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May 15, 2009

Ike Skelton, Chairman
John M. McHugh, Ranking Member
House Armed Services Committee
United States House of Representatives
Washington, D.C. 20515

TESTIMONY FOR THE RECORD: Regarding FDA approval of hyperbaric oxygen therapy (HBOT) to treat traumatic brain injury (TBI), off-label prescription drug use by the Department of Defense for TBI and post-traumatic stress disorder (PTSD), and the potential relationship of this drug use to the incidence of suicides in United States Service members.

Dear Chairman Skelton & Ranking Member McHugh:

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. Careful questioning of over 30 veterans and in-depth interviews with detailed physical examinations of 19 of these veterans exposed to concussive blasts has revealed significant abnormalities in those patients with loss of consciousness from their blast exposure. These abnormalities have been supported by psychological and cognitive testing abnormalities that are consistent with the diagnoses of "TBI" and "PTSD" bestowed by military evaluators.

The National Brain Injury Rescue and Rehabilitation Project continues 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, preliminary 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 and is known to be a non-specific biological repair therapy for acute and chronic wounds. 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 characterized by loss of consciousness. **HBOT is the only FDA-approved treatment known to biologically repair and regenerate human tissue and activate growth factors at a DNA level. It is FDA-approved to treat conditions like blunt trauma, crush injury and non-healing wounds.** Three of the 13 FDA-approved indications are for neurological injury. Physicians are permitted to use an approved drug or device "off-label" when they believe the underlying mechanisms of action may help a patient with a non-approved condition.

The statement has been made that "HBOT is not FDA approved for brain injury" and that is why Tricare and VA are not paying for this therapy. While true, this does not tell the whole story. **In fact NONE of the drugs currently being used and paid for by Tricare and the VA are FDA-approved to treat TBI.**

Only two, Paxil and Zoloft, are approved to treat PTSD. Both of those carry FDA Black Box warnings urging caution in 17-24 year olds because of the increased risk of suicide of these medications in this age group. Some of my military patients in this age group have reported to me they were threatened with UCMJ action if they failed to take these drugs, even though they were in the known risk group.

An article was published in The Army Times about the HAC-D committee's (and all Americans') concern over the high rate of suicides in our veterans and the lack of effective treatment for TBI and PTSD. **With respect to the suicide epidemic I would like to suggest to the committee that they investigate as a causative factor the high rate of <u>off-label</u> usage of the multitude of psychoactive drugs currently prescribed to modulate the symptoms of TBI and PTSD.** (See appendix for list and side effects listed in the Physicians Desk Reference.)

As stated previously, many of these drugs have black box warnings of increased rates of suicides, specifically the more modern antidepressants. 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 would seem to include a significant number of our brain-injured veterans. Use of most of these drugs long term also results in a loss of a security clearance, which for many of these personnel, effectively ends their military careers.

As an alternative I would like to suggest the expansion of off-label usage of another FDA-approved drug with a far safer profile, hyperbaric oxygen therapy. This therapy does not result in a loss of a security clearance for active duty personnel. In the past 20 years I have extensively and successfully applied a lower dose of hyperbaric oxygen therapy (HBOT 1.5) to a wide array of neurological diagnoses, including TBI. Twenty-three cases in this experience have been presented to a House Appropriations Subcommittee and House Government Oversight Committee on three separate occasions in 2002 and 2004. While we expected clinical and cognitive improvements in these casualties, our recent surprise in treating brain-injured veterans was an improvement in PTSD symptoms in a significant number of these patients. The protocol I have developed has now been successfully applied by other physicians (please see the N-BIRR Scorecard submitted to you by Dr. William Duncan) and has been duplicated in an animal model that I published two years ago. The safety profile with this drug (HBOT 1.5) and protocol is extremely safe and carries no FDA black box warning. Further experience is in process through a formal pilot trial that I am conducting at LSU School of Medicine, New Orleans. The Scorecard contains some of those results.

