Testimony for the Record: Effective Treatment Exists for Mild-Moderate TBI & PTSD

Carl Levin, Chairman
John McCain, Ranking Minority Member
Senate Armed Services Committee
United States Senate
Washington, D.C. 20510

Ike Skelton, Chairman
Howard "Buck" McKeon, Ranking Member
House Armed Services Committee
United States House of Representatives
Washington, D.C. 20515

TESTIMONY FOR THE RECORD: Suicides in U.S. Military Personnel, Veterans of the War in Iraq and Afghanistan, and the Core Medical Treatment for Mild-Moderate Traumatic Brain Injury & PTSD

Dear Chairman Levin & Skelton & Ranking Members McCain & McKeon: June 22, 2010

Imagine the hope that would be engendered in battle casualties across America if they knew there were effective treatments for brain injury or post-traumatic stress disorder. They would be less likely to commit suicide if they understood there was hope. There are effective treatments for TBI, PTSD and depression.

This letter is sent in earnest to reiterate, reinforce, and refresh for the Committees a message I sent to the House and Senate Armed Services committees on May 15, 2009, suggesting to the Committees that a further major contribution to the suicide epidemic in veterans was likely the "off-label" use of prescription drugs, especially antidepressants, that carry Black-Box warnings from the FDA. My concern was echoed on February 24, 2010 when the House Veterans Affairs committee heard this same testimony from others in "Exploring the Relationship Between Medication and Veteran Suicide.[i]" **The actual FDA warning reads, "Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of (*insert name of antidepressant*) or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24…"** The age group described by this warning includes a significant number of our brain-injured veterans.

While these Black-box labeled drugs have been prescribed off-label in abundance for our veterans, there has been a simultaneous refusal by military medicine to use a safe drug, "oxygen," off-label at hyperbaric doses. This refusal occurs despite outstanding success of high dose oxygen for the last 20 years in treating many neurological conditions, including acute severe traumatic brain injury. Senator Vitter, a member of this committee and my Senator and former Congressman, introduced me in March 2002 to the Labor-HHS-Education appropriations subcommittee where I first told Congress about the ability of oxygen to heal brain injuries. Brain injury remains the single most expensive public health condition, affecting education, incarceration, welfare, individual productivity and tax revenue. Thus federal and state governments are the biggest beneficiaries of the adoption of this treatment for brain injury. The IHMA first told DoD Medicine about this discovery in 2002.

Instead of having these discoveries embraced, there have been direct actions against the conduct of scientific research on this well understood and valid medical treatment. This non-patentable treatment, hyperbaric oxygen therapy (HBOT), is FDA-approved for other neurological diagnoses, and has been shown to reduce the major amputation rate by 75% in diabetic patients with foot wounds. Since the IHMA submitted diabetic foot wound for a National Coverage Determination, and won approval by Medicare in 2003, hyperbaric oxygen therapy has saved the legs of countless diabetic patients. Medicare found that treatment is cheaper than amputation and is estimated

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to save over $300 million per year. If hyperbaric oxygen were used to treat brain injury in our society, the savings would be tens of billions per year in current federal and state programmatic costs. In addition, improved individual productivity and increased tax revenue would result.

Preliminary application of this same therapy to our brain injured veterans has returned nearly 80% of these veterans to work, duty or school with a life-time savings to the government of $2.6 million dollars for each active duty member returned to duty, and $2 million for each injured service member returned to work or school. Post-concussion syndrome, PTSD and depression has been shown to decrease by 40%, 30% and 51% respectively, thus greatly reducing the need for mental health services in these casualties. These life-time benefits and savings more than justify the costs of treatment. Expansion of this off-label treatment to the estimated hundreds of thousands of brain-injured veterans would result in a dramatic improvement in health, reduction in costs, and retention of highly trained and redeployable men and women in our military.

The off-label psychoactive drugs, on the other hand, have not been effective at returning casualties to duty. They are prescribed in large numbers, without adequate understanding of their effects, side-effects, or the effects of the combination of these drugs on patients with blast-induced traumatic brain injury and PTSD. Many of the veterans I have successfully treated with hyperbaric oxygen are prescribed multiple psychoactive drugs off-label. These include anti-depressants and atypical antipsychotics, both of which are black-box labeled, as well as the anti-convulsants, which have been recently revealed to have an increased risk for suicide. The majority of these patients describe bizarre feelings, "zombie-like" sensations, and increasing depression after dosing their medication. After hyperbaric oxygen therapy nearly half of them have decreased or discontinued their medications. In combination with hyperbaric oxygen therapy this resulted in a substantial improvement in their symptoms and a reduction in medication costs. This committee has expressed great concern to military medicine about the cost of prescription drugs.

James Wright, M.D. (COL, USAF, Ret), a former member of SOCOM medicine, former director of the Brooks City Air Force hyperbaric and aerospace medicine fellowship, and former director of hyperbaric medicine research for the Air Force, attended many briefings prior to his retirement that urged him out of necessity to prescribe off-label black-box labeled psychoactive medications for his brain injured airmen. Despite lack of evidence, it appeared to be the only option at the time. For Dr. Wright, it was pretty clear, "Young men don't have headaches." So, "If a young man had been blown up, and was having headaches, he must have a traumatic brain injury." Fortunately, there is another option for Dr. Wright and other military physicians; hyperbaric oxygen therapy. Its time is long overdue. With an estimated 600,000 war veterans who have suffered injury the time for effective treatment of TBI and PTSD is now. Your committee has heard about hyperbaric medicine from the American Legion this year, and the Commandant of the Marine Corps has testified about the importance of this treatment for his Marines on many occasions. The Marine Corp Law Enforcement Foundation and Semper Fi Fund provided money for the research results I reported earlier this year. We are very grateful to the Marines for advancing the science of combat casualty treatment.

