14 August 2015

Carolyn M. Clancy, MD
Interim Under Secretary for Health
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington DC 20420

Dear Dr. Clancy,

I have just read your reply on behalf of Mr. Robert A. McDonald, Secretary of Veteran Affairs, to the letter from Representative Walter Jones and other Representatives concerning use of HBOT 1.5 to treat Veterans and active duty Military personnel who suffer from the effects of Traumatic Brain Injury (TBI). This is a very serious issue with multiple considerations and your letter deserves a serious and considered response.

I am very disappointed that someone in your position would respond in a way that seems to ignore and disparage the large amount of relevant, peer reviewed and published medical literature on this subject. Unfortunately, your response leads me to believe that either you have not done any serious investigation of the published medical literature on the subject, or that you have a fundamental unwillingness to find out more about it. Repeating the Army's published conclusions, without any serious assessment or evaluation of what the data actually collected and reported indicates, borders on negligence, especially when your response reverts back to arguments that have been discredited years ago.

I have no way of knowing if you have personally had any direct experience with serious efforts to heal brain injuries or if you have only reviewed certain selected publications. If the later, then your stance becomes (somewhat) understandable. Nevertheless, relying on Inaccurate and/or misleading interpretations of data can only lead to inaccurate conclusions.

As I am told by my daughter-in-law, a Doctor, and as I have always believed, the primary, cardinal rule for all Medical Personnel is – 'First, Do No Harm'. And while it may not be quite as well understood or articulated, the second rule is – 'Work to Restore Health'. As I see it, if a treatment (in this case HBOT 1.5) has few to no side effects, and there is repeatedly good evidence for its use, a Physician not only has a right, but has a moral <u>obligation</u> to use it.

As I am sure you understand, HBOT 1.5 is not being presented as a 'magic bullet'. It can be and is one more treatment for brain injury, not the 'be and end all' of treatment.

As I read your reply, you seem to be saying that only approved treatments should be used to treat our Veterans. Yet the evidence clearly shows that this is not the way it is in the DoD/VA Medical Community. As one individual said, "….**Not (a single) one of the 70+ therapies, countless computer applications, and 114+ drugs prescribed in DOD/VA/Army medicine has been approved by the FDA for TBI. All are used off-label for TBI. All are controversial at some level. Many of them are brand-new and haven't even been explored in the literature. Yet neither the DOD nor the VA will provide Hyperbaric Oxygen Therapy, used off-label, to treat and heal brain injury, the one therapy proved by multiple clinical trials and evidence-based clinical medicine inside DOD/VA and around the world to treat and help heal TBI, safely and effectively.** ***No one has died while treating TBI/PTSD with HBOT***.**"**

There are significant distortions or misunderstandings/misstatements in your response. Among these are the following:

A. **"We are committed to providing the best proven treatments and technologies to assist in the care of our Nation's Veterans."**

The intention of the Veterans Administration to care for veterans is not at issue. What seems evident is that there is a serious effort to avoid treatments that appear to work in favor of a culture of drug prescriptions to palliate, not treat and heal, brain injuries. Your contention that the VA is using "the best proven treatments and technologies" -- with the implication that there is a lowered risk to the veteran -- has to be weighed against the VA's record and culture surrounding brain injuries and associated pain and suffering. Couple all that with the dismissive and desultory (and expensive) research approach to dealing with an epidemic, and it seems clear that there is no evident sense of urgency about dealing with the current suicide epidemic.

- Data from IMS Health, a health care information company, show the number of hydrocodone/acetaminophen prescriptions written by U.S. physicians for civilians rose 68 percent from 2002 to 2011. Prescriptions of the drug written by VA doctors climbed 360 percent during the same period.
- The Institute of Medicine recently issued a report that highlights the plethora of ineffective off-label treatments being used across the military, and their negative utility. The report and a summary notes: ***"The Defense and Veterans Affairs departments spent $9.3 billion to treat post-traumatic stress disorder from 2010 through 2012, but neither knows whether this staggering sum resulted in effective or adequate care. . . ."***
- ***"DOD spent $789.1 million on PTSD treatment from 2010 through 2012. During that same time period, VA spent $8.5 billion, with $1.7 billion treating 300,000 Iraq and Afghanistan veterans. DOD lacks a mechanism for the systematic collection, analysis and dissemination of data for assessing the quality of PTSD care, and VA does not track the PTSD treatments a patient receives, other than medications, in its electronic health record".*** The IOM said

this in the congressionally mandated 301-page report, 'Treatment for Posttraumatic Stress Disorder in Military and Veteran Populations: Final Assessment.'"

