Coordinated Federal and State Psychedelic Policy

So Outrageous It Just Might Work?

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Deaths of despair in our nation rose sharply over the last decade, despite significant increases in spending on mental health care. Given the continuously worsening trajectory and the failure of the mental health industry to keep pace with the advances made in nearly every other area of medicine over the last 50 years, we have reached a unique moment of urgency for bold but thoughtful measures to change the status quo.

Suddenly, psychedelic medicines no longer seem so crazy, do they? In fact, the coveted FDA breakthrough therapy designation has been given to both MDMA- and psilocybin-assisted therapies. This designation is meant to expedite the development of drugs intended to treat a serious condition where preliminary clinical evidence demonstrates substantial improvement over available therapy on a clinically significant endpoint.

In our mission to prevent deaths of despair, Reason for Hope has worked on a variety of policy initiatives over the last year, seeking to increase access to these potentially life-saving treatments for those most in need, while also streamlining the comprehensive regulatory infrastructure necessary to ensure MDMA- and psilocybin-assisted therapies are provided as safely and affordably as possible in the long run. Nonetheless, given the widely acknowledged bottleneck of qualified, trained providers based on expected demand, we believe a phased roll out—balancing urgent access and safety—is warranted. However, the success of this strategy depends heavily on proactive measures from the federal government in advance of potential FDA approval of MDMA- and psilocybin-assisted therapies.

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Around a year ago, Reason for Hope began educating members of the Biden Administration on the need to establish an interagency federal task force. Considering the critical role that agencies such as the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) will play from both a cost and access perspective in how this field develops, we need a dedicated federal entity working with a broad mix of stakeholders — rather than just pharmaceutical companies — to inform the various agencies' decision-making. This form of "participatory democracy" would enhance public trust in the process.

Reason for Hope devoted significant time on a volunteer basis working to advance this proposal over the last year, including preparing briefings for both the White House Domestic Policy Council and leadership within the U.S. Department of Health and Human Services (HHS), before seeking support for this initiative from a bipartisan group of federal and state legislators.[1] The broad concept of the task force—at least as we proposed it—is to work with stakeholders to develop standards for training, credentialing, and state licensure for a broad-spectrum workforce of interdisciplinary clinical and non-clinical practitioners, and to build out necessary educational materials and peer support networks for communities throughout the country. Additionally, the task force should establish nationwide safety and ethical violation reporting systems that can hold session facilitators accountable both inside and outside the medical model. Guidelines developed through this collaborative process should then be published in the federal register, so states could adopt or adjust the guidelines to meet their individual needs.

Critically, throughout this process, the task force must ensure that relevant agencies such as the FDA and DEA are apprised of the guardrails being put in place, as to prevent potentially harmful overregulation that inhibits equitable access to these novel treatments once available. For example, potential FDA approval of MDMA- and psilocybin-assisted therapies would be tied to a Risk Evaluation and Mitigation Strategy (REMS) that determines the parameters of safe use. The REMS may involve considerations of who can provide treatment (i.e. requiring the presence of a medical doctor), where it can be provided, and how it can be provided (i.e. the number of required sessions, conducting group therapy, etc.). These are traditionally matters of state authority—regulating the practice of medicine and therapy—which have not historically been decided by the FDA. Further, state infrastructure that extends beyond the traditional medical model would create the conditions for the DEA to reschedule all psilocybin, allowing states to experiment with purely intra-state regulatory systems (such as in Oregon) without violating federal law.[2]

Finally, the task force should develop independent economic analyses to determine healthcare and broader social cost savings that will inform insurers on reimbursement, including working with the Centers for Medicare and Medicaid Services to ensure adequate coverage. Unfortunately, however, prohibition has left us scarce

[1] Recently, the letters of support sent to The Honorable Xavier Becerra, Secretary of HHS, both from Congress and from state legislators and Reason for Hope (along with a small group of other stakeholders), were made public. As was the response to our letters from Assistant Secretary of Mental Health and Substance Use, Dr. Miriam-Delphin Rittmon (on Secretary Becerra's behalf), which generally agreed with our underlying policy arguments and noted the Biden Administration was exploring the establishment of the proposed task force.

[2] Separately, the task force should work with the DEA to issue updated guidelines on Religious Freedom and Restoration Act exemptions from the Controlled Substances Act.

data with which to conduct such analyses or determine optimal protocols that balance safety, efficacy, and access.

Reason for Hope's state policy initiatives seek to address this knowledge gap by establishing coordinated state-funded pilot programs throughout the country, utilizing the FDA's existing expanded access program. According to the FDA's 2018 Expanded Access Program Report, the agency has a 99% expanded access approval rate across all application types. Yet, clinicians hesitate to take advantage of this program due to the time, cost, and administrative burden of securing FDA and Institutional Review Board approvals. For MDMA and psilocybin, Schedule I licensing requirements and administrative hurdles further impede this option.

While far from a perfect option to navigate some of these expanded access bureaucratic obstacles, Reason for Hope is working to establish state pilot programs that will allow approved treatment sites to split administrative costs, fund the treatment of a select number of qualified patients (including Veterans), and collect and analyze real-world data.[3] Coordination between these types of state pilot programs and the federal task force would create a thoughtful and intentional common-sense mechanism to advance the field, as opposed to having dozens of states across the country conducting their own work groups, task forces, or literature reviews exploring the efficacy and regulation of these therapies, without any additional data to inform best practices. The real-world evidence developed through these pilot programs can be utilized by the federal task force—both before and after FDA approval—to flexibly update guidelines as we learn new information.

We recognize, however, that these initiatives will take time to develop. As a team primarily connected by the loss of loved ones to suicide or deaths of despair (for me, my grandfather to suicide when I was young, and my mom to suicide in 2018), we are acutely aware that some people do not have the luxury of time to wait. Thus, Reason for Hope and the recently formed Veteran Mental Health Leadership Coalition (VMHLC) provided a letter in support of the Right to Try Clarification Act (RTTCA) for Senators Cory Booker and Rand Paul.[4] The RTTCA has the potential to open immediate access to MDMA- and psilocybin-assisted therapies for those at serious risk of suicide who have exhausted all other treatment options.

Access to these treatments under the Right to Try Act is particularly significant to our VMHLC members, who have already funded over 1,000 Veterans to receive psychedelic-assisted therapy in other countries after exhausting all available treatment options. With thousands of additional Veterans on the waiting lists for these organizations, and a conservatively estimated 17-22 Veterans dying by suicide every day, the status quo cannot be justified. Individuals struggling with mental health conditions who have exhausted all treatment options deserve the opportunity to access breakthrough therapies that can be safely provided, with informed consent, here at home.

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Reason for Hope is named in memory of Brett's mom, Sherrie Hope Waters, who he lost to suicide in 2018. Brett's grandfather, a fighter pilot in WWII, also died by suicide when Brett was young. These losses are the driving force behind his work, which to date, has been solely on a volunteer/pro bono basis. Prior to founding Reason for Hope, Brett served as the Policy and Advocacy Chair for the American Foundation for Suicide Prevention, NYC Chapter.

[3] Earlier this year, we worked with Connecticut legislators to successfully pass a law creating the first such program, which passed as part of the state's budget bill. Additionally, the bill includes provisions to streamline the post-FDA approval regulatory process for MDMA and psilocybin through automatic rescheduling and language to automatically consider adoption of the federal guidelines that we anticipate will be developed by the task force and published by HHS.

[4] https://www.booker.senate.gov/imo/media/doc/vmhlc.pdf