



## **Testimony for Senate Veterans Affairs Committee Field Hearing**

**August 22, 2025**

### **Introduction**

Senator Tuberville, members of the Senate Veterans Affairs Committee, thank you for the chance to testify at this important field hearing today. Improving the mental health of veterans is a national imperative, and we appreciate your leadership to achieve this goal.

My name is Dr. Steve Levine, and I serve as the Chief Patient Officer for Compass Pathways. Compass Pathways is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. Our mission is to improve the lives of individuals living with serious mental health conditions who do not benefit from current treatment options.

Our lead compound, COMP360, is a synthetic, pharmaceutical-grade formulation of psilocybin being studied in robust clinical trials in treatment-resistant depression (TRD) and post-traumatic stress disorder (PTSD). COMP360 was granted Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for TRD in 2018 and will potentially be a first in class treatment.

Compass Pathways is leading the way in psychedelic clinical trial research and is conducting the largest ever FDA-regulated clinical trials studying the safety and efficacy of psilocybin. In TRD, we have generated positive primary endpoint data in two large well-controlled clinical trials. In November 2022, the positive results of our 233 participant Phase 2b trial were published in the *New England Journal of Medicine* and in June 2025, we announced the successful achievement of the primary endpoint in the first of two ongoing Phase 3 trials. This first randomized, double-blind, placebo-controlled Phase 3 study dosed 258 participants, and our second Phase 3 trial will evaluate the safety and efficacy of psilocybin in approximately 560 additional participants.

Along with clinical development in TRD, in May 2024, Compass Pathways announced positive top-line results from our 22 participant Phase 2 open label 12-week safety and tolerability study in PTSD. That study showed COMP360 was well tolerated and indicated both rapid and durable improvement in symptoms from baseline observed following a single administration. Compass is currently finalizing plans to initiate a late-stage trial in PTSD.

### **The Need**

The United States is in a mental health crisis<sup>1</sup> with 1 in 5 adults<sup>2</sup> experiencing mental illness in any given year. Veterans are among those disproportionately impacted. Among the most pressing and debilitating conditions within this crisis are PTSD and TRD. Both conditions are marked by severe symptoms, high suicide risk, and limited pharmacological treatment options, necessitating evidence-based, novel treatment options for these underserved conditions.

### *Post-Traumatic Stress Disorder*

Post-Traumatic Stress Disorder (PTSD) is a serious mental health condition that can develop after exposure to traumatic events<sup>3</sup> such as personal assault, combat, natural disasters, or serious accidents. Characterized by symptoms such as intrusive memories, avoidance behaviors, negative shifts in mood and cognition, and heightened arousal<sup>4</sup>, PTSD affects approximately five percent<sup>5</sup> of adults in the U.S. annually. Symptoms may appear within months of the trauma or be delayed, and they must persist for over a month<sup>6</sup> and interfere with daily functioning to meet diagnostic criteria.

PTSD can impact anyone, though certain populations<sup>7</sup>—including veterans, first responders, and survivors of abuse—are at elevated risk. Individuals living with PTSD frequently experience comorbid mental health conditions<sup>8</sup>, most commonly, depression, anxiety disorders, substance use disorders, as well as a significantly increased risk of suicide. These overlapping conditions can intensify distress and complicate treatment.

Affecting approximately 13 million<sup>9</sup> people in the U.S. each year, PTSD is an underserved condition. There are currently only two FDA-approved medications for PTSD.

### *Treatment Resistant Depression (TRD)*

Depression, one of the most common mental health conditions, significantly impacts relationships, work performance, overall quality of life, and is associated with an increased risk of suicide<sup>10</sup>. Major depressive disorder (MDD) has been ranked as the third cause of the burden of disease worldwide in 2008 by the World Health Organization (WHO), which has projected

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<sup>1</sup> <https://www.cdc.gov/mental-health/about/what-cdc-is-doing.html>

<sup>2</sup> <https://www.nami.org/about-mental-illness/mental-health-by-the-numbers/>

<sup>3</sup> <https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd>

<sup>4</sup> <https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd>

<sup>5</sup> [https://www.ptsd.va.gov/understand/common/common\\_adults.asp](https://www.ptsd.va.gov/understand/common/common_adults.asp)

<sup>6</sup> <https://www.nimh.nih.gov/health/publications/post-traumatic-stress-disorder-ptsd>

<sup>7</sup> <https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd>

<sup>8</sup> <https://my.clevelandclinic.org/health/diseases/9545-post-traumatic-stress-disorder-ptsd>

<sup>9</sup> <https://www.va.gov/columbia-south-carolina-health-care/stories/hope-and-healing-initiatives-for-ptsd-awareness-and-veteran-support/>

<sup>10</sup> <https://www.who.int/news-room/fact-sheets/detail/depression>

that this disease will rank first by 2030<sup>11</sup>. An estimated 21 million adults in the United States suffer from major depression<sup>12</sup>, and approximately 9 million are drug treated<sup>13</sup>.

