Chairman Miller-Meeks, Ranking Member Brownley, and Members of the Subcommittee, thank you for opportunity to testify before you today.

I am Dr. Frederick Barrett, PhD, Associate Professor of Psychiatry and Behavioral Science, Associate Professor of Neuroscience, and Associate Professor of Psychological and Brain Sciences at the Johns Hopkins University School of Medicine. I am also the Director of the Johns Hopkins Center for Psychedelic and Consciousness Research. I am also a standing member of the Johns Hopkins Medicine Institutional Review Board, co-chair of the Psychedelics Task Group of the National Network of Depression Centers, editorial board member of the academic journal Psychedelic Medicine, and author of over 40 peer-reviewed scientific articles on psychedelic drugs.

I am providing testimony today as an individual, and not as a representative of any institution. The following views are my own, and do not necessarily reflect those of Johns Hopkins University or Johns Hopkins Medicine.

I have been conducting human research with psychedelic drugs in healthy individuals and patients with mood and substance use disorders at Hopkins for over 10 years. This program of research began in 1999, with the approval of one of the first human psilocybin studies in the modern era, led by my mentor, Dr. Roland Griffiths. This study not only demonstrated that psilocybin could be safely administered in a laboratory setting, but it demonstrated that carefully screened and appropriately supported healthy individuals could benefit from ingesting of psilocybin in a controlled setting. This study, published in 2006, is widely recognized as the study that reignited academic and medical interest in psilocybin. Since then, peer-reviewed empirical reports of clinical trials have been published testing the safety and potential efficacy of psilocybin and closely related compounds to treat patients with tobacco use disorder, alcohol use disorder, headache disorders, existential dread associated with a terminal cancer diagnosis, obsessive compulsive disorder, complex trauma, anxiety, and importantly major depressive disorder and treatment resistant depression, and there are many more clinical trials currently under way to study the effects of psilocybin in these and many other psychiatric disorders. Of note, two FDA-regulated, multi-site, phase 3 registration trials are currently under way to determine the effects of psilocybin in patients with mood disorders. Successful trials may lead to FDA approval of psilocybin to treat depression. We also come at a time when the FDA is considering whether to approve a related compound, MDMA, for the treatment of patients with post-traumatic stress disorder. Depression, substance use disorder, PTSD, and trauma more broadly are not only leading causes of disability in the United States and around the world, but they are particularly vexing illnesses that are plaguing our veterans. I urge the committee to do everything in their power to facilitate the careful and thoughtful implementation of these therapies and importantly the expansion of access to these therapies to all veterans in the event that they receive FDA approval. Such expansion and access may also pave the way for greater expansion and access to care givers, family members, loved ones, and those in the community who are impacted by the suffering of our nation's best, who are willing to sacrifice their lives to defend our freedoms.

Studies of the safety and potential medical efficacy of psychedelic drugs have now been spearheaded or sponsored and conducted by Hopkins as well as a small number of other academic medical institutions and private entities. These studies are building a growing record of information demonstrating both the relative safety and potential efficacy of psychedelic therapies in a wide range of psychiatric indications. These studies have been funded nearly entirely by private philanthropy. Our center at Hopkins was founded by a 17-million-dollar gift from the Steven and Alexandra Cohen Foundation as well as from Tim Ferriss, Matt Mullenweg, Craig Nerenberg, and Blake Mycoskie – philanthropists who had the wisdom, vision, and capacity to establish our center and provide support to our now more than 40 professionals, including faculty, therapists, and staff, who now continue this important work. Only recently has the National Institute on Drug Abuse and the National Center for Complementary and Integrative Health come through with a notable grant for the investigation of clinical use of psychedelics.

Evidence to date demonstrates the relative safety of psychedelic drugs for appropriately screened individuals in controlled settings. Psilocybin, for instance, is known to evoke a modest but reliable increase in heart rate and blood pressure. Risks of increased blood pressure and heart rate are mitigated in research by screening out those with substantial cardiac abnormalities. The most apparent risks of psilocybin are psychological. These risks are mitigated by screening out individuals who have a personal or family history of psychosis or mania. These risks are further mitigated by careful counseling and preparation by trained therapists who then accompany a study participant during the 4-6 hours of acute subjective effects of a high dose of psilocybin. Participants then undergo debriefing followed by aftercare and therapy for the days and weeks following their experience. With these procedures in place, we have safely administered over 800 doses of psilocybin to well over 400 individuals since 1999.

