



Testimony

"Effective Treatment for Traumatic Brain Injury and Post-Traumatic Stress Disorder Is Available to Meet the Nation's Current Emergency"

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on behalf of

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for the

**Round Table Discussion:
Innovative Treatments for TBI and PTSD**

**House Veterans Affairs Committee
United States House of Representatives**

July 21, 2010

INTRODUCTION AND BACKGROUND

Chairman Filner, Ranking Member Buyer, Members of the Committee, thank you for the opportunity to present a highly innovative solution to the medical crises of traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) that are seriously impacting U. S. Armed Services members, the U.S. military, V.A. medical systems, American society, and the criminal justice system. Due to a surprising new elusive enemy battlefield weapon and despite rapidly developed counter measures of body and vehicle armor, service members' extremities and heads appear to have borne the brunt of battle in Afghanistan and Iraq. Multiple reports, including the Washington Post articles three days ago, have documented the devastating toll of injury and death that improvised explosive devices (IED's) have taken on our forces.



This statement will first provide a blast-injured Veteran's case report of the effects of Hyperbaric Oxygen Therapy using 1.5 atmospheres absolute for one hour per treatment (HBOT 1.5) for a minimum of forty treatments. It will also outline the scientifically-valid results on the numerous blast-injured war Veterans suffering from the symptoms of TBI and/or PTSD and the duplicated results published by a military physician. We will describe the National Brain Injury Rescue and Rehabilitation Project (NBIRR), a highly innovative observational study (where all subjects will receive the treatment protocol) that uses Bayesian Statistical Methodology. The Bayesian Methodology is a modern FDA-approved research methodology¹ that does not require a placebo control group.² We will then briefly discuss brain injury and post-traumatic stress disorder and how hyperbaric medicine works.

¹ "Guidance for the Use of Bayesian Statistics in Medical Device Clinical Trials" U.S. Food and Drug Administration, Center for Devices and Radiological Health, Division of Biostatistics, Office of Surveillance and Biometrics, Center for Biologics Evaluation and Research. Document issued on: February 5, 2010

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The RAND Report (April 2008) estimated that approximately 33% of all U.S. service members deployed to Iraq or Afghanistan might have one or a combination of three conditions: TBI, PTSD, and/or major depression. With 1.9 million U.S. service members deployed through the end of 2009 the number afflicted could be over 600,000. In March of this year the Army Surgeon General reported 9,003 war Veterans in Wounded Warrior brigades across the nation who in the absence of recovery may well be discharged, and be eligible for treatment by the VA. Thousands more may be undiagnosed and untreated, and remain unemployed, homeless, incarcerated, or even suicidal from their wounds. We believe we are presenting to this Committee and to the VA an innovative, practical, cost-effective medical solution to these problems and circumstances through HBOT 1.5.

In 2005 a 25-year old U.S. Marine machine gunner serving in Fallujah experienced blast-induced loss of consciousness from an IED. The resultant headaches, ringing in his ears, and sleep disturbance were accompanied by post-traumatic stress disorder (PTSD) three months later. Meanwhile, his symptoms intensified due to six more brain-rattling IED and rocket-propelled grenade explosions in the next 15 months. Due to his TBI, PTSD, and sleep deprivation, he became increasingly impaired, dysfunctional, and unable to perform his duties as effectively as before these combat injuries.

Upon return to the U.S. he was diagnosed with traumatic brain injury (TBI)/post-concussion syndrome (PCS), PTSD, depression, hearing loss, tinnitus, and was discharged from the Marines with minimal compensation and disability. Disaffected and brain injured, he struggled with a deteriorating quality of life, failing relationship, nightmares, headaches, and

² This methodology is now widely used to provide Level 1 data acceptable to the FDA for new medical devices and new indications for approved devices. It is being widely used throughout the government, such as at CDC.

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other disabling symptoms of his injuries. Three years later through his father's intervention he was treated in my private practice in New Orleans with a protocol that I had developed and refined over the previous 20 years in civilian medicine. Seventy other patients with chronic TBI had been successfully treated at that time. After 25 hyperbaric oxygen therapy (HBOT) 1.5 treatments this injured Marine was cognitively and symptomatically improved and his PTSD effectively reversed. Having finished the first half of the protocol (40 treatments), he returned to his hometown and began employment at a pre-arranged job he stated he could never have sustained in his injured state. He subsequently received the second half of the protocol (40 more HBOT 1.5 treatments), received a promotion in his job, and is now living a functional married life two and one half years later. He has declined half of his awarded VA disability; he is paying taxes, and pursuing attainment of a college degree. He, his father (a criminal court judge), and I believe the HBOT 1.5 treatment has restored his potential for a productive life, and his current quality of life, and has saved U.S. taxpayers money. His case is reported in the June, 2009 issue of BioMed Central's Cases Journal as the first successful treatment of blast-induced TBI and PTSD with HBOT 1.5.³

