clinical trials in the United States. It seems obvious that our Nation's heroes should not be forced to leave the country that they selflessly served in an attempt to save their own lives.

We also urge the committee to ensure sufficient funding for large scale VA research programs that better reflect real world settings, as well as funding for education and training of providers, including veteran peer supporters, in the specialized form of care delivery. While our coalition has sought to do its part by helping to unlock over $12 million in state funding this year for these purposes, it is critical that the Federal Government and the VA step up and take a leading role to protect the future of our veterans. Thank you for your time today and I look forward to answering your questions.

[THE PREPARED STATEMENT OF BRETT WATERS APPEARS IN THE APPENDIX]

Ms. MILLER-MEEKS. Thank you, Mr. Waters. Ms. Mercer, you are now recognized for 3 minutes to deliver your opening statement.

STATEMENT OF JULIANA MERCER

Ms. MERCER. Chairwoman Miller-Meeks, Ranking Member Brownley, and members of the subcommittee, on behalf of the millions of veterans who suffer from PTSD and the organization that I represent, Healing Breakthrough, thank you for the opportunity to provide remarks on the great hope that MDMA assisted therapy holds for those living with chronic complex PTSD, a leading cause of veteran suicide. My name is Juliana Mercer. I am a 16-year Marine Corps veteran. My military career spanned my 20's and 30's and almost two decades of war in which I deployed to Iraq and Afghanistan and served on the Marine Liaison team at the Wounded Warrior Battalion.

After active duty, I dedicated my life to seeking solutions to the veteran suicide epidemic. Over the years, I have lost too many brothers and sisters to the ravages of war. Combat deployments, the loss of friends in combat, and the many more lost here at home to suicide took a massive toll on my mental health. Though immersed in purposeful work, I found myself in a place with no purpose. I needed help, and like other veterans, I left the country to access a breakthrough therapy not available in the United States and was able to reconnect to my purpose.

We lost 5,461 servicemembers in post-911 hostile combat operations, and in the last two decades, over 6,000 have committed suicide each year. We have lost more veterans here on American soil

to suicide than we have in the global war on terrorism, over 100,000 more. That annual rate has remained consistent over the years, implying that nothing currently on the market or in practice has meaningfully addressed the root cause of PTSD or decreased veteran suicide rates. This is a reality worth repeating because it is what motivates me to fight for my brothers and sisters every single day.

Despite billions of taxpayer dollars spent addressing this issue, we are still losing over 6,000 veterans per year. That is more per year than in 20 years of combined wars. If we continue doing what we have been doing, we may be saying the same thing 20 years from now.

Thankfully, there is hope on the horizon. An FDA designated breakthrough therapy known as MDMA assisted therapy offers scientifically validated hope for veterans who have PTSD. MDMA assisted therapy trials concluded that after three sessions, 86 percent of patients struggling with PTSD reported clinically significant reduction in symptoms, while 71 percent of patients experienced complete remission of PTSD symptoms.

The implications of these peer reviewed trial results cannot be overstated. MDMA assisted therapy has proven its efficacy in treating PTSD and is on the path to FDA approval next year. I am here today asking that you lead, as Congress must, in such moments of crisis and continue to urge the VA to implement a nationwide program for this breakthrough therapy as soon as possible. Every day wasted means more lives lost. Thank you for letting me share my story and for allowing me to advocate on behalf of my fellow veterans. Chairwoman Miller-Meeks, Ranking Member Brownley, this concludes my testimony. I would happily answer any questions you or the subcommittee may have.

[THE PREPARED STATEMENT OF JULIANA MERCER APPEARS IN THE APPENDIX]

Mr. BERGMAN. [Presiding.] Thank you. Thank you to all of you and Chairwoman Miller-Meeks, you know, had to, as we all do around here, we are juggling between different hearings and meetings. Number one, thank you, all of you, for your honest and heartfelt and direct testimony without bias or prejudice in any way, because you have, in many cases, lived this. I will recognize myself for 5 minutes here.

By the way, I just got a couple of questions, and anybody who wants to provide an answer can. Do not feel you have to if you do not, you know, it is not in your wheelhouse. Some critics have pushed fear mongering comparisons between psychedelic assisted therapy and state medical marijuana programs, where individuals can often take home essentially limitless amounts of the substance, in this case, some form of cannabis, with doctor approval. Given your experience and what we have heard from Dr. Yehuda in the previous panel, is this a fair comparison? Jonathan.

Mr. LUBECKY. I think a lot of that has to do with the context of use. If it is done at a VA or in a medical facility under proper supervision, I think it is a very inappropriate comparison. For one, I will be honest, I used cannabis for 5 years to abate suicidal ideation, and it was highly effective. When I moved to South Carolina and could no longer do that, everything came back. I did MDMA

assisted therapy 9 years ago, and I have not taken any mental health medication since.

Mr. BERGMAN. Okay. Anybody else? Again, we see when this topic first came up, there were entities that tried to scare our colleagues. Mike.

Mr. MULLETTE. Thank you, Congressman. I think it is important to note the way in which MDMA assisted therapy would be delivered in a clinical practice or within the VA in this instance. First of all, as Dr. Yehuda had mentioned earlier, medicine is provided on a one-time treatment basis, meaning it is delivered one set of medication for one treatment session at one time to individuals in a healthcare setting to be taken in the presence of a healthcare provider. That would be repeated one month later and then one month after that.

It is really important to understand that the delivery of this product will be very well controlled if approved by the FDA. We also anticipate that a REMS program, a risk evaluation and mitigation strategy, will be implemented by the FDA as well, further refining the way in which we can deliver this product one at a time in front of a healthcare provider.

Mr. BERGMAN. Okay. Anybody else?

Mr. RAMCHAND. I would just note that there is a lot of activity happening at the state and local levels concerning hallucinogenic deprioritization in their criminal justice kind of efforts. I do not think the comparison, I think the medical purposes, is really well intentioned and guided. This is happening at the same time that there is a lot of legislative action happening that may make availability of psychedelics more or may make psychedelics more accessible just due to what is happening at state and local levels.

Mr. BERGMAN. Okay.

Mr. WATERS. I think one of the critical components to the legislation that I have referenced, as well as Dr. Barrett with the Breakthrough Therapies Act, in terms of reducing the barriers to research and compassionate use by rescheduling from Schedule 1 to Schedule 2, one of the key things that could, you know, come about from that is kind of preventing that state-by-state approach and the kind of ballot initiative or legislative legalization, whether for medical use or recreational use that we saw with the rollout to cannabis. One of the critical and very valid talking points for many people who are suffering is that some people just do not have time to wait, and maybe they either cannot leave the country or they do not have the financial resources to do so. By rescheduling and making it easier both to conduct clinical trials, to get funding for those trials, and to ensure compassionate use is at least available to those who might not qualify for ongoing trials, that is a critical way that we can make sure through the medical system that this is legally available to people and can actually prevent some of that state-by-state approach that we have been seeing.

Mr. BERGMAN. Okay. Juliana, any thoughts? You do not have to.

Ms. MERCER. I think it is important to note that with the cannabis, it is self-medication, and with the MDMA, it is under the care of a healthcare provider, and it includes therapy that helps you work through your problems.

Mr. BERGMAN. Okay. Thank you. Sometimes when we do not understand something, we fear it. One of the goals of our committee, both sides of the aisle here, is to take the temperature down, get rid of the fear mongering, and get right into the realistic research and the outcomes that we know are potentially available. In fact, when we developed the Psychedelics Advancing Therapies (PATH) Caucus, we added GOOD to it. You got to have good acronyms here in D.C. GOOD stands for Get Off Opioid Dependency. One, two, or three, and done, not a continual life of medications.

I can guess, but I am just going to ask the question. Just give me a head nod. Can we give veterans access to these promising new treatments without legalizing recreational use of psychedelics? Okay. Thank you. With that, Ranking Member Brownley, I yield to you.

Ms. BROWNLEY. Thank you, Mr. Chairman. Thank you to the witnesses for being here. I wanted to ask all of you the same question I asked on the first panel with regards to if there is any awareness of clinical trials having to do looking at effectiveness on women veterans versus men veterans with these kinds of therapies, if you are aware of any research or trials that are going on?

Mr. BARRETT. Thank you very much, Ranking Member Brownley, for the question. There is a distinct lack of a clear scientific record in human clinical trials comparing the effects of MDMA, psilocybin, or other psychedelics between those with different biological sex. I can say that I just came from the Society for Neuroscience Conference where I chaired a press conference demonstrating a number of preclinical animal model trials that demonstrate potential sex differences in the response to psilocybin and other psychedelic drugs. This has not yet made it to the level of human clinical trials, and I think it desperately needs to.

Ms. BROWNLEY. Thank you. I could not agree with you more. Thank you very much. Sergeant Lubecky, thank you for being here. Thank you for your testimony. I think you have made it clear after 9 years of therapy that you are healed, not cured. Is that an accurate way to express it?

Mr. LUBECKY. Yes, ma'am. I mean, there is nothing that, if I had a traumatic experience, would say I would not get PTSD again. I am currently PTSD free, even after all the traumas that I outline in my testimony, which have happened in the past 9 years.

Ms. BROWNLEY. Does that mean that the triggers before you had the treatment, the triggers that would lead you to want to take your life and other things, are those triggers, have they just disappeared? Or do you know how to deal with them in a more effective way? I am kind of curious to know exactly how that works.

Mr. LUBECKY. Well, I think the best way to answer that question, ma'am, is the 4th of July before I took my first MDMA dose, I was in South Carolina. They love their fireworks. I was in a closet in my body armor having flashbacks of Iraq with my service dog.

This past May, on my last trip to Ukraine, as with every trip, Kyiv came under fire. This is where I learned air raid sirens are the same all over the world, unlike police sirens, which change from country to country. I was able to, once I assessed the situation, made sure my building was not damaged, there was nobody hurt around me, I rolled over and went back to sleep and did not

have any nightmares. I have not had any nightmares like that since I have been home either.

The triggers still exist. There is still people dropping bombs in this world. They just do not affect me the way they did. I have a proper emotional response, and then it does not come up again.

Ms. BROWNLEY. Thank you for that. Again, thank you for being here. Dr. Ramchand, I think we all agree that—I think all of us here agree that we need more research. Research is obviously very, very critical. I wanted you to speak to why it is so important that the VA is funding research for veterans and veterans specifically. If you could just speak to that.

Mr. RAMCHAND. I mean, the VA has a huge office of research that in order to access care, I mean, I think that this was described in the first panel, their clinical practice guidelines said that there were not enough veterans enrolled in trials. They did not have enough evidence for veterans. That was one of the reasons that they have not kind of prioritized at this point, psychedelic assisted treatments.

I think that the VA is the natural place to conduct research on veterans. If that is going to be held as a criteria for making policy decisions about the availability of these compounds, then I think, you know, the VA needs to be at the forefront doing this research, and that is why we need to invest in research within the VA.

Ms. BROWNLEY. Yes, I agree, and I think that, you know, suicide rates are higher in the veteran community. They have different health issues that are not necessarily consistent throughout the general public. I personally think it is really critically important that we focus on the community of veterans, both men and women. Women are the fastest growing cohort within the veteran community. Thank you for that.

Last, I will ask Ms. Mercer. You have talked about, again, you know, more research. I think the question that I just wanted to ask you about is what do you see as the key things for the VA and the committee to focus on the very near term?

Ms. MERCER. The VA needs to be prepared for the logistical challenges around implementing a novel treatment. We have worked really closely with VA stakeholders to identify some of these critical logistical challenges and potential solutions. They are going to need to train thousands of clinicians. They are going to need to find the right facilities, the room where they are going to be able to access for over 8 hours to be able to facilitate this treatment.

There is going to need to be education and outreach to both staff and to patients. There are so many things that need to be done before they are able to be successful in implementing an MDMA program.

Ms. BROWNLEY. Thank you. I yield back, Mr. Chairman.

Mr. LUTTRELL.

[Presiding.] Thank you, ranking member. There was a very good question or statement in quite a few of your opening remarks. Mr. Waters, I am going to start with you, and then, Dr. Barrett, I am going to shift over to you. The rescheduling from Schedule 1 to Schedule 2, and this is not a debate, but open for interpretations on your behalf. We are in our infancy, though these efforts have been around for a while, Mr. Barrett, we are surely in our infancy.

My concern in the conversations that I have quite often on the direction that we are trying to take is the rescheduling and the concern of the expansion away from what we are trying to accomplish. Do you think the rescheduling from 1 to 2, do you think we are in a place that that is necessary to happen right now, Mr. Waters? Or is that something that longitudinally we can bring out with the VA's help, because I am going to be working in parallel with them, is there a timeframe?

Mr. WATERS. I believe it is necessary, and it is logical that it should happen now, because the way that the system currently works is that after FDA approval, these products automatically have to be rescheduled within 90 days. The advantage that we get by rescheduling at this point, before these are FDA approved for use in interstate marketing, and, you know, we will be seeing these on commercials, there is an interim step in the process where we will make it easier to do research, to fund that research, and to enable compassionate use of these treatments that we will be able to help buildup the evidence base and give us a better understanding of their use in real world settings.

The move from Schedule 1 to Schedule 2 really is pretty small. There is no change in criminal penalties. Other, you know, from misuse or diversion.

Mr. LUTTRELL. You would be surprised how not small that move is on our side.

Mr. WATERS. Well, for the barriers to research, it is significant for compassionate use.

Mr. LUTTRELL. I understand and appreciate the research aspect of it.

Mr. WATERS. Yes.

Mr. LUTTRELL. I am just saying on this side, that is a very large boulder to shove.

Mr. WATERS. I am sure.

Mr. LUTTRELL. I am sorry, go ahead.

Mr. WATERS. There is otherwise, you know, because these are not approved treatments yet, they are not going to be available to be marketed in widespread use. That is certainly where we are hopefully going to be seeing MDMA in very short order, hopefully by early 2025.

Mr. LUTTRELL. Mr. Barrett.

Mr. BARRETT. Thank you for the really important question, Representative Lutrell. I, of course, make no claims to be a policymaker or understand the intricacies therein, but I do acutely understand the barriers to research. I have to say that one of the largest barriers to entry of some of the most qualified scientists in the world to be studying these things is highly tied up in obtaining approval for using Schedule 1 substances in research. The barriers for using Schedules 2 through 5 are far lower.

My understanding was that it would make this not only far more accessible to incredibly qualified researchers who it may be very difficult to access otherwise, but this would speed the process of answering the multitude of very important questions that we still have not answered that have been asked in this panel today, in this hearing, including, well, what about repeated dosing? How long will the effects last? What is the schedule? What is the exact

appropriate dose for a given individual in a given population? What about all of these other compounds? I can go on for days about how many questions we do not have answered.

Frankly, having this move and allowing for greater research before approval would make the post approval world safer, possibly more effective, and possibly easier to implement. Of course, this is speculation, but that is my initial response.

Mr. LUTTRELL. I think there are just so many little nuances that we need to run in breast with each other. If anything gets out in front that should not be, we will lose this like we did back in the 60's. That is not somewhere where we need to be and where we need to go. Thank you for those answers. I will move it over to you for closing statements.

Ms. BROWNLEY. Well, this has been a very important hearing, hopefully the beginning of many more to stay on the trajectory of getting to where we would, I think, all like to get to. I really thank the witnesses here today for, first of all, being here for doing the work that you are all doing to move these therapies forward.

I am a believer but we do need to do more research. We do need to make sure that we have got all of our—that everything is in place. All the, I think, Ms. Mercer, you talked about all of the logistical things that need to get done. I think those are really good suggestions in terms of training and everything else that we can begin to be doing now in anticipation of.

I am just, you know, very, very grateful really to all of you. Sergeant Lubecky, thank you particularly for being here and sharing. It is always, I think, for all of us here, it is really important to hear from our veterans, hear what the impacts are, and your kind of personal assessment of this. I can imagine that as you speak to so many other veterans, how desperate many, many are to have the same kind of experience that you were able to have. It is our obligation to try to meet those needs. Thank you all very much.

Mr. LUTTRELL. Thank you, ma'am. I would like to thank everyone for their participation in today's hearing and for this thoughtful examination of emerging therapies and the potential promise in combating veteran suicide. For many, this is a new and challenging topic, but I hope that this oversight hearing provided the measured discussion vital to ensuring policymakers have the needed background and scientific information with regards to potentially lifesaving therapies.

My colleagues and I are committed to serving our veterans and doing everything possible to move the needle in addressing the suicide and substance abuse crisis. This committee will not shy away from exploring new avenues and approaches in this fight. I appreciate everyone's willingness to come here today and for their input. Above all, thank you for your work serving our veterans. I look forward to the continued achievement and advancements in science and will be watching this space closely in the coming months and years.

The complete written statements of today's witnesses will be entered into the hearing record. I ask unanimous consent that all members have 5 legislative days to revise and extend their remarks and include extraneous material. Hearing no objections, so

ordered. I thank the members and the witnesses for their attendance and the participation today. This hearing is adjourned.

[Whereupon, at 3:48 p.m., the subcommittee was adjourned.]

A P P E N D I X

PREPARED STATEMENTS OF WITNESSES

Prepared Statement of Carolyn Clancy

Good afternoon, Chairwoman Miller-Meeks, Ranking Member Brownley and distinguished Members of the Subcommittee. Thank you for the opportunity today to discuss ongoing clinical trials within the Department of Veterans Affairs (VA) involving emerging therapies, and specifically, psychedelic assisted therapy and immersive technology, like virtual reality that supplements treatment Veteran treatment. Accompanying me today is Dr. Ilse Wiechers, Deputy Executive Director, Office of Mental Health and Suicide Prevention and Dr. Rachel Yehuda, Patient Care Center Director.

VA Psychedelic Research for Post-Traumatic Stress Disorder

VA is committed to studying interventions that promote the health of the Nation's Veterans. In line with this goal, VA conducts studies under stringent protocols at various facilities Nation-wide to identify if compounds such as MDMA (3,4-Methylenedioxy-methamphetamine) and psilocybin in combination with intensive psychotherapy are efficacious in treating Veterans with post-traumatic stress disorder (PTSD), treatment resistant depressive disorder, major depressive disorder and potentially other mental health conditions, such as substance use disorders. VA also continually monitors ongoing psychedelic research outside VA. Based on our assessment of the literature to date, there is still much to learn, and much yet to be understood, about the potential benefits of psychedelic compounds. Our Department is not only focused on finding the best innovative treatments and cures but doing so safely.

While there are several research studies on the use of psychedelic-assisted therapy for the treatment of mental health conditions being conducted at VA facilities, they are funded by outside organizations, not by VA. Medical research with these substances takes place legally through a specific process that involves review of the study protocol by the Food and Drug Administration (FDA) and obtaining a research registration from the Drug Enforcement Administration (DEA). VA complies with all applicable laws in obtaining and using psychedelics in its research studies. While ORD's intramural research program is not currently funding research in this area, the office is closely following the growing research literature and is working with OMHSP determine whether additional studies of psychedelics for Veterans are warranted.

Safety comes first in all of the clinical research conducted within VA. Investigational treatments are delivered in a safe clinical environment using pharmaceutical grade medications under careful quality controls. Potential research participants undergo careful medical and psychiatric screening to make sure it is safe for them to participate. Finally, dosing of psychedelic medication is supported by staff trained in psychedelic-assisted therapy who are knowledgeable to monitor for adverse events and follow clear protocols for using psychotherapy in combination with psychedelic medication.

Psychedelic State of the Art Conference

ORD and OMHSP co-hosted a "State of the Art (SOTA) Conference: Psychedelic Treatments for Mental Health Conditions" in September 2023, to help address two major objectives. The first objective was to better understand the current state of scientific evidence and to identify a strategic framework to consider future psychedelic treatment research for select mental health conditions. The second objective was to determine the necessary next steps for potential VA system-wide clinical implementation for psychedelic compounds for potential future use.

The Psychedelic SOTA Conference took place in two parts. The SOTA virtual seminar occurred September 6–8, 2023, and included speakers from industry, non-VA academia and Veterans' advocacy groups, as well as attendance from Congressional stakeholders and Federal agencies participating in the SOTA Workshop. These seminars provided a summary of the available data on MDMA and psilocybin, informa-

tion about current studies, and stakeholder perspectives, as background for the SOTA Workshop discussions. The SOTA Workshop occurred September 27–28, 2023, in Denver, Colorado. Seventy-two (72) participants included key internal VA stakeholders, clinicians, and psychedelic researchers along with representatives from key partner Federal agencies (such as the National Institutes of Health, FDA, Department of Defense (DOD), Substance Abuse and Mental Health Services Administration, and the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Health). SOTA Workshop attendees were broken into four workgroups for intensive discussion and deliberation on four key areas of strategic planning: Pre-Clinical Research, Clinical Research, Clinical Practice Logistics and Implementation, and System Wide Clinical Decision-Making and Scale. The workgroups provided recommendations for future research directions and potential clinical implementation considerations.

Research Regarding Therapeutic Potential MDMA for PTSD treatment

Two phase 3 trials[1] of MDMA treatment for PTSD have shown statistically significant reductions in PTSD symptoms, with the publication of the second trial just occurring last month. In that most recently published trial, 87 percent of subjects who received MDMA vs. 69 percent of subjects who received a placebo had a clinically meaningful response. The Bronx VA Medical Center was a recruiting site for both of these trials. Although each study is different, all current psychedelic studies within VA are paired with non-drug treatments (that is, psychotherapy). These treatment protocols involve intensive psychotherapy with at least one licensed clinician. Two clinicians were required for MDMA sessions in the Phase 3 trials cited here: **MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study Nature Medicine. Based on a recent review of the literature**, VA and the Department of Defense (DoD) determined the current evidence regarding MDMA as a treatment was insufficient to be included as a recommended treatment in the updated VA/DoD Clinical Practice Guidelines (CPG) for the Management of PTSD and Acute Stress Disorder (ASD); released in June 2023). VA/DoD CPGs follow a rigorous process of reviewing the quality of evidence, the balance of risks and potential benefits, and the feasibility of implementing interventions for PTSD and ASD across health care systems. Primary concerns with the MDMA-assisted psychotherapy data included the small number of Veterans in the trials that had been published (32 Veterans included), and a relatively small number of total participants (176 overall), as well as the use of inactive placebo as a comparison condition. The use of inactive placebo has allowed participants to correctly guess what treatment they received, which can bias results significantly and is a particular problem for a novel treatment with anecdotal support (leading to increased expectation of benefit for the participant). The two studies both used inactive placebos.

One of the key gaps in research identified at the SOTA was the need for more trials conducted with Veterans, specifically with the unique and diverse population of Veterans who receive care through VHA. The issue of needing more rigorous study (such as one that uses an active comparator rather than placebo) in VA patients is important because studies conducted in our population typically show smaller effects than studies conducted outside of VA.

