

## Memorandum for Presidential Consideration and ACTION: Allowing use of Veterans Access, Choice, Accountability Act (VACAA) of 2014 (CHOICE) to procure Hyperbaric Oxygen Therapy for TBI/PTSD/PCS.

SUMMARY: The effort proposed below will accomplish six major tasks:

1. Provides immediate help to veterans with brain injury
2. Provides immediate relief to overloaded VA system
3. Starts a process of farming out needed services to private sector
4. Short-circuits establishment's efforts to continue researching a problem that it cannot and will not solve on its own
5. Delivers on the new Administration's promise to act quickly to cut through establishment bureaucracy
6. Saves money and lives

### MEMORANDUM FOR THE NEW PRESIDENT AND HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

SUBJECT: Enabling Service Members with diagnosed brain injuries [Traumatic Brain Injury (TBI), Post Traumatic Stress Disorder (PTSD) and/or Post and Persistent Post Concussive Symptoms (PCS/PPCS)] to use the CHOICE program to acquire Hyperbaric Oxygen Therapy (HBOT) in the civilian sector to treat their wounded brains.

The Memo urges immediate ACTION to help treat and heal brain injuries in service members denied treatment by DOD/VA/Army medicine.

Section 1. Purpose. This memorandum calls on the new President and his Cabinet to direct relevant executive departments and agencies (agencies) to perform certain functions to enable service members with diagnosed TBI/PTSD/PCS/PPCS to go outside the VA to acquire HBOT services, which services are not available within the VA Health system.

Sec. 2. Background. Throughout the past two Administrations, the DOD/VA/Army medical community have struggled with the growing problem of brain injuries not only in the services and among veterans, but across the country. DOD has reported that mental illness ranks as the leading cause of hospitalization for active-duty troops.<sup>i</sup> Insiders worry that the epidemic of brain injuries and mental health will continue to accelerate for many more years.<sup>ii</sup> The components of the problem include admitted

epidemics of service member suicide -- now 20 a day<sup>iii</sup>; hundreds of thousands of diagnosed and undiagnosed traumatic brain injuries (TBI) and Post Traumatic Stress Disorder (PTSD)<sup>iv</sup>; a massive prescription drug epidemic and accompanying deaths through overdosing<sup>v</sup>; disproportionate service member homelessness, joblessness and incarcerations<sup>vi</sup>; bad-paper-discharges<sup>vii</sup>; and spousal abuse and secondary PTSD among caregivers<sup>viii</sup>.

The implications for force readiness are yet to be fully understood, but ADM McRaven reported that Special Operations warriors commit suicide at twice the rate of the regular force.<sup>ix</sup> Mis- and mal-diagnosed brain injuries sap morale and send a negative message to future volunteers. Despite evidence to the contrary<sup>x</sup>, DOD and VA medicine insist that there is no treatment for TBI, while billions of dollars continue to be expended on palliative drugs and long-term care of treatable "invisible wounds."<sup>xi</sup>

As confounding are statements by two previous Secretaries of Defense and the last Secretary of Veterans Affairs. They publicly acknowledged their individual inabilities while in office to affect or to control their departmental bureaucracies in critical health matters. In the matter of helping secure improvements in the care of combat soldiers and other wounded, they disclosed that they had been personally ineffective in moving their respective bureaucracies to accept more enlightened practices, expressing frustration - even personal failure - in these regards.<sup>xii</sup>

Brain injuries are pandemic in America, not just in DOD or the NFL. Brain diseases and injuries affect millions of Americans.<sup>xiii</sup> The Centers for Disease Control and Prevention reports 2.5 million new injuries per year; 50,000 die. 3.5M+ citizens are wholly disabled due to TBI, and the number rises every year, even without war casualties.<sup>xiv</sup>

The Institute of Medicine reports that DOD and the VA spent \$9.3 billion to treat post-traumatic stress disorder from 2010 through 2012, but neither knows whether this sum resulted in effective or adequate care.<sup>xv</sup> The expenditures and outcomes for TBI are similar. Billions are spent on drugs, none of which have been tested and approved for use with brain injuries, and too many of them warn of "suicidal ideation" as a side effect.<sup>xvi</sup> In the face of the national crisis and the paucity of funds for research and clinical medicine, this cycle of expanding time lines and bloated budgets should not continue. It does not need to.

Army medicine has run trials investigating the use of Hyperbaric Oxygen to treat and help heal Traumatic Brain Injury. They have shown that HBOT is both safe and effective: "Randomization to the chamber . . . offered statistical and in some measures *clinically significant improvement over local*

*routine TBI care.*" Also: "... total scores for [both] groups revealed *significant improvement over the course of the study for both the sham-control group .... and the HBO2 group....*"<sup>xvii</sup> Expert outside consultants declared that "[HBOT] is a healing environment."<sup>xviii</sup> Despite these findings in all their studies, HBOT is not available for use in either DOD or VA facilities, despite the epidemic of brain injuries, suffering and suicides.