LSU PILOT STUDY ON TBI AND PTSD

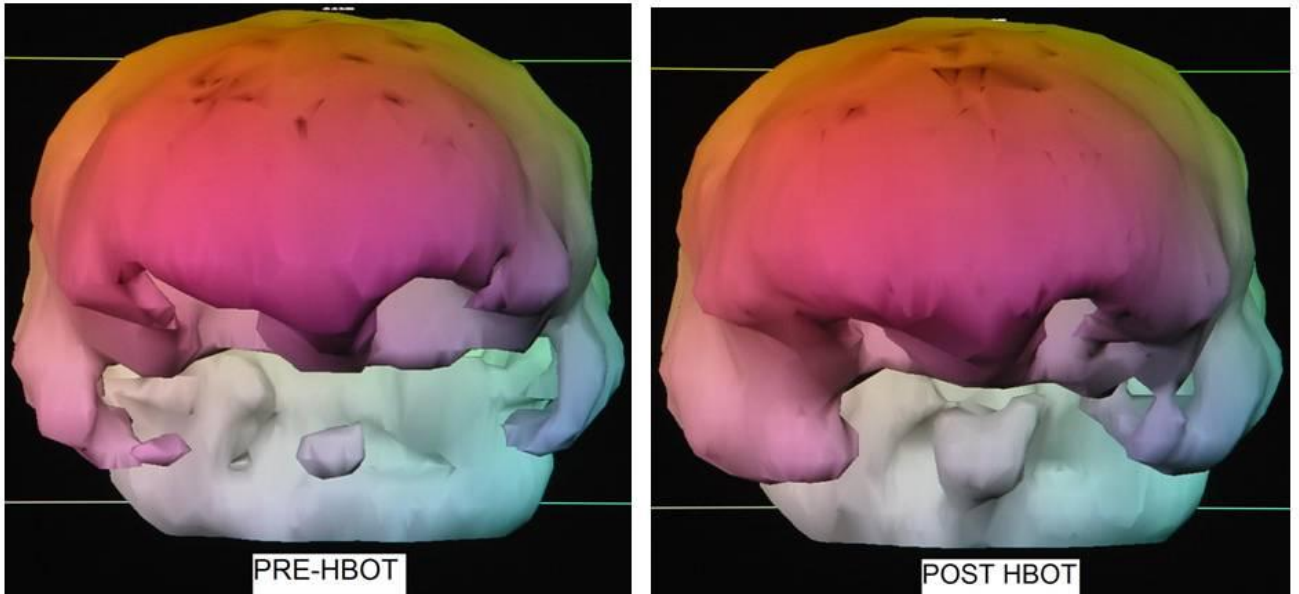
Mr. Chairman, this case report is typical in its description of the injuries and symptoms sustained by estimated thousands of TBI and PTSD-affected Veterans from the current Afghanistan and Iraq Wars. What is highly encouraging is the dramatic improvement in the condition of this young man three years after a brain injury for which modern medicine has no other effective treatments. Fortunately, this Marine is by no means an isolated case. Since his treatment in 2008 over 40 chronic mild, moderate, and severely brain injured U.S. Veterans have

³ Harch PG, Fogarty EF, Staab PK, Van Meter K. Cases J. 2009 Jun 9;2:6538

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**Case Report: Navy SG Meeting - Aug. 2008
25 year old Humvee Machine Gunner**

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



Treated in 2008. PTSD disappeared. From living in a dark room since returning from Iraq, he became gainfully employed, turned down ½ of his disability, worked and made \$39,000 per year, and has returned to college after 2nd 40 treatments.

been successfully treated under my supervision, nearly all of whom had been diagnosed with TBI and PTSD.

Specifically, twenty-eight of these individuals have been treated under an ongoing Demonstration Pilot Protocol approved by the Louisiana State University School of Medicine Institutional Review Board (the Pilot Protocol). Using standard psychometric testing, the enhancements to functional brain imaging, cognitive, symptom, quality of life, and other results on the first 15 Veterans in this study were accepted and reported on 12 March 2010 at the 8th World Congress on Brain Injury in Washington, D.C. On average, these 15 Veterans

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experienced permanent 15 point IQ increases (i.e., roughly the difference between a laborer and an engineer), 40% reduction in post-concussion symptoms, 30% reduction in PTSD, a 51% decrease in depression, and concomitant improvements in memory, attention and concentration. All of these improvements were statistically significant, and, as a practical matter, unequaled by any other known therapy or therapies for TBI/PTSD. To further emphasize the reliability of these results, all of the clinical and imaging effects had earlier been underpinned by improvements in memory and increased blood vessel density in an animal model of chronic traumatic brain injury which tested an earlier but substantially equivalent version of the HBOT 1.5 protocol used in the Pilot Study results reported to the World Congress. This animal improvement, using the human protocol, was the first demonstration of improvement in chronic brain injury in animals in the history of science.⁴

Importantly, and as noted above, these 15 preliminary study subject results from blast-injured war Veterans, were obtained using only the first half of the Harch-Neubauer HBOT 1.5 protocol (40 treatments), instead of the protocol's full 80 treatments. Based on past experience, greater improvements can be expected upon application of the final 40 treatments to TBI/PTSD patients. The other significant objective point is that all of the testing before and after treatment was performed by independent collaborators, a licensed neuropsychologist from LSU School of Medicine, Dr. Susan Andrews, and the chairman of the Department of Radiology from the University of North Dakota School of Medicine, Dr. Edward Fogarty.

Despite a number of LSU grant applications and interest shown by the Congress (including directed funding), no part of this Pilot Trial has been funded by the U.S. Government. Instead, this work was funded by military support organizations such as The Marine Corps Law

⁴ Harch PG, Kriedt C, Van Meter KW, Sutherland RJ. Brain Res. 2007 Oct 12;1174:120-9. Epub 2007 Aug 16.

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Enforcement Foundation, The Marine Corps Semper Fi Fund, The Coalition to Support America's Heroes, Soldier's Angels, Operation Homefront Louisiana, Veterans Airlift Command, private citizens, foundations, and others whose names are listed in the Cases Journal article above.

