



Request: Pass The TBI Treatment Act

Are You Ready to Do Something to Help Your Military Constituents With Traumatic Brain Injury or PTSD?

Do You Want to Boost Economic Productivity in Your State?

Do You Want to Stop a Huge Drain on the Federal Budget?

Then Support Senator Inhofe & Pass the TBI Treatment Act, Section 731 of the House Armed Services Bill!

Dear Senator:

November 28, 2011

A pathway is needed to quickly get effective treatment for traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) to our injured war veterans. TBI is a physical injury to the brain that often produces psychiatric-like symptoms such as depression, impulse control issues, etc. PTSD may be purely emotional in nature or may also have a physical injury component. PTSD and TBI share many symptoms making it to differentiate between them based on symptoms alone. Sadly, current treatment practices in our military communities treat both diagnoses with therapies developed for purely psychiatric conditions. That is like counseling to a person with a compound fracture of a leg to not walk on it. The leg needs to be set and splinted. Similarly, when a brain is injured such as by exposure to blast and/or high levels of life-threatening stress it needs physical repair. Once that is accomplished, existing psychiatric tools, if still needed at all, work much better.

The civilian world has developed effective treatments for TBI and PTSD, yet there is no pathway currently available to speed deployment of these treatments into DoD or VA medicine. A possible such pathway has been developed and is being considered by the United States Senate this week as part of S. 1867, "National Defense Authorization Act for Fiscal Year 2012" (NDAA). This provision is the "TBI Treatment Act," H.R. 396. This provision has been endorsed by the Brain Injury Caucus and many veterans groups. It would require DoD and VA to pay for treatment for a brain injury only when it works for a given veteran. This language is already contained in the House NDAA bill as section 731 of H.R. 1540. It has been reported to us that Senator Inhofe is planning to offer this provision as an amendment to S. 1867. We ask for support of the Inhofe Amendment and support for House section 731 in Conference for the NDAA.

Despite Congress providing billions to the government's medical bureaucracy to find effective treatments for TBI and PTSD, today's war veterans with those injuries are not significantly closer to being able to receive effective treatment than they were when the war started. There may be over 700,000 of these veterans now in the civilian sector, and the presence of those numbers is being reflected in the figures for veteran unemployment, homeless and incarceration.

Further, one recent article in *Military Medicine* reported that as much as 40% of the current active duty force may have these kinds of injuries.

On July 21, 2010, the House Veterans Affairs Committee heard from many civilian physicians and practitioners that there is more that can be done. Real treatments that dramatically improve patient outcomes were described. However, the trail-blazing civilian practitioners could not get paid for their treatments, even in the face of extensive clinical experience and published data that they were effective. Meanwhile, the House VA committee was told that an untreated brain injured veteran costs society, on average, about \$60,000 per year for incarceration, lost productivity, health care and other expenditures. Instead of effective treatment, the DoD and VA medical establishments continue to spend hundreds of millions of dollars for drugs for TBI or PTSD symptoms, without the same level of research evidence or safety considerations being required for more effective and available treatments. Many of these currently prescribed drugs are black-labeled by the FDA as increasing the risk for suicide. This may help explain why in the two current wars it appears that we have lost more service members to suicide than to combat.

The TBI Treatment Act will help spur translational medicine, the practice of moving bench science discoveries into clinical practice. The bill requires the VA or TRICARE to pay for ANY treatment for traumatic brain injury (TBI) or post-traumatic stress disorder (PTSD) that WORKS. It requires payment to be made within 30 days to any treatment facility that 1) provides a treatment using an already FDA approved drug or device; 2) follows an IRB-approved protocol; 3) and can demonstrate improvement by means of standardized independent pre-treatment and post-treatment neuropsychological testing, accepted survey instruments, neurological imaging or clinical examination.

The legislation also requires payment for diagnostics. Thus, diagnostics like Functional 3CT MRI, developed by Dr. Haake at Wayne State University in Michigan, will also be paid for through this legislation. This will permit imaging to be brought to bear that is 100x more effective than anything previously available for brain diagnostics and research, and will enable those technologies to be used to verify the results of the treatments under the TBI Treatment Act.

The legislation does not mention any specific treatment. Some of the treatments that could be paid for include cognitive rehabilitation which was used to help Congresswoman Giffords recover to her current level. Another currently unreimbursed treatment developed by the International Brain Research Foundation in New Jersey awakens those in a coma over 80% of the time, saving many thousands of dollars for these patients. The TBI Treatment Act would also include hyperbaric oxygen therapy (HBOT). HBOT when delivered at 1.5 atmospheres in accordance with a well-tested protocol has caused nearly all of the veterans recently treated to have significant improvements. Veterans' TBI and PTSD symptoms have resolved or been significantly improved.

Hyperbaric oxygen therapy has been requested for veterans by Commanders and Veterans Service organizations alike. General Conway, when Commandant of the Marine Corps, reported to the House Armed Services Committee about sending some of his most injured Marines to Dr. Harch in New Orleans to receive Hyperbaric treatment. **General Chandler, as**

Vice Chief of Staff of the Air Force requested Chairman Levin provide hyperbaric treatments to his Airmen in the SASC hearing on Suicide in 2010, and Chairman Levin agreed. The **American Legion** asked for this treatment in their Senate testimony last year. The TBI Treatment Act is the only provision in the Senate Armed Services bill that will permit the Chairman to keep his pledge to General Chandler, and does so in real time.

