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HOUSE OF REPRESENTATIVES
COMMONWEALTH *of* PENNSYLVANIA

House Democratic Policy Committee Hearing

Addressing Treatment-Resistant Depression
Tuesday, September 16, 2025 | 1:00 p.m.
Representative Jennifer O'Mara

OPENING REMARKS
1:00 p.m. Rep. Jennifer O'Mara, D-Delaware

PANEL ONE
1:05 p.m. Ryan Gardill, President
Manheim Township Professional Fire Fighters Association

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

Q & A with Legislators

PANEL TWO
1:35 p.m. Dr. Daniel Orr, Owner
Eagle Direct Primary Care

Dr. Michael Thase, Professor of Psychiatry
Perelman School of Medicine, University of Pennsylvania

Q & A with Legislators

PANEL THREE
2:05 p.m. Ryan Bastle, PhD, MBA, Senior Medical Science Liaison
Compass Pathways

Tess Bettler, Associate Director of Government Affairs
Compass Pathways

Q & A with Legislators

Good afternoon and thank you for having me. My name is Ryan Gardill and I am the President of Manheim Township Professional Firefighters, Central Coordinator for the Central Pennsy Peer Support team through the PPFFA, and the Peer Support team leader for Local 5423.

My history with mental health began after my return from Sangin, Afghanistan in 2011. At the time, the Sangin Valley was named by Time Magazine as the most dangerous place in the world. I returned in one piece, but not as the same person. In 2013, I was medically retired from the Marine Corps after a diagnosis of PTSI and severe clinical depression. I went through the common VA treatments which included various therapies, and a list of medications where the side effects were worse than the symptoms. After feeling like there was no end, I attempted suicide in 2015.

Today, I am in the best state I have ever been in. My wife and children, lifestyle changes, acceptance, advocation, and my rewarding career as a firefighter have led me towards a more happy and healthy life. While my life has taken a turn for the better, the underlying issues of PTSI and depression are still very prevalent in my daily life. Each day is spent wearing a happy mask. It not only affects me, but my family and my career as well. I am fortunate to work for a department where mental health is a top priority and strong support system exists.

Mental health in the fire service is a serious but invisible issue. While the sigma has started to lift due to advocacy, those experiencing these issues remain silent. Becoming vocal about my experiences led to a realization that the fire service is filled with those experiencing a crisis but not knowing where to turn. More importantly, the common and widely accepted treatments are not working. To further this point, there are statically almost twice as many firefighter suicides than Line of Duty Deaths every year.

If there is one thing that I could choose to advocate for on this topic, it is for the general knowledge of how serious of an issue mental health really is. In my line of work, there are times when unconventional actions are needed to solve a complex situation. Firefighters are called day and night to assist the public on their worst day. It is time to assist firefighters on theirs. I fully support the use of any alternative medicine available for the treatment of mental health. Instead of working to live with poor mental health, let’s cure it.

Thank you.

Testimony of Brett Waters, Esq.

Co-Founder and Executive Director, *Reason for Hope*

Pennsylvania House Democratic Policy Committee

Tuesday, September 16, 2025

“Addressing Treatment-Resistant Depression”

Introduction

Thank you for the opportunity to testify at today's hearing on treatment-resistant depression and psilocybin. My name is Brett Waters. I am an attorney, co-founder and Executive Director of Reason for Hope, and policy counsel for the Veteran Mental Health Leadership Coalition—organizations dedicated to preventing deaths of despair by expanding access to psychedelic and other emerging therapies for difficult-to-treat mental health conditions. I was a co-author of "Developing an Ethics and Policy Framework for Psychedelic Clinical Care: A Consensus Statement" (JAMA Network Open, June 4, 2024)[1] and served as a quality assurance reviewer for the RAND paper, "Considering Alternatives to Psychedelic Drug Prohibition" (June 27, 2024).[2]

Personal Background

As a multi-generation survivor of suicide loss, who grew up in Lower Merion and lived in Philadelphia for several years, testifying here in Pennsylvania during Suicide Prevention Month is especially meaningful to me. When I was young, I lost my grandfather to suicide. He was a WWII fighter pilot who experienced both physical and invisible wounds of war when he was shot down in the South Pacific while still only a teenager. In 2018, I lost my mom, Sherrie Hope Waters, to suicide after a long battle with depression and suicidality. Reason for Hope is named in my mom's memory.

