Timeline of the Use of Hyperbaric Oxygen Therapy for TBI/PTSD/Concussion

Note: This is written from the perspective of the TreatNOW Coalition. Ten years of experience by hundreds of veterans working pro bono and both inside and outside DOD/Intelligence Community for 30+ years, and the VA has lent up-close-and-personal experience with many of the personalities who have made it difficult to impossible to get Hyperbaric Oxygen Therapy (HBOT) approved for use as a reimbursed therapy for TBI/PTSD. [See attached "The Obvious Question."]. These short notes are backed by a wealth of information, research, articles, papers, etc., in a Knowledge Base on the website: www.treatnow.org/knowledgebase/

SUMMARY OF ISSUES STANDING IN THE WAY OF SUCCESS, SUCCESS DEFINED AS, AT A MINIMUM, *Hyperbaric Oxygen Therapy (HBOT) as an approved, reimbursed, first-line intervention for TBI/PTSD/Concussion, both in DOD/VA and across medicine in general.* Obstacles are erected to slow-roll HBOT. All of these issues used to keep Congress, the White House and the public in the dark about what is possible have been debunked, but the drumbeat of naysaying continues. *Here are some of the arguments against HBOT.* 

- We don't even know how to define a Concussion, TBI or PTSD. Treating symptoms is the best we can do.
- HBOT does not work for TBI/PTSD. It is variously described as unsafe, too expensive, not proven, quack science, over-hyped, not readily available, another way to exploit the wounded and/or offers false hope.
- DOD/VA/Army studies prove it does not work.
- More research is necessary before HBOT can be shown as not too risky or dangerous.
- HBOT infrastructure does not exist to be offered in the VA.
- HBOT is much too expensive.
- We're doing the best we can, but you can't heal a wound to the brain. The best we can hope for is to palliate the symptoms and help the body heal itself. Almost everyone who gets a concussion gets better.
- Our front-line interventions for TBI/PTSD are working in most cases. Psychopharmacology and cognitive psychotherapy are our first, best, and ongoing line of defense.
- Too many claims of brain injury are erroneous
- The medical community in general and the NFL/NCAA/NFL in particular claim that there is no therapy to cure brain injury and much more research is required to prevent concussions and make sports, war, and life safer.
- Pharmaceuticals will provide a breakthrough. We need more money for research.
- We're doing all that is humanly possible. Look at how much money we're devoting to understanding the problem.

Timeline: HBOT for TBI/PTSD/Concussion May 2019

1. The FDA had approved 14 Hyperbaric Oxygen Therapy (HBOT) indications by 1990. The VA approves of and uses some of those [esp. for burns; sometimes carbon monoxide poisoning and the rare cases of decompression sickness] though they do not have HBOT chambers available for general use in VA facilities. The VA discourages use of HBOT for brain injury, even warning veterans against use, even threatening to reduce disability ratings should HBOT prove effective. Even the mention of HBOT for mental health/brain wounds is a rarity. There is no "informed consent" about HBOT as an alternative treatment [see attached paper on "Interventions."]

- 2. Four of those indications are similar to brain injuries and some have argued that HBOT is already proved safe and effective. Worldwide research has been conducted on HBOT for TBI/PTSD. DOD/VA/Army research concludes in five studies that HBOT does not work. The data in those studies say the opposite. Worldwide condemnation of that DOD/VA/Army research has been recorded for over six years [see "SHAM Discussion" attached.] A Consensus Conference on HBOT for TBI was held by DOD in NOV-DEC 2008. HBOT was declared by acclamation to be safe. DOD/VA/Army determined on research to test efficacy. Ten years and over \$130M in expenditures what a senior Army PM called "an obscene amount of money" and the DOD/VA/Army continue to insist that they don't know enough, can't move too fast, and other alternatives deserve equal exploration.
- 3. A few members of Congress believe in HBOT and have worked for over 10 years to get it funded. The Army Surgeon General claims HBOT does not work and has testified repeatedly to the standard arguments, above. Every session, Pete Sessions and Walter Jones have tried to push HBOT addenda to the National Defense Authorization Act, but the language has been rejected in the Senate. More members and some Senators are signing up to get HBOT approved.
- 4. RAND and others estimate 800,000 brain wounded veterans since 9/11, and an equal number from Vietnam. Over 125,000 service members post 9/11 have received "Other Than Honorable" discharges; an estimated 65% of them are brain injured. OTH separates them from health coverage and other benefits from their service. 20+ service members [mostly veterans] commit suicide every day; Special Operations forces commit suicide at twice the rate of the normal force. Of the 3-4 dozen we have helped heal, all confide that SpecOps are hollowed out with brain wounds. Even though HBOT chambers exist across DOD and the world, active military medicine is barred from using them because of Army findings that HBOT does not work.
- 5. An active research group within DOD/VA/Army medicine advise against using HBOT. They are paid to research the problem, not to solve it. The NFL, NCAA, NHL and other professional sports are unconvinced that they have a problem that can be addressed with HBOT, even though some medical professionals among the NFL ranks would like to see HBOT adopted, a chamber in every locker room.

