

Testimony

“Neurological Treatments with Hyperbaric Medicine
will save billions in
Government Health Care, Disability and Education Costs”

The International Hyperbaric Medical Association

Paul Harch, M.D.

President



Before the

Labor, Health and Human Services and Education Subcommittee

Of the Committee on Appropriations

United States House of Representatives

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CONGRESSIONAL TESTIMONY OF PAUL G. HARCH, M. D.,
APRIL 27, 2004
UNITED STATES HOUSE OF REPRESENTATIVES
APPROPRIATIONS SUBCOMMITTEE ON
LABOR, HEALTH, HUMAN SERVICES, AND EDUCATION

Dear Chairman Regula, Mr. Obey and other distinguished members of the Committee, thank you for the opportunity to address the Subcommittee on Labor, Health, Human Services, and Education once again. I am reporting on the progress of my research and practice which is repairing brain injured individuals and returning them to work, school, and productive life in a cost-effective manner. As you are well aware the number of Americans who struggle daily with the residual effects of stroke, traumatic brain injury, toxic brain injury, cerebral palsy, Alzheimer's Disease, drug abuse, and all other forms of brain injury is in the tens of millions with millions more added each year. Internationally the figure is in the hundreds of millions. As you may also be aware, there is virtually no effective treatment, let alone cost-effective treatment, for these conditions.

The toll in personal suffering and secondary effects on family members, loved ones, and other caregivers is staggering and inestimable. Your committee directly funds these programs from research to Social Security Disability and IDEA at the Department of Education. There are estimated to be 6.8 million children on IDEA, many of whom would benefit from this treatment. You are spending \$8,165 per child at a cost this year of \$11 billion for FY 2004. That is just 20% of what the states are spending. You are all spending that next year and year after year. I estimate that 20% of these children can be brought to "near normal" status for between \$8,000 and \$16,000 and most of the rest could be significantly improved with the treatment I am testifying about today. That means you won't be paying for these children when they become eligible for TRIO or Social Security Disability and you may prevent them from entering prison due to treatment of their dysfunction. Next week I'll be testifying with other IHMA board members to Mr. Burton's committee regarding a new and very effective autism protocol.

The actual financial cost is also formidable and compounded by the effects on the economy from lost productivity of both the patients and family member caregivers. For just one diagnosis, traumatic brain injury, the acute and chronic costs for 1995 were estimated at \$55 billion dollars (Thurman DJ. Epidemiology and Economics of Head Trauma. In: Miller L and Hayes R, eds. Head Trauma Therapeutics: basic, preclinical and clinical aspects. New York, NY: John Wiley and Sons, 2001). We can likely cut that by 20-50%.

In the past 15 years through my work and the work of others it has become apparent that hyperbaric oxygen therapy is a cost-effective generic drug for repair of acute and chronic brain injury (Harch PG and Neubauer RA. Chapter 18, Hyperbaric Oxygen therapy in Global Ischemia, Anoxia, and Coma. In: K.K. Jain, ed. Textbook of Hyperbaric Medicine, 3rd Edition. Seattle, WA: Hogrefe and Huber Publishers, 1999: 319-345). In acute brain injury the initial insult, regardless of cause, is responsible for only a minority of the subsequent injury and disability. The great majority of the brain damage results from the secondary effects of the injury cascade called reperfusion injury that are largely mediated by the inflammatory reaction, that ubiquitous response to any

injury to human tissue. While there are peculiarities to human brain tissue and its response to injury the overall sequence of events is very similar to the inflammatory reaction anywhere else in the body such as in a bruise to muscle, a heart attack, broken bone, or infection. In now multiple studies in different animal and human models of different types of injuries involving different organs the effect of a single high pressure exposure to hyperbaric oxygen therapy (HBOT) within a few hours of the injury has been the same, namely, a dramatic reduction in injury severity. In other words, the scientific literature suggests that the most powerful drug for treating the vast majority of acute injuries to the human body is one pressurized dose of oxygen to saturate the body's tissues. That dose appears to have a generic effect regardless of the cause of the injury or its location in the body (Harch PG. Generic Inhibitory Drug Effect of Hyperbaric Oxygen Therapy (HBOT) on Reperfusion Injury (RI). *Eur J Neurol*, 2000;7(Suppl 3):150).