Growing up, my family never spoke about my grandfather's suicide; I didn't learn the truth about how he died until many years later. After losing my mom, I decided I would not continue down the same path of silence, and I became deeply involved in mental health and suicide prevention advocacy. However, I also understand why so many remain in the shadows: I have struggled with the profound feelings of guilt, pain, abandonment, and sense of failure that often accompany suicide loss, and I often have to dissociate when speaking about my personal loss to avoid reliving the pain. But it is critical that we have these conversations, reduce stigma, and find a better path forward for those still suffering.

My sister and I—perhaps unsurprisingly—have faced our own significant mental-health challenges, both before and after losing our mom, including depression, anxiety, and eating disorders. We've also experienced the limitations of commonly prescribed front-line antidepressant medications such as SSRIs and standard talk therapy. Psilocybin was the one thing that immensely helped us both, in ways that broadly reflect its incredible potential as a rapid-acting, transdiagnostic mental health treatment.

Mental Health Crisis and Limitations of Approved Treatments

Our nation is suffering a devastating mental health crisis, which has been exacerbated by the COVID-19 pandemic and increased isolation.[3] Currently, about 1 in 5 adults suffer from a mental

[1] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2819456
[2] https://www.rand.org/pubs/research_reports/RRA2825-1.html
[3] https://www.kff.org/mental-health/the-implications-of-covid-19-for-mental-health-and-substance-use/

health condition, with approximately 21 million suffering from major depressive disorder.[4] Major depression is generally defined by at least 2 weeks of depressive symptoms, including symptoms of impairment such as loss of interest or pleasure in usual activities, difficulty sleeping, fatigue, appetite or weight change, difficulty concentrating, agitation, feelings of worthlessness or excessive guilt, or recurrent thoughts of death or suicide.[5] There is often a complex and interrelated mix of biological, psychological, and social factors that contribute to depression, making treatment similarly complex.

For decades, front-line antidepressant medications have been SSRIs (selective serotonin reuptake inhibitors) or SNRIs (serotonin and norepinephrine reuptake inhibitors), which are slow-acting antidepressants that need to be taken daily and usually take 6-8 weeks to have an effect.[6] This latency period is incredibly challenging and is a period of elevated risk for suicide. While they help some patients, they don't work at all for many people, offer only limited benefit for most, and often carry significant side effects such as weight gain, sexual dysfunction, cognitive impairment, and emotional numbing.[7] Moreover, while they were studied in short trials (with 12-week endpoints), in practice many people remain on these daily medications for years, if not a lifetime. Particularly for long-term patients, attempts to discontinue can cause significant and debilitating withdrawal effects.[8]

Personally, after losing my mom, I was on SSRIs for nearly five years. While I had a slight initial benefit despite the side effects, I gradually became more emotionally numb and disconnected over time. Several years after starting on SSRIs, I inadvertently missed taking a few doses and endured severe "brain zaps" that served as a serious shock to my system - and a wakeup call that I needed to begin the process of discontinuation before becoming more dependent. However, even with a slow taper, I experienced significant withdrawal and failed multiple attempts before finally weaning off. The issues of dependency and withdrawal that I experienced have been downplayed in psychiatry for years, and only recently have started getting more widespread attention from clinicians, researchers, regulators, and the media.