- Among all veterans receiving VA services nationally in a single year, 2005, a VA researcher calculated 1,013 had died of accidental drug overdoses — double the rate of the civilian population, when accounting for age and gender. More current data from the CDC reports that the accidental drug overdose in the Army is 33% higher than in the civilian sector.
- Coincidentally, since 2006, not a single one of the hundreds of veteran service members treated with Hyperbaric Oxygen Therapy (HBOT) has died of oxygen or any other drug overdose during or after treatment. The vast majority of those treated have been returned to a quality of life far exceeding that promised them by a lifetime spent on drugs and welfare. Additionally, they are able to quit taking most of the drugs prescribed them by DOD/VA/Army.

The nation faces an unprecedented suicide epidemic in the military community. **22+ successful and 44 failed suicide attempts per day** are testimony to the failure of the DOD/VA to comprehend, much less successfully address, over 24,000 acts of desperation every year. DOD has reported that mental illness ranks as the leading cause of hospitalization for active-duty troops. Insiders worry that the epidemic of brain injuries and mental health will continue to accelerate for many more years.

The implications for force readiness are yet to be fully understood or even seriously addressed, but ADM McRaven reported that **Special Operations warriors commit suicide at twice the rate of the regular force**. Mis- and mal-diagnosed brain injuries sap morale and send a negative message to future volunteers. And we now read that a new government report calls the suicide rate of female military veterans "staggering." **Female military veterans commit suicide at nearly six times the rate of other women; for females between 17 and 25, the rate is twelve times the national rate.**

DOD/VA continue to insist that there is no effective treatment for TBI brain-injured service members, even as they spend billions of dollars on unproven, unscientific, undocumented, and even dangerous interventions with drugs, devices, processes and providers. Meanwhile, the suicide epidemic across the force and within DOD, including Reserves and the National Guard, continues unabated.

B. "HBo2 Therapy uses increased pressure to attempt to provide oxygen into injured or diseased tissue to improve tissue functioning."

Such a constricted and myopic view of the proven Mechanisms of Action and the benefits of Hyperbaric Oxygen in research and clinical Medicine discounts the demonstrated healing powers of 100% oxygen, and even ambient air, under pressure. Oxygen under pressure (whether 21% in room

air or at 100% concentration) increases the amount of oxygen carried by the blood, enabling the oxygen to be delivered into the hard-to-reach plasma, lymph, and cerebrospinal fluids surrounding the brain and spinal cord, providing a greater opportunity for healing.

Put succinctly, HBOT:

- Increases stem cell mobilization, providing regeneration and repair of injured and low performing organs.
- Returns cell, organ and brain metabolism to optimal levels
- Stimulates the growth of new blood vessels to locations in the body with reduced circulation
- Reduces swelling, decreases inflammation, strengthens the immune system, and stimulates the release of stem cells
- Creates an adaptive increase in superoxide dismutase, one of the body's antioxidants and free radical scavengers, promoting the ability of white blood cells to fight disease and infection

C. "...while HBo2 is not a prescription medication that may have related side-effects or addictive qualities, there are still associated risks when using the therapy at higher pressures, including middle and inner ear injury, lung injury, and central nervous system toxicity (confusion, seizures, brain damage)."

Oxygen is defined as a drug and is treated as such by the FDA. Normal safety procedures always apply under strict procedures during all applications. All drugs have risks, yet hundreds are prescribed and administered by physicians attempting to deal with the symptoms of brain injury and mental health.

- A 2008 DoD Consensus Conference on Hyperbaric Oxygen Therapy in Traumatic Brain Injury attended by hundreds of researchers and practitioners from across the USG, DOD, VA and civilian medicine concluded **HBOT at 1.5 ATA** 100% O2 was completely safe.
- HBOT is used tens of thousands of times a day routinely around the world and is so safe that it has been deregulated in the United Kingdom by an Act of Parliament in 2008.
- Higher pressure treatments are routinely applied for wounds, tissue necrosis, and recalcitrant infections of bone without increased morbidity or mortality due to HBOT.
- A 73 year review of hyperbaric medicine world-wide revealed that fatal accidents or explosions had not occurred in North America up to 2008, making it one of the safest clinical procedures in medicine.
- The Samueli Institute, hired by the Army to "provide an independent, objective, and transparent analysis of the research conducted to date on HBO2 for TBI" stated that "HBOT is a healing environment." They also noted in Summary Conclusions that

"improvements in outcomes .... cannot be ignored....HBO2 may be of value and could benefit these patients (moderate-severe TBI) as a relatively safe adjunctive therapy if feasible."

