



## International Hyperbaric Medical Association

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Senator  
Washington, DC 20510

### Request for Appointment to Discuss HR4568, the "TBI Treatment Act," Added to H. R. 5136, the House Armed Services Bill as Section 727, and Effective Treatment to Biologically Repair Brain Injury, PTSD, and Depression

Dear Senator:

July 5, 2010

On May 28, 2010, the House added HR4568, "the TBI Treatment Act," to HR 5136, the House Armed Services bill. We urge the Senate to add this same provision to the Senate Armed Services bill or recede to the House provision. With its inclusion, war veterans can begin receiving treatment that works for TBI or PTSD.

The TBI Treatment Act is endorsed by the House Brain Injury Caucus. It makes it possible for members of the Armed Forces and veterans to seek treatment from civilian physicians who are successful at treating traumatic brain injury or post-traumatic stress disorder. There are civilian physicians who have helped war veterans make remarkable recoveries under their care. Unfortunately bureaucratic agendas have prevented access. The TBI Treatment Act creates a mechanism so that these veterans can get the latest treatment. They can then return to productive lives and careers. These treatments have already saved many millions of tax dollars for war-injured veterans, and many have already paid for themselves.

For example, the **International Brain Research Foundation has been able to successfully awaken 84% of coma victims from their comas**, thus greatly reducing the costs of a severe TBI patient. However, DoD medicine has not been willing to reimburse for this treatment. Awakening a patient from a coma saves \$2,000 per day in medical costs. This bill would reimburse for every successfully awakened war veteran.

On March 12th, at the 8th World International Brain Injury conference, Dr. Paul Harch of Louisiana State University's School of Medicine, presented the results of his study of treatment of blast injured veterans using hyperbaric oxygen therapy to biologically repair brain injuries. **These veterans experienced a statistically significant 15 point IQ increase (the equivalent difference between a high school dropout and a college graduate), a 40% reduction in post-concussion syndrome symptoms, a 30% reduction in post-traumatic brain injury symptoms, and a 51% reduction in concussive depression.** Eighty-percent of those treated have been able to return to duty, work, or school. HR 4568 was written after two airmen were returned to active duty and Tricare refused to pay the physician for treatment, despite the obvious success and the federal savings of \$2.6 million over the life of each veteran. Both have since had their medical board's cancelled, and been promoted.

We have a national crisis of hundreds of thousands of blast injured veterans. We would like to meet with you about making effective treatments immediately available to our war veterans, and the other 30 million persons living with brain injury. HR 4568, the TBI Treatment Act, endorsed by the Brain Injury caucus, will help make this possible.

These innovative treatments the potential to truly help control entitlement spending. Untreated brain injury is the single most expensive chronic public health cost in America. It is billions in entitlement costs, mandatory spending, education costs, and lost productivity and tax revenue. Savings is possible. For example, in 2003, Medicare approved the IHMA's request for coverage of diabetic foot wounds with hyperbaric oxygen because it prevents 75% of all amputations. Today Medicare is saving an estimated \$347 million from preventing just 11% of the amputations, thanks to oxygen.

Please contact me for an appointment at [wduncan@dc-strategy.com](mailto:wduncan@dc-strategy.com). We look forward to briefing you. Please help with the Senate version of the TBI Treatment Act. Thank you for helping for our nation's veterans.

DR. WILLIAM A. DUNCAN  
Vice President for Government Affairs  
International Hyperbaric Medical Association

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Congress of the United States  
Washington, DC 20515

February 4, 2010

Support our Injured Troops and Veterans by Co-Sponsoring the

# TBI Treatment Act

## (H.R. 4568)

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.

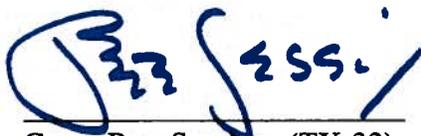
Currently, private physicians across the United States are treating brain injury patients with new and innovative treatments, not currently available within the Department of Defense (DoD) and Department of Veterans Affairs (VA) medical facilities, with remarkable results. The TBI Treatment Act helps 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 Jim Silliman of Congressman Pete Sessions office at Jim.Silliman@mail.house.gov or in the office at 202.225.2231.

