

States Navy honored GySgt. Basilone's service through the commissioning of the USS *Basilone* (DD-824) and the USS *John Basilone* (DDG-122), which will be commissioned on November 9, 2024. His hometown of Raritan, New Jersey began hosting the annual Basilone Parade in 1981, which continues to be the only annual parade in the United States that honors a war hero. In 2005, the United States Postal Service included GySgt. Basilone as one of the four distinguished Marines commemorated on the 37-cent stamp issued on November 10, 2005. In 2010, Steven Spielberg and Tom Hanks adapted his story as a storyline in the HBO miniseries titled *The Pacific*. Most recently, on March 23, 2016, Congress approved renaming the Raritan Post Office to the Gunnery Sergeant John Basilone Post Office, cementing his memory in brick and mortar within his hometown. GySgt. Basilone has roads, bridges, and highways named after him in several states, and every enlisted Marine is taught about GySgt. Basilone's courageous actions during their time in boot camp. It brings me tremendous honor to commemorate the Birthday of this American hero and native son of New Jersey. I would also like to recognize the Basilone Memorial Foundation for their tireless work honoring GySgt. Basilone and supporting our active military, veterans, and others in need. I am truly honored to represent a district home to such a hero and an organization that continuously works to support our Military.

#### CELEBRATING THE 100TH BIRTHDAY OF CATHERINE O'MALLEY-BASTIAN

#### HON. TIMOTHY M. KENNEDY

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, November 5, 2024*

Mr. KENNEDY. Mr. Speaker, I rise today to celebrate Ms. Catherine O'Malley-Bastian on her 100th birthday. As she celebrates her 100th birthday, her life story is a beautiful tapestry woven with love and resilience.

Born on December 13, 1924, Ms. O'Malley-Bastian has not only witnessed a century of history but has also shaped the lives of those around her with her unwavering spirit and dedication to her community.

Ms. O'Malley-Bastian's career with the IRS exemplifies her commitment to service, where she contributed her skills and knowledge for many years. Beyond her professional achievements, she has devoted her time to volunteering with the Red Cross, embodying the true meaning of selflessness and compassion. Her contributions have made a lasting impact on countless lives, showcasing her belief in the power of community and kindness.

As a proud member of the Amherst Garden Club, Ms. O'Malley-Bastian has not only nurtured beautiful gardens but also friendships that have blossomed over the years. Her love of nature and her ability to cultivate beauty reflects her vibrant spirit and zest for life.

Ms. O'Malley-Bastian's faith has been a cornerstone of her life. For the last 50 years, she has been a devoted parishioner at St. Christopher's Church, a testament to her deep-rooted commitment to her faith and community. Her spirituality has been a guiding light, inspir-

ing those around her to embrace love, kindness, and generosity.

Today, as we celebrate this incredible milestone, let us honor not just the years that Ms. Catherine O'Malley-Bastian has lived, but the legacy she has created. Her dedication to family, faith, and community serves as an inspiring example for us all. Please join me in wishing Ms. Catherine O'Malley-Bastian a very happy 100th birthday.

#### HONORING DR. ROBERT LEE WEST

#### HON. GREGORY F. MURPHY

OF NORTH CAROLINA

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, November 5, 2024*

Mr. MURPHY. Mr. Speaker, I rise today to honor a distinguished fellow physician and beloved friend, Dr. Robert Lee West, of Greenville, NC. Dr. West grew up working on his family's farm and received his medical degree from the University of North Carolina at Chapel Hill in 1959. He certainly left his mark on the Tarheel medical community, serving a year as the Chief Resident.

After receiving his certification from the American Board of Pathology in 1964, Dr. West committed to serving our Nation by enlisting in the U.S. Army. He was assigned to Walter Reed Memorial Hospital, and we as a nation are forever indebted to Dr. West for his contributions to the health of our soldiers, as he helped establish the hospital's first Clinical Research Unit.