The following set of facts, listed by most recent back to 2008, give some insight into our work and what we are up against in trying to change minds and medicine.

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, Reserves and athletes [timeline starts at the bottom in August 2008]

- At the end of November 2018, over 6,100 brain-wounded veterans, citizens, active duty and athletes have experienced significant medical improvement since 2010 in the 85+ TreatNOW Coalition clinics using HBOT and other alternative therapies. See <a href="http://treatnow.org/treatments/treatment-centers/">http://treatnow.org/treatments/treatment-centers/</a>
- Dr. Daphne Denham, the nation's premier expert on HBOT treatment of acute concussion, reports that 98% of her patients [248 out of 250] treated within ten days of suffering a concussion, completely resolved their symptoms in five treatments or less [average of 2.4 treatments]. https://tinyurl.com/ybldktgn
- The Center of Compassionate Innovation in the U.S. Department of Veterans Affairs (VA) announced it will offer Hyperbaric Oxygen Therapy (HBOT) as a treatment option for a small number of Veterans with persistent post-traumatic stress disorder (PTSD) symptoms resistant to standard options. Pilot sites are Tulsa Wound Care and Hyperbaric Center at Oklahoma State Medical Center in Tulsa, OK, and the David Grant Medical Center on Travis Air Force Base, CA. Unfortunately, only 9 patients have been treated (all successfully) in seventeen months. Two additional Centers are being added in 2019: Joint Base San Antonio; and Tampa FL Wound Care. <a href="http://bit.ly/2pAOWPV">http://bit.ly/2pAOWPV</a>. Explanations for the glacial pace relate to
- Col. Rachel LeFebrvre (USAF), Brooke Army Medical Center, reports that "miraculous" results are achieved with hyperbaric treatment in San Antonio, TX. http://bit.ly/2C9748v
- Mar 2018. A <u>court filing by a group of former NFL</u> players who were part of the class action lawsuit against the league regarding concussions claims that the league is failing to meet its obligations under the settlement agreement. "The NFL seeks to rig the Settlement system," the filing reads. "This is part of the league's DNA. Historically, it has always engaged in scorched-earth litigation, and that is what the League is doing here, making this a Settlement in name only." The filing states that of more than 1,100 dementia claims filed by ex-players to date, only six have been paid out, despite the NFL's projection that 430 claims would be paid out within 12 months of the settlement agreement's implementation. It also states that more than half of all claims have been placed into audit or denied, causing delays of payment with no end in sight.
- VA and DOD facilities in seven states [AL, FL, GA, MD, NJ, TX, OK] began paying for and/or treating TBI and/or PTSD using HBOT "because it is the right thing to do," according to a neurologist in a Florida VA. In addition to the legislation already passed in OK, TX and IN, KY and AZ, legislators in a dozen states are crafting legislation to make HBOT available for treating brain-wounded veterans using HBOT [FL, AL, LA, AR, NV, ND, IA, CO, ID, OH, NY, VA].
- Nineteen US Congressional Legislators from eleven states (NJ, TX, CO, NC, FL, CA, OH, AL, MI, VA and IN) sign letters encouraging DOD and the VA to urgently use HBOT for PTSD/TBI/Concussion.
- At the August conference of HBOT2018, researchers showed evidence that further validated the safety and efficacy of HBOT for TBI/PTSD/Concussion. <a href="http://bit.ly/2x4tWUf">http://bit.ly/2x4tWUf</a>
- Continuing the accumulation of positive data, Dr. George Wolf, the US Government's premier HBOT expert, reported recently that "[HBOT] for mild [TBI]

and PTSD should be considered a legitimate adjunct therapy." <a href="http://bit.ly/2x8WDiT">http://bit.ly/2x8WDiT</a>