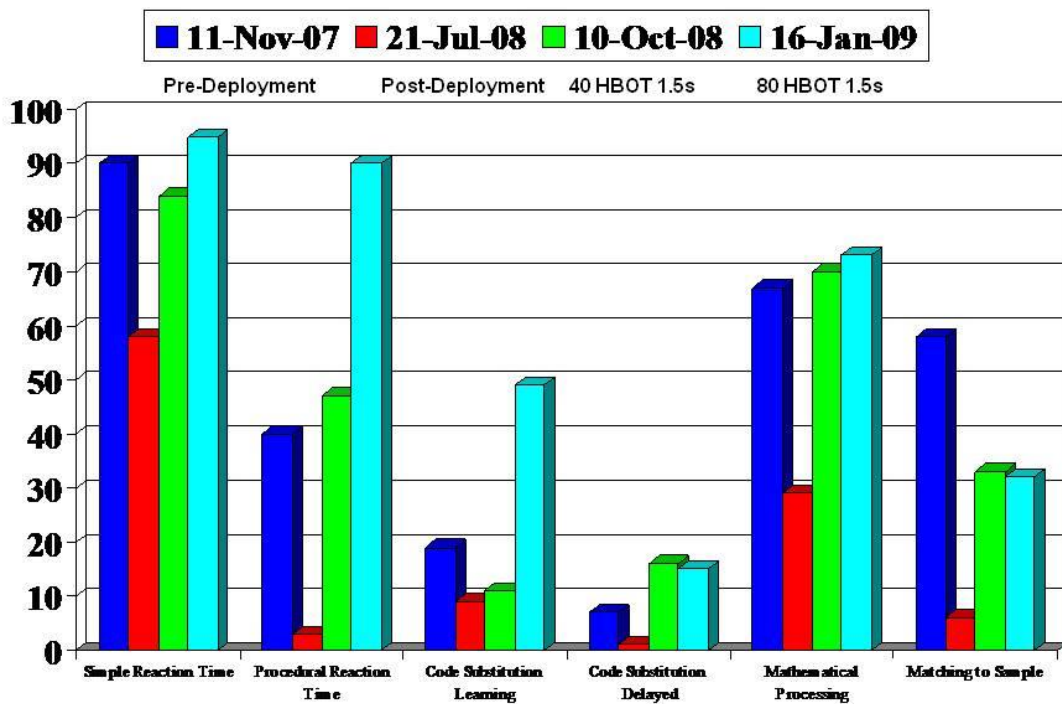
CORROBORATION OF HARCH PROTOCOL RESULTS TO DATE

Mr. Chairman and Committee members, I can assure you with the utmost conviction, sincerity, and integrity that the science I am reporting to you today is not a fluke or statistical aberration. It is innovative, confirmed science performed by many doctors before me, namely the late Dr. Richard Neubauer, and many after me. The HBOT 1.5 protocol was first applied to a blast-injured Soldier of the United States Army, Brigadier General Patt Maney, in 2007 while he was a patient at Walter Reed Army Medical Center. General Maney was diagnosed by the Army with TBI after an IED in Afghanistan rendered him cognitively impaired and non-functional. Available therapy delivered at Walter Reed for nearly a year after his injury achieved only modest improvement. At the request of his family and family friend, hyperbaric physician and professional colleague, Dr. Eddie Zant of Fort Walton Beach, Florida, the HBOT 1.5 protocol and requisite training in its use was delivered in Washington over the next 6 months. Many in the military medical system saw his recovery. General Maney was subsequently retired from the military, but was quickly able to resume his civilian occupation as a State Trial Judge. He has resumed his previous workload and currently is making major contributions to the Veterans Court system for the State of Florida as well as to the current VA Veteran Courts Project.

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Since that time an initiative by James Wright, M.D. (Colonel, USAF, Ret.) former director of Air Force Hyperbaric Medicine Research and its Hyperbaric Medicine Fellowship, made available the HBOT 1.5 protocol treatment for 12 active duty brain injured service members. The HBOT 1.5 protocol has been delivered by Eddie Zant, M.D., to these individuals, and they became "essentially well." These results have duplicated the LSU results with one important difference: all of the active duty personnel have returned to duty with their medical boards – if any - cancelled. Most were redeployable. Many have received promotions since their returns to duty.

Airman B ANAM Percentile Scores



This is DoD's own Neuropsychological Test

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Two of these Airman cases were recently reported in the medical literature by Drs. Wright and Zant.⁵ Drs. Wright and Zant's results made an important contribution to HBOT research: they were able to provide the treatment of these Airmen before the brain injuries were

⁵ Wright JK, Zant E, Groom K, Schlegel RE, Gilliland K. Undersea Hyperb Med. 2009 Nov-Dec;36(6):391-9.

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complicated and deepened by the progressive effects of PTSD (The published results of one Airman's ANAM results are shown below). This was not so in the case of the Veterans I treated: the average patient time from injury to treatment was nearly 3 years. Had my patients been treated sooner following their injuries, most, if not all could have been retained in the service. Instead, they had incurred prior to their HBOT treatment prolonged expensive evaluations, non-treatment, and eventual ineffective, often injurious treatment with psychoactive FDA-black box labeled drugs that are strongly associated with increased suicide rates.

UNDERSTANDING MILD-MODERATE TBI & PTSD

The most apt explanation of the effect of HBOT 1.5 in my markedly delayed treatment cases and Drs. Wright and Zant's early treatment cases lies in an understanding of the simple physiology of "mild" traumatic brain injury and PTSD. "Mild" traumatic brain injury, unfortunately, is a misnomer that correctly describes the degree of injury to brain tissue, but minimizes the profound consequences for the injured Veteran, his/her family, the military, the medical system, and society. In the most common form of mild blast-induced TBI where there is an altered level or a short loss of consciousness; the primary structures damaged are the white matter tracts connecting different areas of the brain. The white matter includes the microscopic "cables" or fibers that transmit messages between the brain cells or neurons. A small, but significant, percentage of these fibers are severed or divided by the shear forces impacting the brain as it is impact-shaken back and forth within the skull. The fibers progressively retract over the subsequent year, leaving the brain with lesser capacity for transmission of information. This is identical to the effect of a reduction in bandwidth when one downgrades computer access from high-speed cable DSL to an 18k telephone modem.

