

# XIV INTERNATIONAL CONGRESS ON HYPERBARIC MEDICINE

October 2-5, 2002 San Francisco, California, USA

www.ichm.net

# President's Message

It is a great pleasure and honor to write my first President's Message and invite everyone to the XIV International Congress on Hyperbaric Medicine, to be held in San Francisco, California, October 2-5, 2002.

This will be the third time that the Congress has met in the United States. The III Congress was held in Durham, North Carolina in 1965 under the leadership of Professor Brown of Duke University. The VIII Congress was held in Long Beach, California in 1984 with President Jacobson presiding. It therefore seems appropriate that with 19 years between the first two in the USA, the third will follow at an 18 year interval.

San Francisco was the site of a pioneer HBO symposium in 1974 under the direction of Dr. Jefferson Davis and Dr. Thomas Hunt. This resulted in the publication of a landmark textbook which clearly advanced the specialty of Clinical Hyperbaric Medicine in the United States. Dr. Hunt continues to practice surgery and wound healing research at the University of California-San Francisco and remains the world's top authority on the role of oxygen in wound healing and infection.

It therefore seems appropriate to convene the International Congress in the City-by-the-Bay. October is the best month of the year in San Francisco, with sunny days which are not too hot and without rain - almost guaranteed by the local chamber of

commerce.

The venue will be the elegant five star hotel, the Westin St. Francis. This was the first world class hotel built west of the Mississippi River in 1904. Destroyed but still standing following the earthquake of 1906, it was rebuilt in it's original splendor and continues to this day as the premier hotel in the city. Located in the heart of the shopping and theatre district, all scientific sessions will be held in the hotel.

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A preliminary schedule has been arranged. On Tuesday night, **October 1st**, a reception for international delegates will be held in the famous Compass Rose cocktail lounge just off the lobby. The next day, **October 2nd**, Professor Marroni of Italy will preconduct a postgraduate course entitled "Introduction to Hyperbaric Medicine". It will provide an overview of the field in lecture format and is intended for individuals who are new to the specialty. It will serve to enhance understanding during the subsequent three the days of scientific papers.

A formal reception will follow the postgraduate course on Wednesday evening on the top (32nd) floor of the new building. The view of the city at night is fantastic and will be an appropriate start for the Congress.

Thursday morning, **October 3rd**, will be the official opening ceremonies. Following a short (promise) Presidential Address, the Invited Boerema Lecture will be given by Professor Bakker of the University of Amsterdam. Dr. Bakker was a protege of Professor Boerema during the early days of Hyperbaric Medicine in the Netherlands. It is a great honor that he has accepted this invitation. The Boerema Lecture is certain to be a highlight of the Congress.

Scientific sessions will follow in the morning and afternoon. Dr. Paul Sheffield has kindly agreed to be the Scientific Program Chairman and will organize an outstanding program. On Thursday evening the delegates and guests will depart from Pier 33 for an evening dinner cruise on the Hornblower Yacht. The San Francisco Bay is the largest natural harbor in the world and many of us believe - the most beautiful. The captain will sail under the Golden Gate Bridge as we enjoy the sunset - a truly memorable evening.

The next day, Friday, **October 4th**, will offer a one-half day of scientific sessions. The afternoon and evening will be free. Tours will be arranged to the famous wine country of Sonoma and Napa Valleys as well as San Francisco and the most popular tourist destination, Alcatraz Island. Visits to local HBO facilities will also be available to the delegates.

A poster session will begin the scientific sessions on Saturday morning, **October 5th**. Paper sessions will follow in the morning with a full afternoon of scientific papers also scheduled. A gala banquet, with surprise San Francisco entertainment, will provide a suitable closing ceremony for the Congress. Dr. Jordi Desola, President-elect for the next Congress in Barcelona in 2005, will be recognized to welcome everyone to his country.

A post Congress study tour of United States hyperbaric facilities is also planned. It will begin by chartered bus from the St. Francis Hotel on Sunday morning, **October 6th**. The group will proceed south along the California coast road with the first evening at the Hearst Castle. The next day will include two nights at the Disneyland Hotel with visits to two important hyperbaric venues. The tour will then travel overland to Flagstaff, Arizona and the Grand Canyon. Following this will be visits to prominent hyperbaric facilities in Las Vegas, Nevada. The final evening will be spent enjoying the fantastic sites of Yosemite

National Park in California. The study tour will conclude with a drop-off at the San Francisco International Airport or the

St. Francis Hotel.

October is the prime tourist season in San Francisco. The Congress has negotiated a 30% discount on a 250 room block at the Westin St. Francis Hotel which will be given out on a first come basis to delegates. The reservations will be accepted by the hotel starting October 1, 2001. Everyone is encouraged to plan ahead and reserve their rooms early. Of course, everyone must be registered with the Congress to receive the reduced room rate. The annual Clinical Congress of the American College of Surgeons will convene immediately following the ICHM

in San Francisco, October 6-11. This will be an added advantage for those hyperbaric physicians who wish to attend the premier United States surgical meeting of the year.

Further details will be posted on the website of the Congress, www.ichm.net, as they become available. The official language of the Congress will be English. The past Congresses held in Fuzhou, China in 1993 and Kobe, Japan in 1999 brought to my attention the sometimes difficulty in understanding English by our Asian colleagues. I am therefore pleased to announce that an educational grant has been requested from the Oxygen Research Foundation which will provide simultaneous translation of the papers into Chinese and Japanese. Of course, this is not yet certain, but I am optimistic that it will happen.

Finally, I am pleased to announce that Life Members of the congress will be offered a priority, guaranteed, advance registration with a \$50 discount. This will serve as a small thank-you for the generous support of the Foundation by our Life Members.

I look forward to seeing all of you at the XIV International Congress in San Francisco. Please plan to bring your family as well.