HBOT is the only non-hormonal biological repair and regeneration treatment approved by the FDA. The latest HBOT 1.5 TBI/PTSD peer-reviewed and published results (Journal of Neurotrauma, October 25, 2011) are remarkable. Those results are from the first 15 persons treated under a pilot trial funded in large measure by the Semper Fi Funds and the Coalition to Salute America's Heroes. On average, using only half of the recommended HBOT 1.5 protocol (as used in the NBIRR-01 study sponsored by the International Hyperbaric Medical Foundation (IHMF)), blast-injured war veterans experienced an average 14.8 point IQ increase from post-injury to post-HBOT 1.5 treatment ($p < 0.001$) (the difference between a high school drop-out & a college graduate) and an average 39% reduction in post-concussion symptoms [$p = 0.0002$ (np)] with 87% reporting a substantial headache reduction. Study subjects also reported a 30% reduction in PTSD symptoms ($p < 0.001$), and a 51% decrease in depression scores ($p < 0.001$) with a concurrent substantial reduction in suicide ideation. Further, the improvements have been found to be lasting. Based on clinical experience and NBIRR-01 results to date, further treatment for these patients would be expected to further improve these outcomes. Medication costs for study subjects were reduced with 64% reporting a reduced need for psychoactive or narcotic prescription medications. Most subjects have been able to return to duty, work or school. There has been consistency across physicians whenever the correct protocol has been followed.

These Journal of Neurotrauma reported results have been further validated in the IHMF's ongoing NBIRR-01 study (NCT01105962 registered at www.clinicaltrials.gov.) This multi-center study, with over a score of sites across the nation, uses several neurocognitive tests, including ANAM and CNS-Vital signs, as well as the DoD/VA accepted survey instruments for PTSD, Post-Concussion Syndrome, depression, health status and quality of life. Contrary to recent media reports, the IHMF's preliminary findings have validated DoD's ANAM as an accurate assessment of cognitive change. Where pre-deployment ANAM baselines were available, post-injury scores accurately reflected that cognitive change had occurred. As HBOT treatment progressed, ANAM measured the improvement. The ANAM post-treatment cognitive change scores accurately cross-correlated with CNS-Vital signs and other standardized instruments (e.g., PCS and depression scales, etc.) and examination by clinicians. Based upon IHMF's experience, the Congressionally-ordered ANAM pre-deployment baselines serve as an important national resource that will help reflect whether a given treatment is effective by accurately recording post-treatment cognitive changes.

The quality of life improvements resulting from HBOT intervention, including the ability of many to return to work, are documented in the study. Four of the study subjects for which there were ANAM baselines were service members being "medically boarded" out of the military following injury. All have been returned to duty following treatment. Examination of outcome data has shown HBOT is very cost effective. Biologically repairing brain injury is far less costly than the other consequences. Over time, the improved productivity and reduced medication

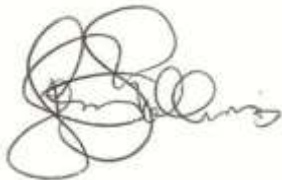
costs more than justify HBOT treatment. Further, biological repair with HBOT helps make all other effective treatments for brain injury or PTSD even more effective and less costly.

Though TRICARE has been paying intermittently and the VA have paid occasionally, HBOT treatment for TBI or PTSD is not yet routine, even though Tricare, VA and Medicare pay for 13 other approved HBOT indications. Note that HBOT is already FDA-approved, and paid by these payers, for 3 kinds of neurological indications and 3 kinds of non-healing wounds. The same cannot be said for any of the FDA-Black labeled drugs routinely given to our veterans suffering from TBI or PTSD.

The science is clear. There is, in fact, more evidence right now for HBOT 1.5 for treating brain injury or PTSD than there was for tPA for stroke treatment or angioplasty when they were both approved by Medicare and paid throughout the government system.

The veterans of this war need help now. The DoD and VA bureaucracies have been ineffective at delivering effective treatment, despite billions of dollars in funds and a mandate to do so. The TBI Treatment Act is a pathway, funded with just \$10 million, to provide a way to get war veterans in your communities more effective treatment quickly and do so in a way that captures the data needed to pave the way for treatments that prove effective to be moved into standard care pathways. We urge you to support Senator Inhofe's amendment, the House's Section 731 provision and Congressman Pete Sessions' House legislation.

For further information, contact the Senator Inhofe's office or the House sponsor, Representative Pete Sessions of Texas.

A handwritten signature in black ink, appearing to read 'Kenneth Stoller', with a stylized, cursive script.

KENNETH STOLLER, M.D.

President

International Hyperbaric Medical Association



Public Policy Brief

A Primer on Traumatic Brain Injury

Untreated TBIs and other brain insults represent the single most expensive public health problem in America and drive the costs of many entitlement programs and incarcerations.

What is Traumatic Brain Injury? Traumatic brain injury (TBI) is as an alteration in brain function, or other evidence of brain pathology, caused by an external force. Damage to the brain can be focal or diffuse. It can be the result of a closed or penetrating head injury. A third form of TBI can also occur as a result of air embolism from a blast exposure or diving accident.

What are the Symptoms of a TBI? Symptoms of a TBI can range from mild or moderate to severe. The symptoms may present immediately after the injury or emerge several days, weeks or even months later. These variations are due to the type and severity of the injury as well as the focal point in the brain that is injured.