Following his military service, Dr. West relocated to Greenville with his business partner, Dr. Charles Gilbert, where he practiced for 47 years. Together, they helped establish the Department of Pathology at Pitt County Memorial Hospital, providing pathological services throughout Eastern North Carolina. Dr. West brought his decades of clinical experience to educate aspiring physicians by joining the faculty at the ECU Brody School of Medicine in 1983. While he was a professor, Dr. West was recognized by Cambridge's Who's Who for his leadership in higher education.

Upon his retirement in 2013, he was granted the title of Professor Emeritus and received the Clinical Faculty Development Award for the Department of Pathology and Laboratory Medicine at the University of North Carolina at Chapel Hill. Dr. West made remarkable and enduring contributions to the field of pathology at every stage of his career.

Words do little justice when trying to fully capture the profound impact he had on our Nation, his community, and the medical field. Dr. West went to be with the Lord on September 28, 2024, leaving a void felt deeply by all who knew him. I hope that we can all learn from his legacy and strive to meaningfully contribute wherever we are, whenever we can, and to whomever we can, just as he did. I am honored and humbled to extend this chamber's recognition to this incredible, faithful servant leader. May Dr. West forever rest in peace.

#### PROTECTING PUBLIC HEALTH AND SAFETY WITH PSYCHEDELICS ADVANCING THERAPIES (PATH)

#### HON. JACK BERGMAN

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, November 5, 2024*

Mr. BERGMAN. Mr. Speaker, I rise today to include in the RECORD an updated open letter from myself and Congressman CORREA, the founders of the PATH Caucus, to ensure stakeholders have a voice in crafting the rules and regulations surrounding psychedelic-assisted treatments. This is an updated version of the letter from my previous submission to the RECORD on August 9, 2024. It serves to extend our requested deadline for responses to February 28, 2025.

DEAR COMMENTER: In 2022, a new Congressional caucus was created to raise awareness among federal lawmakers about the therapeutic potential of psychedelic and entactogenic drugs to treat several mental health conditions that were refractory to contemporary evidence-based therapies. The Congressional Psychedelics Advancing Therapies (PATH) Caucus aimed to accelerate and support clinical research in the use of these novel substances, specifically psilocybin and 3,4-methylenedioxymethamphetamine (MDMA).

To better inform Congressional members, the bipartisan PATH Caucus is seeking input on how to implement programs and policies that address the range of complex issues with potential novel therapies that may use a psychedelic or entactogenic drug in medically supervised and interpersonally supportive settings.

To gain a more complete understanding of the issues associated with use of these substances, the PATH Caucus believes that taking an inclusive, intentional, and reasoned approach to gathering input from the public may engender valuable insights that can more accurately and comprehensively characterize how different modalities incorporate the use of these substances while also ensuring responsible, accountable, safe, and ethical use. We seek information from the general public, those who have received psychedelic-assisted therapies as an intervention, interested stakeholders, and those individuals and entities working within the bio-psycho-social-spiritual behavioral health ecosystem (e.g., palliative care, addiction services), which stresses a holistic system of care comprised of clinical providers, counseling, and peer support (Courtney et al., 2023; D'Souza, 2007; Urutia et al., 2023).

It will be essential to receive input from people and organizations with specialized experience in implementing therapies where psychedelic or entactogenic drug substances are administered, such as in clinical research protocols (e.g., depression, palliative care, substance use disorders, post-traumatic stress disorder (PTSD)), or experience in training others for such therapies. As a part of the PATH Caucus information gathering effort, we acknowledge the significant anthropological role of certain psychedelic substances such as ayahuasca, peyote, and Psilocybe mushrooms. Some indigenous peoples of the Americas have extensive traditions dating back hundreds to thousands of years, where they incorporated these substances into spiritual ceremonial or ritual healing practices. The PATH Caucus believes that respectful, inclusive, cultural knowledge sharing from these communities may provide substantial insights, further informing our overall understanding, and we welcome their input.

