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SEPARATING FACT FROM FICTION: EXPLORING ALTERNATIVE THERAPIES FOR VETERANS' MENTAL HEALTH

FIELD HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS UNITED STATES SENATE

ONE HUNDRED NINETEENTH CONGRESS

FIRST SESSION

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AUGUST 22, 2025

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FRIDAY, AUGUST 22, 2025

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

This field hearing was held, pursuant to notice, on August 22, 2025, at 11:02 a.m., in American Village, Liberty Hall, 3727 Highway 119, Montevallo, AL, Hon. Tommy Tuberville, presiding.

Present: Senator Tommy Tuberville

OPENING STATEMENT OF HON. TOMMY TUBERVILLE, U.S. SENATOR FROM ALABAMA

Senator TUBERVILLE. I'd like to call this Committee hearing into session. Today, the Senate Veterans' Affairs Committee will conduct oversight and receive testimony on the importance of access to alternative therapies and treatment for veterans struggling with mental health conditions. It is a huge problem.

Today, we will hear directly from the Department of Veterans Affairs researchers in the field and veterans with personal experience. Thank you all to the witnesses for coming to my home State of Alabama, where more than 400,000 veterans call home, and thank you to Chairman Moran for allowing me to hold this hearing today. He's the Chairman of the Armed Services Committee in Washington, DC.

The room we are sitting in today may look familiar, but no, we're not here in the White House. It is pretty though. It looks nice. We're sitting in a replica of the first or the East Room of the White House in Montevallo, Alabama, the American Village. American Village is leading the way in educating generations of Alabamians and Americans on the founding of our great nation.

American Village has also been designated and dedicated as a veterans' living legacy, and sits on the same grounds as the Alabama National Cemetery. I cannot think of a better location for today's hearing.

Unfortunately, what we're here to discuss is not new. We lose an average of 18 veterans a day to suicide. Think about that, 18 veterans a day, and our veteran class is growing because of all these 20-year wars that we've been fighting over the last few years. We cannot sit back while those who put their lives on the line for our great nation suffer day in and day out.

We have a lot of suffering. We're on a race against time. One life lost is way too many. Our veterans deserve access to innovative, critical lifesaving therapies and treatment. Over the last two decades, the VA has added many evidence-based therapies to better care for the mental health of our veterans. And in many of these cases, veterans will see an improvement in their mental health within weeks and months after using one of these therapies.

I applaud the work being done by the VA, but there is still a lot more that we have to do. That's why earlier this year, I introduced HBOT Access Act. This bill would simply require the VA to provide Hyperbaric Oxygen Therapy, or HBOT, as a treatment option to any veteran who is suffering from PTSD, or TBI, who has already tried no less than two evidence-based treatment options.

HBOT is one of many therapies we will hear about here today. States across the Nation are also introducing their own pieces of legislation to expand access or to fund alternative treatment options for our veterans. I'm eager to hear how the VA is working to study and provide access to treatments outside of medication such as opioids and a depressants traditional psychotherapy.

Last December, for the first time since the 1960s, VA has announced that it would fund a study on MDMA-assisted therapy for PTSD and alcohol use disorders. The first time. And to date, the VA has sponsored 11 clinical trials for evidence-based psychedelic-assisted psychotherapies. VA Secretary Doug Collins said himself that the VA is continuing to look at new alternative treatments.

As a Member of this Committee, I look forward to working with him and get this done. I'm confident that under leadership of Secretary Collins, Secretary Kennedy, and President Trump, we will see generational change at the VA for our veterans struggling with their mental health.

So, today we will have 5-minute opening statements from our witnesses. We have two witness groups. First, I'd like to introduce Dr. Ilse Wiechers—is that close enough?

Dr. WIECHERS. It's Wiechers.

Senator TUBERVILLE. Wiechers?

Dr. WIECHERS. Yes——

Senator TUBERVILLE. There you go.

Dr. WIECHERS [continuing]. Sir.

Senator TUBERVILLE. Dr. Wiechers is currently serving as the Deputy Executive Director for the Office of Mental Health at the Veterans Health Administration at the U.S. Department of Veterans Affairs. In this role, Dr. Wiechers oversees the timely development and implementation of policies and programs to ensure veteran-centered, evidence-based, and high-quality mental health services to over two million veterans annually.

She leads OMH's legislative policy and partnership work, engaging regularly with key congressional and veteran service organizations stakeholders. Dr. Wiechers is a practicing board certified Adult and Geriatric Psychiatrist who completed her medical education at Duke, residency at MGH/McLean Hospitals, and fellowship at Yale.

She received a master's degree in Public Policy from Duke, and a master's degree in Health Science from Yale University. She also serves as faculty at University of California San Francisco and

Yale. Thanks for traveling here today, Doctor, and a Distinguished Fellow of the American Association for Geriatric Psychiatry and the American Psychiatric Association, and has been elected to the membership of the American College of Psychiatrists.

Then we have Dr. Miriam Smyth—is that right?

Dr. SMYTH. Yes, Senator.

Senator TUBERVILLE. I want to get as close as possible. It's not as bad as Tuberville. I promise you that.

[Laughter.]

Senator TUBERVILLE. Doctor is also accompanied by Miriam Smyth, Acting Director of Brain, Behavioral and Mental Health Broad Portfolio at the Office of Research and Development at the U.S. Department of Veterans Affairs. She focuses on advancing precision mental healthcare within the VA and conducting research into high priority areas such as post-traumatic stress disorder and depression.

Dr. Smyth has also overseen a program of $105 million in clinical research funding, and approximately 430 ongoing research projects to improve veterans' health and well-being, and serving as ORD's Clinical Research and Development Service Acting Director since March 2022.

Dr. Smyth has initiated many high-visibility national projects to advance ORD's goals, particularly in the area of precision mental health and emerging therapies. She leads the PTSD psycopharma—how do you pronounce that?

Dr. SMYTH. Psychopharmacology.

Senator TUBERVILLE. Okay, good. Alright. We're going to have a lot of that today—Initiative, and has worked to advance research on the use of psychedelics, cannabis, and transcranial magnetic simulation to treat mental health conditions that are resistant to today's first-line approaches.

She recently led ORD efforts to issue VA's first request for application in psychedelic research to treat veterans mental health conditions, and she has co-authored "Research and Implementation of Psychedelic-Assisted Therapy in the Veterans Health Administration," published in *The American Journal of Psychiatry* in January 2025.

So, we are here today to try to find answers. Folks, we have a lot of people in trouble. In my five years in the Senate, I've never seen a problem like this that continues to grow, get bigger, and it's only going to get bigger. And so, here today with two experts that can hopefully give us some answers and what they've studied and what they've seen.

So, we'll do 5-minute opening statements with each witness. Doctor, please.

PANEL I

STATEMENT OF ILSE WIECHERS, MD, MPP, MHS, DEPUTY EXECUTIVE DIRECTOR, OFFICE OF MENTAL HEALTH, VETERANS HEALTH ADMINISTRATION, U.S. DEPARTMENT OF VETERANS AFFAIRS ACCOMPANIED BY MIRIAM J. SMYTH, PHD, EXECUTIVE DIRECTOR, BRAIN, BEHAVIORAL AND MENTAL HEALTH BROAD PORTFOLIO, OFFICE OF RESEARCH AND DEVELOPMENT, U.S. DEPARTMENT OF VETERANS AFFAIRS

Dr. WIECHERS. Thank you, sir. Good morning, Senator Tuberville, and to everyone here today. Thank you for allowing us to discuss new effective ways to care for our Nation's heroes. I'm Dr. Ilse Wiechers, Deputy Executive Director of VA Office of Mental Health, and alongside me is Dr. Miriam Smyth, Executive Director of the Brain, Behavioral and Mental Health Broad Portfolio within Office of Research and Development.

Today, I will discuss VA's research and clinical efforts in emerging therapies, including psychedelic-assisted therapy and Hyperbaric Oxygen Therapy, or HBOT, as well as other innovative treatments. VA operates the largest integrated health system in the United States, providing comprehensive services to over nine million enrolled veterans annually.

Our mission centers on caring for those who have borne the battle, their families, and caregivers. Mental health care is crucial, which is why we continuously strive to support a robust clinical and research program focused on improving mental health outcomes for veterans.

While current evidence-based treatments such as prolonged exposure therapy, cognitive processing therapy, eye movement, desensitization, and reprocessing, and medications help many, approximately one-third of veterans with PTSD or major depression do not find relief. This is what has driven our commitment to researching and implementing innovative therapies that may offer significant benefit to veterans. VA is exploring the therapeutic potential of psychedelic compounds like MDMA and psilocybin.

As of July 2025, we have 12 clinical research studies in psychedelic treatments for mental health conditions at nine VA medical centers studying MDMA, psilocybin, DMT, and LSD, focusing on PTSD, major depressive disorder, generalized anxiety disorder, and substance use disorders.

This fiscal year, VA announced funding for a study on MDMA-assisted therapy for PTSD and alcohol use disorder among veterans. This trial will be taking place at the Providence VA Medical Center. All studies comply with Federal guidelines for clinical research and use of controlled substances while gathering scientific evidence regarding the efficacy and safety of these compounds when combined with psychotherapy.

These therapies remain investigational and it is important to not self-medicate with psychedelics outside of a clinical research setting, as doing so can carry significant risks. Although HBOT is recognized for conditions like decompression sickness and wound heal-

ing, the FDA has not authorized it for use with PTSD or TBI treatment.

VA and DoD clinical practice guidelines (CPG), found insufficient evidence to recommend HBOT for PTSD and strongly recommend against its use for mild TBI. Published results of scientifically rigorous VA and DoD research on TBI have repeatedly shown that HBOT has the same impact as a placebo and no clinically relevant long-term effects.

In addition to the lack of patient improvement, the use of HBOT after a mild TBI may have harmful impacts including seizures. VA continues to closely monitor the research on HBOT and none of the recently published studies have changed our recommendations at this time.

Beyond psychedelics in HBOT, VA evaluates other innovative treatments to address difficult to treat mental health conditions. For example, I helped lead the national rollout of ketamine and esketamine treatments for treatment-resistant depression, and I continue to be a practicing psychiatrist providing ketamine infusions to veterans each week.

As scientific evidence evolved, these treatments were incorporated into the recommendations in the 2022 VA/DoD clinical practice guidelines for major depression. VA has gone from eight facilities offering these treatments 10 years ago to now offering them in 49 facilities across the country.

Another example is ganglion block, which involves injecting local anesthetic into a cluster of nerve cell bodies in the neck. Although promising, there is insufficient evidence from current research to recommend SGB as a standard clinical treatment for PTSD. However, VA is supporting ongoing studies at VA facilities to clarify its potential benefits and determine its efficacy in treating PTSD among veterans.

While VA's research efforts continue, veterans will receive the mental health care and support that they need whenever and wherever they need it. Our proven evidence-based care options for veterans experiencing PTSD or depression include mental health care at our VA facilities, assistance with reintegration into their communities, counseling at Vet Centers across America, 24/7 access to qualified crisis responders at the Veterans Crisis Line, emergent suicide care for veterans at any VA or non-VA facility at VA expense, and much, much more.

In conclusion, VA is committed to continuing to research and to advance the science behind emerging therapies and ensuring they're safe, effective integration into mental healthcare, through rigorous scientific evaluation. We will ensure new therapies undergo thorough testing and peer review for safety and effectiveness tailored to meet our veterans' unique needs. By exploring and integrating innovative therapies, we aim to leave no veteran behind. We appreciate the Committee's support and this shared mission. My colleague and I are ready to respond to any questions you may have.

[The prepared statement of Dr. Wiechers appears on page 39 of the Appendix.]

Senator TUBERVILLE. Thank you. And as we do these, I've got about 10, 12 questions. We'll start with you, Doctor, if you want to add anything to that we'll—if you don't, fine. But let's get as much information as we possibly can. I think it would be good.

So, if we're rolling out a new therapy, such as we are quite often, what's the process? How do we do that? How does that work? How do we roll a process out of doing a new drug or a new therapy to help veterans?

Dr. WIECHERS. Sure. Thank you for that question, Senator. I think I'll use as an example our rollout of esketamine or Spravato, which was FDA-approved March 2019. It required a different way to think about the time spent in a clinic because there was a requirement for people after the dosing, which is an intranasal dosing, to stay for monitoring for 2 hours. And that's not what a typical mental health clinic visit looks like.

So, we developed a national protocol. We met with folks who were using similar agents like ketamine and learned from them by learning about best practices. We created a community of practice that was nationwide and everyone learned from one another together as we rolled out our national protocols.

We went to our folks with research experience in that area with that type of agent. And they were our first sites to implement clinically. And then we learned from them and rolled out, to kind of in phases, to the next level. And that is how we kind of, in a phased approach, learning each phase kind of in an iterative way so that we learn lessons before we roll things out more broadly.

Senator TUBERVILLE. Ms. Smyth, you want to add anything to that? Would you like?

Dr. SMYTH. No, thank you, Senator.

Senator TUBERVILLE. Okay. So, you have to work directly with the FDA when bringing out a new drug, or is it a drug already tested and they're allowing you to test it on veterans? How does that work?

Dr. WIECHERS. So, in terms of studying drugs that are still investigational, I will actually defer to Dr. Smyth to say a little bit about how our researchers work with investigational drugs.

Dr. SMYTH. So, we have quite a bit of experience with this, Senator, because we began working with Schedule 1 drugs in 2017, which involved cannabis. And so, our researchers have to get FDA approval and had to get a license from the DEA. And then, they have to go through various regulatory steps, including institutional review boards. So, the process is very well defined and is working for us.

Senator TUBERVILLE. Good. Thank you. What's the biggest challenge that the VA faces in terms of implementing these new programs? For VA, what's your biggest challenge? What do you have to fight? Because it seems like every time we do something for the veterans, it's almost a fistfight to get something done. Nobody wants to approve anything. Doctor?

Dr. WIECHERS. Thank you for the question, sir. I think one of the biggest challenges is just change. Change is hard especially if a change in practice is asking our providers to do something they've never done before. So, I think just the efforts to educate and ensure everyone has the information they need about a new treatment or

a new type of service that we're delivering. So, I think educating and informing everyone, and getting everyone's buy-in to help move things along as we innovate and implement new things.

Senator TUBERVILLE. There has had to be some experience though from some of these drugs used not on veterans, but just some average citizens. Correct? I mean, do y'all use that experience from what they've learned from some of these other programs to try to help people with other mental disorders?

Dr. WIECHERS. So, thank you. Sure. We certainly learn a lot from the scientific literature studying kind of a community or general population. But the veterans using Veterans Health Administration services are unique in many ways, and that's one of the reasons why we want to ensure that we have studies and scientific study of that population specifically to make sure that, number one, it's safe in that population. Because a lot of our veteran population have significant mental health burden as well as substance use disorder and lots of medical conditions as well, more so than the general population.

And so, first, to ensure its safety in our veteran population, and second, to ensure that it is as effective in the veteran population as it is in the general community population. So, that's one of the reasons why we like to see scientific evidence that supports its use in the veteran population specifically.

Senator TUBERVILLE. Yes. And if you have people here today, and we have veterans that will watch this online, it's a sense of urgency. Sometimes we don't feel a sense of urgency because people are dying every day. I know we have somebody every month that dies of suicide from PTSD that's a veteran. And I know we want to do the right things, but we also need to feel that sense of urgency, you know. How does the VA track the success? When something good happens, how do we assess that across the country when it's being used?

Dr. WIECHERS. So, thank you, sir, for that question. We actually have a really robust set of—at least in mental health that I'll speak to—a robust set of metrics and measurements that we're tracking that look at outcome, that look at access, that look at utilization of services, that really help us in real time, identify how veterans are doing and how individual health systems are doing across the Nation.

And so, we have lots and lots of data at the VA, actually, which is one of the benefits of being at the VA is we've got a really robust data set that allows us to learn from the health system in a robust way in addition to what we learn from the scientific studies that we do in the research side of the house. So, we can learn things as a clinical system, and we are a learning health system that allows us to kind of evolve as we go.

Senator TUBERVILLE. And I think it's so important that we pass that information on down. I know in the five years, we've spent tens of billions of dollars in the VA and we still hadn't been successful of really getting just information from the DoD to the VA. I mean, because different servers on each end. Communication is the key to anything. I think we all know that.

And so, if we're going to study drugs and study therapies, we need to do it as quickly as we possibly can, but do it the right way.

What criteria does the VA use to approve these new therapies? I mean, what list do you go down to approve these?

Dr. WIECHERS. So, in speaking about pharmaceuticals——

Senator TUBERVILLE. Anything. You know, is there a grocery list that we have to go through to from start to finish to approve a drug for a veteran to use?

Dr. WIECHERS. So, there's not a list per se, but there is an existing process with our pharmacy benefits management national formulary, that whenever a new drug is approved by FDA, it kind of starts automatically this standard process of review that the national formulary team undertakes.

And that has a group of experts from across the country that review the data that the FDA reviewed, that review data about safety and efficacy in the veteran population specifically and then make determinations about the availability of it. And if there are certain criteria that we will utilize inside VA for who is eligible for receiving that medication.

Senator TUBERVILLE. Do veterans get to sign up for these experiments? How does that work when you have a new therapy that you want to try? How do they find people to try it on? I mean, it's got to be used somehow to see if it works. How does that work?

Dr. WIECHERS. So, I'll defer to Dr. Smyth to say a little bit about recruitment for VA research studies.

Dr. SMYTH. So, Senator, I will say that veterans, as a group, have been remarkably generous to each other. It's just phenomenal how willing they are to sign up for clinical trials, and how willing they have been to join our Million Veteran Program, which actually hit the enrollment of a million veterans this past fall. So, we offer opportunities for veterans to join clinical trials, and again, they sign up.

Senator TUBERVILLE. Good. Thank you. Doctor, your testimony, you mentioned ketamine.

Dr. WIECHERS. Ketamine, yes.

Senator TUBERVILLE. Ketamine and——

Dr. WIECHERS. And esketamine.

Senator TUBERVILLE. Yes. That's good—I couldn't pronounce nor spell it—as emerging therapies at the VA. How is this therapy administered to the veteran, and what does it look like?

Dr. WIECHERS. Sure. So, ketamine infusions are very similar to any other kind of infusion clinic. So, for example, if you've been to an infusion clinic for chemotherapy, it oftentimes will look similar to that. The one where I practice in San Francisco has four bays with recliner chairs, and IV poles, and blood pressure cuffs, and pulse ox machines.

And so, each veteran will come in and have a seat. They talk with you first to check in and see how things are going. A nurse will start an IV and then for about 40 to maybe 50 minutes the medication is infused through that IV. And then, they rest afterwards for a little bit. We check in after, and then they head home. And that is what a ketamine infusion treatment looks like. So, in total, they're probably in the clinic for about 90 minutes to 2 hours.

Intranasal esketamine is kind of like your allergy medication that you use. And it's self-administered same way. So, you squeeze and inhale. It oftentimes, our clinics look similar to our ketamine

clinics; our recliners, because you need to be in a reclined position when you do the inhalation.

The veteran comes in, checks in with nursing and the doctors. They are given the device to administer. They self-administer with the nurse and doctor there watching. And then, they rest and are monitored blood pressure and pulse ox for about 2 hours afterwards, which is part of the requirement by FDA, to monitor people for 2 hours afterwards and rest. And then talk with the team after, and then head home. And so, again, they are there for about maybe two, two and a half hours for an esketamine treatment.

Senator TUBERVILLE. So, we're still in experimental stage with these two?

Dr. WIECHERS. No, this is clinical practice, sir. Both of those are FDA-approved medications. Esketamine is specifically FDA-approved for the indication and treatment of treatment-resistant depression. Ketamine is an anesthetic agent that is being used off-label, but it's an FDA-approved medication that's been used since the 1950s, I believe.

Senator TUBERVILLE. Results?

Dr. WIECHERS. Results are good. Results are quite good for many people. It doesn't work for everyone. It's not a magic bullet, but the data looks good for those for whom it helps. It can help quite a bit.

Senator TUBERVILLE. Side effects?

Dr. WIECHERS. Side effects are feeling drowsy, feeling a sense of dissociation, which is sort of a little bit like leaving your body or having distorted perceptions for a period of time. While the infusion is running for ketamine or while shortly after the inhalation of the intranasal treatment with esketamine, we can see a short-term increase in blood pressure that usually then goes away within 20 to 40 minutes. And for the most, sometimes nausea and occasionally vomiting. Those are the common side effects.

Senator TUBERVILLE. Availability?

Dr. WIECHERS. So, we have ketamine and esketamine one or both available at about 49, 50 sites around the country right now.

Senator TUBERVILLE. Good. So, you're seeing good results.

Dr. WIECHERS. We're seeing good results.

Senator TUBERVILLE. Ms. Smyth, you'd like to add anything to that?

Dr. SMYTH. No, sir. She covered it quite well.

Senator TUBERVILLE. She covered it. Good. Alright. Transcranial magnetic stimulation therapy.

Dr. SMYTH. Yes.

Senator TUBERVILLE. Let's talk about that.

Dr. WIECHERS. Yes. So, we have TMS at 62 facilities around the country right now. It is also indicated for FDA and approved for treatment of depression that has failed at least two trials of oral medications. And it is a special TMS machine that has a chair and then a device that comes down over the head that delivers magnetic stimulation through probes. You come and you sit down in the chair and receive your treatment. And then, and then go home.

The treatment course is every day for a period of time which is a little bit different and more intensive in terms of coming into the clinic than with the ketamine or esketamine where we do twice a week for a couple of weeks. And then, we aim to do every couple

of weeks one or once a month. So, the TMS is a course of treatment over a course of daily for a couple of weeks.

Senator TUBERVILLE. So, it's not abrasive?

Dr. WIECHERS. It is not abrasive, no. It sometimes causes headaches, but for the most part it's generally very well tolerated.

Senator TUBERVILLE. It's working?

Dr. WIECHERS. And it is working.

Senator TUBERVILLE. Yes. How many places do we have this?

Dr. WIECHERS. 62, sir.

Senator TUBERVILLE. 62?

Dr. WIECHERS. Yes.

Senator TUBERVILLE. I wonder if we have those in Alabama. Do you know?

Dr. WIECHERS. I can get you an answer, but I'll have to check and get back to you to confirm which of these we have, and where nearest by we have them and reach out.

Senator TUBERVILLE. How new is this?

Dr. WIECHERS. TMS has been around for quite a while. There are innovative types of treatment, kind of the protocol that is—so there's innovations happening in the protocol that make it more rapid. So, kind of condensing the number of treatments so that you do a whole lot in one or two days rather than every day for weeks. The evidence is still growing on those to see if those are more effective or as effective as the standard protocol that we use today, but this treatment has been around for quite some time.

Senator TUBERVILLE. That's awesome. All right. I'm sure you're monitoring the Compass Pathways COMP360.

Dr. WIECHERS. Yes.

Senator TUBERVILLE. Again, there's another drug there. What is it called? P-S-I-L-O-C—how do you pronounce that?

Dr. WIECHERS. Psilocybin.

Senator TUBERVILLE. Okay. Assisted therapy as it's going through FDA trials. How's that going?

Dr. WIECHERS. I will defer to my colleague, Dr. Levine, to speak more about that on Panel 2, specifically about the Compass work. But I will say that VA has been partnering with Compass and other of the private sector companies who are working in the psychedelic space so that we can—and we're meeting with them regularly to be updated on how their progress is going.

Senator TUBERVILLE. Good, good. Besides approving new therapies, how can we use the programs like the Fox Suicide Prevention Grant to help our veterans who are struggling with mental health?

Dr. WIECHERS. Thank you for that question, sir. One of the great things about the Fox Grants Program is that it's meeting veterans in the community where they are in ways that often, we don't with VA, properly engage with those folks.

I think at least from where I'm sitting, I think one of the most important missions we have right now is engaging the veterans who don't already come through our doors and getting them to engage in services that will help them with mental health, substance use, or suicidal ideation, and problems that they're having.

So, the Fox Grants helps extend beyond us and beyond our walls to access and ensure that veterans are getting help they need.

Senator TUBERVILLE. So, let's talk about something that I've been trying to push through the VA for 5 years, is hyperbaric chambers. Obviously, it's expensive. A lot of the VAs don't have them, don't want to spend the money on them. But no matter what it costs, we've got to take care of our veterans.

And, you know, this bill that I presented, you have to go through two other therapies before you're able to use the hyperbaric. Now you can use them either in the VA or out of the VA. We've got to find, you know, some alternative way to help some of these people that some drugs don't help or other therapies. So, what's your thoughts on HBOT?

Dr. WIECHERS. Thank you, sir, for the question. So, in regards to hyperbaric oxygen treatment, it is FDA-approved and authorized for use in a variety of different medical conditions. It has not been authorized for use as treatment for PTSD or TBI. It also is not covered and reimbursed by CMS and most private insurance as treatment for PTSD or TBI.

Our review of the evidence available and as stated in our VA/DoD clinical practice guidelines, we don't find there to be sufficient evidence to support it as an evidence-based treatment. And given, as you mentioned, the expense, but also how intensive the HBOT treatment is, and based on some of our experiences with the clinical pilot program we ran back in 2018 to 2021 for the Hannon Act, Section 702, we have determined that the feasibility of kind of using this clinically, given the lack of evidence at this time, that suggests it is more beneficial than other existing treatment options we have available. That's the rationale we have for not offering it as a clinical service at this time.

Senator TUBERVILLE. Are we doing studies on HBOT?

Dr. WIECHERS. So, I'll defer to Dr. Smyth to speak to the state of research currently.

Dr. SMYTH. So, currently, Senator, we are not doing any studies on HBOT. The reason being that none of our principal investigators in the field are researchers out there at our 102 sites. None of them have chosen to submit a proposal to us for HBOT research.

Senator TUBERVILLE. Good. Well, you know, I bring this up because of my experience of coaching, over the years, a lot of the different schools that I coached at, we had hyperbaric chambers that kids with concussions. We felt like it helped, it enhanced, it cleared their mind to some point. I think my wife caught onto a little bit. She actually bought me one [laughter]. I don't know what that says [laughter], but I get in one at least twice a week. You know, it's an hour, and it's not pressure of going up. It's like pressure going 100 feet under the water, and you breathe straight oxygen.

Now, I can't tell you whether it's helped me or not, but I do know that we hear quite a few people that do it on their own that it's helped. So, hopefully, in the future, we can bypass some of the red tape and at least try. Some therapies that are not working on some veterans, hopefully, it can help in that area.

So, earlier this year, Secretary Collins made statements on social media that his administration was looking into alternative therapies. Do you know if that's an accurate statement, or are y'all getting feedback down from the top level that we're looking into the different therapies like HBOT?

Dr. WIECHERS. We are committed to continuing what we have been doing for many years, which is researching and reviewing research from outside on all of these innovative treatments for mental health.

Senator TUBERVILLE. Again, anything it would help. Anything. So, on our next panel, we'll have Dr. Jim Wright testify on the efficiency of HBOT. To date, we've had 12,000 veterans with TBI or PTSD. They have received HBOT treatments with near universal improvement with depression scores being reduced by at least 39 percent. So, is that a good number? You'd think if you're doing a therapy and you've got 39 percent increase in help, your thoughts and your experience.

Dr. WIECHERS. So, I'd be happy to take a look at the studies referencing that number to better understand what that means. But in context, I'm happy to hear that there are veterans that are experiencing improvement in symptoms. And so, anything that's helping folks, I agree, is a good thing. But before I commit resources, and put a lot of energy and emphasis into things at a system-wide level, I need to see more convincing and rigorous scientific data.

Senator TUBERVILLE. So, how often does the VA update its evidence-based therapy and complementary and integrity health list? And can it keep pace with all the emerging effective treatments?

Dr. WIECHERS. So, that's a great question. So, our clinical practice guidelines are on average about every five years reviewed and updated. But in the intervening period between, we can implement change in our system and the care that we provide. And the perfect example of that is ketamine and esketamine.

So, it wasn't until the 2022 clinical practice guidelines that they became recommended treatments for treatment-resistant depression. But we were deploying and implementing that starting in 2019 because the FDA-approved esketamine and we had the scientific evidence that these were safe and effective treatments. So, we actually started deploying it, and then the CPG caught up after. So, the CPG doesn't stop us from doing something clinically if the evidence has been gathered that supports its use clinically.

Senator TUBERVILLE. Thank you. In your testimony, you mentioned that the HALT Fentanyl Act gave private, non-governmental entities the ability to expand their control, Schedule 1 and Number 2 research protocols. Can you provide additional details on what this means to the VA and ongoing efforts of research and on controlled substances?

Dr. WIECHERS. So, that more applies to folks outside the VA and the research that they do, which of course, we monitor and follow. And that helps inform what we know about our veteran population. And it is kind of in adjacent to, in addition to, the work that we are hoping to do and that we have ongoing at our VA facilities currently.