Fred Cramer, President XIV International Congress on Hyperbaric Medicine 1592 Union Street San Francisco, California 94123, USA



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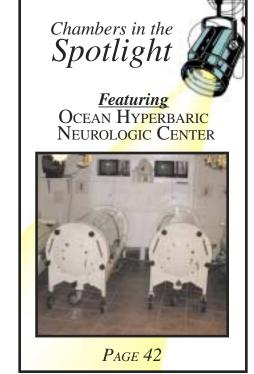


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#### LETTERS TO THE EDITOR

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# LETTERS FROM OUR READERS

#### Hyperbaric & Brain Injury Legislation in Texas

I support this worthwhile and needed legislation with personal knowledge, after being Director of Hyperbaric Medicine and Wound care at the two largest hospitals in Corpus Christi. In about 1983, Memorial Hospital, the former city county hospital for Nueces County was one of 11 hospitals in the United States to treat the Multiple Sclerosis patients free of charge for a period of one year, on an investigational protocol. In all, I have treated about 200 MS patients during the past 18 years with very gratifying results. My experience in acute strokes, CP, ALS and other neurological diseases is limited, but, it is pretty obvious to me that there has got to be benefits if you understand basic anatomy, physiology, biochemistry, and pathology and also have the knowledge of how hyperbaric oxygen works! I am a retired Flight Surgeon, and Submarine and Diving Medical Officer and have been working with HBO for the past 32 years. Sincerely,

Billy J. Blankenship, DDS, MD Captain, Medical Corps, US Navy (Ret) Corpus Christi, Texas 78418 bjblanks@aol.com

## Reimbursement for HBOT in Cerebral Palsy

I have been preparing for my final appeal for reimbursement for HBOT. This has been a 2-year battle. Twice I have appeared before a panel to state my case. Both times they tabled my case because they needed to review all the information I submitted or get an outside opinion.

I received a letter from Blue Cross Blue Shield again, stating their denial of payment based on the latest information I submitted. This is what they said:

- 1) There is no sound scientific evidence that hyperbaric oxygen is effective in the treatment of cerebral palsy.
- 2) We consider procedures or services to be investigational if they are under study or in clinical trial to evaluate toxicity, safety, or efficacy for a particular diagnosis or set of indicators. The prevailing opinion within the appropriate specialty of the United States medical profession is that the service or supply needs further evaluation for a particular diagnosis or set of indications before it is used outside clinical trials or research settings.
- 3) BCBS's medical policy is based on the review of nationally accepted guidelines and standards of practice, BCBS Association technical evaluations, Peer-reviewed, published scientific literature, consultations with experts in the specific policy area, including practicing physicians and information from appropriate government regulatory bodies.

I am asking for those of you "in the know"

how I should respond to the above. My plan of attack is to challenge them that they do pay for services that lack the double-blind peer reviewed criteria. Also I am going to try and say that I am simply using HBO as an off label use. I believe the argument is simply, does BCBS pay for things that lack the double-blind peer reviewed criteria? (Yes) and on what basis are services paid for or denied?

Anyone, who has any ideas or help, please contact me. Here is a fitting quote from Voltaire "It is dangerous to be right in matters in which the established authorities are wrong".

I believe the established authorities are wrong. Enjoying the Journey,

Kevin Bals 73 Spring Lake Garden Court Spring Lake, NJ 07762 Phone: 732-449-1244 kbals@rocketmail.com

I am an emergency physician in NY and I have two questions:

Is the antabuse effect of flagyl significant in HBOT?

I saw a study last year or so that concluded that there was probably no benefit to HBOT in CO poisoning; have there been any more definitive studies?

Thanks, Ronald Shaw RONALDPSHAWMD@aol.com

Dear Dr. Shaw:

Although metrondazole has an antabuse effect in a patient drinking alcohol, there is no evidence in the literature that it has an effect of inhibition of superoxide dismutase production like antabuse does. In fact, one article suggests that metronidazole has an anti-oxidant effect by improving neutrophil response to reactive oxygen species. There is no scientific data I know of to state that it is either hazardous OR safe to use in the hyperbaric environment. Common usage would suggest, however, that a fair number of patients with metronidazolesensitive infections are probably treated in hyperbaric chambers around the country while taking the drug. I would welcome comments from anyone who has seen an oxygen toxicity related event that could be attributed to metronidazole.

And now for the \$64,000 question. I assume that your comments about the carbon monoxide efficacy are prompted by the press that Scheinkestal's article received in the Medical Journal of Austraila. That article prompted a significant response not only in the journal where it was published, but in others as well. Multiple faults were found in the methodology of the study, grouping of patients, and psychometric testing, among other things.

There was a recent Cochrane Review of hyperbaric oxygen for carbon monoxide poisoning. Their conclusion is that "there is no evidence that unselected use of HBO in the treatment of acute CO poisoning reduces the frequency of neurological symptoms at one month. However, evidence from the available randomized controlled trials is insufficient to provide clear guidelines for practice. Further research is needed to better define the role of HBO, if any, in the treatment of carbon monoxide poisoning."

This is, I believe, a fair statement. The medical community is divided between those of us (mainly hyperbaricists) who feel that HBO is beneficial [the believers], and those who feel it is not useful [the heritics]. The problem, as evidenced in a survey published in Undersea & Hyperbaric Medicine a few years ago, is that even where HBO treatment is performed, there is tremendous variability in the time and pressure used for treatment. Some programs used their standard wound protocol (2.4 ATA for 90 minutes), some used the US Navy Treatment Table 5, and some used a so-called CO Treatment table (3 ATA for 80 minutes or some other variable of time). Hyperbaric programs also had widely different thresholds to determine when a patient received treatment with so much discrepancy in the hyperbaric treatments used, it is obvious that amassing a large amount of treatment data is difficult. A more recent article, although biased towards

hyperbarics, stated, "hyperbaric oxygen established, an although inconclusively proven, treatment option." My personal feeling is that, as our hyperbaric research community further delineates the mechanisms of cellular toxicity and other actions of CO and standardizes the treatment (time/pressure), we may have a better handle on the complete picture. For now, based on what I know and the results I see, I will continue to treat my severely poisoned CO patients with HBO, (acknowledging that there is no clearly accepted definition of 'severely' in our literature).

Thomas M. Bozzuto, D.O. President, American College of Hyperbaric Medicine

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#### **Billing Ouestion**

I am a physician running a free standing hyperbaric oxygen therapy center and we are unable to get payment from Medicare for the covered services i.e. wound healing, osteomyelitis, and failed grafts. I just found the new code c1300 on your message board. Is this the correct code? I'm told that the technical component is billed through Medicare part A, which can only be billed as a hospital. Is this true? Anybody have any suggestions?

Thanks. ASPIEGE1@TAMPABAY.RR.COM

C1300 is the new HCPCS number. Status Indicator is #S. # is "New technology **APCs** (range 0970-0984)" S is "Significant procedure, not discounted when multiple" This information can be downloaded directly from the HCFA web site

http://www.hcfa.gov/medicare/itemelig.xls

#### **HBOT** and **CP** in Fort Worth, TX

In August we started a trial treating children with cerebral palsy with HBOT. We started with motor skills testing on twenty children and are treating them five at a time. We continue to follow the patients waiting to get in the chamber so the kids waiting for therapy act as a "control" although it is not a blinded study. The therapy is 60 treatments of HBOT at 1.5 ATA for 60 minutes. It takes more than 12 calendar weeks to finish a group through 60 treatments so we have just finished our second group. We had two drop out prior to HBOT for personal reasons. So far we have put PE tubes in everyone but with the third group we are going to try to do it without tubes. We talked to Dr. Neubauer in Florida and he does not put tubes in any of his patients. This would significantly reduce the cost to us for the therapy. Since this is a study, our patients are paying nothing out of pocket. Things we have learned so far if and when we do a larger study - placebo controlled blinded. I would make the next group mainly kids less than 8 or 10 years old with spastic CP. The spasticity seems to be the thing that HBOT benefits the most. We need to have a better diagnosis of CP. Some parents say their kids have CP when it is really some congenital / chromosomal abnormality. There needs to be a better measure of spasticity. This may not be invented yet. Muscle spasticity seems to get better. However with each growth spurt the spasticity gets worse again so HBOT may need to be repeated.

