

Paul G. Harch, M.D.

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March 6, 2009

Congressman John Murtha  
Chairman, House of Representatives  
Appropriations Defense Subcommittee  
United States Congress  
2423 Rayburn House Building  
Washington, D.C. 20515

Congressman William Young  
Ranking Member  
House of Representatives  
Appropriations Defense Subcommittee  
United States Congress  
2407 Rayburn House Building  
Washington, D.C. 20515

Re: Hearing on TBI and Psychological Health and Off-Label Usage by U.S. Military Medicine of Prescription Drugs with FDA Warning Labels for Increased Suicide Risk.

Dear Chairman Murtha and Congressman Young:

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. Two days ago I learned of the present hearing on TBI and Psychological Health of our brain-injured service members. Simultaneously, an article was published in The Army Times about the 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 off-label usage of the multitude of psychoactive drugs currently prescribed to modulate the symptoms of TBI and PTSD.**

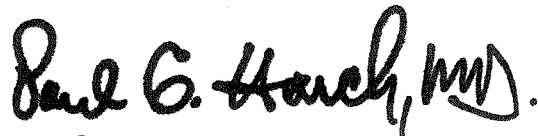
Many of these drugs have black box warnings of increased rates of suicides, specifically the more modern antidepressants. The actual FDA warning reads, "Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in 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 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 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 preliminary results of this study are partly reported in the Scorecard mentioned above and will form the foundation for a larger randomized prospective study on veterans later in the year. This randomized study was funded by a congressional appropriation to LSU from your committee in FY 2009, however to date none of the funds have arrived to assist us in advancing this effort.

Thank you for your attention.

Sincerely,

A handwritten signature in black ink that reads "Paul G. Harch, M.D." The signature is written in a cursive, flowing style.

Paul G. Harch, M.D.  
Clinical Associate Professor,  
Director of the Hyperbaric Medicine Department  
LSU School of Medicine, New Orleans

March 6, 2009

**Cover Sheet for Appendix to Letter from Paul Harch, M.D. to the  
House Defense Appropriation Subcommittee Hearing,  
Tuesday, March 3, 2008**

**There is no drug currently approved by the FDA to treat TBI. The only drug approved for PTSD is Zoloft. 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 was inaccurate. In fact about 90% of psychiatric prescriptions are off-label.**

The following list of drugs are ones that Dr. Paul Harch in New Orleans, who has been treating a number of TBI/PTSD casualties with HBOT 1.5, has found previously prescribed for these patients.

**Neurology**

Alzheimer's

Ebixa  
Neurontin  
Lyrica  
Topamax  
Parkinson's  
Symmetrel

Cymbalta  
Effexor  
Wellbutrin  
Remeron  
Desyrel

Antimanic

Tegretol  
Lamictal  
Eskalith  
Topamax  
Depakote

Antipsychotics

Clozaril  
Zyprexa  
Seroquel  
Risperdal  
Geodon

Abilify  
Lectopam  
Klonopin  
Tranxene  
Valium  
Dalmane

Also

Adderall (Detro  
Amphetamine)  
Dexamethylphenidat  
e (Ritalin, Concerta,  
Methylin)  
Provigil (Modafinil)  
Seraquil  
Resperdo

**Psychiatry**

Antidepressants

Celexa  
Lexapro  
Prozac  
Luvox  
Paxil  
Zoloft

The pages following are from the Physicians Desk Reference for these drugs. Note that a number of them are black labeled by the FDA as 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.)"<sup>1</sup> 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.