- The State of Israel has recently installed two 20-person multi-place chambers in Tel Aviv to treat the Israel Defense Forces and to further their safe, effective and precedent-setting peer-reviewed research into the use of HBOT for traumatic brain injury and other brain insults.

D. "The Department of Defense (DoD) sponsored the first ever placebo-controlled studies in this line of research to provide objective scientific data that is missing from earlier studies and anecdotal reports. This rigorous line of DoD research, with participation from the Veterans Health Administration (VHA), included three randomized, blinded, placebo-controlled trials that examined the effect of Hbo2 on Service members with symptomatic mild TBI."

Even a casual reading of the literature about the international controversy stirred up by the DOD/VA/Army studies would discover that these studies are fundamentally flawed – and a reading of previous, background literature, as well as rational thought, shows that these flaws were repeated multiple times.

The authors characterize the DoD studies as sham-placebo controlled clinical investigations. The definition of a sham is that it "omits a key therapeutic element of the treatment or procedure under investigation". The definition of a placebo is "a substance or procedure… that is objectively without specific activity for the condition being treated", in short, that it must be inert. The key therapeutic elements in hyperbaric therapy are both pressure and hyperoxia, neither of which is inert. Therefore, the Cifu, et al study is neither sham, placebo, nor controlled; all groups were treated with either increased pressure, hyperoxia, or both.

Published literature from around the World has repeatedly stressed that "….Using controlled conditions, Scott Miller, et al have added yet more evidence that hyperbaric treatment is of benefit to patients with mild neurological conditions. This was clearly not the intention of this pilot study but the attribution of the remarkable improvements recorded to 'ritual' demonstrates that the science involved is not understood. A 20% increase in ambient air pressure cannot be regarded as a "sham" treatment because the concentration of the respired oxygen increases from 158 to 190 mm Hg (at a barometric pressure of 760 mm Hg). As the alveolar water vapour and carbon dioxide partial pressures remain constant, there is a proportionally greater increase in the plasma oxygen tension, and an abrupt increase in respired gas concentrations is also accompanied by beneficial osmotic changes at cellular level."

And, "....we had unconvertible evidence that even a very small pressure could produce the same positive effects as much higher dosage of HBOT.... We have much more knowledge about the physiology of hyperbaric therapy in neurological conditions and this should help us understand and accept the impact of small increases of pressure on brain function. By definition 'sham' is something 'false or empty'."

Hyperbaric treatments at 1.2 ATA substantially increase the amount of dissolved oxygen in the blood and simultaneously induce cascades of metabolic changes and genes activation. Therefore, the supposedly sham treatment of Miller's study is not close to being a placebo. An increase of just 0.2 ATA is an effective treatment and is used to save lives in patients with mountain (altitude) sickness. It has to be considered as a treatment arm. Always.

And, "….breathing regular air under hyperbaric conditions of 1.3 ATM leads to more than 50% elevation in tissue oxygenation. There are many case reports illustrating significant effects due to small increases in air pressure, including effects on the brain. Moreover, even a slight increase in partial pressure, such as to 1.05 ATM at altitude 402 m below sea level (the Dead Sea), can lead to noticeable physiological effects. Since 50% elevation in tissue oxygen can have significant physiological effects, treatment with room air at 1.3 ATM is not an 'ineffectual treatment' as is required from a proper sham control. Yet, a recent randomized, controlled trial on mTBI patients by Wolf et al, used room air at 1.3ATM as sham control for treatment with 100% oxygen at 2.4 ATH. Both groups revealed significant improvements in cognitive symptoms and in the measure of post traumatic stress disorder (PTSD). We find these results very important: they actually demonstrate that the significantly less expensive and logistically simpler treatment of mTBI patients with mild HBNO2 (mild hyperbaric pressure of 1.3 ATM and regular air) can lead to meaningful improvements . . . . Put aside this weakness, the study suffers from a logical flaw: The authors mention that their study was motivated by the results of Wolf, et al., and they accepted the interpretation that any observed improvements should be a reflection of placebo effect and have nothing to do with the HBOT. If placebo can indeed be so powerful in mTBI patients, one would expect that stress related to the idea of breathing half the normal level of air may trigger (a) powerful negative placebo effect."