Treatment-Resistant Depression

Generally, those who do not adequately improve after at least two antidepressant medications given at adequate dose and duration qualify as having "treatment-resistant depression" (TRD), which affects approximately one-third of those with major depression. However, there are likely far more (such as myself) who could be considered "treatment-resistant" when considering how many do not achieve remission based on front-line treatments, or who experience other limitations such as side effects that not only drive non-adherence but also often leave people feeling worse than they did when they sought treatment to begin with.[9]

Those with TRD, or under treated depression, generally have more severe symptoms and comorbid conditions, higher mortality, and face increased risk of suicidal ideation and completed

[4] https://www.nimh.nih.gov/health/statistics/major-depression
[5] https://my.clevelandclinic.org/health/diseases/24481-clinical-depression-major-depressive-disorder
[6] https://pmc.ncbi.nlm.nih.gov/articles/PMC2835848/
[7] https://pmc.ncbi.nlm.nih.gov/articles/PMC4970636/
[8] https://www.sciencedirect.com/science/article/pii/S0165178125001453
[9] https://pmc.ncbi.nlm.nih.gov/articles/PMC10503923

suicide. With approximately 50,000 lives lost to suicide in 2023, 17-44 Veterans lost to suicide or deaths of despair (including overdose and alcohol-related deaths) every day, and suicide being the second and fourth leading cause of death for all Americans aged 10-34 and 35-44 respectively,[10] there is an urgent need for more effective treatments to help those who are suffering from depression and related mental health conditions - particularly treatments that reduce our dependence on daily medication.

Esketamine (Spravato), a ketamine derivative, was FDA approved in 2019 as an adjunctive treatment for TRD (used in combination with a daily antidepressant), received a label expansion in 2020 for major depression with acute suicidal ideation or behavior, and **another expansion as a standalone treatment for TRD in 2025**.[11] Esketamine can provide rapid symptom relief—particularly relevant in acute suicidality—but its durability of effects appear limited, requiring frequent ongoing maintenance to sustain benefits (recent real-world data suggests even after a two-month course of treatment, many patients required weekly maintenance treatments).[12] It remains subject to an FDA Risk Evaluation and Mitigation Strategy (REMS) requiring treatment only in certified health-care settings under clinical supervision, with post-dose monitoring due to its psychoactive effects such as sedation and dissociation.

Generic (racemic) ketamine is also frequently used as an off-label treatment for depression (often with therapy), but it has similar durability limitations to esketamine – and because it lacks FDA approval, patients generally must pay significant out-of-pocket costs, which is particularly concerning for those who need ongoing maintenance treatment.[13]

Personal Experiences With Psilocybin

The one thing that has truly helped both me and my sister has been psilocybin - the active ingredient in "magic mushrooms," which is a classic psychedelic that causes profound acute alterations in perception and mood.

For me, a single experience with psilocybin in college (over a decade ago) helped alleviate a long-standing anxiety-based eating disorder I've had since childhood—avoidant/restrictive food intake disorder (ARFID), which is easiest described as an aversion or phobia of eating (or even trying to eat) most normal adult foods. Growing up wrestling, I could somewhat hide my ARFID behind cutting weight and preferred people assume I was anorexic rather than explain what I was actually experiencing. However, over time, ARFID became increasingly physically unhealthy and socially isolating.

Fortunately, my experience with psilocybin created a window of about six months where my anxiety over trying new foods was reduced by around 80%. I didn't suddenly like everything and was not "cured," but it changed the course of my life—I was able to begin eating a range of new adult foods that enabled me to live healthier, have an improved social life, and generally have

[10] https://www.nimh.nih.gov/health/statistics/suicide
[11] https://jamanetwork.com/journals/jama/article-abstract/2837026;
https://www.jnj.com/media-center/press-releases/spravato-esketamine-approved-in-the-u-s-as-the-first-and-only-monotherapy-for-adults-with-treatment-resistant-depression
[12] https://pubmed.ncbi.nlm.nih.gov/40926574/
[13] https://www.sciencedirect.com/science/article/abs/pii/S0165032724003422?via%3Dihub

increased hope that things could improve. I realized that I was not permanently "broken" or "unfixable"; and at the same time, I was also more self-accepting of being "different."

More recently, for my sister, psilocybin therapy helped process long-held trauma and rapidly reduce her debilitating migraines—accomplishing what a decade of therapy and an intense cocktail of medications could not (recognizing that the decade of therapy helped prepare her for a better experience, and she was fortunate to have incredibly qualified professional support).