Following my formal presentation and testimony to the Surgeon General of the Navy (Admiral Robinson) and Assistant Commandant of the Marine Corps (General Amos), military medical experts, dignitaries and three of my recently HBOT treated brain injured veterans on August 14, 2008 at BUMED, Dr. Wright decided to try hyperbaric oxygen therapy on two active duty airmen under his care. The result was a reversal of their symptoms, healing of their brain injuries, cancellation of their medical boards, retention in the service, and subsequent promotions. Their pre and post-deployment ANAM test scores, and their ANAM test scores following 40 and 80 hyperbaric treatments, accurately demonstrated their level of injury and their level of recovery. Twelve active duty personnel have been treated under Dr. Wright's care. He reports that all have been retained in the service and most were redeployable. These outcomes differ substantially from the 30 Marines who languished in the Wounded Warrior barracks in September 2008 when our proposed HBOT treatment was blocked by Navy medicine. The

consequences of military medicine's delay are tragic. Instead of quickly moving to verify the results presented, it is estimated that over 10,000 veterans have committed suicide since the date of that BUMED presentation. (Suicide rate numbers provided by CBS News investigate reports-17 per day on average among veterans, with 20-24 year olds between 2 and 4 times the rate of their non-veteran peers).[1]

The successful treatment of three of these veterans has been published in peer reviewed journals by myself and Dr. Wright. After Tricare refused to pay the $24,000 medical bill for the two airmen, the House introduced HR 7299 in the last Congress. It has become HR 4568 in the present Congress. It is endorsed by the House Brain Injury Caucus. This sensible legislation requires the DoD and VA medical establishments to pay civilian health care providers for treatment for traumatic brain injury or post-traumatic stress disorder whenever those treatments are successful. That included the great work done by the International Brain Research Foundation. Their research awakened 84% of coma patients; a $2,000 per day savings in the costs of care. (To date military medicine has refused to release the member project funds Chairman Murtha provided in 2008 for the IBRF and has refused to release the 2008 funds to LSU for our hyperbaric research program.) Under HR 4568, all data from those treatments must be collected under IRB-approved protocols so that we can advance science while offering treatment. This is similar to the CMS "Coverage with Evidence" program. Weeks ago, the House of Representatives added HR 4568, the TBI Treatment Act, to the House Armed Services bill on the Floor. We hope that you will positively add this same amendment to the Senate Armed Services bill, or recede to the House on this provision during conference.

Our dilemma is that Tricare and the VA will not reimburse for HBOT because HBOT is not FDA-approved for brain injury, even though they pay for hyperbaric medicine for other kinds of non-healing wounds. While it is true that HBOT is not FDA-approved for brain injury, this does not tell the whole story. **In fact NONE of the drugs currently used and paid for by Tricare and the VA to treat our brain injured veterans are FDA-approved to treat TBI.** As the attached chart shows, only two, Paxil and Zoloft, are approved to treat PTSD. Both of these and nearly all of the anti-depressants carry FDA Black Box warnings urging caution in 17-24 year olds because of the increased risk of suicide. Additionally, a 1/31/2008 FDA Alert informed the medical community of the increased suicide risk of nearly all of the currently prescribed anti-epileptic drugs. Many of these drugs are prescribed off-label to our veterans with TBI and PTSD. Due to dysphoria and depressive feelings caused by a number of these drugs some of my military patients have refused to take these medications or refill their prescriptions. This has resulted in threats of UCMJ action.

Gen. Peter Chiarelli, the Army's vice chief of staff, told NPR that the military took traumatic brain injuries "extremely seriously." Chiarelli, who has worked to raise awareness about the severity of so-called invisible wounds such as mild traumatic brain injury and PTSD, said medical officials must diagnose and treat a complicated mix of illnesses. "It's time we realize that TBI and PTSD are real injuries," Chiarelli told "Talk of the Nation" host Neal Conan on June 9, 2010. "We've got to ensure our soldiers get the care that they need."

Despite General Chiarelli's and General Conway's and General Amos' diligent efforts to increase awareness and ensure access to care, the ineffectiveness of current military medicine and VA treatment for these battle casualties is having a devastating effect on our injured veterans and society. Now, nine years into the war, there are an estimated 154,000 homeless war veterans, a rising percent of our jail population is comprised of recent veterans, and the all volunteer Army is strained by readiness and retention challenges. Families are devastated by unemployment, domestic violence, divorce, substance abuse, and suicides. In many cases the dysfunction of these veterans is seemingly inexplicable due to the failure to diagnose and treat early. This scenario is remarkably similar to the legacy of Vietnam veterans.

[1] Keteyian, Armen; " Suicide Epidemic Among Veterans: A CBS News Investigation Uncovers A Suicide Rate For Veterans Twice That Of Other Americans, NEW YORK, Nov. 13, 2007
http://www.cbsnews.com/stories/2007/11/13/cbsnews_investigates/main3496471.shtml

As a clinical and academic physician who is integrally involved with the treatment of members of the pan-military epidemic of U.S. servicemen afflicted with traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), and depression I feel compelled to offer information that may contribute to the solution of these vexing problems. In-depth interviews, detailed physical examinations, and HBOT treatment of nearly 40 of these veterans exposed to concussive blasts has revealed significant abnormalities in those patients with loss of consciousness. These abnormalities have been supported by psychological evaluations, cognitive testing, and functional brain imaging abnormalities that are consistent with the diagnoses of "TBI" and "PTSD" bestowed by military evaluators.

Our efforts continue to reaffirm the biological nature of blast-induced brain injuries incurred by coalition forces in Iraq and Afghanistan. In the last 40 years scientific research has documented loss of brain tissue in individuals who have experienced traumatic loss of consciousness from mild-moderate TBI. While the majority of these individuals "recover" from their injury they are not "normal." There is a true "signature" of the injury that remains in the brain and which can be elicited by stress conditions.

Fortunately, scientific evidence at multiple centers suggests that these TBI war casualties respond to a low pressure protocol (HBOT 1.5) of hyperbaric oxygen therapy. This treatment uses oxygen as an FDA-approved drug that is known to be a non-specific biological repair therapy for acute and chronic wounds. No wound can heal without oxygen, and oxygen CAN NEVER BE A PLACEBO. Oxygen is used directly or indirectly in nearly all cellular processes and when elevated to hyperbaric doses oxygen has been documented to have the added benefit of activating DNA to transcribe growth and repair hormones. Congruent with past reports in the medical literature, where the same or a similar protocol has been given to patients with chronic post-concussion syndrome from TBI of non-blast causes, these veterans are showing improvement with HBOT 1.5. This response supports the argument that there is a biological injury/scar in the brain from blast-induced TBI that is defined by loss of consciousness.

HBOT is the only non-hormonal FDA-approved treatment known to repair and regenerate human tissue. HBOT repairs and regenerates tissue by two oxygen-dependent processes, the activation of growth factors at a DNA level and the improvement of blood supply to wounds. These salutary effects of hyperbaric oxygen apply in a variety of FDA-approved indications such as the acute wounds of traumatic loss of blood supply, traumatic hemorrhage, crush injury, and a number of neurological injuries. These effects also apply in FDA-approved conditions with chronic wounds such as diabetic foot wounds, radiation wounds, and chronic bone infections. The salutary effects of HBOT apply regardless of the location of the wounds in the body. As a result, HBOT can be considered a generic drug for repair of acute and chronic wounds in the body.