VA Immersive: Virtual Reality for Physical and Mental Well-Being

VA is leveraging immersive technology to test a non-pharmaceutical approach to help Veterans address the day-to-day challenges related to physical and mental well-being. VA recognizes that immersive technology—like virtual reality (VR) and augmented reality (AR)—has the ability to transform care delivery and experience, and VA is focused on efforts to expand its application and evidence-based implementation. Immersive technology leverages the senses of sight, sound and touch to bring a new level of engagement and sense of presence to each Veteran's health care experience. Immersive technology also expands the footprint of the health care system, increasing access by offering Veterans opportunities to receive care at medical care facilities and from the comfort of their home. This technology, when used to supplement care provides a more immersive, engaging experience than traditional telehealth or care by creating more enjoyable therapeutic environments, gamifying the approach, or by transporting the patient to environments otherwise difficult to access in the presence of a clinician. Additionally, it can also provide a means for standardized assessment and metric completion in-device to be shared with the cli-

[1] **MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study Nature Medicine** Mitchell JM et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med. 2021 Jun 27(6):1025–1033.

nician decreasing interrater variability in some instances and allowing VA to better capture Veteran impact. One example of this effort is the potential implementation of VR to aid chronic pain management. Multiple VR-based programs are being evaluated, which have received preliminary approval, and are now being evaluated for higher level approval. One of the VR-based programs is being co-developed with VA and another FDA-authorized treatment for chronic low back pain. Given that experiencing pain is a significant risk factor for suicide among Veterans, this is being pursued as part of VA suicide prevention efforts.

Eliminating Veteran suicide is a top VA priority, and we continue to work diligently across the Department and with Federal, tribal, state and local governments to advance a public health approach to suicide prevention. The VA suicide prevention strategy is guided by the National Strategy for Preventing Veteran Suicide 2018–2028 and is in alignment with the President's 2021 National Strategy for Reducing Military and Veteran Suicide. Part of VA's suicide prevention strategy is to fund innovation through demonstration and special projects to inform promising and best practices with measurable outcomes. Projects are prioritized for their ability to reach specific high-risk/vulnerable Veteran populations. Results from these projects inform potential wider dissemination and implementation of interventions. VA has a robust process in evaluation of these projects. Proposed demonstration project proposals must be time limited (typically 1–2 fiscal years), provide specific background justification including literature review, provide clear and measurable outcomes to evaluate return on investment, include an implementation and evaluation plan, must be aligned with national internal and external suicide prevention strategies and provide a detailed budget for each fiscal year (FY). The project must be used to pilot potential long-term solutions to improve outcomes for Veteran wellness and suicide prevention.

Innovative projects are critical to advance suicide prevention with regards to complex risks associated with suicide, such as pain. Recent data indicates that about 9 percent of Americans who have died by suicide had chronic pain. Furthermore, people with moderate or severe pain are three times more likely to have suicidal ideation, and two to three times more likely to die by suicide than people without pain. Emerging research exists regarding the use of VR to treat a variety of physical and mental health conditions.[2] Ongoing study is needed. Systematic reviews and meta-analysis studies evaluating the evidence for VR-based treatment of acute and chronic pain management and PTSD have returned mixed evidence for treatment and indicate the need for more research in this area (Langener et al., 2021; Wu et al., 2022; Baker et al., 2022; Knaust et al., 2022).

OMHSP and the Office of Health Care Innovation and Learning partnered at the beginning of FY 2023 to develop a pilot program that addresses intersections of suicide as it relates to pain. Specifically, VA established a 60-site pilot that has deployed 300 VR headsets to mental health and non-mental health providers to VAs across the country. This pilot leverages software that is being evaluated for use as a tool to help clinical care teams address chronic pain and or suicidality. This pilot also includes utilization of positive environments to distract from negative stressors and to build positive coping mechanisms and resilience related to chronic pain and mental health diagnoses like development of VR applications to support breathing exercises, sequential muscle relaxation, or other evidence-based complimentary modalities. In addition, it includes co-development of multiple in-vivo exposure environments, like a restaurant or grocery store, to supplement treatment for trauma-related triggers or phobias as Veterans transition into civilian life. This will include data collected regarding ease of use and experience in addition to patient reported outcomes for pain, anxiety, suicidality, pain interference, depression and mood. As of October 2023, over 450 VR sessions have been completed with over 200 unique Veterans being served through this pilot.

Conclusion

When it comes to improving veteran mental health, VA will continue to fully implement the current evidence-based interventions we know works to move forward

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[2] Baker, N. A., Polhemus, A. H., Ospina, E. H., Feller, H., Zenni, M., Deacon, M., DeGrado, G., Basnet, S., & Driscoll, M. (2022). The state of science in the use of virtual reality in the treatment of acute and chronic pain: A systematic scoping review. Clinical Journal of Pain, 38(6), 424–41. https://doi.org/10.1097/AJP.0000000000001029; Cieslik, B., Mazurek, J., Rutkowski, S., Kiper, P., Turolla, A., & Szczepanska-Gieracha, J. (2020). Virtual reality in psychiatric disorders: A systematic review of reviews. Complementary Therapies in Medicine, 52, 102480. https://doi.org/10.1016/j.ctim.2020.102480; Dellazizzo, L., Potvin, S., Luigi, M., & Dumais, A. (2020). Evidence on virtual reality-based therapies for psychiatric disorders: Meta-review of meta-analyses. Journal of Medical Internet Research, 22(8), e20889. https://doi.org/10.2196/20889;

treatment of mental health concerns, while we simultaneously encourage ongoing innovation paired with strong program evaluation and research to assess for new effective interventions. Our Department is not only focused on finding the best innovative treatments and cures but doing so safely. We appreciate the Committee's continued support in this shared mission. Nothing is more important to VA than supporting the health and well-being of the Nation's Veterans and their families. My colleagues and I are prepared to respond to any questions you may have.

Prepared Statement of Jonathan Lubecky

My name is Jonathan Lubecky, and I am an American Veteran. I served four years in the Marines, and upon seeing the Towers fall I joined the North Carolina Army National Guard. I served in Iraq 2005–2006 with Bravo Battery, 5th/113th FA and was medically retired in 2009 after a total of 12 years service.

As a Veteran, I have the privilege to have my trauma be socially acceptable, unlike so many others, because it is easily understood why a Veteran who deployed, whose base was shelled almost daily would have PTSD. As someone who frequently shares their story publicly, I fully understand why many chose not to share such intimately personal details of their trauma.

Most of my story is shared by hundreds of thousands of Veterans. I am but one voice of many. I grew up in a house where my siblings were abused. Where one of my siblings suffered from addiction. Like so many, I left for boot camp because I wanted to help people, and to escape.

After all I saw, and experienced in Iraq had cracked my mental health, I returned home to find my house empty, my dog gone, and my wife living with someone else. So in the early hours of Christmas morning 2006, less than two months after returning home, after going to Sacred Heart Church in Raleigh and being turned away because they were full. Going to Womack Army Medical Center and being told to "come back after the holidays" and I was sent home. I did what 136 Americans, including Veterans, did. I tried to end my life. I put a gun to my head and pulled the trigger. I will forever remember the peace I felt as the hammer fell, because it would all be over. At last. I heard the pop, I thought I was dead, but the pain was still there. It was then that I realized the ammo malfunctioned.

That was the first of 5 suicide attempts that should have been successful. That doesn't include the daily ideation, the hundreds of times I stood on a bridge. Following my last attempt, I was passed a note from an MUSC Intern that said "Google MDMA PTSD", and I did. I discovered that MAPS PBC was conducting a clinical trial in Mt Pleasant, SC just across the bridge. I was the 26th person in a 25 person study of Veterans & First Responders. I was able to participate because someone else was healed after 1–2 sessions, and declined further treatment, so it could be expanded to include me. I went through a clinical trial lasting about 4 months. I took MDMA and sat with trained therapists for 8 hrs only three times. To be clear, I have only taken MDMA three times in my life, 9 years ago.

The MDMA doesn't fix anything. Like Anesthesia, it puts the mind, body and spirit in the place it needs to be so the therapy can work. Much like when I was given fentanyl, prior to my back surgery, the anesthesia didn't fix my back, the surgeon did. For the first time I was able to freely talk about my demons, without my body betraying me. And with the help of Michael and Annie Mithoefer I not only worked through my trauma from Iraq, but my whole life, and excised those demons, for good.

The VA in their formulary currently has exceptionally powerful drugs such as Ketamine, Fentanyl, and long list used as anesthesia that the VA has been able to properly handle and use in a medical environment. MDMA-Assisted therapy is the same, and likely objectively safer than many of those drugs.

And through a guiding hand, I have been placed in circumstances where if I was not healed, I would crack.

For example, attempting to rescue a drowning victim in my backyard, attempting to save a gunshot victim in Charleston, and most recently providing humanitarian aid on the front lines of the Ukraine/Russia war.

I am not special. My story is the same as every other Veteran suffering with PTSD, my story changes because I went through MDMA Assisted Therapy. I was blessed by being able to participate in a clinical trial. Most Veterans face the choice of leaving the country that sent them to war, the country they love, and have shown they will die for, so they can heal, because otherwise they will sacrifice their life for this great country far from a battlefield, at home, alone, in the dark.

Veterans Exploring Treatment Solutions (or VETS) provides scholarships to do just this. VETS receives thousands of applications annually, and can only send 230–

250 people per year. They specifically focus only on Special Operations Personnel. So far they've helped almost 1,000 Special Operators get access to psychedelic treatments, and 100 percent of those surveyed say they'd recommend the treatment to other veterans. The only entity that can ensure that ALL Veterans have access to the same treatment I went through in a safe and effective manner, with trained therapists and medicinal grade substances, is the VA.

I measure my failures by a list of people I know who have committed suicide. It hangs on my fridge. We as a Nation have left these Veterans to suffer, we have left them behind. It is beyond time for this country to mean it when they say "we don't leave anyone behind" and ensure that there are more sons and daughters, mothers and fathers, and fewer loved ones left with nothing but a folded flag, because I know that the sole reason my son has a father instead of a folded flag is because I went through MDMA Assisted therapy. Every Veteran who is suffering from PTSD and is at risk of suicide should have access to the treatment I received by going to he VA. I vehemently oppose the idea that you can achieve the same results that I did by removing the therapeutic component, and using untested and potentially lethally tainted drugs. Veterans have earned the right to heal, by doing what this august body asked them to do, it is unconscionable to prohibit research given where the science and evidence currently sits.

Every time I made the choice to end my life it was because I had lost all hope of a better day. Hope of a day like I now have everyday. Because I share my story publicly, I often have Veterans reach out begging for help, for access to the treatment I went through that saved my life. I am now begging the Veterans on this committee, and for the whole of Congress to please, give them hope of a better day, we all know it won't be tomorrow, but I beg for you to give them hope of some day.

I thank you for this opportunity and stand ready to answer any questions.

Biography

Jonathan M. Lubecky, U.S. Army SGT(R) , is the founder of Lubecky Strategic Direction, Legislative Director for Veterans Exploring Treatment Solutions, and VP Communications at Apollo Pact. He is a 12-year retiree of the U.S. Armed Forces, serving in both the Marine Corps and the Army. He has been a freelance journalist since 2014. Since 2016 he has been a Strategic Communications & Governmental Affairs Consultant advocating for psychedelic medicine and Veterans. Jonathan returned from a deployment to Iraq in 2006. Shortly after returning, he was diagnosed with posttraumatic stress disorder (PTSD) and a traumatic brain injury. While battling PTSD, enduring multiple forms of treatment, and taking dozens of pills per day to manage symptoms, he attempted to take his life five times. While recovering from that fifth attempt in the hospital, he was surreptitiously instructed to "Google MDMA PTSD". Beginning exactly 8 years after being released from active duty from Iraq, Jonathan began MDMA-assisted therapy in a MAPS Phase 2 study and completed the protocol in early 2015. As of **November 22, 2022 he has been healed of PTSD as long as he had PTSD**

Jon was appointed the National Veterans Director for the Rand Paul for President campaign. Realizing the potential of psychedelic medicine to heal his fellow veterans and the millions of Americans suffering as he once did, he has been involved in media, politics, and government affairs, with a focus on the Department of Defense, Department of Veterans Affairs, and Media ever since receiving MDMA therapy. Jonathan graduated with honors from The Citadel in Charleston, South Carolina, as a Veteran Day Student. He has a bachelor's in political science with a concentration in international politics and military affairs with a minor in intelligence analysis. He is based in Washington D.C.

Prepared Statement of Frederick Barrett

Chairman Miller-Meeks, Ranking Member Brownley, and Members of the Subcommittee, thank you for opportunity to testify before you today.

I am Dr. Frederick Barrett, PhD, Associate Professor of Psychiatry and Behavioral Science, Associate Professor of Neuroscience, and Associate Professor of Psychological and Brain Sciences at the Johns Hopkins University School of Medicine. I am also the Director of the Johns Hopkins Center for Psychedelic and Consciousness Research. I am also a standing member of the Johns Hopkins Medicine Institutional Review Board, co-chair of the Psychedelics Task Group of the National Network of Depression Centers, editorial board member of the academic journal Psyche-

delic Medicine, and author of over 40 peer-reviewed scientific articles on psychedelic drugs.

I am providing testimony today as an individual, and not as a representative of any institution. The following views are my own, and do not necessarily reflect those of Johns Hopkins University or Johns Hopkins Medicine.

I have been conducting human research with psychedelic drugs in healthy individuals and patients with mood and substance use disorders at Hopkins for over 10 years. This program of research began in 1999, with the approval of one of the first human psilocybin studies in the modern era, led by my mentor, Dr. Roland Griffiths. This study not only demonstrated that psilocybin could be safely administered in a laboratory setting, but it demonstrated that carefully screened and appropriately supported healthy individuals could benefit from ingesting of psilocybin in a controlled setting. This study, published in 2006, is widely recognized as the study that reignited academic and medical interest in psilocybin. Since then, peer-reviewed empirical reports of clinical trials have been published testing the safety and potential efficacy of psilocybin and closely related compounds to treat patients with tobacco use disorder, alcohol use disorder, headache disorders, existential dread associated with a terminal cancer diagnosis, obsessive compulsive disorder, complex trauma, anxiety, and importantly major depressive disorder and treatment resistant depression, and there are many more clinical trials currently under way to study the effects of psilocybin in these and many other psychiatric disorders. Of note, two FDA-regulated, multi-site, phase 3 registration trials are currently under way to determine the effects of psilocybin in patients with mood disorders. Successful trials may lead to FDA approval of psilocybin to treat depression. We also come at a time when the FDA is considering whether to approve a related compound, MDMA, for the treatment of patients with post-traumatic stress disorder. Depression, substance use disorder, PTSD, and trauma more broadly are not only leading causes of disability in the United States and around the world, but they are particularly vexing illnesses that are plaguing our veterans. I urge the committee to do everything in their power to facilitate the careful and thoughtful implementation of these therapies and importantly the expansion of access to these therapies to all veterans in the event that they receive FDA approval. Such expansion and access may also pave the way for greater expansion and access to care givers, family members, loved ones, and those in the community who are impacted by the suffering of our nation's best, who are willing to sacrifice their lives to defend our freedoms.

Studies of the safety and potential medical efficacy of psychedelic drugs have now been spearheaded or sponsored and conducted by Hopkins as well as a small number of other academic medical institutions and private entities. These studies are building a growing record of information demonstrating both the relative safety and potential efficacy of psychedelic therapies in a wide range of psychiatric indications. These studies have been funded nearly entirely by private philanthropy. Our center at Hopkins was founded by a 17-million-dollar gift from the Steven and Alexandra Cohen Foundation as well as from Tim Ferriss, Matt Mullenweg, Craig Nerenberg, and Blake Mycoskie – philanthropists who had the wisdom, vision, and capacity to establish our center and provide support to our now more than 40 professionals, including faculty, therapists, and staff, who now continue this important work. Only recently has the National Institute on Drug Abuse and the National Center for Complementary and Integrative Health come through with a notable grant for the investigation of clinical use of psychedelics.

Evidence to date demonstrates the relative safety of psychedelic drugs for appropriately screened individuals in controlled settings. Psilocybin, for instance, is known to evoke a modest but reliable increase in heart rate and blood pressure. Risks of increased blood pressure and heart rate are mitigated in research by screening out those with substantial cardiac abnormalities. The most apparent risks of psilocybin are psychological. These risks are mitigated by screening out individuals who have a personal or family history of psychosis or mania. These risks are further mitigated by careful counseling and preparation by trained therapists who then accompany a study participant during the 4–6 hours of acute subjective effects of a high dose of psilocybin. Participants then undergo debriefing followed by aftercare and therapy for the days and weeks following their experience. With these procedures in place, we have safely administered over 800 doses of psilocybin to well over 400 individuals since 1999.

To conduct this research, investigators must assemble an expert team including physicians, therapists, often pharmacists, regulatory specialists, and other scientists to first tackle the substantial regulatory burden that precedes any drug administration. We first seek the approval of our institution review boards, and we also submit an Investigational New Drug application to the FDA. With institutional and FDA permissions in hand, we then must apply for DEA approval. This regulatory process

takes us an average of about 9–12 months from first regulatory submission to approval to receive drug product and begin our research. This process is onerous and arduous at best, and while ultimately surmountable, provides a substantial barrier to entry even to seasoned senior scientists with valuable contributions to make who have not yet begun conducting psilocybin research. Given the barriers to entry, work in this area is currently still limited to large and expansive academic medical institutions who can secure private philanthropic support that will not only fund the research, but that will also provide funding and support for over a year's worth of professional effort for a team of investigators to simply file the paperwork to attempt to begin. Given the promise and prospect of our current findings, as well as the myriad questions that still need to be addressed within this field, I believe that greater access should be given to qualified investigators who want to contribute with new and rigorous research, and that we re-evaluate whether that barriers that have been put in place to protect our public from the most dangerous compounds really apply appropriately to psychedelic compounds.

As we anticipate approval of psychedelic drugs as medicine by the FDA, we are also faced with numerous questions that have yet to be answered. These include whether the current treatment paradigms are optimal for all psychiatric or medical indications. Will some disorders require higher or lower doses of psilocybin or MDMA for treatment? Will some individuals require follow-up or repeated visits? How well can we integrate models from group therapy into a paradigm that currently relies on one-to-one therapy or a one-to-two relationship between patient and a therapist dyad? How can we predict who will respond well and who will not respond to treatment, and can we optimize the delivery of care to maximize the chances that someone will have a therapeutic response? When rolling out MDMA and psilocybin therapies, these questions will be present in the minds of the clinicians on the front lines who are delivering this care. Answering these questions will only serve to further benefit the veterans who will receive access to this care.

One striking question that is imminent upon FDA approval is how best to train clinicians to deliver this new therapy. Current FDA requirements include that at least one of the therapists be a licensed mental health practitioner, but qualifications, background, and training are not specified any further. We at the Johns Hopkins Center for Psychedelic and Consciousness Research are exploring these and other implementation questions now and in the future, but more attention must be paid to this critical element of the entire care package, and this must specifically be addressed as these therapies are offered to veterans.

While incredibly promising, psychedelic science is still underfunded, hidden behind restrictive regulatory barriers, and importantly not well understood by clinicians, policymakers, and the general public unless those individuals are deeply immersed in the field. There are clear next steps that can be taken to address these deficits.

I urge the representatives of this committee to support programs that will allow for the education of at least stakeholders, if not the general public, about the risks and potential therapeutic benefits of psychedelics. This comes in the context of many local ballot initiatives and proposed state legislation that seeks to increase access to psychedelics despite current federal regulations. Educational initiatives will help to ensure that we can move forward not only with informed and appropriate policy, but with an informed electorate and society.

I urge the representatives of this committee to consider funding initiatives that will not only foster a greater level of investment in psychedelic research in the VA, but also more broadly within academic medicine, as fundamental questions regarding dose, delivery, training, and optimization will help veterans as well as the broader base of patients in this country. Funding support will be necessary if we are to have any chance of answering these questions.

Finally, I urge the representatives of this committee and the House to support the bicameral Breakthrough Therapies Act, introduced by representatives Mace and Dean, as well as senators Paul and Booker. This act proposes that Schedule 1 compounds that are granted "breakthrough therapy designation" by the FDA be automatically re-scheduled to Schedule 2. Schedule 1 compounds are defined as drugs with no currently accepted medical use and a high potential for abuse. FDA breakthrough designation is granted to drugs that are intended to treat a serious condition, where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy. It is inordinately more difficult to study Schedule 1 compounds than compounds in any other schedule. FDA acknowledgement of preliminary evidence of medical benefit should justify movement of a drug to Schedule 2, which would substantially ease the burden of academic research into these compounds, especially in the case of psilocybin and MDMA, while not substantially increasing risk to the public.

Thank you for this opportunity to speak with you on a topic that I believe has such great import and relevance to the health and welfare of our nation's veterans, as well as our country as a whole.

Prepared Statement of Mike Mullette

Chairwoman Miller-Meeks, Ranking Member Brownley, and Members of the subcommittee, thank you for the opportunity to offer this statement for the record. As the Chief Operating Officer of MAPS PBC, I sincerely appreciate your leadership in holding this first of its kind hearing on emerging therapies and their potential for treating Veterans suffering from PTSD and other mental health conditions.

MAPS Public Benefit Corporation ("MAPS PBC") is a clinical-stage company focused on developing prescription psychedelics to bring new options to those living with mental health conditions. Based in San Jose, California, MAPS PBC has completed two phase 3 clinical trials evaluating investigational 3,4-methylenedioxymethamphetamine-assisted therapy (MDMA-assisted therapy) as a potential treatment for post-traumatic stress disorder (PTSD), both of which met their pre-specified primary and secondary endpoints.[1] Founded in 2014, MAPS PBC is a subsidiary of the Multidisciplinary Association for Psychedelic Studies, a 501(c)(3) non-profit organization changing the way mental health conditions are treated.

Background on MDMA-AT

MDMA (3,4-methylenedioxy-methamphetamine) is an entactogen – a class of psychoactive drugs that produce experiences of emotional communion, oneness, relatedness, emotional openness and are thought to have use for various medical conditions.[2] In the 1960's and 1970's, MDMA was used in conjunction with psychological therapy by mental health providers to enhance patients' access, processing, and communication of difficult emotions and experiences.[3] In 1985, the U.S. Drug Enforcement Agency ("DEA") made MDMA a Schedule I drug under the Controlled Substances Act preventing it from being used for recreational or medical use.[4] Since then, research has shown the unique properties of MDMA allow it to act as a catalyst to support psychotherapy by helping attenuate the brain's fear response allowing patients to access and process painful memories without being overwhelmed.[5] With a growing body of evidence supporting the potential medical use of MDMA, in 2017 the U.S. Food and Drug Administration ("FDA") granted MDMA-assisted therapy Breakthrough Therapy designation, a process designed to expedite the development and review of drugs intended to treat serious conditions and that preliminary clinical evidence indicates that it may demonstrate substantial improvement over available therapies. MAPS PBC expects to submit a new drug application including data from two Phase 3 studies (MAPP1 and MAPP2) that showed clinically significant improvements in PTSD symptoms following acute treatment with MDMA-assisted therapy to the FDA in 2023. If approved by the FDA, the DEA would reschedule MDMA from a Schedule I drug, making it available for prescription medical use. MDMA-assisted therapy is also being studied in other indications.[6, 7, 8, 9]

Background on PTSD

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[9] ClinicalTrials.gov Identifier: NCT05584826

PTSD is a mental health condition affecting approximately 13 million Americans each year[10], yet currently available treatments only provide moderate efficacy.[11] People with PTSD can experience debilitating symptoms that impact nearly all areas of a person's life.[12] They also frequently experience comorbidities including anxiety, depression, and substance use disorder.[13] PTSD has an enormous economic impact resulting in an annual burden of over $200 billion.[14] Currently available treatments for PTSD are inadequate to address the full spectrum of patients who need treatment and may not provide adequate relief from debilitating symptoms.[15] These limitations combined with high treatment discontinuation rates in psychotherapy underscore the urgent need for novel and effective therapies.[16] Moreover, PTSD disproportionately impacts Veterans. According to the U.S. Department of Veterans Affairs' National Center for PTSD, 7 out of every 100 Veterans (7 percent) will have PTSD at some point in their life.[17]

Critical Mission Ahead

MAPS PBC's mission to alter the way mental health conditions are treated is personal for me. For the past two decades I have seen my wife, who is a therapist, struggle to find effective solutions for her patients with PTSD. I joined this company with a goal to help healthcare providers like her and their patients have access to new treatment options. As you are aware, there has not been significant innovation in the treatment of PTSD in decades. Despite growing mental health needs, development of new treatments has been slow, and the complexities of treating PTSD have grown. People with PTSD frequently experience comorbidities including anxiety, depression, and substance use disorder.