Psilocybin's Therapeutic Potential - Growing Body of Research

Our experiences align with a growing body of research showing that psilocybin can produce rapid, robust, and durable symptom relief across a range of mental health conditions, including treatment-resistant and major depression, anxiety (including end-of-life anxiety), PTSD, substance use disorders, eating disorders, migraines, and many other conditions.[14] Research suggests a complex mechanism of action driving these clinical improvements through a combination of enhanced neuroplasticity ("rewiring of the brain"), moderated fear responses, and profound psychological insights, allowing for the re-processing of trauma and behavioral changes that help achieve meaningful, long-lasting recovery.[15]

Notably, psilocybin has received multiple FDA Breakthrough Therapy designations for treatment-resistant depression and major depressive disorder, indicating a favorable safety profile and that it may be significantly more effective than existing treatments for these conditions. Acute negative psychological side effects (often referred to as a "bad trip") and physiological adverse events (e.g., headache, nausea) are typically transient and well managed in clinical trials through careful screening, preparation, monitored dosing with trained professionals, and structured follow-up.

In terms of durability, a paper published earlier this month reported remarkable five-year follow-up outcomes from a psilocybin-assisted psychotherapy trial, with 67% of patients in remission from depression five years after treatment, along with significant improvements in anxiety and functional impairment. Patients reported positive changes in mindset, emotional health, empathy, self-acceptance, and improved interpersonal relationships.[16] These findings are incredible in their own right – and especially so when compared to the limited breadth and depth of benefits from daily use of SSRIs (and again, many do not experience even these limited benefits).

Moreover, no serious adverse events were reported in this five-year follow-up study, which is consistent with results from prior long-term follow-up studies of up to 12 months for depression and up to 4.5 years for cancer-related distress, which found sustained benefits without new safety concerns.[17] However, particularly for patients with complex mental health conditions, it will be important to monitor for both acute and long-term safety in real-world settings (e.g., onset or

[14] https://www.frontiersin.org/journals/psychiatry/articles/10.3389/fpsyt.2021.800072/full
[15] https://link.springer.com/article/10.1007/s11920-022-01361-0
[16] https://akjournals.com/view/journals/2054/aop/article-10.1556-2054.2025.00461/article-10.1556-2054.2025.00461.xml
[17] https://pubmed.ncbi.nlm.nih.gov/31916890/; https://pubmed.ncbi.nlm.nih.gov/35166158/

worsening of suicidality, psychosis, serious psychiatric symptoms) and to distinguish drug-related adverse events from underlying illness.

FDA Approval and Patient Access

Over the next couple years, we anticipate FDA approval for at least one psilocybin therapy for treatment-resistant depression and/or major depressive disorder. The FDA will almost certainly mandate a Risk Evaluation and Mitigation Strategy (REMS) requiring treatment be offered only in-clinic at specially certified facilities with trained providers, similar to the approval of esketamine (which is the closest approved comparator to psilocybin), with a dedicated patient registry to monitor adverse events and long-term outcomes. While this will maximize safety, unfortunately it creates a major cost and barrier to access, so public and private insurance coverage will be critical for most patients to afford this through our traditional healthcare system.[18]

Recommendations

Untreated and undertreated mental health conditions can be life-threatening, and we must act accordingly. Time matters. Following any FDA approval, Pennsylvanians should not face delays accessing potentially lifesaving psilocybin treatment from qualified healthcare providers. That is why **H.B. 1439** is a step in the right direction to ensure prompt state rescheduling of FDA-approved psilocybin treatment ("pharmaceutical composition of crystalline polymorph psilocybin") aligned with federal scheduling, avoiding unnecessary lags between federal approval and state access.[19]

We applaud the leadership and insight supporting this rescheduling bill. However, we also suggest the state take a broader, more efficient, forward-looking approach. Nearly every major psychedelic—MDMA, psilocybin, DMT, LSD, ibogaine, 5-MeO-DMT, and methylone—is in FDA-regulated trials; and six have FDA Breakthrough Therapy designations. The Breakthrough Therapies include MDMA and methylone for PTSD; three psilocybin therapies for depression; and an LSD-based therapy for generalized anxiety disorder. Ibogaine also shows strong Breakthrough Therapy potential for traumatic brain injury and/or opioid use disorder.