Hyperbaric Oxygen Therapy (HBOT) involves breathing 100% oxygen under pressure in a comfortable, certified safe pressure chamber. HBOT causes an abundance of O<sub>2</sub> to diffuse into the blood plasma, leading to growth of new blood vessels and new tissue development; reduced swelling; and accelerated wound healing. HBOT has been used for decades for decompression sickness ("bends"), carbon monoxide poisoning, diabetic foot wounds, crush injuries, and thermal burns and radiation tissue damage.<sup>xix</sup> Worldwide research is accelerating to understand how HBOT multiplies and mobilizes the body's circulating stem cells, leading to neurovascular regeneration. All this occurs through the simple process of pressurizing oxygen to accelerate the body's natural healing processes.

Using a network of US civilian clinics, over the last three years a Coalition of mostly veterans working pro bono has successfully treated over 2,300 PTSD/TBI Veteran and civilian casualties. The Coalition has had dramatic, life-altering success returning each of the fully-treated patients to a quality of life far above what they could receive from traditional or DOD medicine. A significant number were returned to active military duty, including special forces, at cost savings running into the millions.<sup>xx</sup>

In parallel with DOD/VA research on HBOT treatments for PTSD and TBI, complementary and alternative medicine research has been going on in the civilian sector worldwide that may provide immediate help to those suffering invisible wounds and/or contemplating suicide.<sup>xxi</sup> Scientific evidence continues to accumulate for such therapies as the simple use of OMEGA 3s, Magnetic resonance therapy (MRT)<sup>xxii</sup>, cognitive electrical stimulation (CES)<sup>xxiii</sup>, near-infrared therapy (NIR)<sup>xxiv</sup> and other non-invasive treatments.<sup>xxv</sup> Each of these can be studied while treating and comparisons about relative safety, effectiveness and risk can be done in near-real time. Urgency, immediacy and treatments under protocol should be the operational objectives.

A national effort would be the most dramatic approach to staunch the bleeding and address the larger issues of military medicine in general and a fast-track approval of treatments which show the most promise.

The focus of this national effort must be on suicides and treating and healing TBI, but must simultaneously focus on alleviating suffering in families and veterans. A report from the RAND Corporation on Military Caregivers

sponsored by the Elizabeth Dole Foundation, found that between 275,000 and a million or more "caregivers in general suffer from physical strain and overall worse health and tend to put their own concerns behind those of the individuals for whom they are caring."<sup>xxvi</sup> The journal *Neurology* reports that TBI in older veterans was associated with a 60% increase in the risk of developing dementia. Results suggest that TBI in older veterans may predispose toward development of symptomatic dementia and raise concern about the potential long-term consequences of TBI in younger veterans and civilians.<sup>xxvii</sup>

Albert Einstein said that insanity is doing the same thing over and over expecting different results. A private-public partnership could break the logjam and would focus a near term recognition and need to break the cycle of study/research/ spending/failure with respect to the suicide epidemic . The precedent exists: the FDA has approved the use of *brincidofovir* to treat Ebola symptoms during emergency situations.<sup>xxviii</sup> Using an Emergency Investigational New Drug/Device Application, a drug or device can be used in the event of an emergency.<sup>xxix</sup> Rapid, low-risk, high-payoff experimental treatments can be started immediately to deliver fast results. Bayesian Adaptive Trials testing the use of alternative medical treatments might be effective in arresting the suicide epidemic. They could commence in days, using current technology and installed treatment facilities, and return results in as little as 60 days. Importantly, the SECDEF can control the stop-go switch: potential successes get continued attention, while lack-of-success can be stopped quickly.

Few opportunities will exist immediately for this Administration to demonstrate the vision, planning, execution and report-of-results on a matter of such significance for the services and the nation. Looked at through the lenses of ethics, need, importance, cost or impact, no crisis rises to this level of urgency, importance, or near-certainty of success. The new Secretary of Defense could crack this code and earn the gratitude of hundreds of thousands of brain injured and redeem the oath that we leave no soldier behind, especially on the battlefield at home.

Therefore, this Memorandum, calls for the new Administration to take whatever steps are necessary to immediately and urgently ensure service members with TBI/PTSD/PCS/PPCS get insured access to HBOT to help treat and heal the wounds to their brains, however acquired. In addition, it calls for directing the creation of an interagency working group to further implement the policies and priorities described in this memorandum.

Sec. 3. Policy. The Veterans Access, Choice, Accountability Act (VACAA) of 2014 is a law that expands the number of options Veterans have for

receiving care to ensure Veterans have timely access to high-quality care. Veterans Choice Program (VCP) provides primary care, inpatient and outpatient specialty care, and mental health care for eligible Veterans when the local U.S. Department of Veterans Affairs (VA) health care facility cannot provide the services due to:

- lack of available specialists.
- long wait times.
- extraordinary distance from the Veteran's home.

Eligible Veterans must contact HNFS to obtain authorization for all care under VCP. Veterans are encouraged to access health care through the HNFS comprehensive network of community-based, non-VA medical professionals who meet VA quality standards. These highly qualified providers are contracted as part of Health Net's URAC accredited Patient-Centered Community Care (PCCC) network and proudly serve our Veterans today in PCCC and VCP.

However, VCP allows a Veteran to choose a provider outside of the PCCC preferred network when a PCCC provider is not available or the Veteran has a preference for another community provider. Health Net Federal Services must verify the provider outside of the PCCC preferred network meets the certification and license requirements of VCP and the provider must agree with program requirements prior to scheduling an appointment.