Senator TUBERVILLE. So, I believe there's a common misconception that these substances, if approved for treatments for veterans with PTSD or other mental health conditions, will be able to self-medicate. Could you please address this misconception and provide details about these treatments and how they may entail the VA in the future, if approved for treatment?

Dr. WIECHERS. So, if any of the psychedelic substances are approved in the future, I anticipate that they would be approved with what's called a REMS program, Risk Evaluation Mitigation System program, that FDA puts in place for high risk medications when they approve them. And that REMS, I would assume, would want this to be administered in a medical setting.

So, this is not going to be a take-home medication. These are going to be medications administered like ketamine and esketamine in a clinic at one of our facilities in some future, should they be approved.

Senator TUBERVILLE. So, I have people, veterans, come to my office quite often and say, Coach, I've gone to another country and a drug at this—a certain drug has helped. What advice would you give to that veteran? And can they pass that along? And do we look into that? What's the process on that?

Dr. WIECHERS. So, thank you for asking about that. I know, and I have heard and spoken with veterans as well who have gone elsewhere to take these medications. I caution my own veterans that I see in clinic from using psychedelic substances on their own, and I would caution any other veterans from——

Senator TUBERVILLE. Would you suggest that?

Dr. WIECHERS. I would not personally suggest that. I would ask them to look for a clinical trial nearby and engage in using one of these substances in a way that allows for rigorous monitoring and safety insurances.

Senator TUBERVILLE. So, if they've gone through something like this, what would you tell them? Who do they see in our country to pass this information along, whether it helped or didn't help? Who do they go to?

Dr. WIECHERS. So, I appreciate that many veterans have had these experiences and that they have had profound positive impacts on them. So, I want to make sure that that is clear. So, I appreciate that, and I appreciate that many of those veterans are sharing those stories with us so that we can learn and hear about it.

One thing I do want to say is that veterans can feel comfortable to speak with their own providers if you're coming to the VA about this type of experience because it helps us understand, it helps your provider understand where you're at, and what you've experienced, and what you've been through.

So, I would just encourage veterans to make sure that their healthcare providers know about things like this so that they can help make good shared decisions about next steps with their treatment based on what they've tried in the past.

Senator TUBERVILLE. So, how can you help us back in Congress balance innovation and safety? What advice would you give to myself and my colleagues on the VA Committee, direction we go in terms of balancing all the new innovation that's coming in, how we make sure it's safe. What would you tell us as a group?

Dr. WIECHERS. I would say that we need to continue to study in a safe way so that we can ensure the safety of something before we implement using something clinically. So, continued support for research of innovative mental health treatments is what I would suggest is what we need your help with.

Senator TUBERVILLE. Yes. We're about done here with this group. So, any comment that you'd like to make to this group and to our audience that's going to watch on closed circuit? How do we help our veterans? What do we do? What new directions do we need to take? How do we save these 18 lives that are being taken a day in our country?

Dr. WIECHERS. I would say that if there are any veterans out there who are in crisis, to reach out to friends, to family, to people who you trust. Pick up a phone and call 988 and press 1 for the Veterans Crisis Line. Go to your local VA. Go to someone that you trust, and let them know that you're having trouble, and you need help. And the VA is here to help you.

Senator TUBERVILLE. Thank you. And the number one thing that I hear is to tell somebody you are close to your problem. Don't keep it to yourself. It's really sad the point we've gotten to, but I think help is on the way. I think we're working on it more. We're putting more money. If money could solve this problem, it would have already been solved.

But money's not going to solve this problem. People are going to solve this problem, and we've all got to work on it together. So, thanks for both of you for coming from so far away, coming here and being part of this. Again, psychedelics, HBOTs, anything that we can do to help our veterans, we want to do.

And again, it's not about money, it's about people. And we're going to continue to work on. Again, we have 400,000, and just in this state alone. You know, the hundreds and hundreds of thousands and millions of veterans are looking for answers. And we need to get those answers for them.

So, thanks, both of you. Thanks for coming. Thanks for coming this far away, and hopefully, we can continue this dialogue in the future. Give them a hand. Thank y'all.

[Applause.]

Senator TUBERVILLE. Alright. We'll start. And again, we have four instead of two. We've got a little bit longer introduction, but again, we're here for a reason, and so we want to make sure we do this right.

In our next panel of witnesses, we will cover a wide variety of perspectives on alternative therapies for our veterans. We'll hear from Compass Pathways, a biotechnology company with a psilocybin therapy going through FDA approval. Two veterans who will share their lived experience with alternative therapies and their work to get our heroes access to them. And lastly, a professor and a former trauma surgeon who has conducted cutting edge research on HBOT, and PTSD, TBI for our veterans.

This panel will help set the record straight on what alternative therapies look like in practice. We will use this time to separate fact from fiction, whether that be on psychedelic-assisted therapies, HBOT, or even peer-to-peer mentoring.

Our veterans who are already suffering from mental health conditions connected to their time and service should not have to risk their lives and well-being overseas just to receive an alternative form of treatment. Veterans should also be able to safely access these evidence-based alternative treatments here in the United States within the guardrails of the law.

The American people and our veterans deserve to know the facts. I look forward to working with each and every one of you here to get our veterans access to life-saving and life-changing alternative treatments for their mental health. So, let's see if we can make some progress here.

We'll have 5-minute opening statements, but I'd like to start and introduce each one before we start those. Dr. Steve Levine. Doctor, thanks for being here today. Currently, serves as the chief patient officer for Compass Pathways. Dr. Levine is a board-certified psychiatrist that has spent his career working across the healthcare system to improve people's lives through creating access to innovation.

He completed internship and residency in psychiatry at New York Presbyterian Hospital, Weill Cornell Medical Center. He then completed fellowship subspecialty training in psychosomatic medicine, psycho-oncology at Memorial Sloan Kettering Cancer Center in New York Presbyterian Hospital.

Before coming to Compass, he founded Actify Neurotherapies that built new models of care delivery across U.S. for interventional psychiatry treatments. Dr. Levine has been published extensively in both peer-reviewed journals and lay audiences around the world. He has served in leadership roles for professional societies and not-for-profit entities and received numerous awards for leadership and service. Dr. Levine, thanks for being here, and I hope I didn't hack that up too bad.

Dr. LEVINE. Thank you, sir.

Senator TUBERVILLE. Adam Marr. I'll introduce one of my constituents here. Adam's based in Slocomb, Alabama. Adam is the director of operations for the Veteran Mental Health Leadership Coalition. The Veteran Mental Health Leadership Coalition is a national coalition of individuals and organizations united by the mission to prevent suicide, drive innovation, and reshape the future of mental health care for veterans and their families.

Adam is a U.S. Army veteran—thanks for your service—where he served as an Army captain and an AH–64 Apache pilot with the deployment to Iraq. He also co-founded the Warrior Angels Foundation with his older brother Andrew, a decorated Green Beret who suffered from combat-related brain trauma, to give veterans access to innovative treatments for TBI.

Adam is also the national co-host for the American Legion national podcast, *Tango Alpha Lima*. Today, he is accompanied in the audience by his wife of 16 years, Elisa, their children; Amelia, Austin, and Aria Marr, his mother, Shirley Marr, and in-laws Kenny and Sheila Austin. You got a large group here.

[Laughter.]

Senator TUBERVILLE. I'm glad we got a big enough arena. Thanks for being here, Adam.

Dr. Jim Wright, our next witness. Another one of my constituents of Vestavia Hills, Alabama. Dr. Wright is an adjunct assistant clinical professor at the University of Alabama, Birmingham. Dr. Wright held the rank of Colonel and served for 28 years in the United States Air Force. Thank you for your service. He held several roles in the Air Force, including plastic surgeon at Clark Air Force Base in the Philippines, chief plastic surgeon at Wilford Hall

Medical Center, and chief of hyperbaric medicine research at Brooks Air Force Base and special tactic surgeon.

Dr. Wright completed a fellowship in undersea and hyperbaric medicine at the United States Air Force School of Aerospace Medicine in 2007. Along with Dr. Eddie Zant, Dr. Wright initiated HBOT for active-duty military. He was also a principal investigator for the National Brain Injury Rescue and Rehabilitation Study, which used HBOT for TBI and PTSD. And after his years of service, Dr. Wright became a hyperbaric and wounded care physician in Washington State before coming to Alabama to work as a burn trauma surgeon. Thanks for being here, Dr. Wright.

And then, Brian Schiefer, our fourth and final witness. Brian is a United States Air Force veteran—thank you for your service—and a founder of SCI–DI. Brian is a former U.S. Air Force Tactical Air Control Party (TACP) member and served in both Afghanistan and Iraq. In 2008, during his pre-deployment training excise in California, Brian's life was forever changed.

After recovering from his injuries and spinal fusion surgery, Brian made the commitment to redefine his recovery. He has since become an advocate for innovative therapies for veterans and others with spinal cord injuries, TBI, and neurological conditions by founding his organization SCI–DI.

I am thrilled to have each one of you here today to share your experiences in alternative therapies, and I welcome each of you to give your opening statement. Dr. Levine.

PANEL II

STATEMENT OF STEVE LEVINE, MD, CHIEF PATIENT OFFICER, COMPASS PATHWAYS

Dr. LEVINE. Thank you, Senator. Senator Tuberville, all present, thank you for the chance to testify at this important field hearing today. Improving the mental health of veterans is a national imperative, and we appreciate your leadership to achieve this goal.

My name is Dr. Steve Levine. I'm a psychiatrist, and I serve as the chief patient officer for Compass Pathways. Compass is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. Our lead compound COMP360 is a synthetic pharmaceutical grade form of psilocybin being studied in robust clinical trials in treatment-resistant depression and post-traumatic stress disorder or PTSD.

COMP360 was granted FDA breakthrough therapy designation for TRD in 2018 and will potentially be a first-in-class treatment. Compass is leading the way in psychedelic clinical trial research and is conducting the largest ever FDA regulated clinical trials studying the safety and efficacy of psilocybin.

We have already generated positive primary endpoint data in two large well-controlled clinical trials of a single administration of psilocybin in a supervised medical setting. In May 2022, the positive results of our 233-participant Phase 2 trial were published in the *New England Journal of Medicine*, and in June 2025, just two months ago, we announced the successful achievement of the primary endpoint for 258 participants in the first of two ongoing

Phase 3 trials. Our second Phase 3 trial will enroll approximately 568 additional participants.

In addition to TRD, in May 2024, Compass announced positive top line results from a Phase 2 study in PTSD, which showed COMP360 was well-tolerated with both rapid and durable improvement in symptoms from baseline observed following a single administration.

Compass is currently finalizing plans to begin a late-stage trial in PTSD. The United States is in a mental health crisis with one in five adults experiencing mental illness in any given year. Among the most pressing and debilitating conditions within this crisis are PTSD, affecting 13 million Americans, and TRD in about 3 million. Both conditions are marked by severe symptoms, high suicide risk, and limited medication treatment options.

Amid a national mental health emergency where anywhere from 17 to 44 veterans die by suicide each day, we must urgently explore and advance novel treatments to help patients struggling with depression, PTSD, and other serious mental health conditions.

Well-controlled clinical studies of the safety and efficacy of innovative treatments like psychedelics are currently underway. That is why it's essential to set standards like those available through the FDA framework to facilitate the safe, effective, and efficient delivery of these treatments to veterans in need.

Compass shares the Committee's goals to ensure that our Nation's veterans can access appropriate care and treatments. We commend the VA for its openness to new treatment options, and for the significant research that has performed related to psychedelics. While these compounds are still being studied for potential review by the FDA, we encourage the VA to prepare for the possible entry of psychedelic therapies into the VA health system so that it is ready should these treatments be approved.

We recommend that the VA begin by developing treatment protocols, training personnel, and preparing clinical care settings. Compass is committed to partnering with the VA to ensure that sites have the required infrastructure and training in place for successful implementation as we've begun to do in regular meetings with the VA's integrated project team. Our shared goal must be to ensure that safe, effective medications for the treatment of depression and PTSD are accessible to veterans as soon as possible.

In closing, possible FDA approval for certain psychedelic compounds is on the horizon as there are several ongoing late-stage clinical trials. FDA-approved psychedelics enhance patient safety by ensuring that these drugs have been proven to be safe and effective for specified conditions and patient populations, and that they are prescribed by licensed and trained healthcare professionals for the appropriate patient at the appropriate dose.

Again, we thank the Committee and Senator Tuberville for holding this important hearing, and I'm happy to answer any questions.

[The prepared statement of Dr. Levine appears on page 46 of the Appendix.]

Senator TUBERVILLE. Thank you. Doctor Adam.

STATEMENT OF ADAM MARR, DIRECTOR OF OPERATIONS, VETERAN MENTAL HEALTH LEADERSHIP COALITION

Mr. MARR. Senator Tuberville, thank you for the honor of sharing my American veteran story at this field hearing today, and for your bold leadership helping to elevate this conversation. My full written testimony has been submitted for the record. Today, I'll focus on the essentials, but before I begin, I do want to recognize my family and friends and colleagues here today, and I'm going to dedicate these remarks to my late father, Woody Marr. He went home to be with the Lord this year. He loved his wife, and his four sons, who all served.

He and mother prayed every day that we would return from our deployments and we did. We just didn't know that that's when the real battle was going to begin. My older brother, Andrew an SF Green Beret came home with TBI and PTSD. The system's answer; 13 symptom-masking medications and they told him; this is your new normal.

My younger brother, Austin, an infantry sergeant with two combat tours, medically separated, spiraled into depression, placed on SSRIs, and one night I found him unresponsive after a suicide attempt in the park in our hometown. Me, the Apache helicopter pilot, middle brother. Well, sir, I brought all my soldiers' home, but I watched my own brothers collapse, all while I tried to figure out how to pull out of my own nose low dive.

You see, sir, this isn't just our story, unfortunately, it's become an American veteran story. But veterans aren't broken, though parts of the system are. For decades, care has numbed instead of healed; pills, brief therapy sessions, and labels that never address the root cause of trauma.

In the past 20 years alone, we've lost more veterans to suicide and overdose than in Iraq, and Afghanistan, and Vietnam combined. Out of desperation, veterans began building something different, emerging therapies delivered with rigorous care models and veteran-led support.

Andrew found hope initially through neurohormone replacement and anti-inflammatory protocols with Dr. Mark Gordon of Millennium Health Centers. Austin and I had different injuries. We required different therapies. After Austin's suicide attempt, he sought psychedelic-assisted therapy with 5-MeO-DMT from Dr. Martin Polanco through The Mission Within. My own journey, I became one of the single most transformative experiences of my entire life, reconnecting me to my purpose, my faith in Jesus Christ, and my call to serve.

These treatments do, however, carry risks and require medical oversight. For us, though, for my brothers, for my family, they were lifesaving. But what happens on the other side of these therapies when proper integration and community support is applied? What happens when veterans begin to become whole again? I'll tell you, sir, they stand back up to serve and they help those still struggling because that's what we were trained to do.

That's what my brother and I did. We created Warrior Angels Foundation in 2015, one of the first Global War on Terrorism nonprofits to focus on funding root cause treatments for TBI and PTSD. We helped to change the stigma and culture around being

too tough to ask for help. In the years since, a new wave of veteran leaders has stepped forward, creating new nonprofits to meet the urgent need for care. Their focus has been on therapies like psychedelics, neurorestorative care, TMS, HBOT, and whole-health approaches grounded in the strength of peer-led community support, coupled with education and advocacy efforts.

Now, since 2022, through the VMHLC, under the leadership of Lt. Gen. Martin R. Steele, USMC (Ret.), we've united 50-plus of these organizations. 50 plus of these organizations exist, sir, each represented by veterans, families, clinicians, and researchers on the front lines of these innovative programs and care models. All this so we can collectively educate and advocate for these approaches.

Meanwhile, nearly every major psychedelic from MDMA, to psilocybin, to ibogaine, to 5-MeO-DMT, is in FDA trials. Six of them have earned breakthrough therapy status from the FDA. But until last year, the VA with nearly $1 billion research budget has only committed $1.5 million to a single trial.

Acknowledging that that has since changed, but just like the representatives set up here before, that's the greatest challenge they're facing; change. That must change. We must invest in research, expand access, and do so expeditiously. We are requesting from Congress, sir, simply put, partnership to fund research and pilot programs at scale; to support and fund community-based veteran services; to prepare for FDA approval by training clinicians in building the infrastructure now.

Veterans didn't wait for the system to save us, Senator. We couldn't. We had to build what was needed because this is about moving from suffering to solutions, about healing veterans and families, and about those in service being able to return to service. Now it's time for the VA and the Federal Government to continue to step up and support in a large way to bring these solutions home.

My father's prayers were answered when his sons came back from war. However, too many families are still praying for their loved ones to come home, physically, mentally, emotionally, spiritually, and morally. It's time their prayers are answered. It's time for partnerships, sir.

Thank you, Senator Tuberville. May God bless you. May God bless our Nation, and may God bless the veterans and families who fought for our freedoms. Thank you.

[Applause.]

[The prepared statement of Mr. Marr appears on page 50 of the Appendix.]

Senator TUBERVILLE. Thank you, Adam. Well said. You might need to run for politics.

[Laughter.]

Senator TUBERVILLE. Dr. Wright.

STATEMENT OF JAMES K. WRIGHT, MD, ADJUNCT ASSISTANT CLINICAL PROFESSOR, UNIVERSITY OF ALABAMA AT BIRMINGHAM

Dr. WRIGHT. Thank you, Senator, and thank you for allowing me to give some information on hyperbaric oxygen treatment for neurologic injuries in veterans.

Hyperbaric oxygen is the delivery of 100 percent oxygen to a person in a pressurized chamber and is used as a treatment for certain diseases and conditions. Oxygen levels 7 to 14 times that are achieved by breathing room air are possible. The therapy affects more than 8,100 known human genes and thousands of cellular processes, and is effective in treating a variety of conditions from neurologic injury to chronic wounds.

Hyperbaric oxygen has been used as a treatment for brain and nerve injuries for 89 years since it was first described by Dr. Albert Behnke in the U.S. Navy for the treatment of the brain and spinal cord injuries in decompression sickness. Since then, it has been used for a variety of brain and nerve injuries in addition to decompression sickness such as carbon monoxide poisoning, stroke, postconcussion syndrome, traumatic brain injury, PTSD, depression, chronic pain syndromes, post-COVID illness, and narcotic addiction recovery.

It is useful to think of the actions of hyperbaric oxygen as occurring in four ways in brain and nerve injury. One, it provides oxygen to the damaged areas of the brain and spinal cord, which don't have enough oxygen to function or heal. Two, it promotes the synthesis of growth factors, which cause the in-growth of new blood vessels and allow nerve axons to reconnect and damage tissue to heal. Three, it's a potent suppressor of inflammation, which is a component of TBI, PTSD, depression, anxiety, chronic pain, and other neurologic disorders. And four, it acts directly on nerve cells in the brain and spinal cord to enhance function and suppress pain.

In treating TBI and PTSD, hyperbaric oxygen has had remarkable results over the past 20 years. It is universally effective. Few, if any recipients fail to improve and many are made completely well from debilitating injuries. Brain function and cognition is improved even after decades of TBI or PTSD. Depression scores are reduced by 39 percent, and suicidal ideation is usually abolished.

Quality of life and everyday function is improved. Medication requirements are reduced and chronic pain is also reduced. These results are long lasting or permanent after a single series of 40 treatments, though, some veterans require more treatment depending on the severity and length of illness.

To date, more than 30,000 individuals with TBI and PTSD have received hyperbaric oxygen treatment in the United States, 40,000 in Israel, and with nearly universal improvement. More than 12,000 of these individuals were veterans. Nearly all—of these treatments have been provided free to veterans through the generosity of our citizens. Of all these people, we are aware of only two suicides in the last 15 years. That is a remarkable achievement.

The use of hyperbaric oxygen treatment for spinal cord injuries is in its infancy in the United States, but results so far have shown similar benefits as in TBI, or PTSD, as well as the halting of func-

tional deterioration and the improvement in function in a few cases, especially early after injury.

As a solution, I propose that hyperbaric oxygen treatment be made immediately available to our veterans with TBI, PTSD, and spinal cord injuries. The huge quantity of case reports, as well as numerous randomized controlled studies, speak to the utility and safety of the treatment, as well as providing more than enough evidence of efficacy for approval as part of the standard of care.

It would be well to ensure the established safety protocols are strictly adhered to, and that all treatments are directed by properly trained physicians in approved chambers. Additionally, good recordkeeping would validate the utility of these treatments. Finally, I recommend that a working group be established to design the implementation of this effort.

[The prepared statement of Dr. Wright appears on page 76 of the Appendix.]

Senator TUBERVILLE. Thank you, Dr. Wright. Thank you for your research. Very important. Brian, saved the best for last down on the end.

STATEMENT OF BRIAN SCHIEFER, U.S. AIR FORCE VETERAN, FOUNDER, SCI–DI

Mr. SCHIEFER. Thank you, Senator. Thank you for inviting me to this panel. I'm Brian Schiefer, a former Air Force TACP who served in Afghanistan, 2003, Iraq '05–'06, again, '06–'07. In 2008, during a pre-deployment training exercise in California, my life was forever changed after a Humvee rollover accident left me with severe injuries, including fractures in my spine at four different levels, multiple broken vertebrae, broken ribs, broken clavicle, broken sternum, bilateral hemopneumothorax, torn shoulder ligaments, a skull fracture, and severed the number six nerve in my left eye.

Stabilized with chest tubes and airlifted to Loma Linda University's polytrauma center. I then underwent a spinal fusion surgery that took 14 hours, followed by 6 weeks in the ICU where I was informed that I had less than a 1-percent chance of ever walking again. While it was not possible to distill in 5 minutes my lived experience during the last 17 years since the accident, I'm able to present those aspects that directly inform why I'm here today.

Despite the VA's various strengths and good intentions, the severity of my injuries equally revealed its limitations for veterans with complex injuries. It is my testimony that, had I relied only on the standards of care within the VA, I would not be here today. Refusing to accept defeat, I instead became my own advocate, making it my mission to learn everything about my injuries and their impact on my new life.

What ensued was a process of trying and in many ways, unambiguously benefiting from a range of underutilized therapies and activities that were unavailable, unknown or actively discouraged within the VA. Through redefining my own recovery, I became committed to advocating for innovative therapies leading to my founding of SCI–DI, an organization empowering veterans and others with spinal cord injuries, TBI, and other neurological conditions.

Despite having only one working eye and one working arm, during my initial hospital-based postsurgical recovery was marked by continued work on my Bachelors in International Relations, as well as my relentless research on how to improve my condition. My recovery continued with 5 months at the La Jolla VA SCI inpatient unit followed by grueling therapy at the Detroit Medical Center's Center for Spinal Cord Injury Recovery.

Measurable progress to my lowers was limited and TBI symptoms—cognitive fatigue, vision issues, and emotional strain from my skull fracture and nerve damage complicated rehabilitation. In a 2009 ceremony, I was medically retired from active service by PACAF Commander, Lt. Gen. Utterback. I then relocated to the Florida Panhandle to adapt to paraplegia, tackling challenges like thermoregulation, hand-controlled driving, and daily tasks like grocery shopping and cleaning—without the proprioceptive feedback, a constant struggle learning to deal with my paralyzed body.

In addition, cognitive struggles were persistent. Despite my medical history of a skull fracture and severely compromised lung function in the immediate aftermath of my accident, my cognitive struggles were attributed to my adjustment of paralysis. Then, in 2010, prompted by TACP colleagues receiving PTSD and TBI care under an Air Force Special Operations Command protocol in Destin, Florida, I secured a formal TBI diagnosis from the VA. That was nearly two years post-accident.

With this new diagnosis, I enrolled in a Hyperbaric Oxygen Therapy, HBOT, study under Dr. Eddie Zant at his private clinic in Destin, Florida. I experienced immediate improvements in cognition, sleep, memory, and relationships, and no longer waking up in a fog. With over 300 HBOT dives to date, therapeutic benefits include enhanced TBI recovery, tissue healing, and post-surgical outcomes.

For years, I traveled to UCLA for surgeries, including shoulder reconstructions and spine procedures. My former TACP teammates, who served under me, flew in for weeks to carry me post-op, a humbling experience of brotherhood addressing the gaps the VA overlooked during my inpatient stay. My experience with UCLA Operation Mend exemplified comprehensive care, as specialists collaborated to address my complex symptoms, setting the gold standard care and for veteran healthcare.

The VA's care, even for basic needs like wheelchairs, seating cushions, catheters and hand controls, has been problematic at best. Procurement often required me to navigate, essentially alone, bureaucratic hurdles for essential prosthetic devices and general medical care. Over the years, there have been situations that required my persistent attention for weeks, months and sometimes even years to resolve the issue.

I continue to advocate and push for innovative approaches to ensure no one has to endure the hardships and misery I've faced, pressing for systemic changes to make VA care more responsive and effective for veterans with complex injuries. Such advocacy includes over a decade of service as a Consumer Reviewer for the Congressionally Directed Medical Research Programs (CDMRP), evaluating grants for SCI, TBI, orthopedic outcomes, and neurological conditions.

This role exposed the critical research gaps, particularly in the underfunded fields of SCI and TBI, with veterans three times more likely to suffer a SCI than their civilian counterparts. In 2018, I discovered adaptive scuba diving and working with a small team, pioneered techniques tailored to my needs. Underwater is in a barrier-free 3D environment, I found liberation—reduced pain, better sleep, and relief from TBI-related cognitive fog, much like HBOT but with the freedom of floating and movement. I now have nearly 100 scuba dives to date.

A final example of how I benefited from an unorthodox therapy is my personal experience with psychedelics. Among the many benefits was an unexpected and remarkable restoration of my sense of connection to my body and the lost sensation areas and the proprioception areas that I can no longer feel. I noticed less inflammation in my body, improved cognition and sleep and a deeper sense of connection and well-being with those around me.

This further inspired me to found SCI–DI in 2022, and we filed for nonprofit status in 2025, to make adaptive diving and innovative therapies like HBOT, psychedelics, noninvasive neuromodulation, and ketones accessible to others. SCI–DI bridges medical science, adaptive sports, and cutting-edge technology to empower the 294,000 Americans with SCI, including 42,000 veterans, and 17,730 new cases annually.

Our team of medical, academic, and military experts collaborates in "skull sessions" to explore bold ideas, from standardizing HBOT protocols to researching psychedelics for inflammation reduction using objective measures like cytokines. Driven by a "don't talk about it, be about it" ethos, SCI–DI partners with institutions like the Lakeshore Foundation and Alabama Brain Lab, leveraging novel neuromodulation devices like BRAIN Buds and ELVis as new, scalable healing modalities.

We continue to pursue grants through CDMRP, ARPA-H, and the DoD that align with our team's interests and skill sets. We've recently spoken at the 2024 and 2025 Aerospace Medicine Association meetings, hosting workshops and talks on neuromodulation, vagus nerve and photic stimulation, and psychedelics. Sparking vital conversations with pilots, divers, and aerospace and hyperbaric medicine technicians and thought leaders, and other consumers at the concurrent Undersea and Hyperbaric Conference.

Although the VA is not currently structured to provide therapies like HBOT or psychedelics, veterans should not have to wait for historically slow systemic changes. A way forward is partnering with nonprofits like SCI–DI, which have the experience and agility to offer these treatments. For example, voucher systems or VA reimbursement to such organizations would ensure veterans gain timely access to life-changing therapies, bypassing bureaucratic delays.

My journey from a near-fatal accident to championing for alternative therapies was only possible by accessing these very novel therapies that, not only promoted my recovery, but allowed me to flourish. My experience underscores the urgent need for these innovative, accessible solutions for inadequately served veterans with complex injuries.

I'm here today to share how HBOT, adaptive sports, psychedelics, and non-invasive neuromodulation can transform lives and urging this Committee to support research funding the policies to bridge these gaps for our Nation's heroes. Thank you for your time.

[Applause.]

[The prepared statement of Mr. Schiefer appears on page 78 of the Appendix.]

Senator TUBERVILLE. Thank you, Brian. Thank you for your service. And God bless you, what you're going through. Okay. We're here today, and again, we've got video on this, not just for the people here, but hundreds of thousands of veterans will watch this. So, I've got a couple dozen questions.

Make it short and sweet, but give these veterans something that you know that can help them. Give them advice. Give them an understanding of there's people here to help. And you, as Brian just said, what he's been through, the tough times. So, everybody will have questions, but if you've got something that you want to add to somebody, just break in. This is a conversation.

Steve, thanks for coming. Thanks for the update on Compass Pathways. I hear a lot of misinformation about psychedelic-assisted therapies. I think we all do. Can you walk us through and from start to finish on how these therapies work?

Dr. LEVINE. Thank you, Senator. I think the first thing that may come to mind for many people would be the baggage of psychedelics from 1960s. Counterculture. What they——

Senator TUBERVILLE. Back during my day.