Rather than limiting legislation to psilocybin alone, we urge you to **establish automatic state rescheduling for any FDA-approved controlled substance**. This streamlined approach would

[18] Millions of people already use psilocybin despite its status as a Schedule I drug, and the number is only increasing as more learn of its benefits. We expect the number will continue to increase post-approval, particularly if it is too difficult for those with mental health conditions to access through the healthcare system. As such, the state should do as much as possible to ensure FDA-approved psilocybin treatment is affordable and accessible. We also expect in the coming years, legislators will be asked to consider legislation allowing for supervised adult use of natural psilocybin and other psychedelics, similar to programs recently established in Oregon and Colorado.

[19] Specifically, following FDA approval of the pharmaceutical composition of crystalline polymorph psilocybin, within five business days of its rescheduling by the United States Drug Enforcement Administration, the secretary shall transmit notice to the Legislative Reference Bureau for publication in the next available issue of the Pennsylvania Bulletin, and the rescheduling shall take effect 30 days after such publication.

conserve state time and resources moving forward, avoid duplicative bureaucracy, and—most importantly—prevent avoidable delays in patient access to potentially lifesaving treatments. This is particularly logical since any approved treatment will likely come with a REMS (similar to esketamine), ensuring safety guardrails are already in place.

Finally, we suggest the state invest in patient access and real-world research programs that track long-term outcomes and cost-effectiveness for the state, particularly for Medicaid. Several states have already begun investing in psilocybin and broader psychedelic research for various purposes, including:

- Texas invested $2 million for a psilocybin trial for Veterans with PTSD, led by our Chief Science Officer, Dr. Lynnette Averill at Baylor College of Medicine, and recently passed legislation to allocate a historic $50 million for ibogaine drug development trials.

- Illinois appropriated $6 million for a Breakthrough Therapies for Veteran Suicide Prevention Program to support MDMA and psilocybin research.

- Maryland appropriated $1 million in funding to its Post-Traumatic Stress Disorder and Traumatic Brain Injuries Alternative Therapies Fund for Veterans, which should soon be funding research of MDMA-assisted therapy comparing group versus individual treatment protocols.

- Connecticut appropriated $2 million for a transdiagnostic open label trial of psilocybin prioritizing treatment of Veterans, first responders, and frontline healthcare workers.

- Arizona invested $3 million into clinical trials of natural psilocybin mushrooms and is allocating $5 million for ibogaine trials.

- Georgia appropriated $1 million to Emory Healthcare Veterans Program for PTSD treatment and wrap-around services for Veterans and their families, which is intended to fund a trial of MDMA and/or psilocybin with prolonged exposure therapy.

- The state of Washington appropriated $2 million to the University of Washington for clinical research of psilocybin therapy for substance use disorder treatment.

Thank you again for the opportunity to testify today, and I look forward to answering any questions.

PENNSYLVANIA ACADEMY *of* FAMILY PHYSICIANS

Treatment-Resistant Depression (TRD)
Pennsylvania Majority Policy Committee Hearing
Tuesday, September 16, 2025
Dr. Daniel Orr, MD

On behalf of the Pennsylvania Academy of Family Physicians (PAFP), I wish to provide this statement on the important topic of Treatment-Resistant Depression. PAFP represents thousands of physicians who specialize in family medicine. I have been a lifelong member of PAFP and frequently serve as faculty at their continuing education conferences on mental health issues and treatments.

At the present time there is controversy regarding the appropriate definition of TRD. The FDA defines TRD as: patients who remain depressed and do not achieve an adequate response (50% improvement of symptoms) and satisfactory level of functioning even after two or more courses of treatment, having failed to improve after two adequately performed trials of antidepressant medications. These non-responders are considered "treatment resistant." It is estimated that at least 30% of people with depression meet the definition of TRD. Some, but certainly not all of the factors that may lead to treatment failure are:

1) Choice of anti-depressants,
2) Adherence of patients to the medication regime,
3) Regimen of add-on psychiatric medications,
4) Persistence of the practitioner,
5) Co-morbid psychiatric disorders,
6) Co-morbid medical disorders such as diabetes and cardiac disorders, and
7) Unsuccessful psychotherapy (Such as CBT or IPT).