Sincerely,



Cong. Pete Sessions (TX-32)



Cong. Bill Pascrell Jr. (NJ-08)  
Brain Injury Task Force, Co-Chair



Cong. Todd R. Platts (PA-19)  
Brain Injury Task Force, Co-Chair

# PETE SESSIONS U.S. CONGRESSMAN

32nd District of Texas



For Immediate Release: February 03, 2010

Contact: [Emily Davis](#), 202.225.2231

## Sessions Introduces TBI Treatment Bill for Troops, Vets

**Washington, DC** – U.S. Congressman Pete Sessions has introduced the *TBI Treatment Act* (H.R.4568) to expedite new and innovative treatments, not currently available within Department of Defense (DoD) and Veterans Affairs (VA) facilities, to our nations’ veterans and active duty soldiers suffering from Traumatic Brain Injuries (TBI).

“Thousands of our brave servicemen and women are returning from combat with mild to severe cases of TBI, resulting in an inability to hold a job, properly care for their families, or in some cases, to overcome suicidal tendencies,” stated Sessions. “As a nation, we have the responsibility for their care and recovery, and I am encouraged with the potential of expediting innovative treatments for brain-injured soldiers suffering from TBI.”

The *TBI Treatment Act* creates a five-year pilot program that allows active duty and veteran TBI patients to receive reimbursable health care from private physicians who are utilizing an array of leading-edge, successful therapies to treat TBI. Under Sessions’ legislation, physicians may voluntarily treat soldiers and veterans with TBI using any government-approved treatments to stimulate neurons throughout the brain to regain function, including but not limited to Hyperbaric Oxygen Therapy (HBOT), flash doses of approved drugs, and small devices that operate like brain pacemakers. Using these and other treatments in the private sector, a multitude of evidence from numerous cases shows substantial progress in brain function and personality in TBI patients, leading to promising treatment options for injured troops.

Through a “pay-for-performance” plan, physicians may qualify for payment from DoD or VA after proving through independent pre- and post-treatment neuropsychological testing, accepted survey instruments, neurological imaging, or clinical examination that a patient has experienced demonstrable improvement. Treatment and reimbursement safeguards in the bill ensure immediate access to innovative private health care treatments while reserving payment only for treatments that work.

“Our soldiers and veterans suffering from TBI need help and hope right now,” said Sessions, “and I believe that they deserve immediate access to the most effective treatments available, whether through government or private health care. By prioritizing treatment results over treatment location, my legislation immediately opens up the most innovative and most effective treatments for brain-injured soldiers and veterans even as the federal government evaluates and builds the capabilities to offer new treatments on its own in the future.”

To reach the long-term objective of incorporating leading-edge medical practices into military hospitals, Sessions’ *TBI Treatment Act* 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 facilities. This process will help encourage a constant flow of new and innovative treatments into military medicine.

Since 2006, Sessions has been actively engaged in finding proven, high-quality treatment options for troops and veterans with TBI, which is an increasingly-common and life-threatening non-healing wound among troops in combat regions. Sessions has met with physicians, scientists, researchers, the Department of Defense, the Department of Veterans Affairs, and service members regarding new therapies for TBI in military and VA medical facilities as well as immediate access through private health care. Sessions' *TBI Treatment Act* builds on legislation he passed in 2009 to begin the evaluation and reporting process for the use of innovative TBI treatments in military and veteran facilities.

“Our soldiers and veterans have made very costly sacrifices for American security and prosperity, and they deserve unwavering support from a grateful nation. I will continue to stand up for our injured soldiers and veterans to ensure that they receive the best quality care in America,” Sessions concluded.

###

111TH CONGRESS

2D SESSION **H. R. 5136**

**AN ACT**

To authorize appropriations for fiscal year 2011 for military activities of the Department of Defense, for military construction, and for defense activities of the Department of Energy, to prescribe military personnel strengths for such fiscal year, and for other purposes.

**SEC. 727. PILOT PROGRAM ON PAYMENT FOR TREATMENT**

**9 OF MEMBERS OF THE ARMED FORCES AND**

**10 VETERANS FOR TRAUMATIC BRAIN INJURY**

**11 AND POST-TRAUMATIC STRESS DISORDER.**

12 (a) **PAYMENT PROCESS.**—The Secretary of Defense  
13 and the Secretary of Veterans Affairs shall carry out a  
14 five-year pilot program under which each such Secretary  
15 shall establish a process through which each Secretary  
16 shall provide payment for treatments (including diagnostic  
17 testing) of traumatic brain injury or post-traumatic stress  
18 disorder received by members of the Armed Forces and  
19 veterans in health care facilities other than military treat  
20 ment facilities or Department of Veterans Affairs medical  
21 facilities. Such process shall provide that payment be  
22 made directly to the health care facility furnishing the  
23 treatment.

