Congress of the United States
Washington, DC 20515

February 11, 2022

The Honorable Xavier Becerra
Secretary of Health and Human Services
US Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Re: Establishing an Inter-agency Taskforce on Psychedelic Medicines and Therapies

Dear Secretary Becerra:

Thank you for your hard work on behalf of the American people and your dedication to solving the many healthcare issues our nation faces as we continue to battle the COVID-19 pandemic.

It has come to our attention that the Food and Drug Administration (FDA) is likely to approve MDMA for the treatment of Post-Traumatic Stress Disorder (PTSD) and psilocybin for the treatment of depression within approximately 24 months. Moreover, as National Institute on Drug Abuse (NIDA) Director Nora Volkow noted during a recent psychedelic workshop, "the train has left the station" regarding therapeutic use of psychedelics, and people are going to use them regardless of whether regulators act[1].

To that end, we are requesting your consideration in establishing an inter-agency taskforce on the proper use and deployment of psychedelic medicine and therapy – and that the taskforce be situated in the Office of the Assistant Secretary of Health.

Given the mental health and substance abuse crises exacerbated by the ongoing COVID-19 pandemic, we believe it is critical to ensure our nation's healthcare system has all tools at its disposal to combat these crises effectively. It is apparent that psychedelic medicines represent not just a new wave of psychiatry, but a significant shift in the delivery of mental health care, which does not neatly fit within our current system. The time intensive treatment process, including preparation, an administration session lasting several hours, and integration therapy (generally referred to as "psychedelic-assisted therapy"), will require an interdisciplinary approach with specialized training for session facilitators, and vastly different cost, insurance coverage, and infrastructure considerations.

With millions of Americans suffering from depression, PTSD, and suicidality, we believe we must take proactive measures to ensure we are prepared to safely and responsibly roll out new these new treatments when they become available. Thus, we are very encouraged to learn that Biden

[1] https://darik.news/southdakota/top-federal-drug-official-says-train-has-left-station-on-psychedelics-as-reform-movement-spreads/202201474253.html

Administration officials are considering authorization of an inter-agency strategic task force to address the complex clinical, regulatory, and public policy issues necessary for the 'real-world' deployment of psychedelic medicine and therapy. **We suggest the federal task force be situated in the Office of the Assistant Secretary of Health, where it can ideally leverage the convening authority of the Office of Management and Budget, and ensure all relevant federal agencies work in partnership with public and private sector stakeholders, including state agencies, to draft necessary regulations and guidelines.** This prudent measure will help to ensure our nation has a framework for the responsible, accountable, safe, and ethical deployment of psychedelic therapies for mental health disorders when the FDA approves their use.

Nevertheless, while FDA approval will likely be tied to a Risk Evaluation Mitigation Strategy (REMS) that determines the parameters of safe use, we know that psychedelic medicines, and particularly psilocybin, can and will be broadly acquired from other non-FDA approved sources – whether before or after the particular substance is rescheduled – which will not be subject to those same REMS protocols. This will be particularly true should FDA-approved therapies prove unaffordable or inaccessible to large segments of the population, which will rapidly fuel underground use or the establishment of a patchwork system of state decriminalization and/or legalization efforts. Indeed, psilocybin and other psychedelic compounds can be cultivated at home relatively easily, and several states have already passed or proposed measures for decriminalization or the creation of intrastate regulatory systems authorizing cultivation, production, distribution, research, and supervised or therapeutic use of non-FDA approved formulations of psilocybin or psilocybin mushrooms.

Further, unlike the already complex state regulatory patchwork created by marijuana, psychedelic treatments require the regulation of both a drug *and* a therapy, the latter of which is traditionally a matter of state authority. For example, Oregon is already determining the necessary qualifications to facilitate supervised adult use of psilocybin through a collaborative process between the Oregon Health Authority and an Advisory Board of stakeholders; while states such as New York have introduced legislation that would require medical scope of practice considerations and qualifications for psilocybin-assisted therapy (involving psilocybin produced within the state).