#### Sec. 4. Preliminary Plan

1. This Administration needs to declare that the suicide epidemic is an emergency, along with the need to alleviate the pain and suffering of the invisible wounds of war through urgent, accelerated, emergency action to treat now the invisible wounds of TBI and PTSD.
2. This Memorandum declares for immediate actions with drug-free complementary and alternative medical interventions that have been shown to be safe and potentially useful with respect to the ravages of traumatic brain injury and the attendant symptoms of PTSD and post concussive syndrome: headaches, dizziness, fatigue, hyper-vigilance, sleeplessness, depression, imbalance, and loss of executive and emotional control leading in some cases to violence and loss of life.
3. CHOICE Cards shall be authorized to be used for acquiring HBOT treatments in the private sector.
4. A Supervisor shall be appointed to create a short-term [no longer than six months] proof-of-principle application of complementary and alternative medical treatments that show promise, and a medium-term [no longer than 2 years] organizational structure, empowered to oversee all

treatments and make scientific judgments about safety and effectiveness of the treatments under review.

5. Set in place the organizational structure and funding for a major, independent, long term [perhaps five years] clinical program to get to the bottom line—a clinical study whose purpose is twofold: to address the mechanisms of action behind these brain injuries; and, foremost, to identify and use known treatments in the clinical trials that immediately lead to help in healing. The trials must be aimed at intervening immediately via clinical medicine with all high-probability-of-success alternative treatments. An adjunct outcome of the research will be to gain the acceptance of the medical community as a whole through open, unbiased, collaborative data sharing, improving medical education and upgrading the accepted standard of care for TBI/PTSD.

Sec. 5. Strengthening Interagency Coordination on matters related to brain injury.

(a) Federal Interagency Working Group. There is hereby established an interagency Working Group on Mental Health to be co-chaired by the Secretaries of the Departments of Defense, Veterans Affairs, Health and Human Services and the Services, or their designees. The Working Group shall also include an agency Co-Chair, to be rotated annually among the Secretaries of Defense and Veterans Affairs, or their designees. The Working Group will coordinate the development and execution of treatment plans for brain injury, to include alternative therapies that show promise in stanching the epidemics that can be tied to brain injury. The Working Group may consult and engage with other Federal interagency working groups as appropriate to ensure that related activities are coordinated. The Working Group shall meet at least quarterly.

(b) Representation. In addition to the NEC and DPC, the Working Group shall include representatives from:

1. the Department of Defense;
2. the Department of Veterans Affairs
3. the Department Health and Human Services
4. any other Federal agencies, offices, or initiatives invited to participate by the Co-Chairs.

Sec. 5. General Provisions. (a) This memorandum shall be implemented consistent with applicable law.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Secretary of the Department of Veterans Affairs relating to budgetary, administrative, or legislative proposals.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

## ADDENDUM

### Recap of information as it relates to the need to provide Hyperbaric Oxygen Therapy (HBOT) treatment to suicidal, concussed and brain-injured active duty, veterans National Guard, and Reserves

- July 2016. The VA reports that 20 service members a day commit suicide. Another 45 a day try and fail: over 23,000 acts of desperation every year. Special Operations warriors commit suicide at twice the active-duty rate. Female veterans are 12 times more likely to commit suicide than their civilian peers. Researchers found that the risk of suicide for veterans is 21 percent higher when compared to civilian adults. From 2001 to 2014, as the civilian suicide rate rose about 23.3 percent, the rate of suicide among veterans jumped more than 32 percent.
- June 2016. In what is being called a breakthrough study, Dr. Daniel P. Perl and his team at the Uniformed Services University of the Health Sciences in Bethesda, Md., [the medical school run by the Department of Defense], have found evidence of tissue damage caused by blasts alone, not by concussions or other injuries. The New York Times calls it the medical explanation for shell shock: preliminary proof of what medicine has been saying without proof for nearly 100 years -- blasts cause physical damage, and this physical damage leads to psychological problems, i.e., PTSD. The importance of this admission cannot be overstated: this is a DOD discovery with documented evidence that blast injury [IEDs, explosions, breaching, whether in training or combat, enemy and/or friendly fire] can lead directly to physical brain damage and the accompanying effects, many of which have been heretofore diagnosed as "only PTSD." In effect, the over 325,00 diagnoses of PTSD in service members must now be considered to be something much worse: physical injury that has gone untreated.
- June 2016. A peer-reviewed journal article [Neurology] states: *"There is sufficient evidence for the safety and preliminary efficacy data from clinical studies to support the use of HBOT in mild-to-moderate traumatic brain injury/persistent post-concussion syndrome (mTBI/PPCS). The reported positive outcomes and the durability of those outcomes has been demonstrated at 6 months post HBOT treatment . Given the current policy by Tricare and the VA to allow physicians to prescribe drugs or therapies in an off-label manner for mTBI/PPCS management and reimburse for the treatment, it is past time that HBOT be given the same opportunity. This is now an issue of policy modification and reimbursement, not an issue of scientific proof or preliminary clinical efficacy."*
- May 2016. The TreatNOW Coalition reports that free-standing HBOT clinics have treated and helped heal over 2,20000 service members, police, fire, first-responders, athletes and civilians with brain injury: TBI/PTSD/Concussion/PCS