And, most recently, "The TBI/PCS studies that used HBAT (pressurized, non-oxygen enriched air) as a 'sham' were, in reality, a dose comparison study. The DoD/VA and Army sponsored studies demonstrated that HBAT is a safe and effective dose and HBOT is an effective intervention to treat the symptoms and cognitive impairment of a TBI/PCS. Higher treatment pressures appear to be less effective, probably due to increased toxic effects on the central nervous system. HBAT and HBOT elicit therapeutic effects on the brains of TBI/PCS victims.... The "sham" interventions used in the three trials (DoD/VA, Army)… were not shams, but different doses of an active ingredient (or ingredients). The design flaw in each study invalidates the conclusions of a placebo effect, supporting the alternate conclusion: HBOT and HBAT are both neuroprotective and

neurorestorative. The controls that the study authors used were defined as shams, but all the evidence points to pressurized air (21% O^2) having biological and therapeutic activity."

E. **"Clinical support for using HBo2 for neurological conditions is primarily based on anecdotal case data. There is currently no objective empirical evidence indicating that HBo2 is effective or of benefit to Veterans with TBI or PTS."**

It is clear from a cursory review of the References in Attachment A, that the statement above is simply not true. I cannot imagine why you included it in your response.

BLAST INJURY: Silent Killer

In your letter, there was no mention of the latest research into Blast-Induced Post-Concussion Syndrome and Post-Traumatic Stress Disorder and the growing body of evidence that brain injuries sustained in combat that result from ***over-pressure*** are distinctly different from common, impact concussions. There is a significant population of veterans with a common group of signs and symptoms (signature or silent wounding –Blast Induced Traumatic Brain Injury). The injuries, experienced by a large percentage of Veterans with this constellation of signs and symptoms, are now being attributed to the exposure to sudden and severe over-pressure in the combat zone. Sources of over-pressure include, but are not limited to, explosions, (e.g., IED's), detonations (i.e. breeching), crew served weapons firing (e.g., Karl Gustav Recoilless Rifle MAAWS/RAWS weapons system) and sustained firefights. In fact, as early as 2004, in an article published in the New England Journal of Medicine, author Charles W. Hodge, M.D. showed a positive correlation between PTSD and firefights.

Vann et al, in an article entitled ***Decompression Illness*** in the *Lancet 2011, Vol 377, Jan 8, 2011* concludes "Decompression illness occurs in a small population, but is an international problem that few physicians are trained to recognize or manage. Although its manifestations are often mild, the potential for permanent injury exists in severe cases, especially if **unrecognized or inadequately treated**. Emergency medical personnel should be aware of manifestations of decompression illness in the setting of a patient with a history of recent diving or other exposure to **substantial, sudden pressure change**."

The Traumatic Brain Injuries experienced by our Combat Forces are not a new phenomena. The current response of the VA, Military Medicine, and your stated reaction to this are very real reminders of how the VA and Military Medicine responded to the 'Agent Orange' conditions during and after our involvement in Vietnam. As you will remember, it was only after some 40 years and thousands of deaths that it was even recognized as being 'Real' – and not 'All in their heads'. Why are we, as a people and a society, repeating this?

I look forward to your response. It takes a very special kind of person to admit an error in their judgment or assessment. I hope you are able to do this. More importantly, I urge you in the strongest terms, to take action on behalf of the service men and women who have been told there is no hope for their (often invisible) brain injuries. The Civilian Medical Community has demonstrated that there is not only hope, but a transformative way back into their communities for theses warriors.

Please allow and support Veterans to seek HBOT treatment in the civilian clinics that are eager and willing to help heal them.

Sincerely,

Rainey Owen
Grandfather of a 'Restored from TBI' Veteran
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ATTACHMENT A - HBOT RESEARCH AND SCIENCE

Cc: . Robert A. McDonald, Secretary of Veteran Affairs