Since 2003, numerous peer-reviewed articles have been published that demonstrate hyperbaric oxygen treatment is effective at repairing the injured brain, even years after injury. The most recent report in blast injured veterans was presented 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 ($p<0.001$) (the difference between a high school graduate and an engineer), 40% reduction in post-concussion symptoms [$p=0.002$ (np)], 30% reduction in PTSD symptoms ($p<0.001$), and a 51% decrease in depression ($p<0.001$).** The magnitude of these changes was striking, not previously seen with any other therapy for our veterans, yet consistent with past published reports of HBOT in chronic brain injury, including research by the military on brain-injured children. These results were accompanied by functional brain imaging that showed an improvement in brain blood flow. The fact that statistically significant results were reported with only 15 patients

was remarkable. More importantly, these preliminary study results were measured by an independent licensed neuropsychologist and a radiologist and were consistent with treatment results from the other 13 FDA-approved HBOT indications.

Fortunately, we have a cost-effective solution to the current lack of effective treatment for veterans with TBI that may also impact their PTSD and suicide epidemic. As an alternative to the use of FDA Black Box labeled drugs I would like to suggest the immediate approval of HR 4568, "the TBI Treatment Act," with an expansion of the $10 million for which the pilot is currently approved. The International Hyperbaric Medical Foundation through its National Brain Injury Rescue and Rehabilitation Project (N-BIRR) has a national IRB-approved study that is poised to treat 1,000 veterans at 14 sites, with more sites joining each month. The only impediment to activation at existing sites and expansion of HBOT 1.5 at more treatment centers is reimbursement for those who show a positive response to treatment.

Costs must be taken into consideration. If hyperbaric oxygen therapy were charged at the average CMS-set civilian rate of $200 per treatment, the cost per casualty would be $16,000. If the military treated these members themselves, it would cost a maximum of $50 per treatment ($35 labor and $15 for oxygen) or $4,000 per casualty. Compare these costs to the cost of getting a new E-1 to join the service ($20,000), to get that E-1 through the lowest-cost basic training and advanced course ($155,000), the value of an NCO ($500,000), the value of an officer ($750,000), a SOCOM member or pilot ($5 million), and the cost savings from biologically repairing an injured veteran become pretty clear. According to the RAND report, the annual ongoing costs per year of the current treatments for mild-TBI is about $32,000. A one-time cost between $4,000 and $16,000 is much less expensive than current practices.[2]

In addition to the application of HBOT 1.5 for chronic brain injury we would like to advocate for HBOT 1.5 in acute severe traumatic brain injury. A few HBOT 1.5 treatments within hours of injury, can change military casualty care immensely. Acute treatment in severely brain-injured patients, for example, has been shown in multiple randomized trials to decrease mortality by 59%, the largest reduction in mortality since the invention of the ambulance, the use of helicopters in Vietnam for battle casualties, and penicillin for infection.

Due to medical politics, physicians ignored this science and prevented the adoption of HBOT 1.5 in June, 2001, three months before 9/11 initiated the battle casualties that continue today. Because of his personal experience with HBOT 1.5, I would like to recommend to the Committee that Colonel Virgil Deal, M.D., the Surgeon General for SOCOM, should be put in command of a team that would bring this treatment to the battlefield as quickly as possible. His position is independent of the Surgeon Generals of the other branches of the military. Military commanders sent a 10-liner and have asked for hyperbaric equipment and treatment in the field. That request was rejected by military medicine because military medicine repeats the myth and mantra that there is no evidence for HBOT. The British, the Russians, the Serbs and the Israelis have all successfully applied hyperbaric medicine to combat causalities. In 2009, we proposed to Chairman Murtha the same treatment for our Afghanistan casualties with the High Altitude Mortality Reduction (HAMR) program. We believe the time has come to bypass the obstructions to deployment of this **life and quality of life-saving** treatment and institute this therapy immediately for our injured warriors. We further believe that when physicians entrusted with the care of these wounded men and women ignore scientific evidence for irrational reasons congress must act to override their arbitrary decisions.

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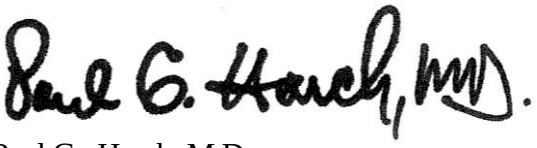
[2] RAND Report: "Invisible Wounds of War: Psychological and Cognitive Injuries, Consequences, and Services to Assist Recovery." Tanielian, Terri; Jaycox, Lisa, April 2008, page xxii-xxiii: Two year costs within the first two years the service member returns home; PTSD $5,904 to $10,298 depending on whether we count the lives lost to suicide; Two year costs for major depression, $15,461 - $25,757; co-morbid PTSD and major depression; $12,427 to $16,884; One year costs for traumatic brain injury diagnosis: $25,572 to $30,730 in 2005 for mild cases ($27,259 to $32,759 in 2007 dollars), and $252,251 to $383,221 for moderate or severe cases ($268,902 to $408,519 in 2007 dollars.) These costs, largely treating symptoms, continue to have outyear costs and outyear consequences in terms of disability payments, inability to work, etc. Given that the HBOT ONE TIME cost for service members who need all 80 treatments averages $16,000 at Medicare Reimbursement rates for a 1 hour treatment. (The cost is lower in some states and higher in urban areas, with known rates set by CMS.) Hyperbaric medicine alone, and hyperbaric medicine in conjunction with other treatments, is very cost effective. If provided acutely within hours of injury, the treatment is even more effective and massively more cost effective.

We look forward to a future hearing when we can present the evidence in person and place before you for your questioning brain-injured veterans who have received the benefits of HBOT 1.5. Among them will be General Patt Maney (retired) who was the first U.S. battle casualty to receive HBOT 1.5 for his blast-induced brain injury in Afghanistan.[3] His treatment was ordered after 9 months of therapy at Walter Reed had shown minimal improvement. As a result of his injuries he was non-functional and unable to return to his job, let alone redeploy to Afghanistan. He received the protocol I developed, completely without my involvement, at George Washington University Medical Center. After treatment he was discharged from Walter Reed and returned to his civilian job as a Florida state judge. Yes, a Florida State Judge.

Unfortunately, Tricare will not reimburse for HBOT 1.5 for brain injury, even when the therapy has been successful. Instead, the cost of treatment has been borne by the clinics and doctors who have treated these needy veterans or paid for by military charities. Meanwhile, the DoD is reimbursing for off-label use of FDA Black Box labeled drugs that have been implicated in the marked suicide rate in our injured veterans. These drugs mask symptoms or act as chemical restraints, leaving untouched the underlying brain injury that is repaired by HBOT 1.5. We urge the committee to encourage the Department of Defense to apply a reasonable reimbursement standard to the only FDA-approved treatment that biologically repairs non-healing wounds, Hyperbaric Oxygen Therapy. Please add HR 4568 to the Senate Armed Services bill and make sure that successful treatments are funded. Thank you for your attention.