Today, in emergency rooms everywhere, we are giving drugs to improve blood flow and reduce clotting so that more oxygen can get into the brain, with all of the complications and side effects those treatments carry. Using this HBO Therapy, we simply put the oxygen where we want it rather than hoping that other mechanisms will get it there. A perfect example of this is the landmark study done by Dr. Rockswold and colleagues in Minnesota. Over a six year period in a randomized controlled experiment Dr. Rockswold found that patients with acute severe traumatic brain injury who were treated with HBOT approximately 24 hours after injury experienced a 50-60% reduction in death compared to the controls who did not receive HBOT (Rockswold GL, et al. Results of a prospective randomized trial for treatment of severely brain-injured patients with hyperbaric oxygen. *J Neurosurg*, 1992;76(6): 929-934). Dr. Rockswold has followed these patients for over 12 years and reported to me privately that the HBOT treated patients have achieved higher levels of neurological function than those who received standard care. If this could be documented it would likely reveal a reduction in cost of care for these patients.

To give a few additional examples, the same effect of HBOT in acute traumatic brain injury has also been demonstrated in pediatric birth injury and resuscitation from cardiac arrest. The potential for this therapy in pediatric brain injury is especially appealing since children have their entire lives in front of them; a significant brain insult at the outset of life is extremely disabling and costly over a lifetime. Forty-one years ago Dr. Hutchison reported in the world renowned medical journal, *The Lancet*, that one high pressure dose of HBOT to babies who were born not breathing and had failed resuscitation attempts resulted in 54% of the children discharged from the hospital "apparently well." (Hutchison JH, Ker MM, Williams KG, Hopkinson WI. Hyperbaric oxygen in the resuscitation of the newborn. *The Lancet*, 1963;2:1019-1022). In other words, 54% of would-be dead babies were resuscitated and discharged from the hospital apparently well after all attempts to salvage them were exhausted. With modern medicine we are also able to resuscitate many of these babies, but few of them are discharged from the hospital well. What allows the better outcome for HBOT resuscitated babies is the effect of HBOT on reperfusion injury described above. Similarly, my senior partner, Dr. Keith Van Meter, has shown that he can resuscitate nearly 90% of juvenile piglets 25 minutes after cardiac arrest with one high pressure HBOT (Van Meter KW, Sheps SS, Swanson HT, Wilson JP, Barratt DM, Kodu U,

Roycraft EL, Moises JP, Nolan TA, Harch PG. A controlled prospective randomized open chest cardiopulmonary resuscitation (CPR) pilot comparing use of 100% oxygen in mechanical ventilation of swine at one, two, and four atmospheres ambient pressure after a 25 minute normothermic cardiopulmonary arrest at one atmosphere. *Annals of Emergency Medicine* 1999;34(4, Pt. 2):S11). This research was spawned from Dr. Van Meter's successful resuscitation of a drowned commercial diver who had a similar 25 minute delay to medical care (Van Meter K, Weiss L, Harch PG. Chapter 36, *Hyperbaric Oxygen in Emergency Medicine*. In: K.K. Jain, ed. *Textbook of Hyperbaric Medicine*, 3rd Edition. Seattle, WA: Hogrefe and Huber Publishers, 1999: 556-589). The obvious potential for this therapy worldwide in human cardiac arrest, birth injury, and myriad other similar conditions is beyond comprehension.

Similarly, the evidence that HBOT is beneficial in chronic brain injury is continuing to accumulate. In my previous testimony of May 2, 2002 I presented 15 patients with chronic brain injury of a variety of different causes whose lives have been significantly improved by HBOT. As a follow up on a few of those patients I would like to report that the Alzheimer's patient continues to respond to courses of HBOT despite the downhill progression of the disease. It appears that the disease process has been slowed by the HBOT, but HBOT has only a partial effect. The patient is expected to undergo testing for mercury toxicity to see if additional therapies can be added to the HBOT to maintain his level of function. The 23 year old traumatic brain injury and substance abuse patient is now happily married with children and maintaining steady employment. This individual had been totally incapacitated by frequent migraine headaches and cognitive dysfunction. His headaches are now mild and controllable with Excedrine Migraine formula and he maintains cognitive improvement. The 21 year old female traumatic brain injury rape victim has been promoted and continues to function at a high level in her high-pressure job that requires good executive function. The 44 year old mental retardation patient rarely experiences seizures, has been promoted at work, has matured his relationship with his family, and continues to function at a higher level than anyone believed possible. He is now capable of living semi-independently. The three year old autistic child has made additional socialization progress and was recently featured on a New Orleans news program. Lastly, the 48 year old traumatic brain injured patient is functioning more efficiently at a higher level of performance in his position as a congressional aide. That patient, Dr. William Duncan, is right here sitting in the congressional staff section today.

