Testimony

"Announcement of a New Treatment Protocol for Autism Spectrum Disorders and other Neurological Impairments"

The International Hyperbaric Medical Association Foundation

Paul Harch, M.D.

President

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Entitled

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International Hyperbaric Medical Association Foundation
46 Draper Circle, Suite B Stafford, Virginia 22554-4754
Office: 540-720-3844 Fax: 540-720-4837

TESTIMONY OF PAUL G. HARCH, M.D
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GOVERNMENT OVERSIGHT COMMITTEE
SUBCOMMITTEE ON HEALTH AFFAIRS
CHAIRMAN, DAN BURTON

Chairman Burton and distinguished members of the Subcommittee, thank you for the opportunity to present the findings of my research and practice on the hyperbaric oxygen therapy (HBOT) treatment of children with autism, autism spectrum disorders, and persistent developmental delay. These findings will hopefully be encouraging, and when coupled with the testimony of the other physicians, exciting. Together we would like to suggest a new approach to the acute treatment of the insults that predispose to these disorders as well as the delayed treatment when the disorder is well established.

The key announcement today is about an evidence-based medicine study that will combine two treatments that have been found to be effective in treating autistic children – mercury detoxification and hyperbaric oxygen. The IHMA Foundation is collaborating with the American Board of Clinical Metal Toxicology (ABCMT) under the supervision of the Oklahoma University Health Sciences Center on this revolutionary new treatment for autism. The Institutional Review Board (IRB) approved protocol will use transdermal DMPS chelation and hyperbaric oxygen. Transdermal DMPS, with absorption through the skin, has a number of advantages over oral, IV, or injected chelation which enhances its effectiveness. After several months on the transdermal chelator, hyperbaric oxygen treatments will be administered using the Neubauer-Harch dive protocol, and then after another time period has elapsed, the second set of HBOT treatments will be administered.

The transdermal chelator will continue to be used until the next set of hyperbaric treatments is applied. It is expected that the combination of the two therapies will double the effectiveness of the chelator and allow the hyperbaric oxygen to cause permanent neural recovery. All patients enrolled in the study will have extensive before and after neurological scans and neuropsych testing performed by independent observers, and all will receive real treatment. After all, no placebo group is necessary when you know the outcome for untreated patients. By definition neither oxygen or the chelator can be a placebo since both have known effects as a drug.

Rashid Buttar, DO, whom you just heard testify, developed this transdermal chelator and has had excellent success with the treatment of over 40 patients. Dr. Buttar is one of the Board members of the IHMA Foundation and also Vice Chairman of the ABCMT.

Dr. Buttar's treatment has clear and demonstrable effects as we can all see here today. The older a child is, however, the more difficulty they have clearing their brain. Bob Nash, MD, Chairman of the ABCMT is a neurologist and certified in chelation and hyperbaric medicine. He explained that you often have to 'pound away' with chelation at patients for a long time because the neurons are stunned and do not have proper metabolism, so they cannot clear the heavy metals and cells cannot pick up the chelate. The addition, hyperbaric treatments kick start the neurons and 'light them up' so when the chelator is present it becomes easier to eliminate the heavy metals that are preventing the neuron's normal function. We expect this combination of therapies to shorten the time that these patients will have to be treated, returning them to more

normal status more quickly, and also result in a more complete recovery than if they had each individual treatment by itself.

Dr. Nash came to this conclusion when he examined the brain scans of several of my patients where I used a scan-dive-scan diagnostic to determine recoverable brain tissue. I will cover this evidence in just a moment.

This treatment is available now on a limited basis. Due to collaboration between the IHMA Foundation, Oklahoma University Health Sciences Center, and the treating physicians who have developed this therapy, we expect it to be available in many locations across the nation later this year. After that we expect it to become the standard of care for all autistic children, nation-wide.

Consider that Wisconsin is spending $30,000 in tax dollars on each autistic child per year right now in a special "training program," with a 3 year cost of $90,000 that still leaves children autistic at the end. The outcome is some behavioral improvement. Our treatment program is expected to cost about $20,000 and result in children who can function normally. We expect the states to adopt this protocol quickly and help fund the general treatment for these children once they see the results of this study.