Many of these casualties have been able to return to duty, work or school. Their post-concussion syndrome has improved clinically. Standardized independent neuropsych tests like IQ or ANAM, and PTSD standard questionnaires have all shown improvement. Functional brain imaging of whatever type has shown repair of the neural structures and function within the brain. No wound can heal without oxygen. **In fact, the functional imaging demonstrates the brain responds to HBOT 1.5 just like any other non-healing wound area in the body. The FDA has approved HBOT for treating non-healing wounds. Tricare and many third party payers reimburse for HBOT non-healing wound treatment.**

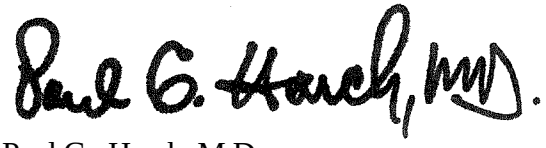
In addition, the recent Institutional Review Board approval of the national N-BIRR protocol enables practitioners from across the nation to begin treating with HBOT 1.5 and track and publish those results. The scientific information from these studies will be of appropriate scientific rigor to allow the application for FDA-pre-market approval for use of HBOT for TBI and PTSD. Since there is no patent on oxygen, the funds simply have not been available to acquire level I evidence previously.

Now, seven years into the war, we are seeing the results of untreated brain injuries throughout society. We have about 154,000 homeless war veterans, a rising percent of our jail population is comprised of recent veterans, and the all volunteer Army has been strained by readiness and retention challenges. Fortunately, the N-BIRR team has already saved DoD $6.3 million in recruiting and retraining costs by returning five veterans to duty at a civilian treatment cost of $62,500.

Unfortunately, Tricare has not chosen to reimburse for HBOT 1.5, even when the therapy saves the government money by restoring an individual service member to duty. Instead, much of this cost has been borne by the doctors who have treated our veterans at their own expense. DoD is only reimbursing for drugs that mask symptoms or act as chemical restraints. They also pay for counseling that while helpful, does not treat the underlying cause of the changes in combat veteran's behavior resulting from a biological injury. I 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.

Thank you for your attention.

Sincerely,



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**Cover Sheet for Appendix to Letter from Paul Harch, M.D. to the House Armed Services Committee Hearing,**
**Friday, May 15, 2009**

**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 Hearing statement that DoD is not paying for 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 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.)" [1] 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.

In addition to the increased risk of suicide with these drugs there is also a risk to abrupt withdrawal and a risk to driving while medicated and ingesting alcohol (a frequent problem with post-combat veterans):

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

Risk to abrupt withdrawal:

a) (most 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

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# 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<br>• 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:<br>• Treatment of adults with agitation associated with Schizophrenia or Bipolar I Disorder, manic or mixed episodes | **Yes - Black Box Warning**<br><br>INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED<br>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**<br><br>AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. ADMINISTRATION<br>OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME MAY LEAD TO<br>DRUG DEPENDENCE. PARTICULAR ATTENTION SHOULD BE PAID TO THE<br>POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR<br>NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS AND THE DRUGS<br>SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.<br>MISUSE OF AMPHETAMINE MAY CAUSE SUDDEN DEATH AND SERIOUS<br>CARDIOVASCULAR ADVERSE EVENTS. |
| Celexa | Forest Pharmaceuticals | Celexa (citalopram HBr) is indicated for the treatment of depression.<br><br>The antidepressant action of Celexa in hospitalized depressed patients has not been adequately studied. | **Yes Black Box Warning:**<br><br>Suicidality and Antidepressant Drugs<br>Increased risk of suicidal thinking and behavior in children, adolescents, and young adults<br><br>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.<br><br>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.<br><br>CLOZARIL is indicated for reducing the risk of | **Yes - Black Box Warning**<br><br>*INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS*<br><br>CLOZARIL® (clozapine) IS NOT APPROVED FOR THE TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS (SEE BOXED WARNING). |