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1 (b) **CONDITIONS FOR PAYMENT.**—The approval by a  
2 Secretary for payment for a treatment pursuant to sub  
3 section (a) shall be subject to the following conditions:

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

7 (2) The treatment or study protocol used in  
8 treating the member or veteran must have been ap  
9 proved by an institutional review board operating in  
10 accordance with regulations issued by the Secretary  
11 of Health and Human Services.

12 (3) The approved treatment or study protocol  
13 (including any patient disclosure requirements) must  
14 be used by the health care provider delivering the  
15 treatment.

16 (4) The patient receiving the treatment or  
17 study protocol must demonstrate an improvement as  
18 a result of the treatment on one or more of the fol  
19 lowing:

20 (A) Standardized independent pre-treat  
21 ment and post-treatment neuropsychological  
22 testing.

23 (B) Accepted survey instruments.

24 (C) Neurological imaging.

25 (D) Clinical examination.

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1 (5) The patient receiving the treatment or  
2 study protocol must be receiving the treatment vol  
3 untarily.

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

9 (c) ADDITIONAL RESTRICTIONS PROHIBITED.—Ex  
10 cept as provided in this subsection (b), no restriction or  
11 condition for reimbursement may be placed on any health  
12 care provider that is operating lawfully under the laws of  
13 the State in which the provider is located with respect to  
14 the receipt of payment under this Act.

15 (d) PAYMENT DEADLINE.—The Secretary of Defense  
16 and the Secretary of Veterans Affairs shall make a pay  
17 ment for a treatment or study protocol pursuant to sub  
18 section (a) not later than 30 days after a member of the  
19 Armed Forces or veteran (or health care provider on be  
20 half of such member or veteran) submits to the Secretary  
21 documentation regarding the treatment or study protocol.  
22 The Secretary of Defense and the Secretary of Veterans  
23 Affairs shall ensure that the documentation required  
24 under this subsection may not be an undue burden on the

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1 member of the Armed Forces or veteran or on the health  
2 care provider.

3 (e) PAYMENT SOURCE.—Subsection (c)(1) of section  
4 1074 of title 10, United States Code, shall apply with re  
5 spect to the payment by the Secretary of Defense for  
6 treatment or study protocols pursuant to subsection (a)  
7 of traumatic brain injury and post-traumatic stress dis  
8 order received by members of the Armed Forces.

9 (f) PAYMENT AMOUNT.—A payment under this Act  
10 shall be made at the equivalent Centers for Medicare and  
11 Medicaid Services reimbursement rate in effect for appro  
12 priate treatment codes for the State or territory in which  
13 the treatment or study protocol is received. If no such rate  
14 is in effect, payment shall be made at a fair market rate,  
15 as determined by the Secretary of Defense, in consultation  
16 with the Secretary of Health and Human Services, with  
17 respect to a patient who is a member of the Armed Forces  
18 or the Secretary of Veterans Affairs with respect to a pa  
19 tient who is a veteran.

20 (g) DATA COLLECTION AND AVAILABILITY.—

21 (1) IN GENERAL.—The Secretary of Defense  
22 and the Secretary of Veterans Affairs shall jointly  
23 develop and maintain a database containing data  
24 from each patient case involving the use of a treat  
25 ment under this section. The Secretaries shall en

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1 sure that the database preserves confidentiality and  
2 be made available only—

3 (A) for third-party payer examination;

4 (B) to the appropriate congressional com  
5 mittees and employees of the Department of  
6 Defense, the Department of Veterans Affairs,  
7 the Department of Health and Human Services,  
8 and appropriate State agencies; and

9 (C) to the primary investigator of the insti  
10 tutional review board that approved the treat  
11 ment or study protocol, in the case of data re  
12 lating to a patient case involving the use of

13 such treatment or study protocol.

14 (2) ENROLLMENT IN INSTITUTIONAL REVIEW

15 BOARD STUDY.—In the case of a patient enrolled in  
16 a registered institutional review board study, results  
17 may be publically distributable in accordance with  
18 the regulations prescribed pursuant to the Health  
19 Insurance Portability and Accountability Act of  
20 1996 (Public Law 104–191) and other regulations  
21 and practices in effect as of the date of the enact  
22 ment of this Act.