Amongst the nearly 400 brain injured patients that I have evaluated and treated in the past 15 years with HBOT and SPECT are approximately 20 children with Autism, Autism Spectrum Disorders, and Persistent Developmental Delay. When evaluated with the sequence of SPECT, one HBOT, repeat SPECT I have found that these children's' brain blood flow pattern improves and predicts permanent improvement with additional HBOT similar to the boxers, divers, and patients with other diagnoses. This change in blood flow after one HBOT is clearly demonstrated in the 8 year old Persistent Developmental Delay/Autism patient I presented to Chairman Regula and which I present again today. His three dimensional brain scans are seen in the attached Case 1.

In addition, I have included two other cases, Cases 2 and 3. In all three cases you seen an improvement in brain blood flow and hence, metabolism, after one HBOT or a course of HBOT that was matched by an improvement in their autistic symptoms and behaviors. One child was able to be weaned from the powerful psychoactive drugs Ritalin and Prozac, and improve his emotional outbursts, autistic behavior, ability to play sports, and attend school. Another child whose autistic behavior was causing a significant emotional disturbance with inhibition of school performance in her six year old sister began to interact with her sister and family more normally with a resultant improvement in the sister and family unit. The third child experienced improvement in attention, understanding, sleep, vocabulary, inappropriate behavior, and emotional state.

Unfortunately, HBOT did not "cure" any of these patients but all of them improved remarkably. This is partly due to the great delay in application of this therapy and the fact that I didn't know Dr. Buttar when I treated these patients. Many physicians who treat with the Neubauer-Harch low-pressure hyperbaric protocol and some form of chelation have reported that the combination works better than either of the two therapies alone. I firmly believe that the combination of these two therapies will yield tremendous results in these patients, especially in those children who develop normally only to have a deterioration to autism by 2-5 years of age.

This approach is exactly what we will be following in our planned study through the IHMA Foundation's Treatment Registry. We're anxious to get started and can treat about 100 children for about $2 million. We are working to raise these funds now.

In the past 40 years a steadily accumulating body of animal and human research has led to the conclusion that the appropriate application of hyperbaric oxygen therapy to human and animal disease is a vast untapped inexpensive health resource with limitless potential. This is no surprise when one considers that the basis for all human life is oxygen, the vast majority of human illnesses have as their root pathophysiology an absence of blood flow and oxygen to tissues, and the restoration of oxygen in all of these conditions makes common sense. Thanks to this research and literature, it now also makes good scientific sense. Unfortunately, for a variety of political non-scientific reasons these simple facts have been lost on the medical profession often leading to the deplorable situation where patients have to become their own doctor in order to treat themselves with this life-saving and life-improving therapy.

To give you a few examples of the phenomenal potential of HBOT, I would like to quote from my testimony to Chairman Regula's House Appropriations Subcommittee on Labor, Health, Human Services, and Education last week, "…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)." The benefits of HBOT in acute injury are most demonstrable and dramatic in the treatment of acute brain injuries, collectively the condition which is responsible for the vast majority of disability and human suffering and the condition for which doctors have been traditionally "brainwashed" that there is no treatment. For example, HBOT successfully resuscitated over half of a group of 65 babies in England born not breathing who failed standard resuscitation. (Today, sadly, the only way one can procure this therapy is if you are a high priced newborn thoroughbred racehorse in Kentucky or Florida whose racing future is jeopardized by birth injury from lack of oxygen and blood flow.)

In humans this application has never advanced beyond the original scientific report in 1963. Similarly, the great majority of 336 acute coma and cardiac arrest patients in China and 170 near-hanging patients in Northern France were successfully resuscitated with a single high pressure HBOT. HBOT delivered shortly after these brain insults seemed to work identically to the manner in which it has worked all of these years in the classic accepted application of HBOT, decompression illness of divers (Harch PG. Late Treatment of Decompression Illness and Use of SPECT Brain Imaging. In: Treatment of Decompression Illness, 45th UHMS Workshop, Eds. RE Moon, PJ Sheffield, Undersea and Hyperbaric Medical Society, Kensington, MD. 1996). Specifically, it treats the common major underlying problem called reperfusion injury, or the injury that occurs once blood flow and oxygen are restored.