At MAPS PBC we have made significant progress researching a new investigational treatment for PTSD known as MDMA-assisted therapy. This investigational acute treatment entails a unique combination of medicine and talk therapy. While MDMA-assisted therapy is novel, the components are not new. Both prescription treatments and talk therapy are currently used to treat mental health conditions. What is unique is using them together. In our clinical studies, the participants received either MDMA and therapy or placebo and therapy three times over a twelve-week period, with three therapy sessions prior to commencing the medication sessions and three therapy sessions after concluding the medication sessions (for a total of nine therapy sessions).

Both of our phase 3 clinical trials evaluating investigational MDMA-assisted therapy as a potential treatment for PTSD, met their pre-specified primary and secondary endpoints. The results of the most recent Phase 3 study, MAPP2, were published in the September issue of *Nature Medicine*.[18] In that study, participants in the MDMA-assisted therapy group experienced a significant reduction in PTSD symptoms versus participants receiving placebo with therapy. This was measured by a change from baseline at 18 weeks in Clinician-Administered PTSD Scale for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (CAPS–5) score—the gold standard in PTSD measurement.[19] MDMA-assisted therapy also sig-

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[15] Morina N. Remission from post-traumatic stress disorder in adults: a systematic review and meta-analysis of long term outcome studies. Clin Psychol Rev. (2014) Apr;34(3):249–55. doi: 10.1016/j.cpr.2014.03.002.

[16] Varker T. Dropout from guideline-recommended psychological treatments for posttraumatic stress disorder: A systematic review and meta-analysis. Journal of Affective Disorders Reports (2021) Apr 2021, 100093. doi: 10.1016/j.jadr.2021.100093

[17] VA National Center for PTSD. US Department of Veterans Affairs. Accessed October 17, 2023. https://www.ptsd.va.gov/understand/common/common__veterans.asphttps://www.ptsd.va.gov/understand/common/common__veterans.asp

[18] Mitchell JM, Ot'alora MG. et al. MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial. Nat Med. 2023 Sept 14 doi: 10.1038/s41591–023–02565–4

[19] See more information from the VA's National Center for PTSD at https://www.ptsd.va.gov/professional/assessment/adult-int/caps.asp.

nificantly reduced clinician-rated functional impairment which was measured by a change from baseline in the modified Sheehan Disability Scale (SDS). This scale measures impairment in functioning in three areas: work, social life, and family life. No serious adverse events were reported in either the MDMA group or the placebo control group.

Just last week I had the honor of spending time with a trial participant who is a former Naval Academy graduate. When asked why he had been interested in participating in our study he shared that despite exceptional success in the military he had struggled with suicidal thoughts and what eventually was diagnosed as PTSD for many years, not just due to combat trauma but because of many factors throughout his life. He said he tried many other things, but he felt despondent and hopeless and was desperate for some relief. While the safety and efficacy of MDMA-assisted therapy has not been demonstrated and it has not been approved by the FDA, this participant shared that he hopes other veterans have access to potential treatment options if they are approved. He hears from many of them on a regular basis and knows they feel desperate for new options to be available in the VA medical system rather than having a growing number of Veterans feel forced to seek treatment for their PTSD outside the United States.

At present MAPS-PBC is aggregating all data and preparing our new drug application for submission to the FDA by year end. If successful, we anticipate MDMA-assisted therapy for the treatment of PTSD could be approved by the FDA next year, making it the first emerging therapy of its kind available to patients suffering from PTSD.

The Veterans Administration has the opportunity to create innovative care models to ensure treatments for PTSD are scalable, accessible and, importantly, covered in a timely manner for veterans in need.

Thank you again for your leadership on this issue, and your continued commitment to the health and safety of Veterans. I am happy to respond to any questions the Committee may have.

Mike Mullette

Prepared Statement of Rajeev Ramchand

Testimony

RAJEEV RAMCHAND

Improving Treatment Outcomes for Veterans with Mental Health Conditions

Strengthening the Evidence Base for and Considering Barriers to Psychedelic-Assisted Therapies

CT-A3043-1
Testimony presented before the U.S. House Committee on Veterans' Affairs, Subcommittee on Health, on October 19, 2023

For more information on this publication, visit www.rand.org/t/CTA3043-1.

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Published by the RAND Corporation, Santa Monica, Calif.

Improving Treatment Outcomes for Veterans with Mental Health Conditions: Strengthening the Evidence Base for and Considering Barriers to Psychedelic-Assisted Therapies

Testimony of Rajeev Ramchand[1]
The RAND Corporation[2]

Before the Committee on Veterans Affairs
Subcommittee on Health
United States House of Representatives

October 19, 2023

Chairwoman Miller-Meeks, Ranking Member Brownley, and members of the subcommittee, thank you for your invitation to testify today. My name is Dr. Rajeev Ramchand. I am a senior policy researcher at the nonprofit, nonpartisan RAND Corporation. I am an epidemiologist, and my research focuses on improving the mental health of service members and veterans, as well as their families and caregivers. My comments today are based on research conducted within the RAND Drug Policy Research Center and the RAND Epstein Family Veterans Policy Research Institute, where I serve as codirector. I would be remiss not to acknowledge a friend and veteran, Dylan Tete, and a family member, Michael Pollack, who long before it was "in vogue" encouraged me to consider the potential role of psychedelic compounds for assisting those with mental health conditions.

My colleagues on the panel will discuss the potential therapeutic benefits that psychedelics hold for helping veterans with posttraumatic stress disorder (PTSD) and other mental health conditions. My comments will focus on two adjacent yet critical areas for policymakers to consider as we learn more about the benefits and risks associated with these treatments.

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First, we have a tremendous amount to learn about the potential therapeutic benefits of psychedelic treatment. I will argue that continued federal investment in research and improving scientists' access to psychedelic drugs for research studies are critical for discovering treatment options that reach more veterans and yield greater reductions in their mental health symptoms.

Second, we should be having more conversations like the one we are having here today to develop sound policy solutions that surmount potential barriers to veterans' ability to access psychedelic treatments if and when they become available. In my testimony, I will focus on three components to access that we should be preparing for: (1) how the cost of psychedelic treatment will affect access, (2) whether the U.S. Department of Veterans Affairs (VA) should provide psychedelic treatment directly or outsource such care, and (3) what kinds of safety rails are needed to ensure that veterans receive the highest-quality care.

Research Funding Is Needed to Identify New Treatment Options to Reach More Veterans and Produce Greater Improvements

Let me be clear: There are good treatments currently available for veterans with mental health conditions like PTSD. At the top of that list are prolonged exposure therapy, cognitive processing therapy, and eye movement desensitization and reprocessing, often referred to as EMDR. VA prioritizes these three treatments in its clinical practice guidelines because rigorous research has demonstrated that these treatments yield the best outcomes to date.[3] Prioritizing evidence-based treatments may, in part, explain why the clinical quality of mental health care provided in VA is often better than non-VA care.[4]

This does not mean, however, that we should not invest in new, promising treatments. The psychotherapies with the strongest evidence behind them work, but they do not work for everyone. In even the most stringent of experimental settings, between 18 and 30 percent of patients drop out of these three treatments,[5] and dropout rates may be higher among veterans.[6] Around one-quarter to one-third of veterans with PTSD who receive these treatments do not

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[3] U.S. Department of Veterans Affairs and U.S. Department of Defense, *VA/DoD Clinical Practice Guideline for Management of Posttraumatic Stress Disorder and Acute Stress Disorder*, U.S. Government Printing Office, 2023.

[4] Eric A. Apaydin, Neil M. Paige, Meron M. Begashaw, Jody Larkin, Isomi M. Miake-Lye, and Paul G. Shekelle, "Veterans Health Administration (VA) vs. Non-VA Healthcare Quality: A Systematic Review," *Journal of General Internal Medicine*, Vol. 38, No. 9, July 2023; Claire O'Hanlon, Christina Huang, Elizabeth Sloss, Rebecca Anhang Price, Peter Hussey, Carrie Farmer, and Courtney Gidengil, "Comparing VA and Non-VA Quality of Care: A Systematic Review," *Journal of General Internal Medicine*, Vol. 32, No. 1, January 2017; Amal N. Trivedi, Sierra Matula, Isomi Miake-Lye, Peter A. Glassman, Paul Shekelle, and Steven Asch, "Systematic Review: Comparison of the Quality of Medical Care in Veterans Affairs and Non-Veterans Affairs Settings," *Medical Care*, Vol. 49, No. 1, January 2011.

[5] Catrin Lewis, Neil P. Roberts, Samuel Gibson, and Jonathan I. Bisson, "Dropout from Psychological Therapies for Post-Traumatic Stress Disorder (PTSD) in Adults: Systemic Review and Meta-Analysis," *European Journal of Psychotraumatology*, Vol. 11, No. 1, 2020.

[6] Paula P. Schnurr, Kathleen M. Chard, Josef I. Ruzek, Bruce K. Chow, Patricia A. Resick, Edna B. Foa, Brian P. Marx, Matthew J. Friedman, Michelle J. Bovin, Kristina L. Caudle, et al., "Comparison of Prolonged Exposure vs Cognitive Processing Therapy for Treatment of Posttraumatic Stress Disorder Among US Veterans: A Randomized Clinical Trial," *JAMA Network Open*, Vol. 5, No. 1, January 2022.

respond to them, and more than half retain a diagnosis of PTSD even after they complete treatment.[7]

This evidence points to a pressing need for treatments that work for more veterans and that yield better outcomes. Psychedelics are part of the menu of options that may help us reach this potential. They are among a suite of options that are being studied to improve mental health conditions. These options include improved care delivery models (for example, massed treatments that offer therapy sessions more frequently than once per week or that encompass peer support specialists or virtual therapy[8]), new types of psychotherapies (for example, written exposure therapy[9]), novel clinical procedures (for example, stellate ganglion block[10]), and other pharmacotherapies (for example, ketamine or riluzole[11]).

Researchers should not only investigate these treatments in isolation but should consider how they can complement each other to achieve treatment success. Different regimens should be tested under experimental conditions using advances in statistical methods, such as sequential, multiple assignment, randomized trials.[12] These designs replicate real-world conditions and provide mental health practitioners with evidence-based guidance on substituting, augmenting, or complementing one treatment with another. It is critical that providers are empowered with evidence like this to guide the care decisions they are required to make rather than relying on their intuition to make ad hoc decisions on a case-by-case basis.

Continued federal investment in research is necessary to discover treatments that work for more veterans and that yield better outcomes. This includes adequate funding to entities like the National Institute of Mental Health, the National Institute on Drug Abuse, VA, the Department

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[7] Schnurr et al., 2022.

[8] Alan L. Peterson, Tabatha H. Blount, Edna B. Foa, Lily A. Brown, Carmen P. McLean, Jim Mintz, Richard P. Schobitz, Bryann R. DeBeer, Joseph Mignogna, Brooke A. Fina, et al., "Massed vs Intensive Outpatient Prolonged Exposure for Combat-Related Posttraumatic Stress Disorder: A Randomized Clinical Trial," *JAMA Network Open*, Vol. 6, No. 1, January 2023; Melba A. Hernandez-Tejada, Wendy Muzzy, Matthew Price, Stephanie Hamski, Stephanie Hart, Edna Foa, and Ron Acierno, "Peer Support During In Vivo Exposure Homework to Reverse Attrition from Prolonged Exposure Therapy for Posttraumatic Stress Disorder (PTSD): Description of a Randomized Controlled Trial," *Trials*, Vol. 21, 2020.

[9] Denise M. Sloan, Brian P. Marx, Ronald Acierno, Michael Messina, and Travis A. Cole, "Comparing Written Exposure Therapy to Prolonged Exposure for the Treatment of PTSD in a Veteran Sample: A Non-Inferiority Randomized Design," *Contemporary Clinical Trials Communications*, Vol. 22, June 2021.

[10] Kristine L. Rae Olmsted, Michael Bartoszek, Sean Mulvaney, Brian McLean, Ali Turabi, Ryan Young, Eugene Kim, Russ Vandermaas-Peeler, Jessica Kelley Morgan, Octav Constantinescu, et al., "Effect of Stellate Ganglion Block Treatment on Posttraumatic Stress Disorder Symptoms: A Randomized Clinical Trial," *JAMA Psychiatry*, Vol. 77, No. 2, February 2020.

[11] Adriana Feder, Sara Costi, Sarah B. Rutter, Abigail B. Collins, Usha Govindarajulu, Manish K. Jha, Sarah R. Horn, Marin Kautz, Morgan Corniquel, Katherine A. Collins, et al., "A Randomized Controlled Trial of Repeated Ketamine Administration for Chronic Posttraumatic Stress Disorder," *American Journal of Psychiatry*, Vol. 178, No. 2, February 2021; Patricia T. Spangler, James C. West, Catherine L. Dempsey, Kyle Possemato, Danielle Bartolanzo, Pablo Aliaga, Carlos Zarate, Jr., Meena Vythilingam, and David M. Benedek, "Randomized Controlled Trial of Riluzole Augmentation for Posttraumatic Stress Disorder: Efficacy of a Glutamatergic Modulator for Antidepressant-Resistant Symptoms," *Journal of Clinical Psychiatry*, Vol. 81, No. 6, 2020.

[12] Kelley M. Kidwell and Daniel Almirall, "Sequential, Multiple Assignment, Randomized Trial Designs," *JAMA*, Vol. 329, No. 4, January 24/31, 2023.

of Defense, the Congressionally Directed Medical Research Programs, the Agency for Healthcare Research and Quality, and the Patient-Centered Outcomes Research Institute. Research funding for mental health conditions has historically fallen short of the estimated burden attributed to them.[13] Arguably, the need for treatments has never been greater: Rates of depression and anxiety were increasing even before the coronavirus disease 2019 pandemic,[14] and the United States continues to confront both suicide and overdose crises.[15] Federal investment in treatment for conditions, such as PTSD, that disproportionately affect veterans is even more important because, in many cases, these conditions are attributed directly to traumas experienced in service to the nation.[16] It is also necessary because private funding for novel therapies for mental health conditions is waning.[17] This may be partly because many of the more promising natural psychedelic molecules have been around long enough that some question if they have any patent or profit potential.[18]

In addition to investing in research, Congress can expedite this research by making the process for conducting research on psychedelic compounds more efficient. Many of the most promising psychedelic compounds, including MDMA and psilocybin, are classified as Schedule I drugs, requiring researchers to register with the Drug Enforcement Administration for permission to use them and comply with the necessary security regulations. As Director of the National Institute on Drug Abuse Dr. Nora Volkow recently testified, these steps are notoriously time-consuming, confusing, and expensive for researchers,[19] resulting in delays in the evidence we need to maximize the benefits these treatments may offer. In 2021, the White House proposed provisions to facilitate research on Schedule I drugs;[20] provisions like these would

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[13] Daniel Arias, Shekhar Saxena, and Stéphane Verguet, "Quantifying the Global Burden of Mental Disorders and Their Economic Value," *The Lancet*, Vol. 54, December 2022.

[14] A. H. Weinberger, M. Gbedemah, A. M. Martinez, D. Nash, S. Galea, and R. D. Goodwin, "Trends in Depression Prevalence in the USA from 2005 to 2015: Widening Disparities in Vulnerable Groups," *Psychological Medicine*, Vol. 48, No. 8, June 2018; Renee D. Goodwin, Andrea H. Weinberger, June H. Kim, Melody Wu, and Sandro Galea, "Trends in Anxiety Among Adults in the United States, 2008–2018: Rapid Increases Among Young Adults," *Journal of Psychiatric Research*, Vol. 130, November 2020.

[15] Mark Olfson, Rajeev Ramchand, and Michael Schoenbaum, "Tempering Optimism Concerning the Recent Decline in US Suicide Deaths," *JAMA Psychiatry*, Vol. 79, No. 6, June 2022; Centers for Disease Control and Prevention, "Understanding Drug Overdoses and Deaths," webpage, May 8, 2023, https://www.cdc.gov/drugoverdose/epidemic/index.html.

[16] Rajeev Ramchand, Rena Rudavsky, Sean Grant, Terri Tanielian, and Lisa Jaycox, "Prevalence of, Risk Factors for, and Consequences of Posttraumatic Stress Disorder and Other Mental Health Problems in Military Populations Deployed to Iraq and Afghanistan," *Current Psychiatry Reports*, Vol. 17, No. 5, May 2015.

[17] Joshua R. Wortzel, Brandon E. Turner, Brannon T. Weeks, Christopher Fragassi, Virginia Ramos, Thanh Truong, Desiree Li, Omar Sahak, and Hochang Benjamin Lee, "Trends in Mental Health Clinical Research: Characterizing the ClinicalTrials.gov Registry from 2007–2018," *PLOS One*, Vol. 15, No. 6, 2020.

[18] Sara Reardon, "What's Next for MDMA in Psychiatry?" *Nature*, Vol. 616, April 20, 2023b.

[19] Nora D. Volkow, "The Overdose Crisis: Interagency Proposal to Combat Illicit Fentanyl-Related Substances," testimony before the Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives, National Institute on Drug Abuse, December 2, 2021.

[20] White House, "Biden-Harris Administration Provides Recommendations to Congress on Reducing Illicit Fentanyl-Related Substances," press release, September 2, 2021.

expedite research into psychedelic-assisted therapy and help get novel treatments to veterans struggling with debilitating mental health conditions.

Policy Solutions Are Needed to Address Potential Barriers to Veterans' Ability to Access Psychedelic Treatments If and When They Become Available

Currently, the psychedelic drug closest to receiving approval from the U.S. Food and Drug Administration (FDA) is MDMA, for the treatment of PTSD, so I will focus my comments on access to this treatment. The most recent Phase 3 MDMA treatment protocol entails 15 or more clinical visits over three to four months,[21] three of which include taking MDMA. The sessions without receiving MDMA are around 90 minutes each. The three visits with MDMA are six to eight hours each and often include an overnight stay. Each of the sessions is led by a psychotherapy pair that includes at least one licensed provider; in addition, one person at the site must be licensed to manage and administer controlled substances.[22] Except for the three sessions in which MDMA is administered, the treatment protocol is comparable in treatment duration and session length to that of current evidence-based treatments for PTSD, including prolonged exposure,[23] cognitive processing,[24] and EMDR.[25]

If granted FDA approval, MDMA will have federally recognized medical value. Such recognition presents tremendous opportunities for veterans with PTSD to benefit from this care. But how will they get it? Veterans access mental health treatment from VA or from non-VA community-based providers. It can be paid for by VA, other public or private insurance, philanthropic sources, or veterans themselves. A veteran's eligibility, preferences, and resources dictate where they get care and how they pay for it. This means that U.S. policies need to consider and address all these potential care pathways. And across all care pathways, these policies should consider issues of cost, availability, and quality.

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[21] There were 15 psychotherapy sessions in the most recent Phase 3 clinical trial (Jennifer M. Mitchell, Marcela Ot'alora G., Bessel van der Kolk, Scott Shannon, Michael Bogenschutz, Yevgeniy Gelfand, Casey Paleos, Christopher R. Nicholas, Sylvestre Quevedo, Brooke Balliett, et al., "MDMA-Assisted Therapy for Moderate to Severe PTSD: A Randomized, Placebo-Controlled Phase 3 Trial," *Nature Medicine*, September 14, 2023). The Multidisciplinary Association for Psychedelic Studies (MAPS) website also says that there are 15 sessions (Multidisciplinary Association for Psychedelic Studies, "MDMA-Assisted Therapy for PTSD," webpage, undated, https://maps.org/mdma/ptsd/). However, a MAPS consent form for participation in the clinical trial indicates 17 visits (Multidisciplinary Association for Psychedelic Studies, subject information and consent form for study titled "A Test of MDMA-Assisted Psychotherapy in Subjects with Chronic Posttraumatic Stress Disorder (PTSD)," undated, https://maps.org/research-archive/mdma/protocol/ic_070705.html).

[22] Mitchell et al., 2023.

[23] National Center for PTSD, "Prolonged Exposure (PE) for PTSD," webpage, U.S. Department of Veterans Affairs, undated, https://www.ptsd.va.gov/understand_tx/prolonged_exposure.asp.

[24] National Center for PTSD, "Cognitive Processing Therapy (CPT) for PTSD," webpage, U.S. Department of Veterans Affairs, undated, https://www.ptsd.va.gov/understand_tx/cognitive_processing.asp.

[25] National Center for PTSD, "Eye Movement Desensitization and Reprocessing (EMDR) for PTSD," webpage, U.S. Department of Veterans Affairs, undated, https://www.ptsd.va.gov/understand_tx/emdr.asp.

Cost

Cost-effectiveness analyses from 2022 estimate that MDMA-assisted psychotherapy will initially cost at least $11,500 per patient.[26] Relative to the costs that untreated PTSD symptoms pose to individuals and society at large, it is a cost-effective treatment.[27]

Nonetheless, cost may be a barrier to VA's ability to offer psychedelic-assisted therapy to veterans. The estimated cost is substantially greater than the costs of other psychotherapies that VA currently offers to treat PTSD.[28] VA is explicitly permitted to consider cost in making decisions in what it covers and has historically had a more restrictive formulary than other health care organizations.[29] On the other hand, VA has begun to make breakthrough treatments more readily available to veterans. For example, in March 2023, VA made available to veterans with Alzheimer's the newly FDA-approved lecanemab, which has an annual list price of $26,500.[30] VA made this decision at a time when the Centers for Medicare and Medicaid Services (CMS) had provided limited coverage for the drug to its Medicare beneficiaries.[31] (Since then, CMS has expanded eligibility with criteria comparable to VA criteria).[32]

Market forces will determine what community-based providers will charge for MDMA-assisted therapy. Price will be determined by at least three conditions: first, the size of the market, which will be guided by state policies that typically dictate licensure and other requirements; second, whether and how much insurers, including VA Community Care and CMS, will pay for this treatment; and third, demand for care that is not restricted to veterans (Approximately 5 percent of American adults have PTSD in a given year.[33]). In Oregon, where it is now legal for adults to purchase supervised psychedelic psilocybin services from state-licensed providers, but where these services are not yet covered by insurance, some clinics are charging between $2,000 and $3,400 for a six-hour guided psychedelic session that occurs after two

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[26] Elliot Marseille, Jennifer M. Mitchell, and James G. Kahn, "Updated Cost-Effectiveness of MDMA-Assisted Therapy for the Treatment of Posttraumatic Stress Disorder in the United States: Findings from a Phase 3 Trial," *PLOS One*, Vol. 17, No. 2, 2022.