The most common post-TBI symptoms involve a cluster of physical, emotional and cognitive problems, with cognitive challenges being the hallmark of TBI. These challenges include problems with attention and concentration, impaired memory and learning, slowed processing speed, and reduced problem-solving skills. Emotional and behavioral problems are also common and can include delayed onset of depression and/or anxiety, as well as anger management problems, irritability and difficulty with emotional control. The person may also report feeling dazed or not like themselves for several days or weeks, even years after the initial injury. Other frequent symptoms of mild TBI include:

- Headache
- Confusion
- Lightheadedness
- Dizziness
- Weakness
- Blurred vision
- Difficulty with language expression and/or comprehension
- Tired eyes
- Ringing in the ears
- Bad taste in mouth
- Change in sleep patterns
- Behavioral or mood changes
- Trouble with memory, concentration, attention, or thinking (executive function)

A person with a moderate or severe TBI may exhibit some symptoms seen with mild TBI, but may also experience:

- A headache that gets worse or does not go away
- Repeated vomiting or nausea
- Convulsions or seizures
- Inability to awaken from sleep
- Dilation of one or both pupils of the eyes
- Slurred speech
- Weakness or numbness in the extremities
- Loss of coordination, and/or increased confusion
- Restlessness
- Agitation

How Many People in the United States are affected by TBI? CDC data indicate there are approximately 1.4 million brain injuries in the United States annually that are sufficiently severe to result in an emergency room visit. Of those, approximately 230,000 people are hospitalized and survive, and approximately 80,000 live with significant disabilities as a result of their injury. That means that over a 40 year period, there are about 3.2 million people living with observable challenges from TBI. The number with more subtle residuals, such as difficulty with anger management, can be expected to be substantially higher. Every year approximately 60,000 new cases of epilepsy occur as a result of head trauma.

Repeated mild TBIs occurring over an extended period of time (i.e., months, years) can result in cumulative neurological and cognitive deficits. Repeated mild TBIs occurring within a short period of time (i.e., hours, days, or weeks) can be catastrophic or fatal.

What are the Direct and Indirect Costs of TBI? \$60 billion annually in the United States (2003 numbers)

- Survivor costs account for approximately \$31.7 billion annually.
 - Lifetime costs for one person surviving a severe TBI can reach \$4 million.
 - Estimated medical and non-medical (e.g., home modifications, vocational rehabilitation, and health insurance) per TBI survivor can average \$150,000.
 - Average costs associated with TBI rise dramatically for those undergoing rehabilitation. One study cited by the Family Caregiver Alliance (FCA) found that, after 4-year follow-up, average costs for medical and long-term care services averaged \$196,460 for those receiving rehabilitation services.
- **What are the Psychological and Neurobehavioral Consequences of TBI?** TBI is a risk factor for subsequent psychiatric disorders, particularly depression, substance abuse, generalized anxiety and post-traumatic stress disorder (PTSD). TBI can cause a wide range of functional short- or long-term changes that affect thinking (i.e., memory and reasoning), sensation (i.e., touch, taste, smell), language (i.e., communication, expression, and understanding), and emotion (i.e., depression, anxiety, personality changes, aggression, anger management). **33% will have “Anger” issues rising 56.7% with co-morbid depression.**

Does TBI Affect Employment? Yes, individuals living with TBI often are seriously impacted in their ability to work or find future employment.

- In one recent study, 62% of brain-injured individuals were employed at the time of their injury, however; only 32% were employed after two years. Multiple studies have confirmed that 2 years post-injury, the unemployment rate amongst TBI survivors tends to jump 30 to 45 percentage points from their pre-injury status.
- Future life-time income is often cut by one-half after even a mild traumatic brain injury.

Are Those Who Serve in the Military at Greater Risk of TBI? Yes. Traumatic Brain Injury (TBI) and Post Traumatic Stress Disorder (PTSD) are considered the “Signature Injuries” in the Military Actions of the last 10 years. “Official” estimates of numbers service members returning from Iraq or Afghanistan with a TBI range from 200,000 (DOD 2000 to 2010) to 442,000 (RAND estimate of 320,000 out of a total of 1.64 million who had served as of 2008 extrapolated to the current total of 2.27 million who have served). The RAND report strongly cautioned that its figure was probably an underestimate. Another study of soldiers in an Army combat brigade returning after a one-year deployment to Iraq found a TBI rate of about 22.8%. Applying that ratio to total who have served yields an estimate of 517,000. These numbers help explain the increased populations that federal, state and local governments are seeing in the number of unemployed; in college remedial education; incarcerated or on VA disability.

Active duty military and veteran populations are, as a group, disproportionately affected by TBIs. PTSD, usually considered a psychological problem, actually includes mTBI symptoms in its definition. For example, it has been shown that prevalence of depression following TBI ranges from 15 to 61%. This has led to confusion and an inability within DoD and VA medicine to distinguish reliably between the two conditions. Thus health care professionals tend to overlook mTBI, especially when the patient lacks visible wounds. Jordan Grafman, a neuroscientist who studies Vietnam veterans at the National Institutes of Health states that “mild brain injuries are really difficult to evaluate” because of the overlap in symptomology and that “doctors are likely to default to psychological diagnoses especially when they see a lot of PTSD”

For information including regarding TBI, effective and available treatment, as well as the sources of the statistics contact: info@HyperbaricMedicalAssociation.org. See www.clinicaltrials.gov study number NCT01105962 or www.NBIRR.org. Study results are available.

Adapted from the Manuscript: *Untreated Brain Injury: Scope, Costs & a Promising New Treatment* (Doering & Reimers, 2011)



Request: Cosponsor The TBI Treatment Act

Subject: **Request to Cosponsor H.R. 396, “the TBI Treatment Act”
Help Heal War Veterans with Traumatic Brain Injury (TBI) or PTSD**

Dear Member of Congress:

February 1, 2011

In the 111th Congress, “the TBI Treatment Act” nearly became law. This provision was included in the House and Senate Armed Services bills and was strongly supported by the Brain Injury Caucus, members of the Mental Health Caucus, the leadership of many Veterans Service Organizations and organizations such as the Long Beach California Chamber of Commerce. It was taken out last minute.