Another exciting example of the use of HBOT is the combination of hyperbaric oxygen therapy with radiation therapy in the treatment of cancer patients. It has been shown the kill ratio of cancer cells by radiation is directly proportional to the oxygen content of the tissue. What more obvious common sense method to increase the oxygen content of tumors than by the administration of hyperbaric oxygen therapy? So thought researchers 35 years ago in New Orleans where some of this seminal work was performed. In just the past three years doctors in

the Far East have delivered radiation therapy to patients with one of the most deadly of all cancers, brain cancer, within 15 minutes of exit from a hyperbaric oxygen chamber and shown an approximately 50% increase in survival. Marlo Thomas, the famous actress and benefactor of St. Jude's Medical Center in Memphis, Tennessee recounted to Chairman Regula immediately before my testimony last week how the researchers at St. Jude's are desperately seeking and hope to develop new therapies for the treatment of brain cancer in children with the addition of a new $80 million brain cancer center.

As I mentioned to Chairman Regula, that treatment of yesterday is here today; it is hyperbaric oxygen therapy. Interestingly, and seemingly paradoxically, this same treatment that is potentially so effective acutely in combination with radiation therapy is by far the most effective therapy for treatment of the late effects of radiation therapy. In now 67 of 74 worldwide studies on HBOT in the treatment of radiation injury to multiple different areas and organs of the human body the results were strongly positive (Feldmeier JJ, Hampson NB. A Systematic Review of the Literature Reporting the Application of Hyperbaric Oxygen Prevention and Treatment of Delayed Radiation Injuries; An Evidence Based Approach. Undersea and Hyper Med, 2002;29(1):4-30.

While we have evidence for the great potential of HBOT in acute injury my concern today is for the millions of individuals in the United States and hundreds of millions of individuals worldwide who suffer from chronic brain injury of all types. Given the information above about the nature of acute brain injury, namely, the deprivation of oxygen and blood flow, and the common underlying process of secondary injury in so many of these conditions, it is no surprise that many chronic conditions, especially of the brain, are characterized by low oxygenation and blood flow. In l990 I realized that we could treat this chronic injury by discovering that a lower dose of HBOT pioneered in South Florida by Dr. Richard Neubauer in stroke and multiple sclerosis patients could be successfully applied to, once again, the classic accepted condition for HBOT, decompression illness of divers.

I found that divers who had failed standard United States Navy HBOT or divers who presented weeks to months after their diving accident with decompression illness of the brain could be permanently improved neurologically, cognitively, and emotionally and return to a functional high quality life. My partners, Drs. Keith Van Meter and Sheldon Gottlieb, simultaneously were proving this in brain injured boxers. With these two doctors I then extended the findings in divers to patients with now over 50 different neurological conditions using SPECT brain blood flow imaging before and after a single HBOT to predict which patients had injured brain tissue that could respond to a course of HBOT.

This pattern of response first seen in a stroke patient of Dr. Neubauer's and then in the boxers and divers was yet another generic response to HBOT that I identified in the vast majority of the fifty additional diagnoses, including the first cerebral palsy case in North America (Harch PG, Gottlieb SF, Staab P, Van Meter KW. HMPAO SPECT Brain Imaging and Low Pressure HBOT in the Diagnosis and Treatment of Chronic Traumatic, Ischemic, Hypoxic, and Anoxic Encephalopathies. Undersea and Hyper Med, 1994;21(Suppl):30. In other words, if one HBOT could change the pattern of brain blood flow in a neurologically abnormal patient to a more normal pattern, this was evidence that that injured brain could positively and permanently respond to a course of HBOT.

In summary, Chairman Burton, we have a treatment, right now, for autism, that combines these two proven therapies. It produces demonstrable results as you have seen today. We also have a treatment for acute and chronic brain injury that is so simple, giving oxygen, specifically hyperbaric oxygen, as to be astounding that is not more universally applied in the field of medicine. Given the research and experience to date and its potential application to autism I do not hesitate to tell you that HBOT will revolutionize the treatment of brain injury in the world.

Thank you for this opportunity.

Paul Harch, M.D., President
International Hyperbaric Medical Association Foundation