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| Drug Name | Manufacturer | Label Indications | Suicide or Increased Mortality Risk |
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| | | 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:<br>• Major Depressive Disorder (MDD)<br>• Generalized Anxiety Disorder (GAD)<br>• Diabetic Peripheral Neuropathic Pain (DPNP)<br>• Fibromyalgia (FM) | **Yes Black Box Warning:**<br><br>Suicidality and Antidepressant Drugs<br>Increased risk of suicidal thinking and behavior in children, adolescents, and young adults<br><br>Cymbalta<br>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.<br><br>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<br><br>(Trazadone) | Apothecon Inc<br><br>Div Bristol Myers Squibb Product Research | Depression (also known as major depression or clinical depression).<br>Desyrel is not approved for use in childhood depression.<br>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:<br>Alcoholism, Anxiety, Insomnia, Panic disorder.<br>(http://mental-health.emedtv.com/desyrel/desyrel-uses-p2.html) | **Yes, Black Box Warning:**<br><br>Antidepressants (including Desyrel) may increase the risk of suicidal thinking or behavior in children, teenagers, and adults |
| Dexmethylphenldate<br><br>Focalin<br><br>Ritalin (Methylphenidate) Concerta, Methylin) | Novartis Pharmaceuticals Corporation | Attention-deficit/hyperactivity disorder (ADHD)<br>Narcolepsy.<br><br>**Controlled Substance and can lead to dependence.** | **Yes: Black Box Warning on Sudden Death, Potential for Abuse**<br><br>Warnings for Amphetamine, Dextroamphetamine, Lisdexamfetamine dismesylate, Methamphetamine, Mixed Salts of a Single Entity Amphetamine Products<br>Adderall, Adderall XR, Desoxyn, and Dexedrine (SR)<br>• 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 |
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| | | | 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.<br>• Drug dependence: Administration of amphetmaines for prolonged periods of time may lead to drug dependence and must be avoided.<br>• Serious Adverse Events: Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events<br>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.<br>Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD.<br>Increased Blood Pressure and Heart Rate: have been reported.<br>• Psychotic Symptoms: may be exacerbated in patients with psychotic disorders<br>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)<br>• 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.<br>• Aggression: Monitor for appearance of or worsening of aggressive behavior or hostility<br>• Long-Term Suppression of Growth: monitor height and weight in pediatric patients at appropriate intervals.<br>• Seizures: The threshold for seizures may be lowered.<br><br>**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**<br><br>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 |
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| | | | behavior (suicidality) in children, teens, and young adults.<br><br>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.<br><br>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<br>Bipolar Mania<br>Acute Agitation in Schizophrenic Patients | **Yes: Black Box Warning:**<br>Increased Mortality in Elderly Patients with Dementia-Related Psychosis—<br>Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an<br>increased risk of death. |
| Klonopin<br>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).<br>Bipolar | *Yes: Clinical Worsening and Suicide Risk Associated with Bipolar Disorder:*<br><br>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<br>Bromazepam | Roche | For the short-term, symptomatic relief of manifestations of excessive anxiety in patients with anxiety neurosis.<br><br>Benzodiazepines are only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress.<br><br>As with other benzodiazepines, bromazepam | **Yes: Black Box Warning**<br><br>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 |
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| | | 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<br>Generalized Anxiety Disorder | **Yes: Black Box Warning**<br><br>Suicidality and Antidepressant Drugs<br>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.<br><br>Lexapro is not approved for use in pediatric patients. . |
| Luvox | Jazz Pharmaceuticals, Inc<br>Solvay Pharmaceuticals Inc. | Social anxiety disorder (SAD) — people with SAD, also known as social phobia, have an ongoing intense fear of social situations<br>Obsessive compulsive disorder (OCD) — people with OCD have 2 key symptoms: obsessions and compulsions | **Yes: Black Box Warning**<br>Suicidality and Antidepressant Drugs<br>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.<br><br>Not approved for use in pediatric patients. |
| Lyrica | Pfizer | LYRICA is indicated for:<br>• Neuropathic pain associated with diabetic peripheral<br>neuropathy (DPN)<br>• Post herpetic neuralgia (PHN)<br>• Adjunctive therapy for adult patients with partial onset seizures<br>• Fibromyalgia | Yes:<br>Reports of Suicide in Clinical Trials Suicide was a reported adverse event during the development research - it was considered a rare event. |
| Neurontin<br><br>(Gabapentin) | Pfizer | Postherpetic Neuralgia<br>Neurontin (gabapentin) is indicated for the management of postherpetic neuralgia in adults.<br>Epilepsy<br>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<br>– 12 years. | Yes:<br><br>Suicide attempts were reported in the clinical trial as 'infrequent' (choices were frequent, infrequent, and rare) |
| Paxil<br><br>paroxetine | GlaxoSmithKline | Major Depressive Disorder: PAXIL is indicated for the treatment of major depressive disorder. | **Yes: Black Box Warning:**<br><br>Suicidality and Antidepressant Drugs |