Sincerely,



Paul G. Harch, M.D.
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Director of the Hyperbaric Medicine Department
LSU School of Medicine, New Orleans
Vice President, International Hyperbaric Medical Association
President, International Hyperbaric Medical Foundation

[3] The first battle casualty, a U.S. Army Reserve General, blown up in Afghanistan, was treated with HBOT 1.5 while a patient at Walter Reed Army Medical Center. He received treatment from George Washington University Medical Center at the Tricare Reimbursement rate of $250 per treatment. He spent months at Walter Reed making no progress. Counting lost time and hospital costs in the Army Accident pamphlet, his months at Walter Reed cost DoD $400,950, with a permanent disability loss to the service of $1.3 million. With HBOT 1.5 earlier, he would have been able to remain on active duty, a savings of $1.3 million, but more importantly, the 5 months of recovery once he began receiving HBOT 1.5 cost $133,650, a savings to the government of $287,300. No other patients were treated at Walter Reed's brain injury center, despite the General's remarkable recovery that everyone on the staff witnessed. The $20,000 for his hyperbaric medical treatment was more than justified.

Cover Sheet for Appendix to Letter from Paul Harch, M.D. to the Senate Armed Services Committee Hearing, Tuesday, June 22, 2010.

There is no drug currently approved by the FDA to treat TBI. The only drugs approved for PTSD are Zoloft and Paxil. All other treatment with drugs for these conditions is off-label and intended to treat symptoms. Therefore the DoD Secretary's Hearing statement to Congressman Jones at the House Armed Services committee hearing in 2009 that DoD is not paying for any off-label treatment continues to be inaccurate. In fact, a significant percentage of psychiatric medications are prescribed off-label. Further, the use of antipsychotics in these patients is often as a chemical restraint.

The following list of drugs are FDA approved for psychiatric and neurologic disorders. The great majority of these drugs have been and are currently prescribed by DoD Medicine off-label for TBI/PTSD in the service members Dr. Harch has treated with HBOT 1.5 in New Orleans.

Neurology

Alzheimer's
- Ebixa
- Neurontin
- Lyrica
- Topamax
- Symmetrel

Psychiatry

Antidepressents
- Celexa
- Lexapro
- Prozac
- Luvox
- *Paxil
- *Zoloft

*FDA Approved for PTSD

- Cymbalta
- Effexor
- Wellbutrin
- Remeron
- Desyrel

Antimanic
- Tegretol
- Lamictal
- Eskalith
- Topamax
- Depakote

Antipsychotics
- Clozaril
- Zyprexa
- Seroquel
- Risperdal
- Geodon
- Abilify

Anti-anxiety
- Lectopam
- Klonopin
- Tranxene
- Valium
- Dalmane

Also Known to be Prescribed
- Adderall (Dextro Amphetamine)
- Methylphenidate (Ritalin, Concerta, Methylin)
- Provigil (Modafinil)

The attached pages describing drug risks have been extracted from the Physicians Desk Reference. Note that a number of them are black labeled by the FDA for causing increased suicidality in patients 24 and under.

Note: The official DoD White Paper for the December 2008 HBOT in TBI Consensus Conference states, "Side effects from HBOT are uncommon, and severe or permanent complications are rare, especially at the doses of HBOT used "off-label" for TBI patients (approximately 1.5 atm abs for 60 minutes.), compared to HBOT for HHS covered indications (2 to 2.4 atm abs for 120 to 90 minutes.)" [4] For the mild traumatic brain injury patient, clinical experience demonstrates this treatment is far less risky to patients than leaving them untreated. It is also less risky than being in Iraq or Afghanistan.

[4] DoD "HBOT for TBI" Consensus Conference White Paper, 28 October 2008

In addition to the increased risk of suicide with these drugs there is also a risk to abrupt withdrawal. This is a special problem for those departing the service. They often have problem getting prescriptions refilled by the VA in a timely manner, and are at higher risk of suicide as a result. Further, there is a risk to driving while medicated and ingesting alcohol (a frequent problem with post-combat veterans, and one that has resulted in UCMJ action, and dishonorable discharges of decorated war veterans):

There is a Risk to abrupt withdrawal with the following drugs:

a) (Almost any SSRI antidepressant or sedative drug):
Discontinuation of Treatment with Zoloft:
During marketing of Zoloft and other SSRIs and SNRIs (Serotonin and Norepinephrine Reuptake Inhibitors), there have been spontaneous reports of adverse events occurring upon discontinuation of these drugs, particularly when abrupt, including the following: dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g. paresthesias such as electric shock sensations), anxiety, confusion, headache, lethargy, emotional lability, insomnia, and hypomania. While these events are generally self-limiting, there have been reports of serious discontinuation symptoms.

Patients should be monitored for these symptoms when discontinuing treatment with Zoloft. A gradual reduction in the dose rather than abrupt cessation is recommended whenever possible.

b) Benzodiazepines - clonazepam, valium

Risk to driving while medicated and ingesting alcohol:

Sedative (DWI) Risk:
all drugs except Wellbutrin, SSRIs, Adderall, Ritalin, Provigil, etc

The following Endnote was not in the original testimony. However, it confirms Dr. Harch's personal findings in discussions with veterans about the effect of the prescriptions they have received from military medicine or the VA, and their descriptions of the effects of these drugs on these patients.

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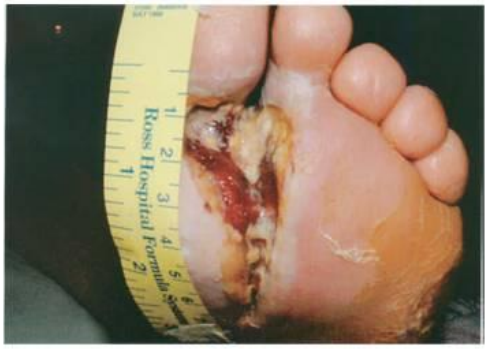
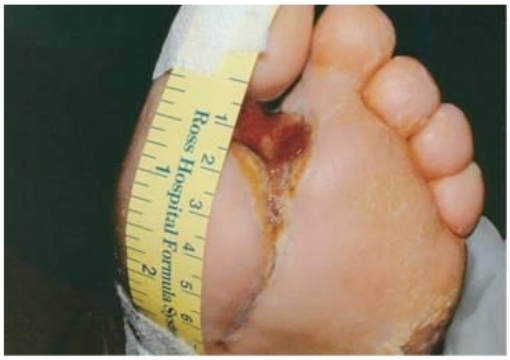
[i] http://veterans.house.gov/hearings/Testimony.aspx?TID=62166&Newsid=525&Name= Peter R. Breggin, M.D.
"....IX. Conclusion: There is overwhelming evidence that the SSRIs and other stimulating antidepressants cause suicidality and aggression in children and adults of all ages. The evidence suggests that young adults aged 18-24 (the age of many soldiers) are especially at risk for antidepressant-induced suicidality. There is a strong probability that the increasing suicide rates among active duty soldiers are in part caused or exacerbated by the widespread prescription of antidepressant medication. In addition, antidepressants frequently cause manic-like reactions, including loss of impulse control and violence, posing potentially grave risks among military personnel. Little will be lost and much will be gained by stopping the prescription of antidepressants to military personnel. The military should rely upon the psychological and educational programs that are currently under development for preventing suicide and ameliorating other psychiatric disorders among service members. Antidepressants should be avoided in the treatment of military personnel."