To conduct this research, investigators must assemble an expert team including physicians, therapists, often pharmacists, regulatory specialists, and other scientists to first tackle the substantial regulatory burden that precedes any drug administration. We first seek the approval of our institution review boards, and we also submit an Investigational New Drug application to the FDA. With institutional and FDA permissions in hand, we then must apply for DEA approval. This regulatory process takes us an average of about 9-12 months from first regulatory submission to approval to receive drug product and begin our research. This process is onerous and arduous at best, and while ultimately surmountable, provides a substantial barrier to entry even to seasoned senior scientists with valuable contributions to make who have not yet begun conducting psilocybin research. Given the barriers to entry, work in this area is currently still limited to large and expansive academic medical institutions who can secure private philanthropic support that will not only fund the research, but that will also provide funding and support for over a year's worth of professional effort for a team of investigators to simply file the paperwork to attempt to begin. Given the promise and prospect of our current findings, as well as the myriad questions that still need to be addressed within this field, I believe that greater access should be given to qualified investigators who want to contribute with new and rigorous research, and that we re-evaluate whether that barriers that have been put in place to

protect our public from the most dangerous compounds really apply appropriately to psychedelic compounds.

As we anticipate approval of psychedelic drugs as medicine by the FDA, we are also faced with numerous questions that have yet to be answered. These include whether the current treatment paradigms are optimal for all psychiatric or medical indications. Will some disorders require higher or lower doses of psilocybin or MDMA for treatment? Will some individuals require follow-up or repeated visits? How well can we integrate models from group therapy into a paradigm that currently relies on one-to-one therapy or a one-to-two relationship between patient and a therapist dyad? How can we predict who will respond well and who will not respond to treatment, and can we optimize the delivery of care to maximize the chances that someone will have a therapeutic response? When rolling out MDMA and psilocybin therapies, these questions will be present in the minds of the clinicians on the front lines who are delivering this care. Answering these questions will only serve to further benefit the veterans who will receive access to this care.

One striking question that is imminent upon FDA approval is how best to train clinicians to deliver this new therapy. Current FDA requirements include that at least one of the therapists be a licensed mental health practitioner, but qualifications, background, and training are not specified any further. We at the Johns Hopkins Center for Psychedelic and Consciousness Research are exploring these and other implementation questions now and in the future, but more attention must be paid to this critical element of the entire care package, and this must specifically be addressed as these therapies are offered to veterans.

While incredibly promising, psychedelic science is still underfunded, hidden behind restrictive regulatory barriers, and importantly not well understood by clinicians, policy makers, and the general public unless those individuals are deeply immersed in the field. There are clear next steps that can be taken to address these deficits.

I urge the representatives of this committee to support programs that will allow for the education of at least stakeholders, if not the general public, about the risks and potential therapeutic benefits of psychedelics. This comes in the context of many local ballot initiatives and proposed state legislation that seeks to increase access to psychedelics despite current federal regulations. Educational initiatives will help to ensure that we can move forward not only with informed and appropriate policy, but with an informed electorate and society.

I urge the representatives of this committee to consider funding initiatives that will not only foster a greater level of investment in psychedelic research in the VA, but also more broadly within academic medicine, law, and public policy. Fundamental questions persist regarding dose, delivery, indications, training of therapists, and optimization of care delivery. Answering these questions will help veterans as well as the broader base of patients in this country. Billions of dollars have been spent since the 1980s to research AIDS and HIV, developing approaches that have now saved countless lives. These were dollars that were not going to be spent by drug companies. We need a similar federal investment now for the mental health,

safety, and lives of our veterans, and for society as a whole. Billions of dollars in today's age is a drop in the bucket of the federal budget, but the lives saved and benefits to society in the future, especially for our men and women in uniform, are incalculable. Funding support will be necessary if we are to have any chance of answering these questions.

Finally, I urge the representatives of this committee and the House to support the bicameral Breakthrough Therapies Act, introduced by representatives Mace and Dean, as well as senators Paul and Booker. This act proposes that Schedule 1 compounds that are granted "breakthrough therapy designation" by the FDA be automatically re-scheduled to Schedule 2. Schedule 1 compounds are defined as drugs with no currently accepted medical use and a high potential for abuse. FDA breakthrough designation is granted to drugs that are intended to treat a serious condition, where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy. It is inordinately more difficult to study Schedule 1 compounds than compounds in any other schedule. FDA acknowledgement of preliminary evidence of medical benefit should justify movement of a drug to Schedule 2, which would substantially ease the burden of academic research into these compounds, especially in the case of psilocybin and MDMA, while not substantially increasing risk to the public.

Thank you for this opportunity to speak with you on a topic that I believe has such great import and relevance to the health and welfare of our nation's veterans, as well as our country as a whole.