In medications derived from psychedelic or entactogenic drug substances are ultimately approved for therapeutic indications by the FDA, it is important for States to understand the risk mitigations frameworks FDA has established and develop ways to make sure they are supported. Aspects of real-world risk reduction and mitigation frameworks may include, but are not limited to, providing comprehensive transparent public education, implementing substance misuse prevention programs, minimizing the potential for adverse reactions, and developing implementable risk mitigation, safety, and ethical monitoring strategies. Moreover, it will be vital to consider how Congress can best support states in developing and adopting scalable infrastructures and sustainable service delivery systems that ensure proper accountability and monitoring, as well as facilitate access and equity in utilization, with a particular focus on communities that may be at risk for experiencing inequities in care resulting in disparate health outcomes (e.g., veterans, the uninsured, those who are experiencing homelessness, people with lower incomes, and individuals living with mental illness and/or co-occurring substance use disorders; Ortiz et al., 2022). In addition, when federal agencies such as the Department of Veterans Affairs make these products available, we need to be sure there is sufficient infrastructure to ensure patient safety. All of these components, when collectively addressed, may contribute to more responsible, accountable, safe, and ethical use of psychedelic and entactogenic derived substances in medically supervised and interpersonally supportive settings.

The PATH Caucus seeks input that can inform Congress so any potential future appropriations will support states collectively addressing the relevant issues and support necessary federal initiatives such as research, implementation and FDA regulation. Congress believes that by listening and learning from the broader ecosystem, staying abreast of potential innovative evidence-based therapies that may treat individuals with behavioral health disorders refractory to current treatment modalities, and simultaneously undertaking proactive measures for developing real-world risk reduction and mitigation frameworks, will help protect public health and safety.

#### CURRENT STATE OF PSYCHEDELIC AND ENTACTOGENIC CLINICAL RESEARCH

Clinical data continue to be collected regarding the safety profiles and potential benefits from therapies that use psychedelic or entactogenic drug substances across a variety of diagnoses such as major depressive disorder (MDD), treatment resistant depression (TRD), demoralization, PTSD, generalized anxiety disorder (GAD) and substance use disorders, in conjunction with appropriate supervision and support from qualified mental health professionals (Belouin et al., 2022; Carhart-Harris et al., 2021; Davis et al., 2021; Griffiths et al., 2016; Jerome et al., 2020; Mitchell et al., 2021; Ross et al., 2016; Siegel et al., 2021; Xi et al., 2023). Additionally, FDA has granted requests for Breakthrough Therapy designation to specific development programs involving MDMA for the treatment of PTSD (Multidisciplinary Association of Psychedelic Studies, 2017), psilocybin for TRD (COMPASS Pathways, 2018; Goodwin, G.M., et al. 2022) and MDD (Khan, 2019; Raison et al., 2023), CYB003 for MDD (Cybin, 2024), and MM120 (lysergide d-tartrate) for GAD (MindMed, 2024). The Breakthrough Therapy designation process facilitates and expedites the development and review of certain new drugs that have the potential to address unmet medical needs. This designation is available for drugs that are intended to treat

a serious or life-threatening disease or condition and where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available treatments on clinically significant endpoint(s) (U.S. Food and Drug Administration, 2022). It should be noted that a Breakthrough Therapy designation does not mean that the FDA has made a safety or efficacy determination for a drug, and the Breakthrough Therapy designation is not a substitute for marketing approval. Currently, FDA has not approved any drug containing MDMA, psilocybin, psilocybin analogs, or LSD or other psychedelics or entactogens as being safe and effective for any therapeutic indication(s).