Alvin Mathe, DO

Asst. Professor, Dept. of Internal Medicine University of North Texas Health Science Center at Fort Worth.

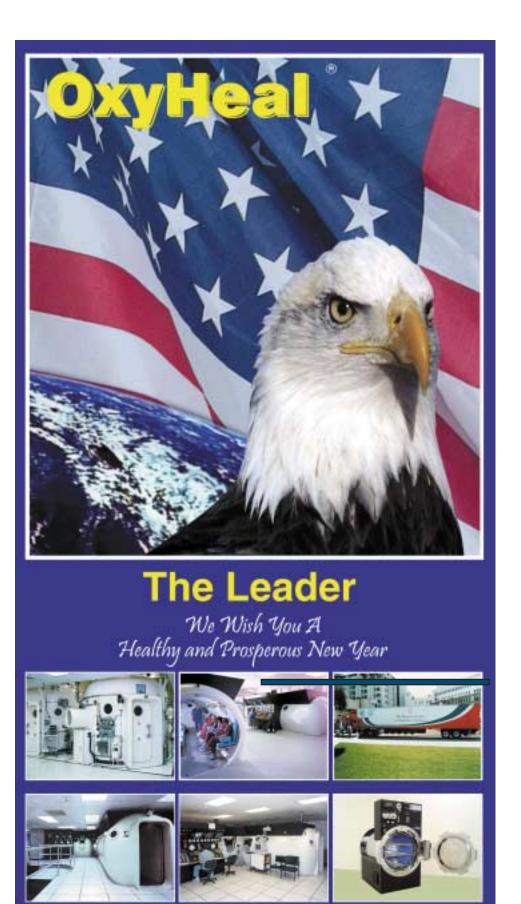
amathe@hsc.unt.edu

#### My daughter is undergoing HBO for petitmal seizures

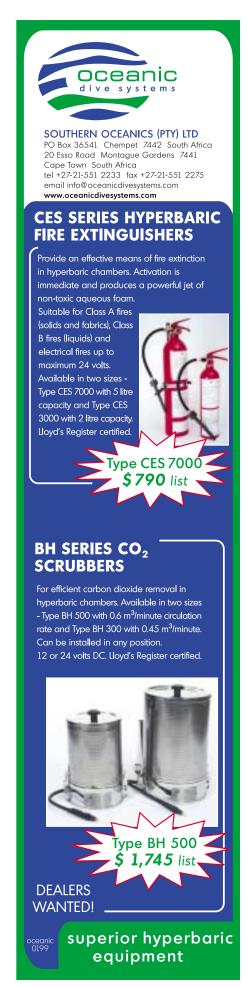
My daughter Rachael is 13 years old and we just found out that she has petit mal seizures along with brain damage, either from anoxia at birth or undiagnosed seizures. My D.O. prescribed 100 hours of HBOT. So far we haven't got the insurance company to pay. How does that work? So far my daughter has shown improvement and we want to continue with treatments.

Please let me know any inside secrets that will get the insurance to cover this. Thank you for your time.

Jamie Nelson JNelsonPeace@aol.com



OxyHeal Health Group, U.S.A.



Dear Ms. Nelson:

This is indeed a timely question because there is now a growing grassroots movement starting to approach the problem of reimbursement for HBOT in treating neurological disorders on a State-by-State basis. The first State to pass such a law is Texas (HB 1676) which went into effect on September 1, 2001. The need for such legislation is obvious; insurance companies will not pay for any therapy they don't have to pay for, and no one is making them pay for treating neurological conditions with HBOT, so they don't. In the case of the Texas bill, the wording is nonspecific, "A health benefit plan may not limit or exclude coverage for cognitive therapy, neuropsychological testing or treatment, or community reintegration activities necessary as a result of a traumatic brain injury." As you can read there is no mention of HBOT, but Texas law has something called legislative intent, and in the case of HB 1676, almost all the testimony on behalf of the legislation was from proponents of HBOT. I have just started working on a Bill I would like to see introduced in New Mexico, but my State does not have "legislative intent," so we must make the wording very specific, for example, the below is how I propose the wording of the New Mexico Bill would start off: "COVERAGE FOR NEUROPSYCHOLOGICAL TESTING AND TREATMENT

A. Each individual and group health insurance policy, health care plan and certificate of health insurance delivered or issued for delivery in this state shall provide coverage for Hyperbaric Oxygen Therapy, neuropsychological testing or treatment, or community reintegration activities necessary as a result of either a traumatic brain injury or any other disorder affecting the central nervous system, including but not limited to stroke, cerebral edema, cerebral palsy, multiple sclerosis, anoxic encephalopathies, any other autoimmune or other disease affecting the central nervous system." I can e-mail the proposed New Mexico Bill on request (info@simplyhyperbarics.com) to any interested reader, but it should be obvious that we have to be very specific with the wording. Most brain-injured children are Medicaid recipients, and according to Title XIX of the Social Security Act, as described in 42 U.S.C. §1396 (a)(43), Medicaid-participating states must provide to eligible minors under the age of 21 certain mandatory medical services including Early and Periodic Screening, Diagnostic, and Treatment Services (EPSDT). Also, in paragraph (5) of the EPSDT statute found in 1396d(r), is a requirement that States provide "such other necessary health care, ...treatment and other measures...to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan." The Medicaid law for children (the EPSDT), is found at 42 USC § 1396d(r), and can be found on the internet at:

http://caselaw.lp.findlaw.com/casecode/ uscodes/42/chapters/7/subchapters/xix/ sections/section%5F1396d.html

Paragraph 5 is the most relevant for Hyperbaric Oxygen Therapy. Ten years ago Paragraph 5 was added, it reads "(5) Such other necessary health care, diagnostic services, treatment, and other measures to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan." It is no typographical error that "medically necessary" is not found in Paragraph 5. The authors knew that it can take as long as 10 or 15 years before a treatment, procedure, drug, or device could be categorized as "medically necessary." Therefore the language of Paragraph 5 provides the opportunity for the EPSDT statute to create its own definition of medical necessity based on whether the service is necessary to correct or ameliorate a defect or condition. In the case of Hyperbaric Oxygen Therapy, the efficacy of the treatment can be verified by objective scientific analysis of SPECT-scan imaging before HBOT and after a certain number of treatments. Incidentally, Medicaid was created by, Lyndon Baines Johnson specifically for brain-injured children. When it was created in 1967, President Johnson stated "The problem is to discover, as early as possible, the ills that handicap our children. There must be continuing follow-up and treatment so that handicaps do not go untreated." (13 Congressional Record 2883. February 8, 1967). I would like to believe that State Medicaid offices are more interested in enabling brain-injured children than in perpetuating disability, but the only way to find out is to request coverage for HBOT on a State-by-State basis.