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



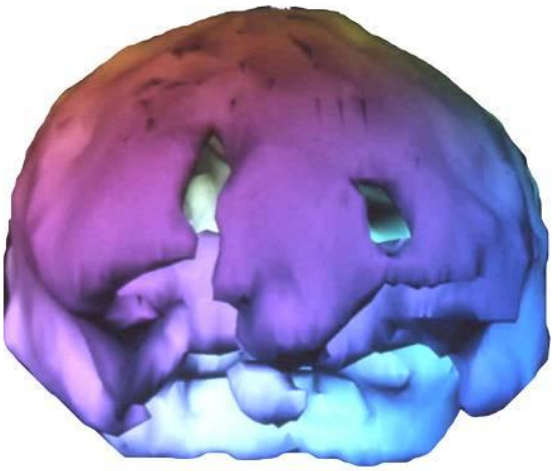
26 HBOT Treatments

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

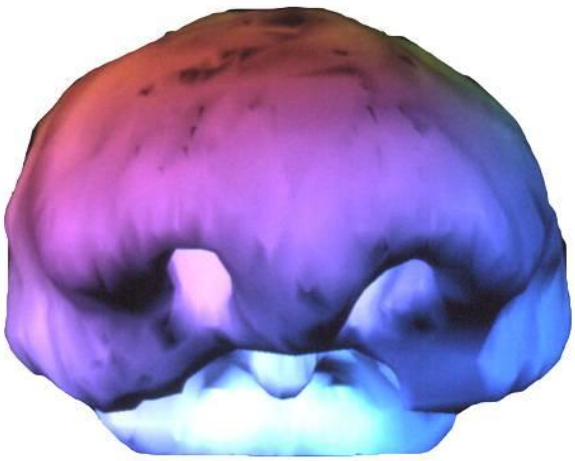
These photographs are the property of Kenneth P. Stoller, MD, FAAP
Permission given by Dr. Stoller to the IHMA to publish on this CD (2004)

Non-Healing Wound to the Brain

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



Pre-HBOT 1.5



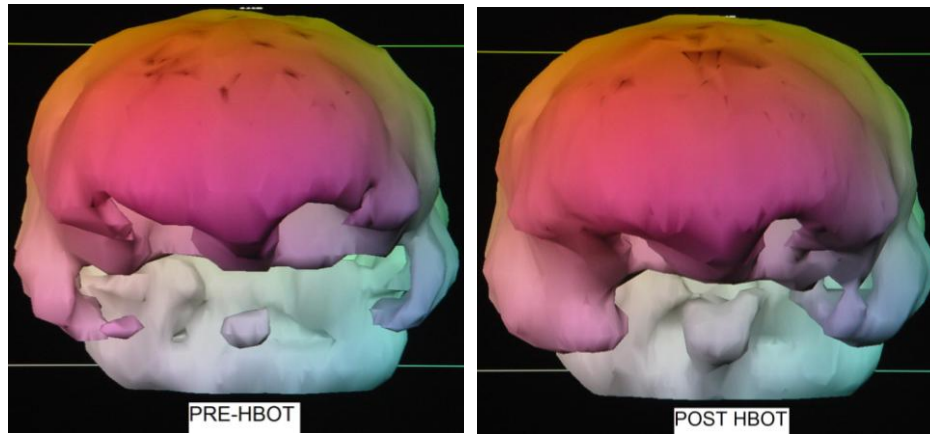
Post-HBOT 1.5

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: Navy SG Meeting - Aug. 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.

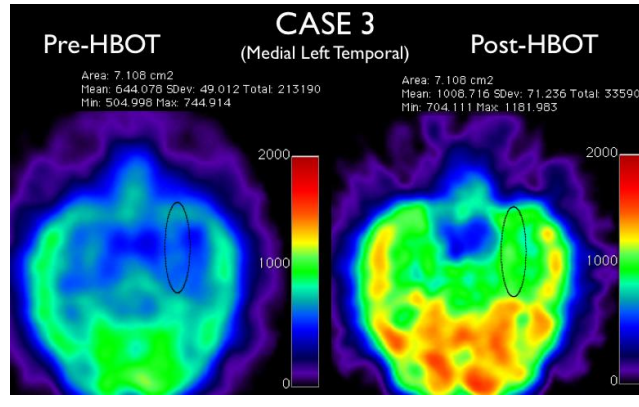
HBOT 1.5 Restores Brain Blood Flow & Doubles Metabolism

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 up take 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

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
Abilify	Bristol Myers Squibb	• Treatment of Schizophrenia in adults and adolescents aged 13 to 17 years • Treatment of manic or mixed episodes associated with Bipolar I Disorder as monotherapy or adjunctive to lithium or valproate in adults and pediatric patients aged 10 to 17 years • Adjunctive treatment of Major Depressive Disorder in adults as an injection for: • Treatment of adults with agitation associated with Schizophrenia or Bipolar I Disorder, manic or mixed episodes	**Yes - Black Box Warning** INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDALITY AND ANTIDEPRESSANT DRUGS
Adderall (Detro Amphetamine)	Shire Pharmaceuticals, Inc.	Adderall is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).	**Yes: Black Box Warning on Death** AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO DRUG DEPENDENCE. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY. MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS CARDIOVASCULAR ADVERSE EVENTS.
Celexa	Forest Pharmaceuticals	Celexa (citalopram HBr) is indicated for the treatment of depression. The antidepressant action of Celexa in hospitalized depressed patients has not been adequately studied.	**Yes Black Box Warning:** Suicidality and Antidepressant Drugs Increased risk of suicidal thinking and behavior in children, adolescents, and young adults Celexa is not approved for use in pediatric patients.
Clozaril	Novartis Pharmaceuticals	CLOZARIL® (clozapine) is indicated for the management of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia. Because of the significant risk of agranulocytosis and seizure associated with its use, CLOZARIL should be used only in patients who have failed to respond adequately to treatment with appropriate courses of standard drug treatments for schizophrenia. CLOZARIL is indicated for reducing the risk of	**Yes - Black Box Warning** *INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS* CLOZARIL® (clozapine) IS NOT APPROVED FOR THE TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS (SEE BOXED WARNING).