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With less capacity to carry information in the brain, people lose neurological function. They can lose motor, sensory, coordination, balance, vision, hearing and other abilities. Most commonly in "mild" TBI they can no longer multi-task, remember details, handle high stimuli environments, react quickly, and/or effect complex thinking. The brain and its connecting tracts are simply overwhelmed. In the military this translates to decreased capacity for situational awareness, slowed reaction times, decreased attention and concentration, inability to think fast in a complex highly fluid environment (i.e. on the battlefield), decreased ability to fight, and likely injury and possible death. One of my Veteran patients described the result on him of his reduced mental capacity as "thinking with my machinegun."

While the brain's natural healing processes attempt to repair the damage, in fact healing occurs with the formation of scar tissue. The notion that the brain heals itself with no evidence of residual injury has been disproven by modern imaging studies. When injured, all organs respond with the inflammatory process which proceeds to form scars, scar tissue and chronic wounds. The brain is no different. A number of patients can adapt to this wound and compensate, but many do not. Clinical research has shown that under oxygen deprivation stress such as high altitudes, the asymptomatic scar in the brain can again become symptomatic. A Veteran's combat blast-induced injury is different from typical traumatic brain injury when the physical injury is compounded by PTSD, the equivalent of low-oxygen altitude stress. PTSD induces increased mental vigilance, difficulty falling asleep, frequent awakenings due to nightmares, and constant anxiety that results from progressive sleep deprivation and elevation of injurious stress hormones. The sleep deprivation and accompanying high levels of adrenaline become the stress factors that magnify the underlying TBI symptoms. With successive TBI's and worsening PTSD the detrimental effects of both conditions are compounded, possibly

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because the areas injured by both PTSD and TBI have been shown to overlap considerably. These circumstances may explain why many of the Veterans in the LSU Pilot Trial experienced improved recovery from both TBI and PTSD symptoms.

If the initial untreated TBI is not incapacitating, the Soldier may be quickly returned to duty, albeit with a maturing brain wound, slowed reaction time, damaged memory, decreased attention/concentration, sleep disruption, headaches, irritability, and other symptoms. The immediate effect of these deficits in battle is loss of combat effectiveness and increased casualties. If the brain injury is more severe, and/or when the Soldier is returned to the U.S., the Soldier's symptoms and diminished capacity may cause relationship problems, domestic violence, substance abuse, depression, criminal activity, unemployment, incarceration, medical boarding out of the military, and homelessness as the brain's white matter fibers continue to deteriorate, worsening the service member's condition. This deteriorating process is amplified by the adrenaline and other PTSD-inducing stress hormones that also have been shown to cause shrinkage of brain tissue in the temporal lobes, the critical areas of the brain that control memory. Given a lack of understanding of the above process by traditional neurology, the brain-injured Veteran is thrust upon a short-staffed military medicine workforce already hampered by lack of or misinformation on "mild" traumatic brain injury. Delayed diagnosis, misdiagnosis, non-diagnosis and delayed treatment, mistreatment, possible ridicule, and non-treatment beset the Veteran as he is processed through the medical system. With non-confirmation of the physical brain injury by medical authorities the Veteran loses that critical validation of the disease state provided by a credible, authoritative medical specialist. Progressively, the Veteran loses his attachment to the terra firma of diagnosis and he involutes, becomes depressed, and eventually, emotionally and psychologically downward spiral. As his relationships are strained

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and lost the Veteran loses that final support and attachment to terra firma, the spouse or close personal loved one. With no support the Veteran degenerates to substance abuse, violence, homelessness, and incarceration. A final insult in this process is the desperate attempt to treat these diagnoses with the current "standard of care", the off-label psychoactive FDA black-box labeled suicide-inclining medications. Fortunately, there is another choice, HBOT 1.5 therapy, that actually repairs the wounds of explosive devices and PTSD.

HBOT FOR ACUTE AND CHRONIC WOUNDING: APPLICATION TO DIABETIC FOOT WOUNDS AND CHRONIC BRAIN INJURY

To date, the only theory that has been advanced in derogation of the legitimacy of the HBOT 1.5 treatment successes is "placebo effect." A sensitivity analysis performed on the preliminary LSU Demonstration Pilot data showed that 50-75% of the measured effect in these Veterans would have to be due to a placebo effect for the data to lose significance. But over and above this analysis, placebo effect is definitively refuted by the highly significant changes in brain blood flow imaging that have never been associated with a placebo. The bottom line is that the data is significant and the beneficial effect on these Veterans is real and is lasting. The vast majority of those treated have been able to return to duty, work, or school, and virtually all had improved quality of life outcomes.

It is important to realize that HBOT therapy is not new. It is a 74 year old therapy⁶ that has been proven to be the most effective treatment for wounds and whose protocols are under continuous, progressive refinement. The mechanisms of healing with hyperbaric oxygen have recently become better understood. In the past 15 years sophisticated biochemical research has

⁶ Behnke, Albert R; Shaw, Louis A; Messer, Anne C; Thomson, Robert M; Motley, E Preble "The circulatory and respiratory disturbances of acute compressed-air illness and the administration of oxygen as a therapeutic measure". American Journal of Physiology 114 (3): 526-533. <http://ajplegacy.physiology.org/cgi/content/citation/114/3/526> (January 31, 1936).

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shown that the primary action of HBOT is in the DNA of injured cells. Single and repetitive treatment activates genes that code for growth and repair hormones and genes that inhibit inflammation. The net effect is growth of new blood vessels, increase in protein-rich supporting tissue, bone, and skin, and the healing of wounds regardless of location in the body.