Kenneth Stoller, MD, FAAP Medical Director of Simply Hyperbarics Santa Fe, New Mexico www.simplyhyperbarics.com

#### Sickle Cell Anemia

Do you have any information on HBOT and sickle cell anemia? Does it help?

Debbie Cone djcone@intellisys.net

A review of the literature will show several papers published on HBOT & sickle cell conditions. We will be posting a collection of various papers on conditions treated with HBOT and sickle cell anemia will be one of them. We will also be running an article on HBOT & sickle cell anemia in the very near future.

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This letter to our readers is by far the hardest I have ever had to write, for many reasons. The first is my most heartfelt apology to all of our readers and advertisers for our lengthy delay. Without your support this publication could not have been possible. As a small company tasked with many projects and limited funds we have definitely over-extended our capabilities as far as production and timing. We will not sacrifice quality or in-depth coverage of our field just to produce something in print. It is my deepest desire that our readers can understand the need for such a publication and bear with us through our infancy as we develop into a more reliable and timely publication that brings our field closer together through truth and awareness.

The second hardest thing about delivering this issue is that it spans some of our world's darkest days. The terrorist attacks on America brought the world to a stand still as everyone everywhere focused on their most important assets, their families and livelihoods for a safe tomorrow. Our publication is no different. After securing our families' safety we started prioritizing our goals, schedules, and obligations to our readers and advertisers. I was in the air on the morning of September 11th bound for Austin, TX to work on the

implementation rules for the new brain injury law in Texas. While this meeting was rescheduled and ultimately helped lead to the new rules, it all seemed a distant second to the events unfolding around us. We are committed to this field and indebted to all of you as we strive to bring you the latest news and information (even if it must be by e-mail to expedite its delivery).

When the Brain Injury Legislative meeting finally convened on October 2, 2001, we started crafting the rules for implementation of the new law on Brain Injury. The newly formed International Hyperbaric Medical Association (IHMA) was proud to be a part of this rule-making process to help Texans receive quality health care. I was present; representing the IHMA and working to keep the law focused on patient care instead of further research projects. While our field can definitely stand to gain from quality research, the Governor signed this Bill into Law and Texans have a right to receive the best quality of care available under the laws of their state. I can only hope that other state legislators will follow the examples set by the great leadership of Texas State Representatives, Lon Burnam and Harryette Ehrhardt, as they broke new ground in quality, cost effective health care. New Mexico, Mississippi, California, and Florida all have people working to enact similar laws.

One of the hottest topics since our last issue has been a yet unpublished report by the UHMS Ethics Task Force. This report was scheduled to print in its entirety this issue but legal matters over the copyright of the manuscript have prevented us from doing so at this time. This ground-breaking report has several recommendations coming from the UHMS that will be helpful to the entire field. I have been in contact with the Editor of the UHMS journal as well as several committee members and all have assured me that they are printing the paper in their very next issue. I look forward to its release so we can all better understand and deal with the ethical dilemmas we face in our field. From conducting research trials to getting new "off label" indications approved, this report outlines several recommendations that could help to bring about positive change for our field.

As the hyperbaric community plans to descend upon San Francisco for the 14th International Congress on Hyperbaric Medicine, I look forward to seeing our international colleagues come together in a professional forum and present their scientific findings for all the world to share. From our shared experiences will come new advancements and questions. We will no doubt leave the Congress better informed and ready to face future challenges based on the findings presented. This meeting is scheduled to have a much-anticipated debate on the science behind HBOT and neurology. This of course will be a standing room only presentation as leaders from around the world come forward.

If there is anything I have learned from our extreme delay on this issue, it is that this journal needs more time and space to print each issue. To that end we are switching to a 72 page minimum layout and a quarterly schedule. Both of these changes will be easier targets to achieve with our continued collaboration of readers, commercial supporters, and generous personal contributors. This next volume will have several specialty sections such as Surgery, Infectious Disease, Environmental Medicine, and Neurology. By expanding our size we can also broaden our content base to include a larger range of topics. As we expand our topics we will need to expand our authorship. If you have considered publishing information from your center or if you have viewpoints you would like to express, please contact us and let us know your thoughts.

We have weathered hard times and have learned many lessons, now it is time to enact our education and make HMT a better publication. If I have not said it enough already let me say it here again, I personally bear all responsibility for this issue being so late and ask for your continued support to make our field better informed. Many good things are on the horizon for this medical community and this journal is here to make sure we all stay informed.

The future of hyperbaric medicine is in our hands and we can shape our future just as Sir Alexander Fleming did with Penicillin, Dr.s O'Shaughnessy, Latta, and Lewins did with IV Fluids, and Dr. Semmelweiss did by simply washing his hands. A quick lesson in medical history would remind us that "it is impossible to learn what we think we already know".

Thank you for enduring the hardships of our journal. Please stay with us and help us to see a new and improved field of hyperbaric medicine. Most importantly, welcome back to Hyperbaric Medicine Today.

Kink Locklan



# Hyperbaric Oxygen Therapy and Direct-to-Consumer (DTC) Advertising: How We May Benefit

By: Roque R. Wicker, CHT

Hyperbaric oxygen therapy for the most part has remained a nearly unknown treatment in the world of western medicine. There may be many reasons for this, but none more important than the lack of awareness on the part of both physicians and the general community. With the advent of the information age, numerous websites are providing more and more information on hyperbaric oxygen therapy. This growth of information is making consumers more aware of therapies available for various health concerns through the Internet. Although this is a good thing, the fact remains that hyperbaric oxygen therapy is still as unfamiliar a treatment as it was prior to the birth of the information age.

What else can be done to bring about the awareness of HBO? Are we doing everything we can to increase the awareness of this therapy?