To illustrate the potential cost effectiveness of HBOT in chronic brain injury I wanted to present three demonstrable cases. The first patient is a 47 year old single mother of four who was completing her master's degree program in social work when she was hit by a drunk driver. She sustained a traumatic brain injury that two and one half years later prevented her from returning to work, completing her degree program, and caused great difficulty managing her family. I evaluated her clinically, with SPECT brain imaging, and psychometric testing. The testing showed a very abnormal brain blood flow scan and cognitive functioning significantly below her pre-injury level of performance. Following a 6 week course of HBOT repeat testing demonstrated a 40% improvement in memory scores and generalized improvement in brain blood flow. I subsequently hired her to assist me in this work and to test her ability to perform cognitively. After four months she applied for and was hired as the coordinator of an

NIH funded grant at Louisiana State University Medical Center where she remains today. She recently helped me complete an NIH grant application to further this work. In summary, a six week course of HBOT returned a totally disabled adult to productive employment. The benefit to this patient is the salvage of her life; the benefit to society is a return of a productive adult to the workforce, a positive contributor to the community, a taxpayer to the government, and an effective mother to her family. The cost was approximately \$8,000, not even the cost of one year of Social Security Disability.

The second case is a 72 year old demented man who after the death of his wife was facing institutionalization. He began to have confusional episodes at night where he couldn't recognize family members and at one point took off all his clothes and chased his terrified grandchildren through the house. In trying to relocate to his son's home in another state over a four week period of time he became lost on three occasions and found himself admitted to hospitals for various medical problems, including dementia. He was evaluated with SPECT brain imaging and hyperbaric oxygen therapy and after a six week course of treatment experienced global cognitive improvement. His dementia score improved 45% along with his energy level, behavior, chronic obstructive pulmonary symptoms, and overall level of function. He now lives with his son who works full-time. Essentially, a 72 year old man who was to require 24 hour/day nursing care has been elevated to a level of function that preserves his quality of life and prevented a massive government expenditure. All for about \$7,000.

The third case is a seven year old boy with a difficult birth that was the likely cause of his subsequent persistent developmental delay and autistic behaviors. Extensive medical evaluation over the years identified no treatable disease and the family was left with a child who required 24 hour/day one-on-one attendance. The birth injury resulted in global cognitive/learning problems, speech difficulty, emotional outbursts, attention deficit, and in-coordination. The boy was taking powerful psychoactive drugs, Ritalin and Prozac, to barely control his inappropriate and self-abusive behavior. He was evaluated in New Orleans with SPECT and hyperbaric oxygen therapy and after a four week course of treatment he was successfully permanently weaned from the Ritalin and Prozac. His father reported that "the attention deficit is 1000% improved and the emotional outbursts and autistic tendencies 100,000%." The child has now advanced in school and sports and no longer requires his previous degree of care and supervision. The improvement in the quality of life for this child and his family and the impact on his future, coupled with the savings in future government caretaking, are beyond description. Again, all for about \$6,000.

These cases are dramatic, possibly miraculous, but not necessarily unusual. Many other individuals have experienced similar improvements in function with HBOT years after their brain injury. Some diagnoses respond to a greater degree than others, however, early intervention has the potential to return function to a large number of individuals in a cost effective manner.

This is not anecdotal evidence, as your committee's report language has reflected in years past. Your staff has been provided with 44 peer reviewed articles on acute traumatic brain injury alone. When Mr. Istook arranged for me to present diabetic foot wound treatment to CMS two years ago, I used 129 peer-reviewed animal and human scientific citations to show we could reduce diabetic foot amputations by 75% with this therapy. Today as a result, Medicare now covers this treatment and is saving \$130,000 in

cost to the system for each series of amputations for about \$7,000 worth of therapy. That is a significant savings to your budget Mr. Chairman. As you are aware, we are spending 26.5% of the entire Medicare budget on diabetes and its complications.