- Dr. Lindell Weaver, recently concluded the Brain Injury and Mechanisms of Action of HBO2 for Persistent Post-Concussive Symptoms After Mild Traumatic Brain Injury (BIMA) Protocol with 71 patients. His conclusions: "By 13 weeks, HBO2 improved post-concussive and PTSD symptoms, cognitive processing speed, sleep quality, and vestibular symptoms, most dramatically in those with PTSD." http://bit.ly/2x6d2EN
- Dr. Gary Steinberg of Stanford University and team are "stunned" and "shocked" at the progress made using stem cells on stroke patients. [http://wbur.fm/2BT1qof] Israeli research studying HBOT for Stroke shows that HBOT increases the production of stem cells in the bone marrow with transfer to the Central Nervous System, making them available for brain wound healing and growth of new brain cells, neuronic tissue, and repair of white and grey matter. http://bit.ly/2CaGfP6
- Dr. Paul Harch and team published results showing 30 subjects undergoing HBOT for brain injuries experienced a significant reduction in suicidal ideation and anxiety. At the same time, they were able to discontinue or decrease the dosage of their psychoactive medications and 52% no longer met the criteria for PTSD. http://bit.ly/2zyFrAr
- August 2018. The final approval of a \$75 million concussion settlement with the National Collegiate Athletic Association is on hold until an independent auditor completes its review of a notice program that has apparently been plagued with problems. Reports are that over 500 lawsuits against the NCAA are pending.
- Israeli researchers publish results showing the mechanisms by which HBOT induces brain neuroplasticity using highly sensitive MRI techniques of DSC and DTI. HBOT can induce cerebral angiogenesis and improve both white and gray microstructures indicating regeneration of nerve fibers. The micro structural changes correlate with the neurocognitive improvements. http://bit.ly/2C7NC9H Drs. Harch and Edward F. Fogarty published a Case Study of HBOT in near-drowning. Short duration normobaric oxygen and hyperbaric oxygen therapy in the subacute phase of drowning recovery resulted in video-documented near-complete resolution of severe neurological deficits and near-complete reversal of gray and white matter atrophy on MRI. Hyperoxic and hyperbaric gene signaling-induced growth of both gray and white matter is the most likely explanation. http://bit.ly/2yCfZdq and http://bit.ly/2DUigv9
- At the UHMS Florida conference in June, multiple presenters spoke of ongoing research proving the safety and effectiveness of HBOT to treat TBI/PTSD/Concussion. An intriguing breakthrough paper by Kent McLaughlin found significant pro-angiogenic stem cell mobilization at much lower pressures than previously discovered. One UHMS official said that his findings cast a shadow over their definition of hyperbaric medicine which wrongly declares that anything below 1.4ata has no medicinal properties. Of course, DOD/VA/Army studies have wrongly depended on that definition to "prove" statistical non-significance for HBOT, even though their data in all 5 studies clearly show that all patients showed significant medical improvement.
- At the same UHMS conference, Dr Shai Efrati's team from Israel divulged continuing research on the mechanisms of action of HBOT when treating non-

healing wounds to the brain. They showed how the use of Hyperbaric Oxygen addresses directly the negative cascade of damage and degeneration both in the acute phase of wound stabilization after TBI/PTSD/Concussion, and in the acute and chronic phases of wound healing. This is accomplished by:

- ✓ Decreasing levels of inflammatory biochemicals
- ✓ Increased oxygenation to functioning mitochondria
- ✓ Increases in blood flow independent of new blood vessel formation
- ✓ Angiogenesis from the addition of oxygen: (growth of new blood vessels in the acute and chronic phases)
- ✓ Up-regulation of key antioxidant enzymes and decreasing oxidative stress
- ✓ Increased production of new mitochondria (the energy factories of the cells)
- ✓ Neurogenesis: (growth of new neuronal tissue and Remyelination during and after the treatments are completed)
- ✓ Bypassing functionally impaired hemoglobin molecules, the result of abnormal porphyrin production, thereby allowing increased delivery of oxygen directly to cells
- ✓ Improvement in immune and autoimmune system disorder
- ✓ Direct production of stem cells in the brain
- ✓ Increases in the production of stem cells in the bone marrow with transfer to the Central Nervous System
- 2 February 2018. The NFL announces a change to their Concussion Protocol: Super Bowl 52 is the first Super Bowl in which four independent concussion specialists will be made available by the National Football League. The NFL began to employ unaffiliated neurological consultants (UNC) or independent concussion specialists during the 2013 season as a response to the league's head injury epidemic. Prior to this, team doctors would evaluate players for a concussion, sometimes asking just a few questions before sending the player back in the game. With an independent specialist available, players must pass a much more rigorous test before returning to the field, and the league can eliminate the risk of teams not following procedures in order to quickly get players back in the game. In 2016, players in the league suffered 243 concussions. In 2017 281 concussions were diagnosed. The latter figure, which includes preseason (91) and regular season (190) diagnosed head injuries, is the most since the league began to share the data back in 2012. ESPN estimates that on any given Sunday, over 400 people are employed spotting for concussions across the NFL. Given what we know, none are employed treating and healing those concussions as soon as they occur.
- June 2018, the Pro Football Retired Players Association and TreatNOW hosted a Reception on Capitol Hill to honor brain-injured veterans. <a href="https://youtu.be/I2jOv8GQ-38">https://youtu.be/I2jOv8GQ-38</a>. Speaking to nineteen members of Congress, two dozen retired Hall of Famers and numerous treated veterans and staffer, the Executive Director of PFRPA, Mr. Robert Schmidt, struck a hopeful note: "Hyperbaric Oxygen Therapy (HBOT) greatly improves cognitive ability and pain relief for Traumatic Brain Injury. We hope to convince Congress, the DOD, and the VA to recognize the beneficial use of HBOT or, at a minimum, to fund such additional studies as they feel necessary even though we feel the evidence already exists to justify mass treatment. Football players will also benefit from action by the

DOD and VA but that is secondary to our desire to help heal our combat veterans." See Roy Jefferson: <a href="https://bit.ly/2MDg1JV">https://bit.ly/2MDg1JV</a>

- A new Veterans Administration Secretary, Robert Wilkie, was sworn in. Part of his charter from Congress is to confront the mental health epidemic among veterans who cannot get appointments and sufficient care. Executive Orders and legislation have put in place means to allow veterans to procure care outside the VA system when it is unavailable, or the wait times are egregious. Certainly HBOT qualifies as such a treatment since it is not even held out as an option for veterans; neither can they procure it inside the VA. Billions of dollars continue to be spent on interventions that do not treat the physical wound to the brain. Not one of the 80+ therapies/processes/ procedures/devices, countless computer applications, nor 114+ prescribed drugs has been approved by the FDA for TBI, nor do they "treat" wounds. 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. No risk analysis has been performed, and no tracking is done. Yet neither the DOD nor the VA provide Hyperbaric Oxygen Therapy used off-label to treat and heal brain injury. With evidence over 10 years from over 5,000 successes in over 80 independent clinics around the US, HBOT is the one therapy proved by multiple clinical trials inside DOD/VA and around the world to treat and help heal the wound to the brain, safely and effectively.
- 2017. Deb Hardin-Ploetz's 2017 lawsuit stood out among the waves of concussion-related litigation filed against the NCAA because it was the first to reach a jury trial. A verdict in her favor, that the NCAA was legally responsible for the death of Greg Ploetz -- a scrappy linebacker and defensive tackle for the University of Texas in the late 1960s and early '70s -- would have likely left the association open to liability in an avalanche of other cases and drawn more attention to an issue already under fierce public scrutiny.
- May, 2017. 6.5 percent of post-9/11 ex-service members have received Other Than Honorable discharges. That totals nearly 125,000 people. 62 percent, or 57,141 of the 91,764 service members separated for misconduct from fiscal years 2011 through 2015 had been diagnosed within the two years prior to separation with post-traumatic stress disorder (PTSD), traumatic brain injury (TBI), or certain other conditions that could be associated with misconduct. Of the 57,141 service members, 23 percent, or 13,283, received an "Other Than Honorable" characterization of service, making them potentially ineligible for some or all government veteran benefits. US Government. Accountability Office. (2017, May 16). DOD Health: Actions Needed to Ensure Post-Traumatic Stress Disorder and Traumatic Brain Injury
- January 7, 2017. Plaintiffs won nearly \$1B in suit against the National Football League and NFL Properties LLC (the Settlement Agreement refers to both of these as the "NFL Parties"), claiming that Retired NFL Football Players received head trauma or injuries during their NFL Football careers, which caused or may cause them long-term neurological problems. They accused the NFL Parties of being aware of the evidence and the risks associated with repetitive traumatic brain injuries, but failing to warn and protect players against those long-term risks and ignoring and concealing this information from players. The NFL Parties denied these claims. After extensive settlement negotiations, the Plaintiffs and the NFL Parties

ended the litigation and agreed to this Settlement. Click <u>here</u> to read the Recitals of the Settlement Agreement.