[27] Marseille, Mitchell, and Kahn, 2022.

[28] Quang A. Le, Jason N. Doctor, Lori A. Zoellner, and Norah C. Feeny, "Cost-Effectiveness of Prolonged Exposure Therapy Versus Pharmacotherapy and Treatment Choice in Posttraumatic Stress Disorder (the Optimizing PTSD Treatment Trial): A Doubly Randomized Preference Trial," *Journal of Clinical Psychiatry*, Vol. 75, No. 3, March 2014; Ifigeneia Mavranezouli, Odette Megnin-Viggars, Nick Grey, Gita Bhutani, Jonathan Leach, Caitlin Daly, Sofia Dias, Nicky J. Welton, Cornelius Katona, Sharif El-Leithy, et al., "Cost-Effectiveness of Psychological Treatments for Post-Traumatic Stress Disorder in Adults," *PLOS One*, Vol. 15, No. 4, 2020.

[29] Milena Sullivan and Ekemini Isaiah, "The VA National Formulary for Top Medical Benefit Drugs Is Narrower Than Current Medicare Part B Drug Coverage," Avalere, August 13, 2019.

[30] Joshua Cohen, "VA Will Cover Alzheimer's Disease Drug Lecanemab, Provided a Detailed Set of Inclusion and Exclusion Criteria Are Met," *Forbes*, March 15, 2023.

[31] Cohen, 2023.

[32] Centers for Medicare and Medicaid Services, "Statement: Broader Medicare Coverage of Leqembi Available Following FDA Traditional Approval," press release, July 6, 2023.

[33] Simon B. Goldberg, Tracy L. Simpson, Keren Lehavot, Jodie G. Katon, Jessica A. Chen, Joseph E. Glass, Paula P. Schnurr, Nina A. Sayer, and John C. Fortney, "Mental Health Treatment Delay: A Comparison Among Civilians and Veterans of Different Service Eras," *Psychiatric Services*, Vol. 70, No. 5, May 2019.

preparatory sessions and one integration session.[34] In Australia, where MDMA-assisted therapy recently became available, estimates range from $10,000 to $30,000 per patient.[35] These harbingers suggest that MDMA-assisted therapy, when offered in the community, will not be cheap—especially in the early years. Cost will likely be a barrier for veterans who want care outside VA's walls, disproportionately affecting those who have historically faced the greatest cost barriers: those living in poverty, those who are unmarried, and racial and ethnic minorities.[36]

It is critical to ensure that cost is not a barrier to veterans' ability to access MDMA-assisted therapy, not only to meet veterans' preferences for care but also to ensure veterans' safety. Access barriers to MDMA-assisted therapy in controlled settings may push some veterans to access the drug in illegal markets, where a dose or pill might cost between $10 and $50 but there is less control over the drug's quality and the dose or pill could include adulterants, such as methamphetamine.[37] Like all drugs, use of MDMA has also been linked with potential side effects that, if the drug is taken in an unsupervised session, may go unnoticed and untreated and result in severe and even fatal outcomes. And, as discussed later, drugs procured in illegal markets are unlikely to be administered alongside psychotherapy, which many argue is critical for achieving improvements in PTSD symptoms.

Availability

With respect to health care access, the concept of *availability* describes whether health systems have the workforce and resources to provide timely, geographically convenient care that meets patients' needs. When it comes to VA, a fundamental issue will be whether VA has the workforce and resources to provide MDMA-assisted therapies within its existing behavioral health infrastructure or whether it will be better to pay for this care through the existing Community Care Network or through new partnerships with private-sector or nonprofit providers.

If it offers MDMA-assisted treatment within its own system, VA will need to establish guidance to determine which types of providers should deliver this treatment and what training and certification will be required. The most recent Phase 3 MDMA trial includes a psychotherapy pair that includes one licensed provider, and VA will need to decide whether it too will require a paired approach and, if so, the types of pairs who will provide the care. Amid a

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[34] EPIC Healing Eugene, homepage, undated, https://www.epichealingeugene.com/; Polly Thompson, "It Costs Up to $3,400 to Experience Magic Mushrooms at the First Legal Psilocybin Center—and Thousands Want to Take a Trip," Insider, September 16, 2023.

[35] Gary Nunn, "MDMA: Australia Begins World-First Psychedelic Therapy," BBC News, June 30, 2023.

[36] Danielle Kilchenstein, Jim E. Banta, Jisoo Oh, and Albin Grohar, "Cost Barriers to Health Services in U.S. Adults Before and After the Implementation of the Affordable Care Act," *Cureus*, Vol. 14, No. 2, February 4, 2022.

[37] Ariana Eunjung Cha, "Real-Time Testing of Drugs at Music Festivals Shows 'Molly' Often Isn't 'Molly,'" *Washington Post*, July 11, 2017; Nina Golgowski, "What Is 'Molly'? Illegal Drug MDMA Sees Rise in Popularity on Street and in Songs," *Daily News*, last updated January 10, 2019; Jeff Saunders, "Ecstasy Pills Valued at Nearly $1.35 Million Seized in Portage County Traffic Stop," Yahoo! News, February 6, 2023. The *New York Times* reports that fentanyl has not yet been detected in MDMA, but public health organizations warn that it may be present in pills from illegitimate sources (Rachel Nuwer, MDMA Is One of the Safer Illegal Drugs. But There Are Risks," *New York Times*, August 18, 2023; APLA Health, "Fentanyl," webpage, undated, https://aplahealth.org/fentanyl/).

national mental health workforce shortage,[38] it may need to expand its cadre of mental health professionals to meet veteran demand for psychedelic-assisted therapy. VA has done this in the past: In 2010, it began hiring licensed professional mental health counselors and marriage and family therapists to help meet veterans' demand for timely mental health care.[39] Training programs in psychedelic therapy are burgeoning across the country and could provide one avenue for expanding the mental health workforce, but VA will need to consider the merits of these programs, as they have varying eligibility requirements.[40] In Oregon, for example, licensed psilocybin guides are required to have a high school degree or an equivalent and up to 200 hours of training from an approved program.[41]

VA will also need to adapt its scheduling processes to incorporate a new protocol that will require three eight-hour sessions supervised by two providers and potentially an overnight stay. VA has had to flex to accommodate treatments that might better suit veterans' preferences in the past,[42] and it could do so again. But it may face challenges meeting expectations to provide care to veterans in a timely manner, given recent and ongoing difficulties meeting existing demand for mental health care. Meeting these expectations will require balancing demand for psychedelic-assisted therapy while ensuring that timely care is still available for other veterans who want or need other types of therapies.

Given these logistical hurdles, the government may conclude that relying on community-based partners to provide MDMA-assisted therapy makes intuitive sense. There are, however, at least four hurdles with VA outsourcing this care. First, the market may become volatile: VA employed an outsourcing model to provide ketamine infusion therapy for treatment-resistant depression,[43] but less than a year later, a chain it partnered with closed, leaving veterans who had been receiving the treatment in peril.[44] Second, there is no evidence that care provided in the community will be more readily available to veterans than care provided in VA. Although the expansion of community-based care for veterans originated from a demand for more-timely care, the VA is the only health care system in the United States that publicly reports appointment wait times; thus, whether expanded community care offerings have reduced veteran wait times

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[38] Nathaniel Counts, "Understanding the U.S. Behavioral Health Workforce Shortage," Commonwealth Fund, May 18, 2023.

[39] U.S. Government Accountability Office, *Veterans Health Care: Efforts to Hire Licensed Professional Mental Health Counselors and Marriage and Family Therapists*, GAO-22-104696, March 2022.

[40] Danica Jefferies, "Psychedelic Therapies Are on the Horizon, but Who Will Administer the Drugs?" NBC News, December 26, 2022.

[41] Oregon Health Authority, "Oregon Psilocybin Services - Training Programs with Approved Curriculum," webpage, undated, https://www.oregon.gov/oha/ph/preventionwellness/pages/psilocybin-training-programs-approved-curriculum.aspx.

[42] Cynthia Yamokoski, Heather Flores, Vanessa Facemire, Kelly Maieritsch, Sara Perez, and Ashley Fedynic, "Feasibility of an Intensive Outpatient Treatment Program for Posttraumatic Stress Disorder Within the Veterans Health Care Administration," *Psychological Services*, Vol. 20, No. 3, August 2023.

[43] Rachel Nostrant, "VA Community Clinics Expand Ketamine Treatment Options for Depression," *MilitaryTimes*, September 29, 2022.

[44] Melissa Chan, "Abrupt Closure of Ketamine Clinic Chain Blindsides Veterans and Others with Severe Depression and Chronic Pain," NBC News, updated March 24, 2023.

remains an open question.[45] Furthermore, licensing and credentialing providers for MDMA-assisted therapy will vary by state, and cost of this care will depend on regional market forces. These factors may require VA to establish and monitor multiple contracts to accommodate state-level variation in the cost and regulation of this care.

Quality

As with any care provided to U.S. veterans, the government has an obligation to ensure that the care is safe and of high quality. Some of the points I have already raised relate also to quality of care. For example, it will be critical to ensure that providers who deliver and oversee administration of psychedelic treatment are adequately trained and have met all licensing requirements established across states. However, it will be equally critical to determine which veterans will be eligible for treatment based on individual medical history, what treatment protocol will be required, and how quality of care will be monitored.

Not all veterans may have immediate access to psychedelic-assisted therapies. For example, the Phase 3 trial for MDMA-assisted therapy excluded those with some comorbid mental health conditions, those who were acutely suicidal, those with a recent history of ecstasy use, and those with unmanaged cardiovascular conditions.[46] Given the treatment's projected cost and intensity, VA and others paying for care may consider whether the treatment should be eligible to any veteran with PTSD or to only those who have tried and not benefited from another evidence-based treatment. However, if veterans are required to have undergone past treatment and are prescribed one or more psychiatric medications, these drugs may need to be discontinued before psychedelic-assisted therapy is commenced, as they were for participants in the Phase 3 trial.[47] This process needs to be monitored closely, as withdrawal symptoms from even common antidepressants can be severe and persist for long periods of time.[48]

MDMA-assisted treatment for PTSD occurs in the context of a course of psychotherapy treatment, which is deemed a critical component of the treatment by the Multidisciplinary Association for Psychedelic Studies and by providers and veterans who have been part of clinical trials.[49] However, the FDA typically does not regulate psychotherapy,[50] leaving monitoring to such entities as VA, states, or other insurers. If VA were to provide MDMA-assisted treatment, it would need to decide how closely it would adhere to the FDA-approved protocol and how, in

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[45] Carrie M. Farmer, "Wait Times for Veterans Scheduling Health Care Appointments: Challenges with Available Data on the Timeliness and Quality of VA Community Care," testimony before the U.S. Senate Committee on Veterans' Affairs, RAND Corporation, CT-A2291-1, September 21, 2022, https://www.rand.org/pubs/testimonies/CTA2291-1.html.

[46] Mitchell et al., 2023.

[47] Mitchell et al., 2023.

[48] James Davies and John Read, "A Systematic Review into the Incidence, Severity and Duration of Antidepressant Withdrawal Effects: Are Guidelines Evidence-Based?" *Addictive Behaviors*, Vol. 97, October 2019.

[49] Sara Reardon, "US Could Soon Approve MDMA Therapy—Opening an Era of Psychedelic Medicine," *Nature*, April 19, 2023a; Hans Petersen, "Exploring Psychedelics for the Treatment of Veterans," VA News, September 26, 2023.

[50] Reardon, 2023a.

practice, it would monitor providers' adherence to this protocol. VA currently does not have a process for monitoring quality of care that it pays for and that is delivered in the community, creating yet another hurdle to outsourcing psychedelic-assisted therapy in a newly emerging marketplace.

Finally, whether or not VA decides to provide and/or cover psychedelic-assisted therapy, a marketplace is already forming, and we should expect it to grow. Increasing numbers of states and municipalities are making psychedelic therapies available to residents, including veterans, in the communities they govern. Services will be targeted to veterans, and veterans will be curious about these treatments. VA should provide guidance to prepare its providers to talk to their patients, who may be considering accessing this treatment outside of VA, like they did in 2017 for marijuana-assisted therapy.[51] In addition, VA should encourage veterans to speak with their providers about their interest in these treatments without fear of losing VA benefits.

Conclusion

Mental health conditions, such as PTSD, can be debilitating and cost the United States hundreds of billions of dollars each year.[52] Although existing treatments are good, the U.S. government can improve the way it cares for individuals with PTSD, including veterans, whose conditions often arise from their service to the country. Psychedelic-assisted therapies hold great promise, but their full benefits will be realized only with continued investment in research, improvements in access to these compounds for research purposes, and careful planning for how this care can be offered to ensure that all veterans who need and want these treatments can benefit from them. Ensuring veterans' equitable access to psychedelic-assisted therapies will require attention to the potential barriers that I have outlined today: addressing psychedelic treatment costs, determining where and how psychedelic treatment is made available to veterans, and ensuring that veterans who receive this treatment do so safely.

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[51] Bryce Pardo, Beau Kilmer, Rajeev Ramchand, and Carrie M. Farmer, *Psychedelics and Veterans' Mental Health*, RAND Corporation, PE-A1363-6, December 2022, https://www.rand.org/pubs/perspectives/PEA1363-6.html; U.S. Department of Veterans Affairs, "VHA Publications: Directives," webpage, last updated October 6, 2023, https://www.va.gov/vhapublications/publications.cfm?pub=1.

[52] Lori L. Davis, Jeff Schein, Martin Cloutier, Patrick Gagnon-Sanschagrin, Jessica Maitland, Annette Urganus, Annie Guerin, Patrick Lefebvre, and Christy R. Houle, "The Economic Burden of Posttraumatic Stress Disorder in the United States from a Societal Perspective," *Journal of Clinical Psychiatry*, Vol. 83, No. 3, May–June 2022.

Prepared Statement of Brett Waters

Testimony of
Brett Waters, Esq.
Co-Founder & Executive Director
Reason for Hope &
Veteran Mental Health Leadership Coalition

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

November 14, 2023

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

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:

Thank you for the opportunity to testify today on the tremendous potential of emerging therapies for America's veterans. My name is Brett Waters, and I am the co-founder and Executive Director of Reason for Hope and the Veteran Mental Health Leadership Coalition. Reason for Hope is named in memory of my mother, Sherrie Hope Waters, who I lost to suicide five years ago. My grandfather, her father, also died by suicide when I was young. He was a fighter pilot in World War II, whose plane was shot down in the South Pacific at the age of 16.

Our co-founder and President of the Veteran Mental Health Leadership Coalition, Lieutenant General Martin R. Steele, USMC (Ret.), was initially scheduled to appear in this hearing before it was rescheduled. He has long been at the forefront of cutting-edge veteran mental health and suicide prevention work, including having served on the VA Commission on Care in 2015-2016 exploring the future of VA healthcare.

Lt.Gen. Steele has testified before this committee on several occasions about mental health and suicide prevention, and I am honored to testify in his place today on behalf of Reason for Hope and the Coalition. These organizations focus on advancing safe and affordable access to psychedelic therapies to combat the PTSD, suicide, and addiction crises. While devastating to our nation writ large, these crises have particularly impacted the veteran community. Around 44 veteran lives are lost per day to suicide, overdose, or other forms of self-injury.

Despite the clear limitations of our current treatments, we have seen little in the way of private innovation or bold government initiatives with the potential to create the transformational change needed to mental healthcare. Hopefully, today's hearing is the first step in the right direction of a major paradigm shift. There is an urgent need to develop novel therapeutics – including MDMA, psilocybin, DMT, ibogaine, and 5-MeO-DMT (amongst others) – which may offer rapid and robust improvement of symptoms, particularly for those who have not benefitted from existing options.

While these psychedelic therapies are powerful and should be used with caution, evidence suggests they can be safely provided with proper preparation, monitoring, and integration support. However, the Schedule I status of these psychedelics under the Controlled Substances Act unfortunately makes them difficult to research, and Schedule I blocks patient access to

compassionate use under the Right to Try Act. This has a profoundly negative impact on the veteran community.

Specifically, our Coalition's founding members include several researchers and mental health providers advancing veteran-focused studies with these therapies both inside and outside the VA healthcare system. Schedule I not only delays their research, but ultimately the timeline for patient access to these potentially lifesaving therapies. Our Coalition members also include the leaders of various Veteran Service Organizations that have either funded or supported veterans seeking these psychedelic therapies in other countries. For the veterans who've sought these treatments abroad, it was almost never their initial choice, it was their last line of defense after exhausting available treatments at home.

I've had the honor to work alongside many of these Veterans treated outside our borders, who had profoundly beneficial experiences. They often credit psychedelic therapy not only with saving their lives, but also with helping instill a renewed sense of purpose, meaning, and connection to themselves, their families, and their communities. However, with dozens of veterans dying by suicide each day, it is morally unacceptable that so many have been forced to leave the country they served to access these lifesaving therapies.

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.

The situation is more difficult to stomach when you consider that some veterans are traveling abroad – or risking criminal prosecution at home – to access treatments that the FDA has designated as Breakthrough Therapies, 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.

A timely report from the Canadian Senate Veterans Affairs Subcommittee, released November 8, 2023, recommended the immediate implementation of a robust psychedelic therapy research program funded by Veterans Affairs Canada (VAC) and other government partners. The report noted that VAC's "wait-and-see approach when it was given this rare opportunity to explore new treatment options . . . [was] ill-suited to the leadership role it should be taking on, wherein it should be doing everything in its power to improve the health of veterans, particularly those who have exhausted all the treatment options available to them."[1]

So, too, here. At a minimum, the committee should ensure significant funding goes toward research and implementation of Breakthrough Therapies, particularly with MDMA-assisted therapy approaching FDA approval for the treatment of PTSD. Our Coalition has sought to do its part by helping to unlock more than $12 million in state funding this year for Breakthrough

[1] https://sencanada.ca/content/sen/committee/441/SECD/Reports/VEAC_TimeisNow_Report_e.pdf

Therapies research and the training of healthcare professionals in this specialized form of care delivery. However, the time has come for the federal government to step up and take a leading role. We need at least 10x this amount ($120 million) to answer some of the critical questions necessary to inform safe and effective treatment delivery in real-world settings.

Substantially more will be needed (at least $1 billion dollars over the next five years) to advance compounds not as far along in the research and development process, such as ibogaine and 5-MeO-DMT. For these compounds, NIMH may be viewed as a more appropriate source of funding.[2]

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.

The Breakthrough Therapies Act would automatically reschedule any Schedule I drug to Schedule II on an expedited timeline if it is an active ingredient of a drug that receives FDA Breakthrough Therapy Designation or Expanded Access approval. This would reduce 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.

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

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[2] An estimated 90% of NIMH's $2.2 billion budget is allocated toward neuroscience research, while breakthrough psychedelic therapies that veterans throughout the country swear have been lifesaving receive virtually no support. This status quo is offensive to many patients currently suffering, and should urgently be changed to reflect a more even balance between neuroscience and clinical trials of promising investigational treatments. https://ps.psychiatryonline.org/doi/10.1176/appi.ps.202000739

VETERAN
MENTAL HEALTH
LEADERSHIP COALITION

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.

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.

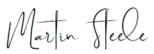
In some areas of healthcare, we have done a great job upholding our moral obligation to those who served. However, when it comes to mental health care and suicide prevention, we have fallen woefully short. Indeed, we lose around 40 Veterans every day to suicide or other forms of self-injury. Male Veterans 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 R. Steele
Lieutenant General, US Marine Corps (Retired)
Founder and President
Veteran Mental Health Leadership Coalition


Reason for Hope
NAVY SEAL FOUNDATION
A Nation of Support
SOAA
SPECIAL OPERATIONS ASSOCIATION OF AMERICA
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AMERICAN LEGION
GRUNT STYLE
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GS
THIS WE'LL DEFEND
FOUNDATION
Warrior Angels Foundation
THE MISSION WITHIN
SEAL FUTURE FOUNDATION
NO FALLEN HEROES FOUNDATION
THE hope PROJECT
HEALING POWERFUL WOMEN
VETERANS HEALING FARM
BVN
BALANCED VETERANS NETWORK
SABE
VETERANS REBUILDING LIFE
warrior wellness solutions
INVI
VAHA
VETERANS ALLIANCE FOR HOLISTIC ALTERNATIVES
Field to Healed
Scottsdale Research Institute Foundation
SŌHEI BIOTECH

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

Reason for Hope

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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Co-Founder and Executive Director
Reason for Hope
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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

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[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

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[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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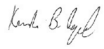

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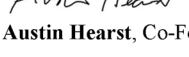

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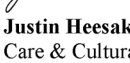

Justin Heesakker DAOM, M.S., L.Ac. Dipl. OM, CPTR, VHA Office of Patient Centered Care & Cultural Transformation (OPCC&CT)

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

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Chief Medical Officer, Osmind & Co-Founder, Fermata

Andrew Penn, MS, PMHNP
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Co-Founder, Organization of Entheogenic and Psychedelic Nurses (OPENurses)

s/ Brian Richards

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Clinical Psychologist, Sunstone Therapies

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Clinical Instructor, Department of Psychiatry, Yale University
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Deborah Tan

Deborah Tan, **MBA**
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s/ Angela Terhune

Angela Terhune, MHA
Senior Director, Elligo Health Research

Eric Utecht

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

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.

Tracy E. Pennycuick, U.S. Army (Ret.)
Pennsylvania State Representative
Prime Sponsor, Public Health Benefits of Psilocybin Act

Jennifer O'Mara (signed)
Jennifer O'Mara
Pennsylvania State Representative
Prime Co-Sponsor, Public Health Benefits of Psilocybin Act

Michelle Loness Cook
Deputy Speaker
Connecticut State Assembly
Member, Connecticut Psilocybin Study Working Group

Josh Elliott
Connecticut State Representative
Legislative Lead Sponsor and Member,
Connecticut Psilocybin Study Working Group

Alex Dominguez
Texas House of Representatives
Lead Sponsor, Texas HB 1802

Brett Waters

Reason for Hope
Brett Waters, Co-Founder & Executive Director
Lt. Gen. Martin R. Steele, USMC (Ret.), Co-Founder
Lynnette Averill, PhD, Co-Founder
Brigadier Gen. Stephen Xenakis, MD, U.S. Army (Ret.), Co-Founder
Rear Admiral Mark Leavitt, USN (Ret.)
Jesse MacLachlan, Former 3-Term Connecticut State House Representative

Martin Steele

Martin R. Steele
Lieutenant General, US Marine Corps (Retired)
U.S. Global Leadership Coalition, National Security Advisory Council
Veterans Florida, Vice Chairman

Denise F. Bottiglieri, PhD
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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
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

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
Matthew Buckley
Sandra Samberg
Susan Ousterman
Brigadier Gen. Stephen Xenakis

Prepared Statement of Juliana Mercer

Statement of Juliana Mercer, USMC Veteran
Director of Veteran Advocacy and Public Policy, Healing Breakthrough
Before The United States House Committee on Veterans' Affairs
Subcommittee on Health
With Respect To

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

November 14, 2023 – 2:00 pm
Washington, D.C.