Congressman Pete Sessions of Texas has reintroduced this legislation as H.R. 396 in the House in the 112th Congress. We urge you to cosponsor this legislation. Contact Schylr Greggs in his office at (202) 225-2231 or Schylr.Greggs@mail.house.gov.

Please unleash 21st century medicine so that innovative practitioners can assist you in solving society’s single most expensive public health problem; untreated brain injury. The residual effects of TBI drive social safety net and worker’s compensation costs plus slash workforce productivity. Untreated TBI cuts the federal tax base by at least \$313.7 billion per year. The societal impact of an untreated injured war veteran is estimated to cost \$60,000 per year in social safety net, incarceration and other costs.

This bill will help boost America’s Translational Medicine capabilities by creating a mechanism to more quickly bring legal, ethical and available treatments to veterans suffering from TBI or PTSD. The bill requires payment be made for medical treatment but only when the treatment actually works. The bill also mandates human subject research regulations be followed.

Translational Medicine takes bench science and translates it to clinical practice. Many policy makers are frustrated that it often takes 12-18 years to translate a practice into the “standard-of-care.” Some treatments take 30 or more years. Our brain injured veterans do not have 12-30 years; they are in crisis now. In recent years several promising brain injury treatments have been developed. We discuss two examples. This legislation will help bring those and other treatments into general medical use much faster, using valid scientific methods, with the result that even patients with severe brain injuries, such as your colleague Congresswoman Giffords, will have a much better chance of favorable outcomes.

The veteran crisis is reflected in the statistics. The RAND Report (April 2008) indicated one-third of those who have served in the two current wars sustained some form of brain injury. Over 2,000,000 have served in theater. The injured total is likely over 600,000. Many are unaware that their new life challenges result from an injury for which there are now promising treatments. Hundreds of thousands are unemployed, homeless and families are shattered. According to CBS News investigative reporting using CDC Statistics, veterans are committing suicide at the rate of 120/week. In many areas, like the State of California, veterans make up 10% of the current county jail population. Testimony before the VA committee last July revealed injured veterans cost society, on average, \$60,000 per year when left untreated. RAND reported drug and rehab treatments cost \$32,000 per year. Many of these costly treatments have questionable efficacy.

These 600,000 injured young men and women are some of our finest youth. They are leaders, risk-takers who answered our nation’s call. Without the war, they would be forming families,

buying houses and entering the workforce. Instead they are costing society because their brain injuries are not being biologically repaired. Imagine how different our economy would be! The TBI Treatment Act is designed to speed the movement of promising clinical discoveries into medical practice, in a manner similar to the CMS "Coverage with Evidence" program.

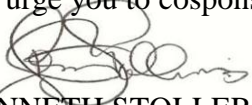
Let it be noted that three mild-TBI symptoms were inserted into the PTSD definition which was then labeled as an emotional adjustment problem. This is why DoD and VA medicine is unable to distinguish between PTSD and mild-TBI. This has caused great confusion in finding solutions.

The 1990s were known as the "Decade of the Brain" and many innovative treatments were developed. Neurological imaging and molecular biology and biophysics all made tremendous leaps as a result of these innovations. Two treatments, further developed during this period, help illustrate the significant outcomes that can be anticipated as a result of enacting this legislation.

The International Brain Research Foundation, lead by Dr. Phil DeFina, has awakened 82% of severe traumatic brain injury from coma. Military physicians who previously had many of these patients in their care have said, "Patients wake up all of the time" or "It must be a fluke." Following that logic, Dr. DeFina has an 82% fluke success rate. In fact the treatment he is using is both legal and available and represents a huge savings over current care of coma patients. By adding \$500 per day to the current \$2,000 per day treatment cost, over 4/5ths of Dr. DeFina's patients awaken from their coma in as little as two months of an expected 4 month rehabilitation hospital stay. For these patients the cost of care is cut by many thousands of dollars. IBRF's treatments qualify for payment in the TBI Treatment Act for successes. Under Chairman Murtha IBRF received an earmark of \$6.2 million. It is unknown whether DoD research finally released the funds to IBRF.

Hyperbaric oxygen therapy is another treatment that has had excellent clinical successes. HBOT saturates the body with 7 to 12 times as much oxygen as can be breathed normally, using a chamber like the one used to treat the bends. HBOT is the only FDA-approved non-hormonal treatment that biologically repairs and regenerates human tissue. Thanks to molecular biology, hyperbaric oxygen's mechanisms of action are now well known. No wound can heal without oxygen. HBOT restores stunned cells previously deprived of oxygen, grows new blood vessels, builds new bone, skin, fights infections and stimulates a patient's stem cells 8x normal. HBOT is approved to treat three types of brain injury including decompression sickness (74 years.) Oxygen has been used for diving accidents since the 1930s and was officially adopted by Navy Medicine in 1968. HBOT is FDA-approved for treating three kinds of non-healing wounds (radiation necrosis, non-healing and diabetic foot wounds, compromised flaps and grafts). Its use in stroke and brain injury began after German neurological research published in 1977. Based on this science, the most recent study in blast injured veterans was reported at the 8th World Conference on Brain injury in Washington, D.C. on March 12, 2010. **On average, using only half of the HBOT 1.5 protocol, blast-injured war veterans experienced 15 point IQ increases from post-injury to post-HBOT 1.5 treatment (p<0.001) (the difference between a high school drop-out & a college graduate), 40% reduction in post-concussion symptoms [p=0.002 (np)], 30% reduction in PTSD symptoms (p<0.001), and a 51% decrease in depression (p<0.001).** About 80% of everyone treated has returned to duty, work or school. About 55% no longer needed medication. Improvements are lasting. HBOT is very cost effective. Biologically repairing brain injury is far less costly than the other consequences.