[Laughter.]

Dr. LEVINE. Yours are the 1980s and 1990s, right?

Senator TUBERVILLE. Yes, yes, 2000s.

Dr. LEVINE. What they may be less informed about is the therapeutic potential of psychedelics. And they may not be aware that there are many trials undergoing late-stage trials that are moving rapidly toward FDA approval that may create new options on a range of conditions that include PTSD, depression, treatment-resistant depression, which is a difficult to treat depression.

And what these treatments tend to look like is as described a bit by Dr. Wiechers earlier; these happen in supervised medical settings. This isn't like an SSRI, a traditional antidepressant where somebody picks up a prescription at a pharmacy and takes this every day at home and has side effects typically on a daily basis because of it.

This is typically one or maybe a few administrations over a longer period of time with the support of a healthcare professional in a supervised setting, having some preparation ahead of time for it, having follow-up afterwards.

But what we are seeing so far in conditions like PTSD and depression is that people can have almost immediate reduction in their symptoms, almost immediate relief and a return to life that can have very lasting effects even after just a single administration.

Senator TUBERVILLE. Thank you. So, to be clear, all this should be done in a VA, right? Don't be doing it on your own?

Dr. LEVINE. Correct. And that is a misunderstanding. People may think that because they've done this on their own at some point, that they may know what the effect that this treatment could have on them. But the setting is really important, and being adequately prepared and the safety setting around you being there is critically important. And that is how these medicines are being studied. That's how they will likely be approved, and that's where we see the best outcomes.

Senator TUBERVILLE. So, today's title of this hearing is separating fact from fiction. What's the most misunderstood thing about psychedelics? The most misunderstood.

Dr. LEVINE. Yes, I think it's largely where I started here about there's a lot of excitement about psychedelics right now. There's the baggage that's attached historically, but I think people don't recognize that the way that they're being studied right now in rigorously designed clinical trials is very different than someone just taking a psychedelic on their own.

This is for somebody who's been shown in research to be able to benefit from this treatment, supported by somebody who knows about their condition, who can safely support them. And people may not realize how close we are getting actually to potentially having FDA approvals here. As I mentioned in my opening remarks, we are currently running our Phase 3 studies. We've already had the results from the first of those Phase 3 studies, so things are progressing rapidly. And you said it best earlier, Senator, that we need to move with a sense of urgency here.

Senator TUBERVILLE. This is for the whole panel, and we'll start with Adam here. What are the one or two actions that we in Congress could take to address the mental health crisis of veterans or all Americans?

Mr. MARR. Well, sir, I think it goes back to what I was originally saying, and I think that's partnership. With Congress, partnership with the VA, partnership with the Federal Government. Because my whole story is about finding these things out of desperation and being able to still be here to talk about it. Then a nonprofit was started to be able to help get more people access, and then after that happened, then we're coming together to be able to share those stories. That's leading to the recommendations and the policy roadmap that we have and submitted in our public record.

So, I think Pathways is like right to try, which is currently available. And then I also believe that being able to partner with these veteran organizations, the VSOs from 2015 on, the new Global War on Terrorism VSOs, that have these programs, that are conducting the research, that are submitting it, that are writing the policy reforms and legislation. And sir, we've been developing infrastructure outside of the VA for the last 10 years.

So, it's a change management problem and being able to come together maybe in a joint task force where those veteran experts that have been doing this, were consulted on that, and we can help move this along a lot quicker.

Senator TUBERVILLE. Dr. Wright, anything? Any advice to Congress?

Dr. WRIGHT. I'll try to phrase it nicely, but I think the VA needs to take immediate action. We have suicides occurring every day,

6,500 a year. To delay action on these potential therapies because they need more study or we don't want to set up a research program, is ineffective in treating the suffering veterans. We need immediate action, not platitudes, words, or more studies on some of these conditions. Some treatments are ready to go, like hyperbaric oxygen, probably some of the other treatments, they're ready to go. Let's demand that the VA take immediate action.

[Applause.]

Senator TUBERVILLE. Thank you. And before we go to Brian on this, Dr. Wright, I'd like to ask you this; can you explain the difference between treatment-resistant depression, TRD, and PTSD, and are they often coexisting?

Dr. WRIGHT. They are often coexisting. I'm not a psychiatrist, but I do know that one component of PTSD and TBI is depression. And these are caused in part by inflammation in the brain, and the structural damage that is caused by the concussive events. And there are alterations in brain structure in PTSD also, so I understand, so that they're all mixed together. And it's no wonder that certain single therapies don't work for everybody and people fail and they try another therapy. We need all the tools in the toolbox, not one or two. And it isn't always drug-related, but maybe there are some new drugs which are very helpful, but sometimes we need other therapies in addition to drugs.

Senator TUBERVILLE. Brian, you got anything to add to that?

Mr. SCHIEFER. Yes, I will try to be nice as well. I guess the main thing would be there are individuals and groups in the community already doing this. I think the fastest way to get it to veterans would be to partner with those—waiting for the bureaucratic red tape of the VA to finally get on board with this is going to take months, probably years. And these treatments are available currently to the public and the civilians, so why can't we get access to the veterans for that?

[Applause.]

Senator TUBERVILLE. Good, good.

Dr. LEVINE. And Senator, if I can weigh in as well.

Senator TUBERVILLE. Yes, go ahead.

Dr. LEVINE. Yes, and if you're asking about the similarities between TRD and PTSD. First, just for the veterans who are watching who may not be familiar with some of these terms and some of the audience, TRD stands for treatment-resistant depression. And what that means is that somebody has a major depressive disorder, and they've been failed by at least two treatments.

So, this is a difficult to treat depression and TRD treatment-resistant depression and PTSD are like thunder and lightning. They're two different things, but they often travel together. So, the majority of veterans who have treatment-resistant depression, also with PTSD, they do have a lot of overlap in terms of the difficulties that arise with having these conditions, like difficulties with mood, or sleep, or concentration, irritability, risk of suicide. And in fact, veterans who have both TRD and PTSD are twice as likely to attempt suicide.

Senator TUBERVILLE. If one of you can answer this, because we got quite a few questions go through here, what's the biggest mis-

conception about therapies that you'd like to correct today? Anybody?

Mr. MARR. I would just say with respect to psychedelics, there's a misconception out there sometimes that these are the cure all, the panacea, that it's kind of one and done. And I just don't think that that that's a good way to approach these really multiple, structured settings. What I mean by that is I've experienced a powerful psychedelic called ibogaine, only twice, 7 years apart. One time was at the worst time in my life, another time I had done a lot of work, a lot of processing of that information, peer support, and community to be able to integrate that in. So, I needed all that time for the next one to be able to have the effects that it did.

So, I think looking at these as one and done isn't a great way to do it. But these therapies are producing better and lasting outcomes because they're able to go to the root cause as opposed to masking the symptom.

Senator TUBERVILLE. Dr. Wright, you want to add to that?

Dr. WRIGHT. Yes. I have some comments about what the VA thinks about hyperbaric oxygen. Their thinking is flawed. The studies that the DoD and the VA did were all flawed. They used hyperbaric air as a sham treatment. Well, we've known since the '70s that air delivered under pressure is a treatment for lingering neurologic conditions. And guess what? Everybody got better in these studies. In fact, the Air Force later retracted its opinion on its paper, saying, the sham treatment got better, and hyperbaric treatment got better, it must not be effective. And they're both effective and they retracted what they said.

So, that study has been retracted by the Air Force. The only outlying study was done by the Navy, and they reported no objective findings in 24 Marines, who if they said they got better, this is all subjective. They would lose their VA benefits and nobody does a hyperbaric study with just subjective TBI findings. That's an inappropriate study.

And then, they also did some eye movement reports. So, these are elite athletes and they are elite Marines with marksmanship skills that are beyond the public's ability. And so, their eye movement scores are going to be in the 95th, 96th percentile to start with. So, to ask them to improve that with hyperbarics is very difficult. So, they're outlying; they picked the wrong measurement. So, those studies are flawed.

Since then, we've had 13 other studies which show that it works. Everybody gets it to work except the VA and DoD. It doesn't matter what country; Israel, China, and the United States, and thousands of people have improved. There have been no seizures, by the way. It's a safe and effective treatment.

Senator TUBERVILLE. Thank you. Brian, let's talk about regulatory real quick. As founder of the SCI–DI, you're working daily to get veterans access to therapies like HBOT or scuba, and alongside other alternative treatments. What's some of the biggest regulatory hurdles that you face helping get veterans across the finish line?

Mr. SCHIEFER. A lot of it, from what I've found over the years is education. People only know what they know, and I've spent probably 90 percent of my time just educating folks on what these

therapies are, what they can do. And really from that, it comes into the community involvement. We've got a great community partner down in Destin for diving. Dr. Zant has been a great, great help for HBOT and treating so many veterans over the years, pretty much off his own dime.

I think the big thing is, once again, regulatory hurdles in dealing with the VA, and how do we get through the red tape and get folks these treatments. I've had folks that have gone down to Mexico to receive the ibogaine treatment, and were told from their VA provider they were going to lose their benefits if they went. And these were folks that were taking two shoe boxes full of medications, came back and they're taking nothing.

Senator TUBERVILLE. What advice do you give them on that?

Mr. SCHIEFER. What's that?

Senator TUBERVILLE. When they go South of the border?

Mr. SCHIEFER. I think everybody has a need. And if the needs aren't being addressed here in the states, I would encourage them to go find what can work best for them. Everybody's physiological makeup is completely different, and everybody's going to react differently to these therapies based on their environment, past histories, traumas, things like that. So, I think the big thing right now is just access. Giving access to veterans to allow them to go where they want to go, where they don't have to fall into the VA catchment is going to be huge. Having community resources available to them locally.

And I think that's going to be the biggest hurdle right now, is just education. Like Adam said, is not only are psychedelics great, but there's a misconception that it's the one and done. No. That's just the beginning of the work, and it's the integration afterwards and that longitudinal study that we really need to keep a track on to really make sure that we're helping these guys and girls.

Mr. MARR. Sir, I'd just like to add on to that with what we recommend when folks go down to Mexico to experience these, because last November I had the opportunity to advise setting up a veterans' program in Mexico at one of these clinics. The program's called Beönd Service. It's a 9-week best-in-class program. This is what we've learned along the way because of what we've had to tell people to go down and prepare.

So, it's 4 weeks of preparation calls in a group of five because we train together in groups. So, it's very familiar to us. When we do that, you're down there for 8 days onsite at this clinic. You're there with medical support and intake, 9 ER doctors, emergency care nurses, therapeutic staff, and then a culinary that's making sure that you're eating the right things to put into your body.

And then there's an environment where you can have this experience where you're prepared, where you're there with your peers. And then on the other side of that, we don't rush you back into your environment at home. So, you have time to be able to start to come back into your body from the effects of this medicine.

And then on the other side, we don't abandon you. It's 4 weeks of integration, coaching calls, and then when you say peer support and community, that's ongoing for a lifetime. But that's familiar to somebody that was in the military, to somebody that was on a sports team. And it's not familiar if you've just been on your own

your whole life. And so, being able to design programs like this. But we got to design them outside of the United States, sir, unacceptable.

But we've done 10 cohorts in this year alone, 50 veterans, female cohorts, because female veterans experience military sexual trauma, and we've learned to not put males in their cohorts so that they can be able to heal from their wounds. We also have two cohorts of veteran spouses because it's not just about the veteran, it's about the whole family, and it's about being able to support them on the other side.

[Applause.]

Senator TUBERVILLE. Good. Steve, what can the VA do to increase the number of available alternative therapy treatments? What can we do?

Dr. LEVINE. You know, I think the VA it's less about how the VA makes new treatments available than I think making them available as quickly as possible once they are. Right? The FDA primarily has the responsibility in protecting the public good to evaluate the risk-benefit profile of potential new treatments. Once that has been proven, then I think there can be no delay in the VA rolling these treatments out and actually getting them to veterans.

It's why I applaud the work that the integrated project team is doing at the VA now to start preparations. I think that one action that could be taken is increased support for that work so that there are the resources available and necessary to make sure that personnel are trained, that the space is set up, that that the healthcare providers are trained in these protocols and they're ready.

Because the reality is, that if right now, we know that veterans are not well served for these conditions. If we look at what's in development to the pipeline is what it's called, other than psychedelics and perhaps some of the other treatments we're talking about today, there isn't much.

But there are many, many psychedelics in development right now. And even if Compass Pathways isn't successful, I hope we are, but we may not be, the likelihood is that in the near future, there will be one or more new psychedelic treatments that are FDA-approved. And if the VA waits until an approval to start to get ready, they'll be behind the eight ball and there'll be undue delays for veterans.

[Applause.]

Senator TUBERVILLE. Thank you. Dr. Wright, you've talked about challenges with HBOT. Why's the VA so stubborn about this? Is it cost?

Dr. WRIGHT. I think that might be part of it. Part of it could be ignorance. We first met with the VA and their chief scientists in 2011, and they brought an FDA staffer, and we were appalled by their ignorance. The FDA staffer said, oh, hyperbarics are dangerous. There could be a fire. You know, hyperbaric therapy's been around since 1936, so I don't know why they are ignorant.

Same problem with the DoD of which I was part, and they were just totally against it. And they wanted incontrovertible proof. Well, now we have that proof. They wanted level 1 proof. We have that proof. We have 70,000 people who have been treated success-

fully, no seizures, no serious side effects, and everybody that we know of got better, and very few if—and the two suicides, that's all we know about. That's remarkable.

I think that's enough evidence to proceed. I don't know why they're so resistant. Maybe they're afraid they don't have enough evidence. They do. I don't know. It's hard for me to figure out. I don't know the answer, Senator.

Senator TUBERVILLE. Thank you. Maybe we can figure it out. Brian, I'll start with you. Adam, I want you to answer this one too. You two veterans, if you've started your own organizations to get veterans alternative treatments, you have a unique perspective and you face your own unique set of challenges. What challenges have your organization faced in working with the VA or community care providers in getting veterans access to all these therapies? Brian?

Mr. SCHIEFER. We haven't worked with the VA for that reason.

Senator TUBERVILLE. At all?

Mr. SCHIEFER. It's just been difficult, and just being a new organization, we haven't really found the need to work with the VA, per se. Dealing with veterans is a very unique population of individuals; very driven, very motivated to get things done.

So, what we found is people are going to look for their own alternative therapies outside of the VA, even if the VA is telling them no. And so, how can I, as an individual who's gone through my own experiences, tell somebody they don't have a right to treatment or don't have a right to try these different things?

And so, currently, no, we're not working with the VA for that reason. We're just using veteran outreach, different VSOs, relationships that we have, and things like that, and kind of bypassing the VA system.

Senator TUBERVILLE. Adam?

Mr. MARR. It's a similar response, although there's been a little bit more time working in the space. So, initially, what were the pathways to be able to do it, especially if you're starting a new VSO, I would compare it to like being an established corporation. If you want to bring a new innovation in, you go out and you acquire the startup or you have an R&D.

I don't know where or how that exists within the VA, but now as the director of operations for the Veteran Mental Health Leadership Coalition, I can say at the higher levels, like we're having these type of conversations, but it still comes down to systems reform, systems change, and being able to, like you so eloquently said, sir, what is the balance between innovation and safety? Right now?

I don't think there's a good balance. I think it's overly focused on safety for all the reasons that we know. Medically, there has to be greater emphasis on accelerated innovation.

Senator TUBERVILLE. Steve, you want to add anything to that?

Dr. LEVINE. Nothing to add.

Senator TUBERVILLE. Okay. Alright, Dr. Wright, for those listening in the room, we might have jumped over this a little bit, but if they're not familiar with HBOT, if veterans watching this today are not familiar with that, can you walk kind of, shortly, through a process of what they go through, how they would do it? You

know, the procedure, and how many therapies they might need to show some kind of progress?

Dr. WRIGHT. Sure. So, hyperbaric oxygen is provided in a hard-sided chamber run by trained personnel directed by a physician. So, if you see one of these blow-up spa-type chambers, don't go there. And they'll usually, with those blow-up things, put an oxygen concentrator in it. That's not safe, and it's violating the FDA certification of those chambers. They're only good for air, and they don't go deep enough to provide the type of treatment we want.

So, you have to find a certified hyperbaric facility that would treat you, and many of these are outside of hospitals. Most hospital chambers won't do it because they won't get paid right now by anybody. But you can find certain private ones. The TreatNOW Coalition, if you just get on the web, you can find them and they can direct you to one that might treat you.

Several (13) states have approved treatment with hyperbaric therapy, and especially North Carolina and Kentucky have allotted money for the treatment of their veterans. That should say something to the FDA when the states are stepping forward and providing the treatment the VA is not providing. And if you're in Alabama, unfortunately we don't have that yet, but we're hoping to do that in the future, but you got to find a certified chamber. You can always call me or another member of this group that works with veterans and we can direct you to one in your area.

And many people like Dr. Zant, we started the treatment. We treated the military people for free. We didn't tell the surgeon general, we just did it. It worked. And he's still treating some people for free. His accountant told him, you can't do this forever. But God bless him. And there are many people who do this on their own nickel. So, it's a little difficult trying to hook up with a chamber, but it can be done.

The other thing I should add is that many of our veterans with PTSD actually also have TBI, but nobody asks them about that. And so, they go together. So, sometimes they'll tell you, "I was okay, and then I got concussed and then things started to go downhill." So, getting a proper diagnosis would be helpful. So, that's why the physician comes in.

Senator TUBERVILLE. I think that's why my wife bought me one [laughter]—I ran into a lot of trees at one time with a football helmet [laughter], but a lot bigger than me. Very informative.

But we're going to take 2 minutes each, 2 minutes and tell what—just look in the camera and tell the veteran what do they need to do? I mean, they're in trouble. Take two short minutes each, give them your spiel, tell them what you believe in, and we'll end this up. Steve, let's start with you.

Dr. LEVINE. Thank you, Senator. You know, because as you say speaking directly to the veterans who are watching this right now, I think the most important thing for them to hear is that you can hear from this panel, from this room, from the attention being paid here, that there's a recognition that there are tremendous unmet needs in the treatment of PTSD and the treatment of depression that we are currently not meeting the moment right now in caring for our veterans.

However, that there are many promising treatments in development, and I hope that that creates some hope because the most dangerous thing is the loss of hope. And so, I think that veterans can look forward to a time, hopefully in the near future, where they don't have to leave the country they served in order to receive these treatments. That they continue to move through the FDA pathway, through regulatory pathways.

And we are firmly committed to partnering with the VA, to working with our government, to everyone who is united in this mission, to ensure that we do create new options for our veterans, whether that's psilocybin, and other psychedelic treatments, or other innovation that is so sorely needed.

Senator TUBERVILLE. Thank you. Adam?

Mr. MARR. Sir, I would say that these are not alternative therapies. These are emerging therapies. These are breakthrough therapies. These are the innovations of our time. So, if you're a veteran and you're considering one of these, and you're worried about the stigma or things that you've heard in the past, look to your left and right to a brother. Come to the VMHLC, because we're out front advocating for these things.

But we're advocating because we help expand access, because we help document and make sure that we're producing the research outcomes that we're helping to draft the policy based off what we've learned through going through the hardships year after year. We're not starting from scratch. We have 10 years of infrastructure to be able to ensure that training the processes, the technologies, and the inter-agency coordination all the way up to the highest councils in the land to make these things happen.

So, it is happening. And if you want to come there, then we're not going to be able to get you one of those treatments, but one of our 50 partner organizations are. And, Senator, that list is continuing to grow, and grow, and grow. And so, that's what I would recommend.

And lastly, I would just thank you for this opportunity, for elevating this beyond alternative into the conventional. And we are ready to partner on this to be able to move forward together because that's the way it needs to be done, in unity, in ways that we haven't been able to before. Thank you.

[Applause.]

Senator TUBERVILLE. Thank you. Dr. Wright?

Dr. WRIGHT. I would say if you're a veteran and you're not at the VA getting treated for some reason, maybe if you can find it in your heart to go back there and try, do that. If you don't get satisfaction, write your Senator and your Congressman and tell them about it.

And now, if you want hyperbaric oxygen, my best suggestion is contact the TreatNOW Coalition—just like two words struck together—they're on the internet, or one of these other agencies, and they'll put you in contact with a facility that offers treatment to veterans.

Senator TUBERVILLE. Thank you, Dr. Wright. Brian?

Mr. SCHIEFER. I would say you have to be your own best advocate. Nobody knows you, and your body, and your physical condition, mental state better than you. So, understanding that, there

are organizations out there that can help and are willing to help, but you have to do your own research and kind of sort that out, and kind of sort your way through it.

Just because the VA tells you no, doesn't mean it's a hard no. There are a lot of alternative therapies that are coming online right now. Everybody has to find what works best for them. What works for me may not work for Dr. Wright and vice versa.

So, be willing to try new things with your own risk factor. And there is hope out there. And I think these alternative therapies are going to provide hope for thousands of veterans and the civilian population.

Senator TUBERVILLE. Thank you. So, I don't think people really understand. Hopefully, they got this from today, that this is a national emergency, this is bad. You know, we got a lot of problems in this country. This is really bad, and it's getting worse. It's not going to get any better. We're having more and more veterans that we're adding into the VA.

I don't think people realize that the VA is the largest healthcare system in the world, but sometimes we think that the VA is for the employees. It is not. It is for the veterans. We need to help our veterans. And again, we're in tough times, but tough times are handled by tough people. And so, hopefully, today's hearing opened some eyes.

Again, a lot of people are going to watch this. And we got have two great panels, the one at the beginning and the one here. But we're just anxious to see the VA improve, and hopefully, that these alternative therapies will help. Just talking about them, visiting about them, understand a little bit more about them. The Committee to consider legislation that authorized the use of alternative therapies like HBOT. I hope they listen. I really do.

New treatments are being studied every day, not just to help veterans, but everybody in this country. But we need to stop the red tape. The red tape is what gets in the way of the greatest country ever. And for some reason, we continue to add red tape instead of getting things out of the way so we can help people.

Our veterans, they put their life on the line and they deserve a fighting chance. We need to give that to them. Money is not the problem, folks. We spent a lot of money at the VA, a lot of money. These guys can tell you that. But a lot of money is not spent the right way, and we need to put our foot down.

So, I'd like to include the following items for the record; a statement from HBOT4Heroes. I'd like to put that in for the record, and three documents from Clinicom. And those will be added to the record. An article by Dr. William Jamie Tyler. I think it would be very, very important. So, that will be included for the record.

[The items referred to begin on page 83 of the Appendix.]

Senator TUBERVILLE. So, I'd like to thank both groups today for being here, all of you, for being here, showing your interest. Again, folks, our veterans are in trouble. Anything can happen at any time, and hopefully, today, we can start a process for some of these therapies that we talked about.

We educated some people. Not enough people know what's going on. They're living. Everybody's busy. Their lives are very busy.

We're all busy every day, but there's nothing more important than saving people's lives that have saved the greatest country on the face of the earth; United States of America.

So, God bless y'all, what you're doing. God bless our first panel. God bless those of you that came here today. God bless our military people today that are in active duty and our veterans, and God bless our country. This hearing is adjourned.

[Applause.]

[Whereupon, at 12:48 p.m., the hearing was adjourned.]

A P P E N D I X

Prepared Statements

STATEMENT OF
ILSE WIECHERS, M.D., MPP, MHS
DEPUTY EXECUTIVE DIRECTOR
OFFICE OF MENTAL HEALTH
VETERANS HEALTH ADMINISTRATION
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE
ON
"SEPARATING FACT FROM FICTION: EXPLORING ALTERNATIVE THERAPIES FOR VETERANS' MENTAL HEALTH"

AUGUST 22, 2025

Good morning, Senator Tuberville and everyone joining us here today. Thank you for the opportunity to discuss the importance of seeking new and effective ways to care for our Nation's heroes. I am Dr. Ilse Wiechers, Deputy Executive Director of the Department of Veterans Affairs (VA) Office of Mental Health (OMH). Joining me today is Dr. Miriam Smyth, Executive Director of the Brain, Behavioral, and Mental Health Portfolio within the Office of Research and Development (ORD). My testimony will focus on VA's research and clinical efforts regarding emerging therapies, including psychedelic-assisted therapy and hyperbaric oxygen therapy (HBOT), as well as other innovative treatments.

Background

VA operates the largest integrated health care system in the United States, providing comprehensive services to over 9 million enrolled Veterans annually. Our mission centers on caring for those who have borne the battle, their families, and caregivers. Mental health care is a critical aspect of our services, and we continuously strive to support new and innovative research studies, as well as to integrate

scientifically-based and evidence-based treatments into current protocols to treat conditions such as posttraumatic stress disorder (PTSD), depression, and anxiety.

Current evidence-based treatments for these conditions, such as Prolonged Exposure Therapy, Cognitive Processing Therapy, Eye Movement Desensitization and Reprocessing, and medications are effective for many. However, putting Veterans first means finding new ways to help approximately one-third of Veterans with PTSD or major depression who do not find relief from conventional treatments. This has driven our commitment to researching and integrating innovative therapies that may offer significant benefits for Veterans.

Psychedelics

VA is exploring the therapeutic potential of psychedelic compounds. We recognize that psychedelic drugs like MDMA (3,4-methylenedioxymethamphetamine) and psilocybin are drawing attention as potential treatments for some mental health conditions. As of July 2025, there are 12 clinical research studies on psychedelic treatment for mental health conditions underway at 9 VA medical centers (VAMC). These studies involve MDMA, psilocybin, dimethyltryptamine, and lysergic acid diethylamide. They focus on PTSD and Major Depressive Disorder but also look at generalized anxiety disorders and substance use disorders.

This fiscal year, VA announced funding for a research study on MDMA-assisted therapy for PTSD and alcohol use disorder among Veterans. This clinical trial will take place at the Providence VAMC in Rhode Island. While a formal policy process will be critical to expand the scope of VA's existing research efforts, VA is pleased to support the HALT Fentanyl Act (S331) signed by President Trump in July 2025, that allows private, non-governmental entities to expand their controlled schedule I and II research protocols.

As with all VA research, treatments are conducted in a clinical setting with strict safety protocols and in compliance with all appropriate Federal guidelines for conducting studies with controlled substances. Through this research, VA intends to gather rigorous scientific evidence on the potential efficacy and safety of psychedelic compounds when used in conjunction with psychotherapy.

Hyperbaric oxygen therapy (HBOT)

HBOT is recognized for its efficacy in treating conditions such as decompression sickness and wound healing. However, the Food and Drug Administration (FDA) has not authorized its use for the treatment of PTSD or traumatic brain injury (TBI).[1] VA has explored its potential benefits for TBI and mental health conditions, particularly PTSD. VA and the Department of Defense (DoD) have developed evidence-based clinical practice guidelines (CPG) for TBI and PTSD. The most recent update for the TBI CPGs was completed in June 2021, while the most recent update for the PTSD CPGs was completed in June 2023. The CPGs for PTSD found insufficient evidence to recommend HBOT as a treatment for PTSD. There have been two published trials since the CPGs for PTSD were published, yet both trials would not be enough to change the CPGs recommendations as the evidence was insufficient. The CPGs for TBI strongly recommend against the use of HBOT for patients with symptoms attributed to mild TBI.

There has been no randomized controlled trial study completed since the publication of CPGs for TBI. Published results of scientifically rigorous VA and DoD research on TBI have repeatedly shown that HBOT has the same impact as a placebo and no clinically relevant long-term effects. In addition to the lack of patient improvement, the use of HBOT after a mild TBI may have harmful impacts, including seizures. Current empirical evidence does not support the widespread use of HBOT as a primary or adjunct therapy for PTSD or TBI. VA remains committed to monitoring ongoing research and will revisit its potential use based on future findings.

Other Emerging Therapies

In addition to psychedelic-assisted therapy and HBOT, VA continues to evaluate several other innovative treatments to address mental health conditions among Veterans. These emerging therapies show promise in treating conditions that have been resistant to traditional methods. Our goal is to ensure that Veterans have access to the most effective and cutting-edge treatments available. I will outline some of these therapies and their current status within VA.

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[1] https://www.fda.gov/consumers/consumer-updates/hyperbaric-oxygen-therapy-get-facts

- **Stellate Ganglion Block (SGB):** Although promising, current research indicates insufficient evidence to recommend SGB for PTSD. Ongoing studies are being conducted to clarify its potential benefits and determine its efficacy in treating PTSD among Veterans.
- **Ketamine and Esketamine:** Ketamine and its derivative, esketamine, are evidence-based treatments that are offered at 49 VA facilities for treatment-resistant depression and acute suicidality. In fiscal year (FY) 2024, these treatments saw a 17% increase in usage compared to FY 2022.
- **Transcranial Magnetic Stimulation (TMS):** TMS is an FDA-approved treatment for major depressive disorders. TMS is available at 62 VA facilities and is being further investigated to determine its efficacy for PTSD. TMS offers a non-invasive option for Veterans whose depression has not responded to other treatments.

