Martin R. Steele
Lieutenant General, US Marine Corps (Retired)
Chief Executive Officer, Reason for Hope

Lynnette A. Averill, PhD
Chief Science Officer, Reason for Hope

Brett M. Waters, Esq.
Executive Director, Reason for Hope
brett@reason-for-hope.org

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The Veteran Mental Health Leadership Coalition (VMHLC), including the undersigned organizations and advisors, is proud to support the Right to Try Clarification Act introduced by Senators Rand Paul and Cory Booker.

My name is Martin R. Steele, and I am a retired Lieutenant General in the United States Marine Corps., a Vietnam-era combat Veteran, and Chief Executive Officer of Reason for Hope. I served on the Commission on Care during the Obama Administration (nominated by Senator Mitch McConnell), was twice nominated by President Trump to serve as the Secretary of Veterans Affairs, and I am now leading the VMHLC in what I consider to be the most significant mental health policy and advocacy initiative of my lifetime. The Right to Try Clarification Act is the first in a series of forthcoming bills that VMHLC plans to lead as part of our fight to prevent suicide and deaths of despair – not only for Veterans – but for all Americans – through increased access to safe and affordable psychedelic-assisted therapy. While the Right to Try Clarification Act is the narrowest in scope of our planned forthcoming legislation, it is also the most urgent, as it seeks to open access to MDMA- and psilocybin-assisted therapy for a small subset of Veterans who are at serious risk of suicide and have exhausted all other options.

Veterans who exhausted all options are precisely those that our coalition represents: specifically, the thousands of Veterans who nearly lost all hope after struggling through (sometimes double digit) ineffective medications and therapies – which often left them worse off than where they started – before eventually leaving the country they served in a last-ditch effort to receive psychedelic-assisted therapy in Mexico, Costa Rica, Jamaica, and other countries where they could legally access this life-saving treatment. Indeed, our coalition members Veterans Exploring Treatment Solutions (VETS), Heroic Hearts Project, SEAL Future Foundation, the Hope Project, Sabot Foundation, and Veterans of War, together have funded around 1,065 Veterans to receive psychedelic-assisted therapy outside our nation's border, with over 600 of those Veterans treated at The Mission Within, a clinic on the outskirts of Tijuana, Mexico. The number is much larger when considering those who were fortunate enough to be able to self-finance travel and treatment outside the country. And for most of these Veterans, psychedelic-assisted therapy has proved not only lifesaving, but life-restoring.[i]

However, we find it morally unacceptable that our nation's Veterans should be forced to take such extreme, and often detrimentally expensive routes to potentially lifesaving interventions. Recently, I testified before the state of Connecticut Public Health Committee that "we have a **duty, responsibility**, and more than ever, an ***urgency***, to help . . . all those suffering from trauma – to heal and move forward as

productive members of society. Unfortunately . . . we have failed to do so for far too long."[ii] The Right to Try Clarification Act is a small step in the right direction toward saving lives, which we urge lawmakers on both sides of the aisle to strongly support. There is simply no reasonable justification for the status quo when ***MDMA and psilocybin-assisted therapies both have been granted a Breakthrough Therapy designation by the FDA,*** which is a: "process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)."[iii]

We also note that our support for this bill is not an attempt to merely circumvent the regulatory infrastructure needed to provide these therapies safely and affordably on a larger scale, with treatment covered by insurance. Indeed, we have been leading an ambitious initiative to streamline the regulatory infrastructure for MDMA- and psilocybin-assisted therapy through advocating for the establishment of an interagency task force within the Department of Health and Human Services, which is meant to issue guidelines that assist states in addressing the complex clinical, regulatory, and public policy issues necessary for the 'real-world' deployment of these treatments.[iv] Along the way, we received letters of support sent to Secretary Becerra from a bipartisan group of federal and state legislators, including Congresswoman Madeleine Dean and Congressmen Brian Fitzpatrick, Dean Phillips, Mike Waltz, and Earl Blumenauer, along with the Chair of the New York Assembly Health Committee, Richard Gottfried, and state bill sponsors from New York, Pennsylvania, Texas, and Connecticut. We also successfully led the passage of legislation in Connecticut establishing an innovative, first in the nation, expanded access pilot program for these therapies, which includes funding for the treatment of Veterans, first responders, and front-line health care workers and which will explore different therapeutic protocols and provide real-world data to inform the Federal Task Force in establishing best practices and standards of care.

We are proud to share that the Substance Abuse and Mental Health Service Administration, on behalf of Secretary Becerra, recently responded in agreement with these letters and indicated plans to move forward with the suggested Federal Task Force.[v] However, these regulatory initiatives will take time to develop (in parallel with final FDA approval of MDMA and psilocybin); time that some Veterans unfortunately do not have the luxury of waiting on, as Veteran suicides are still (likely conservatively) estimated between 17-22 per day and nationwide deaths of despair continue to rise despite increased spending on mental health care. [vi]

We know that America can do better and the Right to Try Clarification Act is a small step in the right direction. We hope to see widespread bipartisan support for this potentially life-saving legislation.