Instead of answering these questions myself, I looked to what the pharmaceutical companies are doing to promote their prescription medications. Since 1997 direct-to-consumer (DTC) advertising of prescription medications has been the key element in the success of the pharmaceutical industry. With reported returns as low as 21 percent and as high as 116 percent, DTC advertising has proven to be the trump card of the pharmaceutical companies. In this article we will explore the benefits and possible risks of direct-to-consumer (DTC) advertising and what effects it could have on the hyperbaric community as a whole if we choose to employ it. Furthermore, we will examine how DTC advertising has affected the consumers in making health care decisions as well as its success in increasing the awareness, and inevitably the demand for the advertised drugs.

Advertising hyperbaric oxygen therapy is uncharted territory for the most part. The high cost of mainstream print and media advertising in comparison with small returns makes advertising unjustifiable. Those that have tried to advertise hyperbaric oxygen therapy only do so on a small scale for a high price. The frequency (number of times an ad runs) required for effectiveness is usually in direct conflict to the available financial resources budgeted for most centers. Budget constraints are a major factor in any clinical hyperbaric program. Without the financial resources, promoting a hyperbaric program through advertising seems to be an unattainable goal. This results in direct mail and cold calling campaigns to physicians in hopes that they will refer patients for HBO therapy. Knowing that direct mail usually ends up in the wastebasket, I tried it anyway. As a freestanding facility, taking the time to send out 5000 mailers and getting 2 patients out of it is justifiable marketing as long as it pays for itself. In this particular case it did not.

Frustrated by this poor response to direct mail marketing, I looked at what pharmaceutical companies were doing to promote their prescription drugs. What I found was phenomenal: they have been promoting directly to both physicians and consumers. With an all time success rate credited mostly to DTC advertising (direct-to-consumer), pharmaceutical companies are showing profits above their projected yearly goals.

#### Spend money to make money

The advertising for prescription drugs has exploded in recent years according to the

National Institute of Health (NIH). We all have seen and heard these promotions on TV, radio, and full page magazines like Time, Newsweek, GQ and the like. The drug companies are doing the smartest thing they can do in marketing by going directly to the folks who buy the end products---consumers.

Advertising prescription drugs using the same principles as for regular consumer products like soap, toothpaste, or canned goods is clever and highly effective. Direct-to-consumer (DTC) advertising has increased annual sales. Changes in the political and regulatory climate, cultural shifts emphasizing the patient's role in making medical decisions, and expanding profits from drug sales have encouraged the pharmaceutical industry to pursue more direct marketing strategies.<sup>1</sup>

#### Thank the FDA

It was the FDA that sparked this recent rapid growth in mass media advertising of prescription drugs. In 1997, the FDA laid out the rules for advertising prescription drugs to the pharmaceutical companies. This action made it easier for the pharmaceutical companies to launch their DTC campaigns without fearing the FDA's intervention.<sup>2</sup>

The pharmaceutical industry has the right to claim that they are only educating and raising the awareness to the consumers about different illnesses and what drugs are available for them. The fact remains that they have permission from the FDA to launch such campaigns provided they remain within the rules set forth by the agency (21 CFR

202.1, Prescription drug advertising, rev. Apr, 2000).

The consumer empowerment movement led by an aging baby boomer population has also contributed to the growth of DTC advertising.1 The proliferation of medical information on the Internet has also driven the consumers to want to participate in decisions concerning their health. these factors combined make for a more informed consumer when it comes to their own health according to the proponents of DTC advertising. Prescription drugs that have launched DTC advertising campaigns showed a steep increase in sales averaging 43 percent a year. Sales for non-advertised generic drugs only resulted in an average yearly increase of 13.3 percent. The evidence is clear that advertising which directly targeted the consumers resulted in a 30 percent growth increase over traditional advertising methods. At the end of this article is a table of prescription drugs launched by highly effective DTC advertising campaigns and their yearly returns.

One of the best selling anti-arthritis drugs in the nation just launched the most successful DTC campaign in history.\(^1\) Celebrex contributed more than any other single drug (7.4 percent) to the rise in overall drug spending in 1999. They reported \(^1\).3 billion in sales for their first year. The pharmaceutical industry knows how to create a demand for their products. A typical company spends upwards of \(^3\)30 million annually for advertising.

There are claims that the consumers are opting for the costlier drugs instead of the generic versions available because of such DTC campaigns. However, it has not been established that DTC is directly responsible for the rise in prescription spending.

In terms of yield from physician-targeted promotion, studies overwhelmingly show that doctors strive to please their patients and that they are open to patients' requests to try new treatments.3 According to the study a doctor is more likely to prescribe a new medicine if (a) it is being promoted to him and (b) the patients ask for it. Hence, Directto-Consumer marketing makes sense by making physician-targeted promotion more effective.

#### What about HBO?

The two biggest challenges that everyone faces everyday in the field of Hyperbaric Medicine are both the lack of public and professional knowledge about hyperbaric oxygen therapy and the lack of funding for educating the community at large as well as the physicians.

The public has limited information as well as limited access to Hyperbaric Medicine. To bring about the expansion of our field, we must surmount such problems through collaboration. We must begin to work together to raise the awareness of HBO to the general population. We all have been quite successful in providing information over the Internet, but the time has come when we have to do more than just that. Hyperbaric oxygen therapy is a drug. People need to become more educated about its therapeutic uses. This would be most effectively achieved by Direct-to-Consumer marketing.

HBO has been around for centuries and yet 9 out of 10 people are still not aware of it. If we can, on a state-by-state or countyby-county basis, come up with a campaign to raise the awareness of hyperbaric oxygen therapy, we may move past the emerging phase and actually grow into mainstream western medicine.

#### **Putting theory into practice**

Working on pure gut instincts, we devised a plan to release a couple of advertisements to test the market. The plan was simple. We ran a small advertisement in the health section of a local paper and had them guarantee us an advertorial. An advertorial is an article that is written by the advertiser and edited by the newspaper staff. In some papers they offer this service free of charge, but you have to ask for it to get it. In this case we negotiated a frequency contract that guaranteed an advertorial for every advertisement that we ran. After a couple of weeks, a full-page article on HBO with a picture of the chamber was printed. The advertorial was basic in content. It mentioned what HBO is, what the benefits are, which indications get treated, and where the nearest chambers may be found. The FDA has regulations on what you can and cannot claim in drug advertisements, so it is very important that the editorial staff of the paper contact the clients prior to making any changes. The results were overwhelming, 100 calls for information in one day. Most calls were legitimate and these patients were told to ask their doctors about HBO and possibly getting referred for treatments. We got calls from as far as the opposite coast and referred them to the nearest chamber in their respective areas. It worked! Getting to the physicians through their patients pays off 20 times more than sending out direct mail. Physicians who tried to talk their patients out of having HBO for no good reason have

been faced with the reality that the patients have become more educated about treatment options available to them and that patients want to become more involved in decisionmaking when it comes to their health. This turned into a case of schooling the physicians through their patients.