- April, 2016. The former director of the Combat Casualty Care Research Program, U.S. Army Medical Research and Materiel Command confided that "we spent over \$132Million researching HBOT for TBI . . . and OBSCENE amount of money." Nevertheless, that investment produced data that showed that HBOT is both safe and effective: *"Randomization to the chamber . . . . offered statistical and in some measures clinically significant improvement over local routine TBI care."* Also: *".... total scores for [both] groups revealed significant improvement over the course of the study for both the sham-control group .... and the HBO2 group....."* Despite their own findings, the Army continues to push the idea that HBOT does not work.
- April, 2016. The Department of Veterans Affairs plans to contact nearly 25,000 veterans nationwide to say they're entitled to new exams for traumatic brain injury because their TBI exams were not done by the proper specialists from 2010-2014.
- March 24, 2016. The New York Times Finds Massive Flaws in NFL's Concussion Studies downplaying the effects and dangers of concussions in professional football.
- March 14, 2016. Jeff Miller, NFL Executive Vice President of Health and Safety Policy for the first time admitted a link between football and Chronic Traumatic Encephalopathy (CTE): "the answer to that [link] is certainly yes." The NFL issued a statement the following day saying "The comments made by Jeff Miller yesterday accurately reflect the view of the NFL." Owners tried to walk that admission backward a week later, claiming the science was not solid.
- March 2016. Dr Ann McKee reports that 90 of 94 brains of former football players autopsied showed signs of CTE.
- February 24, 2016. The SCIENTIST reports that "Each and every TBI drug that has reached late-stage clinical trials has failed [41 of 41]. This 100 percent failure rate represents a huge human and economic cost. " The former head of Army Research states that "it is time to think differently."
- Feb 8, 2016. Canadian researchers report that "Adults with a diagnosis of concussion had a three-fold increase in the long-term risk of suicide, particularly after concussions on weekends. Greater attention to the long-term care of patients after a concussion in the community might save lives because deaths from suicide can be prevented."
- Jan 2016. A meta-analysis of literature on the use of HBOT for TBI concludes: *"Compelling evidence suggests the advantage of hyperbaric oxygen therapy (HBOT) in traumatic brain injury. ...Patients undergoing hyperbaric therapy achieved significant improvement....with a lower overall mortality, suggesting its utility as a standard intensive care regimen in traumatic brain injury."*
- Jan 5, 2016. DOD's Suicide Prevention Office calls the increase in suicides among the Army's active and reserve components alarming.

- Dec 2015. TreatNOW Coalition reports that over one dozen former NFL football players and over three dozen Special Operations warriors have experienced significant medical improvement after treatment with HBOT for their brain injuries.
- Nov, 2015. USAF reevaluation of data in original DOD/VA/Army HBOT-for-TBI study finds that *".... Hyperbaric oxygen therapy for mild traumatic brain injury and PTSD should be considered a legitimate adjunct therapy...."*
- An neurosurgeon advising the NFL's head-neck-and-spine committee wrote in a textbook: *"Substantial animal and human research now suggests that...natural dietary supplements, vitamins and minerals, and the use of hyperbaric oxygen may be a better first-line choice for the treatment of [concussion] which has generally been underreported by both athletes and the military."*
- Jan 2015. Johns Hopkins reports that the brains of Iraq and Afghanistan combat veterans who survived blasts from improvised explosive devices and died later of other causes show a honeycomb of broken and swollen nerve fibers in critical brain regions, including those that control executive function. The pattern is different from brain damage caused by car crashes, drug overdoses or collision sports, and may be the never-before-reported signature of 'shell shock' suffered by World War I soldiers.
- A June 2014 report by DOD says that 7 in 10 of America's youth cannot qualify for entry into the military. "The quality of people willing to serve has been declining rapidly," says the head of Recruitment Command, leading to a relaxation in recruitment standards.
- June 2014. The journal PLOS ONE reports on the effects of HBOT: "Repetitive Long-Term Hyperbaric Oxygen Treatment (HBOT) Administered after Experimental Traumatic Brain Injury in Rats Induces Significant Remyelination and a Recovery of Sensorimotor Function", further validating the reported positive biological effects of HBOT for TBI. Myelination, the insulation around the nerve fibers, does not fully complete in young men until around the age of 25 and is an added variable in the TBI epidemic of our young service members.
- 2014. "The patient-safety system is broken." Dr. Mary Lopez, a former staff officer for health policy and services under the Army surgeon general.
- 2014. Echoing recent concerns about the effectiveness of military mental health efforts, an American Legion survey of veterans found that nearly half thought clinical help they received for post-traumatic stress and traumatic brain injury had little or no effect on their conditions. Veterans also expressed frustration with physicians' reliance on medication to address their symptoms. More than half of those on prescriptions said they take five or more medications; 30 percent said they use 10 or more.
- June 2014. IOM Report: "Treatment for Posttraumatic Stress Disorder in Military and Veteran Populations: Final Assessment." 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.

- Current DOD/VA response to TBI treatments do not include even informing the brain injured that a potential treatment for TBI exists -- HBOT. There is effectively no "informed consent" to brain-injured service members from military medicine about even the possibility that HBOT might alleviate the symptoms and underlying physiological brain injuries. The same is true across the United States medical community, including in the NCAA, high schools and professional sports.