<sup>1</sup> DoD "HBOT for TBI" Consensus Conference White Paper, 28 October 2008

## Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
Abilify	Bristol Myers Squibb	<ul style="list-style-type: none"> <li>• Treatment of Schizophrenia in adults and adolescents aged 13 to 17 years</li> <li>• 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</li> <li>• Adjunctive treatment of Major Depressive Disorder in adults as an injection for:</li> <li>• Treatment of adults with agitation associated with Schizophrenia or Bipolar I Disorder, manic or mixed episodes</li> </ul>	<p>Yes - Black Box Warning</p> <p>INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS and SUICIDALITY AND ANTIDEPRESSANT DRUGS</p>
Adderall (Detro Amphetamine)	Shire Pharmaceuticals, Inc.	Adderall is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).	<p>Yes: Black Box Warning on Death</p> <p>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.</p>
Celexa	Forest Pharmaceuticals	<p>Celexa (citalopram HBr) is indicated for the treatment of depression.</p> <p>The antidepressant action of Celexa in hospitalized depressed patients has not been</p>	<p>Yes Black Box Warning:</p> <p>Suicidality and Antidepressant Drugs Increased risk of suicidal thinking and behavior in children, adolescents, and young adults</p>

### Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		adequately studied.	Celexa is not approved for use in pediatric patients.
Clozaril	Novartis Pharmaceuticals	<p>CLOZARIL<sup>®</sup> (clozapine) is indicated for the management of severely ill schizophrenic patients who fail to respond adequately to standard drug treatment for schizophrenia.</p> <p>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.</p> <p>CLOZARIL is indicated for reducing the risk of 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.</p>	<p>Yes - Black Box Warning</p> <p><i>INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS</i></p> <p>CLOZARIL<sup>®</sup> (clozapine) IS NOT APPROVED FOR THE TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS (SEE BOXED WARNING).</p>
Cymbalta	Eli Lilly & Company	<p>Cymbalta<sup>®</sup> is a selective serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for:</p> <ul style="list-style-type: none"> <li>• Major Depressive Disorder (MDD)</li> <li>• Generalized Anxiety Disorder (GAD)</li> <li>• Diabetic Peripheral Neuropathic Pain (DPNP)</li> <li>• Fibromyalgia (FM)</li> </ul>	<p>Yes Black Box Warning:</p> <p>Suicidality and Antidepressant Drugs Increased risk of suicidal thinking and behavior in children, adolescents, and young adults</p> <p>Cymbalta is not approved for use in pediatric patients</p>
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	

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Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		<p>awakening.</p> <p>Dalmane can be used effectively in patients with recurring insomnia or poor sleeping habits, and in acute or chronic medical situations requiring restful sleep.</p>	
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	<p>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:</p> <p>Alcoholism, Anxiety, Insomnia, Panic disorder. (<a href="http://mental-health.emedtv.com/desyrel/desyrel-uses-p2.html">http://mental-health.emedtv.com/desyrel/desyrel-uses-p2.html</a>)</p>	<p>Yes, Black Box Warning:</p> <p>Antidepressants (including Desyrel) may increase the risk of suicidal thinking or behavior in children, teenagers, and adults</p>
Dexmethylphenidate  Focalin  Ritalin (Methylphenidate) Concerta, Methylin)	Novartis Pharmaceuticals Corporation	<p>Attention-deficit/hyperactivity disorder (ADHD) Narcolepsy.</p> <p><b>Controlled Substance and can lead to dependence.</b></p>	<p>Yes: Black Box Warning on Sudden Death, Potential for Abuse</p> <p>Warnings for Amphetamine, Dextroamphetamine, Lisdexamfetamine dimesylate, Methamphetamine, Mixed Salts of a Single Entity Amphetamine Products Adderall, Adderall XR, Desoxyn, and Dexedrine (SR)</p> <ul style="list-style-type: none"> <li>• High abuse/diversion potential: Amphetamines</li> </ul>

### Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
			<p>have a 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.</p> <ul style="list-style-type: none"> <li>• Drug dependence: Administration of amphetamines for prolonged periods of time may lead to drug dependence and must be avoided.</li> <li>• Serious Adverse Events: Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events</li> </ul> <p>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.</p> <p>Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD.</p> <p>Increased Blood Pressure and Heart Rate: have been reported.</p> <ul style="list-style-type: none"> <li>• Psychotic Symptoms: may be exacerbated in patients with psychotic disorders</li> </ul> <p>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)</p> <ul style="list-style-type: none"> <li>• Emergence of New Psychotic or Manic Symptoms: Treatment-emergent</li> </ul>

## Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
			<p>psychotic or manic symptoms without a prior history can be caused by stimulants at usual doses.</p> <ul style="list-style-type: none"> <li>• Aggression: Monitor for appearance of or worsening of aggressive behavior or hostility</li> <li>• Long-Term Suppression of Growth: monitor height and weight in pediatric patients at appropriate intervals.</li> <li>• Seizures: The threshold for seizures may be lowered.</li> </ul> <p>Serious methylphenidate side effects include suicidal thoughts.</p>
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).	<p>Yes: <b>Black Box Warning</b></p> <p>Suicidality and Antidepressant Drugs Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, teens, and young adults.</p> <p>EFFEXOR XR® (venlafaxine HCl) is not approved for use in children and teens.</p>
Eskalith	By Cardinal Health for GlaxoSmithKline	<p>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.</p> <p>Typical symptoms of mania include pressure of speech, motor hyperactivity, reduced need for sleep, flight of ideas, grandiosity, elation, poor judgment, aggressiveness and possibly</p>	

### Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		hostility. When given to a patient experiencing a manic episode,	
Geodon	Pfizer	Schizophrenia Bipolar Mania Acute Agitation in Schizophrenic Patients	<b>Yes: Black Box Warning:</b> 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 ( $\geq 2$ years of age). Bipolar	<i>Yes: Clinical Worsening and Suicide Risk Associated with Bipolar Disorder:</i>  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 should not be used in individuals with	<b>Yes: Black Box Warning</b>  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
		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	<b>Yes: Black Box Warning</b>  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	<b>Yes: Black Box Warning</b> 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: <ul style="list-style-type: none"> <li>• Neuropathic pain associated with diabetic peripheral neuropathy (DPN)</li> <li>• Post herpetic neuralgia (PHN)</li> <li>• Adjunctive therapy for adult patients with</li> </ul>	<b>Yes:</b> Reports of Suicide in Clinical Trials Suicide was a reported adverse event during the development research - it was considered a rare event.

### Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		partial onset seizures • Fibromyalgia	
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.  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.	Yes: <b>Black Box Warning:</b>  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.  PAXIL CR is not approved for use in pediatric patients.
Provigil (Modafinil)	Cephalon Inc.	PROVIGIL® (modafinil) Tablets [C-IV] are	Yes: Suicide Ideation has been reported

## Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		<p>indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome, and shift work sleep disorder.</p>	<p>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.</p> <p>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.</p>
Prozac	Eli Lilly & Company	<p>Prozac® (fluoxetine capsules, USP and fluoxetine oral solution, USP) is a psychotropic drug for oral administration. Prozac is indicated for the treatment of</p> <ul style="list-style-type: none"> <li>• Major depressive disorder</li> <li>• Obsessive Compulsive Disorder</li> <li>• Bulimia Nervosa</li> <li>• panic disorder, with or without agoraphobia</li> </ul> <p>It is also marketed for the treatment of premenstrual dysphoric disorder</p>	<p><b>Yes: Black Box Warning:</b></p> <p>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.</p>
Remeron (Mirtazapine)	Organon (Schering Plough)	<p>REMERON® (mirtazapine) Tablets are indicated for the treatment of major depressive disorder.</p>	<p><b>Yes: Black Box Warning:</b></p> <p>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</p>

## Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
			disorders. REMERON® is not approved for use in pediatric patients.
Risperdal	Janssen Pharmaceutica	RISPERDAL® is an atypical antipsychotic agent indicated for: <ul style="list-style-type: none"> <li>• Treatment of schizophrenia in adults and adolescents aged 13-17 years</li> <li>• 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</li> <li>• Treatment of irritability associated with autistic disorder in children and adolescents aged 5-16 years</li> </ul>	Yes: <b>Black Box Warning</b> WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS 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.
Seraquil	Astra Zeneca	Bi polar Disorder	Yes: <b>Black Box Warning</b> 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	Yes: <b>Black Box Warning</b> :  Elderly patients with dementia-related psychosis treated

## Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		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.	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 <u>anticonvulsant</u> drug. following <u>seizure</u> types: Partial seizures with complex symptomatology (psychomotor, <u>temporal lobe</u> ). Patients with these seizures appear to show greater improvement than those with other types. Generalized tonic-clonic seizures ( <u>grand mal</u> ). Mixed seizure patterns which include the above, or other partial or generalized seizures. Absence seizures ( <u>petit mal</u> ) do not appear to be controlled by Tegretol  Trigeminal Neuralgia Tegretol is indicated in the treatment of the pain associated with true	Yes: <b>Black Box Warning - Death</b>  SERIOUS AND SOMETIMES FATAL DERMATOLOGIC REACTIONS, INCLUDING TOXIC EPIDERMAL NECROLYSIS (TEN) AND STEVENS-JOHNSON SYNDROME (SJS), HAVE 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

## Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
		<p>trigeminal <u>neuralgia</u>. Beneficial results have also been reported in glossopharyngeal neuralgia.</p> <p>This drug is not a simple <u>analgesic</u> and should not be used for the relief of trivial aches or pains.</p>	<p>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.</p> <p><b>APLASTIC ANEMIA AND AGRANULOCYTOSIS</b> APLASTIC ANEMIA AND AGRANULOCYTOSIS HAVE BEEN REPORTED IN ASSOCIATION WITH THE USE OF TEGRETOL.</p>
Topamax Topiramate	Ortho-McNeil Pharmaceutica	<p>Monotherapy Epilepsy in patients 10 years of age and older with partial onset or primary generalized tonic-clonic seizures.</p> <p>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.</p> <p>Migraine TOPAMAX® (topiramate capsules) Sprinkle Capsules are indicated for adults for the prophylaxis of migraine headache.</p>	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.	<p>Yes both in treatment and withdrawal</p> <p>In those patients in which a degree of <u>depression</u> accompanies the <u>anxiety</u>, <u>suicidal</u> tendencies may be present and protective measures may be required.</p>

### Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
Valium	Roche Laboratories	<p>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.</p> <p>In acute alcohol withdrawal, Valium may be useful in the symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis.</p> <p>Valium is a useful adjunct for the relief of skeletal 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.</p> <p>Oral Valium may be used adjunctively in convulsive disorders, although it has not proved useful as the sole therapy.</p> <p><b>Schedule IV Drug with DEA - may produce psychological and physical dependence.</b></p>	<p>Yes Suicide Risk is Present</p> <p>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.</p> <p>Psychiatric and paradoxical reactions are known to occur when using benzodiazepines. stimulation, restlessness, acute hyperexcited states, anxiety, agitation, aggressiveness, irritability, rage, hallucinations, psychoses, delusions, increased muscle spasticity, insomnia, sleep disturbances, and nightmares.</p> <p>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.</p>
Wellbutrin Bupropion <i>Zyban</i>	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	<p>Wellbutrin is an antidepressant medication.</p> <p>Wellbutrin is used to treat major depressive disorder and seasonal affective disorder.</p> <p>At least one brand of bupropion (Zyban) is used to help people stop smoking by reducing cravings and other withdrawal effects.</p>	<p>Yes: <b>Black Box Warning</b> WARNINGS-Clinical Worsening and Suicide Risk</p> <p>It should be noted that WELLBUTRIN is not approved for use in treating any indications in the pediatric population</p>

### Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
Zoloft	Pfizer	<p>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</p> <p>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</p> <p>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.</p>	<p>Yes: <b>Black Box Warning</b></p> <p><b>Suicidality:</b> 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 &gt;24 yo, and risk decreased in pts &gt;65 yo; observe all pts for clinical worsening, suicidality, or unusual behavior changes; not approved in pediatric pts except for obsessive compulsive disorder</p>
Zyprexa	Eli Lilly & Company	<p>ZYPREXA (olanzapine) is a psychotropic agent that is indicated for the treatment of schizophrenia, acute mixed or manic episodes associated with Bipolar I Disorder. maintaining bipolar patients</p>	<p>Yes: <b>Black Box Warning</b></p> <p><b>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.</b></p>