# Drugs Being Prescribed for PTSD and TBI Patients

| Drug Name | Manufacturer | Label Indications | Suicide or Increased Mortality Risk |
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| | | Panic Disorder: PAXIL is indicated for the treatment of panic disorder, with or without agoraphobia, as defined in DSM-IV.<br><br>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).<br><br>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.<br><br>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<br><br>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<br>Modafinil is not approved for use in pediatric patients for any indication.<br>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<br>• Major depressive disorder<br>• Obsessive Compulsive Disorder<br>• Bulimia Nervosa<br>• panic disorder, with or without agoraphobia<br>It is also marketed for the treatment of premenstrual dysphoric disorder | **Yes: Black Box Warning:**<br><br>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:**<br>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.<br>REMERON® is not approved for use in pediatric patients. |
| Risperdal | Janssen Pharmaceutica | RISPERDAL® is an atypical antipsychotic agent indicated for:<br>• Treatment of schizophrenia in adults and adolescents aged 13-17 years | **Yes: Black Box Warning**<br>WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS<br>WITH DEMENTIA-RELATED PSYCHOSIS |

# Drugs Being Prescribed for PTSD and TBI Patients

| Drug Name | Manufacturer | Label Indications | Suicide or Increased Mortality Risk |
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| | | • 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<br>• 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**<br><br>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<br>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:<br><br>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.<br><br>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<br><br>Amantadine | Endo Labs<br>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:**<br>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**<br><br>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<br>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.<br>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.<br><br>**APLASTIC ANEMIA AND AGRANULOCYTOSIS** APLASTIC ANEMIA AND AGRANULOCYTOSIS HAVE BEEN REPORTED IN ASSOCIATION WITH THE USE OF TEGRETOL. |
| Topamax<br>Topiramate | Ortho-McNeil Pharmaceutica | Monotherapy Epilepsy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures.<br>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.<br>Migraine TOPAMAX® (topiramate capsules) Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache. | Yes: Suicides were reported in clinical trials. |
| Tranxene<br><br>(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<br><br>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.<br>In acute alcohol withdrawal, Valium may be useful in the symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis.<br>Valium is a useful adjunct for the relief of skeletal | Yes Suicide Risk is Present<br><br>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.<br>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.<br>Oral Valium may be used adjunctively in convulsive disorders, although it has not proved useful as the sole therapy.<br>**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<br>These reactions are more likely to occur in children and the elderly. |
| Wellbutrin<br>Bupropion<br>*Zyban* | GlaxoSmithKline GSK Pharm<br>Phys Total Care Direct Dispensing<br>Glaxo Wellcome<br>GSK Pharm Phys Total Care DRx DHS, Inc. Direct Dispensing<br>Southwood PD-Rx Pharm DispenseXpress | Wellbutrin is an antidepressant medication.<br><br>Wellbutrin is used to treat major depressive disorder and seasonal affective disorder.<br><br>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**<br>WARNINGS-Clinical Worsening and Suicide Risk<br><br>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.<br>obsessions and compulsions in patients with obsessive-compulsive disorder.<br>panic disorder in adults, with or without agoraphobia. premenstrual dysphoric disorder (PMDD) in adults.social anxiety disorder, also known as social phobia in adults<br><br>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<br>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**<br><br>**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**<br>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,<br>acute mixed or manic<br>episodes associated with Bipolar I Disorder.<br>maintaining bipolar patients | Psychosis — Elderly<br>patients with dementia-related psychosis treated with<br>antipsychotic drugs are at an<br>increased risk of death.<br>ZYPREXA (olanzapine) is not approved for the treatment of<br>patients with dementia-related psychosis |