As an example, the following slide is a diabetic foot wound before and after HBOT in a patient who was unable to walk for a year. In 2003, thanks to the help of Congressman Istook, the Centers for Medicare and Medicaid Services approved reimbursement for the treatment of diabetic foot wounds, the first new indication for HBOT in 18 years. The decision was based on the application and scientific argument we submitted to CMS on behalf of the International Hyperbaric Medical Association. When applied properly HBOT can prevent 75% of major amputations in diabetics with serious foot wounds. In addition to the enhanced safety and quality of life for each patient this reduction in major amputations is estimated to save Medicare \$348 million/year.

A potential reduction in major amputations has particular significance for this Committee. In 2010 an estimated 3,000 Veterans with diabetes will undergo amputation of one or more feet. The Long Beach, California, and San Antonio, Texas, VA hospitals, according to our information, are the only VA hospitals routinely using HBOT to treat diabetic foot wounds.

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



50 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.

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

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This same ability to salvage would-be amputated extremities also applies to IED injured arms and legs. HBOT is approved by the FDA for crush/blast injury, burns, compartment syndrome, and acute interruption of blood supply in extremities. When applied in a timely fashion wounded Veterans' arms and legs can be salvaged. Unfortunately, that is not happening. Instead, the VA continues to amputate and proceed to prosthetic placement. Last year the VA Appropriations Committee put \$50 million into prosthetics research. As laudable as that is, it does not reduce the amputation rate.

According to the Centers for Disease Control, the cost of amputating a Veteran's diabetic wounded foot is \$38,400. An estimated 3,000 amputations cost \$115.2 million PER YEAR, exclusive of rehabilitation and prosthetic costs which can easily double this figure. An operational 12 person hyperbaric center with chamber costs \$1.3 million. If 75% of the annual VA hospital amputations were prevented with HBOT in one year the savings would pay for the purchase of 66 multi-person hyperbaric centers. Two years worth of savings would equip nearly

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all of the 141 VA hospitals. VA satellite clinics could be equipped with two large single person chambers for less than \$300,000 per center. Both hospital-based and satellite clinic hyperbaric departments would be able to treat not only the wounds predisposed to amputations, but also all of the additional acute and chronic conditions amenable to HBOT. The health benefits to Veterans and cost savings to the Veterans Administration would be substantial.

The application of HBOT to acute and chronic wounds such as diabetic foot wounds has been extended and refined with its application to acute and chronic brain wounds through a reduction in dose. Based on the similarities in disease processes of acute and chronic extremity wounds and acute and chronic brain wounds American and international researchers in the past 40 years have made significant progress. An important LSU contribution to this refinement was the discovery in the 1980s in New Orleans that we were not treating nitrogen bubbles in the brains of our divers with decompression sickness. In fact, we were treating the damage to the brain caused by the bubbles. In treating divers from the 90-mile-distant Gulf of Mexico who had belatedly reached our hyperbaric unit, the bubbles had long since passed and we were treating the residual damage from bubble passage, i.e., tiny strokes. As we treated divers with greater and greater delays to their treatment we realized we were treating chronic brain injury. Soon we treated boxers, patients with earlier strokes, traumatic brain injuries, carbon monoxide poisoned patients, children with cerebral palsy, autism, and other chronic brain injuries. It proved gratifying that the majority of them improved as we treated their chronic brain wounds. The surprise in the application of this maturing therapy to U.S. Veterans with blast-induced brain injury was that the accompanying PTSD responded favorably as well.

My message today is that an innovative effective treatment to biologically repair brain injury is available to help this committee and the VA favorably resolve the futures of America's

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TBI/PTSD war Veterans. The facts are that hyperbaric oxygen therapy is the only non-hormonal treatment approved by the FDA for biologically repairing and regenerating human tissue. It is approved and effective for the treatment of non-healing wounds elsewhere in the human body, and is currently FDA-approved as the primary treatment for three different brain injuries: carbon monoxide poisoning, arterial gas embolism, and cerebral decompression sickness.

Hyperbaric oxygen therapy is poised to help the nation with the thousands of battle casualties still on duty and throughout our society. There are 1,000 hyperbaric centers in all parts of the nation. Our experienced team of physicians has learned a great deal about brain injury and its treatment with HBOT 1.5; we have requested meetings and look forward to discussing HBOT 1.5 with the appropriate VA leadership.

IMPLICATIONS OF FURTHER DELAYS TO TREATMENT OF TBI AND PTSD

Since we briefed HBOT 1.5 to the Navy Surgeon General on August 14, 2008, an estimated 120 Veterans per week or more than 10,000 overall have committed suicide, according to CDC numbers investigated by CBS News. As this committee heard earlier this year, many of these suicides are related to the use of FDA Black-box labeled drugs. These drugs carry specific warnings about increased suicide rates in patients under 25 years old, the age group identified with the highest suicide rate by the recent NPR/ProPublica News series.

Nearly all of these medications are prescribed **off-label** by Military Medicine and Veterans Administration physicians as standard of care for blast-induced TBI and PTSD despite little or no research to support this prescribing. While we realize that they are prescribed in desperation, there is a tested, clear-cut alternative, HBOT 1.5. In May, 2009 I provided similar written testimony to the House Armed Services committee calling attention to the contribution of these drugs to the Veteran suicide epidemic. My testimony was intended to question the

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Secretary of Defense's response to Congressman Walter Jones that hyperbaric medicine was precluded from DoD use because it was "off-label" and they never prescribe off-label.⁷ In fact nearly all of the medications prescribed for TBI and PTSD are off-label and are black-box labeled regarding increased risk of suicidality. In contrast, **hyperbaric oxygen therapy is on-label for treating non-healing wounds, acutely and chronically, and for treating three types of brain injury.** It also has fewer side effects, having been deemed safe by the DoD even prior to the DoD Consensus Conference on HBOT in TBI of December 5-6, 2008.

