



## **Request: Pass The TBI Treatment Act**

### **Are You Ready to Do Something to Help Your Military Constituents With Traumatic Brain Injury?**

*Do You Want to Boost Economic Productivity in Your State?*

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

## **Then Pass the TBI Treatment Act, Attached to the House Armed Services Bill!**

Dear Senator:

October 7, 2011

Everyone has been talking about the dramatic rise in Traumatic Brain Injury (TBI) in our troops. You can do something this month to help them and the nation, and at the same time help the economy. There are likely over 600,000 current war veterans suffering from blast exposure or other forms of brain insults! According to House VA Testimony, each such veteran can cost \$60,000 per year in federal, state and local budget expenditures when left untreated. That represents a nearly \$36 billion per year drain on the economy!

The TBI Treatment Act, Section 731 of HR 1540, the National Defense Authorization Act for FY 2012, simply permits civilian physicians to apply translational medicine practices to the challenges of these veterans! Numerous clinicians across the nation have made real breakthroughs in treating both traumatic brain injury and post-traumatic stress disorder (PTSD). Unfortunately, when those treatments are given to war veterans, practitioners have not been able to get paid by the DoD or VA medical systems even when the veterans recovered and saved the U.S. Government millions in retraining, disability, drug and other costs. The TBI Treatment Act sets up a rational mechanism so that when veterans are helped, practitioners are paid and the data gets passed to DoD and VA medicine so best practices can be adopted.

The U.S. Government is not yet a third world country in need of charity from the medical community to repair veterans. It was recently reported that VA spent \$717 million on a drug little better than placebo. Further, it has significant side effects.

Contrast that with a very safe treatment using intermittent, high-dose oxygen. This treatment, when provided to veterans disabled to the point where they were economically dysfunctional, has had an 80% success rate at returning veterans to work, duty or school. The Commandants of the Marine Corps, General Conway and General Amos, have both witnessed it and told Congress about it. General Chandler, Vice Chief of the Air Force, asked Chairman Levin for funding for this therapy. This legislation answers the General's request.

For \$717 million, 30,000 men and women, the equivalent of three divisions, could have been restored to duty at CMS specified payment rates with the treatment the Generals have discussed. If DoD had done this treatment internally, at an incremental cost of \$4,000 each, 179,000 men and women could have been restored, many to nearly their pre-injury capabilities.

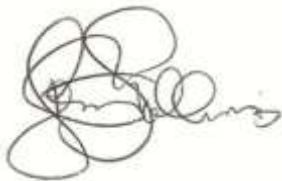
**The TBI Treatment Act does not specify what treatment must be used**, other than the treatment must already be available and FDA-approved for some use. Some treatments that have proven successful include: awakening patients from coma (International Brain Research Foundation); cognitive rehabilitation which assists in retraining a brain after injury; and hyperbaric oxygen therapy (intermittent high-dose oxygen) which has been shown to rebuild the brain's vascular structure and restore non-functioning brain tissue to a higher level of activity.

IRB-approved research funded by the Semper Fi Funds and presented at the 2010 World Brain Injury Conference, indicated that war veterans treated with hyperbaric oxygen experienced **a 15 point IQ increase, a 40% reduction in Post-Concussion Syndrome, a 30% reduction in PTSD, a 51% reduction in Depression. Fifty-five percent of those using prescription psychoactive drugs when they came into the program were not on those prescriptions when they left and the other 45% had reduced their dose.** This occurred after receiving just one half of the currently recommended protocol. Following this therapy many active duty service-members have been able to return to duty, for current year savings of several millions of dollars. **Just four such members saved the government \$11.2 million in single year budget costs (training and recruitment costs) after their medical boards were cancelled and they were determined fit for duty and redeployable.**

The request is simple. The TBI Treatment Act only permits payment for treatments **that actually cause improvement**, and specifies the measures on which they must improve. It is modeled after Medicare's "Coverage with Evidence" program and Doctor/Senator Tom Coburn's novel idea that doctors should be paid for treatment that works. All data is collected under federal rules to protect human subjects, and permit analysis of the data for rapid adoption. The program is capped at \$10 million, a small cost when compared to the alternatives.

**Unleash the medical community to help our men and women in uniform. We urge you to pass the TBI Treatment Act in the Senate and attach it to the Senate Armed Services bill, or encourage your colleagues on the Senate Armed Services Committee to recede to the House position.**

For further information, contact the House sponsor, Representative Pete Sessions of Texas, at (202) 225-2231 or his staff, Schylr Greggs via email at [Schylr.Greggs@mail.house.gov](mailto:Schylr.Greggs@mail.house.gov).



KENNETH STOLLER, M.D.  
President  
International Hyperbaric Medical Association



# Public Policy Brief

## A Primer on Traumatic Brain Injury

2011-1

**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 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)

**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 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](mailto:info@HyperbaricMedicalAssociation.org). See [www.clinicaltrials.gov](http://www.clinicaltrials.gov) study number NCT01105962 or [www.NBIRR.org](http://www.NBIRR.org). Study results are available.