TRD leads to higher costs of health care as well as an increased utilization of the health care system. TRD patients have increased disability costs and increased absenteeism from work. The impairment of psycho-social functioning as well as increased risk of suicidality which includes actual suicide is greater in the TRD population. Untreated TRD is a risk factor for cardiovascular disease, diabetes, obesity, chronic obstructive pulmonary disease, hypertension, certain types of

cancer and immunologic disorders. The needs for newer medications and treatments are clear. Since 30% of those with depression fall into the TRD category, it would be helpful to have new antidepressants that work quickly and maintain their effect over time. An ideal goal of a new antidepressant and/or psychotherapeutic regimen is to reach and maintain remission (not merely response) as well as having tolerable safety and minimal side effects with an affordable cost.

Some add-on treatments for TRD are presently being used such as:

- lithium augmentation
- some atypical antipsychotic medications
- Cytomel (T3)
- L-Methylfolate
- SAME
- Lamotrigine
- IV Ketamine
- ECT
- Vagal nerve stimulation (VNS)
- Transcranial Magnetic Stimulation (TMS)

There are ongoing trials of medications for TRD, which include psychedelics such Psilocybin. In some studies, a few sessions of Psilocybin administration have shown long lasting antidepressant effects for up to six months. Presently risks vs benefits are being determined for the use of specific psychedelics. When treating TRD with psychedelic medications it is important to also treat with psychotherapy before, during and after treatments. Also, it is essential to have well trained clinical personnel to assist as monitors during treatment sessions. Safety precautions and a safe environment for administration and monitoring are imperative during treatment sessions. A special license and education for a practitioner treating with psychedelics should be considered. The Risk Evaluation and Mitigation Strategy (REMS) program that is presently used for Esketamine administration may be used as a blueprint for other psychedelic administration.

Chairman Bizzarro, members of the House Majority Policy Committee, thank you for the chance to testify at this important hearing today.

My name is Ryan Bastle, and I serve as a Senior Medical Science Liaison 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, and the first classic[1] psychedelic to come to market as an FDA-approved product.** Psychedelics represent a potential breakthrough innovation in the field of psychiatry in the coming years.

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 May 2022, the positive results of our 233 participant Phase 2 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. These are the largest clinical trials ever conducted with any classic psychedelic.

Along with clinical development in TRD, in May 2024, Compass Pathways announced positive top-line results from a Phase 2 open label 12-week safety and tolerability study in PTSD. That study showed COMP360 was well tolerated and resulted in both rapid and durable improvement in

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[1] For the definition of classic psychedelic, see Vollenweider, F.X. and Smallridge, J.W., 2022. Classic psychedelic drugs: update on biological mechanisms. *Pharmacopsychiatry*, *55*(03), pp.121-138.

symptoms from baseline observed following a single administration. The results of this trial were just published in the Journal of Psychopharmacology in September 2025. Compass is currently finalizing plans to initiate a late-stage trial in PTSD.

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[2]. 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[3]. An estimated 21 million adults in the United States suffer from major depression[4], and approximately 9 million are drug treated[5].

As you have heard in previous testimony, 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. 40% of TRD patients reported having suicidal ideation in the past year[6].

