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.
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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.

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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:

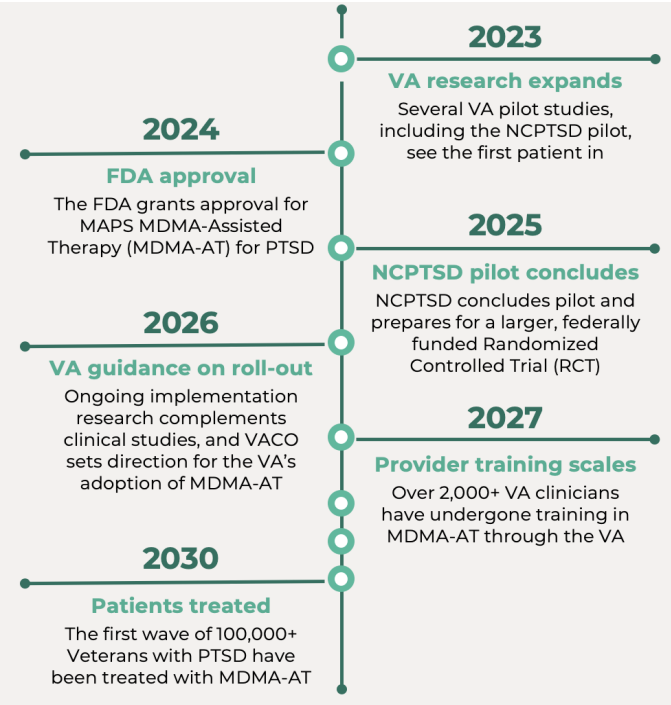
- **Urgency**. Each day that passes, more Veterans die of suicide. Furthermore, with FDA approval in near sight, MDMA-AT will soon trickle into broader society, and more Veterans who deserve access to this new treatment are likely to demand it. Timely VA efforts have the potential to shape a better standard 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.

[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.

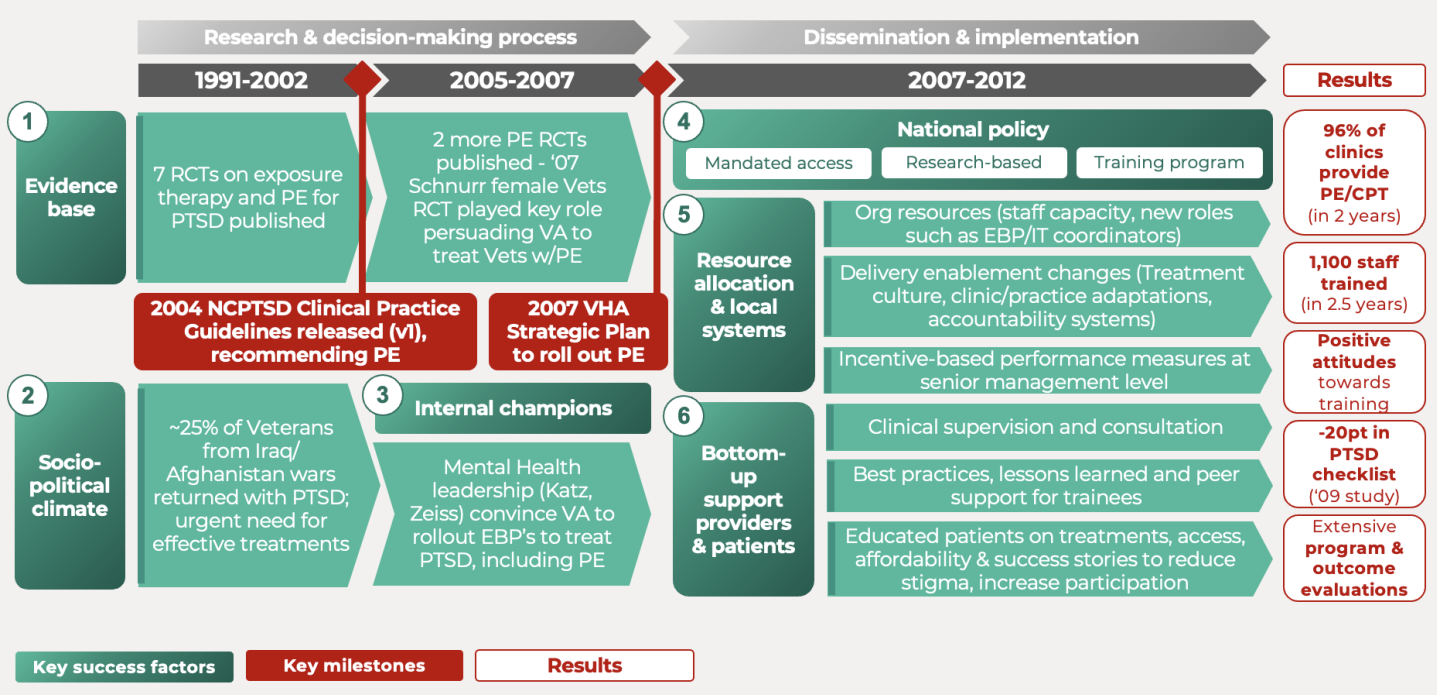
6. **Bottom-up support from providers and patients.** As part of the EBP dissemination initiative, the VA took a variety of significant steps to promote bottom-up support at the local level. These efforts included, but were not limited to, involving local and regional program managers in the initiatives, 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.

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.

[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.

[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.