#### ACKNOWLEDGING THE NEED TO ADDRESS COMPLEX ISSUES

Use of these substances is not without risk. A psychedelic (e.g., psilocybin) or entactogenic (e.g., MDMA) drug can temporarily alter a person's mood, thoughts, and perceptions, and lead to heightened suggestibility, anxiety/panic, and/or paranoia, among other outcomes. For psychedelics, a participant can experience vast changes in their perceptions of reality, including time and space. Moreover, an individual can become extremely sensitive to internal and external stimuli and altered in their cognitive functioning and visuosperceptual skills. Knowing these realities, any therapy that uses psilocybin or MDMA, for example, should involve thorough participant screening, education, and preparation, supportive settings, and close supervision by credentialed and qualified medical and mental health professionals to maximize safety and promote potential therapeutic outcomes (Davis et al., 2021; Johnson et al., 2008; Nichols, 2016; Phelps, 2017).

Furthermore, acknowledging that it has been suggested that some therapies could potentially lead to blurring of ethical boundaries between participants and provider(s) in some cases, as well as the potential for enhanced suggestibility, there might be increased risk for serious intimate ethical boundary violations by session facilitators/monitors, including emotional, physical, and sexual abuse (Anderson, B., Danforth, A., Grob, C., 2020; Goldhill, 2020; Pilecki et al., 2021), though psychedelics and entactogens are by no means unique in this regard. Some populations might have a higher risk for adverse reactions from psychedelic or entactogenic drugs, such as people with a known history of serious cardiac conditions or serious mental conditions such as borderline personality disorder or bipolar disorder (Bender and Hellerstein, 2022; Bradberry et al., 2022; Leonard et al., 2018; Lim et al., 2012; Malcolm and Thomas, 2021).

Given the broad array of potential challenges with therapies that may use psychedelics (e.g., psilocybin) or entactogens (e.g., MDMA), compounded by an absence of consensus about how best to address these challenges, a proactive collaborative approach may be most effective, where a partnership of subject matter expertise can consolidate efforts and collectively work to address relevant issues (Belouin et al., 2022; Belouin and Henningfield, 2018; Xi et al., 2023). Best practices good, credentialing, et.

#### INFORMATION BEING REQUESTED

This letter seeks broad input to address five major landscape domains that may contribute to developing real-world risk reduction and mitigation frameworks that protect public health and safety when considering implementing potential therapies that use a psychedelic or entactogenic drug substance in medically supervised and interpersonally supportive settings. These include: (1) service delivery, (2) promoting participant pro-

tections, (3) engagement of communities, (4) safeguarding equitable access, and (5) best practices for data standards.

#### Service Delivery

What is the spectrum of interdisciplinary practitioners who will be held accountable as session facilitators/monitors for the potential use of these substances in medically supervised and interpersonally supportive settings?

#### Training considerations

What are the minimal training standards for integrated care delivery?

What curriculum is needed that best addresses variations in psychotherapy (e.g., how best to address a participant's vulnerability and manage psychedelic-related challenging experiences)?

#### Credentialing considerations

What are the relevant background education, qualifications, professional experiences, and potential examinations that might be considered for interdisciplinary credentialing?

Which disciplines may represent 'service providers' (e.g., clinical practitioners, counselors, peer support)?

What might be appropriate supervision and practice hour requirements?

What types of guidance documents may be necessary for those who provide close supervision/monitoring of participants using psychedelics or entactogens?

#### Promoting Participant Protections

Provide input on strategies that may be critical to protecting participants, including:

What strategies will be needed to ensure participant education, screening for medical or mental health conditions that may disqualify from participation, and informed consent prior to an individual participating in a therapy that may use a psychedelic or entactogenic drug substance?

What is needed to assess baseline pre-dose and adverse event monitoring post-dose (e.g., suicidal ideation or behavior, physiological reactions, psychological harm, substance misuse, and drug-drug interactions)?

What information is available or needed on how medically supervised and interpersonally supportive settings might incorporate substance misuse screening and prevention, risk mitigation, safety and ethical monitoring strategies that protect participants from potential ethical boundary violations from providers?

What components need to be developed to support ethical-vigilance reporting systems (e.g., state departments of consumer protection, professional societies, state licensing bodies, and law enforcement)?

What data might be collected that improves existing pharmacovigilance reporting systems?