#### Conclusion

Advertising works. It always has and always will. The pharmaceutical companies have changed gears to speed up the process of branding and marketing their products directly to the consumers with exact precision. Unlike traditional promotions targeted only to doctors, they have switched their focus and resources from research and development to marketing directly to the consumers.

Their resulting success of direct-to-consumer advertising is unquestionable when it comes to educating, promoting, and increasing the awareness and inevitably augmenting the demand for new prescription drugs.

Taking some lessons from big companies on DTC advertising may change this small and rather unknown hyperbaric community in mainstream medicine. The future of HBO lies in our hands. Let us follow the example of the pharmaceutical companies. Let us educate the consumer through DTC advertising to make hyperbaric oxygen therapy as common as the nearest emergency room. It worked for them. It can work for

The Direct-to-Consumer Advertising Dilemma, Patient Care, pp. 22-30, Mar. 2001. D. Hillman, N. Ostrove, A Brown
 NIHCM, Prescription drugs and mass media advertising, available at http://www.nihcm.org/index2.html, Oct. 2000
 J. Jerry Avorn, M Chen and R Hartley, "Scientific vs. Commercial sources of influence on the prescribing behavior of Physicians," The American Journal of Medicine, Vol. 73 (July 1982) pp 4-8.

Drug Name	% of sales increase in 1 year with DTC	In Dollar Amounts
Claritin	21%	\$900 mil. to \$2.1 billion in 2 year
Lipitor	50%	\$1.3 billion to\$2.6 bil. in 1 year
Glucophage	e 49%	\$500 mil, to \$1.2 bil. in 1 year
Zyrtec	31.5%	Not Available
Allegra	50%	Not Available
Flonase	38%	Not Available
Flovent	61.2%	Not Available
Nasonex	116%	Not Available



# 2nd International Symposium for Hyperbaric Oxygenation in Cerebral Palsy and the Brain-Injured Child July 25th – 28th, 2001 – Boca Raton, Florida

The 2nd International Symposium for Hyperbaric Oxygenation was a huge success as far as attendance and participation was concerned. Physicians and patients from around the world came together in Florida to share clinical experiences with research information. This was a well attended meeting with a very diverse list of US and foreign speakers. More than a dozen countries were represented, all supporting a common finding that is being reinforced around the globe; low pressure hyperbaric oxygen therapy is having positive effects on various types of brain injury. While we would all like to see more solid (reproducible) evidence to help cement the use of HBOT, time should not be wasted when a therapy with an extremely low incidence of side effects (rare and non-lasting) is available. HBOT is supported with more than a preponderance of anecdotal and scientific evidence and has a low risk/high benefit ratio. We are proud to present Dr. Neubauer's pearls from the symposium and look forward to more stimulating meetings and advances in the field.

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#### Daniel Lacey, M.D., USA What is Cerebral Palsy and its many causes?

Dr. Lacey spoke on cerebral palsy being an umbrella catch-all type of terminology for any child under the age of twelve; prenatal, time of delivery, post-natal, infection, traumatic, and genetic all fall into the category of cerebral palsy.

#### P. B. James, M.D., United Kingdom A Common Denominator in Cerebral Palsy and the Brain-Injured Child – Oxygen Deficiency

Dr. James spoke on the abnormalities of the blood brain barrier in the injured child and the reparative effects of hyperbaric oxygenation and the fact that there are now up to 110 centers with hyperbaric oxygenation chambers in the United Kingdom that are treating, not only multiple sclerosis but also children with cerebral palsy.

# Tragic Mistake of Retinopathy of the Premature Infant

Dr. James also spoke on the tragic mistake of retinopathy in the newborn. A horrendous mistake was made for about fifty years that suggested surface oxygen for the preemie caused retrolental fibroplasia. This has been totally disproved as it was the withdrawal too soon and putting the babies back into the oxygen cured the problem. Since this tragic mistake has been universal, the incidence of cerebral palsy has skyrocketed.

#### William Maxfield, M.D., USA Timely Diagnosis: SPECT Scans / MR Spectroscopy/Ultrasound/Transcranial Doppler

Dr. Maxfield spoke on MR spectroscopy, functional MRI, ultrasound, transcranial Doppler stressing the need for immediate diagnosis, even in utero. Dr. Maxfield also evaluated hyperbaric oxygen therapy in cancer care. He pointed out that the great value of hyperbaric oxygenation in treating extravasation of chemotherapy agents into tissue, which significantly decreases the morbidity. Dr. Maxfield has treated many cancer patients with hyperbaric oxygenation before radiation therapy. He notes that in a report from Japan, hyperbaric oxygenation therapy given immediately prior to radiation therapy for brain tumor showed a 50 percent increase in survival for the patients. He stated that the rumor that hyperbaric oxygenation might stimulate cancer growth is entirely unfounded and feels that there is a significant need to expand the use of hyperbaric oxygenation in the field of cancer care.

#### Michael Uszler, M.D., USA The Utility of Brain SPECT Imaging Associated with HBOT in Childhood and Adult Neurological Disorders.

Dr. Uszler spoke on the importance of documentation with hyperbaric oxygenation and the potential of co-registration with anatomic measurements on MRI. Dr. Uszler has reviewed hundreds of scans, pre and post HBOT and is a firm advocate of this therapy.

#### Pierre Marois, M.D., & Michel Vanasse, M.D., Canada HBOT for Children with Cerebral Palsy: A Multicenter Placebo Controlled

Randomized Clinical Trial

This Clinical Trial demonstrated clearly that the more beneficial effects in the more serious children occurred with the use of hyperbaric oxygenation. Increased atmospheric pressure of 1.35 air, however, did benefit many of the children so thus there was not a statistical difference between the two arms of the study. This is a fortuitous observation in that there are hundreds of thousands of children around the world who could never get to a hyperbaric chamber may now be treated with compressed air (a technique with much age) and clinical documentation.

#### Paul Harch, M.D., USA The Dose of Hyperbaric Oxygenation

Dr. Harch had unusual findings with the dose of hyperbaric oxygenation stating that after forty exposures at low pressure of 1.5 ATA certain of his patients noticed either irrational behavior or fatigue and he related this to oxygen toxicity and suggested a protocol of forty treatments at which time the patient should be given a break and then begin with lesser numbers. \*

#### M. Packard, M.D., USA Evidence Based Research at New York University

Dr. Packard stated that the excellent results obtained in the study done at New York Presbyterian Hospital stressed the need for further treatment. Dr. Packard is a pediatric neurologist and was the main investigator of this study. She also produced the protocol and the scales for evaluation. Her studies suggest highly positive results, but being a true scientist, she spoke again on Saturday morning suggesting the need for further documentation with controlled studies.