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.** 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

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[2] https://www.who.int/news-room/fact-sheets/detail/depression
[3] 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/
[4] https://mhanational.org/conditions/depression/
[5] Zhdanava 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.
[6] Rhee, TG et al. *J Affect Disord*. 2024; 358:342-349.

of innovative treatments, like psychedelics, for the treatment of serious mental health conditions are underway. Before such treatments come to market, it is important to ensure that providers, payers, and policymakers are aware of innovative treatments and the evidence that has been generated on their clinical uses. In the case of psychedelics, such as Compass' COMP360 psilocybin product, these treatments will remain scheduled drugs and have an FDA-mandated Risk Evaluation and Mitigation Strategy (REMS), to ensure proper usage in a medical setting. Importantly, these products will not be offered in retail pharmacies. **They will only be available to patients in medical settings of care, with the supervision of a licensed healthcare provider.**

In conclusion, innovations like psychedelics in mental healthcare are coming soon. In the treatment paradigm Compass is pursuing, this treatment would be FDA-approved, available by prescription only, and delivered in a medical setting of care. We appreciate this committee's commitment to educating key stakeholders on TRD and the innovations coming in the space. Thank you for your time today, and I'm happy to take any clinical questions.

Chairman Bizzarro, members of the Policy Committee, thank you for taking the time to consider HB 1439. My name is Tess Bettler, and I am the Associate Director of Government Affairs for Compass Pathways, and here in support of the bill today. This bill requires the Pennsylvania Department of Health to schedule an FDA-approved formulation of crystalline polymorph psilocybin in the same manner as the federal Drug Enforcement Administration. The bill requires that following DEA rescheduling, the Department act on this directive within five business days, with the final rescheduling occurring 30 days after final publication in the Pennsylvania Bulletin. This bill does not decriminalize or legalize psilocybin, nor does this bill allow access to medications that have not been approved by the U.S. Food and Drug Administration for specified conditions and rescheduled federally by the Drug Enforcement Administration. Rather, it provides hope of timely access to innovative treatments for those suffering from certain mental health conditions.

As you know, mental health remains a significant issue in the United States, with one in five adults experiencing a mental health condition each year. Amidst this crisis, the need for novel treatments to help patients is significant. Yet, new treatments and therapies have not kept pace with the growing crisis. We've experienced a lack of innovation for mental health therapies for decades.

Psilocybin is currently a Schedule I drug both federally and in Pennsylvania, meaning it is considered an illegal substance with no medical use. However, pharmaceutical grade formulations of synthetic psilocybin are currently being studied in FDA regulated clinical trials for mental health conditions, including treatment-resistant depression (TRD) and post-traumatic stress disorder (PTSD). Treatment-resistant depression occurs when a patient suffering with major depressive disorder is failed by two or more medications in a single depressive episode and occurs in approximately 1/3 of patients being treated for major depressive disorder. **There are currently only two treatments approved by the FDA for treatment of TRD.**

As my colleague Ryan has mentioned, these treatments, if FDA-approved, would only be given to patients in medical settings, such as a doctor's office. Furthermore, these treatments would be subject to a Risk Evaluation and Mitigation Strategy as outlined by the FDA to help prevent diversion and help ensure patient safety. And importantly, these prescription medications will

not be available in a retail pharmacy setting for a patient to take home. A healthcare professional will be with the patient every step of the way to safeguard them during their experience. But first, action must be taken to ensure patients will have access to these treatments should they be FDA-approved and DEA-rescheduled.

In the event that a prescription drug containing crystalline polymorph psilocybin, such as Compass' COMP360, is approved by the FDA, the U.S. Drug Enforcement Administration (DEA) will be expected to make a rescheduling decision soon after approval, allowing for prescription medical use of the FDA-approved product in the USA. As Pennsylvania law does not allow for automatic following of the Federal DEA's rescheduling decision, it is important that legislation be passed in anticipation of a potential FDA-approval of new and innovative treatments such as COMP360. Doing so will allow patients in your state with difficult-to-treat mental health conditions such as TRD and PTSD to have access to new crystalline polymorph psilocybin treatments approved by the FDA as quickly as possible after approval and DEA rescheduling. If the FDA does not approve a crystalline polymorph psilocybin product, then nothing happens in Pennsylvania.

In short, this bill helps accelerate access to FDA-approved formulations of crystalline polymorph psilocybin, which are currently being studied for TRD and PTSD. Unless and until an FDA-approved and DEA-rescheduled crystalline polymorph psilocybin product is also rescheduled in Pennsylvania, patients will not have access to it.

Thank you for your time, and I am happy to take any questions.