While VA's research efforts continue, Veterans will receive the mental health care and support they need—whenever and wherever they need it. Our proven, evidence-based care options for Veterans experiencing PTSD or depression include mental health care at VA facilities, assistance with reintegration into their communities, counseling at Vet Centers across America, 24/7 access to qualified crisis responders at the Veterans Crisis Line, emergent suicide care for Veterans at any VA or non-VA facility at VA expense, and much more.

The VA is committed to bring the best in medical and mental health care innovations to our Nation's warriors, but we must caution the public. These therapies remain investigational and are not approved for general use. It is important not to self-medicate with psychedelics outside of a clinical research setting, as doing so can carry significant risks.

Conclusion

VA is committed to advancing the science behind emerging therapies and ensuring their safe and effective integration into mental health care. We achieve this through rigorous scientific evaluation, ensuring all new therapies undergo thorough testing and peer-reviewed research to establish their safety and efficacy. This approach

helps ensure that treatments are tailored to meet the unique needs of Veterans and are seamlessly integrated into existing care frameworks. By exploring and integrating innovative and evidence-based therapies, we aim to ensure that no Veteran is left behind. We appreciate the Committee's continued support in this shared mission. My colleague and I are prepared to respond to any questions you may have.

Department of Veterans Affairs

Senior Executive Biography

Ilse Wiechers, MD, MPP, MHS

Deputy Executive Director
VHA Office of Mental Health

Dr. Wiechers serves as the Deputy Executive Director in VHA Office of Mental Health. In this role, she leads the operations of OMH and the timely development and implementation of policies and programs that ensure Veteran-centered, evidence-based and high-quality mental health services to over 2 million Veterans every year. She leads OMH's legislative policy and partnership work, engaging regularly with key Congressional and Veteran Service Organization stakeholders. She has been instrumental in the development of VHA's portfolio of innovative mental health treatments including ketamine, esketamine, and psychedelic-assisted therapy.

Dr. Wiechers is a practicing board certified Adult and Geriatric Psychiatrist who completed her medical education at Duke University, residency at MGH/McLean Hospitals, and fellowship at Yale. She received a master's degree in Public Policy from Duke University and a master's degree in Health Science from Yale University. She is an alumna of the VA Advanced Fellowship Program in Mental Illness Research and Treatment, the Yale RWJF/VA Clinical Scholars Program, and the John A. Hartford Foundation's Center of Excellence in Geriatric Medicine and Geriatric Psychiatry Training Program. Dr. Wiechers serves as faculty at University of California San Francisco and Yale, is a Distinguished Fellow of the American Association for Geriatric Psychiatry and the American Psychiatric Association and has been elected to the membership of the American College of Psychiatrists. She has authored 35 peer-reviewed publications, 2 invited editorials, 18 book chapters, and co-edited a book on mental health advocacy.

CAREER CHRONOLOGY:

2022 – present	Deputy Executive Director, VHA Office of Mental Health
2020 – 2022	National Director for Psychopharmacology and Somatic Treatment, VHA Office of Mental Health and Suicide Prevention
2017 – 2019	Co-Director, Care for Patients with Complex Problems Program, VHA Office of Mental Health and Suicide Prevention
2014 – 2021	National Director, Psychotropic Drug Safety Initiative (PDSI), VHA Office of Mental Health and Suicide Prevention
2014 – 2022	Associate Director, Northeast Program Evaluation Center, VHA Office of Mental Health and Suicide Prevention, West Haven, CT

EDUCATION:

2014	Master of Health Science, Yale University School of Medicine, New Haven, CT
2005	Doctor of Medicine, Duke University School of Medicine, Durham, NC
2003	Master of Public Policy with certificate in Health Policy, Duke University, Durham, NC
1999	Bachelor of Arts in Political Science, Case Western Reserve University, Cleveland, OH

Department of Veterans Affairs
Senior Executive Biography

Miriam J. Smyth, PhD

Executive Director,
Brain, Behavioral and Mental Health Broad Portfolio
Office of Research and Development
Washington, D.C.

Dr. Smyth has been the Acting Director of the Brain, Behavioral & Mental Health broad portfolio since July 2023. This portfolio focuses on advancing precision mental health care within the VA and conducting research into high-priority areas such as posttraumatic stress disorder and depression.

Dr. Smyth has also provided exemplary leadership to ORD's Clinical Science Research and Development Service as Acting Director since March 2022, overseeing a program of $105 million in clinical research funding and approximately 430 ongoing research projects to improve Veterans' health and well-being.

Dr. Smyth has initiated many high-visibility national projects to advance ORD's goals, particularly in the areas of precision mental health and emerging therapies. She leads the PTSD Psychopharmacology Initiative and has worked to advance research on the use of psychedelics, cannabis, and transcranial magnetic stimulation to treat mental health conditions that are resistant to today's first-line approaches. She recently led ORD efforts to issue VA's first request for applications in psychedelic research to treat Veterans' mental health conditions, and she co-authored "Research and Implementation of Psychedelic-Assisted Therapy in the Veterans Health Administration," published in *The American Journal of Psychiatry* (January 2025).

CAREER CHRONOLOGY:

2022-2025	Director (Acting) Clinical Science R&D Service (CSRD), ORD
2019-2022	Deputy Director/CSRD
2015-2019	Senior Program Manager/Strategic Planning CSRD
2015	Associate Chief of Staff for Research & Development (R&D), Acting, VA Maryland Health Care System (VAMHCS).
2010-2015	Deputy Associate Chief of Staff for R&D, VAMHCS

EDUCATION:

PhD, University of Maryland

Compass

Testimony for Senate Veterans Affairs Committee Field Hearing

August 22, 2025

Introduction

Senator Tuberville, members of the Senate Veterans Affairs Committee, thank you for the chance to testify at this important field hearing today. Improving the mental health of veterans is a national imperative, and we appreciate your leadership to achieve this goal.

My name is Dr. Steve Levine, and I serve as the Chief Patient Officer for Compass Pathways. Compass Pathways is a biotechnology company dedicated to accelerating patient access to evidence-based innovation in mental health. Our mission is to improve the lives of individuals living with serious mental health conditions who do not benefit from current treatment options.

Our lead compound, COMP360, is a synthetic, pharmaceutical-grade formulation of psilocybin being studied in robust clinical trials in treatment-resistant depression (TRD) and post-traumatic stress disorder (PTSD). COMP360 was granted Breakthrough Therapy designation from the U.S. Food and Drug Administration (FDA) for TRD in 2018 and will potentially be a first in class treatment.

Compass Pathways is leading the way in psychedelic clinical trial research and is conducting the largest ever FDA-regulated clinical trials studying the safety and efficacy of psilocybin. In TRD, we have generated positive primary endpoint data in two large well-controlled clinical trials. In November 2022, the positive results of our 233 participant Phase 2b trial were published in the *New England Journal of Medicine* and in June 2025, we announced the successful achievement of the primary endpoint in the first of two ongoing Phase 3 trials. This first randomized, double-blind, placebo-controlled Phase 3 study dosed 258 participants, and our second Phase 3 trial will evaluate the safety and efficacy of psilocybin in approximately 560 additional participants.

Along with clinical development in TRD, in May 2024, Compass Pathways announced positive top-line results from our 22 participant Phase 2 open label 12-week safety and tolerability study in PTSD. That study showed COMP360 was well tolerated and indicated both rapid and durable improvement in symptoms from baseline observed following a single administration. Compass is currently finalizing plans to initiate a late-stage trial in PTSD.

The Need

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The United States is in a mental health crisis[1] with 1 in 5 adults[2] experiencing mental illness in any given year. Veterans are among those disproportionately impacted. Among the most pressing and debilitating conditions within this crisis are PTSD and TRD. Both conditions are marked by severe symptoms, high suicide risk, and limited pharmacological treatment options, necessitating evidence-based, novel treatment options for these underserved conditions.

Post-Traumatic Stress Disorder

Post-Traumatic Stress Disorder (PTSD) is a serious mental health condition that can develop after exposure to traumatic events[3] such as personal assault, combat, natural disasters, or serious accidents. Characterized by symptoms such as intrusive memories, avoidance behaviors, negative shifts in mood and cognition, and heightened arousal[4], PTSD affects approximately five percent[5] of adults in the U.S. annually. Symptoms may appear within months of the trauma or be delayed, and they must persist for over a month[6] and interfere with daily functioning to meet diagnostic criteria.

PTSD can impact anyone, though certain populations[7]—including veterans, first responders, and survivors of abuse—are at elevated risk. Individuals living with PTSD frequently experience comorbid mental health conditions[8], most commonly, depression, anxiety disorders, substance use disorders, as well as a significantly increased risk of suicide. These overlapping conditions can intensify distress and complicate treatment.

Affecting approximately 13 million[9] people in the U.S. each year, PTSD is an underserved condition. There are currently only two FDA-approved medications for PTSD.

Treatment Resistant Depression (TRD)

Depression, one of the most common mental health conditions, significantly impacts relationships, work performance, overall quality of life, and is associated with an increased risk of suicide[10]. Major depressive disorder (MDD) has been ranked as the third cause of the burden of disease worldwide in 2008 by the World Health Organization (WHO), which has projected

[1] https://www.cdc.gov/mental-health/about/what-cdc-is-doing.html
[2] https://www.nami.org/about-mental-illness/mental-health-by-the-numbers/
[3] https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd
[4] https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd
[5] https://www.ptsd.va.gov/understand/common/common_adults.asp
[6] https://www.nimh.nih.gov/health/publications/post-traumatic-stress-disorder-ptsd
[7] https://www.psychiatry.org/patients-families/ptsd/what-is-ptsd
[8] https://my.clevelandclinic.org/health/diseases/9545-post-traumatic-stress-disorder-ptsd
[9] https://www.va.gov/columbia-south-carolina-health-care/stories/hope-and-healing-initiatives-for-ptsd-awareness-and-veteran-support/
[10] https://www.who.int/news-room/fact-sheets/detail/depression

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that this disease will rank first by 2030[11]. An estimated 21 million adults in the United States suffer from major depression[12], and approximately 9 million are drug treated[13].

Due to the limitations of approved existing MDD medications, approximately one-third of patients with MDD will develop TRD. These patients include veterans and our most vulnerable populations. In one study, 68% of psychiatric clinic outpatient veterans met the criteria for TRD[14].

TRD is broadly defined as an inadequate response to two or more appropriate courses of approved anti-depressant medications. TRD has a significantly greater impact on individuals, caregivers, and healthcare systems compared to MDD, leading to residual symptoms, poorer quality of life, increased comorbidities, higher mortality, and an increased risk of suicide compared to non-treatment resistant MDD. Prevalence trends show that the proportion of TRD patients reporting suicidal ideation within the past year ranged from 39.5% in 2009 to 2010 to 43.4% in 2019 to 2020[15].

Despite the availability of many FDA-approved treatments for MDD, TRD is still an area of high unmet need. There are currently only two FDA-approved medications indicated for TRD.

Advancements in New Treatment Options: Psychedelics

In the U.S. there is an urgent need for new and effective treatments in mental health care. Nearly 60 million adults in the U.S.[16] live with a mental illness—including conditions like PTSD and TRD—yet therapeutic innovation has not kept pace with the growing crisis. For decades, progress in mental health pharmacology has been slow, leaving millions underserved.

However, novel scientific approaches, like psychedelics, that aim to potentially meet the scale and complexity of the growing mental health crisis are on the horizon. Well-controlled clinical studies into the safety and efficacy of innovative treatments like psychedelics for the treatment of serious mental health conditions are underway.

Veterans and VA Preparation

[11] Bains N, Abdijadid S. Major Depressive Disorder. [Updated 2023 Apr 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK559078/
[12] https://mhanational.org/conditions/depression/
[13] Zhdanava M, Pilon D, Ghelerter I, Chow W, Joshi K, Lefebvre P, Sheehan JJ. The Prevalence and National Burden of Treatment-Resistant Depression and Major Depressive Disorder in the United States. J Clin Psychiatry. 2021 Mar 16;82(2):20m13699. doi: 10.4088/JCP.20m13699. PMID: 33989464.
[14] Allen CM, Bray C. Improving Patient-Centered Care for Veterans With Treatment-Resistant Depression Using Shared Decision-Making Tools. Journal of the American Psychiatric Nurses Association. 2023;29(1):7-14. doi:10.1177/1078390322114188S
[15] Rhee, TG et al. *J Affect Disord.* 2024; 358:342-349.
[16] https://mhanational.org/news/mha-releases-2024-state-of-mental-health-in-america-report/

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Amid a national mental health emergency where anywhere from 17 to 44 veterans die by suicide each day[17], we must urgently explore and advance novel treatments to help those in our veteran community struggling with PTSD, depression, and other serious mental health conditions. It is essential that we explore all avenues available through our current regulatory framework to facilitate the safe, effective and efficient delivery of these treatments to veterans in need.

We commend the VA for its openness to new treatment options, including psilocybin, and for the significant research it has performed related to psychedelics. While these compounds are still being studied for potential approval by the FDA, we encourage the VA to prepare for the possible entry of psychedelic therapies into the VA health system so that it is ready should these medicines be approved or become available to veterans.

We recommend that the VA begin by developing treatment protocols, standardizing training for personnel, and preparing clinical care settings. Compass Pathways is committed to supporting the VA to ensure that sites have the required infrastructure and training in place for successful integration of psilocybin as a potential new treatment option for veterans. Our shared goal must be to ensure that safe, effective medications for the treatment of mental health are accessible to veterans as soon as possible.

Closing

In closing, the potential FDA approval of psychedelic compounds is drawing closer, with multiple late-stage clinical trials currently underway. Compass Pathways shares the Committee's goal to ensure that our nation's veterans have access to innovative, evidence-based treatments and the comprehensive care they deserve. We stand ready to support the VA in advancing this mission responsibly and safely and in a manner that upholds the highest standards of care. Again, we thank the Committee and Senator Tuberville for holding this important hearing. I am happy to answer any questions.

[17] https://news.va.gov/137221/va-2024-suicide-prevention-annual-report/; https://www.militarytimes.com/veterans/2022/09/17/veterans-suicide-rate-may-be-double-federal-estimates-study-suggests/

VETERAN
MENTAL HEALTH
LEADERSHIP COALITION

Testimony of
Captain Adam Marr. (US Army, Ret.)

Director of Operations
Veteran Mental Health Leadership Coalition

Before the
U.S. Senate Committee on Veterans' Affairs

August 22nd, 2025

"Separating Fact from Fiction: Exploring Alternative Therapies for Veterans' Mental Health"

Introduction: Who I Am and Why This Matters
Senator Tuberville, thank you for the honor of testifying at this field hearing on Alternative Therapies. My name is Adam Marr, and I am a U.S. Army Veteran based in Slocomb, Alabama. My testimony today is grounded in my lived and professional experience—as an Army Captain and AH-64 Apache pilot with over 1,500+ flight hours, including 400+ combat hours deployed to Iraq; as a brother navigating the trauma of war within my own family; as the Co-Founder of the Warrior Angels Foundation; as a former change management consultant at Accenture; and now as a national consultant transforming care for Veterans by working with high-impact organizations like the Veteran Mental Health Leadership Coalition (VMHLC) as their Director of Operations and American Legion as their national podcast cohost.

I am humbled to provide testimony in Alabama-the first place I lived after graduating Texas Christian University and commissioning as a 2nd Lieutenant in the United States Army, I was stationed at Fort Rucker where I completed training to become an AH64 Apache Helicopter Pilot. It is here that I met my beautiful wife, an Alabama native, and where I've since established a life with my family. Today, we live in our home on 30 acres we are proud to own, with our three beautiful children, and a close-knit community that has supported us throughout our journey. I feel blessed to have reached a place in my life where I can say that I am physically, mentally, emotionally, spiritually, and morally healthy, and living a life of Christ centered service and purpose.

Dedication
My testimony today is dedicated to my father, Woody Marr, who went home to be with the Lord this year. He loved his sons, his wife, and his walk with Jesus Christ more than anything. He watched all four of his sons serve-three in combat-and prayed every day we'd come home. We did. We just didn't know that's where the real battle would begin.

My Family's Story: Why This Fight is Personal:
My older brother Andrew, a Special Forces Green Beret, came home with TBI and PTSD from blast injuries. The system's answer? Thirteen medications to mask memory loss, anxiety, depression, and rage among other symptoms. Their words: "This is your new normal."
My younger brother Austin, after two combat tours, was medically separated after a training injury. Over five years he lost his community, spiraled into depression, was diagnosed with a mood disorder, and was put on SSRIs. One night I found him unresponsive after he tried to take his life.

And me-the middle brother-I brought my soldiers home safely, and watched my own brothers collapse.

This isn't just our story-it's an American Veterans' story. I've heard it hundreds, if not thousands, of times. And here's what we learned: Veterans aren't broken. The system is. For decades, care

has numbed instead of healed-pills, brief talk therapy that prioritizes a session agenda over a Veteran's needs and preferences, and labels that never touch the root cause, which often include a complex mix of biological, psychological, spiritual, and social domains.

The Broken System: Why Veterans Keep Falling Through the Cracks

- Disrupted brain networks, changes in structure, function, and brain-matter integrity from blast exposure and concussive injuries[1-10]
- Neuroendocrine collapse from chronic stress and trauma[11-20]
- Neuroinflammation and oxidative stress triggered by toxic exposures[21-26]
- Genetic vulnerabilities and epigenetic changes left unexamined[27-35]
- Gut dysfunction, microbiome imbalance, and nutritional depletion[16, 36-46]
- Deep moral and spiritual injuries from wartime actions or systemic betrayal[47-57]
- Disconnection from tribe, identity, and purpose[48, 58-65]

In the last twenty years, we've lost more Veterans to suicide and overdose than in Iraq, Afghanistan, and Vietnam combined [66-69]. The system is built to stabilize-it doesn't restore. When survival is all we are offered, too many lose hope. A recent *Wall Street Journal* exposé highlighted the VA's "combat cocktail" polypharmacy to treat PTSD, TBI, and related mental health conditions [70]. The VA's own PTSD expert workgroup said back in 2017 there's a lack of supporting evidence for this approach-yet it's only gotten worse [71].

Leading scientific bodies describe a persistent quality chasm driven by access barriers and fragmented and ineffective care, and they call for scaling recovery-oriented, person-centered approaches that measurably improve quality of life [72-76].

A Better Way: Whole-Person, Hope-Driven Care

I recognize there are changes underway inside the VA-but this can't just be about staffing shifts and reductions or Veteran lives will continue to be lost-we need to prioritize system evolution. This does not mean an abandonment of conventional tools or the VA's critical infrastructure. We are calling for a system that finally honors the full spectrum of healing—biological, psychological, and spiritual. We are calling for a system that does not treat the brain and body as two separate entities, but rather a whole integrated person. We are calling for a system that puts the patient's needs before quotas. We are calling for a system that returns the "psyche" (Greek word, soul) back in psychiatry and acknowledges moral injury as real and the pain of lost belonging, connection and identity. Unlike PTSD, which is fear-based, moral injury fractures meaning and erodes trust, leaving Veterans with shame, guilt, and disconnection that conventional trauma therapies rarely resolve. We are calling for a system that takes a 'leave no stone unturned' approach to finding, developing, and implementing emerging alternative treatments with any potential to offer healing rather than treading water in the status quo while Veterans continue to struggle and die.

Without this, we'll continue down our tragic path of polypharmacy where too many Veterans experience minimal temporary relief and brutal side effects, fail to get the care they need, get stuck with unfortunate labels like "treatment-resistant," and eventually, they stop showing up. Not because they don't care, but because they've lost hope. This is the moment many begin to seek alternative therapies outside the system, some legal, some not. And this is also the moment where innovation must meet them. It is wrong that so many Veterans have been forced to leave the country they served or risk criminal penalties to access life-saving treatments when they have exhausted all other options. Our great nation should be able to create a better system than this. There must be a path ahead that isn't just the status quo, take more pills, and 'keep on keeping on.'

Veteran Innovation: Solutions We Built When the System Failed

Out of desperation, Veterans have been building something different: emerging therapies delivered with clinically rigorous models of care and Veteran-led wraparound services. For Andrew and me, it started with a neuro-restorative protocol from Millennium Health Centers when nothing else worked. He got off all 13 medications. It saved his life. In 2015 we founded one of the first post-9/11 nonprofits focused on TBI and PTSD and partnered with Dr. Mark Gordon to help hundreds more. Sometimes, that still wasn't enough.

In 2018, after Austin's suicide attempt, he went to Dr. Martin Polanco at The Mission Within in Mexico for 5-MeO-DMT, a short-acting psychedelic that gave him just enough breakthrough to hold on. Weeks later, I began my own journey with 5-MeO-DMT and ibogaine - another very powerful, long-acting psychedelic medicine. To be clear, these psychedelic therapies are not without risk; they require careful screening, clinical oversight, and real preparation and integration work. In the case of ibogaine, due to cardiac risks, constant EKG and medical monitoring are required. These are not one-size-fits-all, not safe or appropriate for everyone, and not a panacea or cure all; however, for me, it was one of the most profound experiences of my life - clearing my mind, reconnecting me to my faith in Christ, restoring my health, and giving me the will to fight for others.

Across the country, Veterans have risen from the ashes to form new organizations helping our brothers and sisters access psychedelic therapies, transcranial magnetic stimulation (TMS), hyperbaric oxygen, ketamine therapy, stellate-ganglion block, and whole-health care, with wraparound peer-led and ongoing community support for Veterans and their families. Through the Veteran Mental Health Leadership Coalition, where I serve as Director of Operations under Lt Gen. Martin R. Steele, USMC (Ret.), we've united Veterans, families, clinicians, researchers, and mission-aligned partner organizations on the front lines of the crisis to educate and advocate for emerging therapies and improved models of care - informed by lived experience and contributing to a growing body of research.

Notably, observational study reports demonstrate fast-tracked, robust improvements across PTSD, depression, anxiety, suicidal thoughts and behaviors, anger, and substance misuse following ibogaine and 5-MeO treatment in Veteran cohorts [77-80]. Importantly, these Veterans also reported, consistent with my own experience, improvements in cognitive flexibility, meaning and purpose, connection to oneself, others, the world, the divine, and reduced moral injury [77-81]. Veteran-focused studies with psilocybin are yielding similarly positive results. Unfortunately, last year, the FDA declined to approve MDMA-assisted therapy after two Phase 3 trials with incredibly strong results based on agreed upon FDA endpoints - which we believe was the wrong decision and a tragic setback for Veterans and other PTSD patients.[1]

While today's hearing is about "Alternative Therapies" - which could describe most anything outside of the VA's standard polypharmacy - this is a phrase that often carries stigma. When it comes to psychedelics, I prefer emerging or breakthrough therapies, as nearly every major psychedelic - MDMA, psilocybin, DMT, LSD, ibogaine, 5-MeO-DMT, methylone - are in FDA-regulated trials; and six have FDA Breakthrough Therapy designations, indicating they might be significantly more effective than our current options for specific conditions. The Breakthrough Therapies include MDMA-assisted therapy and methylone for PTSD; three different psilocybin therapies for depression; and an LSD-based drug for generalized anxiety disorder. Generally, these psychedelic therapies show the potential to provide rapid and robust improvements in symptoms across various mental health conditions (e.g. PTSD, depression, anxiety, substance use disorders) - when used under careful conditions with preparation, clinical oversight, and integration - and they can facilitate meaningful durable changes in behavior and functioning. They are particularly promising for patients who have not benefited from existing treatments.

Despite the promising results, psychedelic therapies face burdensome regulatory barriers to research and cannot be accessed under the Right to Try Act passed by President Trump in 2018. The minimal federal funding to research these psychedelic therapies is even more difficult to understand, particularly for those designated Breakthrough Therapies for PTSD and depression. The VA has provided a grand total of $1.5 million for a single study of MDMA-assisted therapy to treat Veterans with comorbid PTSD and alcohol use disorder. How has the VA not been leading the charge here? Why have they not been supporting this research at a large scale? This minimal funding is inexcusable given the VA's $980 million annual research budget and how many years into promising research we are with these interventions.

We appreciate the VA has taken some steps to launch an Integrated Project Team and identify gaps in research and implementation,[2] yet the lack of funding and resources to carry out this work

[1] https://www.reasonforhope.org/post/reason-for-hope-vmhlc-submit-comments-for-mdma-drug-application-to-fda-advisory-committee; https://www.reasonforhope.org/post/reason-for-hope-and-vmhlc-provide-comments-to-reagan-udall-foundation-for-the-fda-on-advancing-treat

[2] https://www.ptsd.va.gov/professional/articles/article-pdf/id1643192.pdf

equates to a lack of progress and preparedness for FDA approval, and a continued complacency with the status quo.[3] Seeing the slow uptake for similar FDA approved treatments including esketamine (Spravato) for treatment-resistant depression and 0ff-label ketamine therapy, we know this process may be painful.[4]

States Lead While Washington Lags

In contrast to VA complacency, across the US, states have been stepping up where federal leadership has lagged, largely thanks to the tireless efforts of our coalition members and partners:

- Texas recently passed legislation to allocate $50 million for ibogaine drug development trials and has invested $2 million for a psilocybin trial for Veterans with PTSD, led by our Chief Science Officer, Dr. Lynnette Averill at Baylor College of Medicine.
- Illinois appropriated $6 million for a Breakthrough Therapies for Veteran Suicide Prevention Program to support MDMA and psilocybin research.
- Maryland appropriated $1 million in funding to its Post-Traumatic Stress Disorder and Traumatic Brain Injuries Alternative Therapies Fund for Veterans, which should soon be funding research of MDMA-assisted therapy comparing group versus individual treatment protocols.
- Connecticut appropriated $2 million for a transdiagnostic open label trial of psilocybin prioritizing treatment of Veterans.
- Arizona invested $3 million into clinical trials of natural psilocybin mushrooms and is allocating $5 million for ibogaine trials.
- Georgia appropriated $1 million to Emory Healthcare Veterans Program for PTSD treatment and wrap-around services for Veterans and their families, which is intended to fund a trial of MDMA and/or psilocybin with prolonged exposure therapy.
- The state of Washington appropriated $2 million to the University of Washington for clinical research of psilocybin therapy for substance use disorder treatment

Still, this funding pales in comparison to the significant federal investment that we believe is warranted based on the clinical potential demonstrated through existing research, including real-world studies.

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[3] The Department of Defense has granted $10 million (split between two grants) for MDMA-assisted therapy clinical trials for active-duty servicemembers through the Congressionally Directed Medical Research Program Psychedelic Treatment Research Clinical Trial Award (established via Section 723 of the National Defense Authorization Act for FY2024), with an additional $5 million granted for a study of MDMA-AT including Veterans and civilians through a different grant mechanism.

[4] Despite FDA approval of esketamine in 2019 - and a directive from the Trump Administration urging VA use - only 15 Veterans had received esketamine in the first year. By the end of FY2023, available reports suggest approximately 1,800 Veterans have received ketamine or esketamine treatment. While uptake is growing, this remains staggeringly low given the immense need and the scale of the suicide crisis. Psychedelic therapies will likely prove even more challenging to implement - though we are optimistic they will lead to more robust and durable improvements for many patients, with lower abuse potential.

Words Are Not Enough: Veterans Need Action Now

While we are disappointed in the pace of federal progress, we appreciate the recent supportive statements from leaders in the Trump Administration. HHS Secretary Kennedy has publicly stated his team is working to provide Veterans access to certain psychedelic therapies "within 12 months." VA Secretary Collins has repeatedly expressed support for psychedelic research - including during hearings, on social media, and in internal Cabinet discussions. He has also expressed his support for Veterans accessing these treatments under Right to Try, while voicing frustration with regulations standing in the way.

However, at this point, words are not enough. Lives are on the line and we need action.[5] Hopefully, we all agree that Veterans should not be forced to travel abroad or risk breaking the law to access care that could save their lives. But given the slow pace of progress so far and how overwhelmed the VA is just to keep up with current patient demands, we're more than a little concerned about the path forward. We are committed to working with Congress and the VA to help any way we can - because we cannot continue down the same path.

Finally, to reduce the VA's reliance on polypharmacy, we need to do more to advance access to the most promising non-medication emerging treatments. Many Veterans have greatly benefited from neuromodulation such as transcranial magnetic stimulation (TMS), a non-invasive treatment that uses magnetic pulses to help reset brain circuits involved in depression and other conditions. The VA covers TMS for treatment-resistant depression, but access remains limited with many clinics not having the necessary training or equipment; and we've received many complaints from Veterans about challenges they've encountered getting referrals for community care. Since the standard course of treatment requires daily clinic visits over 6 to 9 weeks, access is nearly impossible for Veterans in rural areas or who do not live near a clinic offering this treatment. Even for those nearby, the time commitment can be a major barrier for Veterans balancing work, family, and other obligations.