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



## **Request: Support the National Defense Authorization Act, HR 1540, Section 731: The TBI Treatment Act**

Subject: **Let Civilian Practitioners Help Solve the TBI and PTSD Crisis among Veterans**

Dear Member of Congress:

June 16, 2011

**War veterans today are in crisis. Are you satisfied with the treatment they are receiving?**

**Neither is the House Armed Services Committee.** On May 25, 2011, Congressman Pete Sessions submitted and achieved passage of Section 731 of HR 1540, the National Defense Authorization Act for FY 2012. The language is the text of HR 396, “the TBI Treatment Act.” The provision is endorsed by the Brain Injury Caucus, and other organizations including the Long Beach California Chamber of Commerce. The language was originally authored by the IHMA and introduced as HR 7299 in the 110<sup>th</sup> Congress by Mr. Cannon. Sessions’ TBI Treatment Act expedites scientific proof for new and innovative treatments that are not currently available through military and veteran medical centers. Section 731 requires payment for these breakthrough treatments whenever a veteran and active duty service member is suffering from Traumatic Brain Injuries (TBI) or Post-Traumatic Stress Disorder (PTSD) and individually has improvement.

Congressman Sessions stated, “I am pleased that the House has recognized the critical need to provide expanded treatment options for thousands of service men and women who have returned from combat with TBI and PTSD. These brave men and women have sacrificed for their country, and we as a nation have a solemn duty to ensure that they have access to the most effective treatments available, whether through government or private health care.”

Sessions’ TBI treatment legislation creates a five-year pilot program that allows active duty and veteran personnel suffering from TBI or PTSD to receive health care from private physicians who are utilizing an array of leading-edge, successful therapies to treat those conditions. Through a “pay-for-performance” plan, physicians are only paid for treatment by the Department of Defense or Veterans Affairs after proving the patient received demonstrable benefit using independently verifiable measurements such as pre- and post-treatment neuropsychological testing, accepted survey instruments, neurological imaging or clinical examination. All treatments must be conducted under standard human subject protections and the treatment results tracked using translational medicine studies, This provides scientific results that can be used to drive best practices. These procedures also permit data collection and public disclosure so these new treatments can be rapidly adopted and deployed by military medicine and the Department of Veterans Affairs.

This legislation helps ensure immediate access to innovative private health care treatments while reserving payment only for treatments that work for an individual patient. The Sessions’ TBI treatment legislation requires an annual report to Congress on the results of the program and how each Department Secretary plans to integrate successful methods into their own medical practices. This process will help encourage a constant flow of new treatments into military medicine.

It is essential to TBI/PTSD casualties and their families that the amendment remain in the final version of the NDAA that will be sent to the President. We hope you will join with us to encourage members of both House and Senate to assure passage of the NDAA with the TBI Treatment language, thus advancing treatment for our brain-injured warriors and the underlying science. Please contact the IHMA at (703) 339-0900 or at [info@hyperbaricmedicalassociation.org](mailto:info@hyperbaricmedicalassociation.org) for more information on TBI/PTSD treatment breakthroughs.

Sincerely,

K. PAUL STOLLER, M.D., President

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# **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 111<sup>th</sup> 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 112<sup>th</sup> Congress. We urge you to cosponsor this legislation. Contact Schylr Greggs in his office at (202) 225-2231 or [Schylr.Greggs@mail.house.gov](mailto:Schylr.Greggs@mail.house.gov).

Please unleash 21<sup>st</sup> 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.**

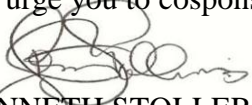
**Let it be noted that three mild-TBI symptoms were inserted into the PTSD definition which was then labeled as an emotional adjustment problem. This is why DoD and VA medicine is unable to distinguish between PTSD and mild-TBI. This has caused great confusion in finding solutions.**

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.**



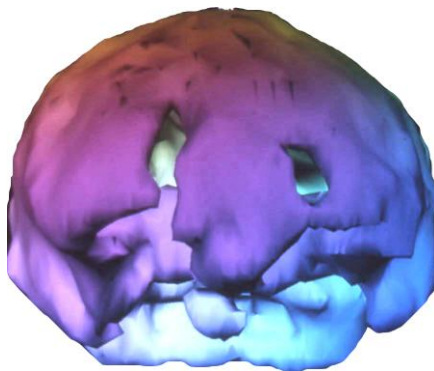
50 HBOT Treatments

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)