## Health News

Noticias en Espai

# 'Off-Label' Drug Use Is Common

### Report ID's 14 Drugs Prescribed for Conditions for Which They Are Not Approved by the FDA

By Salynn Boyles
WebMD Health News

Reviewed by Louise Char

Nov. 24, 2008 -- It is common for doctors to prescribe drugs for conditions they aren't specifically approved for, but in mar cases there is not enough evidence to justify the practice, a new report concludes.

Researchers from Stanford University and the University of Illinois-Chicago identified 14 drugs widely prescribed for so-cal off-label uses that they say are most in need of additional study.

Six antidepressants and three antipsychotic medications made the list, and the most common off-label use for these drugs the maintenance treatment of bipolar disorder.

The antipsychotic drug Seroquel (quetiapine) topped the list. The drug was approved for the treatment of schizophrenia an mania-associated biopolar disorder at the time of the analysis, but the researchers found that three out of four Seroquel prescriptions were written for other conditions.

In May of this year, the FDA also approved the drug for the maintenance treatment of bipolar disorder in patients also taki lithium or divalproex.

The drug's high cost -- averaging about $200 per prescription -- and concerns about an increased risk of death in dementia patients contributed to its No. 1 ranking as a medication that needs further study.

Seroquel is often prescribed off-label for the treatment of depression and anxiety, and researcher Randall S. Stafford, MD PhD, of the Stanford Prevention Research Center tells WebMD that it is often prescribed as maintenance therapy to bipola patients who are not taking lithium or divalproex.

The researchers concluded that the research on antipsychotics for these uses is limited.

### Drugmaker Responds

In response to the report, Abigail Baron, a spokeswoman for Seroquel-manufacturer AstraZeneca tells WebMD that the company does not promote the drug for off-label uses.

It is illegal for pharmaceutical companies to actively market their drugs for uses that they are not specifically approved for, sales reps are allowed to tell doctors about published research that supports these off-label uses.

"Seroquel has helped millions of people suffering from bipolar disorder and schizophrenia and helped many lead more productive lives," Baron notes.

"It is AstraZeneca's policy to promote its medicines in accordance with FDA regulation and to train its sales force to follow policy. We have extensive policies in place to provide direction about the appropriate promotion of our product based upon FDA-approved indications and consistent with FDA regulations."

### Drugs That Need More Study

Stafford agrees that off-label prescribing is an important feature of clinical practice.

But he says many of the most common uses for the drugs identified in his report have not been adequately studied.

There are situations where it makes sense, especially when there are few other treatment options, he says. "But we are t about millions of prescriptions a year, and the size and rigor of the studies that have been done may not justify this."

### Drugs That Need More Study continued...

The blood thinner Coumadin (known generically as warfarin) was included in the report. The drug is widely prescribed for t

treatment of hypertensive heart disease and coronary heart disease, but it is not approved for these uses.

Two other antipsychotics -- Risperidal (risperidone) and Zyprexa (olanzapine) -- also made the list. Both are approved for treatment of schizophrenia, but are often prescribed off-label for the treatment of depression.

The six antidepressants identified in the report included:

- Lexapro (escitalopram)
- Zoloft (sertraline)
- Effexor (venlafaxine)
- Cymbalta (duloxetine)
- Wellbutrin (Bupropion)
- Desyrel ( trazodone)

Once again, the treatment of bipolar disorder was the most common off-label use for most of the antidepressants identifie the report.