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for reexperiencing suicidal behavior, based on history and recent clinical state. Suicidal behavior refers to actions by a patient that puts him/herself at risk for death.	
Cymbalta	Eli Lilly & Company	Cymbalta® is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for: • Major Depressive Disorder (MDD) • Generalized Anxiety Disorder (GAD) • Diabetic Peripheral Neuropathic Pain (DPNP) • Fibromyalgia (FM)	**Yes Black Box Warning:** Suicidality and Antidepressant Drugs Increased risk of suicidal thinking and behavior in children, adolescents, and young adults Cymbalta is not approved for use in pediatric patients
Dalmane	Roche Laboratories	Dalmane is a hypnotic agent useful for the treatment of insomnia characterized by difficulty in falling asleep, frequent nocturnal awakenings, and/or early morning awakening. Dalmane can be used effectively in patients with recurring insomnia or poor sleeping habits, and in acute or chronic medical situations requiring restful sleep.	
Depakote	Abbott Laboratories	Depakote is used to treat seizure disorders. manic phase of bipolar disorders (manic-depressive illness), and to prevent migraine headaches.	
Desyrel (Trazadone)	Apothecon Inc Div Bristol Myers Squibb Product Research	Depression (also known as major depression or clinical depression). Desyrel is not approved for use in childhood depression. On occasion, your healthcare provider may recommend Desyrel for treating something other than depression. This is called an "off-label" use. At this time, there are several off-label Desyrel uses, including the treatment of: Alcoholism, Anxiety, Insomnia, Panic disorder. (http://mental-health.emedtv.com/desyrel/desyrel-uses-p2.html)	**Yes, Black Box Warning:** Antidepressants (including Desyrel) may increase the risk of suicidal thinking or behavior in children, teenagers, and adults
Dexmethylphenldate Focalin Ritalin (Methylphenidate) Concerta, Methylin)	Novartis Pharmaceuticals Corporation	Attention-deficit/hyperactivity disorder (ADHD) Narcolepsy. **Controlled Substance and can lead to dependence.**	**Yes: Black Box Warning on Sudden Death, Potential for Abuse** Warnings for Amphetamine, Dextroamphetamine, Lisdexamfetamine dismesylate, Methamphetamine, Mixed Salts of a Single Entity Amphetamine Products Adderall, Adderall XR, Desoxyn, and Dexedrine (SR) • High abuse/diversion potential: Amphetamines have a

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
			high potential for abuse. Particular attention should be paid to the possibility of subjects obtaining amphetamines for non-therapeutic use or distribution to others, and the drugs should be prescribed or dispensed sparingly. • Drug dependence: Administration of amphetmaines for prolonged periods of time may lead to drug dependence and must be avoided. • Serious Adverse Events: Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events Serious Cardiovascular Events: Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Increased Blood Pressure and Heart Rate: have been reported. • Psychotic Symptoms: may be exacerbated in patients with psychotic disorders Bipolar Disorder: Use with particular care in ADHD patients with comorbid Bipolar Disorder. Before initiating stimulant therapy, obtain a detailed psychiatric history for patients with comorbid depressive symptoms, in order to determine risk for Bipolar Disorder. (5.5) • Emergence of New Psychotic or Manic Symptoms: Treatment-emergent psychotic or manic symptoms without a prior history can be caused by stimulants at usual doses. • Aggression: Monitor for appearance of or worsening of aggressive behavior or hostility • Long-Term Suppression of Growth: monitor height and weight in pediatric patients at appropriate intervals. • Seizures: The threshold for seizures may be lowered. **Serious methylphenidate side effects include suicidal thoughts**.
Ebixa	H. Lundbeck A/S	Ebixa® (memantine) is licensed for the treatment of moderate to severe Alzheimers disease.	
Effexor	Wyeth Pharmaceuticals Inc.	Depression and three anxiety disorders: generalized anxiety disorder (GAD), panic disorder (PD), and social anxiety disorder (SAD).	**Yes: Black Box Warning** Suicidality and Antidepressant Drugs Antidepressants increased the risk compared to placebo of suicidal thinking and

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
			behavior (suicidality) in children, teens, and young adults. EFFEXOR XR® (venlafaxine HCl) is not approved for use in children and teens.
Eskalith	By Cardinal Health for GlaxoSmithKline	ESKALITH (lithium carbonate) is indicated in the treatment of manic episodes of manic-depressive illness. Maintenance therapy prevents or diminishes the intensity of subsequent episodes in those manic-depressive patients with a history of mania. Typical symptoms of mania include pressure of speech, motor hyperactivity, reduced need for sleep, flight of ideas, grandiosity, elation, poor judgment, aggressiveness and possibly hostility. When given to a patient experiencing a manic episode,	
Geodon	Pfizer	Schizophrenia Bipolar Mania Acute Agitation in Schizophrenic Patients	**Yes: Black Box Warning:** Increased Mortality in Elderly Patients with Dementia-Related Psychosis— Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
Klonopin clonazepam	Roche Laboratories a division of Hoffman La Roche Inc.	Klonopin is useful alone or as an adjunct in the treatment of the Lennox-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures. In patients with absence seizures (petit mal) who have failed to respond to succinimides.	
Lamictal	Glaxo Smith Kline	Epilepsy: partial seizures, the generalized seizures of Lennox-Gastaut syndrome, and primary generalized tonic-clonic seizures in adults and pediatric patients (≥2 years of age). Bipolar	*Yes: Clinical Worsening and Suicide Risk Associated with Bipolar Disorder:* Patients with bipolar disorder may experience worsening of their depressive symptoms and/or the emergence of suicidal ideation and behaviors (suicidality) whether or not they are taking medications for bipolar disorder. Patients should be closely monitored for clinical worsening (including development of new symptoms) and suicidality, especially at the beginning of a course of treatment, or at the time of dose changes.
Lectopam Bromazepam	Roche	For the short-term, symptomatic relief of manifestations of excessive anxiety in patients with anxiety neurosis. Benzodiazepines are only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress. As with other benzodiazepines, bromazepam	**Yes: Black Box Warning** Suicidality and Antidepressant Drugs Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, teens, and young adults.