We know that in wound-healing, delay to treatment matters most. This is time-honored, proven and axiomatic in medicine. Active duty personnel treated with HBOT within a year after injury, have returned to duty, had their medical boards cancelled, and became redeployable. The federal government saves an estimated \$2.6 million for each war Veteran who has returned to duty, considering the training, replacement costs, and lifetime disability benefits that would otherwise have been paid had they been medically retired. This also includes lost tax revenue that would otherwise be paid by disabled Veterans. What is not factored in is the loss to the service of unit cohesion, the irreplaceable years of combat experience, loss of productivity in the economy when these Veterans return to the workforce post-military, and the unquantifiable misery and personal loss they experience as a result of their injuries.

In addition, Dr. Wright's and Dr. Zant's active duty personnel treated with the HBOT 1.5 protocol have not had family problems, long term prescription drug use or substance abuse, psychiatric problems, unemployment, homelessness, or incarceration. Their treatment course was relatively uneventful because they still had a support structure around them. The utter

⁷ Not an FDA-approved indication on the indication list of a drug or a device. Twenty-five percent of all drugs and devices are used off-label, about 80% of pediatric prescriptions, and a higher percentage of psychiatric prescriptions.

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discouragement in patients seen after two years of ineffective treatment with psychoactive drugs and counseling is heart-rending. There are over 300,000 "discouraged workers" who are Veterans of this war. Unemployment in this Veteran population is higher than for their non-Veteran counterparts, which is inconsistent with historical statistics. Their families are dissolving, they are unable to support themselves, and according to the State of California, a lot of them end up in jail. Fully 10% of the California jail population is Veterans, and most are combat Veterans from this war.

Taking this immediacy of treatment principle a step further we believe that battle casualties should and must be treated with HBOT in theater in the combat zone after a blast, just like the navies of the world do immediately post-injury for divers. Dr. Wright did a presentation to NATO medicine in 2000.⁸ We so advised Military Medicine in 2005 through our "HBOT at the Forward Edge of Battle" project. Treatment at this early point in the injury process requires a minimum number of HBOT treatments. Adoption of immediate treatment with HBOT 1.5 will likely have a high recovery rate of blast-induced brain injury, improve readiness and retention, and greatly reduce the numbers of Veterans who will need compensation by the VA.

Regardless of time to treatment, however, these brain-injured Veterans can be helped. HBOT 1.5 is effective even years after an injury takes place. It may not restore the Veterans' lives as fully as if they were treated within weeks or months, but the treatment is effective and extremely cost effective. The RAND Report indicates currently accepted treatment protocols cost \$32,000 per year for a mild-TBI patient. The cost of 80 HBOT 1.5 treatments is

⁸ "The Relevance of Hyperbaric Oxygen to Combat Medicine." James K. Wright, Col, MC, FS, USAF School of Aerospace Medicine/FEH, NATO Medical Conference Presentation, 2000.

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approximately \$16,000 at CMS rates for hyperbaric treatment in an out-patient clinic. It would be dramatically less expensive in DoD or VA facilities.

THE SOLUTION

Mr. Chairman, these brain-injured suffering Veterans, their families, and society cannot wait another 3-5 years for large randomized trials to be performed, as DoD has proposed and VA acquiesced. As next steps, the International Hyperbaric Medical Foundation has an active study, recruiting and registered at www.clinicaltrials.gov. It uses modern Bayesian Adaptive Trial Design and Statistical Methodology as a complementary approach to the multi-year DoD studies. The FDA favors Bayesian methodology for its speed, flexibility, transparency and cost effectiveness. The Western Institutional Review Board (WIRB) has approved our study based on this methodology. All subjects receive HBOT 1.5 in our design. Statistical analysis applying Bayesian Methodology calculates the effectiveness of HBOT 1.5 by progressively incorporating the results of each Veteran's treatment. In all respects, the proposed study captures the traditional practice of experienced physicians who learn from every patient. The treatment result of each case informs the physician about the likelihood of the next case responding to the same treatment. Each successive case contributes to the statistical likelihood of the success or failure of a therapy. Because of the power of this statistical methodology, determining end results is achieved with as few as 50-100 patients. The FDA has approved clinical trials of cancer treatment using Bayesian Methodology, leading to improved standards of care. Bayesian Methodology can also be used to quickly assess technologies, such as quantitative electroencephalography (qEEG), that have shown promise in the diagnosis and monitoring of TBI and other brain conditions.

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To enable the Study described above, the Hyperbaric Medical Foundation has an approved National Network of qualified Centers that will incorporate the innovative computational capabilities to process the patient data collected from the Centers and analyze them in conformance with approved Bayesian methodologies. Completion of the Study could be accomplished in months rather than the years required by conventional Clinical Trial process. In discussions with VA R&D leadership, their stated experience and confidence in Bayesian Methodology and in FDA acceptance thereof was truly encouraging to the future of the above NBIRR study network and its potential for rapid civil/government progress in HBOT 1.5 research and evaluation.