The four other drugs identified in the report were:

- The asthma drug Singulair (montelukast), commonly prescribed off-label for chronic obstructive pulmonary disorder (CO
- The arthritis drug Celebrex (celecoxib), with fibromatosis being the most common off-label use.
- The ACE inhibitor Prinivil or Zestril ( lisinopril), most commonly used off label for coronary artery disease.
- The drug Procrit or Epogen (epoetin alfa), approved for anemia in patients with kidney failure, but widely used in patient other chronic diseases.

"We are not trying to say that these uses are necessarily bad," University of Illinois-Chicago economist and study researcl Surrey M. Walton, PhD, tells WebMD. "It is just that there hasn't been enough evidence established for it."

**View Article Sources**



My Notes:

# HHS *NEWS*

*U.S. Department of Health and Human Services*

P98-17
FOR IMMEDIATE RELEASE
June 5, 1998



FOOD AND DRUG ADMINISTRATION
Print Media: 301-827-6242

Consumer Hotline: 800-532-4440


## FDA PROPOSES RULES FOR DISSEMINATION INFORMATION ON OFF-LABEL USES

The Food and Drug Administration today proposed rules allowing greater flexibility for manufacturers to disseminate information -- such as studies published in scientific journals -- about the safety, effectiveness or benefits of "off label" uses for marketed drugs, biologics and medical devices. This information can only be disseminated for "off-label" uses which have been, or will be, studied and submitted for FDA approval. It must also be both reliable and balanced.

When finalized, these rules will implement a provision of the Food and Drug Administration Modernization Act of 1997 (FDAMA) allowing manufacturers and sponsors to impart this information to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, and Federal and State agencies. The proposed rules, which closely track the FDAMA provisions, specify the type of "off-label" or unapproved use information that can be disseminated, and under what conditions it must occur. Under FDAMA, FDA must study its experience with the provision, and the provision will sunset September 30, 2006 or seven years after the final regulation, whichever comes first.

William B. Schultz, FDA Deputy Commissioner for Policy, noted that in the past the concept of allowing manufacturers to disseminate "off-label" information raised concerns about diminishing a manufacturer's incentive actually to develop the safety and efficacy data about these uses that would lead to their approval -- concerns addressed by the legislation and implemented in the proposed rules.

"FDAMA and the new proposed rules tie dissemination of this information to a commitment to do the necessary research on the new uses," Mr. Schultz said. "These proposed rules are intended to implement the statutory provision which will allow health care practitioners to receive information about unapproved uses of approved medications and devices and to stimulate the development of new studies or collection of existing evidence about off-label uses for FDA's review."

Under the proposal, firms or sponsors no longer would have to wait until FDA approves their supplemental application before disseminating certain reliable information about unapproved uses of their products, provided the information:

- concerns a drug or device that has been approved, licensed, or cleared for marketing by FDA;
- is in the form of an unabridged reprint or copy of a peer-reviewed scientific or medical journal article, or an unabridged reference publication, about a clinical investigation that is considered scientifically sound by qualified experts;
- does not pose a significant risk to the public health;
- is not false or misleading;
- is not derived without permission from clinical research conducted by another manufacturer; and
- includes certain disclosures (e.g., that the new use has not been approved by FDA), the official labeling,

and a bibliography of other articles relating to the new use.

The manufacturer also would have to submit to FDA, 60 days prior to dissemination, a copy of the information to be disseminated and other data specified in the proposal.

A firm that has not submitted a supplemental application for the new use could begin disseminating information if it has:

- certified that it has completed the necessary studies and that a supplemental application will be submitted within six months;
- provided an adequate protocol and reasonable schedule for the necessary studies and certified that the application will be submitted within 36 months of the initial dissemination; or
- received an exemption from the requirement to submit an application on the grounds that the necessary studies would be unethical or economically prohibitive.

If FDA determines that the information is not objective and balanced, it can require the manufacturer to include additional objective and scientifically sound information or an objective statement prepared by FDA about the safety or effectiveness of the new use.