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		should not be used in individuals with physiological anxiety or normal stresses of daily living, but only in the presence of disabling manifestations of an appropriate pathological anxiety disorder. These drugs are not effective in patients with characterological and personality disorders or those with obsessive-compulsive disorders. Bromazepam is also not recommended for management of depressive or psychotic disorders.	
Lexapro	Forest Pharmaceuticals, Inc.	Major Depressive Disorder Generalized Anxiety Disorder	**Yes: Black Box Warning** Suicidality and Antidepressant Drugs Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Lexapro is not approved for use in pediatric patients. .
Luvox	Jazz Pharmaceuticals, Inc Solvay Pharmaceuticals Inc.	Social anxiety disorder (SAD) — people with SAD, also known as social phobia, have an ongoing intense fear of social situations Obsessive compulsive disorder (OCD) — people with OCD have 2 key symptoms: obsessions and compulsions	**Yes: Black Box Warning** Suicidality and Antidepressant Drugs Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Not approved for use in pediatric patients.
Lyrica	Pfizer	LYRICA is indicated for: • Neuropathic pain associated with diabetic peripheral neuropathy (DPN) • Post herpetic neuralgia (PHN) • Adjunctive therapy for adult patients with partial onset seizures • Fibromyalgia	Yes: Reports of Suicide in Clinical Trials Suicide was a reported adverse event during the development research - it was considered a rare event.
Neurontin (Gabapentin)	Pfizer	Postherpetic Neuralgia Neurontin (gabapentin) is indicated for the management of postherpetic neuralgia in adults. Epilepsy Neurontin (gabapentin) is indicated as adjunctive therapy in the treatment of partial seizures with and without secondary generalization in patients over 12 years of age with epilepsy. Neurontin is also indicated as adjunctive therapy in the treatment of partial seizures in pediatric patients age 3 – 12 years.	Yes: Suicide attempts were reported in the clinical trial as 'infrequent' (choices were frequent, infrequent, and rare)
Paxil paroxetine	GlaxoSmithKline	Major Depressive Disorder: PAXIL is indicated for the treatment of major depressive disorder.	**Yes: Black Box Warning:** Suicidality and Antidepressant Drugs

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		Panic Disorder: PAXIL is indicated for the treatment of panic disorder, with or without agoraphobia, as defined in DSM-IV. Social Anxiety Disorder: PAXIL is indicated for the treatment of social anxiety disorder, also known as social phobia, as defined in DSM-IV (300.23). Premenstrual Dysphoric Disorder: PAXIL is indicated for the treatment of PMDD.	Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. PAXIL CR is not approved for use in pediatric patients.
Provigil (Modafinil)	Cephalon Inc.	PROVIGIL® (modafinil) Tablets [C-IV] are indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder.	Yes: Suicide Ideation has been reported Serious rash requiring hospitalization and discontinuation of treatment has been reported in adults and children in association with use of modafinil. .Stevens-Johnson Syndrome (SJS) and 1 case of apparent multi-organ hypersensitivity reaction. Several of the cases were associated with fever and other abnormalities. Rare cases of serious or life-threatening rash, including SJS, Toxic Epidermal Necrolysis (TEN) and Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) have been reported, postmarketing Modafinil is not approved for use in pediatric patients for any indication. Psychiatric adverse experiences have been reported in patients treated with modafinil. Postmarketing adverse events have included mania, delusions, hallucinations, suicidal ideation and aggression, some resulting in hospitalization.
Prozac	Eli Lilly & Company	Prozac® (fluoxetine capsules, USP and fluoxetine oral solution, USP) is a psychotropic drug for oral administration. Prozac is indicated for the treatment of • Major depressive disorder • Obsessive Compulsive Disorder • Bulimia Nervosa • panic disorder, with or without agoraphobia It is also marketed for the treatment of premenstrual dysphoric disorder	**Yes: Black Box Warning:** Suicidality and Antidepressant Drugs — Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders.
Remeron (Mirtazapine)	Organon (Schering Plough)	REMERON® (mirtazapine) Tablets are indicated for the treatment of major depressive disorder.	**Yes: Black Box Warning:** Suicidality and Antidepressant Drugs Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. REMERON® is not approved for use in pediatric patients.
Risperdal	Janssen Pharmaceutica	RISPERDAL® is an atypical antipsychotic agent indicated for: • Treatment of schizophrenia in adults and adolescents aged 13-17 years	**Yes: Black Box Warning** WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		• Alone, or in combination with lithium or valproate, for the short-term treatment of acute manic or mixed episodes associated with Bipolar I Disorder in adults, and alone in children and adolescents aged 10-17 years • Treatment of irritability associated with autistic disorder in children and adolescents aged 5-16 years	See full prescribing information for complete boxed warning. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. RISPERDAL® is not approved for use in patients with dementia-related psychosis.
Seraqul	Astra Zeneca	Bi polar Disorder	**Yes: Black Box Warning mortality and suicide** In elderly patients who have lost touch with reality due to dementia (confusion and memory loss), there is a higher risk of death with Seroquel XR and medicines like it. Seroquel XR is not approved for treating these patients Antidepressants have been shown to increase the risk of suicidal thoughts and actions in some children, teenagers, and young adults. Patients of all ages starting treatment should be watched closely by family members and caregivers, and any worsening of depression, suicidal thoughts or actions, or unusual changes in behavior, agitation, and irritability and should be reported to their physician immediately. Seroquel XR is not approved for patients under the age of 18 years.
Seroquel	AstraZeneca	Seroquel XR is indicated for the treatment of acute depressive episodes associated with bipolar disorder, acute manic or mixed episodes associated with bipolar I disorder as monotherapy and as an adjunct to lithium or divalproex; maintenance treatment of bipolar I disorder as adjunct therapy to lithium or divalproex, and acute and maintenance treatment of schizophrenia.	Yes: Black Box Warning: Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death, compared to placebo (4.5% vs.2.6%, respectively). **Seroquel XR** and **Seroquel** are not approved for the treatment of patients with dementia-related psychosis. Antidepressants increased the risk of suicidal thinking and behavior in children, adolescents, and young adults in short-term studies of major depressive disorder and other psychiatric disorders. Patients of all ages started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.
Symmetrel Amantadine	Endo Labs DuPont	Amantadine is used for the treatment of Parkinson's disease and for the short-term management of Parkinson-like symptoms caused by certain medications. It is also used for the prevention and treatment of influenza A infections.	**Yes:** Suicide attempts, some of which have been fatal, have been reported in patients treated with SYMMETREL, many of whom received short courses for influenza treatment or prophylaxis. The incidence of suicide attempts is not known and the pathophysiologic mechanism is not understood. Suicide attempts and suicidal ideation have been reported in patients with and without prior history of psychiatric illness.
Tegretol	Novartis	Epilepsy Tegretol is indicated for use as an anticonvulsant drug. following seizure types: Partial seizures with complex symptomatology (psychomotor, temporal lobe). Patients with these seizures appear to show greater improvement than	**Yes: Black Box Warning - Death** SERIOUS AND SOMETIMES FATAL DERMATOLOGIC REACTIONS, INCLUDING TOXIC EPIDERMAL NECROLYSIS (TEN) AND STEVENS-JOHNSON SYNDROME (SJS), HAVE