A newer accelerated approach, called SAINT (Stanford Accelerated Intelligent Neuromodulation Therapy), uses fMRI brain imaging to pinpoint the best spot to stimulate and delivers a full course of treatment in just 5 days. In a major clinical trial, roughly 80% of people with hard-to-treat depression went into remission, compared to just 10% on a sham treatment. SAINT's mean time

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[5] The Trump Administration has brought in capable subject matter experts including Dr. Mike Davis as FDA Deputy Director for the Center for Drug Evaluation and Research and Matt Zorn as Deputy General Counsel for HHS. And the VA has its own very capable experts, including the VA's witness for today's hearing, Dr. Ilse Weichers, who we appreciate for working to move things forward. We hope to see the expressed public support and expertise of the Trump Administration swiftly translated into meaningful progress for Veteran access to these emerging therapies.

to remission is an astonishingly fast 2.6 days, with efficacy also shown for acute suicidality, offering a potential rapid-response intervention in psychiatric crises. However, despite a prior Breakthrough Device designation, full FDA clearance, and coverage by Medicare and (more recently) Federal Blue Cross, SAINT is not currently offered at any VA facilities or reimbursed through community care.

There are additional accelerated protocols under investigation that seek to further condense TMS treatment into a single 9-hour day, paired with medications that temporarily boost neuroplasticity. Early results are promising, suggesting a one-day TMS protocol is safe and potentially more effective than standard treatment. Assuming the research holds up in more rigorous controlled trials, this would be a significant breakthrough for real-world access by reducing logistical burdens on patients. Given the promise of neuromodulation protocols like these, there is no excuse for the VA to not be front and center, supporting this research and rolling out scalable TMS care and coverage within the VA and their care networks.

Policy Roadmap: What Congress Can Do Today
Below are some concrete steps Congress and the VA can take to expand access to these emerging therapies and begin turning the tide on the Veteran mental health and suicide crisis:

- Dramatically expand federal funding for psychedelic therapy research and implementation including:
    - Public-private partnerships to accelerate potential FDA approvals.
    - Investigator-initiated trials to inform optimal methods of treatment delivery, including use of group therapy and peer support; and transdiagnostic studies that are more inclusive of high-risk/complex patients to improve real-world generalizability.
    - Utilize a diverse mix of sites in as many states as possible, including rural locations.
    - Prioritize Fox Suicide Prevention Grant funding to new (previously unfunded) VSOs with established programs that provide wrap-around services for psychedelic therapies, including preparation, integration, and peer support services.
- Expand adoption of esketamine and off-label ketamine therapy across additional VA facilities for depression, related mental health conditions, and suicidality. Ease the barriers to community care referrals for those who do not live near a VA facility offering this treatment.
- Establish a formal access pathway under the Right to Try Act, allowing qualified physicians to offer eligible investigational psychedelic therapies to patients with terminal or life-threatening conditions (such as un- or under-treated PTSD, depression, and

suicidality) who have exhausted other options and are unable to participate in clinical trials due to strict eligibility criteria,

- Support accelerated approval of MDMA and psilocybin through the FDA's recently established National Priority Review Voucher program, with appropriate REMS requirements to ensure safety and post marketing data collection requirements to better assess durability and adverse events.
- Reduce step-therapy barriers that require Veterans to "fail first" on multiple ineffective medications (often from the same class) before gaining access to alternatives.
- Fund comparative trials of standard TMS with accelerated protocols including SAINT and one-day TMS; ensure insurance coverage for proven accelerated treatments; and invest in the equipment and infrastructure to make these life-saving options available to those most at risk, including in rural settings.
- Establish an emerging therapies task force comprised of VA experts, VSOs engaged in relevant work, and Veteran stakeholders to identify the most promising additional emerging therapies for functional improvement across the spectrum of invisible wounds of war (e.g., other novel psychedelic medicines, neuromodulation, neuro-restorative protocols, hormone restoration, moral injury-targeted programming, integrative wellness approaches), and develop a plan to accelerate adoption of those treatments that includes direction of the DVA Office of Research Oversight and the DoD Congressionally Directed Medical Research Programs (CDMRP) to launch and maintain a federally supported pilot programs mechanism in which these emerging therapies can receive priority funding for initial investigation.
- Support outcomes-based reimbursement models that account for functional improvement, not just symptom reduction.

Closing: Answering Veterans' and Families' Prayers

For me, this hearing is about much more than just separating fact from fiction on Alternative Therapies. I'm grateful to offer recommendations informed by a mix of expertise within our coalition; however, I didn't come here today as a policy expert. I'm here as a Veteran who nearly lost both of his brothers, who spent years watching others fall through the cracks, who experienced my own significant trauma, and who finally had to choose between staying silent or doing something. For me, this hearing is about exploring the full picture of how the system has let so many Veterans down, and how Veterans have been forging a new path to reclaim their lives and help their fellow Veterans - including through the use of various emerging therapies. This hearing is about how we can bring the system along to embrace necessary change, break out of the status quo, and work together to save Veteran lives.

What remains is partnership. If we walk this next part together, we can make real change not just for Veterans, but for the future of mental health itself. I've provided many additional details below that I hope will prove helpful:

- **My Journey and Insights: From Family Crisis to National Advocacy**
  - The Breaking Point: When Every Option Failed
  - Psychedelic Therapies: Lives Saved and My Faith Restored
  - Veteran healing programs and insights: group therapy, peer support, and the importance of family
  - Stronger Together: About VMHLC and Acknowledgements
    - From Lived Experience to Advocacy
    - Partnerships that Drive Change
- **Psychedelic Research and Regulatory Barriers Snapshot**
- **References**

Senators, my father's prayers were answered when his sons came home from war. Many families are still praying for their Veteran to come home-physically, mentally, emotionally, spiritually, and morally. It's time their prayers are answered.

May God bless you, our great nation, and the Veterans and families who fought for our freedoms. Thank you.

APPENDIX

My Journey and Insights: From Family Crisis to National Advocacy
In 2015, my older brother, Andrew, a decorated Green Beret, was spiraling from combat-related brain trauma. I turned down a promotion to Major and an MBA at Rice to help save his life. Together, we launched the Warrior Angels Foundation to give Veterans access to the Millennium Protocol, developed by Dr. Mark Gordon. This approach targeted the hormonal and inflammatory damage caused by TBI, and it saved my brother's life. So, we focused on finding ways to get more Veterans like him access to this treatment through our nonprofit work.

The efforts of our lived experience and this protocol are best captured in episodes #700 and #1056 of The Joe Rogan Experience, where Andrew and Dr. Gordon were guests. It's also documented in our bestselling book, *Tales from the Blast Factory: A Brain-Injured Special Forces Veteran's Journey Back from the Brink,* and the Oscar-qualified and award-winning documentary, *Quiet Explosions: Healing the Brain.*

The Breaking Point: When Every Option Failed
We quickly learned a core truth: trauma is layered and so is healing. Sometimes, what we were offering wasn't enough. More tools were needed. In 2018, my younger brother, an Infantry combat Veteran, attempted to take his own life. We had exhausted every conventional option, but the pain was still too great, despite the biological interventions we tried. We needed something immediate.

That's when family friends retired SEAL Team 6 Operator Marcus Capone and his wife Amber - later the cofounder of Veterans Exploring Treatment Solutions (VETS) - came to our home. He sat with my mother, a devout Christian who had sent her sons to war and nearly lost all of them, not on the battlefield, but from the invisible wounds of war at home. He shared his story and spoke of his own life-saving intervention with a naturally occurring medicine derived from the iboga shrub in West Central Africa, called ibogaine. He told my mother that when everything else had failed him, this treatment gave him the rest and spiritual connection he needed to overcome his trauma. He assured her that he would escort my brother to Mexico, where the treatment would be administered safely under the care of a physician, with clinical oversight, and that it had been highly successful for Special Operations Veterans.

It wasn't easy to accept. But when all the other doors had closed, this one opened.

Sometimes, the only thing powerful enough to break through the darkness is a transformational experience-one that restores identity, renews the spirit, and reconnects a person to life.

Psychedelic Therapies: Lives Saved and My Faith Restored
After years of carrying the burden of others' healing, I reached my own breaking point shortly after saving my younger brother's life, administering first aid after his suicide attempt. I was emotionally exhausted, spiritually disconnected, and physically falling apart. I had helped build a nonprofit to serve Veterans in crisis with TBI through biological interventions. I had walked alongside my brothers through their trauma, trauma that nearly claimed their lives. But somewhere

along the way, I lost myself. The corporate consulting job that paid the bills had become a toxic environment. The mission that once gave me purpose was now consuming me.
That's when I took the step I never thought I would: I sought treatment for myself, because the brother I helped through his worst experience three years earlier was now there to help me through mine.

The Mission Within: A Veteran's Path to Healing with Ibogaine
When I underwent ibogaine treatment outside the U.S., under full clinical care, I had no expectations. I was burned out, disconnected from my body, my spirit, and my mission. The experience wasn't recreational; it was a reckoning I felt ill-prepared to face, but I was desperate.

Ibogaine is a powerful medicine that requires rigorous medical screening and monitoring due to its cardiotoxic potential. At The Mission Within, all participants are evaluated by a cardiologist and undergo EKGs, echocardiograms, complete lab work, and urinalysis before treatment. This high clinical standard made it possible for me to enter the process safely.

Guided through a structured protocol, I confronted long-buried memories and unresolved trauma. It wasn't euphoric. It was demanding, humbling, and deeply personal. But in the days that followed, supported by 5-MeO-DMT-a compound known to support emotional catharsis and spiritual renewal-I felt a complete rejuvenation of hope, joy, and a reconnection to my faith in Jesus Christ. This was not just about relieving symptoms-it was about confronting the deepest wounds of moral injury. Psychedelic-assisted therapy allowed me to revisit traumatic memories from an expanded perspective, no longer trapped in cycles of shame or self-condemnation. For the first time, I experienced forgiveness and compassion for myself and others. These therapies opened a path toward restoring moral clarity and spiritual connection-dimensions of healing that conventional treatments had never touched.

What unfolded was a profound reset-a reordering of thought and emotional patterns long distorted by trauma and chronic stress. The clinical care and coaching I received were thoughtful and professional. Integration support was offered, and the community was present. But even within that container, I found myself back in a corporate boardroom just one week later, trying to deliver for a new client while silently struggling to process what had just occurred.

At the time, I didn't know how to ask for more help. I mistook that need as a weakness or worse, as a disservice to the facilitators who had supported me so well. So, I stayed silent, even as the pressure mounted, later discovering how common this is within the quiet, professional culture of the military.

Transformation, Healing, Reconnection and Faith
That experience taught me a critical lesson: medicine opens the door, but healing doesn't happen on a clock. True integration can't be rushed, and sometimes, the most profound breakthroughs require more time, space, and support than we know how to ask for—something we now call wraparound services. These services provide continuous, holistic care that supports not just the physical and emotional aspects of healing, but also the spiritual, social, and psychological needs of individuals.

I am deeply grateful to Dr. Martín Polanco and The Mission Within—not only for helping save the life of my younger brother but for helping me reorient toward my Christ-centered, humble, servant-driven purpose that I had nearly lost. Their care, courage, and commitment created the conditions for transformation and set me on a path I'm still walking today, and I have even become the Chaplain of my American Legion Post 12.

The Importance of Community Healing
In my experience, one of the most vital aspects of healing for Veterans is the opportunity to heal alongside other Veterans. In 2023, I had the privilege of serving as a peer support facilitator during a groundbreaking Veteran Group Therapy Study, which was published in *Frontiers in Psychiatry* in 2025. The study, conducted by Imperial College London in collaboration with Heroic Hearts Project (HHP) and Beckley Retreats—both VMHLC partner organizations led by our members Jesse Gould and Neil Markey—focused on the profound benefits of peer-driven therapy for Veterans.

The sense of security and understanding among fellow Veterans created an environment where we could share our stories without fear of judgment or misunderstanding. For many, this was the first time they felt truly understood. The shared language of pain fostered a deep bond and allowed us to face our struggles together, building a foundation for real healing.

Veteran Group Therapy Study Insights
The study revealed that Veteran-focused group therapy, particularly in the context of psychedelic-assisted therapy, had substantial benefits for reducing PTSD symptoms. Key findings included:

- Improved PTSD Symptoms: Veterans who participated in the therapy showed a 50% reduction in PTSD symptoms after just a few sessions.
- Decreased Isolation: 70% of participants reported feeling significantly less isolated after engaging in group therapy with fellow Veterans.
- Increased Emotional Regulation: 60% experienced improvements in emotional regulation and coping mechanisms when sharing their experiences in a supportive, peer-driven environment.

- Enhanced Sense of Understanding: Veterans consistently reported feeling more understood and less judged, which helped them confront deep-seated trauma and reconnect with their sense of purpose.

This highlights the need for more programs that prioritize healing in community, specifically those that center the lived experiences of Veterans. Peer-led models, where Veterans facilitate therapy alongside highly trained professionals (many who are Veterans themselves), are proving to be an essential component of effective treatment, offering the critical balance of professional care and the healing power of shared experience.

My work with the Veteran Mental Health Leadership Coalition collaborating with these various programs, leading clinicians and researchers, and Veterans and their family members with a range of lived experiences, has provided me with rich insight on the future of care delivery.

Beönd Service – A Veteran-Led Model
On Veterans Day 2024, almost 7 yrs after my 1st ibogaine treatment, I was invited to help design a program for Veterans that I wish had existed when I first began my healing journey. The result was *Beond Service* a purpose-built, Veteran-led ibogaine therapy initiative within Beond Ibogaine clinic's medical infrastructure in Cancún, Mexico. This is a mission-first program, created by Veterans for Veterans, rooted in clinical safety, spiritual renewal, and post-traumatic growth.

In its first year, more than 50 Veterans participated in the 9-week program, all at no cost to them, thanks to donor funding and strategic partnerships. The program is rigorous: full medical and psychiatric intake, preparatory coaching, ibogaine-assisted therapy under 24/7 clinical supervision with cardiac monitoring, daily peer-led workshops, and trauma-informed integration. There's also a dedicated Home Base track for spouses and family members, with an alumni activation model to support ongoing reintegration and leadership development.
While Beond's medical and clinical infrastructure is critical, it is the care, the culture, the community, and the sense of purpose embedded in every aspect of the experience that makes *Beond Service* so effective. This is a program generating powerful outcomes and producing an evidence base that will demand reform. However, Veterans must leave the U.S. to access it, which is fundamentally wrong. The very people who fought for this nation should not have to cross borders to find healing.

VMHLC is also committed to ensuring that family is included as part of the healing process. Over the last several years, there has been an increasing recognition of the critical role of educating and supporting spouses and family members as Veterans go through these often challenging and transformative programs, with increased programming to help meet this critical need. For example, The Hope Project (now part of Heroic Hearts Project), led by Allison Wilson (spouse of Navy SEAL Johnny Wilson), provides trauma-informed peer support, counseling, retreats, and wellness

programming tailored specifically for military spouses. In addition, Beond Service offers a nine-week, cohort-based ibogaine therapy Spouse Program, along with an At-Home Healing Partner track that integrates functional medicine, nutrition, mindfulness, and peer-led support. These programs allow spouses to pursue their own healing journey while equipping them with tools to support their veteran before, during, and after treatment. Together, they demonstrate that sustainable recovery is achieved when the entire family system is included in care.

The groundbreaking programs and studies we've discussed - including from Warrior Angel Foundation, The Mission Within, Heroic Hearts Project, Beckley Retreats, VETS, and Beond Service - reflect just a portion of the innovation happening within the Veteran community. While research and clinical breakthroughs continue to unfold, the driving force behind these new models of care has always been Veterans themselves. When the traditional system failed to meet the needs of our community, Veterans stepped up.
Veterans have also stepped up to lead advocacy for expanded research and access to these therapies in the United States, so we are not forced to leave the country or break the law to save our own lives.

The Rise of a Unified Coalition
In 2022, a core group of leaders - each representing organizations that had been working tirelessly out of necessity - came together to unify our efforts. Under the guidance of Lieutenant General Martin Steele, USMC (Ret.), CEO of Reason for Hope, what began as an informal collaboration evolved into the Veteran Mental Health Leadership Coalition (VMHLC). Led by General Steele, VMHLC is a national alliance of Veterans, family members, clinicians, researchers, nonprofit leaders, and mission-aligned organizations on the frontlines of the Veteran mental health crisis.

Our work includes education and advocacy to advance the future of Veteran mental health care, with a focus on increasing research funding for psychedelic and other emerging therapies, reducing barriers to innovative treatments and community-based care, expanding the use of peer support and group therapy protocols, improving training and infrastructure, and decreasing reliance on polypharmacy.

From Lived Experience to Advocacy
Many of our members - myself included - are Veterans who have had to seek healing abroad through psychedelic therapy, a reality we consider unconscionable. However, our membership reflects a broad range of healing experiences, including transcranial magnetic stimulation (TMS), hyperbaric oxygen therapy, ketamine, cannabis, and stellate-ganglion block (amongst others), as well as those who have lost loved ones who may have benefited from these tools. Gary Hess, VMHLC's new Director of Advocacy and Peer Support, a USMC Veteran and founder of Veterans Alliance for Holistic Alternatives, embodies the range of lived experience turned to leadership of our members.

It should be no surprise that when Veterans (or anyone else) find something that works - particularly when it's unconventional and we're told it's unavailable - we become passionate advocates to expand access for those in need. Especially as it relates to accessing psychedelic therapies, this passion has led to a diverse mix of often strongly held policy views, with many of our members playing leading roles around the country pushing for various legal reforms to expand access under state laws. While such policies fall outside the scope of our coalition's collective advocacy focused on research and federally legal compassionate and medical use, we respect the different paths our members have taken toward healing and honor the leadership roles they have played in advancing change nationwide.

I firmly believe that, as long as Veterans are informed of the potential risks - both health and legal - they should be trusted to seek their own path to wellness. Sometimes the system simply moves too slowly, especially when every other option has been exhausted.

Maintaining a coalition with such diverse and deeply held beliefs is no small challenge, but it is one we embrace - and one that has been personally and professionally rewarding for me. Our only real requirement is mutual respect and compassion for each other's humanity.

The coalition's ability to hold space for such a broad range of perspectives is, without question, a testament to General Steele's long career of values-based leadership - marked by honor, integrity, and an unwavering commitment to those who serve. As a decorated combat Veteran who rose from enlisted Marine in Vietnam to three-star general, General Steele faced significant reputational risk and had little to gain personally in coming out of retirement to engage in this work. Yet his record shows a long history of being on the leading edge of Veteran mental health care. In this case, his bold leadership has helped raise millions of dollars for psychedelic therapy research, Veteran programs, and advocacy - including from an older generation of philanthropists unfamiliar with these treatments - and he has been instrumental in securing millions more in government funding for Veteran-focused studies. In true General Steele fashion, he has never sought the spotlight or made it about himself; it is always about taking care of the Veteran and their family.

I also want to acknowledge the exceptional partnership and support of General Steele's team of experts at Reason for Hope - a team united by the tragic loss of loved ones to suicide - including Brett Waters, Esq., Lynnette Averill, PhD, and Jesse MacLachlan; as well as Gary Hess, VMHLC Director of Advocacy and Peer Support. Their policy, research, and advocacy expertise has been invaluable to my testimony and our strategic work to advance critical legislation for Veteran-focused research funding and regulatory reform. I am also grateful for the insight and support from Ryan Roberts and his organization, The Journey Home, a VMHLC partner advancing the national conversation on moral injury through Veteran-led coaching, research, and community-based healing frameworks.

Partnerships That Drive Change
Today, VMHLC includes over 100 leaders and 50 partner organizations throughout the country who have spent years tackling this issue from various angles, driven by the urgency of the crisis and the unmet needs of our communities. Many of our advocacy partners are newer state-based organizations such as Texans for Greater Mental Health (led by Logan Davidson), who played a leading role in securing historic funding for psilocybin and ibogaine research in Texas, and the Nevada Coalition for Psychedelic Medicine (led by Navy SEAL Veteran Jon Dalton), who led the effort to pass a state resolution urging various federal research and regulatory reforms. The VMHLC provides infrastructure to bridge individual efforts and ensure we become more than the sum of our parts, so we can elevate our shared goals to save and improve lives.

The Impact of Collaboration and Partnerships
VMHLC is now a leading voice shaping national and international conversations on Veteran mental health and emerging therapies. We have now testified multiple times before Congress and before various state legislatures throughout the country, while leading U.S. engagement in policy initiatives from Canada to the Czech Republic. Our coalition and our individual members and partners have played critical roles unlocking research funding (as outlined above) and driving regulatory reforms, including reducing barriers to research and FDA approved treatments. We appreciate the support from a growing number of leading national veteran organizations who have helped accelerate this momentum, ranging from our coalition partners the Navy SEAL Foundation and Grunt Style Foundation, to Iraq and Afghanistan Veterans of America, Disabled American Veterans, Veterans of Foreign War, and The American Legion, where I serve as co-host of the national Tango Alpha Lima podcast.

In 2023, The American Legion's National Executive Committee passed a landmark resolution on emerging therapies, urging Congress and the VA to support various psychedelic research and clinician training; and I have twice participated in related briefings at the national convention as part of the Be The One Summit.

Psychedelic Research and Regulatory Barriers Snapshot
Psychedelic medicines and assisted-therapies have shown rapid, robust, and durable effects across multiple trials led by premier academic institutions across the world, with generally favorable safety profiles and low risk of abuse. These interventions represent one of the most promising advances in decades, specifically for the signature injuries of war. The wildly delayed pace, limited funding support, and lack of strong top-down support for this research within the VA is inexcusable as the evidence is highly promising specifically in all of the priority mental health domains for Veterans.

Current Evidence Base

- Esketamine – FDA-approved for treatment-resistant depression and suicidality; ketamine used widely off-label; decades of research confirm rapid anti-suicidal and antidepressant effects. Yet, only a small fraction of eligible Veterans have received these treatments inside the VA, despite strong safety and efficacy data and Veterans struggle to get a referral for treatment with a community care partner.
- MDMA-Assisted Therapy – Phase 3 trials demonstrate large, durable effects for PTSD.
  Psilocybin – Phase 2 and 3 trials for major depression show rapid and long-lasting symptom reduction after 1–2 doses; trials underway for PTSD, substance use, and end-of-life anxiety; three FDA Breakthrough Therapy Designations
- Methylone – Phase 2 and 3 trials for PTSD are underway; FDA Breakthrough Therapy Designation
- LSD – Phase 2 and 3 trials underway for Generalized Anxiety Disorder; FDA Breakthrough Therapy Designation
- Ibogaine – Strong observational data in Veteran and international populations suggests dramatic effects on PTSD, depression, suicidality, and OUD. Controlled U.S. clinical trials are urgently needed.
- 5-MeO-DMT – Early phase trials show promise
- Overall – Across compounds, the evidence consistently points to rapid symptom reduction, improved quality of life, and potential life-saving effects for those who have not responded to standard care.

Regulatory Barriers and Federal Progress
Despite the promising results, because most psychedelic compounds remain classified as Schedule I controlled substances, they face the most restrictive barriers to research, and federally legal access in the United States is generally limited to clinical trials.[6] The recent passage of the HALT Fentanyl

[6] Currently, DEA is considering a petition to reschedule psilocybin to schedule II, which was recently transmitted to HHS for a scientific and medical review and scheduling recommendation.

Act reduced some of these barriers to more closely align Schedule I and Schedule II research requirements, which we appreciate, but overall, the barriers remain significant.

Additionally, there remains no mechanism under the Controlled Substances Act to administer these Schedule I breakthrough therapies under the Right to Try Act (passed by President Trump in 2018), even though they qualify as "eligible investigational drugs" under the law. This is a tragic flaw in our regulatory system that defies Congress' and President Trump's clear intent to empower patients with terminal or life-threatening illnesses who do not qualify for clinical trials to have access to these interventions.

These therapies are not fringe science - they are supported by leading medical institutions, published in top-tier journals, and endorsed by the FDA through Breakthrough Therapy designations. For Veterans, they may be the difference between life and death.
We must act now. The VA has both a moral and scientific obligation to support and expedite this research, build the infrastructure, and prepare for clinical implementation. In the vast majority of cases, at worst, these therapies are life-improving. At best, they are life-saving.

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Hyperbaric Oxygen Treatment of Traumatic Brain Injury, Post Traumatic Stress Disorder, and Spinal Cord Injury

Testimony Before the U.S. Senate Committee of Veterans' Affairs, August 22, 2025
James K. Wright, MD, Col, USAF (Ret)

Thank you for allowing me to give some information to the Committee of Veteran's Affairs on hyperbaric oxygen treatment for neurologic injuries in veterans.

Hyperbaric oxygen treatment (HBOT) is the delivery of 100% oxygen to a person in a pressurized chamber and is used as a treatment for certain diseases and conditions. Oxygen levels 7 to 14 times that achieved by breathing room air are possible. The therapy affects more than 8100 known human genes and thousands of cellular processes and is effective in treating a variety of conditions from neurologic injury to chronic wounds.

Hyperbaric oxygen has been used as a treatment for brain and nerve injuries for 89 years since it was first described by Dr. Albert Behnke in the US Navy for the treatment of the brain and spinal cord injuries in decompression sickness. Since then, it has been used for a variety of brain and nerve injuries such as decompression sickness, carbon monoxide poisoning, stroke, post-concussion syndrome, traumatic brain injury, PTSD, depression, chronic pain syndromes, post COVID illness, and narcotic addiction recovery.

It is useful to think of the actions of hyperbaric oxygen treatment as occurring in four ways in brain and nerve injury.

1) Hyperbaric oxygen provides oxygen to damaged areas of the brain and spinal cord which don't have enough oxygen present to function or heal.
2) It promotes up-regulation and synthesis of growth factors which cause the ingrowth of new blood vessels, nerve axons to reconnect, and damaged tissue to heal.
3) It is a potent suppressor of inflammation which is a component of TBI, PTSD, depression, anxiety, and other neurologic disorders.
4) It acts directly on nerve cells in the brain and spinal cord to suppress pain and enhance normal function.

In treating TBI and PTSD, hyperbaric oxygen has had remarkable results over the past 20 years. It is universally effective – few, if any, recipients fail to improve, and many are made completely well from debilitating injuries. Brain function and cognition is improved, even after decades of TBI or PTSD. Depression scores are reduced by 39% and suicidal ideation is usually abolished. Quality of life and everyday function is improved, medication requirements are reduced, and chronic pain is also reduced. These results are long lasting or permanent after a single series of 40 treatments, though some veterans require more treatment depending on the severity and length of illness.

To date more than 30,000 individuals with TBI and/or PTSD have received hyperbaric oxygen treatment in the US, with nearly universal improvement. More than 12,000 of these individuals were veterans. Of all these people, we are only aware of two suicides in the last 15 years. That is a remarkable achievement. In Israel, more than 40,000 individuals have received hyperbaric oxygen treatment for TBI and PTSD with similar results. There it has become part of the standard of care. The use of hyperbaric oxygen treatment for spinal cord injuries is in its infancy in the US, but results so far have shown the similar benefits as in TBI and PTSD, as well as the halting of functional deterioration and the improvement in function in a few cases, especially early after injury.

As a solution, I propose that hyperbaric oxygen treatment be made immediately available to our veterans with TBI, PTSD, and spinal cord injuries. The huge quantity of case reports as well as numerous randomized controlled studies speak to the utility and safety of the treatment, as well as providing more than enough evidence of efficacy for approval as part of the standard of care. It would be well to ensure established safety protocols are strictly adhered to, and that all treatments are directed by properly trained physicians in approved chambers. Additionally good record keeping would validate the utility of these treatments. Finally, I recommend that a working group be established to design the implementation of this effort.

Good afternoon, distinguished Senators. Thank you for inviting me to this vital panel. I am Brian Schiefer, a former U.S. Air Force Tactical Air Control Party (TACP) member who served in Afghanistan in 2003 and in Iraq from 2005–2006 and 2006–2007.

In 2008, during a pre-deployment training exercise in California, my life was forever changed after a Humvee rollover accident left me with severe injuries including fractures of my spine at 4 different levels, multiple broken vertebrae, broken ribs, clavicle, and sternum, bilateral pneumothorax, torn shoulder ligaments, a skull fracture, and a severed sixth nerve in my left eye. Stabilized with chest tubes and airlifted to Loma Linda University's polytrauma center, I then underwent a spinal fusion surgery that took 14 hours followed by six weeks in the ICU where I was informed that I had less than a 1% chance of ever walking again.

While it is not possible to distill into 5 minutes my lived experience during the17 years since the accident, I am able to present those aspects that directly inform why I am here today. Despite the VA's various strengths and good intentions, the severity of my injuries equally revealed its limitations for veterans with complex injuries. It is my testimony that had I relied only on the standards of care within the VA, I would not be here today. Refusing to accept defeat, I instead became my own advocate, making it my mission to learn everything about my injuries and their impact on my new life. What ensued was a process of trying and in many cases, unambiguously benefiting from a range of underutilized therapies and activities that were unavailable, unknown or actively discouraged within the VA.