Manufacturers would have an ongoing responsibility to provide FDA with additional information about the disseminated new uses, and FDA could order the cessation of the dissemination if the additional information indicated that the "off label" use may not be effective or may pose a significant risk to public health.

Written comments on the proposal, which will soon be published in the Federal Register, should be sent during the next 45 days to:

Dockets Management Branch (HFA-305),
Food and Drug Administration,
12420 Parklawn Drive, Room 1-23
Rockville MD 20857

Under FDAMA, the deadline for issuing a final rule is one year from enactment.

####

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FDA HOME PAGE

**HBOT 1.5 Current Score Card: The Results and Costs of Repairing Our War Veterans' TBI & PTSD Injuries -- April 28, 2009**

**HBOT Stats as of 28 April 2009:** To date, in the HBOT 1.5 National Brain Injury Rescue & Rehabilitation (N-BIRR) effort, led by Dr. Paul Harch at LSU in New Orleans, 26 combat veterans have been treated by four different members of the N-BIRR team with 24 treated with HBOT 1.5 and two veterans treated for broken vertebrae, off-label, with the wound care protocol HBOT 2.0 for 90 minutes. Veterans have been treated from 35 days to 150 days. All have had improvement in the first 40 treatments. There has been one veteran who discontinued treatment because of a pre-existing ear infection. All had clinical improvement.

**Clinical Improvement Status:** Each veteran's clinical improvement has been determined through symptom monitoring, independent functional imaging or neuropsychological testing, plus return of executive function. Each of the 26 combat veterans has demonstrated significant clinical improvement and most have had significant improvement or remission of their PTSD symptoms. For those provided with the full battery of neuropsych tests, the results are: Rivermeade Post Concussion Symptom Questionaire. (Average -37 %Δ. -10% is clinically significant.) PTSD symptoms (Average %Δ = -28, more than clinically significant); Average IQ increase has been 17 IQ points. Most have returned to work or other rewarding pursuits.

**How HBOT 1.5 Works:** Oxygen saturation biologically repairs and causes regeneration of neural tissue and brain structure. HBOT 1.5 is in use at nearly 100 clinics across the nation as standard of care for brain insults and injury. Oxygen is used in over 200 cellular processes, and a lack of oxygen causes cells to go into a protective mode to prevent cellular death. This protective process can keep these cells dormant for years. Hyperbaric oxygen therapy has been shown to reverse this oxygen debt protective mode and restore function to these cells. Unfortunately a medical system failure has left this therapy unrecognized for years.

**Box Score: Casualties Returned to Active Duty Status:** Of the 26 patients, five were still eligible to return to duty after treatment. We are pleased that all five have returned to duty. (The other individuals had already been medically boarded out, or otherwise ended their military obligation. Several on active duty are pending a decision by their medical boards.) One of the five veterans returned to Iraq after treatment and received a Silver Star. He had been freshly injured in the line of duty and on a path to be boarded out of the service before he received off-label HBOT 2.0 treatments for fractured vertebrae and nerve damage from the N-BIRR team. He is testified to Congress March, 26th.

| **Treatment Success By Service: Breakout of HBOT 1.5 Treatments** | | | |
|---|---|---|---|
| **Air Force** | **Army** | **Marines** | **Navy** |
| Casualties 4 | 6 | 14 | 2* |
| Colonel Wright, MD (Eddie Zant, MD) (4) | Paul Harch (3) | Paul Harch (12) | Kraig Dorner, USN, Ret (San Diego, CA) |
| | Walter Reed DC (1) | Florida (2) | * Off-Label Wound |
| | Ken Stoller NM (1) | | Care Protocol HBOT 2.0 |

**Retention Benefit Update:** In the first discussion of the HBOT 1.5 treatment for brain injury and PTSD with ADM Walsh, Vice Chief of Naval Operations, last June 5th, his main concern was how many of his injured veterans could be retained in the service and put back to work. Here is the score thus far.
**As of 27 January 2009 – 5 confirmed and 2 potential as detailed below**

| **HBOT Retention Benefit Status** | | | |
|---|---|---|---|
| **Air Force** | **Army** | **Marines** | **Navy** |
| 3 | 1 | 0 (2 treated) | 1 |