I am humbled to say that I have been nominated by Bob Livingston for the NIH Director's Pioneer Award. I also have two grants pending before the National Institute of Neurological Disorders and Stroke. One is an acute stroke trial that we strongly suspect will vastly improve stroke patient outcomes and reduce the cost of caring for patients. The other is a chronic brain injury study to demonstrate for NIH what I've been doing for over 14 years in my medical practice and have replicated in an animal model soon to be published.

Hopefully funding from the NIH will help further convince the medical community of the effectiveness of this therapy and lead to its eventual more widespread application. Even if they do not fund these studies, we will continue this work through the International Hyperbaric Medical Association Foundation, a 501(c)3 research and education organization. We have parents, patients and others contributing sums like \$10 per month to this work because they know from first hand experience that this therapy works and want to see it available to everyone.

The IHMA Foundation is currently working with Oklahoma University where we have established the John Eisenberg Chair for Evidence-based Medicine and the John Eisenberg Treatment Registry for off-label use of FDA-approved drugs and devices. We will also be conducting training at the Medical School in treating neurological and other conditions, like diabetic foot wound for physicians and licensed medical personnel who wish to learn how to do these treatments.

Lastly, Mr. Chairman, when I appeared before your committee 2 years ago, it was just over the date nearly 40 years ago when on March 7, 1962, Dr Claude R. Hitchcock testified before this committee. Representative Winfield K. Denton of Indiana presided. As a result of this committee's efforts, the NIH funded millions to build hyperbaric centers used for the first open heart surgeries around the country. They were built at places like Duke and Stanford, etc. Unfortunately the other uses were never fully developed. For instance Senator Dirksen was treated for his emphysema (COPD) and had improvement. His schedule and the distance to a chamber prevented him from getting further treatment. We are working on a treatment protocol that will arrest COPD in place and recover use of a significant amount of lung tissue for these patients.

Unfortunately the knowledge gained from these efforts in the 1960s was lost and forgotten. Since there is no patent on oxygen there was no money tree to drive further research into this inexpensive therapy. It is extensively used in the former Soviet Union, China, and Japan because it is so inexpensive and effective. There has never been a patent on this prescription drug and its cost remains low.

Thank you for this opportunity to testify and I'll be happy to answer any questions.

BIO OF PAUL G. HARCH, M.D.

Paul G. Harch, M.D. is an emergency and hyperbaric medicine physician who graduated magna cum laude and Phi Beta Kappa from the University of California, Irvine in 1976, with a Bachelor of Science in biology, and subsequently, Johns Hopkins University School of Medicine in 1980 with an M.D. He has worked 19 years in hospital-based emergency medicine and 17 years in hyperbaric and diving medicine. He is board certified in emergency medicine and hyperbaric medicine. His primary interest has been hyperbaric oxygen therapy (HBOT) based/SPECT brain imaging indexed neuron rehabilitation.

Dr. Harch has adapted the concepts of hyperbaric oxygen therapy in shallow perfusion gradient wounds to hypometabolic tissue and shallow perfusion gradient wounds in the central nervous system. His first application of HBOT to the central nervous system began with divers with chronic brain decompression sickness in 1990. The improvements in divers were extended to chronic traumatic brain injury and stroke in 1990, 1991, 1992, and then the first cerebral palsy and autistic children treated with HBOT in North America in 1992, 1993, 1994, and 1995. This first North American application to brain injured children resulted in the propagation of HBOT for brain injured children to South Florida, England, Canada, the United States, and internationally. In the past 14 years he has treated nearly 200 children and 200 adults afflicted with over 50 different neurological conditions, including rare and genetic disorders. Dr. Harch confirmed the human experience in an animal model of chronic traumatic brain injury in 1996. The results were replicated in January, 2001 in a larger number of rats with more powerful statistics. This is the first ever demonstration of improvement of chronic brain injury in an animal model in the history of science.