Chairwoman Miller-Meeks, Ranking Member Brownley, and members of the subcommittee, on behalf of the millions of veterans who suffer from PTSD and the organization I represent, Healing Breakthrough, thank you for the opportunity to provide remarks on the great hope that MDMA-Assisted Therapy holds for those living with complex, chronic, PTSD which is a leading cause of veteran suicide.

My name is Juliana Mercer; I am a 16-year Marine Corps veteran. I graduated boot camp a week before 9/11. Given the timing of my service, my military career spanned my 20s and 30s and almost two decades of war in which I deployed to Iraq and Afghanistan and served on the Marine liaison team at the Wounded Warrior Battalion.

After active duty, I dedicated the last 12 years to working with veteran non-profits, seeking solutions to the veteran suicide epidemic. Over the years, I've lost too many brothers and sisters to the ravages of war. The cumulative effects of trauma eventually caught up to me. Combat deployments, countless funerals of those lost in combat, and the many more lost here at home to suicide - took a massive toll on my mental health. Though immersed in purposeful work, I found myself in a place with no purpose. I needed help, and like other veterans, I left the country to access a breakthrough therapy not available in the United States.

Many veterans have struggled more after returning home than on the battlefield. We lost 5,461 servicemembers in post-9/11 hostile combat operations. Millions of veterans of all wars have been diagnosed with PTSD, and in the last two decades, over 6,000 have committed suicide each year since 2005. Consequently, we have lost more veterans here, on American soil, to suicide than we have in the Global War on Terrorism - over 100,000 more, to be precise. That annual rate has remained consistent over the years, implying that nothing currently on the market or in practice has meaningfully addressed the root causes of PTSD or decreased veteran suicide rates.

This is a reality worth repeating because it's what motivates me to fight for my brothers and sisters every single day: the veteran suicide rate has not budged for over 20 years despite billions of taxpayer dollars spent addressing the issue. We're still losing over 6,000 veterans per

year. That is more per year than in 20 years of combined wars. If we continue doing what we've been doing, we may be saying the same thing 20 years from now.

Thankfully, there's hope on the horizon. An FDA-designated Breakthrough Therapy known as "MDMA-Assisted Therapy" offers scientifically validated hope for veterans who have PTSD. Our government first recognized its potential in 2017, when the FDA granted MDMA-Assisted Therapy "Breakthrough Therapy" status, meaning that the treatment offered "substantial improvement over available therapy on a clinically significant endpoint(s)."[1] Six years later, Phase 3 clinical trials have proven the FDA right: 86% of MDMA-Assisted Therapy patients struggling with PTSD reported clinically significant reductions in symptoms after three MDMA-Assisted Therapy sessions, while 71% of patients experienced complete remission of PTSD symptoms.[2]

The implications of these peer-reviewed trial results cannot be overstated. MDMA-Assisted Therapy has already proven its efficacy in treating PTSD and is on the path to FDA approval next year. At the instruction and urging of Congress, the VA must be prepared to implement a nationwide program for this Breakthrough Therapy as soon as possible. Every day wasted means more lives lost.

I'm here today asking that you lead, as Congress must, in such moments of crisis. Given what we know of MDMA-Assisted Therapy's efficacy, how much longer will veterans like me have to wait before the VA commits its resources to large-scale, nationwide studies of this Breakthrough Therapy, which holds so much potential to save and restore lives? Dedicated and patriotic philanthropists have privately funded most trials to date. However, saving veteran lives must become enough of a priority at the VA for the agency to commit its resources to solving the problem that it is primarily responsible for.

Thank you for letting me share my story and for allowing me to advocate on behalf of my fellow veterans. Chairwoman Miller-Meeks, Ranking Member Brownley, this concludes my testimony. I would happily answer any questions you or the subcommittee members may have.

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[1] Definition of "Breakthrough Therapy," https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy.

[2] MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study | Nature Medicine Mitchell JM et al. MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study. Nat Med. 2021 Jun 27(6):1025-1033.

Bringing a Breakthrough Therapy to Veterans with PTSD: Implementing MDMA-Assisted Therapy in the U.S. Department of Veterans Affairs

An Overview of Healing Breakthrough's Mission and Strategy

October 2023

Healing Breakthrough

Healing Breakthrough is a federally registered 501(c)(3). Any contribution is tax-deductible as permitted by law.
1040 Court Street, San Rafael, CA 94901 – healingbreakthrough.org

This document provides an overview of Healing Breakthrough's strategy to work with the Department of Veterans Affairs (the VA) to bring MDMA-Assisted Therapy to all Veterans with PTSD who could benefit. It describes the challenges associated with implementing a new, breakthrough model of care and outlines an approach that includes both top-down interventions at the level of national policies, resources, and systems, as well as bottom-up interventions to engage local clinic directors, train, and support providers, and educate patients. It is Healing Breakthrough's ambition to accelerate access to this treatment at scale through a coordinated effort, without which adoption could take ten years or more.

This comprehensive strategy document was co-created by Healing Breakthrough leadership along with the several key contributors, including:

- **Michael Mithoefer** is the Senior Medical Director for Medical Affairs, Training and Supervision at MAPS Public Benefit Corporation (MAPS PBC). He is a luminary in the field of MDMA research, and has been a master trainer, clinician, supervisor, and lead investigator on studies of MDMA-AT for the past 20 years.

- **Dan Grossman** is a Managing Director & Senior Partner at Boston Consulting Group (BCG), one of the world's preeminent management consulting firms. He has close to 20 years of experience in BCG's Health Care Practice Area, working with leading biopharmaceutical and medical technology companies on issues of corporate strategy, pipeline development, and commercializing innovation globally. He is currently a member of the MAPS Public Benefit Corporation Board of Directors.

- **Bob Jesse** has long been a quiet, guiding force behind the contemporary psychedelic renaissance. He played an instrumental role in seminal research on psilocybin at Johns Hopkins University, currently serves on various boards, and advises various individuals and groups in the space including the Usona Institute and Berkeley Center for the Science of Psychedelics.

- **Josef Ruzek** retired as Director of the Department of Veterans Affairs National Center for PTSD Dissemination and Training Division in 2018, after helping improve PTSD services in the VA for over 26 years. He has been a member of the VHA Undersecretary's Special Committee on PTSD and served as psychotherapy champion for the joint VA-DoD Clinical Practice Guideline for Management of Traumatic Stress.

- **Ryan J. Vega, MD,** served as the chief officer for the Office of Healthcare Innovation and Learning as part of the Veterans Health Administration (VHA) Discovery, Education, and Affiliate Networks Office. In this role, he had direct responsibility for fostering the discovery and spread of grassroots and strategic innovative solutions, practices, and products across the VA.

This document was developed through exhaustive research into the scientific literature regarding MDMA-AT and trauma-focused psychotherapies for PTSD and an analysis of the unique challenges of working within the VA to improve PTSD treatment for Veterans. It reflects a deep understanding of how the VA works, including its various components, systems, and processes for implementing new mental health services. It articulates a multidimensional strategy to deploy MDMA-AT throughout the VA healthcare system, including rigorous research, national policy, resource allocation, and bottom-up support from local systems, providers and patients.

Any time one sets out to change a system as vast and complicated as the VA, there is going to be a lot of fluidity. At this moment in time, this paper represents the optimal approach and strategy to implement MDMA-AT in the VA. It is intended to be a living document that is revised to reflect the challenges and opportunities that are presented once it is underway.

Healing Breakthrough

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Key Takeaways

- **Healing Breakthrough (HB) is a 501(c)(3) public charity working to provide all Veterans with PTSD that may benefit with access to safe, legal, high-quality MDMA-Assisted Therapy (MDMA-AT) through the U.S. Department of Veterans Affairs (VA)**. Through philanthropic funding, HB sponsors and promotes research, training, and education to support an effort that will not only catalyze access to healing for thousands of Veterans, but also contribute to the treatment's clinical and social legitimacy, paving the way for other breakthrough therapies that have the potential to revolutionize mental healthcare within the VA and throughout American society.

- Despite the promising results of the Multidisciplinary Association for Psychedelic Studies (MAPS) Phase 3 clinical trials and a small number of ongoing pilot studies with Veterans, **a host of challenges remain**. If unaddressed, these **could prevent or substantially delay MDMA-AT from reaching Veterans**. A coordinated approach is required to address these challenges strategically, accelerate momentum, and move MDMA-AT from pilots to widespread adoption.

- Without these coordinated efforts, **it could take 10 or more years** for this treatment to become available to Veterans at scale through the VA. **Healing Breakthrough aims to catalyze the process of adoption down to five years** so any Veteran will be able to go to their VA clinic and receive treatment by the end of the decade.

- Taking MDMA-AT to scale in the VA will require much more than training clinicians. It is a **new model of care**, and as such, its **adoption relies on both top-down and bottom-up efforts. A centralized initiative supported by virtually all levels of national VA leadership** will need to be complemented by ongoing engagement and buy-in of the local and regional clinical leadership in the field.

- **To understand how the VA has successfully adopted and scaled evidence-based psychotherapies** in mental health across the system, one can look to the **case study of Prolonged Exposure (PE)**, one of the VA's recommended treatments for Veteran PTSD, which reveals several critical success factors.

- **HB has developed a multi-pronged strategy in partnership with the VA's National Center for PTSD (NCPTSD)**, the nation's only congressionally mandated center of excellence for the treatment of Veteran PTSD. HB is working in lockstep with NCPTSD to ensure that all relevant sources of evidence are considered when determining how to adopt MDMA-AT.

- HB is **working with all of the relevant constituencies**, including the VA's Office of Mental Health and Suicide Prevention (OMHSP), the VA's Office of Research and Development (ORD), as well as political leadership (House & Senate Committee on VA Affairs, Office of the Secretary of the VA), advocacy groups, and scientific experts to develop a cohesive system that extends MDMA-AT to all appropriate Veteran patients.

Why Veterans and the VA Are Key to Integrating Breakthrough Therapies, such as MDMA-AT, into the US Healthcare System

There is an urgent Veteran mental health crisis. Over 660,000 Veterans within the VA care network are currently known to suffer from PTSD[1], a condition that is commonly underdiagnosed and likely affects many more. Among Veterans who experienced combat trauma, the highest relative suicide risk is observed in those who were wounded multiple times and/or hospitalized for a wound[2]. A history of military sexual trauma (MST) also increases the risk for suicide and intentional self-harm[3]. Researchers at the VA have found that 17 Veterans a day lose their life to suicide, while an independent study discerned that number may be up to 24 suicides a day.[4][5][6] However, the same independent study has found that many other Veterans deaths are due to self-injurious deaths (e.g. accidental overdoses), an important finding as more than 2 out of 10 Veterans with PTSD also has Substance Use Disorder (SUD) and almost 1 out of every 3 Veterans seeking treatment for SUD also has PTSD[7].

Over 50% of Veterans drop out of, or do not experience significant symptom reduction from current gold-standard treatments for PTSD. The Veteran mental health crisis is a problem that not only impacts Veterans, but also their families and communities across the country.

Veterans are a powerful voice of support for the broad public acceptance of MDMA-AT. Veteran mental health is one of the few bipartisan issues that are of strong national interest. The VA has the legal mandate to treat Veteran PTSD and to fund care delivery and research. While Veterans are a unique patient population, they represent every geography, socio-economic status, political affiliation, race, and gender. Veterans are the most important advocates for MDMA-AT.

The VA is best positioned to take MDMA-AT to scale. The Veterans Health Administration is the nation's largest integrated healthcare delivery system with an annual budget of ~$17 billion for mental health care alone. It provides care to 9 million Veterans across 1,200 facilities and employs over 10,000 licensed mental health professionals. The VA has successfully taken other evidence-based psychotherapies to scale and has set the standard of care for PTSD treatment.

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[1] Of the 6 million total Veterans served, about 11% who used VA healthcare in fiscal year 2021 were diagnosed with PTSD according to NCPTSD
[2] Bullman, T. A., & Kang, H. K. (1995). A study of suicide among Vietnam Veterans. Federal Practitioner, 12(3), 9-13.
[3] Kimerling, R., Gima, K., Smith, M. W., Street, A., & Frayne, S. (2007). The Veterans Health Administration and military sexual trauma. American Journal of Public Health, 97, 2160-2166
[4] Department of Veterans Affairs: National Veteran Suicide Prevention Annual Report. 2022.
[5] America's Warrior Partnership: Operation Deep Dive Summary of Interim Report. 2022.
[6] Raines AM, Houtsma C, Boffa JW, Constans JI. A Response to Operation Deep Dive's Interim Report on Veteran Suicide Rates. Mil Med. 2023 May 16;188(5-6):141-142.
[7] According to NCPTSD website

The VA's uptake of MDMA-AT will pave the way for a new class of treatments. The VA's National Center for PTSD is the nation's most respected center of excellence for the treatment of trauma. 70% of physicians and more than 50% of clinical psychologists in the country receive training at the VA. How the VA chooses to roll out and scale MDMA-AT will dictate the standard of care for treatment delivery and provider training of this new PTSD treatment, within and beyond the VA.

VA Research on MDMA-AT will benefit American society at large. The VA has a responsibility to drive research related to their mission of serving Veterans, and also to translate that research into innovations that can improve public health for all Americans. Innovations such as cardiac pacemakers, CAT scans, prosthetics and liver transplants were all originally developed and evaluated in the VA. There is a dire need for research on promising solutions that can benefit Veterans with PTSD, and society has an obligation to Veterans to do just that. Should the VA invest in evaluating MDMA-AT, society has an opportunity to benefit as well.

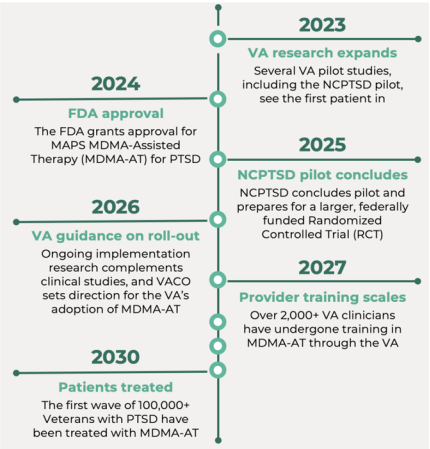
A Coordinated Effort Is Required to Take MDMA-AT to Scale in the VA

While the Veteran community has been a key stakeholder in the emerging field of psychedelic science and subject to a handful of independent pilot studies across the country, there has been no coordinated national effort in support of MDMA-AT for Veterans prior to HB's work.

A coordinated effort among key clinical decision makers and political leadership within the VA is needed to achieve widespread adoption, for multiple reasons:

- **Urgency**. Each day that passes, more Veterans die of suicide. Furthermore, with FDA approval in near sight, MDMA-AT will soon trickle into broader society, and more Veterans who deserve access to this new treatment are likely to demand it. Timely VA efforts have the potential to shape a better standard of care for the treatment.
- **Scale**. Existing Veteran efforts to bring MDMA-AT to Veterans may have the future capacity to reach thousands, or possibly tens of thousands of Veterans, in the next 10-20 years. A top-down mandate combined with a concerted effort to engage clinicians in the field would accelerate adoption across the system and reach over one hundred thousand of the 660,000 Veterans suffering from PTSD.
- **Strategy.** A comprehensive strategy encompassing both top-down efforts (e.g. national policy mandates) and bottom-up efforts (e.g. cultivating grass roots support from clinical teams at VA facilities) are needed to ensure the timely and effective dissemination of MDMA-AT throughout the system. While ongoing efforts such as pilot studies and regional provider training efforts are critical, they are not sufficient.
- **Equity**. HB seeks to create a cohesive system that extends access to MDMA-AT beyond well-resourced sites that are currently running pilot research programs. A coordinated effort that leverages the VA's resources will ensure that all appropriate Veteran patients, regardless of geographic location, can access and benefit from MDMA-AT.

Healing Breakthrough's Vision for MDMA-AT at the VA



A program that was initially incubated by the Psychedelic Science Funders Collaborative (2021), Healing Breakthrough was spun out into a public charity closely affiliated with Evolve Foundation (2022). Healing Breakthrough's mission is to provide all Veterans with PTSD that may benefit with access to safe, legal, high-quality MDMA treatment through the U.S. Department of Veteran Affairs (VA) by 2027.

Translating scientific discoveries into patient benefit is a policy priority of many health research systems. However, it is common for new health treatments to have a lag time of 10-17 years before they are used widely[8]. Unlike MDMA-AT, most new health treatments do not involve the establishment of a new model of care. In the case of MDMA-AT however, the establishment of a new model of care will be essential, and this requires vast amounts of resources, the resolution of bottlenecks in infrastructure, training and dissemination, engagement with the field, and acceptance of a new medication with previous stigma. With 17-24 Veterans dying by suicide every day, and a large number struggling to thrive due to trauma, this lag time is unacceptable to Veterans, their families, and society at large. By working together with the VA and MAPS Public Benefit Corporation (MAPS PBC), Healing Breakthrough aims to catalyze the process of adoption down to five years so any Veteran will be able to go to their VA Medical Center and receive treatment before the end of the decade.

To achieve this vision, HB will execute an approach that includes both top-down interventions at the level of national policies, resources, and systems, as well as bottom-up interventions to engage local clinic directors, train and support providers, and educate patients. HB will closely collaborate with NCPTSD to conduct the critical research to establish the efficacy of MDMA-AT in Veteran patients, and to identify the strategies that allow the VA to quickly take these new treatments to scale. FDA approval in 2024 will pave the way for implementation pilots across the VA system that engage key clinicians and sites, and prepare for a larger scale dissemination. HB

[8] Understanding time lags in translational research, 2011 (link)

intends for the VA and the federal government to take financial and administrative ownership of the process along the way.

HB envisions that, eventually, MDMA-AT will become the new standard of care for Veteran PTSD. The VA's adoption of MDMA-AT into routine clinical care will further impact change beyond the system: It will help alleviate stigma, boost public and political legitimacy, and set the standard of care. By developing a model for the safe and effective dissemination of breakthrough mental health treatments, the VA will pave the way for other breakthrough treatments for patients both within and outside the VA.

Most importantly, HB's vision is that by the end of this decade, the number of Veterans that suffer daily from the debilitating effects of PTSD will have substantially decreased, providing mental and emotional freedom to the millions of Veterans that have bravely fought for the freedom of this country.

Several Challenges Need To Be Overcome To Bring MDMA-AT To Scale

The outcomes of FDA-registrational Phase 3 MDMA-assisted therapy (MDMA-AT) clinical trials have shown remarkable efficacy. However, this type of psychopharmacotherapy is a new treatment paradigm and several challenges impede its swift dissemination.

Challenge #1: FDA approval & DEA Schedule 1 classification

FDA approval & DEA rescheduling is necessary. The US Federal Government will not implement a widespread treatment using a drug that is not FDA-approved and is classified as a Schedule 1 compound by the Drug Enforcement Administration (DEA). The current situation has stifled research and discussion about widespread implementation after approval. MDMA-AT for PTSD is likely to be FDA-approved in the near term and rescheduling by the DEA is expected shortly thereafter.

Challenge #2: MDMA-AT is a new model of care

MDMA-AT is a new model of care for PTSD that differs substantially from existing therapy and medication treatments. It requires a fundamental change in thinking about healing and client engagement that will be new to VA clinicians.

- There is a need for specialized training. There is currently a bottleneck as, out of the thousands of therapists needed to implement this therapy nationwide, there are only limited training slots available through existing training programs combined (MAPS and Mount Sinai).
- The VA will further need to allocate appropriate resources and staff. Current treatment protocols for MDMA-AT require two clinicians for each six-hour MDMA-AT session, as well as one or two for the necessary preparation and integration sessions. While both providers won't necessarily have to be present for all of the non-medication sessions, resource constraints will still challenge appropriate allocation.

Challenge #3: The VA is a unique healthcare system with a unique patient population

There are several characteristics unique to the VA and Veterans that need to be accounted for when considering research design, clinical decision-making, and care delivery.

- Large scale clinical research and implementation projects to evaluate MDMA-AT will be required to gain VA leadership endorsement for taking this treatment to scale. Although small pilot research projects can contribute valuable momentum, lessons learned, and clinical expertise, they alone are not sufficient to drive enduring changes in clinical practice.
- The VA is an enormous, decentralized system with significant latitude at the VISN and individual facility levels, and is slow to implement change. In order to achieve widespread adoption, the treatment must be tailored to fit effectively within the system's constraints, empowering clinicians with both the ability and the motivation to offer MDMA-AT.
- Current treatment and training protocols need to be adapted to military and Veteran culture and tailored to the unique characteristics and circumstances of Veteran PTSD. In the MAPS Phase 3 clinical trial published in 2021, a total of only 19 Veterans were treated, with a protocol that was designed to meet a variety of needs, including those of civilians, sexual assault survivors, and other trauma victims.
- Although various university research settings have been established for the delivery of MDMA-AT across the country, very few of them are located within VA facilities. In current clinical practice and VA infrastructure, there are no appropriate settings for the medication sessions. The VA will need to research, define, and test the optimal setting and allocate appropriate space and local resources within their own facilities. As of 2022, the PACT act (Section 7) provides VA with new authority to lease space with academic affiliates. This space could potentially be used to support MDMA-AT research and clinical practice, particularly in those VA facilities that do not have these resources available.

What It Will Take To Scale MDMA-AT Throughout the VA

The VA is a complex organization with several offices at different levels of the agency contributing to the clinical-decision making process.

Within the Veterans Health Administration, VA Central Office (VACO) is located in Washington DC and sets VA national policies. These policies are executed at the regional level through Veterans Integrated Service Networks (VISN). There are five offices in VACO that will be relevant with regards to the research and decision making around MDMA-AT. Each of these offices reports up to senior leadership whose support will also be necessary in order to execute on our strategy.

- Within Clinical Services, the **Office of Mental Health and Suicide Prevention (OMHSP)**, oversees mental healthcare policy and sets the direction for treatment across VA care facilities. Clinical Services reports to the Chief Medical Officer

- The **National Center for PTSD (NCPTSD)**, which is housed within OMHSP, will be a key party responsible for judging the evidence base for MDMA-AT and generating new evidence where required.
- The **Office for Research and Development (ORD)** is one of the oldest and most established offices within VA and is responsible for both clinical and implementation research of new therapies. Through their Cooperative Studies Program it funds large, multisite trials. ORD reports to Discovery Education and Affiliate Networks (DEAN).
- The **Office of Academic Affiliations (OAA)** sponsors the VA Advanced Fellowships Program which offers post-residency fellowships to physicians in emerging health professions of particular importance to VA and the Nation.
- Lastly, the **Office of Health, Innovation and Learning (OHIL)** is an important contributor: it discovers and spreads grassroots innovative solutions and services to advance VA healthcare delivery. Like ORD, OHIL reports to Discovery, Education and Affiliate Networks (DEAN).