**Costs of Replacing Trained War Veterans**

It costs $20,000 to recruit a new member of the Armed Forces and $35,000 to send them to basic training. Further costs have been incurred to prepare them for combat operations ($100,000 to $150,000), send them through leadership schools, and increase their military skills. SOCOM (Special Forces, SEALS, etc.) cost hundreds of thousands more to train. How much is a senior NCO with 20 years of experience worth, or specialized veterans with technical expertise?

Medicare's payment, on average would be $16,000 if TBI/PTSD treatments were reimbursed. This covers treatments over 150 days with 80 HBOT 1.5 treatments. It costs far less for the military to treat their own injured service members (about $800 per patient for the oxygen.) An airplane pilot costs $5 million to train. Dr. Zant just treated a STO (Special Tactics Officer) whose training costs as much as a pilot. Returning the Naval Academy Graduate SEAL team member, who received a silver star, to duty saved the Federal government far more than $1 million. Not paying the provider the $7,500 owed for the HBOT 2.0 wound care treatment that enabled him to return to Iraq seems short-sighted, particularly so in view of the number of TBI casualties still in the service, many of whom would like to continue to serve.

Recruiting and retention goals in the volunteer armed services have further been hampered by wide publicity associated with untreated casualties returning from theater and being unable to function. Law enforcement, usually a ready source of employment for veterans, has been refusing to hire them because of TBI & PTSD associated with numerous news reports and adverse experience with this veteran population.

| **HBOT Retention Savings (Replacement Cost) to Gov't vs Cost of Treatment** | | | |
|---|---|---|---|
| **Air Force** | **Army** | **Marines** | **Navy** |
| 3<br>2 Airmen: $155,000 ea<br>1 STO: $5 million | 1<br>E-7(P) Helicopter | 0<br>(2 potential in treatment now) | 1<br>Naval Academy Graduate SEAL |
| Replacement Costs $5.03 mil | $596,000 | ($150,000*2=$300,000) | Cost Savings: $706,000 |
| Note: Replacement Costs are Training Costs & Do Not take into account years of service or econometrics of how many Navy personnel, for example, need to be trained to field one qualified SEAL, let alone an E-7 with 20 years of service or qualified Marine or a General officer. [Those metrics will be used as acquired.] Estimates also do not account for the amount to be spent in the future on training a replacement, the cost of replacement of combat experience (priceless), future lost job performance & combat impact, disability payments for life due to unnecessary & premature medical boarding/retirement, & personal, family, & societal costs of the long-term ramifications of untreated TBI & PTSD: unemployment, substance abuse, spousal & child abuse, petty crimes, prison sentences for a range of crimes of violence, & suicide. | | | |
| Unreimbursed Treatment Cost:<br>Zant $35,000 | Harch: $20,000 | (Harch: $40,000) | Dorner: $7,500 |

**Savings to the Gov't: $6.3 million. Medical Treatment Costs Unreimbursed: $62,500**. It is hoped with these demonstrated results, policy makers can find a pathway for HBOT 1.5 reimbursement for those who have recovery. When a treatment consistently restores these casualties to work or duty, it should be fostered and is unlikely to be found a placebo. HBOT itself is paid for by Tricare and VA for 13 other approved indications and is well known to heal non-healing wounds. This therapy is available now and hundreds of casualties could be treated each day. This would restore most of them to functional lives and save millions.

Paul. G. Harch M.D., LSU Hyperbaric Medicine Fellowship Director
Martin Hoffman, former Secretary of the U.S. Army (Gerald Ford)
Dr. William A. Duncan, Capitol Strategy Consultants (below)

For Further Information Contact: Capitol Strategy Consultants, Inc, 46 Draper Circle, Stafford, Virginia 22554-4754, Cell: (703) 505-7530, Fax: (540) 720-7454 wduncan@DC-Strategy.com