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		those with other types. Generalized tonic-clonic seizures (grand mal). Mixed seizure patterns which include the above, or other partial or generalized seizures. Absence seizures (petit mal) do not appear to be controlled by Tegretol Trigeminal Neuralgia Tegretol is indicated in the treatment of the pain associated with true trigeminal neuralgia.Beneficial results have also been reported in glossopharyngeal neuralgia. This drug is not a simple analgesic and should not be used for the relief of trivial aches or pains.	BEEN REPORTED DURING TREATMENT WITH TEGRETOL. THESE REACTIONS ARE ESTIMATED TO OCCUR IN 1 TO 6 PER 10,000 NEW USERS IN COUNTRIES WITH MAINLY CAUCASIAN POPULATIONS, BUT THE RISK IN SOME ASIAN COUNTRIES IS ESTIMATED TO BE ABOUT 10 TIMES HIGHER. STUDIES IN PATIENTS OF CHINESE ANCESTRY HAVE FOUND A STRONG ASSOCIATION BETWEEN THE RISK OF DEVELOPING SJS/TEN AND THE PRESENCE OF HLA-B*1502, AN INHERITED ALLELIC VARIANT OF THE HLA-B GENE. HLA-B*1502 IS FOUND ALMOST EXCLUSIVELY IN PATIENTS WITH ANCESTRY ACROSS BROAD AREAS OF ASIA. PATIENTS WITH ANCESTRY IN GENETICALLY AT-RISK POPULATIONS SHOULD BE SCREENED FOR THE PRESENCE OF HLA-B*1502 PRIOR TO INITIATING TREATMENT WITH TEGRETOL. PATIENTS TESTING POSITIVE FOR THE ALLELE SHOULD NOT BE TREATED WITH TEGRETOL UNLESS THE BENEFIT CLEARLY OUTWEIGHS THE RISK. **APLASTIC ANEMIA AND AGRANULOCYTOSIS** APLASTIC ANEMIA AND AGRANULOCYTOSIS HAVE BEEN REPORTED IN ASSOCIATION WITH THE USE OF TEGRETOL.
Topamax Topiramate	Ortho-McNeil Pharmaceutica	Monotherapy Epilepsy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures. Adjunctive Therapy Epilepsy for adults and pediatric patients ages 2-16 years with partial onset seizures, or primary generalized tonic-clonic seizures, and in patients 2 years of age and older with seizures associated with Lennox-Gastaut syndrome. Migraine TOPAMAX® (topiramate capsules) Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache.	Yes: Suicides were reported in clinical trials.
Tranxene (Clorazepate)	Abbott laboratories	Indicated for the management of anxiety disorders, for the short-term relief of the symptoms of anxiety, as adjunctive therapy in the management of partial seizures and symptomatic relief of acute alcohol withdrawal.	Yes both in treatment and withdrawal In those patients in which a degree of depression accompanies the anxiety, suicidal tendencies may be present and protective measures may be required.
Valium	**Roche Laboratories**	Valium is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic. In acute alcohol withdrawal, Valium may be useful in the symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis. Valium is a useful adjunct for the relief of skeletal	Yes Suicide Risk is Present The usual precautions are indicated for severely depressed patients or those in whom there is any evidence of latent depression or anxiety associated with depression, particularly the recognition that suicidal tendencies may be present and protective measures may be necessary. Psychiatric and paradoxical reactions are known to occur when using benzodiazepines. stimulation, restlessness, acute hyperexcited states, anxiety, agitation, aggressiveness,

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		muscle spasm due to reflex spasm to local pathology (such as inflammation of the muscles or joints, or secondary to trauma), spasticity caused by upper motor neuron disorders (such as cerebral palsy and paraplegia), athetosis, and stiff-man syndrome. Oral Valium may be used adjunctively in convulsive disorders, although it has not proved useful as the sole therapy. **Schedule IV Drug with DEA - may produce psychological and physical dependence.**	irritability, rage, hallucinations, psychoses, delusions, increased muscle spasticity, insomnia, sleep disturbances, and nightmares. Inappropriate behavior and other adverse behavioral effects have been reported when using benzodiazepines These reactions are more likely to occur in children and the elderly.
Wellbutrin Bupropion *Zyban*	GlaxoSmithKline GSK Pharm Phys Total Care Direct Dispensing Glaxo Wellcome GSK Pharm Phys Total Care DRx DHS, Inc. Direct Dispensing Southwood PD-Rx Pharm DispenseXpress	Wellbutrin is an antidepressant medication. Wellbutrin is used to treat major depressive disorder and seasonal affective disorder. At least one brand of bupropion (Zyban) is used to help people stop smoking by reducing cravings and other withdrawal effects.	**Yes: Black Box Warning** WARNINGS-Clinical Worsening and Suicide Risk It should be noted that WELLBUTRIN is not approved for use in treating any indications in the pediatric population
Zoloft	Pfizer	ZOLOFT (sertraline hydrochloride) is indicated for the treatment of major depressive disorder in adults. obsessions and compulsions in patients with obsessive-compulsive disorder. panic disorder in adults, with or without agoraphobia. premenstrual dysphoric disorder (PMDD) in adults.social anxiety disorder, also known as social phobia in adults ZOLOFT (sertraline hydrochloride) is indicated for the treatment of posttraumatic stress disorder in adults. The efficacy of ZOLOFT in the treatment of PTSD was established in two 12-week placebo-controlled trials of adult outpatients whose diagnosis met criteria for the DSM-III-R category of PTSD The efficacy of ZOLOFT in maintaining a response in adult patients with PTSD for up to 28 weeks following 24 weeks of open-label treatment was demonstrated in a placebo-controlled trial. Nevertheless, the physician who elects to use ZOLOFT for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.	**Yes: Black Box Warning** **Suicidality:** incr. risk of suicidality in children, adolescents and young adults w/ major depressive or other psychiatric disorders esp. during 1st months of tx w/ antidepressants vs. placebo; weigh risk vs. benefit; in short-term studies of antidepressants vs. placebo, suicidality risk not increased in pts >24 yo, and risk decreased in pts >65 yo; observe all pts for clinical worsening, suicidality, or unusual behavior changes; not approved in pediatric pts except for obsessive compulsive disorder
Zyprexa	Eli Lilly & Company	ZYPREXA (olanzapine) is a psychotropic agent that	**Yes: Black Box Warning** Increased Mortality in Elderly Patients with Dementia-Related

Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		is indicated for the treatment of schizophrenia, acute mixed or manic episodes associated with Bipolar I Disorder. maintaining bipolar patients	Psychosis — Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. ZYPREXA (olanzapine) is not approved for the treatment of patients with dementia-related psychosis