- June 2014. Military Risk Factors for Alzheimer's Dementia & Neurodegenerative Disease, Alzheimer's Dementia. Increasing evidence suggests that a single traumatic brain injury can produce long-term gray and white matter atrophy, precipitate or accelerate age-related neurodegeneration, and increase the risk of developing Alzheimer's disease, Parkinson's disease, and motor neuron disease. In addition, repetitive mTBIs can provoke the development of a tauopathy, chronic traumatic encephalopathy... Four of the five veterans with early-stage chronic traumatic encephalopathy were also diagnosed with posttraumatic stress disorder. Advanced chronic traumatic encephalopathy has been found in veterans who experienced repetitive Neurotrauma while in service and in others who were accomplished athletes. Clinically, chronic traumatic encephalopathy is associated with behavioral changes, executive dysfunction, memory loss, and cognitive impairments that begin insidiously and progress slowly over decades." Findings from "Military-related traumatic brain injury and neurodegeneration." AC McKee, ME Robinson, in In the same Journal, the Editors write: "Today, there is now growing evidence that a single traumatic brain injury (TBI) sustained early in life might trigger a cascade of neurodegenerative processes. The outcomes may manifest as dementia, Alzheimer's dementia (AD), Lewy Body dementia (LBD), or other motor neuron diseases many years or decades later. The scientific and medical community has known the effects of trauma on boxers since the 1920s. Now, increasing number of studies are showing that even mild repetitive trauma may lead to onset of symptoms in some athletes as early as in their second decade of life. The renewed interest in the idea that mild repetitive trauma to the head can trigger not only chronic traumatic encephalopathy (CTE) but also other neurodegenerative diseases is indeed timely. This important recognition is reinforced by the increased risk and prevalence of TBI and posttraumatic stress disorder (PTSD) among young military personnel associated with combat experiences."

- April 2014. ADM McRaven, head of SOCOM, reports in April 2014 that Special Operations warriors commit suicide at twice the rate of the regular force. An emerging body of research suggests that Special Operations forces have experienced, often in silence, significant traumatic brain injury and

post-traumatic stress disorder [there are eerie parallels between special operator and NFL ballplayer "Can't happen to me" responses to head injury.]

- 2014. Summary of positive findings in Army Studies in use of HBOT for TBI: Army medicine has run trials investigating the use of Hyperbaric Oxygen to treat and help heal Traumatic Brain Injury. They have shown that HBOT is both safe and effective: *"Randomization to the chamber . . . . offered statistical and in some measures clinically significant improvement over local routine TBI care."* Also: *".... total scores for [both] groups revealed significant improvement over the course of the study for both the sham-control group .... and the HBO2 group...."* Expert outside consultants to DOD declared that *"[HBOT] is a healing environment."*
- 2014. The journal *Neurology* reports that TBI in older veterans was associated with a 60% increase in the risk of developing dementia over 9 years after accounting for competing risks and potential confounders. Results suggest that TBI in older veterans may predispose toward development of symptomatic dementia and raise concern about the potential long-term consequences of TBI in younger veterans and civilians.
- The Oklahoma Veterans Traumatic Brain Injury Treatment and Recovery Act of 2014 was signed into law, establishing that "Any Oklahoma veteran who has been diagnosed with a traumatic brain injury (TBI) and prescribed hyperbaric oxygen treatment (HBOT) by a medical professional authorized under Section 2 of this act may receive HBOT at any facility in the state that has a hyperbaric chamber."
- April, 2014. A "wait-time" scandal that started in Phoenix and has led to deaths of veterans has been shown to be replicated at numerous VA facilities across the nation. Presumably, some of the over 500,000 veterans with TBI/PTSD have been negatively affected.
- March 29, 2013. The government has already spent \$134 billion on medical care and disability benefits for veterans returning from Iraq and Afghanistan. . . . [30 to 40 years out] these benefits would cost an additional \$836 billion. Of the 1.56 million troops that have been discharged, more than half have received treatment at Veterans Affairs facilities and filed claims for lifetime disability payments.
- March 2013. PTSD clinical practice guidelines, which also apply to the Defense Department, caution providers against using benzodiazepines to manage PTSD due to "the lack of efficacy data and growing evidence for the potential risk of harm...." The Army determined, like VA this month, that treatment of PTSD with benzodiazepines could intensify rather than reduce combat stress symptoms and lead to addiction. "mounting evidence suggests that the long-term harms imposed by benzodiazepine use outweigh any short-term symptomatic benefits in patients with PTSD."
- 2013. *Military Caregivers*, a report from the RAND Corporation sponsored by the Elizabeth Dole Foundation, found that between 275,000 and a million or more "caregivers in general suffer from physical strain and

overall worse health and tend to put their own concerns behind those of the individuals for whom they are caring." Military caregivers suffer disproportionately from mental health problems and emotional distress. Despite the well-known problems, "no national strategy for supporting military caregivers exists."