We urge you to cosponsor the TBI Treatment Act and speed its passage. Help heal our veterans now.



KENNETH STOLLER, M.D., President

Non-Healing Wound to the Foot

Diabetic Foot Ulcer: This Wagner Grade III was present for one year and unresponsive to conventional therapy.



1 Day Prior to Scheduled Amputation



26 HBOT Treatments

Hyperbaric Oxygenation prevents 75% of amputations in diabetic patients. Therapy approved by CMS for Medicare upon application by IHMA to CMS for coverage, 2002.



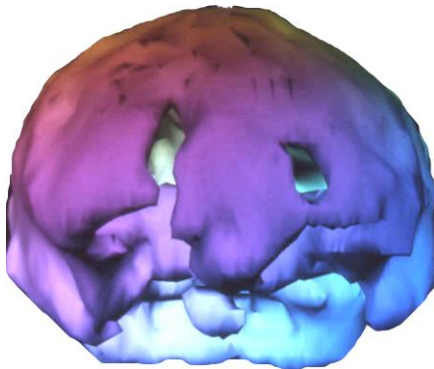
50 HBOT Treatments

These photographs are the property of Kenneth P. Stoller, MD, FAAP. Permission given by Dr. Stoller to the IHMA to publish on this CD (2004)

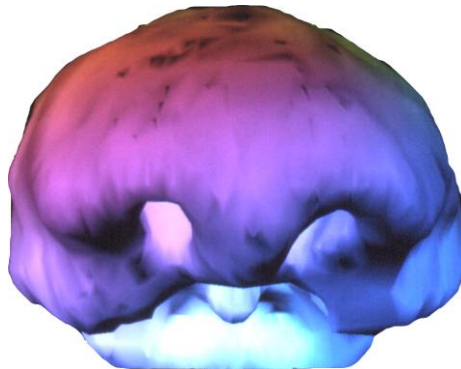


Non-Healing Wound in the Brain

Physical Abuse - 9 years after Injury - 21 y. female



Pre-HBOT 1.5



Post-HBOT 1.5

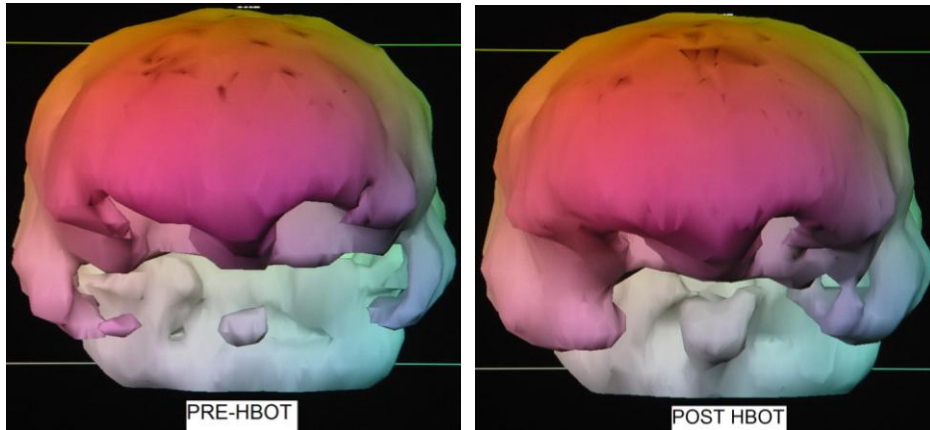
No wound will heal without oxygen!

What is the difference between the diabetic non-healing foot wound and the non-healing brain injury? Essentially nothing.

FDA has already approved HBOT for non-healing wounds.

Case Report: IHMA - Navy SG Meeting - Aug. 14, 2008

25 year old Humvee Machine Gunner 6 IEDs-1 RPG hit in Two Tours in Iraq



40 HBOT 1.5 treatments (1/2 of the Protocol)

From living in a dark room, unable to go to the Mall because of PTSD, after HBOT 1.5 treatments his PTSD cleared, he turned down ½ of the offered VA disability, worked for a year, and after 40 more treatments has returned to college.

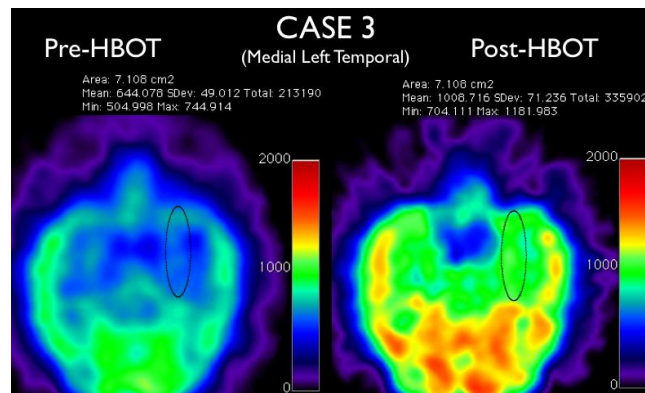
HBOT 1.5 Restores Brain Blood Flow & Doubles Metabolism

Marine Machine-gunner - August 2008 Navy SG Briefing

Scale actually goes from 0 to 2000 so it ENDS at 2000. Those pixels that are hitting near 2000 are red and are the most active, the less metabolically active are "cooler" colors of yellow, green and blue. So if you draw a line across the middle of the scale you can see what pixels are registering at 1000 by the corresponding color.

Both pre and post HBOT sets of images are exactly on the same scale. Below is a quantitative assessment that shows the actually percent increase in uptake to an area of the brain quite vulnerable to TBI. Note the mean uptake in the area went from 644 to 1008. Similar changes are evident everywhere else.

A change from green to red is a doubling of metabolism.