Through redefining my own recovery, I became committed to advocating for innovative therapies leading to my founding of SCI-DI, an organization empowering veterans and others with spinal cord injuries (SCI), traumatic brain injuries (TBI), and neurological conditions.

Despite having only one working eye and arm, my initial hospital-based postsurgical recovery was marked by continued work on my bachelors in International Relations, as well as relentless research on how to improve my condition. My recovery journey continued with five months at the La Jolla VA SCI inpatient unit followed by grueling therapy at the Detroit Medical Center's Center for Spinal Cord Injury Recovery. Measurable progress in my lowers was limited and TBI symptoms—cognitive fatigue, vision issues, and emotional strain from my skull fracture and nerve damage—complicated rehabilitation. In a 2009 ceremony, I was medically retired from active service by PACAF Commander Lt. Gen. Utterback. I then relocated to the Florida Panhandle to adapt to paraplegia, tackling challenges like thermoregulation, hand-controlled driving, and daily tasks—

grocery shopping, cleaning—without proprioceptive feedback, a constant struggle learning to deal with my paralyzed body.

In addition, cognitive struggles were persistent. Despite my medical history of a skull fracture and severely compromised lung function in the immediate aftermath of my accident, my cognitive struggles were attributed to the adjustment to paralysis. Then, in 2010, prompted by TACP colleagues receiving PTSD and TBI care under an Air Force Special Operations Command protocol in Destin, Florida, I secured a formal TBI diagnosis at the VA. This was nearly 2 years post-accident. With this new diagnosis, I enrolled in a hyperbaric oxygen therapy (HBOT) study under Dr. Eddie Zant at his private clinic in Destin. I experienced immediate improvements in cognition, sleep, memory, and relationships, no longer waking in a fog. With over 300 HBOT dives to date, therapeutic benefits include enhanced TBI recovery, tissue healing, and post-surgical outcomes. For years, I traveled to UCLA for surgeries, including shoulder reconstructions and spine procedures. My former TACP team members, who served under me, flew in for weeks to carry me post-op, a humbling act of brotherhood addressing gaps the VA overlooked during my inpatient stay. My experience with UCLA Operation Mend exemplified comprehensive care, as specialists collaborated to address my complex symptoms, setting a gold standard and model for veteran healthcare.

The VA's care, even for basic needs like wheelchairs, seating cushions, catheters and hand controls, has been problematic at best. Procurement often required me to navigate, essentially alone, bureaucratic hurdles for essential prosthetic devices and general medical care. Over the years, there have been situations that required my persistent attention for weeks, months and sometimes even years before resolution. I continue to advocate and push for innovative approaches to ensure no one endures the hardships and misery I've faced, pressing for systemic changes to make VA care more responsive and effective for veterans with complex injuries. Such advocacy includes over a decade of service as a Consumer Reviewer for the Congressionally Directed Medical Research Programs (CDMRP), evaluating grants for SCI, TBI, orthopedic outcomes, and neurological conditions. This role exposed critical research gaps, particularly in the underfunded fields of SCI and TBI with Veterans three times more likely to suffer a SCI than their civilian counterparts.

In 2018, I discovered adaptive scuba diving and working with a small team, pioneered techniques tailored to my needs. Underwater, in a barrier-free 3D environment, I found liberation—reduced pain, better sleep, and relief from TBI-related cognitive fog, akin to HBOT but with the freedom of floating and movement. I now have nearly 100 scuba dives to date. A final example of how I

benefited from an unorthodox therapy is my personal experience with psychedelics. Among the many benefits was an unexpected and remarkable restoration of a sense of connection to my body's lost sensation and proprioception. I noticed less inflammation in my body, improved cognition and sleep and a deeper sense of connection and wellbeing with others around me. This further inspired me to found SCI-DI in 2022, with nonprofit status filed in 2025, to make adaptive diving and innovative therapies like HBOT, psychedelics, noninvasive neuromodulation, and ketones accessible to others.

SCI-DI bridges medical science, adaptive sports, and cutting-edge technology to empower the 294,000 Americans with SCI, including 42,000 veterans, and 17,730 new cases annually. Our team of medical, academic, and military experts collaborates in "skull sessions" to explore bold ideas, from standardizing HBOT protocols to researching psychedelics for inflammation reduction using objective measures like cytokines. Driven by a "don't talk about it, be about it" ethos, SCI-DI partners with institutions like the Lakeshore Foundation and Alabama Brain Lab, leveraging novel neuromodulation devices like BrainBuds and ELVis as new, scalable healing modalities. We continue to pursue grants through CDMRP, ARPA-H, and the DoD that align with our team's interests and skillsets. We've recently spoken at the 2024 and 2025 Aerospace Medicine Association meetings, hosting workshops and talks on neuromodulation, vagus nerve and photic stimulation, and psychedelics, sparking vital conversations with pilots, divers, and aerospace and hyperbaric medicine thought leaders and other consumers at the concurrent Undersea and Hyperbaric Conference.

Although the VA is not currently structured to provide therapies like HBOT or psychedelics veterans should not have to wait for historically slow systemic changes. A way forward is partnering with nonprofits like SCI-DI, which have the expertise and agility to deliver these treatments. For example, voucher systems or VA reimbursement to such organizations would ensure veterans gain timely access to life-changing therapies, bypassing bureaucratic delays.

My journey—from a near-fatal accident to championing alternative therapies was only possible by accessing these very therapies that not only promoted recovery, but flourishing. My experience underscores the urgent need for innovative, accessible solutions for inadequately served veterans with complex injuries. I'm here to share how HBOT, adaptive sports, psychedelics, and non invasive neuromodulation can transform lives, urging this committee to support research, funding, and policies to bridge these gaps for our nation's heroes. Thank you for your time.

Submissions for the Record

Edward R. di Girolamo, PE
Executive Director, HBOT4Heroes.org
CEO, Extivita, Inc., Extivita.org

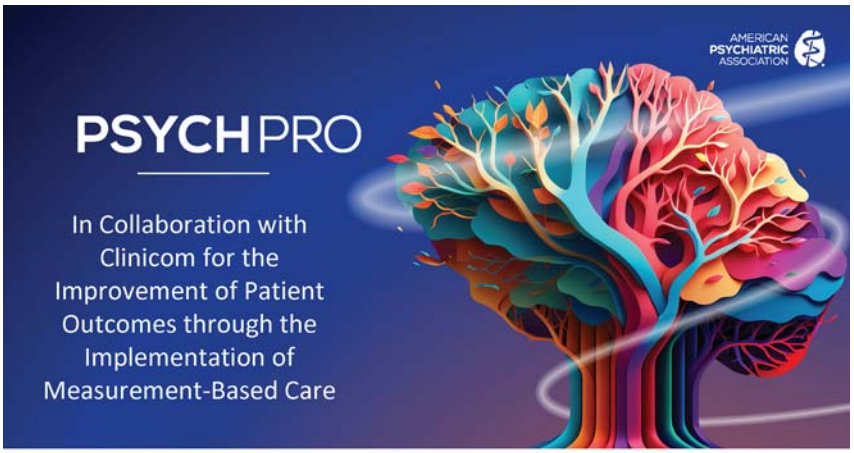
Hyperbaric Oxygen Therapy (HBOT) is a proven, life-saving treatment for veterans suffering from the invisible wounds of war - Traumatic Brain Injury (TBI) and Post-Traumatic Stress Disorder (PTSD). HBOT is not just recent wars but applies to all injured veterans. For more than five decades, far too many of our Vietnam veterans have endured these injuries without access to this therapy, despite overwhelming clinical evidence and real-world success stories our recent war fighters are destine for the same suffering if no action is taken. This is why HBOT4Heroes.org, a 501c3 has stepped up.

At Extivita's Durham location in NC, we provide a multi-chamber clinic where over 9000 thousand hyperbaric treatments to veterans suffering from the war related injuries have been administered at no cost to veterans. We are currently treating approximately 30 veterans during the week - using a standardized 40-session protocol. The results are transformative: measurable improvements in cognitive function, reductions in depression and anxiety, and the complete elimination of suicidal ideation for many. These outcomes mirror the findings of the Treat-Now Coalition, which has documented thousands of veterans successfully treated with HBOT throughout the US.

The cost is a fraction of long-term pharmaceutical and hospital-based care. And yet, the powers that be, continue to delay and leave countless service members to suffer unnecessarily. Every day without action means more lives lost to suicide - lives we have the tools to save right now!

We cannot, in good conscience, allow the next generation of veterans - whether from Iraq, Afghanistan, or future conflicts—to wait 50 years for access to an effective treatment already available in civilian clinics. I urge Secretary Collins and the VA to act immediately: approve and deploy HBOT for PTSD and TBI across the VA system, starting with multi-chamber facilities near major VA hospitals.

The men and women who risked everything for our country deserve timely, effective care - not decades of delay. HBOT is not experimental. It is not "alternative." It is a proven therapy that saves lives, restores families, and honors the service of those who served us.



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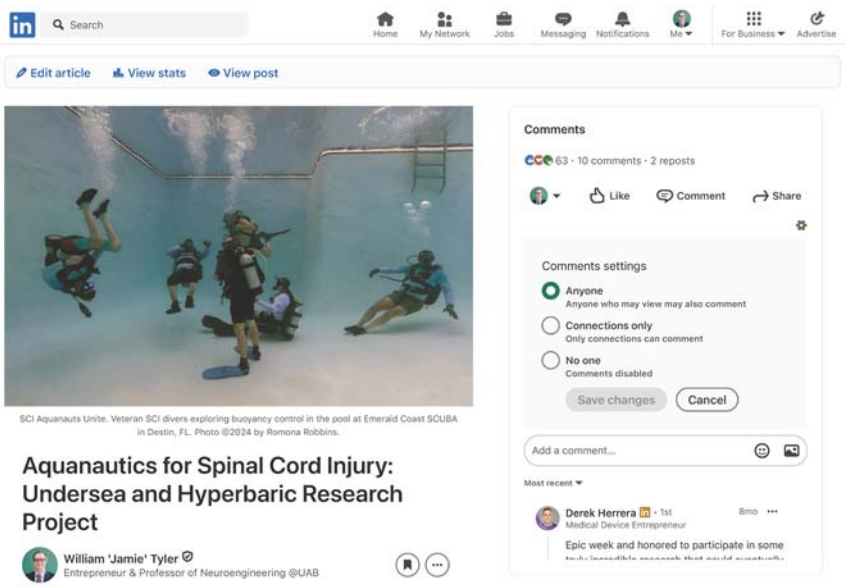


SCI Aquanauts Unite. Veteran SCI divers exploring buoyancy control in the pool at Emerald Coast SCUBA in Destin, FL. Photo ©2024 by Romona Robbins.

Aquanautics for Spinal Cord Injury: Undersea and Hyperbaric Research Project

William 'Jamie' Tyler
Entrepreneur & Professor of Neuroengineering @UAB

September 16, 2024

At the cutting edge of rehabilitation and human exploration, our **Spinal Cord Injury Undersea and Hyperbaric Research Project (SCIUHRP)** aims to bring the world of aquanautics to US Veterans and other individuals with chronic spinal cord injuries (SCI). By pushing the boundaries of undersea (SCUBA) and hyperbaric approaches to healing, this project offers innovative pathways to recovery, improving the health, quality of life, and independence of those with chronic SCI.

Our Mission: Turning Divers into Aquanauts

At the heart of this project is a powerful mission funded by the Combat Wounded Veteran Challenge: to allow veterans and individuals with SCI experience life as aquanauts—explorers of the underwater world—while simultaneously benefiting from cutting-edge rehabilitation approaches. Through innovative undersea and hyperbaric techniques, we aim to unlock new healing possibilities for those with chronic SCI.

SCUBA diving offers more than adventure; it offers therapeutic benefits. We are exploring whether the unique conditions of underwater pressure combined with enhanced oxygen environments—similar to hyperbaric oxygen therapy—can reduce inflammation and support recovery in SCI patients. This initiative blends science, exploration, and hope, offering an opportunity for a better quality of life to those who have been deeply impacted by spinal cord injury.

The Challenge: Diving into the Unknown

The success of this project was made possible by collaboration with several partners who helped push the limits of undersea exploration for our spinal cord-injured, wounded veterans.

We worked closely with Craig Hartzell of Azimuth, Incorporated, leveraging their **Diver6 system** for tracking the GPS positions and dive performance of each diver in real time. Additionally, we recorded physiological data and dive logs using Garmin **Mk2i** and **Mk3i watches**, capturing vital metrics to monitor the safety and well-being of our divers.

We were fortunate to work alongside the dedicated team at Emerald Coast Scuba in **Destin, Florida**, where our participants trained in their pool before heading out to sea. Our open water dives were supported Emerald Coast staff and dive pros aboard the **Aquanaut**, a historic boat featured in the movie *Jaws 2*. We had **Dr. James Wright**, a physician with extensive experience in hyperbaric medicine meet with us to discuss scientific, medical, and technical aspects of HBOT for TBI, PTSD, and SCI. Bert McCasland served as our DSO and we were further supported by experienced physician dive instructors and wilderness medicine experts Drs. Brian Pinkston and Cheryl Lowry. We had further support from experienced DM's Michael Jackson and Hamilton Kinard. Logistics were supported by the CWVC VP of Research, Mr. Reid Carlock.

Veteran SCI diver Brian Schiefer cruising on his DPV through a bait ball being eaten by large amberjacks at the Old Destin Bridge Span dive site near Destin, FL. Photo ©2024 by Romona Robbins.

This groundbreaking initiative was proudly sponsored by the Combat Wounded Veteran Challenge, an organization committed to empowering wounded veterans through adventurous rehabilitation and research projects. All divers involved were disabled veterans with chronic spinal cord injuries, and their courage and determination fueled the success of this first phase of the project. Bringing their special operations backgrounds and attitudes, they worked as true pioneers to establish a framework and approaches to SCI rehabilitation that will end up benefiting many.

Mr. **Brian Schiefer** provided the original inspiration for the project and together we began laying the foundation for the SCI Research arm of CWVC several years ago working from Key West, FL. The entire team's collective expertise and dedication made it possible to turn this long-standing dream into a reality.

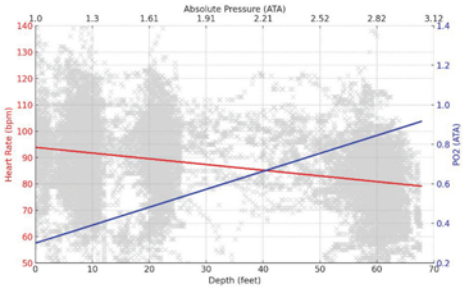
Veteran SCI diver Derek Herrera floating about 3 ATA below the surface on EAN/Nitrox (30% O2). Photo ©2024 by Romona Robbins.

Physiological Insights: Healing Beneath the Surface

Throughout our dives, we monitored several key physiological markers, including heart rate (HR), gas consumption, heart rate variability (HRV), and oxygen partial pressure (PO2). These markers provide insights into how the body responds to diving, especially under increased pressure and enriched oxygen environments.

Veteran SCI divers George Vera and Derek Herrera breathing from a spare Nitrox bottle on an anchor line supported by Drs. Brian Pinkston and Jamie Tyler to increase bottom time and 30% O2 consumption at 3 ATA. Photo ©2024 by Romona Robbins.

The data revealed compelling trends. As depth and pressure increased, we observed a decrease in heart rate, likely driven by the **mammalian diving reflex**, a natural physiological response to conserve oxygen during diving. Additionally, PO2 levels increased with depth, as expected, due to the enriched oxygen and increasing ambient pressure. This aligns with our hypothesis that enriched oxygen may play a role in improving physiological recovery during dives.



The plot shows heart rate data captured using Garmin Mk's across 22 dives by 3 SCI veterans. The data illustrate how HR changes as a function of depth (in feet), absolute pressure (ATA), and partial oxygen pressure (PO2) using Nitrox (30% O2).

BRAIN Buds: Supporting Relaxation and Recovery

In addition to SCUBA, the group was introduced to **BRAIN Buds**, an auricular vagus nerve stimulation device. This innovative technology helps induce relaxation and aids in stress management. BRAIN Buds produce physiological effects similar to the **mammalian diving reflex**, a response seen during SCUBA diving that helps to reduce stress and lower heart rate.

By stimulating the vagus nerve, BRAIN Buds help induce a state of calm and relaxation, making them a natural complement to SCUBA diving. Using BRAIN Buds during rest and recovery periods could further enhance stress management, allowing divers to maximize the therapeutic benefits of their underwater experiences. This synergy between SCUBA and auricular vagus nerve stimulation is an exciting new approach for enhancing rehabilitation and recovery in SCI patients.

Training Outcomes: Certifications and Success

A key objective of the project was to certify our participants in specialized diving techniques. Through their hard work and dedication our divers achieved **NAUI Worldwide Enriched Air Nitrox (EAN)** certification and **PADI Full Face Mask diving certification**. These certifications provide not only a sense of personal accomplishment but also essential safety benefits for future dives. The full face mask certification, in particular, enhances underwater communication, a critical element of safety for spinal cord-injured divers.

Veteran SCI divers Brent South and Brian Schiefer with Jamie Tyler and Hamilton Kinard working on skills training during full face masks dive in Destin, FL.

Next Steps: Advancing Research and Pushing Boundaries

The next phase of our research is set to break new ground. We will focus on using full face masks on spinal cord-injured divers breathing air with different O2 concentrations across depths while keeping the partial pressure of oxygen (PO2) below 1.4 ATA as we aim to minimize the risks of oxygen toxicity and seizure susceptibility while continuing to explore the therapeutic benefits of enriched oxygen in a controlled undersea environment.

Additionally, we plan to track **cytokine levels** in the blood during these therapy sessions, which will allow us to directly measure changes in inflammation and healing markers. This will further solidify our understanding of the therapeutic potential of SCUBA diving for SCI rehabilitation.

Conclusion: Aquanautics as a Path to Recovery

The **Spinal Cord Injury Undersea and Hyperbaric Research Project** is more than a SCUBA challenge—it's a mission to push the boundaries of rehabilitation and recovery. By turning individuals with spinal cord injuries into aquanauts, we are opening new frontiers in both exploration and healing.

Veteran SCI diver Redzuan Razak enjoying his time at depth on 30% O2. Photo ©2024 by Romona Robbins.

The physiological data we've gathered—such as the decrease in heart rate with increasing depth and the enhanced oxygen exposure—supports the idea that SCUBA diving could offer benefits similar to hyperbaric oxygen therapy. As we continue to explore the potential of undersea environments for rehabilitation, we remain committed to pushing the boundaries of what's possible for SCI recovery.

Aquanautics for SCI represents the intersection of adventure, healing, and innovation. We are excited to continue this work, advancing undersea and hyperbaric therapies to improve the lives and rehabilitation outcomes of individuals with chronic spinal cord injuries.

Please reach out to me if you would like to learn more about what we are doing or how you can help.

William 'Jamie' Tyler

Entrepreneur & Professor of Neuroengineering @UAB

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Department of Psychiatry
UPSTATE MEDICAL UNIVERSITY
College Of Medicine

April 30, 2023

To whom it may concern.

I am an Associate Professor of Psychiatry at Upstate Medical University in Syracuse NY, and author of several standardized measurements of psychopathology including the Diagnostic Interview Schedule for Children (NIMH-DISC) and the Columbia Suicide Severity Rating Scale (CSSRS). As measurement expert and active clinician, I am constantly on the lookout for ways to improve the accuracy and efficiency of psychiatric triage and diagnostic assessment.

As Director of the SUNY Student Tele-counseling Network (SUNY-STCN), which provides telepsychiatry services to 56 of the 64 State University of New York undergraduate and graduate campuses we have been using Clinicom for about a year, assessing over 500 new referrals. We find that Clinicom is an accurate and reliable way to triage our students prior to their first appointment; screening for and assessing some 80+ DSM diagnoses. Initially we were cautious in using Clinicom as the claims the technology makes are very lofty. We soon found out that it lived up those expectations. Clinicom empowers our clinicians to focus on the most salient aspects of the assessment and treatments planning and liberating them from routine, rote data gathering.

Using adaptive intelligent assessment of DSM disorder severity scales and diagnoses, as well as the social determinates of health, Clinicom can efficiently and accurately assess the full picture of a patient's presentation, while allowing our clinicians to retain full diagnostic control – reducing false positives and negatives. We started use of Clinicom slowly but soon realized that it could bring bandwidth to our psychiatric tele-psychiatry program psychiatric providers. In addition to using Clinicom to triage our initial student mental health intakes we are now using Clinicom to monitor behavioral health outcomes over time using appropriate follow up assessments on a regular basis. I find use of this tool to promote measurement-based care provides the necessary information to clinicians to make treatment decisions based on standardized ratings of target symptoms.

Students find the experience highly acceptable, with very low rates of non-completion; allowing them to share information in a comprehensive manner and giving them a safe place to disclose sensitive topics. The adaptive nature of the technology allows an accurate assessment to be carried out using the minimum necessary appropriate questions – optimizing time spent. The Clinicom platform can assess very large samples and triage them all automatically, bringing the ability to triage and assess populations within large health delivery systems accurately for their mental health status. Unlike other standardized tools that attempt to assess patients, I believe Clinicom is superior in its capacity, efficiency, accuracy, and quality. Able to be integrated into standard workflows and the electronic medical record, Clinicom also lowers the clinical documentation and administrative burdens of executing high quality care. I strongly recommend Clinicom to any behavioral health organization looking to improve the quality and efficiency of its diagnostic and assessment services.

Yours sincerely,

Christopher P Lucas, MD, MPH.

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Our executives have been repeatedly trusted by Pharma with their most sensitive intellectual property for over 20 years. Our Founder and Chairman, CEO, CMO and VP of R&D, worked together at Harmonex Neuroscience on over 100 clinical studies for Pharma as primary investigators, researchers and research directors, completing a myriad of phase II-IIIB studies. Those studies were undertaken at Harmonex, with the earnings re-invested by our Founder to create the first versions of Clinicom. The clinical research undertaken by these executives has helped bring a myriad of drugs and devices to market; including 23 of the most common CNS drug names listed below.

Clinicom Healthcare CEO Ignacio Handal, is the 2022 recipient of the prestigious 'Christine Pierre Clinical Trials Lifetime Achievement Award'. This has only been awarded 8 times in 21 years.

Hyperbaric Oxygen Treatment of Traumatic Brain Injury, Post Traumatic Stress Disorder, and Spinal Cord Injury

Background Information

James K. Wright, MD, Col, USAF (Ret)

Introduction

This presentation is about hyperbaric oxygen (HBO) and its utility in treating traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), and spinal cord injury (SCI). Hyperbaric oxygen treatment (HBOT) is the delivery of 100% oxygen to a person in a pressurized chamber and is used as a treatment for certain diseases and conditions. Oxygen levels 7 to 14 times that achieved by breathing room air are possible. The therapy affects more than 8100 known human genes and thousands of cellular processes[1] and is effective in treating a variety of conditions from neurologic injury to chronic wounds. At the end of the discussion, I will present some recommendations of how HBOT can be used to treat veterans with TBI, PTSD, and SCI.

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1) History of HBOT in TBI

Hyperbaric air has been used since 1877 to treat decompression illness (DCI) in which the nitrogen bubbles released from a pressurized environment such as diving or caisson work cause neurologic and other symptoms[2]. It was then recognized, but not fully understood, that this use of pressurized air continued to cause improvement in symptoms long after the bubbles from nitrogen release had disappeared.

Hyperbaric oxygen treatment (HBOT) has been used clinically for 89 years since it was first used by the US Navy to treat brain and spinal cord injuries sustained in decompression sickness[3,4]. In 1941, HBOT was adopted by the US Army Air Force for the treatment of altitude decompression sickness[5]. In DCI it was noted that, long after the supposed disappearance of nitrogen bubbles, HBOT was efficacious in treating the neurologic sequelae of DCI in the central and peripheral nervous systems[6,78].

HBOT was used in a variety of brain injuries beginning in the 1960s[9,10]. In Dr. Mogami's series of 51 patients with severe head injury treated with HBO, reported in 1969, half improved, some dramatically[11]. The patients received only one or two treatments and most regressed, though three had permanent improvement. It wasn't until 1985 that a US trial of HBOT in brain injury was reported[12]. At the same time, it was recognized that the neurological sequelae of carbon monoxide poisoning which could appear after CO had been cleared were treatable with HBOT[13]. Successful hyperbaric oxygen treatment for the sequelae of closed head was described in the English language literature by Dr. Neubauer in 1994[14]. It had been earlier described in Japanese and Russian reports. Subsequently HBOT was used to facilitate recovery of consciousness after severe head injury[15], to facilitate recovery in long term brain injury[16], and to facilitate recovery in moderate to severe head injury[17]. A prospective randomized trial of HBOT in brain injured patients with a Glasgow Coma Score (GCS) of 9 or less showed a significant reduction in mortality (17 v. 32%) in the HBOT group, though there was no recognized difference in quality of recovery in survivors[18].

In 2007 Hardy et al. reported on the beneficial use of HBOT for chronic TBI noting improvement in one case[19]. A controlled study from Taiwan (2007) treated 22 patients with moderately severe TBI with HBOT and observed significant improvement in the treatment group[20]. HBOT was first used to treat active-duty military members with

mTBI in 2008 with complete resolution of symptoms, cancellation of medical boards, and return to full duty status[21]. Other reports followed demonstrating improvement in symptoms, physical exam findings, cognitive testing, and quality-of-life measurements, with concomitant significant improvements in single photon emission computed tomography (SPECT)[22].

HBOT was utilized in the treatment of ischemic stroke by the US Navy in 1969. In this case it was recognized that clinical improvement was associated with HBOT three months after the stroke and only occurred after HBOT[23]. Late hypoxic injury to the brain has also been treated successfully with HBOT[24,25,26]. HBOT is an effective treatment for mild TBI (mTBI) resulting in improved brain function, neurocognitive scores, and quality of life years after injury[27,28,29,30]. An early Department of Defense (DoD) sponsored study of HBOT used on participants with post-concussive syndrome (PCS) concluded "... HBO showed no benefits over sham compressions. Both intervention groups demonstrated improved outcomes compared with PCS care alone..." However, re-analysis of DoD studies which used pressurized air as a "sham" treatment showed a consistent treatment effect of pressurized air on mTBI[31]. This perhaps should not be surprising since pressurized air was used as a treatment with known efficacy for lingering effects of DCS dating back to the late 1800s.

The DoD sponsored studies showed a dose response effect using HBOT to alleviate symptoms of mTBI, PCS, and PTSD[32]. When compared to control groups, individuals with TBI treated with HBOT experienced significant clinical improvement[33]. In a randomized controlled study of 50 military members with TBI, Dr. Wolf et al. demonstrated improvement in testing scores of the HBOT and sham compressed air groups[34], as well as the safety of HBOT[35]. Another study of US military members showed HBOT "improved post-concussive and PTSD symptoms, cognitive processing speed, sleep quality, and balance function, most dramatically in those with PTSD." However, in this study, contrary to some others, changes did not persist beyond six months[36].

In the last fifteen years there have been at least eight randomized controlled studies using HBO to treat moderate traumatic brain injury (mTBI) and PTSD, including 352

treated subjects, nearly all of whom improved due to the treatment. (See Appendix 1) In only one study of 40 subjects was no improvement noted. This study involved active-duty military embers as subjects who may have had an incentive to not show improvement for fear of losing Veterans' Administration (VA) benefits[37]. The study also only used eye-tracking as the sole outcome measure, and one wonders what the results would have been if other more common measures such as quality of life assessments and cognitive tests had been utilized. The summaries of the randomized controlled studies are reported in the spreadsheet in Appendix 1.

2) How HBO Works

Cellular effects of HBO

While HBO is known to act in thousands of ways at a cellular level, it is useful to put the known ways it works in neurologic injury into four main categories:

1) provision of oxygen to nerve cells which are hypoxic,

2) promotion of the synthesis of growth factors and other chemicals which help nerve healing and axonal growth and reconnection,

3) reduction of inflammation and its effects, and

4) direct action on nerve cells to reduce pain.

Nerve cells (neurons) are exquisitely sensitive to any change in oxygen concentration, whether offered as hypoxia or any form of hyperoxia such as an oxygen enriched environment, hyperbaric air, or hyperbaric oxygen. A change in oxygen concentration results in gene transcription by the neuron, especially in stress responses, transport/neurotransmission, and signal transduction[38]. Thousands of affected genes have been identified[39]. Several studies have identified HBOT as a direct or indirect DNA signaling agent[40,41].