- July 26, 2012. Secretaries of Defense and the VA in testimony to Congress lament that the cultures in the government's two largest departments "resist change. They resist coordination. They resist trying to work together." Both men vow to "kick ass" to improve service to veterans.
- July 2012. *Journal of Neurotrauma* reports "...that a blast related mTBI exposure can in the absence of any psychological stressor induce PTSD-related traits that are chronic and persistent. These studies have implications for understanding the relationship of PTSD to mTBI in the population of veterans returning from the wars in Iraq and Afghanistan."
- July 2012. Neurological Review reports that multiple epidemiologic studies show that experiencing a TBI in early or midlife is associated with an increased risk of dementia in late life. The best data indicate that moderate and severe TBIs increase risk of dementia between 2- and 4-fold.
- June 2012. SECDEF orders sweeping review of how DOD diagnoses PTSD amid allegations that the Army might have reversed PTSD diagnoses based on the expense of providing care and benefits to members of the military
- June 2012. Editor of major Journal comments: "Every day we are.... gathering more data validating its efficacy.... I feel , as do many of my colleagues, that there is sufficient clinical and research evidence to justify the use of [HBOT] as a standard-of-care treatment for [TBI] that should be reimbursed by CMS and Tricare.... I have no doubt that, over the next several years, [HBOT] will be proven beyond a reasonable doubt to be one of the most effective treatments for [TBI].... There is a preponderance of evidence now to justify the use and funding for the treatment...."
- June 2012. Army cancels a 3-year, \$18M TBI software development program that turns out not to have anything to do with TBI, though the money has all been spent.
- May 2012. DOD reports that mental illness ranks as the leading cause of hospitalization for active-duty troops.
- May 2012. An active-duty Army doctor noted that the "stunning growth in numbers and rates of mental health hospitalizations . . . is undeniable evidence of an unprecedented and arguably unmanageable epidemic that is now threatening the viability of the force...." yet another epidemic to accompany those already identified by the DOD: suicide; TBI/PTSD; sexual assault; drug overdosing and death-through-overprescribed medication; homelessness, joblessness and incarceration; bad-paper-discharges; and violence against families.

- January 2012. Commander of the 1st Armored Division writes: "I have now come to the conclusion that suicide is an absolutely selfish act....I am personally fed up with soldiers who are choosing to take their own lives so that others can clean up their mess. Be an adult, act like an adult, and deal with your real-life problems like the rest of us."
- August 2011. The VA spent \$846 million on Seroquel since 2001 and \$717 million on Risperidone, another atypical antipsychotic, during the same period. A paper published by VA researchers said Risperidone was no more effective than a placebo in treating PTSD. The Army nevertheless reordered \$250M of Risperidone, despite its potential to contribute to suicidal thoughts.
- April 2011, Army Secretary John McHugh made it official: Soldiers could get Purple Hearts for traumatic brain injuries. Hundreds of thousands of service members with "invisible wounds" were finally recognized as having suffered physical damage to their brains, in addition to the psychological consequences of their physically wounded brain
- 2011. RAND issues Report on *Preventing Suicide in the U.S. Military*. RAND estimates the one-year cost for service members who had accessed the healthcare system and received a diagnosis of TBI to range from \$27,259 to \$32,759 (2007 dollars). For moderate to severe cases, the costs ranged from \$268,902 to \$408,519 (2007 dollars). Applying the RAND costs for mild TBI to the current DOD estimated number of 202,481 yields a projected one-year cost of \$5.5B to \$6.6B June 2010. An internal report from the Defense Department's Pharmacoeconomic Center at Fort Sam Houston in San Antonio showed that 213,972, or 20 percent of the 1.1 million active-duty troops surveyed, were taking some form of psychotropic drug: antidepressants, antipsychotics, sedative hypnotics, or other controlled substances.
- February 2010. Congress receives testimony that NONE of the drugs currently used and paid for by Tricare and the VA to treat our brain injured veterans are FDA-approved to treat TBI. Nearly all of the anti-depressants carry FDA Black Box warnings urging caution in 17-24 year olds because of the increased risk of suicide.
- November 2008. Army has not administered its own brain injury assessment test (ANAM) as recommended and has rarely used its results. The Army has so little confidence in ANAM -- developed by the Army at a cost over \$20M -- that the Surgeon General issued an explicit order that soldiers whose scores indicated cognitive problems should not be sent for further medical evaluation.
- November 2008. A TBI Consensus Conference sponsored by DOD/VA/Army declares that Hyperbaric Oxygen Therapy for Traumatic Brain Injury is safe.