Analysis of blast injured veteran in LSU IRB Study # 7051: Edward Fogarty, MD, Neuro-radiologist, Chair, University of North Dakota School of Medicine, (701) 751-9579

www.HyperbaricMedicalAssociation.org

Airman B ANAM Percentile Scores

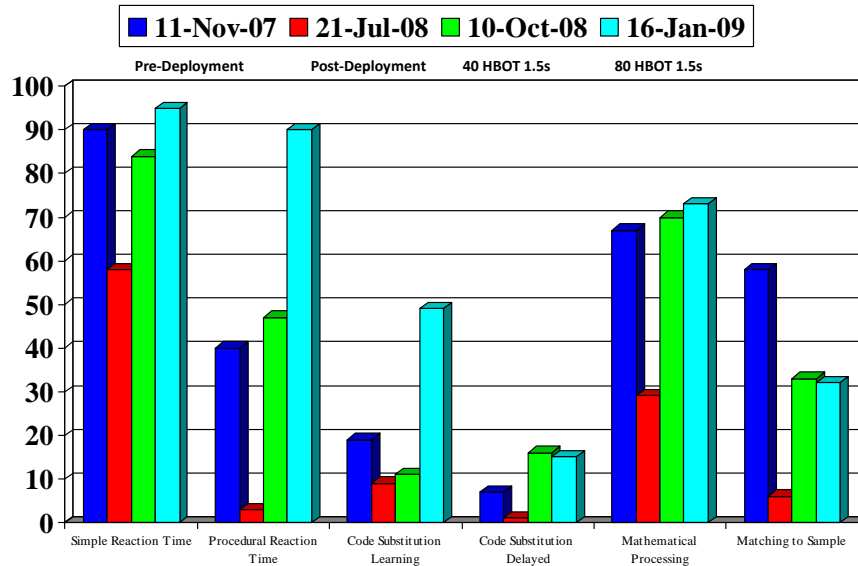


Figure 1: The passenger side of the M915 truck showing the damage caused by the IED.

Conclusion by article authors:

Several aspects of these two cases demonstrate the efficacy of HBO for the airmen treated. Although both airmen had stable symptoms of mTBI/post-concussive syndrome, which had not improved for seven months; substantive improvement was achieved within ten days of HBO treatment. The headaches and sleep

disturbances improved rapidly while the irritability, cognitive defects, and memory difficulties improved more slowly.

Fortunately both airmen had taken the ANAM and presented objective demonstration of their deficits from TBI and their improvements after HBO treatment. Both airmen, who were injured by the same blast sitting side by side, had similar symptom complexes of TBI and improved at similar rates after initiation of HBO treatment. Neither airmen had any other form of treatment for TBI. It seems unlikely to the authors that any explanation other than the HBO treatments can be offered for their improvements.

“Case report: Treatment of Mild Traumatic Brain Injury with Hyperbaric Oxygen: Colonel James K. Wright, USAF, MC, SFS; Eddie Zant, MD; Kevin Groom, PhD; Robert E. Schlegel, PhD, PE; Kirby Gilliland, PhD”

World Brain Injury Conference, Washington, D.C. March 12, 2010, Harch: Report on 15 Blast Injured Veterans under LSU IRB-approved study. Report is clinically and statistically significant and sufficient proof because of dramatic improvement in patients. ½ of NBIRR protocol given: **15 point IQ jump in 40 treatments p<0.001; 40% improvement in Post-concussion Syndrome p=0.002 (np); (10% is considered clinically significant.) 30% reduction in PTSD p<0.001; 51% Reduction in Depression p<0.001**

www.HyperbaricMedicalAssociation.org

Monoplace and Multi-Place Hyperbaric Chambers



Sechrist



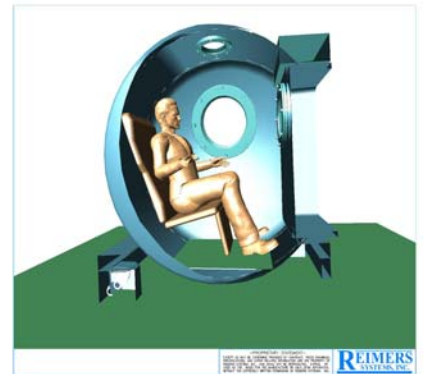
SOS Hyperlite



Perry



ETC Baromed



Reimers Q-Ball



Congress of the United States
Washington, DC 20515

January 28, 2011

Support our Injured Troops and Veterans by Co-Sponsoring the

TBI Treatment Act

(H.R. 396)

Dear Colleague:

Thousands of our brave servicemen and women are returning from combat with severe cases of Traumatic Brain Injury (TBI), resulting in an inability to hold a job, properly care for their families, or in some cases, to overcome suicidal tendencies. As a nation, we have the responsibility for their care and recovery.

Currently, private physicians across the United States are treating brain injury patients with new and innovative treatments, not currently available within the Department of Defense (DoD) and Department of Veterans Affairs (VA) medical facilities, with remarkable results. The TBI Treatment Act helps expedite these ground-breaking treatments to our nations' veterans and active duty soldiers suffering from TBI.

How does the TBI Treatment Act work?

- Establishes a 5-year **"pay-for-performance" pilot program**, not to exceed \$10 million/year
- Physicians treat active duty soldiers and veterans **at no cost to the patient**
- **Only if the treatment is proven successful** does the physician get reimbursed from the VA/DoD respectively (based on independent pre- and post-treatment neuropsychological testing, accepted survey instruments, neurological imaging, or clinical examinations)
- *Treatments must be **FDA-approved** and approved by an institutional review board operating in accordance with regulations issued by the Secretary of Health and Human Services*

The TBI Treatment Act helps fulfill our obligation to our nation's heroes and we look forward to your support. If you would like to become a cosponsor of the TBI Treatment Act, please contact Legislative Assistant Schylr Greggs of Congressman Pete Sessions office at Schylr.Greggs@mail.house.gov or in the office at 202.225.2231.