Due to the limitations of approved existing MDD medications, approximately one-third of patients with MDD will develop TRD. These patients include veterans and our most vulnerable populations. In one study, 68% of psychiatric clinic outpatient veterans met the criteria for TRD<sup>14</sup>.

TRD is broadly defined as an inadequate response to two or more appropriate courses of approved anti-depressant medications. TRD has a significantly greater impact on individuals, caregivers, and healthcare systems compared to MDD, leading to residual symptoms, poorer quality of life, increased comorbidities, higher mortality, and an increased risk of suicide compared to non-treatment resistant MDD. Prevalence trends show that the proportion of TRD patients reporting suicidal ideation within the past year ranged from 39.5% in 2009 to 2010 to 43.4% in 2019 to 2020<sup>15</sup>.

Despite the availability of many FDA-approved treatments for MDD, TRD is still an area of high unmet need. There are currently only two FDA-approved medications indicated for TRD.

### **Advancements in New Treatment Options: Psychedelics**

In the U.S. there is an urgent need for new and effective treatments in mental health care. Nearly 60 million adults in the U.S.<sup>16</sup> live with a mental illness—including conditions like PTSD and TRD—yet therapeutic innovation has not kept pace with the growing crisis. For decades, progress in mental health pharmacology has been slow, leaving millions underserved.

However, novel scientific approaches, like psychedelics, that aim to potentially meet the scale and complexity of the growing mental health crisis are on the horizon. Well-controlled clinical studies into the safety and efficacy of innovative treatments like psychedelics for the treatment of serious mental health conditions are underway.

### **Veterans and VA Preparation**

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<sup>11</sup> Bains N, Abdijadid S. Major Depressive Disorder. [Updated 2023 Apr 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK559078/>

<sup>12</sup> <https://mhanational.org/conditions/depression/>

<sup>13</sup> Zhdanova M, Pilon D, Ghelerter I, Chow W, Joshi K, Lefebvre P, Sheehan JJ. The Prevalence and National Burden of Treatment-Resistant Depression and Major Depressive Disorder in the United States. *J Clin Psychiatry*. 2021 Mar 16;82(2):20m13699. doi: 10.4088/JCP.20m13699. PMID: 33989464.

<sup>14</sup> Allen CM, Bray C. Improving Patient-Centered Care for Veterans With Treatment-Resistant Depression Using Shared Decision-Making Tools. *Journal of the American Psychiatric Nurses Association*. 2023;29(1):7-14. doi:10.1177/10783903221141885

<sup>15</sup> Rhee, TG et al. *J Affect Disord*. 2024; 358:342-349.

<sup>16</sup> <https://mhanational.org/news/mha-releases-2024-state-of-mental-health-in-america-report/>

Amid a national mental health emergency where anywhere from 17 to 44 veterans die by suicide each day<sup>17</sup>, we must urgently explore and advance novel treatments to help those in our veteran community struggling with PTSD, depression, and other serious mental health conditions. It is essential that we explore all avenues available through our current regulatory framework to facilitate the safe, effective and efficient delivery of these treatments to veterans in need.

We commend the VA for its openness to new treatment options, including psilocybin, and for the significant research it has performed related to psychedelics. While these compounds are still being studied for potential approval by the FDA, we encourage the VA to prepare for the possible entry of psychedelic therapies into the VA health system so that it is ready should these medicines be approved or become available to veterans.

We recommend that the VA begin by developing treatment protocols, standardizing training for personnel, and preparing clinical care settings. Compass Pathways is committed to supporting the VA to ensure that sites have the required infrastructure and training in place for successful integration of psilocybin as a potential new treatment option for veterans. Our shared goal must be to ensure that safe, effective medications for the treatment of mental health are accessible to veterans as soon as possible.

## **Closing**

In closing, the potential FDA approval of psychedelic compounds is drawing closer, with multiple late-stage clinical trials currently underway. Compass Pathways shares the Committee's goal to ensure that our nation's veterans have access to innovative, evidence-based treatments and the comprehensive care they deserve. We stand ready to support the VA in advancing this mission responsibly and safely and in a manner that upholds the highest standards of care. Again, we thank the Committee and Senator Tuberville for holding this important hearing. I am happy to answer any questions.

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<sup>17</sup> <https://news.va.gov/137221/va-2024-suicide-prevention-annual-report/>; <https://www.militarytimes.com/veterans/2022/09/17/veterans-suicide-rate-may-be-double-federal-estimates-study-suggests/>