- 
- <sup>i</sup> Mental Illness Is the Leading Cause of Hospitalization for Active-Duty Troops, BOB BREWIN, NEXTGOV.COM, May 17, 2012. Data from Armed Forces Health Surveillance Center, in its *Medical Surveillance Monthly Report*.
- <sup>ii</sup> Caroline Alexander, The Invisible War on the Brain, National Geographic, February 2015, pp. 30-53.
- <sup>iii</sup> Suicide Data Report, 2012, Department of Veterans Affairs, Mental Health Services, Suicide Prevention Program, Janet Kemp, RN PhD, Robert Bossarte, PhD.
- <sup>iv</sup> RAND. Invisible wounds of war : psychological and cognitive injuries, their consequences, and services to assist recovery / Terri Tanielian, Lisa H. Jaycox, 2008.
- <sup>v</sup> Wars on Drugs. RICHARD A. FRIEDMAN. New York Times, April 6, 2013.
- <sup>vi</sup> VA AND DEFENSE CHIEFS CONFRONT REALITY OF 700,000 INCARCERATED VETERANS. Bob Brewin, NextGov, Dec 3, 2013. <http://www.nextgov.com/defense/2013/12/va-and-defense-chiefs-confront-reality-700000-incarcerated-veterans/74816/>
- <sup>vii</sup> 'Other Than Honorable': More Army misconduct discharges. Dave Philipps/The Colorado Springs Gazette, Series. May 19, 2013.
- <sup>viii</sup> RAND/Elizabeth Dole Foundation. Military Caregivers: Cornerstones of Support for Our Nation's Wounded, Ill, and Injured Veterans/Terri Tanielian, 2013.
- <sup>ix</sup> Suicide Rise in Special Ops Spurs Call for Review. Tampa Tribune | Apr 30, 2014 | by Howard Altman. <http://www.military.com/daily-news/2014/04/30/suicide-rise-in-special-ops-spurs-call-for-review.html>
- <sup>x</sup> Rahav Boussi-Gross, Haim Golan, Gregori Fishlev, Yair Bechor, Olga Volkov, Jacob Bergan, Mony Friedman, Dan Hoofien, Nathan Shlamkovitch, Eshel Ben-Jacob, Shai Efrati. Hyperbaric Oxygen Therapy Can Improve Post Concussion Syndrome Years after Mild Traumatic Brain Injury - Randomized Prospective Trial. PLoS ONE, 2013; 8 (11): e79995 DOI: 10.1371/journal.pone.0079995
- <sup>xi</sup> IOM REPORT: DEFENSE/VA HAVE NO CLUE IF \$9.3 BILLION WORTH OF PTSD TREATMENT WORKS. Bob Brewin, NextGov. June 20, 2014. <http://www.nextgov.com/defense/2014/06/iom-report-defenseva-have-no-clue-if-93-billion-worth-ptsd-treatment-works/86929/>
- <sup>xii</sup> PANETTA : DEFENSE AND VA NEED TO 'KICK ASS' TO IMPROVE SERVICE TO VETERANS. Bob Brewin, NextGov, July 26, 2012.
- <sup>xiii</sup> One Mind. UNDERSTANDING AND CONFRONTING THE BRAIN HEALTH EPIDEMIC. <http://onemind.org/The-Epidemic>.
- <sup>xiv</sup> [http://www.cdc.gov/traumaticbraininjury/get\\_the\\_facts.html](http://www.cdc.gov/traumaticbraininjury/get_the_facts.html)
- <sup>xv</sup> IOM REPORT: DEFENSE/VA HAVE NO CLUE IF \$9.3 BILLION WORTH OF PTSD TREATMENT WORKS. Bob Brewin, NextGov. June 20, 2014. <http://www.nextgov.com/defense/2014/06/iom-report-defenseva-have-no-clue-if-93-billion-worth-ptsd-treatment-works/86929/>
- <sup>xvi</sup> The Prozac, Paxil, Zoloft, Wellbutrin, Celexa, Effexor, Valium, Klonopin, Ativan, Restoril, Xanax, Adderall, Ritalin, Haldol, Risperdal, Seroquel, Ambien, Lunesta, Elavil, Trazodone War. As it approaches its tenth year, our nation's longest war is showing signs of waning. Meanwhile, our soldiers are falling apart. Jennifer Senior, Feb 6, 2011. <http://nymag.com/news/features/71277/>. See also TESTIMONY FOR THE RECORD: Suicides in U.S. Military Personnel, Veterans of the War in Iraq and Afghanistan, and the Core Medical Treatment for Mild-Moderate Traumatic Brain Injury & PTSD. IHMA/Dr. Paul Harch, June 22, 2010
- <sup>xvii</sup> Wolf G, Cifu D, Baugh L, Carne W, Profenna L. The effect of hyperbaric oxygen on symptoms after mild traumatic brain injury. J Neurotrauma. 2012;29(17):2606-12. (DoD) (USA). <http://biawa.org/docs/pdf/MTBI%20PCS%20J%20Neurotrauma%202012.pdf>; Paul G. Harch, MD. Letters to the Editor. Journal of Neurotrauma. Hyperbaric Oxygen Therapy for Post-Concussion Syndrome: Contradictory Conclusions From a Study Mischaracterized as Sham-Controlled. 2014. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3837504/>; Cifu DX, Hart BB, West SL, Walker W, Carne W. The Effect of Hyperbaric Oxygen on Persistent Postconcussion Symptoms. J Head Trauma Rehabil. 2013. (DoD) (USA); [http://journals.lww.com/headtraumarehab/Fulltext/2014/01000/The\\_Effect\\_of\\_Hyperbaric\\_Oxygen\\_on\\_Persistent.2.aspx](http://journals.lww.com/headtraumarehab/Fulltext/2014/01000/The_Effect_of_Hyperbaric_Oxygen_on_Persistent.2.aspx); Weaver LK, Cifu D, Hart B, Wolf G, Miller RS. Hyperbaric oxygen for post-concussion syndrome: Design of Department of defense clinical trials. Undersea Hyperb Med 2012; 39(4); 807-814; Paul G. Harch, MD. Letters to the editors, UHM 2013, Vol. 40, No. 5 – LETTERS. Department of Defense trials for hyperbaric oxygen and TBI: Issues of study design and questionable conclusions. <http://www.ncbi.nlm.nih.gov/pubmed/24224289>; Walker WC, Franke LM, Cifu DX, Hart BB. Randomized, Sham-Controlled, Feasibility Trial of Hyperbaric Oxygen for Service