As a result of his work, Dr. Harch has become recognized as one of the foremost authorities in the United States on hyperbaric oxygen therapy for neurological applications. He is the national coordinator and co-principal investigator of the HOTFAST (Hyperbaric Oxygen Therapy for Acute Stroke Trial). In 2001 he completed a study on SPECT brain imaging in toxic brain injury. In May, 2002 he presented 15 cases from his practice to the U.S. Congress' House of Representatives Appropriations Subcommittee on Labor, Health, Human Services, and Education. He is the first President of the newly formed International Hyperbaric Medical Association (IHMA) and recently established International Hyperbaric Medical association Foundation. He has lectured widely, including at the National Institutes of Health in February 2001 and has presented his work at numerous scientific meetings.

He currently divides his time between a hyperbaric medicine clinical practice, primarily devoted to neurological applications, animal and human research, and teaching as Clinical Assistant Professor and Director of the Louisiana State University School of Medicine Hyperbaric Medicine Fellowship Program and Medical Director of the Hyperbaric Medicine Unit at Medical Center of Louisiana in New Orleans, as well as being President of the International Hyperbaric Medical Association and the International Hyperbaric Medical Association Foundation.

Disclosure

Dr. Harch and the International Hyperbaric Medical Association and the International Hyperbaric Medical Association Foundation receive no federal funds. As the President of the International Hyperbaric Medical Association, he has had extensive contact with various Federal and State agencies including the Food and Drug Administration, the Agency for Health Care Research and Quality, the Centers for Medicare and Medicaid Services, and the National Institutes of Health on hyperbaric medicine treatment applications and policy.

Requested Report Language for FY2005 supported by Representative Ernest Istook

Hyperbaric Oxygen Initiative

In accordance with report language from the committee in previous years, the Office of the Director is encouraged to coordinate a hyperbaric oxygen research initiative in coordination with the International Hyperbaric Medical Association, the International Hyperbaric Medical Association Foundation, the American College of Hyperbaric Medicine, and the Undersea and Hyperbaric Medical Society. The NIH is encouraged to work with these three groups to examine widespread use of oxygen saturation technology and treatment for various manifestations of reperfusion injury, such as in blunt trauma and crush injuries, smoke inhalation, organ transplantation, limb reattachment, and before and after surgical procedures involving tourniqueting of extremities: peripheral arterial bypass procedures, amputations, orthopedic procedures, plastic surgery procedures, flap and graft procedures, etc. Investigation of this treatment for hemorrhagic shock, multiple-trauma injury and multiple-trauma crush injury is also indicated based upon animal and clinical research already conducted. Such an initiative should also include the examination of the results of a single before and after hyperbaric treatment for surgery patients. The treatment of surgery patients in this manner could result in significant cost reductions, and both long-term and short-term results should be examined.

In addition, the International Hyperbaric Medical Association has extensive expertise in the use of hyperbaric oxygen treatment for acute, subacute, and chronic brain injuries, such as traumatic brain injury, stroke, toxic brain injury, brain injuries from substance abuse, air embolism, dementia (including Alzheimer's disease), carbon monoxide poisoning, pediatric neurological injury (which would include autism, cerebral palsy, and multiple other childhood neurological disorders), and the broad spectrum of neurological disease. The office of the director is encouraged to work with researchers from this association to explore the short- and long-term cost reduction impact of low-pressure hyperbaric oxygen therapy for these chronic disabling neurological conditions. In addition, the office of the director is requested to explore the cost-saving potential and improved efficiency of single hyperbaric oxygen therapy treatments before and after cardiac surgery which involves heart-lung bypass, and hyperacute hyperbaric oxygen therapy for the entire group of brain injuries that follow global ischemia and anoxia and which are characterized by reperfusion injury. This group of brain injuries includes near-drowning, near-hanging, cardiac arrest, electrocution, suffocation, anesthesia anoxia, perinatal brain injuries (resuscitation at birth, birth apnea, etc.), and other acute brain injuries resulting from cessation and subsequent resumption of cerebral blood flow. The initiative should examine both the clinical applications of these methods and the underlying mechanisms of action taking place as a result of this inexpensive treatment.

The NIH Director is encouraged to coordinate this initiative across all the appropriate institutes and encourage NICHD to examine this with brain-injured children in the Education Department's IDEA program.