A detailed organizational chart of the VA as it relates to the clinical decision-making process for PTSD treatments can be found in the Appendix.

The Case Study of Prolonged Exposure (PE), the VA's gold-standard therapy for PTSD

To illuminate the VA's decision-making process when it comes to scaling mental health treatments, the closest example to look to is the roll-out of Prolonged Exposure (PE) therapy. PE is a specific type of cognitive behavioral therapy that teaches individuals to gradually approach trauma-related memories, feelings and situations. It has become the VA's standard of care for the treatment of Veteran PTSD.

Prolonged Exposure has been disseminated nationally, so that it is available to Veterans in every healthcare facility across the nation. As part of the process of dissemination, the VA developed considerable expertise in the process of bringing a new psychotherapy into large-scale routine care that can serve to inform widespread effective implementation of MDMA-AT. The VA developed and tested an intensive training model that includes systematized workshop training and post-training telephone consultation, development of marketing materials, establishment of a community of practice among clinicians, ongoing access to PTSD program managers, and program evaluation of training itself to ensure its quality and effectiveness. Importantly, the VA took explicit steps to bring training capacity within the VA itself, in order to reduce reliance upon external experts with limited access to and knowledge of VA systems and procedures, and provide for sustainability of training of new clinicians entering VA employment.

Experience has shown that such an approach is necessary to effectively transform delivery of mental health care. This implementation model can be used to ensure the success of the spread of MDMA-AT in the VA.

PE is widely used across the VA. MDMA-AT is different in many respects from PE, yet similar at its core[9]. The story of how and why PE made it into the VA illustrates several critical success factors and helps illuminate the steps needed for MDMA-AT adoption and maintenance, several of which will be different due to the unique nature and history of this treatment.

In 2007, the VA's Central Office made a coordinated push to make evidence-based therapies such as Prolonged Exposure (PE) the standard of care for PTSD treatment.

There were six factors that drove the successful roll-out and dissemination of PE:

1. **Evidence base.** When Evidence-Based Psychotherapies (EBPs) first made it into the VA, there was a lack of effective treatments for Veteran PTSD. Moreover, the treatments that the VA offered were not, by modern standards, evidence-based. Due to a lack of effective alternatives, new treatments were urgently needed, and evidence-based therapies such as PE were among the most promising options.

   Treatments based on rigorous evidence have since become the gold standard, increasing the barriers to entry for new treatments. While clinical decisions used to be made based on consensus of the clinical leadership, this approach has since been replaced by rigorous evaluation methodologies of the evidence landscape such as GRADE[10].

   Seven Randomized Clinical Trials (RCTs) of exposure therapy and PE for PTSD were published between 1991 and 2004, involving a total of 509 participants[11]. At the time of adoption, PE was the PTSD treatment best supported by research evidence. This was the literature that informed the VA's decision to strongly recommend this treatment in the 2004 Clinical Practice Guidelines. Two additional RCTs on PE were published between 2005 and 2007 with a total of 455 participants[12]. These results further informed the VA's decision to implement PE as part of a national effort to scale up Evidence-Based Psychotherapies. A large cooperative, multisite clinical trial[13] and a national evaluation of the PE program[14] have since raised the bar for the required evidence base for new mental health treatments.

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[9] PE is a structured psychotherapy in which the clinician plays a relatively active role in directing the treatment. In contrast, the MAPS protocol uses a less structured, inner-directed approach. Although they are roughly the same overall duration (16 weeks), MAPS requires two therapists to be present during 6-hour medication sessions, PE is delivered in 90 minute individual sessions with a single therapist and does not involve any medication. Despite these significant differences, there are many lessons to be learned from how the VA rolled out another evidence-based psychotherapy. Both require training and supervision to help clinicians develop new competencies, and in both cases there's a need for national and local systems interventions to ensure that there is adequate time and resources to allow clinicians to implement these protocols in practice.

[10] Grading of Recommendations, Assessment, Development, and Evaluations. More information here.

[11] See references in the Appendix "Clinical evidence base for PE"

[12] See references in the Appendix "Clinical evidence base for PE"

[13] Schnurr PP, Chard KM, Ruzek JI, Chow BK, Resick PA, et al. Comparison of Prolonged Exposure vs Cognitive Processing Therapy for Treatment of Posttraumatic Stress Disorder Among US Veterans: A Randomized Clinical Trial. JAMA Network Open. 2022 Jan.

[14] Eftekhari A, Ruzek JI, Crowley JJ, Rosen CS, Greenbaum MA, Karlin BE. Effectiveness of national implementation of prolonged exposure therapy in Veterans Affairs care. JAMA Psychiatry. 2013 Sep.

2. **Socio-political climate.** There was a special urgency for undertaking the task of nationally disseminating EBPs for PTSD during this period (2005-2010) as the nation was at war in both Iraq and Afghanistan and up to 25% of Veterans returned with this devastating disorder. Mental Health leadership during this period appreciated the urgency of the situation and convinced the VA to allocate millions of dollars along with personnel support to support these rollouts. This was seen as an opportunity to advance the cause of EBPs more broadly, so training initiatives were launched to address other mental illnesses such as Depressive Disorders, Anxiety Disorders, and Psychotic Disorders.

   Each of these initiatives followed a similar game plan, supporting in-person training, supervision, consultation, adherence ratings and program evaluation. The criteria for which EBPs were rolled out differed depending on the available medical literature and urgency of need, and were defined in a political process.

3. **Internal champions.** Rapid and comprehensive implementation of new evidence-based treatments in the nation's largest mental health system was enhanced by willingness, coordination, and leadership at multiple levels: VA political leadership, VA clinical leadership, and clinical practitioners.

   During the Iraq & Afghanistan wars, the VA exhibited visionary leadership by defining a progressive mental health approach for these Veterans, as reflected in the guidance outlined within the VA Handbook. At the time, leaders in both VA mental health and PTSD had become strong advocates for evidence-based psychotherapy. The success story of PE is a story of having "the right people at the right time". Champions within the agency, such as Chief Dr. Ira Katz and Deputy Chief Dr. Antonette Zeiss in the Office of Mental Health and Suicide Prevention (OMHSP), were instrumental in helping move forward with the implementation.

4. **National policy.** Beginning in 2007, based on the efforts of internal champions and the evidence base, the VACO launched national policy initiatives to help disseminate Evidence Based Psychotherapies (EBPs), such as the VHA Comprehensive Mental Health Strategic Plan and the VHA Handbook 1160.01: *Uniform Mental Health Services in VA Medical Centers and Clinics*. In addition to the transition to research-based treatments, the initiative also involved mandated access and a comprehensive training program.

   Through mandated access, the VA required the provision of Prolonged Exposure or Cognitive Processing Therapy at every VA hospital. They also began an ambitious new initiative to train thousands of VA clinicians to conduct EBPs for a variety of mental health conditions, including Prolonged Exposure for PTSD. The VA, led by the Office of Mental Health & Suicide Prevention along with the National Center for PTSD, developed online courses and in-person training workshops, supplemental training materials, and supervised practice and ongoing consultation. Trainees were assessed for their adherence to the various training models, and programs were evaluated to determine

whether these protocols work as well in VA clinical practice as they do in research studies. A clear mandate communicated by top leadership combined with top-down training initiatives were vital in persuading regional and local VA leaders to allocate the necessary resources to send clinicians to training, and support positions at each of the hospitals dedicated to EBP implementation.

5. **Resource allocation and local systems.** Organizational resources and staff capacity were an important issue at the local level. PE sessions are typically longer than other health care visits, and require more staff time. This required workload adjustments and "buying out" some clinician time with dedicated funding to enable them to serve as trainers and consultants. Early on, the VA established a PE training workforce that included several positions dedicated to management of the implementation program, as well as 17 national trainers and 70 telephone consultants to support clinicians as they encountered their first training cases. To facilitate the local implementation of EBPs, a full-time EBP coordinator was placed at each VA medical center to serve as a champion for the initiative. In addition, local Information Technology (IT) coordinators were engaged to ensure that clinicians had access to tools in the Electronic Medical Record.

   Several changes to the PTSD treatment culture and adaptation to local clinics and practices were made to enable the delivery of PE. For example, a number of clinics made substantial changes to move from an orientation on symptom management strategies to recovery-oriented, protocol-based therapies. Accountability systems were put into place at the local and national levels to ensure that PE was being delivered as prescribed. For example, performance measures incentivizing the delivery of EBPs were incorporated into the performance plans of senior VA managers at local, regional and national levels, and performance on these measures often impacted their bonuses. Evaluations of each EBP program were published in the scientific literature, providing further visibility into how the initiatives had performed.

6. **Bottom-up support from providers and patients.** As part of the EBP dissemination initiative, the VA took a variety of significant steps to promote bottom-up support at the local level. These efforts included, but were not limited to, involving local and regional program managers in the initiatives, establishing local and regional level champions and mentors, providing focused and targeted recruitment of training participants, and explicating the full requirements for and expectations of training in the recruitment process, as well as requiring local leadership approval for staff to participate in the training programs. Pilots at a number of facilities also evaluated the specifics of whether and how PE could work in the field.

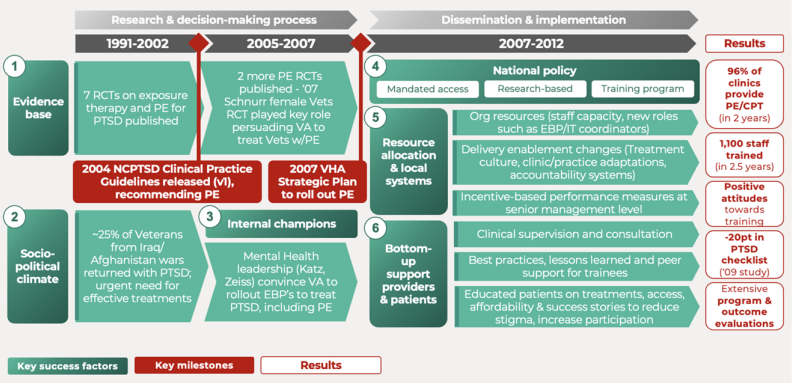
   PE providers were asked to complete a 4-day competency-based training workshop conducted by an approved PE trainer. Clinician trainees had to complete a minimum of two cases under weekly telephone consultation that included the review of therapy tapes, so that training of a clinician averaged six months in duration. After completing their formal training and consultation, PTSD providers could access ongoing consultation through the

NCPTSD Mentoring program which supported an additional consultant in each VA region (VISN). It is this longitudinal support and investment in ongoing clinical supervision and consultation that distinguishes this VA training initiative from many others. The VA also supported the establishment of Communities of Practice around these EBP initiatives, including intranet and sharepoint sites, virtual grand rounds and conferences, all of which provided trainees with the opportunity to learn from and support one another by sharing best practices and lessons learned. All of these initiatives helped drive change management for the clinician community.

Finally, EBPs have little clinical impact unless patients are informed about and engaged in the treatment. To address the lack of awareness and some unfavorable attitudes about EBPs, VA leadership shared success stories and positive patient outcome data to Veterans, family, staff, advocates, communities. Nationally developed EBP brochures, provider fact sheets, patient education videos, and posters were designed to provide education and promote awareness among staff and Veterans. Online courses and award winning mobile apps (*"PE Coach"*) were also developed to support Veterans who were engaged in Prolonged Exposure treatment.

Healing Breakthrough

Disseminating Prolonged Exposure (PE) in the VA: A Case Study



Overview of the PE case study – time and events, success factors, results

Rolling out PE vs. MDMA-AT – Key parallels and differences

While the story of PE provides a good blueprint for how to design the path to system-wide uptake for new evidence-based treatments, the journey will differ based on the challenges unique to MDMA-AT, as outlined previously. The table below explores where MDMA-AT stands on each of the six success factors that drove the successful adoption of PE.

Factor	Prolonged Exposure (PE)	MDMA-Assisted Therapy (MDMA-AT)
Evidence base	Most treatments that the VA offered in the early 2000s were not evidence-based and alternatives were limited. Seven RCTs evaluating PE had been published, which was more evidence than existed for any other PTSD treatment, based on which PE has been "strongly recommended" in every iteration of the VA/DoD Clinical Practice Guidelines since 2004.	**A strong clinical evidence base will be <u>even more important.</u>** 2023 VA/DoD guidelines state that there is not currently sufficient evidence for or against MDMA-AT to make a recommendation. FDA approval will be necessary but not sufficient for these recommendations to change. The required level of evidence and scrutiny for MDMA-AT can be expected to be higher due to stigma related to the Schedule 1 classification (prior to FDA approval and subsequent reclassification). Further, VA leadership will require

		that future MDMA-AT clinical trials use an active comparator such as low-dose MDMA to strive for blinding participants and providers to minimize biases. In addition, due to substantial logistical/resource challenges related to MDMA-AT, there is also a need for implementation research that evaluates the barriers and facilitators to adopting the intervention into routine clinical practice in the field.
Socio-political climate	In the early 2000's, the mental health field moved toward evidence-based treatments and bringing effective interventions into clinical practice in response to large numbers of Veterans returning from Iraq/Afghanistan with PTSD.	**External climate is <u>equally (or more) favorable.</u>** In the early 2020s, psychedelics went mainstream, with two states legalizing psychedelic "services" (at the state level, while remaining federally illegal). A great deal of interest became evident from the medical community, universities and pharmaceutical companies. MDMA-AT, as the first-in-line for FDA approval, will be the most relevant treatment for the VA to explore. Hopes are high that these treatments will help alleviate suffering among Veterans, many of which have been shown not to respond sufficiently to existing treatments. It is widely recognized that many patients drop out from PE and that a significant portion show no improvement, so that if MDMA-AT can address these limitations of PE, there will be significant support for its uptake. The Veteran mental health crisis has not been solved; 17-24 Veterans still commit suicide every day.
Internal champions	The right people took initiative at the right time: leaders in both VA mental health and PTSD were strong advocates for evidence-based psychotherapy and became internal champions.	**Internal champions will be <u>even more relevant</u> and have <u>yet to emerge.</u>** Dr. Paula Schnurr (NCPTSD) conducted studies and set up the initial infrastructure for the roll-out of PE for PTSD. NCPTSD, as the key national center of excellence in PTSD, will be important to securing leadership support. Working closely with experts and key decision-makers in the VA Central Office represents a critical opportunity to pave the way for quicker adoption of MDMA-AT.
National policy	The PE rollout was part of a systematic and resource-intensive initiative to implement Evidence-Based Psychotherapies throughout the VA that included mandated access and a comprehensive training initiative.	**A top-down mandate will be <u>even more necessary</u>.** Due to the magnitude of implementation challenges that need to be overcome, there needs to be a coordinated, national strategy to facilitate system-wide adoption. MDMA-AT is a new model of care that requires vast amounts of resources that the VA is not yet prepared to provide. The personnel and systems resources used to deliver PE are still in operation, and, with leadership support, could be leveraged to implement MDMA-AT.

Resource allocation and local systems	There were a handful of changes to local operations that were made in order to both enable *and* incentivize the delivery of PE as primary PTSD treatment.	**Resource allocation and local systems change will be <u>even more important</u>.** To develop an infrastructure for care delivery, the VA needs to actively allocate both human and financial capital to the dissemination of MDMA-AT. Existing provider capacity will need to be re-allocated, appropriate space converted, and several logistical barriers overcome that are the result of a fundamentally different care model. It is unclear yet how strong incentive structures need to be for clinicians to offer MDMA-AT consistently and at scale. On one hand, the effectiveness of the treatment could be a strong enough motivator to shift clinical practice; on the other hand, changes to routine practice involve major changes to familiar practice and are not always welcomed with enthusiasm. Given there are already existing systems in place, it should be easier to adjust them (versus create new ones to begin with).
Bottom-up support from providers and patients	VA clinical staff were not initially enthusiastic about the adoption of PE, and many felt that it was overly structured, directive, and prescriptive. Various initiatives on the clinic-level were rolled out in order to support clinicians and develop incentives for the adoption of PE. Veterans were not clamoring for PE either – the motivation to implement was primarily top-down and based on research rather than patient demand.	**Bottom-up support will likely be <u>higher</u>.** Grassroots support from Veterans will be critical – the treatment must be valued by Veterans and the major Veteran advocacy organizations as a desired and necessary service to be provided by the VA. The current level of interest in the Veteran community could be an important factor in generating clinician buy-in if mobilized effectively. Clinicians in the field who are following the research closely will make a push to pursue the necessary training and requirements post FDA-approval, which will be critical to widespread access. Clinicians will also work with local leadership to create the necessary conditions for successful implementation - for example, finding appropriate space and relaxing caseload requirements to support 6 hour medication sessions.

A Multidimensional Strategy To Implement MDMA-AT in the VA

Building upon the lessons learned from over a decade of experience, it is safe to conclude that sending someone to a MAPS training course and then back to their VA without any additional support at the local systems level will not be successful. As was the case in the VA EBP rollouts, scaling MDMA throughout the agency will require a multidimensional strategy that includes both top-down and bottom-up efforts.

Key success factors for the implementation of MDMA-AT in the VA

1. **Evidence base**

Healing Breakthrough has created a portfolio of projects that encompass both bottom-up and top-down efforts to implement MDMA-AT in the VA. Four investigator-initiated trials led by VA clinicians have been funded to generate evidence on a variety of research questions relevant to Veterans in a timely and nimble manner. An additional pilot study led by Dr. Paula Schnurr and Dr. Leslie Morland from the National Center for PTSD (NCPTSD) has been coordinated. Demonstration that MDMA-AT is specifically effective for Veterans with PTSD will be needed in order for widespread adoption to occur. In parallel, Healing Breakthrough has worked closely with VA leadership at NCPTSD and the Office of Mental Health and Suicide Prevention (OMHSP) in their efforts to evaluate whether there is sufficient research evidence to justify a formal decision to disseminate this new treatment in a top-down fashion, incorporating key implementation questions into the research.

A portfolio of research projects under the umbrella of NCPTSD

Healing Breakthrough has been working with NCPTSD, independent VA researchers, and the MAPS Investigator Initiated Trials (IIT) team to develop and curate a portfolio of complementary projects that will advance our mission of providing MDMA-AT to all Veterans who could benefit. This portfolio of projects under consideration by NCPTSD leadership includes:

- Individual Therapy (S. Remick, PI; R. Yehuda, PI)
- Couples Therapy (L. Morland, PI)
- Group Therapy (C. Stauffer, PI)
- Combining MDMA-AT with Prolonged Exposure (B. Rothbaum, PI; P. Schnurr & L. Morland Co-PIs)
- Comparing MDMA-AT to Cognitive Processing Therapy (T. Suppes, PI)
- Comparing MDMA-AT to an active placebo (S. Taylor, S. Marder Co-PIs)

To date, Healing Breakthrough's role has been to facilitate the funding of these initial studies that are designed to answer key clinical and implementation research questions. NCPTSD plans to use the results of its pilot studies to develop and execute a larger multi-site Randomized Controlled Trial (RCT). The Healing Breakthrough advocacy team is working with Congress to direct federal appropriations to support this study, rather than relying on philanthropic contributions which has been the case for MDMA-AT studies to date. Once such a larger study is completed, NCPTSD, in collaboration with DoD partners, will evaluate the results and determine whether MDMA-AT can be included as a recommended, evidence-based treatment in the official Clinical Practice Guidelines[15].

Successful implementation of MDMA-AT in real-world clinical settings will require significant efforts that go beyond conducting successful clinical trials. Once trials are underway, NCPTSD will broaden its focus to include study objectives and additional studies that focus on implementation, in various VA clinical practice settings (e.g. Intensive Outpatient programs, Residential Treatment programs). The NCPTSD Dissemination and Training Division that focuses exclusively on dissemination and implementation research will be an important partner in studying the factors that will ensure the sustained adoption of MDMA-AT in VA mental health. Similarly, close alignment with the leadership at the VA Office of Mental Health and Suicide Prevention (OMHSP) will ensure that NCPTSD is in a position to develop strategy and marshall resources to support the national rollout of MDMA-AT.

2. Socio-political climate

Psychedelic research is in full swing, with nearly 500 studies registered in the US alone[16]. Two states, Oregon and Colorado, have already legalized psychedelic services prior to FDA approval of the respective substances. States are increasingly pledging state-level funding towards research. MAPS is anticipated to receive FDA approval by mid 2024 for MDMA-Assisted Therapy, which will be the first federally legal psychedelic therapy. Advocates within and outside Congress are increasingly pushing for federal funding for psychedelic research, which to date has been entirely privately funded. The pressure to respond is increasing, and Healing Breakthrough is actively educating legislators in DC about the potential of MDMA-AT for Veterans and the need for more research. It is a core pillar of HB's strategy to mobilize the urgency and cultural moment around these breakthrough treatments to unlock millions in federal funding. Such funding would have the potential to significantly expedite access, and, as a result, save thousands of lives.

The Veteran voice will be a critical driver to move the ongoing political dialogue forward, given that Veteran PTSD is a bipartisan, national interest. HB believes that politically and culturally, Veterans are the most influential advocates for breakthrough therapies such as MDMA-AT.

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[15] See Appendix for details on the VA/DoD Clinical Practice Guidelines

[16] clinicaltrials.gov

HB's advocacy team has met with over 300 federal staff and policymakers since June 2022, garnering overwhelming support for MDMA-AT therapy for Veterans across the aisle. Over that period of time, they met with every member of the House and Senate Veterans Affairs Committees. In March 2023, 7 members from both sides of the aisle submitted appropriation requests to fund MDMA-AT research at the VA on HB's behalf.

HB's engagement with members of Congress, informing them of the two ongoing plus five new MDMA-AT trials in the VA, drew the attention of the Secretary of VA and the White House after Rep. Nancy Mace (R-SC), who worked with HB's advocacy team to prepare her talking points for questioning of VA Secretary McDonough on getting Veterans with PTSD access to MDMA-AT, discussed MDMA-AT during a House Committee on Veterans Affairs (HVAC) hearing with the Secretary in March 2023. Secretary McDonough has since begun visiting MDMA-AT therapy sites.

The Bergman-Correa amendment passed by voice vote in Congress the last week of July 2023 is a significant step towards achieving HB's goals. HB's team worked closely with the amendment's co-sponsors to craft language that signals Congress' intent to support MDMA-AT deployment through the VA without drawing attention to potentially controversial terms (i.e., "psychedelics"). As such, the amendment passed unanimously with the support of the Republican Study Committee (the conservative "think tank" within the Republican Caucus), the Hispanic Caucus, and the Black Caucus.