23 (3) QUALIFIED INSTITUTIONAL REVIEW

24 BOARDS.—The Secretary of Defense and the Sec  
25 retary of Veterans Affairs shall each ensure that the

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1 Internet website of their respective departments in  
2 cludes a list of all civilian institutional review board  
3 studies that have received a payment under this Act.

4 (h) ASSISTANCE FOR MEMBERS TO OBTAIN TREAT  
5 MENT.—

6 (1) ASSIGNMENT TO TEMPORARY DUTY.—The  
7 Secretary of a military department may assign a  
8 member of the Armed Forces under the jurisdiction  
9 of the Secretary to temporary duty or allow the  
10 member a permissive temporary duty in order to  
11 permit the member to receive treatment or study  
12 protocol for traumatic brain injury or post-traumatic  
13 stress disorder, for which payments shall be made  
14 under subsection (a), at a location beyond reason  
15 able commuting distance of the member's permanent  
16 duty station.

17 (2) PAYMENT OF PER DIEM.—A member who is  
18 away from the member's permanent station may be  
19 paid a per diem in lieu of subsistence in an amount  
20 not more than the amount to which the member  
21 would be entitled if the member were performing  
22 travel in connection with a temporary duty assign  
23 ment.

24 (3) GIFT RULE WAIVER.—Notwithstanding any  
25 rule of any department or agency with respect to

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1 ethics or the receipt of gifts, any assistance provided  
2 to a member of the Armed Forces with a service  
3 connected injury or disability for travel, meals, or  
4 entertainment incidental to receiving treatment or  
5 study protocol under this Act, or for the provision  
6 of such treatment or study protocol, shall not be  
7 subject to or covered by any such rule.

8 (i) RETALIATION PROHIBITED.—No retaliation may  
9 be made against any member of the Armed Forces or vet  
10 eran who receives treatment or study protocol as part of  
11 registered institutional review board study carried out by  
12 a civilian health care practitioner.

13 (j) TREATMENT OF UNIVERSITY AND NATIONALLY  
14 ACCREDITED INSTITUTIONAL REVIEW BOARDS.—For  
15 purposes of this Act, a university-affiliated or nationally  
16 accredited institutional review board shall be treated in the  
17 same manner as a Government institutional review board.

18 (k) MEMORANDA OF UNDERSTANDING.—The Sec  
19 retary of Defense and the Secretary of Veterans Affairs  
20 shall seek to expeditiously enter into memoranda of under  
21 standings with civilian institutional review boards de  
22 scribed in subsection (j) for the purpose of providing for  
23 members of the Armed Forces and veterans to receive  
24 treatment carried out by civilian health care practitioners  
25 under a treatment or study protocol approved by and

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1 under the oversight of civilian institutional review boards  
2 that would qualify for payment under this Act.

3 (l) OUTREACH REQUIRED.—

4 (1) OUTREACH TO VETERANS.—The Secretary  
5 of Veterans Affairs shall notify each veteran with a  
6 service-connected injury or disability of the oppor  
7 tunity to receive treatment or study protocol pursu  
8 ant to this Act.

9 (2) OUTREACH TO MEMBERS OF THE ARMED  
10 FORCES.—The Secretary of Defense shall notify  
11 each member of the Armed Forces with a service  
12 connected injury or disability of the opportunity to

13 receive treatment or study protocol pursuant to this  
14 Act.

15 (m) REPORT TO CONGRESS.—Not later than 30 days  
16 after the last day of each fiscal year during which the Sec  
17 retary of Defense and the Secretary of Veterans Affairs  
18 are authorized to make payments under this Act, the Sec  
19 retaries shall jointly submit to Congress an annual report  
20 on the implementation of this Act. Such report shall in  
21 clude each of the following for that fiscal year:

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

24 (2) The condition for which each such indi  
25 vidual receives treatment for which payment is pro

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1 vided under this Act and the success rate of each  
2 such treatment.

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

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

11 (n) TERMINATION.—The authority to make a pay  
12 ment under this Act shall terminate on the date that is  
13 five years after the date of the enactment of this Act.

14 (o) AUTHORIZATION OF APPROPRIATIONS.—There is  
15 authorized to be appropriated to carry out this Act  
16 \$10,000,000 for each fiscal year during which the Sec  
17 retary of Veterans Affairs and the Secretary of Defense  
18 are authorized to make payments under this Act.