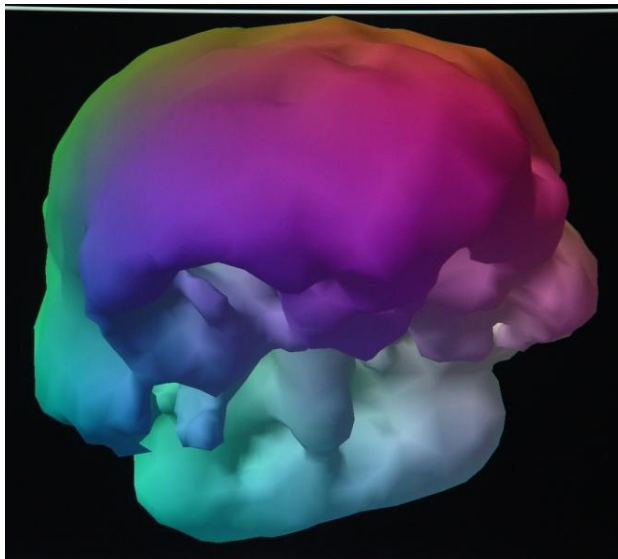
The IHMF's NBIRR study depends on consistent reimbursement for effective treatment, initially for TBI/PTSD participants from private, State and Federal sources. Section 727 of the House Defense Authorization Bill (HR 5136) would enact into law the provisions of HR4568 which requires Federal reimbursement for treatment that actually works to improve military TBI/PTSD cases, using objective measures and conducted using all of the required patient-protection safeguards.

THE DEPTH OF THE PROBLEM AND THE POWER OF THE SOLUTION

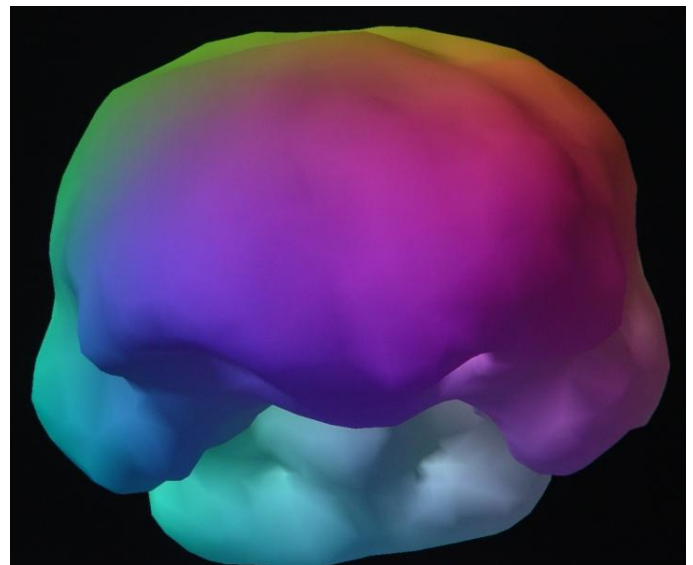
The depth and breadth of the problem faced in brain injured and PTSD afflicted Veterans along with the power of HBOT 1.5 to correct/ameliorate the consequences of these injuries is best embodied in a final case report. Mr. Rusty Ouart was a 45 year old happily married father from North Dakota. He decided that the opportunity a free America had provided him was threatened by the terrorist attacks on 9/11/2001 and should be defended through his service in our Armed Forces. He joined the Army National Guard, became fit for duty, was nominated for Soldier of the Year Award, and deployed to Iraq where he was rendered unconscious by an

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improvised explosive device. Brain injured and unable to function he was returned to the United States where his unwitnessed injury was evaluated by Military Medicine. The psychiatrist, perhaps overwhelmed by the volume of brain injured and PTSD afflicted veterans and lacking witnesses and medical records, diagnosed Mr. Quart with a conversion disorder. A conversion disorder is an unconscious physical manifestation of psychiatric conflict/stress. In other words, Mr. Quart was told that his cognitive and physical deficits were imaginary, or all in his head. In truth, they **were** all in his head because they were due to the blast-induced traumatic brain injury he suffered from the IED.



Before Hyperbaric Treatment



After Hyperbaric Treatment

A year after his injury with his Army diagnosis endorsed by the VA, I evaluated him in New Orleans. A simple X-ray of his left arm found 16 pieces of shrapnel, thus documenting the exposure to the blast. Treated in the LSU Pilot study mentioned above, after one month he had improved symptomatically and cognitively, and experienced a significant improvement reflected in functional brain imaging. In these slides the three-dimensional reconstruction of his brain blood flow scan before treatment shows a brain devastated by the left-sided blast and

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inconsistent with a conversion disorder. After one month of treatment the brain scan shows a remarkable improvement in blood flow consistent with his cognitive and symptom improvements and the causal healing brain metabolism. The evidence provided by this imaging and his cognitive testing has succeeded in reversing the VA endorsement of the conversion disorder misdiagnosis. His case is now under re-evaluation by the Army.

While shocking, this story may not be unusual. According to the Rand Report there are tens of thousands of Veterans with brain injuries similar to my patient. They are not "draftees" who are attempting to avoid duty. They are not trying to defraud the government for benefits because unpopular wars disrupted their lives. I have interviewed scores of them. They are some of America's best and brightest. They were star quarterbacks, captains of wrestling teams, college graduates, privates, corporals, sergeants, officers, special forces members, all with outstanding and expensive skill sets. They have proven their bravery on the battlefield in defense of this country. Yet they cannot obtain this life- and quality-of-life-saving hyperbaric therapy that has been healing non-healing wounds in the body for 74 years. They are subjected to ridicule, prescribed medications that may cause them to commit suicide, become addicted to prescription pain medications, are threatened with disciplinary action when they refuse to take these medications because of their side effects or dissociative feelings, and apparently not unusually, given less than dishonorable discharges for behavioral consequences directly attributable to their injuries.

The study we have organized and the treatment's successes to date are the only hope these men and women have for getting the recovery they need. There is no patent on oxygen, or this protocol. I do not own my own clinic or hyperbaric chambers. Hyperbaric chambers are made by pressure-vessel machine shops throughout the nation, none of whom have a contractual

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relationship with me. There is no monopoly profit in this specialty of medicine. The principle reward has been the satisfaction of seeing fellow citizens restored to bright futures and seeing the improvement to the practice of medicine.