Sincerely,



Cong. Pete Sessions (TX-32)



Cong. Bill Pascrell Jr. (NJ-08)

Cong. Todd R. Platts (PA-19)



January 31, 2011

The Honorable Pete Sessions
U.S. House of Representatives
2233 Rayburn HOB
Washington, D.C. 20515
Via Fax: 202-225-5878

Subject: H.R.396 -- TBI Treatment Act – SUPPORT

Dear Representative Sessions:

The Long Beach Area Chamber of Commerce was pleased to support H.R. 4568 in the 111th Congress and we look forward helping pass the TBI Treatment Act in its reintroduction as H.R. 396.

On behalf of the many Long Beach veterans, the Chamber believes that H.R. 396 would be beneficial to not only our local veterans, but the many veterans across the country seeking much needed treatment for brain injuries and post-traumatic stress disorder. There have been advancements in medical treatments that are making it possible for our veterans to be treated, however sometimes these methods have difficulty getting through the medical bureaucracy.

If passed, H.R. 396 would create a historic opportunity to change medical policy in America to make sure payment is made for medical treatments that work. H.R. 396 will help boost America's Translational Medicine capabilities by creating a mechanism to more quickly bring legal, ethical, and available treatments to veterans suffering from brain injury or post-traumatic stress disorder. This pilot program would make payment to local health care practitioners when these conditions are successfully treated. The results are also tracked and reported and all human subject research regulations must be followed.

One of the most costly challenges to American business interests is untreated brain injury. Every year, millions are spent on workman's' compensation claims, lost work, lost income, and reduced human productive capacity due to these injuries. Further, social costs from persons who have been brain injured, as have so many of our recent war veterans, are now well known. Untreated brain injury costs billions in disability payments, incarceration costs, homelessness, domestic violence, and other safety net programs. This places constant pressure on budgets at every level of government. Finding and implementing an effective treatment for brain injury would save billions, while improving workplace productivity throughout our economy.

We appreciate your work on this very important legislation for our veterans. For these reasons, we support your H.R. 396 and look forward to working with your office if we can be of assistance.

Sincerely,

A handwritten signature in black ink that reads "Randy Gordon". The signature is written in a cursive, flowing style.

Randy Gordon
President and CEO

CC:

The Honorable Laura Richardson	202-225-7926
The Honorable Dana Rohrabacher	202-225-0145
The Honorable Linda Sánchez	202-226-1012
United States Chamber of Commerce	818-884-2511
California Chamber of Commerce	916-325-1272

H.R.396 -- TBI Treatment Act (Introduced in House - IH)

HR 396 IH

112th CONGRESS
1st Session
H. R. 396

To direct the Secretary of Defense and the Secretary of Veterans Affairs to carry out a pilot program under which the Secretaries make payments for certain treatments of traumatic brain injury and post-traumatic stress disorder.

IN THE HOUSE OF REPRESENTATIVES

January 24, 2011

Mr. SESSIONS (for himself, Mr. PLATTS, and Mr. PASCARELL) introduced the following bill; which was referred to the Committee on Armed Services, and in addition to the Committee on Veterans' Affairs, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To direct the Secretary of Defense and the Secretary of Veterans Affairs to carry out a pilot program under which the Secretaries make payments for certain treatments of traumatic brain injury and post-traumatic stress disorder.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the 'TBI Treatment Act'.

SEC. 2. PILOT PROGRAM ON PAYMENT FOR TREATMENT OF MEMBERS OF THE ARMED FORCES AND VETERANS FOR TRAUMATIC BRAIN INJURY AND POST-TRAUMATIC STRESS DISORDER.

(a) Payment Process- The Secretary of Defense and the Secretary of Veterans Affairs shall carry out a five-year pilot program under which each such Secretary shall establish a process through which each Secretary shall provide payment for treatments (including diagnostic testing) of traumatic

brain injury or post-traumatic stress disorder received by members of the Armed Forces and veterans in health care facilities other than military treatment facilities or Department of Veterans Affairs medical facilities. Such process shall provide that payment be made directly to the health care facility furnishing the treatment.

(b) Conditions for Payment- The approval by a Secretary for payment for a treatment pursuant to subsection (a) shall be subject to the following conditions:

(1) Any drug or device used in the treatment must be approved or cleared by the Food and Drug Administration for any purpose.

(2) The treatment must have been approved by an institutional review board operating in accordance with regulations issued by the Secretary of Health and Human Services.

(3) The treatment (including any patient disclosure requirements) must be used by the health care provider delivering the treatment.

(4) The patient receiving the treatment must demonstrate an improvement as a result of the treatment on one or more of the following:

(A) Standardized independent pre-treatment and post-treatment neuropsychological testing.

(B) Accepted survey instruments.

(C) Neurological imaging.

(D) Clinical examination.

(5) The patient receiving the treatment must be receiving the treatment voluntarily.

(6) The patient receiving the treatment may not be a retired member of the uniformed services or of the Armed Forces who is over the age of 65 and entitled to benefits under part A, or eligible to enroll under part B, of title XVIII of the Social Security Act.

(c) Additional Restrictions Prohibited- Except as provided in this subsection (b), no restriction or condition for reimbursement may be placed on any health care provider that is operating lawfully under the laws of the State in which the provider is located with respect to the receipt of payment under this Act.