---

Members With Postconcussion Syndrome: Cognitive and Psychomotor Outcomes 1 Week Postintervention. *Neurorehabil Neural Repair*. 2013. DoD/USA, <http://nnr.sagepub.com/content/28/5/420>; Cifu DX, Walker WC, West SL, Hart BB, Franke LM, Sima A, et al. Hyperbaric oxygen for blast-related postconcussion syndrome: Three-month outcomes. *Ann Neurol*. 2014;75(2):277-86. (DoD) (USA). Army Trials Report from UHMS Conference, June 2013. Press Release: " DoD announces results of first three DoD-Sponsored trials using hyperbaric oxygen for mild traumatic brain injury." R. Scott Miller, M.D., COL, US Army, Director, Hyperbaric Oxygen Research Program, US Army Medical Materiel Development Activity, Ft. Detrick, MD. Effects of Hyperbaric Oxygen on Symptoms and Quality of Life Among Service Members With Persistent Postconcussion Symptoms. *JAMA Intern Med*. doi:10.1001/jamainternmed.2014.5479. Published online November 17, 2014.

<sup>xviii</sup> *JAMA Internal medicine*, November 17, 2014, pp. E1-E2. The Ritual Of Hyperbaric Oxygen and Lessons for the Treatment of Persistent Postconcussion Symptoms in Military Personnel, Charles W. Hoge, MD and Wayne B. Jonas, MD.

<sup>xix</sup> FDA-approved HBOT indications can be found at: <https://www.uhms.org/resources/hbo-indications.html>.

<sup>xx</sup> Wright JK, Zant E, Groom K, Schlegel RE, Gilliland K. Case report: Treatment of mild traumatic brain injury with hyperbaric oxygen. *Undersea Hyperb Med*. 2009; 36(6):391-9. <http://www.echa.net/36-6%20UHM-P391-399.pdf>. Also, The International Hyperbaric Medical Foundation. Summary report from, "The National Brain Injury Rescue and Rehabilitation Trial – a multicenter study of hyperbaric oxygen for mild traumatic brain injury." 32 subjects improved significantly. May 2014. In pre-publication. Personal correspondence from Dr. Zant is available upon request.

<sup>xxi</sup> The Use of Complementary and Alternative Therapies to Treat Anxiety and Depression in the United States. <http://dx.doi.org/10.1176/appi.ajp.158.2.289>; Complementary and Alternative Medicine in VA Specialized PTSD Treatment Programs: "Use of CAM in VA PTSD treatment is widespread. Researchers, therefore, have an excellent opportunity to determine whether offering CAM treatments has an impact on treatment engagement and outcomes. Future research should assess the efficacy of CAM treatments, both as an alternative and as an adjunct to conventional PTSD treatment, and develop methods to tailor these treatments to veterans with PTSD."

<sup>xxii</sup> See for example: <http://www.braintreatmentcenter.com/>; <http://carrickbraincenters.com/>; [http://www.washingtonpost.com/lifestyle/style/brain-zapping-veterans-say-experimental-ptsd-treatment-has-changed-their-lives/2015/01/12/2fc8b3ca-58aa-11e4-8264-deed989ae9a2\\_story.html](http://www.washingtonpost.com/lifestyle/style/brain-zapping-veterans-say-experimental-ptsd-treatment-has-changed-their-lives/2015/01/12/2fc8b3ca-58aa-11e4-8264-deed989ae9a2_story.html), Richard Leiby, "'Brain zapping': Veterans say experimental PTSD treatment has changed their lives." *The Washington Post*, January 12, 2015.

<sup>xxiii</sup> <http://www.fisherwallace.com/?gclid=CIXCuKqrwcMCFdgQodKFsA2g>

<sup>xxiv</sup> <http://www.brainhealthteam.org/the-study/>; "Treatment of Mild and Moderate Traumatic Brain Injury in Veteran Warfighters Using Near-Infrared Phototherapy" at [www.cerescan.com/pages/InvisibleBrainInjuryProject/](http://www.cerescan.com/pages/InvisibleBrainInjuryProject/)

<sup>xxv</sup> <http://www.ptsdupdate.com/three-promising-new-treatments-ptsd/>. Dr. Kathleen Sales, Three Promising New Treatments for PTSD. See also: [www.hbot.com](http://www.hbot.com);

<sup>xxvi</sup> RAND/Elizabeth Dole Foundation. *Military Caregivers: Cornerstones of Support for Our Nation's Wounded, Ill, and Injured Veterans*/Terri Tanielian, 2013, p. 1.

<sup>xxvii</sup> *Alzheimer's & Dementia*. THE JOURNAL OF THE ALZHEIMER'S ASSOCIATION. Military risk factors for Alzheimer's dementia and neurodegenerative disease. Vol 10, #3, Supplement 1 June 2014, p.S90.

<sup>xxviii</sup> <http://www.cbsnews.com/news/fda-approves-testing-new-ebola-drug-chimerix-brincidofovir/>

<sup>xxix</sup> <http://blogs.fda.gov/fdavoices/index.php/tag/emergency-investigational-new-drug-eind/>