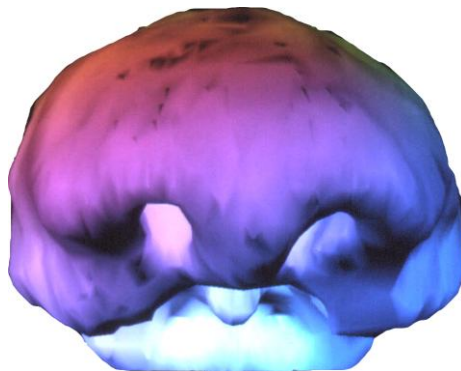


# Non-Healing Wound in the Brain

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



Pre-HBOT 1.5



Post-HBOT 1.5

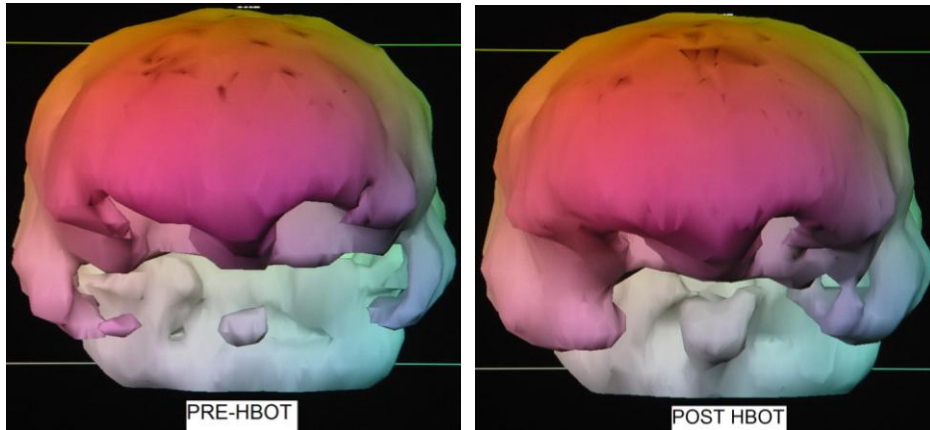
**No wound will heal without oxygen!**

**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.

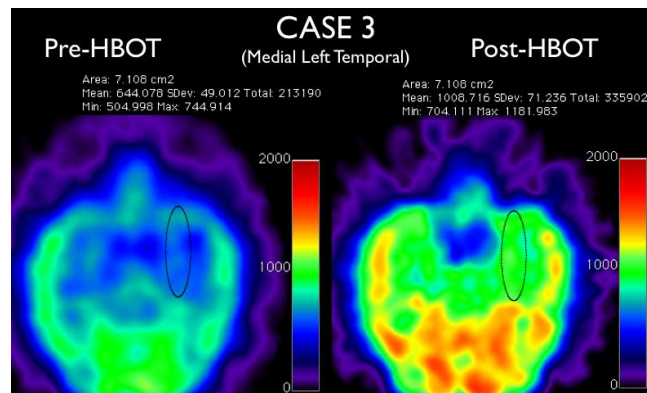
## HBOT 1.5 Restores Brain Blood Flow & Doubles Metabolism

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](http://www.HyperbaricMedicalAssociation.org)

## Airman B ANAM Percentile Scores

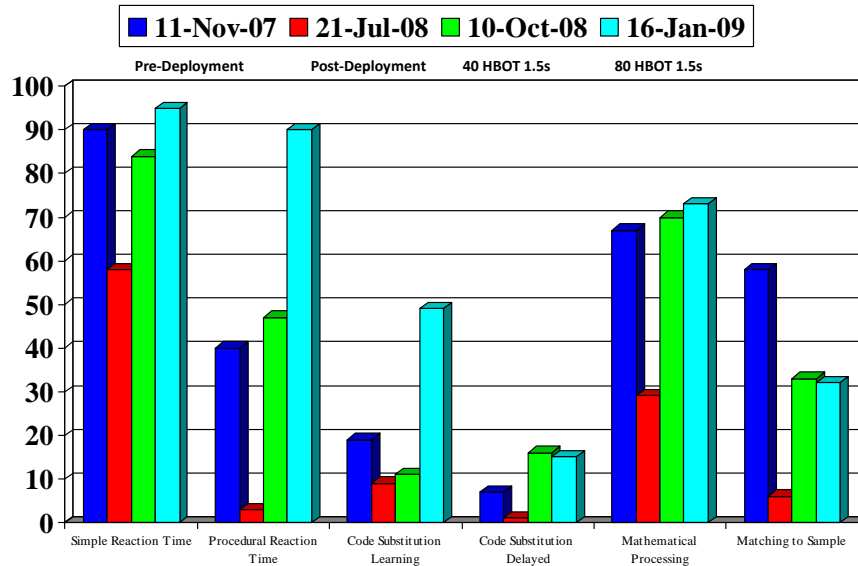


Figure 1: The passenger side of the M915 truck showing the damage caused by the IED.

### 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](http://www.HyperbaricMedicalAssociation.org)

# Monoplace and Multi-Place Hyperbaric Chambers



Sechrist



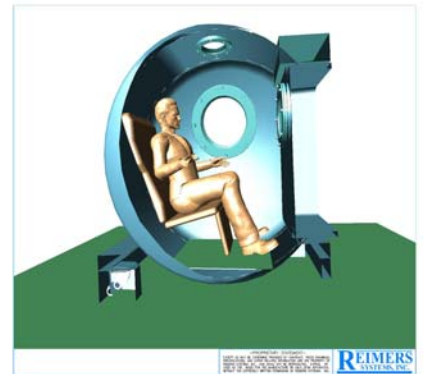
SOS Hyperlite



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 111<sup>th</sup> 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

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**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.

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