How will these strategies complement existing patient protection regulations enforced by FDA that reduce risk for clinical trial participants as well as for users of approved and regulated products?

#### Engagement of Communities

The PATH Caucus invites input to help identify best mechanisms/approaches that achieve engagement with diverse communities, including:

How might some indigenous people's use of psychedelics (e.g., ayahuasca, peyote) as sacraments in spiritual ceremonial or ritual healing practices, improve our understanding to protect public health and safety?

How might we ensure engagement with vulnerable populations disproportionately affected by mental health conditions, including people experiencing homelessness, racial/ethnic minorities, sexual and gender minorities, older adults, people living with disabilities and chronic health conditions, and individuals in the criminal justice system (Ortiz et al., 2022)?

Are there examples of best practices that facilitate provider (e.g., clinical practitioners, counselors, and peer support) engagement with vulnerable populations?

How do we effectively navigate societal stigma associated with psychedelic or entactogenic use?

How do we effectively educate healthcare, local crisis response systems, and law enforcement?

How do we best engage in comprehensive transparent community educational outreach?

#### *Safeguarding Equitable Access*

What should be considered critical elements to the development of capabilities across the following domains or activities?

Reimbursements that ensure equitable access to services.

Healthcare economic impact analyses.

Types of medically supervised and interpersonally supportive therapy settings.

Collaboration on activities that may include input on prescribing, administering, and dispensing.

Manufacturing and distribution standards.

Supporting oversight of the available supply of substances.

Diversion control monitoring.

Information on how potential psychedelic and entactogenic medicinal use might fit within the medication use process and workflow of health care systems.

How should these activities be performed in a manner that complements and supports FDA's regulation of development, manufacturing, distribution, marketing and use of psychedelics?

#### *Best Practices for Data Standards*

What types of data standards and repositories (e.g., Coordinated Registry Networks) may be created to collect data that continually informs best practices and vice versa?

How might current surveillance systems of regulated and unregulated settings be improved?

For example, Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®), Monitoring the Future, National Survey on Drug Use and Health, and the Drug Abuse Warning Network, collect actionable data on psychedelic and entactogenic use; associated adverse events; prevalence of medical and non-medical use; frequency, dose, and use settings; and participant comorbidities, health concerns, long-term effects, as well as demographic characteristics.

Please email your input and feedback to [PATH@mail.house.gov](mailto:PATH@mail.house.gov) by close of business on February 28, 2025. Your responses to these questions are crucial, as they will directly inform Congress on how best to contribute to protecting public health and safety, acknowledging the complex nature of issues associated with these novel therapies that use psychedelic or entactogenic substances in medically supervised and interpersonally supportive settings. We aim to ensure the path we walk is illuminated for all Congressional members where they can make informed decisions on the relevant issues.

sion of his retirement after an illustrious career of public service, leadership, and commitment to the Vallejo community and beyond. With over two decades of residency in Vallejo, Tom's dedication to his community has made a profound and lasting impact.

Throughout his career, Mr. Bartee served in numerous significant roles in the Solano County community. As District Director for Senator Bill Dodd, Assembly Member Mariko Yamada, and Assembly Member Michael Allen, Mr. Bartee worked tirelessly to represent Solano County Districts 4 and 7, coordinating members' engagement with their constituents and advocating for legislative priorities across a six-county region. He managed district offices, engaged with community stakeholders from the business and education sectors, and implemented media strategies to keep constituents informed of legislative initiatives. Mr. Bartee's leadership and coordination between district and Capitol offices were pivotal in serving the needs of over 470,000 constituents, representing a legacy of responsive, engaged, and effective public service.

Mr. Bartee distinguished himself through his commitment to local government and community engagement. Before becoming a District Director, Mr. Bartee served as a Solano County Field Representative for State Senator Patricia Wiggins and City Council Member for Vallejo from 2005 to 2009. During his four years on the Council, Mr. Bartee demonstrated an unwavering commitment to the residents of Vallejo, working diligently to address the City's challenges and promote its growth and revitalization.