HBO as a provider of oxygen

Areas of poor blood flow and localized hypoxia are a hallmark of TBI[42]. These areas correlate with clinical findings and are often larger than areas of injury identified by physical exam or computed tomography (CT) scan. These hypoxic areas generate reactive oxygen species[43] (ROS, or oxygen free radicals), one of the signals for wound

healing, but cannot heal because the low oxygen levels are not high enough to support healing, and this localized environment of high ROS and hypoxia causes further cell dysfunction and death. HBOT can correct these areas of hypoxia permanently and lead to brain healing[44]. Similarly, spinal cord injury is characterized by an area of injury, scar formation, chronic inflammation and hypoxia resulting in progressive neurodegeneration[45], and regional pain syndrome[46].

HBO as a nerve healing agent

HBOT has numerous cellular mechanisms of action which are neuroprotective and assist the injured brain to heal. These include: activation of ion channels, inhibition of hypoxia inducible factor-1alpha, up-regulation of Bcl-2, inhibition of MMP-9, decreased cyclooxygenase-2 activity, decreased myeloperoxidase activity, up-regulation of superoxide dismutase and inhibition of Nogo-A (an endogenous growth-inhibitory factor)[47,48,49]. HBOT enhances mitochondrial recovery and reduces apoptosis (near cell death) in hypoxic nerve cells[50,51]. HBOT promotes neural stem cell activation and growth[52,53], and this effect is seen in the hypoxic damaged brain[54,55,56]. HBOT also alleviates hypoxic induced myelin damage[57,58]. HBOT increases cellular ATP (adenosine triphosphate) levels and cognitive recovery after concussive injury[59]. These findings correlate with the cellular response in humans. For example, in children with autism treated with HBOT, markers of oxidative stress were significantly lowered[60]. In the largest published HBOT trial to date significant cognitive improvements, and these improvements were well correlated with increased activity in the relevant brain areas examined by SPECT.[61]

Axonal disruption in TBI, PTSD, and SCI

One of the characteristics of the damage sustained in TBI is diffuse axonal injury – a disruption of the brain and spinal cord signaling pathways[62]. This type of injury is also a component in decompression sickness[63,64], major depressive disorder[65], and PTSD[66,67,68], and may account for some the commonality of symptoms between TBI and PTSD. These altered pathways may also account for the symptoms of anxiety disorder[69]. HBOT has been shown to help restore the function of damaged axonal pathways in COVID patients[70]. HBOT has been shown to improve neuroplasticity and restore damage brain connections in anoxic brain damage[71], and a variety of other varieties of brain damage

in addition to PTSD and TBI[72]. In acute concussion, HBOT restores EG (electro-encephalogram) findings to normal levels after two to three treatments[73]. Hyperbaric oxygen promotes axonal healing and reconnection by its anti-inflammatory actions, inducing the ingrowth of new blood vessels to damaged areas of the brain and spinal cord (neo-angiogenesis), reducing edema, and inducing healing by growth factor activation[74,75,76,77,78].

While to our knowledge HBOT has not been used systematically for its ability to control inflammation in chronic SCI patients, we suspect it could prove beneficial in enhancing motor and sensory recovery, and most certainly could help by improving mood and cognitive function, in addition to the QoL (quality of life) for SCI survivors. It is now recognized that serious alterations of brain function occur after spinal cord injury, and these alterations contribute to cognitive and mood disorders seen in SCI[79]. In order to treat SCI effectively, the injury should be thought of as an interrelated complex of injuries and sequelae affecting multiple body systems. Effective treatment must take into consideration the interplay of common contributors to dysfunction after SCI, and one of these is inflammation. Encouraging new research from China is showing that HBOT after spinal cord injury can reduce inflammation and pain, increase cognition and quality of life, and is some instances diminish disability and promote return of motor function[80,81].

HBOT as an anti-inflammatory treatment

One of the most powerful agents we possess for reduction of inflammation is hyperbaric oxygen[82,83]. It reduces inflammatory cytokines such as IL-1, IL-6, and TNF-α, while increasing anti-inflammatory cytokines such as IL-10[84,85,86]. HBO has anti-apoptotic (cell death) effects which assist damaged nerve cells to recover rather than progress to cell death. These effects are seen in the brain and spinal cord[87,88]. As an example of these effects, SCI patients receiving HBOT were reported to have reduced levels of biomarkers of inflammation which correlates with significant improvement in motor/pain scores after 30 treatments[89].

Inflammation in depression

Treatment resistant depression has been linked to chronic inflammation which in turn causes blood brain barrier dysfunction and neurodegeneration[90]. Inflammation can drive depressive symptoms and depression may result in inflammation itself[91].

Inflammatory cytokines are elevated in treatment resistant depression, and it is thought that treatment failures are at least partly due to the failure of treatment to reduce these inflammation driving agents whether treatment consists of a single drug or a multi-factor treatment regimen[92]. Interestingly, a number of anti-inflammatory agents have shown promise in treating depression[93,94].

Inflammation in PTSD

33% of veterans with PTSD are resistant to therapy and for others the standard therapies are only partially effective[95]. The high rate of treatment failure is driving a search for new therapies[96]. PTSD is marked by inflammatory cytokine dysregulation and a chronic inflammatory state, and it is thought that inflammation may play a role in the pathogenesis of PTSD[97]. PTSD is also strongly associated with major depressive disorder (MDD)[98]. Elevated inflammatory cytokines are a hallmark of PTSD, and MDD[99,100]. High inflammatory biomarkers are associated with co-morbidity in TBI and PTSD in military members, and higher levels of these biomarkers are associated with higher levels of PTSD[101].

Inflammation in TBI

After a TBI, genes are expressed resulting in an inflammatory cascade, and this inflammation contributes to the severity and duration of the TBI[102]. This inflammation can increase over time leading to increased symptoms of brain injury and worsening neurologic function[103]. This can result in cognitive decline, mood changes, sleep disturbances, chronic pain, and depression.

Inflammation in spinal cord injury

It is now recognized that serious alterations of brain function occur after spinal cord injury, and these alterations contribute to cognitive and mood disorders seen in SCI[104]. One of the common contributors to dysfunction after SCI is inflammation. The long-term sequelae of spinal cord injury are often chronic pain, depression (in more than half of individuals with SCI), deterioration of motor function[105], PTSD (31%)[106], and decline of cognitive ability (even in the absence of TBI)[107,108]. Spinal cord injury can lead to a chronic inflammatory state characterized by progressive neurodegeneration[109]. This

chronic pro-inflammatory state can result in poor rehabilitative progress, failure to recover, and gradual worsening of neurological function for months or years after injury[110]. Post SCI inflammation causes neuro-degeneration and that control and/or reduction of inflammation in SCI can result in improved outcomes. Inflammation is a key component of complex regional pain syndrome[111] often seen in SCI.

In studies using rodent models of SCI, HBOT has been shown to reduce glial scar formation by reducing inflammation[112]. In a recent study from China, SCI patients receiving HBOT were shown to have reduced levels of biomarkers of inflammation which correlated with significant improvement in motor/pain scores after 30 HBOT[113]. Other observations have shown HBOT promotes the production of anti-inflammatory cytokines (cell signaling proteins) and reduces other biomarkers of inflammation in SCI[114].

HBOT in pain management

About 60% of people with TBI suffer from chronic pain[115], as well as up to 90% of those with chronic spinal cord injury[116,117]. Chronic pain is also a significant component of PTSD[118]. Recipients of hyperbaric oxygen therapy for any cause often remark that their chronic pain has been reduced by the therapy. This is one of the expected results of HBOT for fibromyalgia, long-COVID syndrome, TBI, and PTSD. This relief has been reported in patients suffering from various chronic pain conditions, including fibromyalgia[119,120,121], regional pain syndrome[122], myofascial pain syndrome[123], spinal cord injury[124], narcotic dependency[125,126], complex regional pain syndrome[127], idiopathic trigeminal neuralgia[128], migraine headache[129], and cluster headache[130]. HBOT has proven useful in reducing the pain associated with TBI, and this pain reduction is consistent and long-lasting[131]. Additionally, the dependence on narcotic analgesics is significantly reduced[132].

This reduction of pain by HBOT is achieved through several mechanisms. One of the ways HBOT reduces pain is through the up-regulation of NO synthase in the CNS[133,134] which produces NO which in turn acts as a signaling agent for various nerve cell actions[135]. Additionally, HBO acts to block pain sensations through the release of

dynorphin and activation of κ- and μ-opioid receptors in the spinal cord and brain[136,137]. In summary, HBOT acts to relieve pain through at least three mechanisms: inflammation reduction, NO up-regulation in the CNS, and the release of endogenous opioids.

More than 20 years ago, it was proposed that HBOT could be used as an adjunct in alcohol and drug rehabilitation and to mitigate the symptoms of withdrawal[138]. Through a direct action on nerve cells, HBO reduces withdrawal symptom in opioid withdrawal[139]. In a randomized controlled trial, Dr. Ray Quock showed that HBOT reduced pain and improved symptoms in subjects enrolled in an opioid use withdrawal program, and also reduced methadone use[140].

3) How HBOT helps in recovery from TBI, PTSD, and SCI

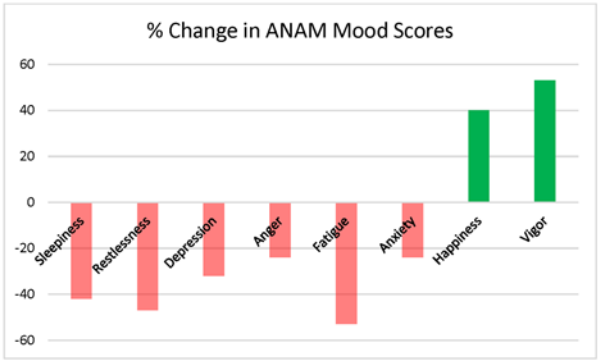
In the past 15 years numerous reports and studies have consistently shown that HBOT is useful in facilitating recovery from TBI, PTSD, and SCI. Thirteen randomized controlled studies have been completed for TBI and PTSD and in all but one improvement with HBOT has been documented (see Appendix 1). Additionally, the results have been consistent and reproduceable. One of the earliest studies (completed I 2013) was the NBIRR (National Brain Rescue and Rehabilitation) effort (see Appendix 2), and because the results reported have been consistently reproduced in other studies, it is useful to take a closer look at these.

The NBIRR Study

In our previous work in the National Brain Injury Rescue and Rehabilitation Study, completed in 2013, we found that all subjects (with mild TBI, PCS, and PTSD) demonstrated improvement in most measures after HBOT, and improvement in 21 of 25 neurocognitive test measures was observed. The objective neurocognitive test components showed improvement in 13 of 17 measures. Earlier administration of HBOT post injury, younger age at the time of injury and HBOT, active-duty military status, and increased number of HBOTs were characteristics associated with improved

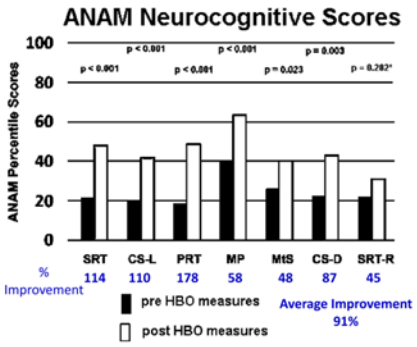
outcomes. The safety of the HBOT protocol at 1.5 ATA was established and there were no adverse events.

The graph below summarizes the changes in mood scores in the NBIRR study. These results have proven remarkably consistent with the findings of other researchers treating PTSD and TBI through the years. For example, an Israeli study by Dr. Efrati and colleagues treating PTSD showed a 39% average reduction in PTSD symptoms, nearly identical to our 37% reduction in negative mood scores[141].



37% Average Reduction in Negative Mood

The improvement in the ANAM cognitive scores was also impressive, averaging 91% and significant in six of the seven measures (SRT-R improved but not at a significant level).



HBOT for spinal cord injuries

It has been recognized for more than 80 years that one of the effects of HBOT in the spinal cord injury in DCI is the correction of regional hypoxia leading to the recovery of function. A review of 11 randomized controlled trials using HBOT to induce healing in spinal cord injury documented improved motor function, sensory function and mental health compared to conventional treatments for SCI[142]. The application of HBOT in incomplete cervical SCI patients resulted in improved spinal cord function, reduction in disability, and improvement in the quality of life[143]. HBOT recipients had a significant average 13-point (25%) improvement in motor scores at 3 years post HBOT over their conventional treatment counterparts, and a 19% improvement in sensory scores. While these results are encouraging, better studies are needed, especially in chronic SCI.

HBOT as a treatment for depression

The utilization of multi-module treatment, combining drugs, psychotherapy and non-pharmacological biological forms of treatment is advocated for treatment resistant depression[144]. The treatment for major depressive disorder (MDD) involves therapies

such as drug therapy, cognitive-behavioral psychotherapy, psychoeducation, aerobic exercise, neuromodulatory treatment through vagus nerve stimulation, transcranial direct current stimulation, repetitive transcranial magnetic stimulation, deep brain stimulation, and light therapy. This plethora of therapies speaks to the ineffectiveness of single therapies and the search for something better. The insufficient effectiveness of pharmacological methods justifies biological and non-pharmacological methods of treating mental disorders that can be used as augmentation of pharmacological treatment[145].

Through the actions of HBOT in reducing inflammation, activating "idling" areas of the damaged brain, inducing neuroplasticity, and improving cognition, it has pronounced anti-depressive properties which are long lasting and often permanent. When used for post-stroke depression, HBOT significantly reduces depression scores more than medication alone, while also reducing biomarkers of inflammation[146].

In the NBIRR Study, depression scores in the PHQ-9 test were reduced 25% ($p<0.001$) after treatment, and suicidal ideation was also reduced by 25% ($p=0.109$). The ANAM depression scores were likewise reduced by 24.8% ($p=0.015$)[147]. In a randomized controlled trial treating spinal cord injured individuals with depression, HBO was found to be as effective as psychotherapy, and reduced anxiety[148]. In this study, the Hamilton Depression Rating Scale score decreased on average by 50% in the HBOT group. Of note also, is that only two of the more than 31,000 individuals (>12,000 were veterans) treated for TBI and/or PTSD by the TreatNOW Coalition since 2007 are known to have committed suicide. This remarkable record speaks to the efficacy of HBOT for depression[149].

4) Conclusions

Enough evidence is available from randomized controlled studies and the effective treatment of more than 31,000 individuals with TBI and/or PTSD including more than 12,000 veterans, to allow immediate, safe, and effective use of HBO for these maladies.

HBOT will has the following mental health benefits:

1) Reduce depression
2) Reduce suicidal ideation and suicide
3) Reduce PTSD symptoms
4) Improve cognition
5) Improve mood and well-being
6) Reduce pain and narcotic dependence

These effects are long-lasting for years, if not permanent, and while they can be achieved with other therapies, a multifaceted approach using HBOT as one of the treatments is preferrable. It is recommended that HBOT be provided as soon as possible to a large number of the veteran population with PTSD and/or TBI, and perhaps as well to those 24,000 veterans with SCI[150] and the more than 160,000 veterans with treatment resistant depression[151]. The cumulative body of evidence of the long history of HBOT for brain injuries, its safety and the thousands successfully treated n the US and Israel (40,000 in Israel), as well as the consistent efficacy shown in randomized studies here and abroad is more than sufficient proof of its efficacy. It is also recommended that strict quality control of HBOT administration be instituted using approved hyperbaric chambers under trained physician direction to ensure adherence to safety and treatment protocols. Good record keeping is also recommended to assess efficacy and identify future areas of HBOT use. Establishment of a working group with veteran representation is one way to determine how to implement these recommendations effectively and rapidly.

Appendix 1 – Summary of Studies of HBOT in TBI and PTSD

Summary of Randomized Controlled Studies of HBOT for Brain injury and PTSD

DoD	Date	Authors	Reference	No. Treated	HBOT used	Control	Efficacy Measures	Authors' Conclusion	Crtique Efficacy Summary	Notes	Effect	mTBI/PTSD	Non-acute TBI
	1985	Rockswold GL, Ford SE	1	168	1.5 ata x 21	Standard of Care (SoC)	mortality, GCS	$\downarrow$ mortality with HBOT	QOL measures may have been useful	severe head injuries only	improved		
	2008	Lin JW, et al.	2	22	2 ata x 20	SoC	GCS	improved GCS	QOL measures may have been useful	severe head injuries only	improved		
	2013	Boussi-Gross R, et al.	3	56	1.5 ata x 40	crossover	Cognitive Function (CF), Quality of Life (QOL)	improved QOL, CF			improved	Yes	56
	2013	Rockswold SB, et al.	4	21	1.5 ata x 3	SoC	Glasgow Outcome Scale (GOS)	$\downarrow$ mortality, improved GOS with HBOT	Acute <24 hrs, from injury	severe TBI only	improved		
	2017	Harch PG, et al.	5	29	1.5 ata x 40	matched "normal" controls	SPECT, PTSD measures	normalized SPECT, $\downarrow$ sicidal ideation & meds		military subjects, not a RCT	improved	Yes	29
Yes	2012	Wolf et al.	6	50	2.4 ata HBO, 1.3 ata air	1.3 ata air	ImPACT, PCL-M	no effect of HBOT	both gorups improved, 1.3 ata air is now recognized as a treatment for TBI	military subjects, disincentive to report improvement	improved	Yes	50
Yes	2018	Weaver et al.	7	36	1.5 ata x 40	1.2 ata air	cognition, QOL	$\uparrow$ cognition & QOL, esp. in PTSD		control group also improved	improved	Yes	36
Yes	2014	Cifu et al.	8	40	0.5, 0.75, 1.0 @ 2 ATA	0.5 O2 @ 2 ATA	eye tracking	no effect of HBOT	active military, disincentive to improve	other Sx not evaluated, possible bias	no improvement reported	Yes	40
Yes	2015	Miller et al.	9	48	1.5 ata, 1.2 ata air x 40	SoC	RPQ only reported	no effect of HBOT	1.5 ata & sham groups improved	military subjects, no objective measures, treated groups improved, possible disincentives	improved	Yes	48
	2010	Rockswald SB, et al.	10	23	1.5 ata x 3	100% O2 1 ata, SoC	Cerebral blood flow (CBF)	$\uparrow$ CBF	Acute < 24 hrs post injury		improved		
	2023	Lin Z, et al.	11	37	1.5 ata x 40, 100% O2 x 40, SoC	100% O2 1 ata, SoC	Cognitive Assessment (MoCA, MMSE, inflammatory biomarkers)	effective in $\downarrow$ inflammation, $\uparrow$ cognition	Chinese study	acute mTBI, injury biomarkers and brain oxygenation $\uparrow$ at 1 month HBOT	improved		
	2022	Hadanny A, et al.	12	15	1.5 ata x 60	Sham (21% O2 @ 1.0 ata)	cognition, QoL, MRI	$\uparrow$ cognition, $\uparrow$ MRI changes, $\downarrow$ behavioral Sx, $\downarrow$ clinical Sx	PPCS, mTBI	average 4.89 years post injury, avg age = 12 years	improved	Yes	15
	2021	Lu Y, et al.	13	78	2 ata x 60	SoC, rehab	cognition, QOL	$\uparrow$ QOL, cognition, ADL (activities of daily living)	Chinese study	subjects admitted to trauma rehab hospital	improved	Yes	78
		Total Treated		**623**									**352**

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Appendix 2 – The NBIRR Study

Cover Letter

International Hyperbaric Medical Foundation
8210 Cinder Bed Road, Ste C-3
Lorton, Virginia 22079-1135

3 May 2013

The Editor
Undersea and Hyperbaric Medicine
21 West Colony Place, Suite 280
Durham, NC 27705

Dear Sir:

The attached manuscript, #2442, "*The National Brain Injury Rescue and Rehabilitation Trial – a multicenter study of hyperbaric oxygen for mild traumatic brain injury with post-concussive symptoms*" has been revised and the suggestions and recommendations of the reviewers have been included in the revision. Among the changes the statistical methods have been explained and additional statistics provided, word corrections have been made and allusions to bias on the part of the authors have been removed. The results section has been shortened.

Statistically we applied the revised phraseology suggested by the reviewers, revised the descriptive summary tables to include mean changes with 95% confidence intervals along with the p values. We have also further explained the preliminary and exploratory nature of this study, and made it clear that results should be considered tentative, and that no conclusive inferences can be drawn from nominally significant results ($p<0.05$) without confirmation from subsequent studies.

All authors have read and approve the manuscript. The article has not been published elsewhere and is not being considered for publication elsewhere.

Please consider the manuscript for publication in *Undersea and Hyperbaric Medicine.*

Sincerely,
//signed//
James K. Wright, M.D.

Cover Sheet

Title:
The National Brain Injury Rescue and Rehabilitation Study – a multicenter study of hyperbaric oxygen for mild traumatic brain injury with post-concussive symptoms

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The National Brain Injury Rescue and Rehabilitation Study – a multi-center study of hyperbaric oxygen for post-concussive symptoms from mild traumatic brain injury

Abstract

The National Brain Injury Rescue and Rehabilitation Project (NBIRR) was established as a preliminary study to test the safety and practicality of multi-center hyperbaric oxygen (HBO2) administration for the post-concussive symptoms of chronic mild traumatic brain injury (mTBI) as a precursor to a pivotal, multi-center, controlled clinical trial. This preliminary report presents the results for the first 32 subjects completing the trial. The subject population was given HBO2 at 1.5 atmospheres absolute (ATA) for one hour per session for 40 to 80 sessions. Outcome measures included repeated self-assessment measures and automated neurocognitive tests. All subjects demonstrated improvement in most measures after HBO2 and improvement in 21 of 25 neurocognitive test measures was observed. The objective neurocognitive test components showed improvement in 13 of 17 measures. Earlier administration of HBO2 post injury, younger age at the time of injury and HBO2 administration, military status, and increased number of HBO2 administrations were characteristics associated with improved outcomes. The safety of the HBO2 protocol at 1.5 ATA (HBO2 1.5) was established and there were no adverse events.

Key words: hyperbaric oxygen, traumatic brain injury, post concussive syndrome, post-traumatic stress disorder

Introduction

During the past two decades several authors have reported beneficial effects from hyperbaric oxygen (HBO2) in subjects with chronic residual effects of moderate to severe traumatic brain injury[152,153,154,155,156]. More recently HBO2 has been applied to patients with the post-concussion syndrome of mild-moderate blast-induced TBI with or without post-traumatic stress disorder (PTSD)[157,158,159,160]. Based on these reports, the National Brain Injury Rescue and Rehabilitation Project (NBIRR) was undertaken to study the safety and practicality of a multicenter study of hyperbaric oxygen (HBO2) administration at 1.5 atmospheres absolute (ATA) for post-concussive symptoms from mTBI with or without co-existing PTSD and PTSD without TBI (See appendix for list of study locations). The study was designed to enroll 1000 subjects in the expectation that improvement of symptoms could be offered to a large number of subjects, many of whom may have been injured in the current Global War on Terror. Follow up testing on subjects enrolled is planned for two years after initial enrollment.

When the NBIRR trial was initiated it was thought that the trial could be a means to treat some of the large number of active duty and veterans returning from war with post-concussive symptoms from mTBI if funding became available. As the study progressed funding was not obtained and it was realized that it would take some time before the 1000 subject goal could be attained. As researchers sought an FDA sanction for a study using HBO2 in post-concussive symptoms from mTBI in an effort to obtain an FDA indication for HBO2 treatment, and a completely redesigned study with appropriate controls was required. The preliminary results of the NBIRR study are potentially useful in designing an FDA sanctioned study and they are

presented here in an effort to speed the effort for interested researchers. This summary is a preliminary report on the first 32 subjects with post-concussive symptoms who completed the protocol while the remainder of the 1000 subject trial continues. At the time of the current data analysis the long term follow up was not yet available and is not part of this report. This report is offered in the expectation that the information learned could be put to use in a well-designed controlled clinical trial.

One of the purposes of the study was to evaluate the safety of the HBO2 1.5 protocol for mTBI post-concussive symptoms and PTSD. While hyperbaric oxygen is generally accepted as safe, potential adverse effects resulting from hyperbaric oxygen administration in brain injured patients include seizures and worsening of psychiatric conditions. The decades long use of HBO2 1.5 in hundreds of patients with multiple sclerosis in millions of sessions in the United Kingdom has established the safety of HBO2 1.5 for neurologic conditions, but at the time this study was designed the safety of HBO2 in mTBI subjects was being actively questioned[161,162].

Hyperbaric oxygen has been used to treat a variety of brain injuries for decades. It was described as a treatment for carbon monoxide poisoning in 1960[163], and it was soon recognized that hyperbaric oxygen had effects impacting brain healing separate from the action to remove carbon monoxide from hemoglobin molecules[164]. Since the adoption of oxygen treatment tables in 1967 the brain injuries of decompression sickness and arterial gas embolism have been effectively treated by HBO2[165]. In 1969, clinical improvement from stroke was demonstrated with HBO2 administered three months after the stroke[166]. Late hypoxic injury to the brain has also been treated successfully with HBO2[167]. Significant changes in cerebral blood flow with simultaneous symptomatic, physical quality of life, and cognitive improvements have recently been demonstrated after HBO2 in a population of blast-induced mild-moderate TBI military veterans with post concussive syndrome (PCS) and PTSD (Harch PG, Andrews SR, Fogarty EF, et al. 2012). That experience replicated the findings in a controlled animal model of chronic traumatic brain injury incorporating an earlier version of the 1.5 ATA protocol where persistent changes in brain vasculature as well as spatial learning and memory were observed[168]. The lack of high quality controlled clinical trials demonstrating the efficacy of HBO2 in brain injury has been a valid criticism[169].

Materials and Methods

The National Brain Injury Rescue and Rehabilitation Study (NBIRR) was a multi-center trial conducted under the auspices of the International Hyperbaric Medical Foundation. HBO2 administration was performed on a voluntary basis by each treating center. The protocol at each participating center was approved by the Western Institutional Review Board and all subjects provided written informed consent. No effort was made to exclude subjects based on the etiology of injury. A control non-hyperbaric group was not included in this initial study; however all participants in this report had mTBI with post-concussive symptoms and a history of at least three months of clinical non-improvement or deterioration at the time of enrollment.

Male and female subjects 18 to 65 years of age were eligible if they had a diagnosis of mTBI with post-concussive symptoms and/or PTSD. Inclusion criteria for subjects in this report were

a) any 18-65 year-old subject with a history of mild TBI with post-concussive symptoms or PTSD, b) a diagnosis of mild TBI with post-concussive symptoms and/or PTSD made by a neurologist or neuropsychologist, c) negative pregnancy test in females, and d) current symptoms or functional impairment attributable to TBI and/or PTSD. Exclusion criteria were a) pulmonary disease that precludes HBO2 administration, b) unstable medical conditions that are contraindicated in HBO2 administration, c) severe confinement anxiety, d) pregnancy, d) a neurological diagnoses other than TBI or PCS, e) participation in another experimental trial with active intervention, f) high probability of inability to complete the experimental protocol, g) insufficient mental or physical capacity to complete the required tests, h) pre- or post-TBI history of systemic illness with impact on central nervous system, i) pre-existing mental illness, and j) any pre-existing chronic infection not related to battlefield injuries or government service.

A new online data entry system (CareVector™) was created to be available to a network of clinics participating in clinical research. The CareVector™ Platform (CVP™) is the repository for all data collected on individual patients in NBIRR. It creates a web-enabled electronic medical record from multiple data sources available from HBO2 sessions, tests, laboratory tests and clinician-patient interactions. It has an analytic engine that can support standard and sophisticated analysis and reporting. The CVP™ is a knowledge base that is available, based on mandatory and discretionary accesses, to participants in the practice or research protocol. CVP™ supports other research and treatment protocols, as well as non-medical applications. The platform also allows for oversight and has a built-in auditor role that supports analysis and data and safety monitoring functions. Security procedures are a built-in aspect of the CVP, with multi-role and multi-site access-controls. To avoid any conflict or bias of analysis, all collected data were analyzed independently by the biostatistician.

The self-assessment measures were a percent back to normal assessment, the PHQ-15 (Patient Health Questionnaire-15), a measure of somatic symptoms associated with mental disorders, the PHQ-9 (Patient Health Questionnaire-9), a measure of depression symptoms[170], a quality of life assessment, and the Rivermead Post-concussion Symptoms Questionnaire[171].

Subjects who met the inclusion criteria underwent a battery of pre-HBO2 administration evaluations and testing including medical history, neurological examination, Automated Neuropsychological Assessment Metrics (ANAM4™), Central Nervous System Vital Signs® (CNS VS), and a variety of self-assessment tests. The neurocognitive test results form the basis of this report. No imaging studies were included in this protocol. A flow diagram of subject participation and inclusion in this report is shown in Figure 1.