### Drugs Being Prescribed for PTSD and TBI Patients

Drug Name	Manufacturer	Label Indications	Suicide or Increased Mortality Risk
			ZYPREXA (olanzapine) is not approved for the treatment of patients with dementia-related psychosis

Better information. Better health. [com/news/20081124/off-label-drug-use-common](http://www.webmd.com/news/20081124/off-label-drug-use-common)

## Health News

Noticias en Espa

### '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](#)Reviewed by [Louise Char](#)

WebMD Health News

Nov. 24, 2008 -- It is common for doctors to prescribe drugs for conditions they aren't specifically approved for, but in many 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-called 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 was the maintenance treatment of [bipolar](#) disorder.

The antipsychotic drug [Seroquel](#) (quetiapine) topped the list. The drug was approved for the treatment of [schizophrenia](#) and [mania](#)-associated bipolar 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 taking 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 bipolar 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, but 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 that 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 talking 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 identified in 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 (COPD).
- 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 patients with other chronic diseases.

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

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# HHS NEWS

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

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## **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 Veterans' TBI & PTSD Injuries -- January 30, 2009**

**In the Spirit of the Game:** Navy came out on top in the annual Service Academy football rivalry, beating both Army and Air Force in winning another in its series of the Commander-in-Chief's Trophy Awards. Air Force was next in gridiron victories in this competition. .

While the score card for recovering our military TBI casualties through the HBOT 1.5 program has a different impact than academy football fortunes, it should still stir a gathering but vital competitive excitement. Similar excitement of the possibilities for hyperbaric therapy was demonstrated at the Navy's "Consensus Conference" which took place on 2008 Army-Navy weekend. Air Force is winning in HBOT-treated war casualties returning to duty, with Army & Navy tied. But the Doctors who treated them have footed the costs.

**HBOT Stats as of 30 January 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, 16 combat veterans have been treated by four different members of the N-BIRR team with 15 treated with HBOT 1.5 and one veteran treated for broken vertebrae, off-label, with the wound care protocol HBOT 2.0 for 90 minutes. One active duty Marine just finished treatment at LSU and another who began treatment last week is showing improvements after just 8 treatments.

**Clinical Improvement Status:** Each of these veteran's clinical improvement status has been determined through symptom monitoring, independent functional imaging and neuropsychological testing, plus return of executive function. Each of the 16 combat veterans has demonstrated significant clinical improvement. Most have had significant improvement or complete remission of their PTSD symptoms; most have returned to work or other rewarding pursuits.

**Box Score: Casualties Returned to Active Duty Status:** Of the 16 patients, five were still eligible to return to duty after treatment. We are pleased that all five have returned to duty. (The other 11 individuals had already been medically boarded out, or otherwise ended their military obligation.) 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 one of the N-BIRR team.

<b>Treatment Success By Service: Breakout of HBOT 1.5 Treatments</b>			
<b>Air Force</b>	<b>Army</b>	<b>Marines</b>	<b>Navy</b>
Casualties 3	5	7	1*
Colonel Wright, MD (Eddie Zant, MD) (3)	Paul Harch (3)	Paul Harch (7)	Kraig Dorner, USN, Ret (San Diego, CA)
	Walter Reed DC (1)		* 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 5<sup>th</sup>, 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**

<b>HBOT Retention Benefit Status</b>			
<b>Air Force</b>	<b>Army</b>	<b>Marines</b>	<b>Navy</b>
3	1	0 (2 currently in treatment)	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?

It costs on average \$16,000 to successfully treat a brain in career combat veterans in 120 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.

<b>HBOT Retention Savings (Replacement Cost) to Gov't vs Cost of Treatment</b>			
<b>Air Force</b>	<b>Army</b>	<b>Marines</b>	<b>Navy</b>
3 2 Airmen: \$155,000 ea 1 STO: \$5 million	1 E-7(P) Helicopter	0 (2 potential in treatment now)	1 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 & <u>Do Not</u> 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: 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)

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