3. Internal champions

NCPTSD and the Office of Mental Health and Suicide Prevention (OMHSP) are the two hubs for thought-leadership and institutional decision-making within the VA for the treatment of Veteran PTSD. NCPTSD is the world's leading research and educational center of excellence on PTSD and traumatic stress, created by Congressional mandate (PL 98-528[17]) to set the agenda for research and education on PTSD without direct responsibility for patient care. Convinced that no single VA site could adequately serve this unique mission, the VA established the Center as a consortium of five divisions, reporting to the Office of Mental Health and Suicide Prevention.

The Secretary of the VA points to NCPTSD as the organization responsible for making MDMA-AT accessible to all VA patients.

> *Congresswoman Mace:* "If we are going to lose 60-70,000 vets over the next decade to suicide, what do we have to do to get this [MDMA-AT therapy] to our vets? … How do we get this to ALL of our facilities across the country?"

[17] See excerpt in Appendix

> *Secretary McDonough:* "We have a National PTSD Center of Excellence that we are very proud of."[18]

Dr. Schnurr, the Executive Director of NCPTSD and our key research partner, has been chair of three VA cooperative studies evaluating the efficacy and effectiveness of PE and Cognitive Processing Therapy (CPT). Those three studies alone enrolled over 1,500 patients. Dr. Schnurr has been Principal Investigator (PI) of three additional research studies and has conducted approximately 20 studies as a co-investigator.[19] She is internationally recognized as an authority in psychotherapy clinical trial design, for example as an invited member of the workgroup that developed the CONSORT standards for reporting non-pharmaceutical trials. International researchers routinely consult with Dr. Schnurr regarding the design of psychotherapy trials. Influential decision-makers such as Dr. Schnurr will be critical in leading the charge to bring MDMA-AT to the VA and overcoming the various barriers that might impede adoption.

4. National policy

At the policy level, MDMA-AT is currently a Schedule 1 substance, which means that it is only available to participants in research trials. FDA approval in 2024 will change the rules of the game, but does not come along with a national VA policy to ensure its effective dissemination. The VA is a conservative organization that wants to see compelling data on MDMA-AT from studies of Veteran patients, ideally those seen in VA facilities. Until such evidence is generated and brought to bear, it is unlikely that the VA will issue formal policies or strategic plans to make MDMA-AT available throughout the system, as they did with the Evidence-Based Psychotherapies.

5. Resource allocation and local systems

Many more accommodations will be required at the local systems level to support the delivery of MDMA-AT than the Evidence Based Psychotherapies. For example, the MAPS protocol specifies three medication sessions, each separated by at least 21 days, and each requiring the engagement of two therapists for six hours at a time. VA clinicians are currently required to see 30 Veterans a week. Delivering MDMA-AT means that they will need workload adjustments and changes to the scheduling grid. Physical facilities are another local challenge. The VA mental health system operates on largely an outpatient basis, and the specific space requirements for MDMA-AT may not align with what is available at each hospital. Finally, coordination between prescriber, pharmacy, and the other clinical services that are delivering the psychotherapy will need to be worked out.

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[18] Mace N, McDonough D: Rep Nancy Mace Questions Secretary McDonough on MDMA-AT for PTSD for Veterans. House Veterans Affairs Committee Meeting Mar 23 2023

[19] See clinical bibliography in the Appendix

In order to ensure that sufficient resources will be allocated and local systems sufficiently adapted, HB is working with various stakeholders within NCPTSD to develop transparency on key challenges and strategies to overcome them.

6. Bottom-up support from providers and patients

MAPS provides outstanding competency-based training in MDMA-AT, and other training programs are rapidly coming online. However, despite their cumulative best efforts, these programs simply do not have the bandwidth to get thousands of VA clinicians trained in a reasonable time frame. Furthermore, these training programs do not have the resources to provide ongoing post-training consultation to all trainees. A key lesson learned from the EBP initiative is that ongoing consultation is one of the most important elements that drive enduring change in clinical practice. Lastly, although there are a number of providers excited to provide MDMA-AT once approved, further messaging will be required to make the therapy more acceptable to VA clinicians who are not yet fully bought into the MDMA-AT approach.

Rollout is a core pillar of HB's strategy, which will not only involve the development of a tailored MDMA-AT training for the VA, but also include initiatives to educate and engage the larger VA clinician community. Existing MDMA training programs do not discuss how a VA clinician may need to negotiate with management to get the time, space and other resources necessary to do the treatment once they return to their facilities, or explore how managers can restructure their services to enable delivery of NDMA-AT under existing staffing constraints. Neither do these programs delve deeply into the topics of combat PTSD, military culture and values, and moral injury - topics of special interest and concern when working with Veteran patients.

As the results of the current trials and lead-in studies become available, it will be important to work with NCPTSD and others to establish smaller scale training programs and implementation projects that don't seek to modify the entire system (in the absence of the data that will be needed) but expand the MDMA-AT offerings that include field evaluation under real-world conditions and in the process develop training and implementation systems/resources and get ready for wider national dissemination.

HB expects Veteran demand for MDMA-AT to be higher than demand for EBPs due to the positive press, but HB is also quite aware that there will be those who are skeptical about engaging it due to concerns about the stigma associated with using MDMA. As in the EBP rollouts, it will be important to meet patients where they are at, and provide them with the resources that they need to make an informed decision about whether this course of treatment is right for them.

Stakeholder engagement and collaboration across the VA (and beyond)

Beyond fostering collaboration across VA clinicians through the portfolio approach and working with MAPS PBC to help start up those collaborations, Healing Breakthrough is also engaging key stakeholders throughout the VA to maximize the support and buy-in necessary for widespread adoption.

(a) VA Central Office leadership

Senior VA leadership

Erica Scavella Chief Medical Officer - Oversees Clinical Services

Carolyn Clancy Assistant Under Secretary for Health for Discovery, Education and Affiliate Networks, Oversees ORD

Beyond NCPTSD, Healing Breakthrough is also collaborating with the Office of Mental Health and Suicide Prevention (OMHSP), Office of Research & Development (ORD), as well as the Residential Rehabilitation Treatment Program (RRTP). HB is engaging the following stakeholders in their respective offices and programs:

NCPTSD - Dr. Paula Schnurr and Dr. Leslie Morland

Office of Mental Health and Suicide Prevention (OMHSP) - Dr. Ilse Wiechers

VA Residential Rehabilitation Treatment Programs (RRTP) - Dr. Jennifer Burden

VA Office of Research & Development (ORD) - Dr. Rachel Ramoni, Dr. Grant Huang

VA ORD Clinical Services - Dr. Miriam Smyth, Dr. Vetisha McClair

VA ORD Health Services - Dr. David Atkins, Dr. Amy Kilbourne

VA Quality Enhancement Research Initiative (QUERI) - Melissa Braganza

(b) The VA Field: Local and regional leadership

Veterans Integrated Service Networks (VISN) and Medical Center Directors: VISNs have considerable autonomy in how VA national policies are implemented in their regions, as do the directors of the Medical Centers within each region. NCPTSD has connections with many important stakeholders at the VISN and Medical Center level. In addition, the HB team is currently building relationships with several of these regional and local leaders through our connections with Veteran Service Organizations and outreach efforts.

(c) Scientific experts and Key Opinion Leaders (KOLs)

HB has formed a Scientific Advisory Board to complement the VA's expertise, as well as a consortium of advisors to NCPTSD's research program, which includes clinical leadership for MAPS PBC.

Healing Breakthrough Scientific Advisory Board - Dr. Tom Insel, Dr. John Krystal, Dr. Husseini K. Manji, Dr. Candice M. Monson

NCPTSD study advisors - Dr. Michael Mithoefer, Ilse Wiechers, Stephanie Taylor

(d) Political leadership

HB is also engaging the House and Senate Committee on Veterans Affairs, the Office of the Secretary of the VA, as well as various members of Congress in our effort to guarantee appropriations for the large, national trial that will follow the current lead-in studies.

(e) Veteran Advocates & Advocacy Organizations

Last, but not least, HB is working closely with other Veteran Advocacy Organizations and key advocates in the space, such as Heroic Hearts Project, Reason for Hope, VETS, MAPS and others.

Conclusion

Healing Breakthrough will support a multi-year, comprehensive approach to safely and equitably implement MDMA-AT throughout the VA. This new model of care will be based on sound evidence, directed at a deserving population, and can save thousands of lives and improve the quality of life for Veterans with PTSD.

HB's approach goes far beyond providing the clinical training that will be necessary, but insufficient to drive sustained adoption of MDMA-AT throughout the system. It will employ both top-down and bottom-up strategies, including a centralized initiative supported by virtually all levels of national VA leadership that will complement ongoing engagement and buy-in of the local and regional clinical leadership in the field.

HB will move forward in lockstep with the National Center for PTSD, which is the most widely respected and influential organization in the VA regarding PTSD treatment. Close collaboration with the Center's Executive Director will greatly accelerate the process of evaluating and implementing MDMA-AT. In fact, NCPTSD is a gate through which other MDMA-AT training and dissemination initiatives must pass, as senior VA leadership typically defers decisions regarding such issues to the VA Office of Mental Health Services and Suicide Prevention (OMHSP), which in turn looks to NCPTSD for guidance.

HB is also working with all of the relevant constituencies including the VA Office of Research and Development as well as political leadership in Congress, advocacy groups and scientific experts to ensure that our comprehensive approach to evaluating and implementing MDMA-AT can be extended to all appropriate Veteran patients.

Without this initiative it could take 10 or more years for this treatment to become available to Veterans at scale through the VA. Healing Breakthrough aims to catalyze the process of adoption down to 5 years so any Veteran will be able to go to their VA clinic and receive treatment by the end of the decade. Veterans with PTSD deserve timely access to this breakthrough treatment and Healing Breathrough's mission is to ensure that they receive it.

Healing Breakthrough

Appendix

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Organizational structure of the VA Central Office

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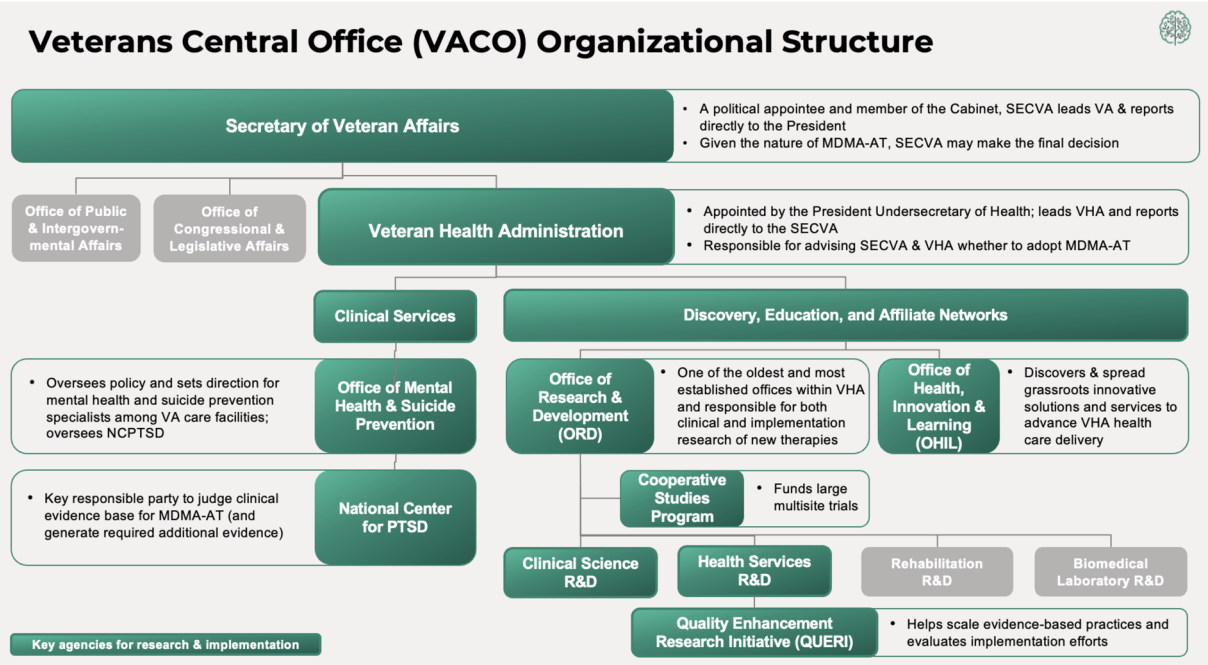

Healing Breakthrough

Primer on the VA/DoD Clinical Practice Guidelines (CPG)

What are Clinical Practice Guidelines?

CPGs are statements that include recommendations, intended to optimize patient care, that are informed by (a) a systematic review of the quality of research evidence bearing on a clinical question, and (b) a set of recommendations involving both evidence and value judgments regarding benefits and harms of different care options. Final CPG recommendations are typically presented as a treatment algorithm or flowchart.

How CPGs are developed

CPGs are based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts with representation from both the VA and DoD, they provide a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.

How CPGs evaluate the quality of evidence

The VA Clinical Practice Guideline for PTSD uses the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess the quality of the evidence base and assign a grade for the strength for each recommendation. Evidence from randomized controlled trials starts at high quality, while evidence from observational studies starts at low quality.

Criteria for a study being included in the CPG

Studies must be published in English, must be a full clinical study or systematic review (abstracts, letters editorials not accepted). Small studies are not included; studies must enroll at least 20 patients (10 per study group). Studies must also have reported an outcome of interest, and must have enrolled a patient population in which at least 80% of patients are diagnosed with PTSD.

2023 VA/Department of Defense CPG Recommendation regarding MDMA

VA and DoD recently released a new CPG for PTSD. The guideline describes the critical decision points in the Management of Posttraumatic Stress Disorder and Acute Stress Disorder and provides clear and comprehensive evidence based recommendations incorporating current information and practices for practitioners throughout the DoD and VA Healthcare systems. For the first time, this CPG makes reference to MDMA-AT, and concludes that there is currently insufficient evidence to recommend for or against MDMA-AT for the treatment of PTSD. The rationale that the guidelines committee provided for this conclusion is as follows.

Discussion

Six small to moderately sized RCTs (including a total of 176 participants)[20] have found this form of MDMA-assisted psychotherapy to benefit individuals with PTSD. However, these studies have differed notably in the control condition used. Some have used low-dose MDMA as the control condition, whereas others have used an inactive placebo. Studies using low-dose MDMA as the control condition generally demonstrated much better blinding.

The VA/DoD Clinical Practice Guidelines for PTSD Work Group systematically reviewed evidence related to this recommendation. Therefore, the recommendation is categorized as a *Reviewed, New-added* recommendation. The Work Group's confidence in the quality of the evidence was low. The body of evidence had limitations, including relatively few participants, including few Veterans and no Service members, studied and differing control conditions that impacted adequacy of blinding and could have biased the outcomes. Additionally, relatively few Veterans or active duty Service members were included. The benefits of MDMA are balanced with the potential harms, which include worsening symptoms and an increase in suicidal ideation (study not included in the evidence base nor impacting the strength of the recommendation). Patient values and preferences varied mainly because of comfort with psychedelic treatment. Thus, the Work Group made the following recommendation: There is insufficient evidence to recommend for or against 3,4-methylenedioxymethamphetamine assisted psychotherapy for the treatment of PTSD.

[20] Jerome L, Feduccia AA, Wang JB, Hamilton S, Yazar-Klosinski B, Emerson A, Mithoefer MC, Doblin R. Long-term follow-up outcomes of MDMA-assisted psychotherapy for treatment of PTSD: a longitudinal pooled analysis of six phase 2 trials. Psychopharmacology (Berl). 2020 Aug.

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Analysis to compare NCPTSD's protocol to the MAPS protocol

Context

Drs. Paula Schnurr and Leslie Morland have proposed a new protocol for their lead-in study with the National Center for PTSD (NCPTSD). The following analysis assesses the degree to which the MAPS MDMA-AT protocol overlaps with the NCPTSD Protocol.

In the new NCPTSD protocol, a single dose of MDMA is embedded within a two week, 100-hour course of intensive Prolonged Exposure (PE). All study clinicians will be MAPS trained, will follow the MAPS protocol for the medication session, and will include MDMA-specific topics in both preparation and integration sessions. Concerns have been raised that this MDMA-PE protocol departs so significantly from the MAPS protocol that it may exclude certain key elements that are thought to be key to the latter's effectiveness. There is a specific concern that the new PE protocol will abandon the "inner directed" approach that is a hallmark of the MAPS approach.

Key takeaway

HB concludes that there is actually a very high degree of alignment between MAPS and MDMA-PE: 22 out of 23 MAPS adherence criteria for preparation sessions are aligned with MDMA-PE, 19 out of 19 for medication sessions (during which both approaches follow the identical protocol), and 11 out of 12 criteria for integration sessions.

The reason for this alignment is twofold; (1) MDMA-PE will adhere to all of the MAPS criteria for the medication session and include MDMA specific content in preparation and integration, and (2) many of the criteria in the MAPS manual reflect the common factors in psychotherapy that are present in almost all good clinical relationships, including those that are developed in PE. Common factors include therapeutic alliance, empathy, and unconditional positive regard.

Methodology

This analysis is anchored in version 6 of the MAPS Adherence Manual which is typically used to rate the extent to which a study clinician's work with an individual client comports with the MAPS model. Each entry in the spreadsheet corresponds with a rating item in the MAPS adherence coding manual. Adherence criteria for preparation, medication, and integration sessions can be found below

Please see the following pages for the detailed analysis.

(a) Preparation

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Adherence Criteria in Preparatory Sessions	MAPS	PE	MDMA-PE
General Behaviors or Actions			
Created and communicated a setting of safety and support	X	X	X
Nurtured an attitude of trust in the healing properties of the therapeutic process and introduced the concept of the participant's inner healing intelligence	X		
Elicited, explored, or addressed participant's expectations, fears or concerns	X	X	X
Discrete Behaviors or Actions			
Validated the importance of positive, affirming experiences as part of the process of healing, growth or meaning-making	X	X	X
Validated the importance of negative, difficult experiences as part of the process of healing, growth or meaning-making	X	X	X
Elicited significant historical information, especially that which was related to trauma history	X	X	X
Assessed participant's knowledge regarding PTSD and its impact on their life; therapist provide education about PTSD as needed	X	X	X
Described the likely effects of MDMA	X		X
Described typical procedures of Experimental Sessions	X	X	X
Explained that this model of therapy uses a largely inner-directed approach and elaborated on the meaning and implications of this approach	X		X
Explained that, in Experimental Sessions, they will encourage the participant to set aside expectations and remain open to whatever emerges	X		X
Explained that they will encourage the participant to have periods of inner focus balanced with periods of verbal communication, which either the therapists or the participant may initiate	X		X
Therapist and participant agreed that at some time during each Experimental Session, the therapist may bring up the trauma if the participant has not spontaneously done so	X	X	X
Explained that in this model of therapy, they will provide support and encouragement for staying present with a difficult experience	X	X	X
Explained that if thoughts or feelings of wanting to leave should arise during the Experimental Sessions, it is important to express them and work with them rather than act on them. Explained that at the beginning of each Experimental Session, they will ask for an agreement that the participant will not leave the clinic until the next morning	X		X
Explained that during treatment, therapist may inquire about participant's bodily sensations and encourage exploration of the body through movement in whatever way may feel appropriate	X	X	X

Discussed the optional use of physical touch during Experimental and Integrative sessions	X		X
Explained that therapist will use music to support the experience without being intrusive and will allow periods of silence, if requested by the participant	X		X
Discussed the rationale for optional use of eyeshades and headphones	X		X
Explained that the therapist will enure the participants physical safety in various ways	X	X	X
Identified a stress innoculation technique that worked well for therapist and/or taught the participant a technique such as diaphragmatic breathing	X	X	X
Invited the participant to talk about their experience of anxiety, including triggers and defenses, and discussed ways that the therapists can help the participant through anxiety stages if and when they occur	X	X	X
Discussed the nature of the participant support system	X	X	X
Discussed the possibility of including a support person in a study session(s)	X	X	X
Total	**23**	**14**	**22**

(b) Medication

Adherence Criteria in Medication Sessions	**MAPS**	**PE**	**MDMA-PE**
General Behaviors or Actions			
Created and communicated a setting of safety and support	X	X	X
Used Physical touch/physical space, respected participants boundaries	X	X	X
Used communication that the participant could easily follow	X	X	X
Encouraged and/or allowed participant to have periods of inner focus balanced with periods of communication	X		X
Used supportive language and conduct that encourages the participant to stay present with their immediate experience, including difficult experiences, if they occurred	X	X	X
Conveyed a non-judgmental attitude towards the participant's experience and did not pathologize transpersonal experiences or multiplicity if they occurred	X		X
Validated positive, affirming experiences or or insights as part of a process of healing, growth or meaning-making	X	X	X
Used a largely non directive approach being guided by the participants experience, offering support in service of unfolding inner directed process	X		X
If the participant repeatedly avoided trauma-related material, the therapist gently encouraged collaborative exploration	X	X	X

If the participant was having a largely inward process, therapists did not interrupt this process to discuss traumatic material	X		X
Therapists treated all material that arose during the session as relevant to the healing process	X	X	X
Therapists used music to support the experience without being intrusive and allowed periods of silence, if requested by the participant	X		X
Both therapists were present in the room for the entire session, with the exception of one therapist at a time taking breaks for the bathroom, short meal breaks, medical needs or nursing	X		X
Therapists worked effectively as a team and respected any therapist preference from the participant	X		X
Discrete Behaviors or Actions			
Encouraged the participant to go inward for an extended period of time, within twenty minutes after MDMA was ingested.	X		X
Brought the participants attention to bodily sensations and, when appropriate, encouraged exploration of any pains, tightness or energy in the body through movement, bodywork and/or emotional processing, or in whatever way felt appropriate to the participant.	X		X
Facilitated processing of any regrets or self-judgment by putting them in perspective as part of the ongoing healing process	X	X	X
If the participant expressed that they were overwhelmed during the onset of MDMA effects, the therapists reassured the participant about safety, encouraged them to use diaphragmatic breathing or other relaxation techniques, and/or reminded them that feelings of intensity would be experienced in waves.	X		X
If the participant expressed that they were overwhelmed by difficult experiences later in the session, the therapists encouraged the participant to "breathe into" the experience and feel or express it as fully as possible.	X	X	X
Therapists ensured the participants physical safety by asking them to sit on the edge of the futon before rising, protecting the participant from falling when walking, and ensuring adequate fluid intake by asking the participant to drink periodically, if necessary.	X		X
Total	**19**	**9**	**19**