(d) Payment Deadline- The Secretary of Defense and the Secretary of Veterans Affairs shall make a payment for a treatment pursuant to subsection (a) not later than 30 days after a member of the Armed Forces or veteran (or health care provider on behalf of such member or veteran) submits to the Secretary documentation regarding the treatment. The Secretary of Defense and the Secretary of Veterans Affairs shall ensure that the documentation required under this subsection may not be an undue burden on the member of the Armed Forces or veteran or on the health care provider.

(e) Payment Authority-

(1) DEPARTMENT OF DEFENSE- The Secretary of Defense shall make payments under this section for treatments received by members of the Armed Forces using the authority in subsection (c)(1) of section 1074 of title 10, United States Code.

(2) DEPARTMENT OF VETERANS AFFAIRS- The Secretary of Veterans Affairs shall make payments under this section for treatments received by veterans using the authority in section 1728 of title 38, United States Code.

(f) Payment Amount- A payment under this Act shall be made at the equivalent Centers for Medicare and Medicaid Services reimbursement rate in effect for appropriate treatment codes for the State or territory in which the treatment is received. If no such rate is in effect, payment shall be made at a fair market rate, as determined by the Secretary of Defense, in consultation with the Secretary of Health and Human Services, with respect to a patient who is a member of the Armed Forces or the Secretary of Veterans Affairs with respect to a patient who is a veteran.

(g) Data Collection and Availability-

(1) IN GENERAL- The Secretary of Defense and the Secretary of Veterans Affairs shall jointly develop and maintain a database containing data from each patient case involving the use of a treatment under this section. The Secretaries shall ensure that the database preserves confidentiality and be made available only--

(A) for third-party payer examination;

(B) to the appropriate congressional committees and employees of the Department of Defense, the Department of Veterans Affairs, the Department of Health and Human Services, and appropriate State agencies; and

(C) to the primary investigator of the institutional review board that approved the treatment, in the case of data relating to a patient case involving the use of such treatment.

(2) ENROLLMENT IN INSTITUTIONAL REVIEW BOARD STUDY- In the case of a patient enrolled in a registered institutional review board study, results may be publically distributable in accordance with the regulations prescribed pursuant to the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) and other regulations and practices in effect as of the date of the enactment of this Act.

(3) QUALIFIED INSTITUTIONAL REVIEW BOARDS- The Secretary of Defense and the Secretary of Veterans Affairs shall each ensure that the Internet Web site of their respective departments includes a list of all civilian institutional review board studies that have received a payment under this Act.

(h) Assistance for Members To Obtain Treatment-

(1) ASSIGNMENT TO TEMPORARY DUTY- The Secretary of a military department may assign a member of the Armed Forces under the jurisdiction of the Secretary to temporary duty or allow the member a permissive temporary duty in order to permit the member to receive treatment for traumatic brain injury or post-traumatic stress disorder, for which payments shall be made under subsection (a), at a location beyond reasonable commuting distance of the member's permanent duty station.

(2) PAYMENT OF PER DIEM- A member who is away from the member's permanent station may be paid a per diem in lieu of subsistence in an amount not more than the amount to which the member would be entitled if the member were performing travel in connection with a temporary duty assignment.

(3) GIFT RULE WAIVER- Notwithstanding any rule of any department or agency with respect to ethics or the receipt of gifts, any assistance provided to a member of the Armed Forces with a service-connected injury or disability for travel, meals, or entertainment incidental to receiving treatment under this Act, or for the provision of such treatment, shall not be subject to or covered by any such rule.

(i) Retaliation Prohibited- No retaliation may be made against any member of the Armed Forces or veteran who receives treatment as part of registered institutional review board study carried out by a civilian health care practitioner.

(j) Treatment of University and Nationally Accredited Institutional Review Boards- For purposes of this Act, a university-affiliated or nationally accredited institutional review board shall be treated in the same manner as a Government institutional review board.

(k) Memoranda of Understanding- The Secretary of Defense and the Secretary of Veterans Affairs shall seek to expeditiously enter into memoranda of understandings with civilian institutional review boards described in subsection (j) for the purpose of providing for members of the Armed Forces and veterans to receive treatment carried out by civilian health care practitioners under a treatment approved by and under the oversight of civilian institutional review boards that would qualify for payment under this Act.

(l) Outreach Required-

(1) OUTREACH TO VETERANS- The Secretary of Veterans Affairs shall notify each veteran with a service-connected injury or disability of the opportunity to receive treatment pursuant to this Act.

(2) OUTREACH TO MEMBERS OF THE ARMED FORCES- The Secretary of Defense shall notify each member of the Armed Forces with a service-connected injury or disability of the opportunity to receive treatment pursuant to this Act.

(m) Report to Congress- Not later than 30 days after the last day of each fiscal year during which the Secretary of Defense and the Secretary of Veterans Affairs are authorized to make payments under this Act, the Secretaries shall jointly submit to Congress an annual report on the implementation of this Act. Such report shall include each of the following for that fiscal year:

(1) The number of individuals for whom the Secretary has provided payments under this Act.

(2) The condition for which each such individual receives treatment for which payment is provided under this Act and the success rate of each such treatment.

(3) Treatment methods that are used by entities receiving payment provided under this Act and the respective rate of success of each such method.

(4) The recommendations of the Secretaries with respect to the integration of treatment methods for which payment is provided under this Act into facilities of the Department of Defense and Department of Veterans Affairs.

(n) Termination- The authority to make a payment under this Act shall terminate on the date that is five years after the date of the enactment of this Act.

(o) Authorization of Appropriations- There is authorized to be appropriated to carry out this Act \$10,000,000 for each fiscal year during which the Secretary of Veterans Affairs and the Secretary of Defense are authorized to make payments under this Act.