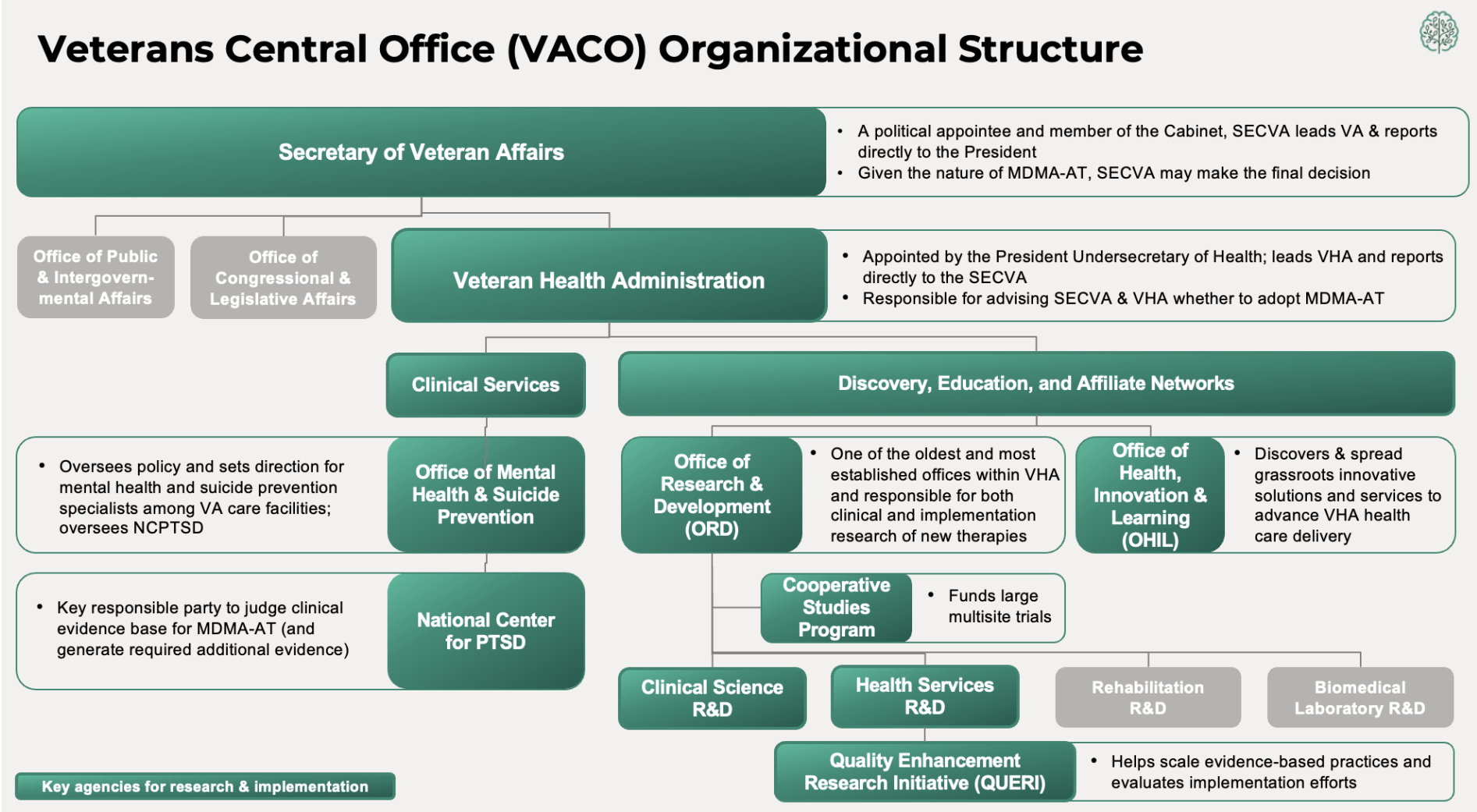
HB is also working with all of the relevant constituencies including the VA Office of Research and Development as well as political leadership in Congress, advocacy groups and scientific experts to ensure that our comprehensive approach to evaluating and implementing MDMA-AT can be extended to all appropriate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

Appendix

Table of Contents

Organizational structure of the VA Central Office



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.

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

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

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 community-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**

Clinical research bibliography Dr. Paula Schnurr (NCPTSD)

1. Schnurr, P.P., Friedman, M.J., Foy, D.W., Shea, M.T., Hsieh, F.Y., Lavori, P.W., Glynn, S.M., Wattenberg, M., & Bernardy, N.C. (2003). A randomized trial of trauma focus group therapy for posttraumatic stress disorder: Results from a Department of Veterans Affairs Cooperative Study. Archives of General Psychiatry, 60, 481-489.

2. Schnurr, P.P., Friedman, M.J., Engel, C.C., Foa, E.B., Shea, M.T., Chow, B.K., Thurston, V., Orsillo, S., Haug, R., Turner, C., & Bernardy, N. (2007). Cognitive-behavioral therapy for posttraumatic stress disorder in women: A randomized controlled trial. Journal of the American Medical Association, 297, 820-830. doi: 10.1001/jama.297.8.820

3. Schnurr, P.P., Friedman, M.J., Oxman, T.E., Dietrich, A.J., Smith, M.W., Shiner, B., Forshay, E., Gui, J., & Thurston, V. (2013). RESPECT-PTSD: Reengineering systems for the primary care treatment of PTSD, a randomized controlled trial. Journal of General Internal Medicine, 28, 32-40.

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)

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.

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

To learn more

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