(c) Integration

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Adherence Criteria in Integration Sessions	MAPS	PE	MDMA-PE
General behaviors or actions			
Facilitated discussion of the participant's emotional and cognitive response to the sessions	X	X	X
Facilitated inquiry into the participant's unfolding somatic experience	X		
Followed the participant's lead regarding how much to talk about the Experimental Session or it's sequelae	X		X
Facilitated processing of emotional distress and cognitive dilemmas that arose for the participant, including regret and self-judgment by putting them in perspective as part of the ongoing process of healing and growth.	X	X	X
Discrete Behaviors or Actions			
Therapists invited the participant to talk more about the experimental session or any sequelae. If the participant does this spontaneously, then active listening constitutes appropriate engagement.	X	X	X
Validated affirming experiences or insights that occurred during or since the experimental session, and if necessary, helped the participant learn to reconnect with and continue to gain from these experiences.	X	X	X
Inquired about whether there were any challenges the participant might be experiencing with regard to integration that would benefit from further exploration and support	X	X	X
Reminded participant that the experience would continue to unfold over time, and communicated that waves of intense emotion or new experiencing, whether difficult or affirming, are part of the dynamically shifting healing process	X	X	X
Reinforced activities, such as journaling, or other creative expression, yoga, use of breath, body awareness, or other activities that support ongoing healing, self-awareness, and integration	X	X	X
Re-emphasized their commitment to support he participant during the integration period by addressing follow-up or on-call provision in case of any difficulties or concerns	X	X	X
On the day of experimental sessions, therapist encouraged the participant not to engage in strenuous, stressful, or over-stimulation activity for the remainder of the day; in later integrative sessions, therapists emphasized the continued importance of gentleness, rest of relaxation	X		X
Encouraged the participant to feel connected with their support system, but cautioned the participant that other people may not understand the depths of their experience and insights.	X		X
Total	**12**	**8**	**11**

Overview of the clinical evidence base for PE

1. Foa EB, Rothbaum BO, Riggs DS et al. Treatment of posttraumatic stress disorder in rape victims: a comparison between cognitive-behavioral procedures and counseling. *J Consult Clin Psychol 1991*; 59(5):715-23. **RCT, n=45**

2. Marks I, Lovell K, Noshirvani H et al. Treatment of posttraumatic stress disorder by exposure and/or cognitive restructuring: a controlled study. *Arch Gen Psychiatry 1998*; 55 (4):317-25. **RCT, n=87**

3. Tarrier N, Pilgrim H, Sommerfield C et al. A randomized trial of cognitive therapy and imaginal exposure in the treatment of chronic posttraumatic stress disorder. *J Consult Clin Psychol 1999*; 67 (1):13-8. **RCT, n=72**

4. Foa EB, Dancu CV, Hembree EA et al. A comparison of exposure therapy, stress inoculation training, and their combination for reducing posttraumatic stress disorder in female assault victims. *J Consult Clin Psychol* 1999; 67 (2):194-200. **RCT, n=96**

5. Paunovic N, Ost LG. Cognitive-behavior therapy vs exposure therapy in the treatment of PTSD in refugees. *Behav Res Ther 2001*; 39 (10):1183-97. **RCT, n=16**

6. Resick PA, Nishith P, Weaver TL et al. A comparison of cognitive-processing therapy with prolonged exposure and a waiting condition for the treatment of chronic posttraumatic stress disorder in female rape victims. *J Consult Clin Psychol 2002*; 70 (4):867-79 **RCT, n=171**

7. Ironson G, Freund B, Strauss JL et al. Comparison of two treatments for traumatic stress: a co-mmunity-based study of EMDR and prolonged exposure. *J Clin Psychol 2002*; 58 (1):113-28 **RCT, n=22**

8. Foa, E. B., Hembree, E. A., Cahill, S. P., Rauch, S. A. M., Riggs, D. S., Feeny, N. C., et al. (2005). Randomized trial of Prolonged Exposure for PTSD with and without cognitive restructuring: Outcome at academic and community clinics. *Journal of Consulting and Clinical Psychology*, 73, 953–964. **RCT, n=171**

9. Schnurr, P. P., Friedman, M. J., Engel, C. C., Foa, E. B., Shea, M. T., Chow, B. K., et al. (2007). Cognitive-behavioral therapy for posttraumatic stress disorder in women: A randomized controlled trial. *Journal of the American Medical Association, 297*, 820–830. **RCT, n=284**

10. Nacasch N, Foa EB, Huppert JD, Tzur D, Fostick L, Dinstein Y, Polliack M, Zohar J. Prolonged exposure therapy for combat- and terror-related posttraumatic stress disorder: a randomized control comparison with treatment as usual. J Clin Psychiatry. 2011 Sep;72(9):1174-80. Doi: 10.4088/JCP.09m05682blu. Epub 2010 Nov 16. PMID: 21208581. **RCT, n=30**

11. Eftekhari A, Ruzek JI, Crowley JJ, Rosen CS, Greenbaum MA, Karlin BE. Effectiveness of national implementation of prolonged exposure therapy in Veterans Affairs care. *JAMA Psychiatry*. 2013 Sep;70(9):949-55. doi: 10.1001/jamapsychiatry.2013.36. PMID: 23863892. **Non-randomized. n=1,931**

12. Meyers, L. L., Strom, T. Q., Leskela, J., Thuras, P., Kehle-Forbes, S. M., & Curry, K. T. (2013). Service utilization following participation in cognitive processing therapy or prolonged exposure therapy for posttraumatic stress disorder. *Military Medicine*, 178, 95-99. doi: 10.7205/MILMED-D-12-00302 **Non-randomized, n=70**

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Clinical research bibliography Dr. Paula Schnurr (NCPTSD)

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4. Watts, B.V., Schnurr, P.P., Zayed, M., Young-Xu, Y., Stender, P., & Llewellyn-Thomas, H. (2015). A randomized controlled clinical trial of a patient decision aid for posttraumatic stress disorder. Psychiatric Services, 66, 149-154. doi: 10.1176/appi.ps.201400062

5. Lang, A.J., Schnurr, P.P., Jain, S., He, F., Walser, R.D. Bolton, E., Benedek, D.M., Norman, S.B., Sylvers, P., Flashman, L., Strauss, J., Raman, R., & Chard, K.M. (2017). Randomized controlled trial of Acceptance and Commitment Therapy for distress and impairment in OEF/OIF/OND Veterans. Psychological Trauma: Theory, Research, Practice, and Policy, 9, 74-84. doi: 10.1037/tra0000127

6. Schnurr, P.P., Chard, K.M., Ruzek, J.I., Chow, B.K., Resick. P.A., Foa, E.B., Marx, B. P., Friedman, M.J., Bovin, M.J., Caudle, K.L., Castillo, D., Curry, K.T., Hollifield, M., Huang, G.D., Shih, M.-C., & the CERV PTSD Study Team. (2022). Comparison of Prolonged Exposure vs Cognitive Processing Therapy for treatment of posttraumatic stress disorder among US veterans. A randomized clinical trial. JAMA Network Open, 5(1)

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Legal Mandate of the National Center for PTSD

(E) special programs of education and training for employees of the Department of Medicine and Surgery and the Department of Veterans' Benefits (also taking into account such provisions);

(F) the appropriate allocation of resources for all such activities; and

(G) any specific steps that should be taken to improve such diagnosis and treatment and to correct any deficiencies in the operations of designated PTSD programs.

National Center on Post-Traumatic-Stress Disorder, establishment.

(c) The Chief Medical Director shall establish and operate in the Department of Medicine and Surgery a National Center on Post-Traumatic-Stress Disorder. The National Center (1) shall carry out and promote the training of health care and related personnel in, and research into, the causes and diagnosis of PTSD and the treatment of veterans for PTSD, and (2) shall serve as a resource center for, and promote and seek to coordinate the exchange of information regarding, all research and training activities carried out by the Veterans' Administration, and by other Federal and non-Federal entities, with respect to PTSD.

(d) The Chief Medical Director shall regularly compile and publish the results of research that has been conducted relating to PTSD.

Report.

(e)(1) Not later than March 1, 1985, the Administrator shall submit to the Committees on Veterans' Affairs of the Senate and House of Representatives a report on the implementation of this section. The report shall include the following:

(A) A list of the members of the Special Committee.

(B) A list of all designated PTSD programs and other programs providing treatment for PTSD, together with a description of the resources that have been allocated for the development and operation of each such program, a description of the education and training that has been provided for Veterans' Administration health-care personnel in such programs and elsewhere within the Veterans' Administration in the diagnosis and treatment of PTSD, and specification of the funding that has been allocated to each such program and elsewhere within the Veterans' Administration to support research relating to PTSD.

(C) The assessment of the Chief Medical Director of the Veterans' Administration, after consultation with the Special Committee, regarding the capability of the Veterans' Administration to meet the needs for inpatient and outpatient PTSD diagnosis and treatment (both through designated PTSD programs and otherwise) of veterans who served in the Republic of Vietnam during the Vietnam era, former prisoners of war, and other veterans eligible for health care from the Veterans' Administration and the efficacy of the treatment so provided, as well as a description of the results of any evaluations that have been made of PTSD treatment programs.

(D) The plans of the Special Committee for further assessments of the capability of the Veterans' Administration to diagnose and treat veterans with PTSD.

(E) The recommendations made by the Special Committee to the Chief Medical Director and the views of the Chief Medical Director on such recommendations.

(F) A summary of the results of research conducted by the Veterans' Administration relating to PTSD.

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Key stakeholders and advisors

Healing Breakthrough Scientific Advisory Board

Husseini K. Manji, MD, FRCPC, is the Global Head of J&J Science for Minds, and the immediate past Global Therapeutic Head for Neuroscience at Janssen Research & Development, LLC, a Johnson & Johnson company. He is a Visiting Professor at Oxford University and Duke University. He is a member of the Scientific Advisory Board of the Stanley Center at the Broad Institute of MIT and Harvard, the World Dementia Council, and the Interim Board of the Healthy Brains Global Initiative. Before joining J&J, Dr. Manji was previously Chief of the Laboratory of Molecular Pathophysiology at the National Institutes of Health (NIH) and Director of the NIH Mood and Anxiety Disorders Program, the most extensive program of its kind in the world.

Tom Insel, M.D., a psychiatrist and neuroscientist, has been a national leader in mental health research, policy, and technology. From 2002-2015, Dr. Insel served as Director of the National Institute of Mental Health (NIMH). More recently (2015 – 2017), he led the Mental Health Team at Verily (formerly Google Life Sciences) in South San Francisco, CA. In 2017, he co-founded Mindstrong Health, a Silicon Valley start-up building tools for people with serious mental illness. In 2020, he co-founded Humanest Care, an online therapeutic community for recovery. Dr. Insel is a National Academy of Medicine member and has received numerous national and international awards, including honorary degrees in the U.S. and Europe.

Candice M. Monson, Ph.D., is a Professor of Psychology at Ryerson University in Toronto. She is one of the foremost experts on traumatic stress and using individual and conjoint therapies to treat PTSD. She has published extensively on the development, evaluation, and dissemination of PTSD treatments. The VA has funded her NIMH, CDC, DoD, and Canadian Institutes of Health for her research on interpersonal factors in traumatization and individual-and conjoint-based interventions for PTSD. She is a Fellow of the American and Canadian Psychological Associations (CPA) and was the CPA Traumatic Stress Section's Trauma Psychologist of the Year in 2013. She also received the Sarwan Sahota Ryerson Distinguished Scholar Award in 2014 and is a fellow of the Royal Society of Canada.

John Krystal, MD is the Chair of the Department of Psychiatry at Yale and is a leading expert in alcoholism, post-traumatic stress disorder, schizophrenia, and depression. His work links psychopharmacology, neuroimaging, molecular genetics, and computational neuroscience to study the neurobiology and treatment of these disorders. He is best known for leading the discovery of the rapid antidepressant effects of ketamine in depressed patients. He is a member of the U.S. National Academy of Medicine. He also serves in a variety of advisory and review capacities for NIAAA, NIMH, Wellcome Trust, Brain, and Behavior Research Foundation, the Broad Institute, the Karolinska Institute, and the U.S. Dept. of Veterans Affairs.

National Center for PTSD (NCPTSD)

Dr. Paula Schnurr is the Executive Director of the National Center for Posttraumatic Stress Disorder (NCPTSD) and had previously served as Deputy Executive Director of the Center since 1989. She is a Professor of Psychiatry at the Geisel School of Medicine at Dartmouth and Editor of the *Clinician's Trauma Update-Online*. Dr. Schnurr is Past-President of the International Society for Traumatic Stress Studies and is a fellow of the American Psychological Association. She previously served as Editor of the *Journal of Traumatic Stress*. She has investigated risk and resilience factors associated with the long-term physical and mental health outcomes of exposure to traumatic events. She is an expert on psychotherapy research and clinical trial design. She has conducted a number of clinical trials of PTSD treatment, including large multi-site trials in the Department of Veterans Affairs.

Leslie Morland, PsyD is a clinical psychologist and a senior researcher at NCPTSD. Women's Health Science Division and a Professor of Psychiatry in the School of Medicine at the University of California, San Diego. Dr. Morland served as the Chief of Outpatient Access and Director of Telemental Health for the VA San Diego Healthcare System for the past 9 years. Prior to this role, she was Deputy Director at the NPSTD Pacific Island Division. As a researcher at NCPTSD over the past 25 years, Dr. Morland has focused on enhancing our knowledge of how to best deliver PTSD care for Veterans and informing policy on a national level on improving access, quality, and efficacy of PTSD care. Dr Morland has executed multiple large federal funded trials focused on evaluating and disseminating the innovative use of technology to increase access and the uptake of evidence-based psychotherapies for PTSD. Her more recent research focuses on examining improving efficacy with the use of medications such as Oxytocin and MDMA to potentiate evidence-based PTSD treatments (e.g., Cognitive Behavioral Conjoint Therapy for PTSD, Prolonged Exposure). Dr. Morland provides research collaboration, consultation and mentorship on multiple research projects and national initiatives and strategy planning. She is known as a leader and innovator in the field of PTSD treatment, prioritizing equity in access to evidence-based care across diverse populations. Dr. Morland's research has resulted in over 100 peer-reviewed publications, chapters and invited presentations.

Jennifer Burden, PhD serves as the National Mental Health Director, Residential Rehabilitation and Treatment in the Office of Mental Health and Suicide Prevention (OMHSP). Dr. Burden joined OMHSP in 2011 initially serving as the National Deputy Director for Mental Health Residential Rehabilitation Treatment Programs (MH RRTP) before serving the National Deputy Director, Substance Use Disorders (SUD) and for a period of time as the Acting Director, SUD. Prior to joining OMHSP, Dr. Burden served as the Network SUD Services Coordinator and Acting Network Homeless Coordinator for the Mid-Atlantic Veterans Integrated Service Network (VISN 6). Dr. Burden has been fortunate to work with the MH RRTPs or SUD programs throughout her more than 20 years with VA. She began her career at the Salem VA Medical Center (where she remains based) as the project

director for an HSR&D funded clinical trial in the Domiciliary SUD program before becoming the Program Director of a 10-bed residential treatment program for Veterans with co-occurring SUD and mental health concerns. Dr. Burden completed her graduate training in Clinical Psychology at Syracuse University.

NCPTSD Strategic Advisory Committee

Michael Mithoefer, MD, completed the first MAPS-sponsored Phase II clinical trial testing MDMA-assisted psychotherapy for crime-related PTSD, a subsequent study with military Veterans, firefighters and police officers, and a pilot study treating couples with MDMA combined with Cognitive Behavioral Conjoint Therapy for PTSD. He has been Medical Monitor for a series of six MAPS-sponsored Phase 2 trials in the US, Canada, Switzerland and Israel, which produced data that led to breakthrough therapy designation by the FDA. Since 2012 he and his wife, Annie, have conducted training for research therapists, and supervising therapists in ongoing MAPS clinical trials, as well as training and mentoring new MAPS trainers and supervisors.

Dr. Stephanie Taylor is a nationally recognized health services researcher and sociomedical scientist with over 25 years' research experience in effectiveness and implementation research at the VA, UCLA and RAND. She is a Senior Investigator at the VA. She directs the VA's national Complementary and Integrative Health Evaluation Center, a QUERI Partnered Evaluation Initiative, which conducts large-scale research studies on the effectiveness and implementation of novel therapies such as meditation, mindfulness, acupuncture, and yoga in partnership with the VA Central Office. For her teams' research in this area, she was awarded the VA's national HSR&D Health System Impact Award in 2019. She also is Co-PI of a study of psychedelic-assisted therapy with MDMA for PTSD among Veterans at the Los Angeles VA and is founding Co-Director of the Los Angeles VA's Veteran Psychedelic Research and Education Center.

Ilse Wiechers, MHS, MD, serves as the Deputy Executive Director in VHA Office of Mental Health and Suicide Prevention. In this role, she leads the operations of OMHSP and oversees mental health and suicide prevention program implementation and operations throughout the Veterans Health Administration. Most recently in her work at the Northeast Program Evaluation Center and as the National Director for Psychopharmacology & Somatic Treatment, Dr. Wiechers led the national clinical rollout of esketamine services in the VA which made these services available to Veterans in greatest need for depression care. Under her direction of the Psychotropic Drug Safety Initiative (PDSI), several evidence-based medication benchmarks saw steady improvement. Dr. Wiechers is a well-known and respected leader, having served as co-director of the Care for Patients with Complex Problems (CP2) program and serving as the OMHSP liaison to the national somatic treatment field advisory committee and national psychiatry chiefs

Healing Breakthrough

To learn more

Please reach out to Healing Breakthough's Executive Director Jason Pyle (jason@evolvevf.com) to learn more.

STATEMENT FOR THE RECORD

Prepared Statement of American Psychedelic Practitioners Association (APPA)

Statement for the Record
Brigadier General (Ret, U.S. Army) Stephen N. Xenakis, M.D.
Executive Director
American Psychedelic Practitioners Association

November 14, 2023

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

U.S. House Committee on Veterans' Affairs
Subcommittee on Health

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AMERICAN PSYCHEDELIC PRACTITIONERS ASSOCIATION

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:

My name is Stephen Xenakis, and I am a psychiatrist and retired Army Brigadier General. I was commissioned as a 2nd lieutenant in 1970 and served in the Army Medical Corps from 1974 until retiring in 1998. I may seem like an unlikely candidate to lead the American Psychedelic Practitioner's Association (APPA), the organization that is developing practice guidelines for these emerging treatments, but I am not. As we know, the military does what it needs to do in order to accomplish its mission, and the best leaders and soldiers are the ones who approach the mission with practicality. Today, our mission is to ensure our soldiers and their families are healthy, and that the American people are healthy. And these emerging therapies present a practical, viable solution to the problems that are plaguing the mental health of the men and women who serve.

Given the promising nature of psychedelic-assisted therapy, we have a duty to diligently pursue all efforts toward the development of these therapies in a thoughtful and strategic way. The life-threatening circumstances and tragedies of day-to-day mental health conditions should even further accelerate innovation in treatments, therapies, policies, and procedures. In order to drive the safe, effective, and time-sensitive development and implementation of these life-saving treatments, the APPA proposes the creation of a public-private partnership, which would bring together key stakeholders to methodologically map out a strategy for the implementation of these emerging therapies. My organization is also strongly recommending the creation of VA pilot programs that would be able to deliver safe and rigorously monitored psychedelic-assisted treatments and therapies to patients.

Initiating a Public-Private Partnership to Methodically Accelerate the Delivery of Care

We know that the best outcomes in this country are brought about with collaboration and teamwork. To decide how to configure the delivery of these emerging treatments in a systematic way, the government should bring together the best of the private sector, universities, and not-for-profit organizations to form a public-private partnership.

Today, the United States healthcare system is at an inflection point. The delivery of mental health care must change dramatically in order to meet the growing mental health crisis. The existing system faces significant challenges in meeting the increasing demand for services. The system was strained before the pandemic, and the subsequent surge in mental health issues has overwhelmed available resources. Long wait times for therapy and psychiatric appointments, limited access to affordable and quality care, and a shortage of mental health professionals have created barriers to timely treatment and support for those in need.

The re-emerging interest in psychedelic-assisted therapy offers an opportunity to mitigate the adverse impact of severe mental health conditions and illnesses. However, we are cautious that the immense need for new and effective mental health treatments not be used to justify insufficient psychotherapy support for these powerful new treatments. Thoughtful attention to psychotherapy is a cornerstone for both the effectiveness and safety of the treatment. Combining the administration of psychedelic medication and therapy within the same treatment session differs significantly from existing psychotherapy practice. It necessitates the development of new processes and competencies, including defining what constitutes good clinical practice, educating about harms and how to reduce them, and updating procedures for drug approval.

What I am describing is an inherently interdisciplinary, inter-agency, multi-stakeholder process. The government is uniquely positioned to lead deliberation and planning by subject matter experts in science, clinical research, policy, and law to explore, develop, and implement optimal policies, procedures, and guidelines for providing psychedelic-assisted treatments and therapies that are effective and safe.

Addressing Complex Veteran Health Issues Through Pilot Programs

Pilot programs, conducted under strict IRB protocols, are essential for exploring and establishing new treatments. These programs must be conducted thoughtfully and conscientiously, with a controlled and methodical approach to risk in particular. As the largest medical provider in the world, the VA is uniquely positioned to lead such efforts.

Currently, veterans who have exhausted all other treatment options and need psychedelic-assisted therapy are forced to leave the country to get the care they need. The proposition that we are outsourcing veterans' mental health care services, when the VA possesses the capabilities to safely develop and provide these treatments domestically, is difficult to accept and fails to fulfill the obligation to the men and women who had served.

Moreover, the VA is well-positioned to host pilot programs for psychedelic-assisted therapy because of the multiple and complex health issues faced by veterans. Understanding comorbidities, as well as the interplay between post-traumatic stress disorder (PTSD), traumatic

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brain injury (TBI), chronic pain, and their contribution to issues like suicide, is crucial for developing safe and effective clinical practice. Many veterans suffer from a syndrome that manifests as the cumulative and synergistic effects of the injuries and illnesses incurred while serving in combat. Over time, the symptoms and impairments experienced by the servicemember become enduring and can be intractable. For example, the long-term consequences of conditions like TBI lead to chronic depression that is treatment-resistant (TRD). There are few, if any, treatments that repair the injuries to the brain, and the veterans spiral downward due to growing problems with thinking, inability to function in their daily lives, and worsening mood. The risk of suicide is linked to the impairments and problems of PTSD and traumatic brain injury (TBI) piling up.

We urge the VA to take a page out of the record of the DoD when it established the Defense Center of Excellence (DCOE) to fast-track diagnostic testing and treatments for PTSD, and the National Intrepid Center (NiCOE) to assess and treat servicemembers for TBI. These Centers operate under strict protocols to apply the latest developments and findings to promote better diagnostics, therapies, and treatments. We suggest that the VA establish a dedicated center to test and assess the effectiveness of psychedelic-assisted treatments and therapy with veterans using the guidelines set by the DoD for the DCOE and NiCOE.

Finally, the hurdles that the VA faces in treating patients with Schedule I substances can be overcome by following guidelines of Measurement-Based Care, formalized with an Institutional Review Board (IRB) protocol that can also be used in operating a dedicated center.

Adopting new initiatives in such a large organization is a major undertaking. But it is achievable, and it is necessary. The physical and mental health of our men and women is fundamental to the strength of our country, a lesson reiterated by the COVID-19 pandemic. By embracing innovation and rigorously pursuing research and development, this country can lead the way in providing effective, life-saving care to those who have served it, and for all who could benefit from it.

Thank you for the opportunity to submit this statement and please feel free to reach out to APPA with any questions.

Respectfully,

Brigadier General (Ret, U.S. Army) Stephen N. Xenakis, M.D.
Executive Director
American Psychedelic Practitioners Association

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