#### Pier Giorgio Data, M.D., Italy Time of Intervention – In Utero: The Italian Overview

Dr. Data related an overview of the Italian

approach that when there is a small fetus or abnormalities in the placenta, the mother is treated with hyperbaric oxygenation sequentially and in most instances, a normal delivery occurs.

#### N. Kazantseva, M.D., Russia Mechanisms of Curative Effect of Minimized Hyperbaric Treatment in Cerebral Ischemia

Dr. Kazantseva came up with a whole new protocol suggesting that their dose is 1.2 ATA for twenty to thirty minutes, twice a day for ten to thirty treatments. The Russians rely more upon change in the RBC membrane, carbon dioxide, and energy metabolism rather than the physical gas laws.

#### Hans Wassman, M.D., Germany Cerebral Energy Crisis in vitro and In Vivo Under Hyperbaric Oxygenation

Dr. Wassman spoke on the cerebral energy crisis in vitro and in vivo under hyperbaric conditions. Cerebral energy measured by lactic acid and glucose metabolism showed that the anaerobic metabolism was best at 1.5 ATA. This has set the standard for most of the pressures used. His earlier studies showed a significant difference in traumatic mid brain injuries treated with hyperbaric oxygenation as opposed to the control group.

#### I. Chavdarov, M.D., Ph.D., Bulgaria The Effects of HBOT on Psychomotor Functions by Children with Cerebral Palsy

Dr. Chavdarov produced long-term, positive results with psychomotor function in children with cerebral palsy using patients as their own control study and also basic studies which seem to agree that the protocol of 1.5 ATA, one hour of treatment should continue as long as there was improvement. Results in Bulgaria substantiate worldwide observations.

# Solany Zerbini, M.D., Brazil The Use of Hyperbaric Oxygenation in Treatment of Chronic Childhood Encephalopathy

Dr. Zerbini noted that in South America the results parallel other countries. However, she quoted Dr. Machado who a number of years ago took babies from the delivery room to the chamber and obtained superior results. The usual protocol of 1.5 ATA for cerebral palsy showed emerging results.

# Lianbi Xue, M.D., China The Effect of HBOT on the Brain -Injured Child: Immediate and LongTerm

Dr. Xue presented data on the effects of

hyperbaric oxygenation in the brain-injured child – immediate and long-term. He noted that the use of hyperbaric oxygenation had positive effects in cerebral palsy and the brain injured child and has had long-term follow-up for a number of years. The number of treatments used was variable depending upon continuing improvement.

#### E. C. Sanchez, M.D., Mexico Management Anoxic Encephalopathies of Neonates with Hyperbaric Oxygenation

Dr. Sanchez presented a very enlightening paper of twins; one with a grossly abnormal ultrasound. The potentially damaged twin was taken immediately after birth to the hyperbaric chamber and with one oxygen treatment, became normal in all aspects. One-hour treatment at the proper time can change a lifetime. Dr. Sanchez advises treatment with hyperbaric oxygenation as soon as possible after delivery—at least in the first 4 hours.

# E. C. Sanchez, M.D., Mexico Management of Necrotizing Enterocolitis of Neonates with

**Enterocolitis of Neonates with Hyperbaric Oxygenation** 

Dr. Sanchez pointed out that other organs of the body may be involved with hypoxia as well as the brain and has treated several cases with necrotizing enterocolitis that would have required surgical removal of a large part of the gut. This was cured with hyperbaric oxygenation. A presentation by Mr. Byrne from Cape Town, South Africa on seventy cases showed that these results are reproducible.

#### G. Heuser, M.D., USA Neurotoxicity: Type of Chamber for Treatment

Dr. Heuser presented very interesting data showing that he has used a canvas type of bag with supplemental oxygen, pressurizing the bag to 1.3 ATA. He had positive clinical results in neurotoxicity and cerebral palsy in children, and substantiated this with SPECT imaging done at Dr. Uszler's laboratory. This new approach deserves substantial attention.

# John Cassidy, M.D., USA (HBOT) An adjunctive Role In the Treatment of Autism

Dr. Cassidy's presentation showed that although autism is a disease entity and often has areas of low perfusion in the brain, by treating such patients with hyperbaric oxygenation, clinical improvement has been noted.

# William Hammasfahr, M.D., USA Possible Synergistic Combinations

#### Vasodilator

Dr. Hammasfahr produced a stimulating talk on the use of vasodilators in cerebral palsy and the brain injured child as well as in the neurologically damaged adult. He has been nominated for the Nobel Prize for his works. This is a must for further evaluation as a synergistic approach with hyperbaric oxygenation.

#### Dean Bonlie, D.D.S., USA High Gaus Magnetic Field Treatment for Cerebral Palsy and the Brain Injured Child

Besides the encouraging and dramatic results coming from Vanderbilt and Wake Forest Universities on the use of high gaus magnets in acute stroke and brain injury and children with cerebral palsy, Dr. Bonlie has now had several patients with macular degeneration who have had almost complete restoration of their vision with as few as four treatments (each treatment lasting eight hours lying on the high gaus magnet). Again, this was done as an adjunct to hyperbaric oxygenation in Cerebral Palsy and the brain injured child.

## James Cole, M.D., & Daniel Lacey, M.D., USA

## Panel Round Table on Ancillary Intervention

Dr. Cole and Dr. Lacey co-chaired a long discussion on the indications and contraindications of Botox injections, oral and pump use of Baclofen, seizure medications and their long-term use, vegal nerve pacemaker for intractable seizure disorder and also the treatments of the gastrointestinal problems including G-tube and fundoplication.

#### William Rader, M.D., USA Current and future therapy concepts of human embryonic stem cells

Dr. Rader, the banquet speaker, spoke on current and future therapy concepts of human embryonic stem cells. This was a fascinating talk on the use of human embryonic stem cells which are obtained from Eastern Europe where the main method of birth control is abortion. These fetuses are between five and eleven weeks old and checked out with PCR DNA: the mothers obtain no funds. The stem cells are put into liquid nitrogen and injected intravenously and subcutaneously. They apparently are pleomorphic and go to the site of damage and have restorative capacities. Case reports were done and at times the results were remarkable. There is a whole new world opening up with stem cells.

## INTERNATIONAL HYPERBARIC MEDICAL ASSOCIATION

The begining of a new hyperbaric era has arrived!