The primary beneficiary of this therapy is the brain and extremity-injured U.S. Veteran. The secondary beneficiaries of this therapy are the American people who are spared the consequences of these improperly or non-treated injuries in the military or civilian sectors. The American taxpayer benefits from the fiscal savings to our government. The savings are both tangible and intangible. The tangible monetary savings are billions of dollars in reduced education costs, incarceration costs, disability payments, Veterans benefits, Social Security, and welfare payments. This is accompanied by increased productivity as injured Veterans return to the workplace. They are able to recoup the 50% lost lifetime income from their TBI and in the process pay local, state, and federal taxes. The intangible savings are human, the improved quality of life for the Veterans and the downstream ripple effect this has on all of their relationships and society.

The International Hyperbaric Medical Foundation, in which I serve as President, has the solution to these problems with the NBIRR HBOT 1.5 multi-center Bayesian study. The single impediment to the conduct of this study and treatment with HBOT 1.5 is reimbursement for treatment. Section 727 of the House Armed Services Committee bill, HR 5136, pending in Conference with the Senate (HR4568) provides reimbursement for all kinds of treatment that works, and will enable physicians to treat Veterans with TBI and/or PTSD. It is based on proof of effect. It applies to numerous therapies that have been found to improve measurable outcomes for patients with TBI or PTSD. Reimbursement will only be provided if the treatment is delivered under an IRB-approved protocol, like the IHMF WIRB-approved nationwide study,

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and is effective in the individual Veteran. This study will not only treat the injured Veterans, but will simultaneously rapidly provide the scientific proof that is so important for physicians to institute the studied treatment as standard of care throughout the U.S.

SUMMARY

Blast induced Traumatic Brain Injury (TBI) is a physical injury to the brain. The injury and its progressive physical effects can be seen on electronic imaging of the brain. Recovery from treatment can also be seen and tracked electronically as beneficial treatment is administered and the brain recovers. Behavioral and mental symptoms from this injury are themselves erosive of normal human behavior and performance, notably in a military setting. These include headaches, loss of short-term memory, loss of impulse control, depression, sleep disorders, anxiety and other mood changes, and loss of energy.

Post Traumatic Stress Disorder (PTSD) often accompanies TBI. It results from the psychic shocks of unusual, deeply disturbing experiences outside the normal ken or experience of its victims. These occurrences – the witnessed deaths of friends and comrades, other shocking injury and destruction to humans and human life, fear for one’s own safety and related wartime battlefield dangers and experiences – impose an injury that may be independent of TBI. When they occur together, however, the impact of PTSD on brain function is progressive if untreated, and can compound the injuries caused by the physical TBI. Several PTSD symptoms overlap with those of TBI, making separation and separate diagnosis of the two difficult.

Hyperbaric Oxygen Therapy (HBOT) is the use of greater than atmospheric pressure oxygen, under pressure, as a drug, to treat disease processes and their diseases. A pressure chamber (sometimes called a “decompression chamber”) is commonly used for the

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administration of HBOT and can accommodate a range of atmospheric pressures or doses. This therapy has been long used by the Navy at various doses to treat decompression sickness incurred in the course of underwater diving. The Air Force also uses HBOT to recover individuals from injuries caused by sudden decompression from loss of cabin pressure in aircraft.

The effect of oxygen under pressure is to dramatically increase the amount of healing oxygen available to wounds and injuries in the human body and in the human brain. Repetitive delivery of HBOT causes elaboration of hormones that stimulate growth and repair of injured tissue. The result is healing of both acute and chronic wounds regardless of location in the body.

LSU research and experience has found HBOT at 1.5 atmospheres to be the most effective pressure for the conduct of successful acute and chronic TBI therapy. A number of civilian-incurred brain injuries have been successfully treated by HBOT, such as traumatic brain injury, stroke, cerebral palsy, and autism. What has emerged is a protocol calling for 80 hour-long HBOT treatments over a period of 120 days (the "standard NBIRR TBI/PTSD protocol"). These developments, it should be underscored, have occurred against a known background of oxygen's effective healing capacities as they apply to the human body, many reflected in 13 applications approved by the FDA, and practiced by over a thousand clinics across the U.S.

HBOT is hardly new, but it is being improved and furthered in its reach and in its known benefits. Its application to militarily incurred TBI/PTSD is certainly a leading example. To that end, LSU has been conducting continued research on the treatment of battlefield brain injury. Most recently this has been through a privately funded demonstration Pilot Trial (LSU IRB #7051) of application of 40 hours of HBOT 1.5 to 30 TBI/PTSD Military wounded (the "Pilot TBI/PTSD Protocol). Apparently a parallel set of 12 cases have been treated by the Air Force in

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Florida with this same protocol for HBOT 1.5 that has achieved similar, beneficial restorative results.

This HBOT 1.5 protocol has been incorporated into a national multi-center observational study, sponsored by the International Hyperbaric Medical Foundation, under the National Brain Injury Rescue and Rehabilitation Project (NBIRR). The first study, NBIRR-01, "Mild-Moderate traumatic brain injury or post-traumatic stress disorder" has been approved by Western IRB (WIRB(r) Protocol #20090761, and is registered at www.ClinicalTrials.gov. It is recruiting patients at sites across the nation that have been approved by the Western IRB. The study uses Bayesian Statistical Methodology. This allows all study participants to receive the HBOT 1.5 protocol and permits rapid scientific proofing of HBOT 1.5's effectiveness. VA patients throughout the United States can voluntarily participate in this study.

We thank the Members and staff of the Committee for their continuing strong support of the Nation's Veterans. We appreciate the opportunity afforded by the Committee to provide information on HBOT 1.5, and we look forward to your questions.