- Sept 2016. Xavier A. Figueroa, PhD and James K. Wright, MD (Col Ret), USAF Hyperbaric Oxygen: B-Level Evidence in Mild Traumatic Brain Injury Clinical Trials. Neurology® 2016;87:1–7 The authors state: "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."
- August 2016. A draft summary of the Army's most recent research states that HBOT is safe and effective for PTSD.
- July 2016. The VA reports that 20-- not 22 as speculated in 2010 -- 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, breeching, 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.
- 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 \$100Million researching HBOT for TBI... and OBSCENE amount of money." Nevertheless, that money produced data showing 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 <u>statement the following day</u> 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...."
- A 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." The NFL's Concussion Protocol is silent about using HBOT for Concussions.

- 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/Army response to TBI treatments do not include even informing the brain injured that a safe 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.
- 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."
- July 11, 2013. The Professional Football Retired Players Association is created. PFRPA is the first independent & court established retired NFL player organization, exclusively designed to develop programs & benefits for the betterment of retired NFL players.

- July 2013. Newsweek and Army Times report that the military is experiencing epidemics in soldier violence against family and friends; and in the number of incarcerations.
- 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."
- March, 2013. NBC reports that despite spending on homelessness of \$5.8B annually, 62,000 veterans remain homeless.
- February 2013. VA Study finds 22 veterans in the United States kill themselves daily, a rate that is about 20 percent higher than the Department of Veterans Affairs' 2007 estimate, according to a two-year study by a VA researcher.
- 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."
- January 2013. Suicides by active duty military personnel in 2012 hit 349, more than the 295 Americans who died in combat in Afghanistan.
- The VA reports it has a backlog of 898,861 disability claims, with 632,358, or 70.5 percent stuck in the system for over 125 days. The length of time it takes to process veterans' claims also continues to rise, with the average processing time now almost 280 days. Veterans Benefit Administration regional offices in New York and Los Angeles average 450 and 500 days respectively to process a claim.
- September 27, 2012. Army suicides in the month of July were so alarming that the service held a worldwide "stand down" or pause in activities -- again -- to try to address the problem. There were 38 potential or confirmed suicides for the month, the highest monthly toll since the Army began to release the data on a regular basis in 2009, according to the Army Times.
- 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. Institute of Medicine reports that neither the DOD nor the VA -- which operate the world's largest electronic health records systems -- tracks

treatments used for PTSD. What's more, DOD does not even know how many PTSD treatment programs it or the services provide.

- 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.
- June 2012. AP reports that the 154 suicides for active-duty troops in the first
  155 days of the year far outdistance the U.S. forces killed in action in Afghanistan
  about 50 percent more.
- May 2012. The Defense and Veterans Affairs departments have spent almost \$2 billion since 2001 to buy drugs to treat mental illness and post-traumatic stress disorder despite growing evidence some of those drugs exacerbate PTSD symptoms.
- The Defense Logistics Agency shows DOD spent \$44.1 million on benzodiazepines from October 2001 to March 2012. The Veterans Affairs Department said it spent \$72.1 million on benzodiazepines during the same period.
- May 2012. DOD reports that mental illness ranks as the leading cause of hospitalization for active-duty troops, what one insider considers an epidemic.
- 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."

- 2012. An ARMY ANAM database of potential brain injuries cannot be found. Apparently, no record exists of the VA tracking those brain-injured as indicated by the ANAM tests.
- November 2011. IHMF Report, "Untreated Brain Injury: Scope, Costs, and a Promising New Treatment" concludes: "Simply put, for less than 1.7% of the current status quo costs, [HBOT1.5] can help in the healing of hundreds of thousands of the wounded and injured with a safe therapy that thus far has enabled approximately 80% of those treated to return to work, school or duty. Left out of this calculation, is the intangible benefit to the wounded and to their families of getting their lives back."
- August 2011. The VA spent \$846 million on Seroquel since 2001 and \$717 million on Risperidone, another atypical antipsychotic, during the same period. A <u>paper</u> 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.
- May 2011. A federal appeals court in California ordered the Veterans Affairs Department to develop a system wide mental health care plan, citing "unchecked incompetence" in the department's care for veterans.
- 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. Jason Luckasevic represents about 500 former players, and it was his initial concussion lawsuit that kicked off the nearly \$1B settlement that is still not settled.
- 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.
- 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 800,000 veterans with TBI/PTSD have been negatively affected.

- 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 uniformly across the United States medical community, including in professional sports.
- 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.

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