Compass Pathways
Testimony to the Senate Health and Welfare Committee
February 18, 2026

Introduction

Compass Pathways is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. Our focus is on improving the lives of those who are living with mental health disorders and who do not benefit from existing standards of care. Compass Pathways is conducting the largest FDA-regulated clinical trials ever studying the safety and tolerability of psilocybin with our lead compound, COMP360.

COMP360 is a synthetic, pharmaceutical grade, proprietary formulation of psilocybin. COMP360 is manufactured according to FDA-enforced Good Manufacturing Practice (GMP) standards for quality, consistency, and purity.

Phase 3 clinical trials are currently being conducted with COMP360 in treatment resistant depression (TRD). Results of the Phase 2b clinical trials for TRD were published in the New England Journal of Medicine in 2022. For your reference, I have included the results of the study. The FDA granted Breakthrough Therapy Designation to COMP360 for TRD in 2018.

Assuming positive results of Phase 3 studies, Compass Pathways plans to seek FDA approval for COMP360 as a medication prescribed and administered under the supervision of a licensed health care professional in a professional health care setting for treatment resistant depression (TRD).

Along with clinical development in TRD, in May 2024, Compass announced positive top-line results from an open-label Phase 2 study evaluating the safety and tolerability of COMP360 in post-traumatic stress disorder (PTSD). Compass plans to pursue further development of investigational COMP360 in PTSD.

We are asking for your help to ensure that patients have access to this innovative treatment, in the event it is FDA-approved and rescheduled by the Drug Enforcement Administration (DEA).

Treatment-Resistant Depression

The United States is in a mental health crisis, and depression is one of the most common mental health disorders. [1,2] Depression significantly impacts relationships, work performance, overall quality of life, and is associated with an increased risk of suicide. [3] 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 that this disease will rank first by 2030. [4] An estimated 21 million adults in the United States suffer from major depression, and approximately 9 million are drug treated. [4] Due to the limitations of existing MDD medications, approximately one-third of patients with MDD will develop TRD. [5]

TRD is broadly defined as an inadequate response to two or more appropriate courses of approved medications.

TRD has a significantly greater impact on individuals 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. [6,7,8,9,10]

There are currently only two medications approved by the FDA for TRD.

Post-Traumatic Stress Disorder

Post-Traumatic Stress Disorder (PTSD) is a serious mental health condition that can develop after exposure to traumatic events, including assault, combat, natural disasters, or serious accidents. [11] It is marked by intrusive memories, avoidance behaviors, negative changes in mood and cognition, and heightened arousal. About five percent of U.S. adults experience PTSD each year. [11,12] Symptoms may emerge soon after the trauma or be delayed, but they must last longer than a month and disrupt daily functioning to meet diagnostic criteria. [13]

PTSD can impact anyone, though certain populations—including veterans, first responders, and survivors of abuse—are at elevated risk. [11] Individuals living with PTSD frequently experience comorbid mental health conditions, most commonly, depression, anxiety disorders, substance use disorders, as well as a significantly increased risk of suicide. [14] These overlapping conditions can intensify distress and complicate treatment. Despite affecting roughly 13 million people in the U.S. annually, PTSD remains underserved despite its prevalence. Only two FDA-approved medications exist for PTSD. This limited pharmacological landscape underscores the urgent need to advance and expand care for patients experiencing this debilitating condition.

PTSD disproportionally affects certain demographics including women, people from different racial and ethnic backgrounds, and military veterans.

Of patients treated for PTSD, only 20–30% reach full remission with currently-approved pharmacological treatments for PTSD. [15]

Rescheduling

All psychedelics, including psilocybin, are currently DEA Schedule I substances which are defined as drugs with no currently accepted medical use and a high potential for abuse. Schedule 1 drugs may not be prescribed, dispensed, or administered.

Upon FDA approval of a current Schedule I medicine, the DEA is expected to review clinical trial information provided by the company during the New Drug Application (NDA) submission and make a federal rescheduling decision.

States will need to reschedule the medicine through their defined process to allow the medicine to be prescribed to patients in their state. In Vermont, legislation must be passed to add a drug to the state's regulated drugs list, ensuring it can be prescribed. Vermont has done this before. In 2018, the legislature passed a law adding FDA-approved cannabidiol drugs to the state's regulated drug list, which allowed for these drugs to be prescribed and administered in the state upon approval of the FDA. I have submitted draft language to make a similar change with respect to synthetic psilocybin to my testimony for review and discussion.

Conclusion

In conclusion, this committee has the opportunity to ensure timely access to this innovative treatment, provided the language we have submitted with my testimony is incorporated into legislation currently moving forward.

Sources:

1. www.cdc.gov/mental-health/about/what-cdc-is-doing.html.

2. www.nimh.nih.gov/health/statistics/major-depression.

3. www.who.int/news-room/fact-sheets/detail/depression

4. National Institute of Mental Health. Major Depression. 2022.

5. McIntyre RS et al. World Psychiatry. 2023;22(3):394–412.

6. Feka-du A, et al. J Affect Disord. 2009;116(1-2):4-11.

7. Rathod S, et al. J Affect Disord. 2022;300:551-562.

8. Kubitz N, et al. PLoS One. 2013;8(10):e76882.

9. Li G, et al. Ann Gen Psychiatry. 2019;18:23.

10. Corral R, et al. Front Psychiatry. 2022;13:812938.

11. www.psychiatry.org/patients-families/ptsd/what-is-ptsd

12. www.ptsd.va.gov/understand/common/common_adults.asp.

13. www.nimh.nih.gov/health/publications/post-traumatic-stressdisorder-ptsd

14. my.clevelandclinic.org/health/diseases/9545-post-traumatic-stress-disorder-ptsd

15. Stein et al, CNS Spectr. 2009 Jan;14(1 Suppl 1):25-31. PMID.

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USE OF U.S. FOOD AND DRUG ADMINISTRATION- APPROVED CRYSTALLINE POLYMORPH PSILOCYBIN

(a) Upon approval by the U.S. Food and Drug Administration (FDA) of a composition of crystalline polymorph psilocybin, the following activities shall be lawful in Vermont:

(1) the clinically appropriate prescription for a patient of the FDA-approved composition of crystalline polymorph psilocybin by a health care provider licensed to prescribe medications in this State and acting within his or her authorized scope of practice;

(2) the dispensing, pursuant to a valid prescription, of the FDA-approved composition of crystalline polymorph psilocybin to a patient or a patient's authorized representative by a pharmacist or by another health care provider licensed to dispense medications in this State and acting within his or her authorized scope of practice;

(3) the possession and distribution of the FDA-approved composition of crystalline polymorph psilocybin by a patient to whom a valid prescription was issued or by the patient's authorized representative;

(4) the possession and distribution of the FDA-approved prescription drug composition of crystalline polymorph psilocybin by a licensed pharmacy or wholesaler in order to facilitate the appropriate dispensing and use of the drug; and

(5) the use of the FDA-approved composition of crystalline polymorph psilocybin by a patient to whom a valid prescription was issued, provided the patient uses the drug only for legitimate medical purposes in conformity with instructions from the prescriber and dispenser.

(b) Within 30 business days following approval by the U.S. Food and Drug Administration of a composition of crystalline polymorph psilocybin the Department of Health must initiate rulemaking to conform to the provisions of subsection (a) of this section.

(c) The term "hallucinogenic drug" does not include the composition of crystalline polymorph psilocybin as approved by the U.S. Food and Drug Administration under section 21 U.S.C. §355 et. seq. or is being used in a clinical investigation under 21 U.S.C. §355 et. seq.