Thus, we find it clear that REMS protocols alone are insufficient to ensure any broad-based harm reduction efforts, including safe supply, safe and ethical use, and accountability of session facilitators for psychedelic therapies, which would be more appropriately addressed through the proposed task force and public-private partnership with stakeholders. Establishing national guidelines through this collaborative process, to be published in the federal register, would significantly ease the burden on individual states attempting to address the myriad of complex issues. Moreover, published national guidelines would be the most effective mechanism in establishing good standards of practice, including provider training, credentialing, state licensure, dispensing, safe and ethical use monitoring, etc. States will be able to then reference these national guidelines when implementing their own frameworks that meet their needs and requirements, with support and federal funding through SAMHSA block grants. Vitally, national guidelines will further facilitate the necessary scale up for a workforce of trained, credentialed, licensed, and

accountable psychedelic-assisted therapy session facilitators, while ensuring the critical safety and ethical monitoring and reporting systems that protect the broader public.

We would be happy to work with you implementing this task force to ensure that the Department of Health and Human Services continues to be at the center of our nation's healthcare regulatory framework, and that all necessary departments and agencies work collaboratively. If you have any questions, please reach out to Chris McCann in Congresswoman Dean's office: Christopher.McCann2@mail.house.gov, and we appreciate your vision and leadership on this issue. Thank you for your full and fair consideration of this matter, consistent with applicable agency guidelines.

Sincerely,

Madeleine Dean
Member of Congress

Earl Blumenauer
Member of Congress

Brian Fitzpatrick
Member of Congress

Dean Phillips
Member of Congress

Michael Waltz
Member of Congress

February 11, 2022

The Honorable Xavier Becerra
Secretary of Health and Human Services
US Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Re: Establishing an Inter-agency Taskforce on Psychedelic Medicines and Therapies

Dear Secretary Becerra:

Thank you for your persistence in addressing the many health care issues challenging our nation as we continue to battle the COVID-19 pandemic.

We have been informed by Reason for Hope, a non-profit policy and advocacy organization, that in advance of anticipated Food and Drug Administration (FDA) approval of MDMA for the treatment of Post-Traumatic Stress Disorder (PTSD) and psilocybin for the treatment of depression (expected within approximately 24 months), the Biden Administration is considering authorization of an inter-agency strategic task force to prepare for the real-world deployment of psychedelic medicine and therapy. We understand that the strategic task force would lead a public-private partnership with various groups of stakeholders, including relevant state agencies, to address the myriad complex regulatory and public policy issues necessary to ensure a framework for the safe and responsible use of psychedelic therapies for mental health care.

Whether through the FDA or state law, it seems clear that legalizing psychedelic medicine is far more complex than a typical drug approval; rather, it represents perhaps the most significant shift in the delivery of mental health care in modern history. The time intensive treatment process, generally including preparation, administration, and integration sessions ("psychedelic-assisted therapy"), does not fit neatly within our current mental health care system. Indeed, we must carefully consider issues of cost, access, infrastructure, and insurance coverage within this new paradigm of care.

We thus fully support the Biden Administration taking an active role in helping states to navigate this landscape. Reason for Hope, who helped prepare the October briefing for HHS and SAMHSA leadership, explained that the intended result of the inter-agency strategic task force would be to publish national guidelines in the federal register pertaining to issues such as provider training, credentialing, state licensure, dispensing, monitoring, instituting good standards of safe and ethical practice, etc. We are encouraged to learn that states would then receive block grant funding and support from SAHMSA to implement or tailor the guidelines to meet their individual needs.

After reviewing the October briefing materials, we are confident that the task force will significantly ease the burden on each state to develop its own novel regulatory system, and enable a scaled-up force of trained, credentialed, licensed, and accountable psychedelic-assisted therapy

session facilitators. Critically, this will also help ensure a cohesive system for safety and ethical monitoring and reporting nationwide. However, while we view this collaborative process as a clearly beneficial starting point, we believe that each state must also retain flexibility to adapt its regulations to meet the needs of its citizens as we learn new information in this emerging space.