Sincerely,

Martin Steele

Lt. Gen. Martin R. Steele, USMC (Ret.), Chief Executive Officer
Lynnette Averill, PhD, Chief Science Officer
Brett Waters, Esq., Executive Director
REASON FOR HOPE o/b/o Veteran Mental Health Leadership Coalition

Veteran Mental Health Leadership Coalition Members

HEROIC HEARTS PROJECT

Jesse Gould (US Army Ranger, Retired)
Founder and CEO, Heroic Hearts Project

SOAA
SPECIAL OPERATIONS ASSOCIATION OF AMERICA

Daniel Elkins
Co-Founder & Chief Executive Director

VETERANS EXPLORING TREATMENT SOLUTIONS

Co-Founder, Veterans Exploring
Treatment Solutions

Warrior Angels Foundation

Andrew Marr (Green Beret, Retired)
Co-Founder, Warriors Angels Foundation

THE MISSION WITHIN

Martin Polanco, MD
Founder and Research Director, The Mission Within

SABOT GROUP FOUNDATION

John Krashna
Sabot Foundation

SEAL FUTURE FOUNDATION

Jonathan Wilson, Navy SEAL (ret.)
Chairman and Co-Founder
SEAL Future Foundation

BVN
BALANCED VETERANS NETWORK

Ron Millward, USAF (Retired)
CEO, Founder & President
Balanced Veterans Network

Mark R. Keller, LCDR, USN (Ret)
No Fallen Heroes

Allison Wilson
Allison Wilson, Founder of The Hope Project

Deran Young
Dr. Deran Young, USAF (Ret.)
Former Military Mental Health Officer
Founder & CEO, Black Therapists Rock

Project Akichita

Jack Boger
Jack Boger, USMC (Ret.)
Founder, Project Akichita

Wyly Gray
Wyly Gray, USMC (Ret.)
Founding Director, Veterans of War

Veteran Mental Health Leadership Coalition Advisory Board

Lynnette Averill, PhD
Chief Science Officer, Reason for Hope
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Author of national bestselling "Weekends at Bellevue: Nine Years on the Night Shift at the Psych ER"
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Martin R. Steele, Lieutenant General, US Marine Corps (Retired)
Chief Executive Officer, Reason for Hope
U.S. Global Leadership Coalition, National Security Advisory Council

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Retired Professor of Strategic Studies and National Defense

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State Policy and Advocacy Coordinator, Reason for Hope
Former 3 term Connecticut State Legislator

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Executive Director, Reason for Hope
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Former Chief of Intelligence Law, NATO and Resolute Support, Kabul, Afghanistan

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Executive Director, CVB Veterans Advisory Council

Mark Leavitt
Rear Admiral, US Navy (Ret.)

Scott J. Vail
Associate Attorney, Ropes & Gray LLP

Lucas Brown
Associate Attorney, Ropes & Gray LLP

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[i] *See, e.g*., A Balm for Psyches Scarred by War, The New York Times, *available at* https://www.nytimes.com/2022/05/29/health/mdma-therapy-ptsd.html; *supra*, n. iv.

[ii] Connecticut General Assembly, Public Health Committee Testimony re: AN ACT INCREASING ACCESS TO MENTAL HEALTH MEDICATION (HB 5396), *available at*, https://www.cga.ct.gov/asp/menu/CommDocTmyBillAllComm.asp?bill=HB-05396&doc_year=2022.

[iii] *See* https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy.

[iv] *See* Exhibits 1 and 2. For an example of these complexities, while FDA approval of MDMA and psilocybin will likely be tied to a Risk Evaluation Mitigation Strategy (REMS) that determines the parameters of safe use, these medicines, and particularly psilocybin, can be broadly acquired from other non-FDA approved sources, such as natural psilocybin-producing mushrooms, which will not be subject to those same REMS protocols. Further, unlike marijuana, psychedelic treatments require the regulation of both a drug *and* a therapy, the latter of which is traditionally a matter of state authority. *See id*.

[v] *See* Exhibit 3.

[vi] From 2010-2019, annual deaths of despair (including suicide, alcohol, and opioid-related deaths) rose sharply from around 94,000-to-150,000 per year (a 50% increase), despite consistent annual spending increases from federal and state governments that totaled around $1 trillion during this same period. *See* Substance Abuse and Mental Health Services Administration, Projections of National Expenditures for Treatment of Mental and Substance Use Disorders, 2010–2020, HHS Publication No. SMA-14-4883, Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014, Table A.6; SAMHSA Spending Estimates - Projections for 2010-2020; Dieleman JL, Baral R, Birger M, et al. US Spending on Personal Health Care and Public Health, 1996-2013. JAMA. 2016;316(24):2627–2646. doi:10.1001/jama.2016.16885; Dieleman JL, Cao J, Chapin A, et al. US Health Care Spending by Payer and Health Condition, 1996-2016. JAMA. 2020;323(9):863–884. doi:10.1001/jama.2020.0734.]].