

Statement for the Record Brigadier General (Ret, U.S. Army) Stephen N. Xenakis, M.D. Executive Director American Psychedelic Practitioners Association

November 14, 2023

"Emerging Therapies: Breakthroughs in the Battle Against Suicide?"

> U.S. House Committee on Veterans' Affairs Subcommittee on Health



The Honorable Mariannette Miller-Meeks Chair Subcommittee on Health House Veterans' Affairs Committee Washington, DC 20515 The Honorable Julia Brownley Ranking Member Subcommittee on Health House Veterans' Affairs Committee Washington, DC 20515

Chairwoman Miller-Meeks, Ranking Member Brownley, and distinguished Members of the Committee:

My name is Stephen Xenakis, and I am a psychiatrist and retired Army Brigadier General. I was commissioned as a 2nd lieutenant in 1970 and served in the Army Medical Corps from 1974 until retiring in 1998. I may seem like an unlikely candidate to lead the American Psychedelic Practitioner's Association (APPA), the organization that is developing practice guidelines for these emerging treatments, but I am not. As we know, the military does what it needs to do in order to accomplish its mission, and the best leaders and soldiers are the ones who approach the mission with practicality. Today, our mission is to ensure our soldiers and their families are healthy, and that the American people are healthy. And these emerging therapies present a practical, viable solution to the problems that are plaguing the mental health of the men and women who serve.

Given the promising nature of psychedelic-assisted therapy, we have a duty to diligently pursue all efforts toward the development of these therapies in a thoughtful and strategic way. The life-threatening circumstances and tragedies of day-to-day mental health conditions should even further accelerate innovation in treatments, therapies, policies, and procedures. In order to drive the safe, effective, and time-sensitive development and implementation of these life-saving treatments, the APPA proposes the creation of a public-private partnership, which would bring together key stakeholders to methodologically map out a strategy for the implementation of these emerging therapies. My organization is also strongly recommending the creation of VA pilot programs that would be able to deliver safe and rigorously monitored psychedelic-assisted treatments and therapies to patients.

Initiating a Public-Private Partnership to Methodically Accelerate the Delivery of Care

We know that the best outcomes in this country are brought about with collaboration and teamwork. To decide how to configure the delivery of these emerging treatments in a systematic way, the government should bring together the best of the private sector, universities, and not-for-profit organizations to form a public-private partnership.



Today, the United States healthcare system is at an inflection point. The delivery of mental health care must change dramatically in order to meet the growing mental health crisis. The existing system faces significant challenges in meeting the increasing demand for services. The system was strained before the pandemic, and the subsequent surge in mental health issues has overwhelmed available resources. Long wait times for therapy and psychiatric appointments, limited access to affordable and quality care, and a shortage of mental health professionals have created barriers to timely treatment and support for those in need.

The re-emerging interest in psychedelic-assisted therapy offers an opportunity to mitigate the adverse impact of severe mental health conditions and illnesses. However, we are cautious that the immense need for new and effective mental health treatments not be used to justify insufficient psychotherapy support for these powerful new treatments. Thoughtful attention to psychotherapy is a cornerstone for both the effectiveness and safety of the treatment. Combining the administration of psychedelic medication and therapy within the same treatment session differs significantly from existing psychotherapy practice. It necessitates the development of new processes and competencies, including defining what constitutes good clinical practice, educating about harms and how to reduce them, and updating procedures for drug approval.

What I am describing is an inherently interdisciplinary, inter-agency, multi-stakeholder process. The government is uniquely positioned to lead deliberation and planning by subject matter experts in science, clinical research, policy, and law to explore, develop, and implement optimal policies, procedures, and guidelines for providing psychedelic-assisted treatments and therapies that are effective and safe.

Addressing Complex Veteran Health Issues Through Pilot Programs

Pilot programs, conducted under strict IRB protocols, are essential for exploring and establishing new treatments. These programs must be conducted thoughtfully and conscientiously, with a controlled and methodical approach to risk in particular. As the largest medical provider in the world, the VA is uniquely positioned to lead such efforts.

Currently, veterans who have exhausted all other treatment options and need psychedelic-assisted therapy are forced to leave the country to get the care they need. The proposition that we are outsourcing veterans' mental health care services, when the VA possesses the capabilities to safely develop and provide these treatments domestically, is difficult to accept and fails to fulfill the obligation to the men and women who had served.

Moreover, the VA is well-positioned to host pilot programs for psychedelic-assisted therapy because of the multiple and complex health issues faced by veterans. Understanding comorbidities, as well as the interplay between post-traumatic stress disorder (PTSD), traumatic



brain injury (TBI), chronic pain, and their contribution to issues like suicide, is crucial for developing safe and effective clinical practice. Many veterans suffer from a syndrome that manifests as the cumulative and synergistic effects of the injuries and illnesses incurred while serving in combat. Over time, the symptoms and impairments experienced by the servicemember become enduring and can be intractable. For example, the long-term consequences of conditions like TBI lead to chronic depression that is treatment-resistant (TRD). There are few, if any, treatments that repair the injuries to the brain, and the veterans spiral downward due to growing problems with thinking, inability to function in their daily lives, and worsening mood. The risk of suicide is linked to the impairments and problems of PTSD and traumatic brain injury (TBI) piling up.

We urge the VA to take a page out of the record of the DoD when it established the Defense Center of Excellence (DCOE) to fast-track diagnostic testing and treatments for PTSD, and the National Intrepid Center (NiCOE) to assess and treat servicemembers for TBI. These Centers operate under strict protocols to apply the latest developments and findings to promote better diagnostics, therapies, and treatments. We suggest that the VA establish a dedicated center to test and assess the effectiveness of psychedelic-assisted treatments and therapy with veterans using the guidelines set by the DoD for the DCOE and NiCOE.

Finally, the hurdles that the VA faces in treating patients with Schedule I substances can be overcome by following guidelines of Measurement-Based Care, formalized with an Institutional Review Board (IRB) protocol that can also be used in operating a dedicated center.

Adopting new initiatives in such a large organization is a major undertaking. But it is achievable, and it is necessary. The physical and mental health of our men and women is fundamental to the strength of our country, a lesson reiterated by the COVID-19 pandemic. By embracing innovation and rigorously pursuing research and development, this country can lead the way in providing effective, life-saving care to those who have served it, and for all who could benefit from it.

Thank you for the opportunity to submit this statement and please feel free to reach out to APPA with any questions.

Respectfully,

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Executive Director

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