Mr. Bartee's earlier career in the private sector included over 20 years with General Mills, where he held various management roles and contributed to economic development initiatives as part of the Loaned Executive Program. In addition, as the owner of Manufacturing Management Consultants, Mr. Bartee further demonstrated his leadership and entrepreneurial spirit.

Mr. Bartee's contributions extend beyond his professional roles to his active involvement in the Vallejo Main Street Program, the Vallejo Chamber of Commerce, and the Downtown Central Core Restoration Corporation (CCRC), where he serves as Vice President. He is also known for his work as a host and producer with VERBA and VCAT, providing a platform for local dialogue and community engagement. Tom's commitment to community development, revitalization, and engagement has left an enduring mark in Vallejo.

Mr. Bartee's legacy of integrity, leadership, and service will continue to inspire those who had the pleasure of working with him. On behalf of the constituents of California's 4th and 8th Congressional Districts, we wish Mr. Bartee the best wishes in his well-earned retirement and extend our sincere gratitude for his countless years of service to the community.

Zekelman Holocaust Center, a cornerstone of education and remembrance in Farmington Hills, Michigan. Since its inception in 1984, the Center has guided countless individuals through the history of the Holocaust while instilling values of tolerance, empathy, and the importance of standing against hatred and antisemitism. Its commitment to preserving the memories of Holocaust victims and survivors is a mission of profound significance, one that will continue to resonate for generations to come.

Founded on the campus of the Jewish Community Center in West Bloomfield and relocated to its current location in Farmington Hills in 2004, the Center's mission is to engage, educate, and empower visitors to create a better future.

As the Zekelman Holocaust Center has grown, so has its impact. The Center reaches over 150,000 individuals annually through educational efforts, virtual museum experiences, and on-site visits. From teacher workshops to an extensive research library and special exhibit galleries, it has become a dynamic institution where visitors can engage with history in a deeply meaningful way.

The Center's exhibits have evolved over the years to elevate the personal experiences of survivors, capturing the strength and perseverance of those who came to call Michigan home, following World War II. Notable features include the Eternal Flame & Memorial Wall and a Holocaust-era boxcar, both curated to ensure that the difficult history of the Holocaust is preserved for and transmitted to future generations.

Just as it delves into some of the darkest moments of the Holocaust, Zekelman Holocaust Center has become a beacon of hope through its Kindertransport and Heroism and Hidden Gallery exhibits. These exhibits tell stories of immense courage and personal sacrifice that celebrate the extraordinary actions of ordinary people who aided Jews and rescued thousands of children.

As one of only eleven sites in the United States to receive a sapling from the tree that grew outside of Anne Frank's hiding place, the Center is able to highlight a symbol of Frank's resilience and her hope that one day humanity would have another chance.

Beyond its physical exhibits, the Zekelman Holocaust Center serves as a resource for understanding and combating antisemitism. The Center works tirelessly to educate younger generations, emphasizing the scale of loss and ensuring they understand the importance of standing up against injustice and hatred.

As we celebrate the Zekelman Holocaust Center's 40th anniversary, let us acknowledge its significant role in educating our communities, shaping compassionate leaders, and fostering a more just world. It is with deep appreciation that I recognize the Center's contributions. May the Zekelman Holocaust Center continue to be a source of knowledge, reflection, and hope for many more years to come.

HONORING TOM BARTEE UPON HIS RETIREMENT

**HON. JOHN GARAMENDI**

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, November 5, 2024*

Mr. GARAMENDI. Mr. Speaker, I rise today, along with Congressman MIKE THOMPSON to recognize and honor Tom Bartee on the occa-

CELEBRATING THE 40TH ANNIVERSARY OF THE ZEKELMAN HOLOCAUST CENTER

**HON. ELISSA SLOTKIN**

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

*Tuesday, November 5, 2024*

Ms. SLOTKIN. Mr. Speaker, today I honor and celebrate the 40th anniversary of the