ANAM4™ is a library of more than thirty computer-based test modules designed for a wide variety of clinical and research applications and is the direct outgrowth of more than twenty years of computer-based test development across all service branches within the Department of Defense[172]. It is a neurocognitive assessment tool that can be used to identify changes in a service member's cognitive function and mood state as a result of some debilitating event. The ANAM4™ test battery used in this study has been tailored to provide an instrument that is sensitive to cognitive changes that often accompany mTBI [173,174]. The ANAM4™ tests included

the mood scores of sleepiness, vigor, restlessness, depression, anger, happiness, fatigue, and anxiety. The ANAM4™ neurocognitive measures were simple reaction time, code substitution – learning, procedural reaction time, mathematical processing, matching to sample, code substitution – delayed and simple reaction time (R), a measure of basic neural processing speed and efficiency. In order to minimize the effect of test-retest improvement the ANAM4™ test system automatically detects when an individual has been previously assessed and will iterate to a new stimulus set[175].

CNS VS is a battery that evaluates verbal and visual memory, psychomotor speed, complex attention, reaction time, and cognitive flexibility through application of the verbal and visual memory test, finger tapping test, symbol digit coding, the Stroop test, the shifting attention test, and the continuous performance test[176]. CNS VS was added as a secondary, objective neuropsychological assessment tool. CNS VS has been validated as a repetitive assessment measure for brain injury[177].

Hyperbaric oxygen (HBO2) was delivered according to the 1.5 ATA protocol developed by Harch, Gottlieb, and Van Meter in the early 1990s based on the 1.5 ATA dose used by Neubauer in chronic brain injury[178]. All subjects received 100% oxygen at 1.5 atmospheres absolute (ATA) in monoplace or multiplace chambers. Monoplace chambers were Sechrist 2500, Sechrist 3200, or Perry Sigma 40 monoplace chambers and 100% oxygen was delivered in the chamber ambient environment. [1] The multiplace chamber was a 12 person Gulf Coast Hyperbarics chamber with oxygen delivered via hood or aviation non-rebreather mask.

Pressurization time was 3-7 minutes and decompression time was 3-7 minutes. The time at 1.5 ATA was 45 minutes for monoplace chambers and 50 minutes for the multiplace chamber. This difference was planned in order to give some equivalence to the amount of oxygen delivered in the two types of chambers since descent and ascent were conducted with 100% oxygen in the monoplace chambers and air in the multiplace chamber. After initial testing, the subjects were to receive 40 HBO2 and were tested again. If, in the opinion of the subject and the site principal investigator, maximum benefit was received evidenced by the initial improvement and then stabilization of symptoms without continued improvement, HBO2 administration was stopped at 40 HBO2 sessions. All subjects receiving 40 HBO2 sessions reported they had benefitted from the HBO2 administration. If possible further benefit was anticipated, another 20 or 40 HBO2 sessions were administered and testing performed again when the HBO2 sessions were complete.

Statistical analysis was performed using R (Version2.15.1, http://www.R-project.org). and post HBO2 administration changes in ANAM Mood Scores, ANAM Cognitive Scores and CNV VS Cognitive Scores were compared using Paired t-test or Wilcoxon signed-rank-test for not-normally distributed scores. Mean and standard deviation of the differences between the scores and its corresponding 95% Confidence Interval and *p*-value were reported. Differences in the neurocognitive scores between the groups were compared by Independent t test or Mann-Whitney U test for not normally distributed data. Average improvement in each subject's neurocognitive test scores were compared to number of HBO2 sessions received by Correlation and Regression analysis. Slopes, correlation coefficients, (r *and* r^2), and *p*-values were reported.

Significance level was set at 0.05, and no adjustment for multiple endpoints was applied.

Results

A total of 49 subjects with mTBI with post-concussive symptoms with or without PTSD were enrolled in the NBIRR study at 5 centers. Twenty nine subjects were males and three were females. Of the 32 subjects in this report, seven subjects (22%) were active duty military at the time of participation, 12 (37%) were veterans and 13 (41%) had no military service. Fifteen (47%) received their injury because of a blast and 17 (53%) were injured because of a blow (Table 1).

The delay from injury to protocol enrollment for the subject population was distributed from 0.37 to 46 years after injury. Two subjects could not remember their injury well enough to establish a clear date of injury (Figure 2). There were 25 potential outcome measures per subject at each time of measurement (pre-HBO2 and HBO2) calculated for this report. For each participant the measures were compared pre and post HBO2 administration (Table 2). The results of the ANAM4™ mood scores are expressed as subjective scales (0-100) and the objective neurocognitive screening measures are expressed as percentile placement compared to the peer populations (Figures 3 and 4).

The changes in subjects on active duty, veterans, or civilian status (no history of military service) were compared to each other as groups (active duty, veteran, civilian). In general the active duty group showed more improvement than the veteran and civilian groups and the civilian group showed the least improvement (Table 3). In comparing subjects with blast injury (N=15) to those receiving injury from a blow (N=17) 4 measures showed post HBO2 administration differences between the two groups with the individuals with blast injury demonstrating more improvement. The measures showing significance were ANAM4™ Fatigue (Mean = -23.8 (percentile change), ± 25.1 (standard deviation), CI (confidence interval): -32.9 – -14.7, p=0.034), ANAM4™ Code Substitution Learning (21.2 ± 27.2, CI: 11.2 – 31.2, p=0.006), ANAM4™ Procedural reaction Time (30 ± 38, CI: 16 – 44, p<0.001), and ANAM4™ Simple reaction Time (R) (8 ± 36, CI: -6 – 22, p=0.025).

Age at the time of injury impacted improvement in CN SVS Processing Speed (slope = 0.642, p=0.043, r = 0.445, r^2 = 0.198), with earlier age at the time of injury resulting in greater test improvement after HBO2 administration. Age at the start of HBO2 administration affected improvement in ANAM4™ Code Substitution – Learning (slope = -0.815, p=0.017, r= -0.427. r^2 =0.182), and ANAM4™ Procedural Reaction Time (slope = -1.567, p=0.001, r= -0.584, r^2= 0.341) with earlier age at the start of HBO2 administration resulting in greater test improvement after HBO2 (Figure 5).

A delay in initiation of HBO2 from the time of injury affected four neurocognitive percentile scores - ANAM4™ Code Substitution – Learning (slope = -0.0201, p=0.008, r= -0.486, r2= 0.286), ANAM4™ Procedural Reaction Time (slope = -0.02984, p=0.004, r= -0.518, r^2= 0.269), ANAM4™ Mathematical Processing (slope = -0.01487, p=0.037, r= -0.389, r^2= 0.152), ANAM4™ Simple Reaction Time R (slope = -0.02398, p=0.022, r= -0.455, r^2= 0.207), and CNS

VS Processing Speed (slope = -0.01271, p=0.019, r= -0.506, r^2= 0.256). A delay in HBO2 administration from the time of injury resulted in reduced improvement in test scores (Figure 5).

The trend toward improved neurocognitive test scores relative to number of HBO2 sessions received is reflected in Figure 6. The average neurocognitive scores improved approximately ½% with each HBO2 received (slope=0.554, p=0.038, r=0.368, r^2=0.136). The number of HBO2 received was associated with improvement in the percentile performance scores in 4 neurocognitive measures: ANAM4™ Mathematical Processing (slope = 0.782, p=0.001, r= 0.562, r^2= 0.316), CNS VS Psychomotor Speed (slope = 0.509, p=0.044, r= 0.424, r^2= 0.18), CNS VS Reaction Time (slope = 0.447, p=0.048, r= 0.417, r^2= 0.174), and CNS VS Executive Function (slope = 0.612, p=0.03, r= 0.453, r^2= 0.206). In each case a larger number of HBO2 received resulted in improved scores.

Seven subjects (22%) had a diagnosis of PTSD in addition to mTBI with post-concussive symptoms. The subjects with a diagnosis of PTSD had more improvement in the ANAM4™ Fatigue mood scale (mean change= -23.8 ± 25.1, CI: -32.9 – -14.7, p=0.012), and the ANAM4™ Matching to Sample neurocognitive test (mean change= 13 ± 31, CI: 2 – 25, p=0.028). A diagnosis of PTSD did not adversely affect any of the outcome measures. No adverse effects or complications were reported in any of the subjects enrolled in the NBIRR study and the administration of HBO2 at 1.5 ATA in this population of brain injury subjects was safe.

Discussion

The NBIRR study demonstrated that a protocol of forty to eighty once a day, five days per week 1.5 ATA, 60 minute HBO2 sessions was safe in this cohort of subjects with mild blast and non-blast TBI with post-concussive symptoms with or without PTSD. The lack of complications in the study is consistent with traditional applications of HBO2[179]. The once a day, five day/week schedule was well tolerated, at least to 80 sessions, in this study.

When the NBIRR study was designed the researchers postulated that mTBI with post concussive symptoms as well as PTSD were dynamic conditions capable of improvement years after diagnosis. For this reason no upper limit on the number of years since injury was imposed on subjects. The results of the study demonstrated that improvement was possible years afters injury, though not as great as for subjects who were treated sooner after injury.

The study also tested the new online data collection system and the research capabilities of a network of hyperbaric clinics. The online data entry system, the CareVector™ Platform developed to support multicenter clinical observational studies, was successful in capturing patient, HBO2 administration, computer-generated tests, and report data from multiple centers. The brain-injured and cognitively impaired subjects were able to successfully manage the computer-based systems necessary to conduct this trial. This portends well for future larger studies of this type as well as other pilot trials with different brain-injured populations. Even though many of the mTBI subjects had lives in disarray, it was remarkable that they were able to commit such a large block of their time and resources to complete the study. It is also notable that each center paid all administrative costs and IRB fees as well as generally treating the

subjects gratis, demonstrating that small pilot HBO2 trials can be successfully conducted without outside funding.

Placebo and Hawthorne effects

The Hawthorne effect is a change in the outcome of an experiment effected through the inclusion in the experiment and thought to be influenced by the increased attention given to subjects and the knowledge among subjects that they are being studied[180]. While the study was not designed nor intended to prove efficacy, it was interesting to observe the magnitude of improvement in nearly all measures in this group of deteriorating or unchanging subjects. In any uncontrolled study placebo and Hawthorne effects cannot be excluded as the source of observed effects.

In the NBIRR study without controls, changes in outcome might be attributed, at least in part, to a placebo effect. The placebo effect in this type of study is a psychobiological phenomenon capable of altering the subject's brain and producing subjective improvement. The increased attention and schedule of appointments for subjects have the capability of altering subject perceptions of one's self and the added structure to personal schedules and commitment to study participation can be perceived as having therapeutic value[181]. Placebo effects have the capability to change the brain and in neurobiology can be considered a form of treatment in some circumstances[182]. Without controls, it is impossible to determine the cause of the improvement seen in the subjects whether it be from the Hawthorne effect, placebo effect, or hyperbaric oxygen, or some combination of the three.

When TBI patients have stabilized symptoms, and have shown no improvement for several months, the likelihood of spontaneous improvement is low. A recent study at the University of Oklahoma Veterans Hospital in veterans of Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF) screening positive for chronic TBI indicated that "for all of the parameters measured, there was no difference in occurrence or intensity (of symptoms) between the subjects who were within 2 years of the TBI and those who suffered the TBI 3-8 years earlier"[183]. The Congressional Budget Office report on the Veterans Health Administration treatment of PTSD and TBI in recent combat veterans released in February 2012 showed that the health care costs of veterans with all types of TBI remained relatively constant and 67% of TBI patients, 76% of PTSD patients, and 96% of TBI/PTSD patients continued to use VA health care services after four years of treatment[184]. The NBIRR subjects had failed to improve, sometimes for decades, and only improved after inclusion in the protocol and HBO2 administration.

We are aware of no other treatment demonstrating the degree of improvement for stable or deteriorating mTBI with post-concussive symptoms as seen in the NBIRR study. Because there was improvement in characteristics such as reaction time and headache that are unlikely to improve as a result of a Hawthorne or placebo effect, the Hawthorne or placebo effect is thought unlikely to have contributed significantly to the overall pattern of observed improvement. It is possible to consider placebos and Hawthorne effects as types of treatment for TBI with potential long lasting effects and demonstrable brain imaging changes. The magnitude of these effects

would have to rely on well-considered controls in a clinical study. Future studies should be designed to separate the possible Hawthorne and placebo effects from that experienced through administration of hyperbaric oxygen.

A diagnosis of PTSD did not appear to have a negative effect on outcomes, and appeared to contribute to better cognitive improvement. For simplicity it would have been useful to exclude subjects with the diagnosis of PTSD and evaluate these subjects in a separate study. It is hoped that these results will prove useful in planning future randomized controlled studies of HBO2 for traumatic brain injury with post-concussive symptoms and post-traumatic stress disorder. Future randomized controlled studies should include objective neurocognitive tests as well as objective self-assessment measures. Objective measures of functionality in daily living would be useful; these might include employment status, earnings reports, education status, grade point averages, changes in marital status, medication records and changes, as well as medical visits and hospitalization for mTBI associated conditions. To allow time for subjects to demonstrate these results and to establish the durability of HBO2 associated improvement, future studies should incorporate long term follow up.

Summary

The HBO2 1.5 ATA protocol for mTBI with post-concussive symptoms with or without PTSD was safe, and could be used in multiple centers. The neurocognitive test scores for subjects improved in 21 of 25 measures. Earlier HBO2 post-injury, younger age at time of injury and HBO2 administration, and 80 rather than 40 administrations of HBO2 were associated with greater improvement in neurocognitive scores. Similarly, active duty or veteran military status was associated with improved outcomes. Inclusion in the protocol with HBO2 administration was accompanied by reductions in symptoms and improvement in neurocognitive test scores even several years after sustaining mTBI.

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Appendix

Study sites were Oklahoma State University Center for Aerospace & Hyperbaric Medicine, Tulsa, OK, San Francisco Institute for Hyperbaric Medicine, San Francisco, CA, Hyperbaric Medicine, Inc., Fort Walton Beach, FL, Restorix Health, Issaquah, WA, Life Force Therapies, Minneapolis, MN.

Conflict of interest

Drs. Stoller, Wright, Mozayeni, and Harch are on the Board of Directors of the study sponsor, the non-profit 501c(3) International Hyperbaric Medical Foundation. Mr. Reimers is the Chief Financial Officer of the International Hyperbaric Medical Foundation, and a vendor of hyperbaric chambers and equipment. Dr. Harch is a small business owner of a consulting company, Harch Hyperbarics, Inc. Drs. Beckman and Mozayeni have an interest in CareVector LLC, the developer of case report form data collection software used to support this study. The other authors have no conflict of interest.

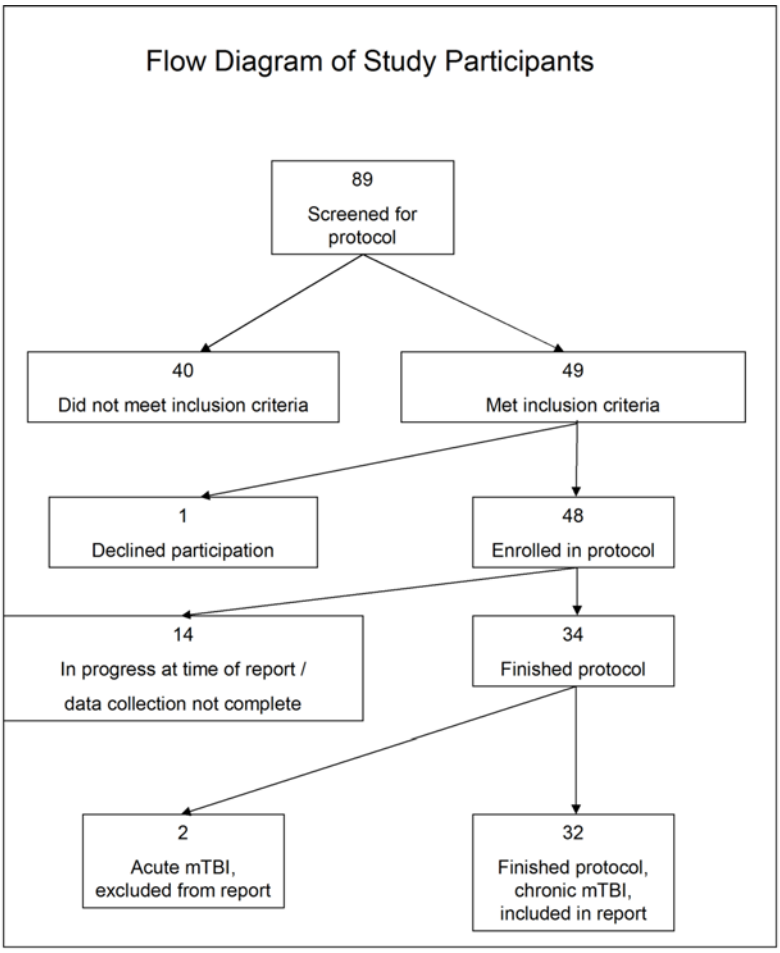

Figure 1: Flow diagram of study participants included in this report.

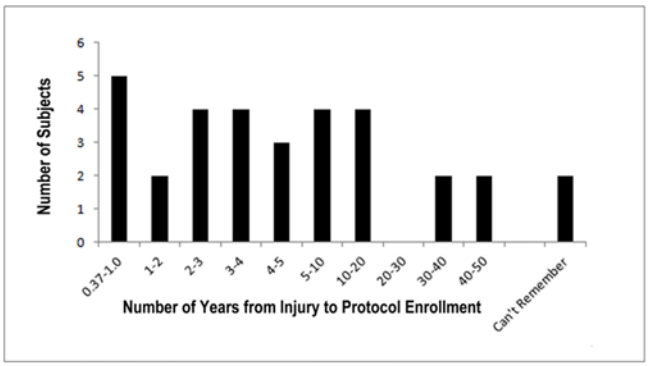

Figure 2: Distribution of subject population time from injury to protocol enrollment

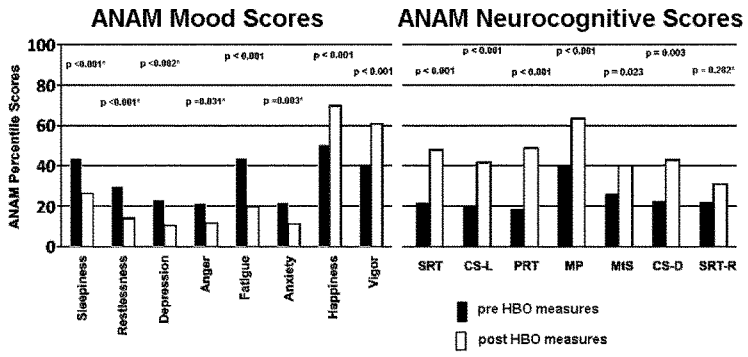

Figure 3: ANAM4™ Mood (left) & Neurocognitive (right) Test Scores. Average values from test subjects are displayed. Prior to each AMAM4™ assessment, subjects were asked to rate eight mood areas (left) before undertaking a battery of neurocognitive test (right). SRT denotes Simple Reaction Time, CS-L Code Substitution-Learning, PRT Procedural Reaction Time, MP Mathematical Processing, MtS Matching to Sample, CS-D Code Substitution-Delayed, SRT-R Simple Reaction Time-R, * non-parametric.

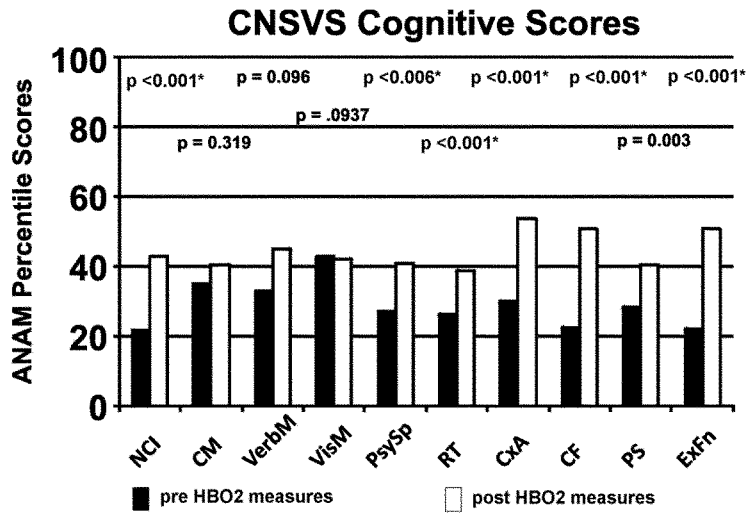

Figure 4: CNS VS Neurocognitive test scores. Average values from test subjects are displayed above. * denotes non-parametric, NCI Neurocognitive Index, CM Composite Memory, VerbM Verbal Memory, VisM Visual Memory, PsySp Psychomotor Speed, RT Reaction Time, CxA Complex Attention, CF Cognitive Flexibility, PS Processing Speed, ExFn Executive Functioning.

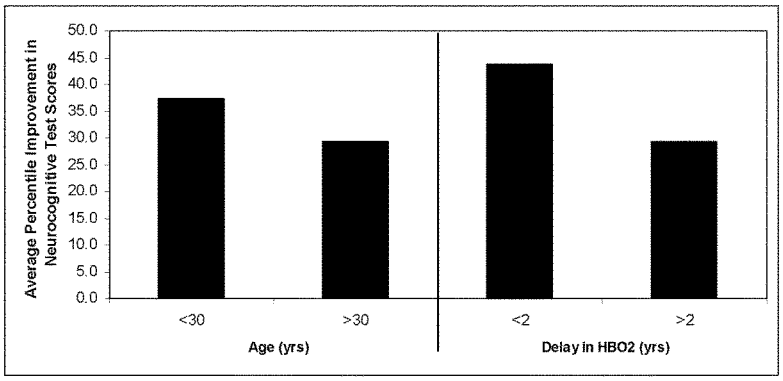

Figure 5: Effect of younger age at time of protocol enrollment and delay in HBO2 administration form time of injury on neurocognitive test score improvement. Neurocognitive scores are expressed as the sum of average improvement in tests administered.

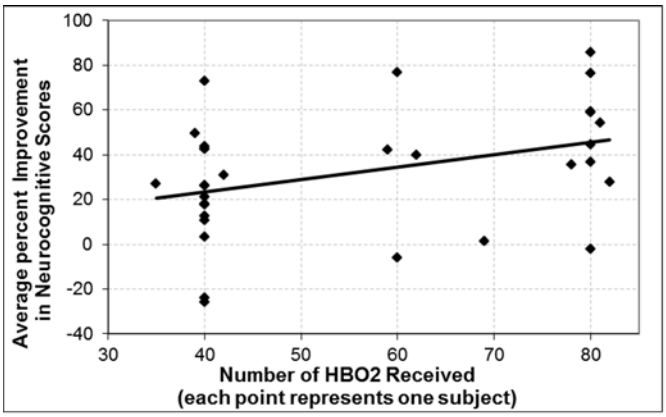

Figure 6: Average improvement in each subject's neurocognitive test scores compared to number of HBO2 sessions received. Each point in the graph represents one subject. The line through the points is a best-fit, linear regression (y=0.5539x + 1.1863) of individual subjects who have undergone 35 and up to 82 hyperbaric oxygen treatments. The trend line slope is 0.55; r = 0.3685, p = 0.038.

Variable	Value
Etiology of injury	
Blast	17 (53%)
Blow	15 (47%)
Total	32 (100%)
Number of concussive injuries	
Median	1.81±1.42
Range	1-7
Age at injury	
Median (yrs)	30.5 ±11.6
Range (yrs)	7-60
Age at protocol enrollment	
Median (yrs)	39.5±14.1
Range (yrs)	22-65
Delay from injury to HBOT start	
Median (yrs)	8.7±12.7
Range (yrs)	0.15-45.8
Duration of HBOT	
Median (days)	107±56
Range (days)	26-304
No. of HBOT	
Median	55.3±18.4
Range	35-82
Diagnosis	
TBI only	25

TBI + PTSD	8

Table 1: Study Population Characteristics

(± designates standard deviation)

Measure	Number of Outcomes
ANAM4™ mood scores	8
ANAM4™ neurocognitive tests	7
CNS VS neurocognitive tests	10
Total number of measures	**25**

Table 2: Outcome Measures

	Active Duty (n = 7)	Veteran (n = 12)	Civilian (n = 13)	Total (n = 32)	p value (ANOVA)
Sleepiness	-1.86±1.46, **p=0.040** CI: -3.21 to -0.50	-1.18±1.25, **p=0.022** CI: -2.02 to -0.34	-0.69±1.25, p=0.089 CI: -1.45 to 0.06	-1.13±1.34, **p<0.001** CI: -1.62 to -0.64	0.156
Vigor	32.7±15.2, **p=0.001** CI: 18.7 to 46.7	27.4±23.9, **p=0.002** CI: 12.2 to 42.6	8.3±24.0, p=0.236 CI: -6.2 to 22.8	20.8±24.2, **p<0.001** CI: 12.1 to 29.5	**0.043**
Restlessness	-27.0±19.4, **p=0.016** CI: -44.9 to -9.1	-18.3±27.0, **p=0.029** CI: -35.5 to -1.2	-6.0±14.4, p=0.182 CI: -14.7 to 2.7	-15.2±21.9, **p<0.001** CI: -23.1 to -7.3	0.066
Depression	-13.7±17.4, p=0.058 CI: -29.8 to 2.4	-18.7±27.6, **p=0.025** CI: -36.2 to -1.1	-6.1±16.1, p=0.184 CI: -15.8 to 3.7	-12.5±21.5, **p=0.002** CI: -20.2 to -4.7	0.512
Anger	-25.4±21.3, p=0.058 CI: -45.1 to -5.8	-9.3±27.4, p=0.398 CI: -26.7 to 8.2	-2.0±9.6, p=0.720 CI: -7.8 to 3.8	-9.8±21.7, **p=0.031** CI: -17.7 to -2.0	0.109
Happiness	25.0±25.7, **p=0.042** CI: 1.2 to 48.8	27.6±21.5, **p<0.001** CI: 13.9 to 41.3	8.5±20.5, p=0.158 CI: -3.8 to 20.9	19.3±23.2, **p<0.001** CI: 10.9 to 27.6	0.089
Fatigue	-35.9±19.1, **p=0.003** CI: -53.5 to -18.2	-34.1±26.0, **p<0.001** CI: -50.6 to -17.5	-7.8±19.1, p=0.164 CI: -19.4 to 3.7	-23.8±25.1, **p<0.001** CI: -32.9 to -14.7	**0.008**
Anxiety	-16.7±17.8, p=0.059 CI: -33.2 to -0.2	-12.6±24.6, p=0.052 CI: -28.2 to 3.0	-5.4±17.8, p=0.294 CI: -16.1 to 5.4	-10.6±20.5, **p=0.003** CI: -17.9 to -3.2	0.342
Simple Reaction Time	64±30, **p=0.001** CI: 36 to 92	17±30, p=0.068 CI: -2 to 36	13±19, **p=0.027** CI: 2 to 25	26±32, **p<0.001** CI: 14 to 38	**< 0.001**
Code Subst. Learning	40.7±29.5, **p=0.011** CI: 13.4 to 68.0	16.8±27.4, p=0.057 CI: -0.6 to 34.3	14.2±21.9, **p=0.047** CI: 0.2 to 28.1	21.2±27.2, **p<0.001** CI: 11.2 to 31.2	0.092
Procedural Reaction Time	67±18, **p<0.001** CI: 50 to 84	29±41, **p=0.033** CI: 3 to 55	10±30, p=0.267 CI: -9 to 29	30±38, **p<0.001** CI: 16 to 44	**0.004**
Mathematical Processing	37.3±31.8, **p=0.021** CI: 7.8 to 66.7	17.4±26.0, **p=0.041** CI: 0.9 to 33.9	21.5±20.5, **p=0.004** CI: 8.5 to 34.5	23.5±25.8, **p<0.001** CI: 14.0 to 33.0	0.262
Matching to Sample	33±28, **p=0.021** CI: 7 to 58	6±31, p=0.539 CI: -14 to 25	10±31, p=0.296 CI: -10 to 29	13±31, **p=0.023** CI: 2 to 25	0.167
Code Subst.	34±32, **p=0.029**	17±29, p=0.069	15±40, p=0.220	20±34, **p=0.003**	0.474

Delayed	CI: 5 to 63	CI: -2 to 35	CI: -10 to 41	CI: 8 to 33	
Simple	73±14 (4), p=0.098	-10±29, p=0.540	3±18, p=0.755	8±36 (27), p=0.282	
Reaction Time (R)	CI: 51 to 95	CI: -29 to 10	CI: -9 to 14	CI: -6 to 22	**0.007**

Table 3: Changes in ANAM4™ test values from start to end of HBOT, within each Military Status (Active Duty/Veteran/Civilian), and for all subjects combined. Final column indicates the significance of differences in ANAM4™ changes between the three groups. Values are expressed as mean change ± standard deviation of changes; CI indicates the 95% confidence interval around the mean change; p indicates the p value from a paired test for a significant mean within-group change.

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