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Dear Members of Congress:

Reason for Hope and the undersigned organizations are proud to support the Breakthrough Therapies Act introduced by Senators Cory Booker and Rand Paul and Congresswomen Madeleine Dean and Nancy Macy. This legislation is a simple and straightforward solution to an obvious problem. It will reduce the regulatory red tape hindering research of urgently needed breakthrough mental health treatments and access to these treatments for patients with terminal or life-threatening conditions.

Our nation's continuously escalating mental health crisis – while complex – highlights the limitations of effective pharmacologic treatments and therapies in our toolbox for stress and trauma-related concerns such as PTSD, depression, and suicidality. Currently available medications prescribed for these conditions fail to work for many people, do not work well enough for most, and often have significant side effects. Moreover, as Tom Insel, our former Director of the National Institutes for Mental Health, noted: "It's a pretty safe bet in most of medicine that if you treat more people, death and disability drop. But when it comes to mental illness, there are more people getting more treatment than ever, yet death and disability continue to rise."

Indeed, the average number of suicides rose from 81-per-day in 2001 to 121-per-day in 2020. Overall, a reported 45,979 Americans died by suicide in 2020; there were an estimated 1.2 million suicide attempts; and 54% of Americans had been affected by suicide in some way, with suicide causing a devastating ripple effect on loved ones left behind. Overdose deaths have increased even more dramatically, with over 100,000 lives lost during the 12-month period ending April 2021.

The federal government should thus not stand in the way of urgently needed investigation of novel therapeutics with potential to offer relief and healing to individuals who have been failed by current treatments, especially those which can offer rapid and robust improvements. Mounting evidence suggests fast-acting therapeutics like MDMA and psilocybin – currently classified as Schedule I drugs under the Controlled Substances Act – have great potential to offer this level of healing to individuals suffering from a variety of mental health conditions.

Significantly, initial clinical trial results have been so promising that the Food and Drug Administration granted Breakthrough Therapy Designations to both MDMA-assisted therapy for PTSD and *two* psilocybin therapies for life-threatening forms of depression (treatment-resistant

depression and major depressive disorder). This means that the FDA hopes to accelerate the approval timeline for these potentially lifesaving therapies, as they demonstrated a substantial improvement over currently available treatments for these serious conditions. Yet, paradoxically, the Schedule I status of MDMA and psilocybin impedes access to these substances, both for clinical research and compassionate use.

Given existing evidence showing these therapies can be safely administered in medical settings and may be substantially more effective than any other available treatment, terminal cancer patients with end-of-life anxiety should not have to wait for full FDA approval to access them. Nor should Veterans with severe PTSD and depression who have exhausted available treatments (and do not qualify for clinical trials due to their complex conditions).

The Breakthrough Therapies Act offers a simple solution by rescheduling these and any future breakthrough therapies from Schedule I to Schedule II on an expedited basis, which would reduce the red tape hindering research and access to treatment. Ultimately, rescheduling could allow a cautious, phased roll-out of these potentially life-saving treatments, with little risk to the public health or safety. This would not only offer critical opportunities for patient access to those with more "complex" comorbid conditions who are ineligible for clinical trials—as is often the case with Veterans—but also provide valuable real-world training opportunities that providers need to be prepared to deliver this highly specialized form of care. Further, it could enable infrastructure development and real-world data collection to inform safety policies and best practices, as well as inform payors on insurance coverage.

The United States should be leading the charge for innovative solutions to the mental health crisis. Yet, we are already falling behind. On February 3, 2023, the Australian government announced it would reschedule MDMA and psilocybin to permit authorized psychiatrists to prescribe them for PTSD and treatment-resistant depression, respectively, subject to strict controls on prescribing and treatment protocols. Australia's decision acknowledged the current lack of options for patients with these specific conditions.

Given this reality, it should be unsurprising that for many patients, MDMA- and psilocybin-assisted therapies – amongst several other psychedelic medicines currently under clinical investigation – represent a reason for hope for a new era of mental health care. Personally, an experience with psilocybin helped treat an eating disorder for which no currently approved medications or therapies exist. Unfortunately, however, I failed to make the connection between the life changing effects I experienced and the broader potential for these substances to help people like my mom struggling with depression and suicidality. By the time I discovered the groundbreaking research, it was too late.

This week marks the five-year anniversary since I lost my mom – Sherrie Hope Waters – to suicide. Reason for Hope is named in her memory. Reflecting on the several notes my mom left behind (written over the course of many years that she was struggling to varying degrees), I cannot help but think she would have benefitted immensely from psilocybin-assisted therapy. This is one

of the many lingering questions I live with for which I will never know the answer. However, I do know that based on the existing evidence, this is the treatment that my sister and I would have worked with my mom to pursue if it were available. And there are many others currently struggling, who fully aware of the evidence of the risks versus the benefits this treatment may offer, would make the same decision. For these individuals, it is not too late, and they deserve the opportunity to pursue this potentially lifesaving treatment in advance of full FDA approval.

Thus, we urge members of Congress to support the Breakthrough Therapies Act, which offers a responsible path forward to usher in this new paradigm of mental health care by reducing barriers to research and limited compassionate use access to breakthrough mental health treatments.

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Endorsing Organizations

BrainFutures • Law Enforcement Action Partnership • Affinity Healthcare Futures
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