Exhibit 1

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

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Brian Fitzpatrick
Member of Congress

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Michael Waltz
Member of Congress

_____ Earl Blumenauer
Member of Congress

_____ Dean Phillips
Member of Congress