Finally, given the ongoing mental health and substance abuse crises exacerbated by COVID, several states have already passed or proposed intrastate regulatory systems for research and supervised use of psilocybin, opting not to wait for FDA approval. Indeed, as NIDA Director Nora Volkow recently stated, "the train has left the station" regarding use of psychedelics as a mental health treatment.[1] And we need not look far to see that without proactive federal leadership and guidance, the result will be a confusing and administratively burdensome patchwork of state laws. However, this state patchwork will prove far more complex than with marijuana, as psychedelic-assisted therapy involves regulation of both a drug *and* the practice of medicine, which is traditionally a matter of state authority.

Thus, we reiterate the urgency to authorize the psychedelic task force and begin the process of federal and state government officials and stakeholders working together to create a cohesive regulatory system, through which states retain control over the practice of medicine.

Please reach out to Brett Waters, Co-Founder and Executive Director of Reason for Hope, or Kayleigh Zaloga, Legislative Assistant to New York State Assemblyman Richard Gottfried, if you have any questions that you would like to discuss: brett@reason-for-hope.org; zalogak@nyassembly.gov. We appreciate your vision and leadership on this issue.

Sincerely,

Richard N. Gottfried
Chair, Committee on Health
New York State Assembly

Patrick B. Burke
New York State Assemblyman
Lead Sponsor, Medical Psilocybin Services Act

[1] https://darik.news/southdakota/top-federal-drug-official-says-train-has-left-station-on-psychedelics-as-reform-movement-spreads/202201474253.html.

Tracy E. Pennycuick, U.S. Army (Ret.)
Pennsylvania State Representative
Prime Sponsor, Public Health Benefits of Psilocybin Act

Jennifer O'Mara (*signed*)
Jennifer O'Mara
Pennsylvania State Representative
Prime Co-Sponsor, Public Health Benefits of Psilocybin Act

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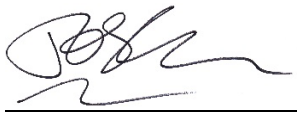

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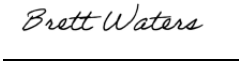
Alex Dominguez
Texas House of Representatives
Lead Sponsor, Texas HB 1802



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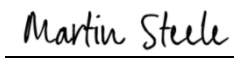
Jesse MacLachlan, Former 3-Term Connecticut State House Representative



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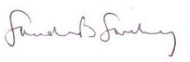

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May 13, 2022

The Honorable Madeleine Dean
U.S. House of Representatives
Washington, DC 20515

Dear Representative Dean:

Thank you for your letter to Secretary Becerra in which you recommend the establishment of an interagency Federal Task Force to develop and lead a public-private partnership that can address the myriad of complex issues associated with the anticipated approval by the Food and Drug Administration (FDA) of 3,4-methylenedioxymethamphetamine (MDMA) for the treatment of Post-Traumatic Stress Disorder and psilocybin for the treatment of depression within approximately 24 months. The Substance Abuse and Mental Health Services Administration (SAMHSA) was asked to respond on the Secretary's behalf.

SAMHSA agrees that too many Americans are suffering from mental health and substance use issues, which have been exacerbated by the ongoing COVID-19 pandemic, and that we must explore the potential of psychedelic-assisted therapies to address this crisis. SAMHSA also agrees that the use of psychedelic medicines will require a broad-spectrum interdisciplinary stakeholder approach to effectively tackle the complexity of issues that stakeholders anticipate will arise with their introduction.

SAMHSA, in collaboration with the Assistant Secretary for Health, is exploring the prospect of establishing a Federal Task Force to monitor and address the numerous complex issues associated with emerging substances. The Task Force may establish and oversee the functions of a public-private partnership that can broadly focus on addressing numerous complex issues associated with psychedelic (psilocybin) and entactogenic (MDMA) medicines but whose risks to public health may require harm reduction, risk mitigation, and safety monitoring. Collaboration across federal agencies with outside stakeholders will be the most effective way to ensure we are thoughtfully coordinating work on emerging substances such as MDMA and psilocybin.

Thank you for taking the time to elevate this important issue.

Sincerely,

Miriam Delphin-Rittmon

Miriam E. Delphin-Rittmon
Assistant Secretary for Mental Health
and Substance Use

CC:
The Honorable Earl Blumenauer
The Honorable Brian Fitzpatrick
The Honorable Dean Phillips
The Honorable Michael Waltz
ADM Rachel Levine