It is with great pleasure and pride that I am writing to you as the first president of the new IHMA. This will likely be appreciated in the future as one of the most exciting periods in the history of medicine, largely because of what is about to evolve with the field of hyperbaric medicine. The advent of the new International Hyperbaric Medical Association marks a new era in hyperbaric medicine. Hyperbaric oxygen therapy (HBOT) has long had the potential to revolutionize medicine, but has been restrained by intrinsic and extrinsic forces and problems.

been formed to simply advance the field of hyperbaric medicine to a level of respect equal to the oldest and most venerable of medical specialties, and accelerate the acceptance and utilization of HBOT worldwide. The IHMA proposes to do this by re-appraising and presenting HBOT to the medical and lay communities, aggressively publicizing the known scientific underpinning of HBOT, informing the world medical community of the proven and potential benefits of HBOT, establishing new lines of communication with the

The International Hyperbaric Medical Association has

public and medical profession, arousing the public consciousness about HBOT, demonstrating the cost-saving potential of HBOT, stimulating HBOT, and rapidly approving it for HBOT.

The IHMA will reach out all inclusively to medical and non-medical professionals, and in unprecedented fashion, to the general public. We will welcome and embrace patients and their families as an integral

part of this organization. This will advance HBOT for the welfare and well-being of all patients. In addition, we will work with top leaders in our government and business to make HBOT affordable and cost-effective. We will accomplish these goals in a very open and fair manner.

Lastly, we will freely collect, catalogue, and disseminate medical information on HBOT and allow doctors to practice medicine in an unfettered fashion for the betterment of their patients. To accomplish these goals we will need the help and contribution of innumerable members working toward a common good. We welcome your membership and participation in the new IHMA.

Thank you,

Paul G. Harch, MD President IHMA

These constraints include the lack of basic animal and human

for HBOT, failure of the hyperbaric

lack of basic animal and human research, lack of appreciation of the existing research, artificially inflated hyperbaric charging, inadequate dissemination of information on the effectiveness of HBOT, absence of visible champions coupled with an abundance of apologists

medicine specialty to explain the science of HBOT to professionals and the lay public, and divisive political infighting in the hyperbaric medicine community that violates the public trust of healthcare professionals.

In 2001, we have finally reached a threshold in hyperbaric medicine that is characterized by the convergence of many different forces. These forces include the rapid ubiquitous dissemination of medical information, an increasing respect for and utilization of alternative and complimentary therapies by allopathic physicians, demand for cost-effective medicine by business and government, widespread sophisticated medical knowledge of the lay public, and scientific proof of the molecular biology of HBOT.

It is a time that is ripe for the emergence of hyperbaric medicine at the forefront of cost-effective medicine. And it is the time for the establishment of a new hyperbaric medical association, one that speaks for the welfare of all patients.

For more information on membership visit us at: www.IHMAonline.org

#### A. Campbell, M.D., USA Vaccination: Relationship to Cerebral Palsy and Autism

This presentation noted more than coincidental findings between vaccination, cerebral palsy, and autism. Associated with various vaccination protocol, he noted particularly the problems with the Hepatitis B vaccination given to the newborn and questioned the reality of their ever being exposed to this disease at such a young age. The serious side effects of vaccination were mentioned as well as that it is noted that in certain areas of Scandinavia, some of the vaccination programs have been discontinued.

#### Charles Golden, Ph.D., USA Changes in Cerebral Metabolism as Measured by SPECT after HBOT: Statistical Evaluation

A statistical measurement of right subcortical/left subcortical areas on SPECT scanning were related with the outcome of hyperbaric treatments. The accrued data treatment outcome on these measures is much more pronounced for the longer, rather than the shorter period of treatment. The data indicates strongly that children with cerebral palsy may be helped with HBOT. It is suggested that longer courses of treatment will result in more dramatic improvements.

#### Yu Hai, M.D., China

# The Effect of HBOT on bFGF and bfGf mRNA expression of neonatal rats after brain hypoxia-ischemia injury

This was an excellent biochemical study on the effect of hyperbaric oxygenation on basic fibroblast growth and mRNA expression of neonatal rats after brain hypoxic-ischemic injury. Basic growth factor expressions were higher in hyperbaric oxygenation than in the control groups. The conclusion was that hyperbaric oxygenation increases both the bFGF and mRNA expression in neo-natal rats after brain hypoxic ischemic injury. Again, basic science substantiates clinical use.

#### M.A. Lobov, M.D., Russia Hyperbaric Oxygenation Treatment of Cerebral Palsy in Childhood

This paper related to rehabilitation of sixty children from age .5 to 15 with various clinical forms of cerebral palsy. The whole spectra range of mild standard isopressure regimes were applied up to 2 ATA (type of chamber not noted), with 40-60 minute exposures of hyperbaric oxygenation with the course lasting from one to ten exposures. The results from preliminary data led to the opinion of the authors to consider hyperbaric oxygenation not only a component of cerebral palsy patient rehabilitation but

also a means to prevent formation of stable neurologic defects in children with perinatal encephalopathy due to dyscirculatory and hypoxic traumatic lesions of brain.

# F. J. Cronje, MBChB, Bsc, Pretoria, South Africa

# The use of HBOT in Children with Cerebral Palsy – A Position Paper

This was an excellent review of the literature along with the classifications of cerebral palsy, the incidence and the various types of treatment, the use of hyperbaric oxygenation therapy in cerebral palsy and its development in South Africa. The conclusion of whether hyperbaric air, supplemental oxygen or hyperbaric oxygen is eventually shown to be beneficial in cerebral palsy or not, the positive therapeutic effect of the active participation of parents and children in this study; the stimulation and hope of improvement; and the social interaction between parents, therapists and children in and around the hyperbaric chamber, also deserves further research. Finally, the creative energy and determination of parents to find innovative sources of relief and improvement for their disabled children should not be bluntly and insensitively opposed because of the published outcome of the Collet study. However, while the search for the truth continues, parents should, perhaps, rather

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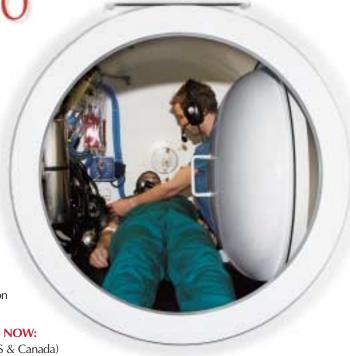
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be redirected towards other suitable and safe therapeutic avenues where there is, maybe, less risk of injury or exploitation. Incidentally, after the *Lancet* paper, Dr. Cronje stopped treating cerebral palsy and the brain injured children.

#### Andras Guseo, M.D., Ph.D., Hungary Biological Effects of Pulsing Magnetic Treatment

was pointed out that pulsing electromagnetic fields may enhance the oxygen applied to the tissues caused by dilation of the blood vessels. Since magnetic fields penetrate the body unhindered, it can act at a cellular level at each organ. There are virtually no side effects and in many cases, portable equipment can be used in the home. The overall results at St. George Hospital in Hungary are an 80 percent improvement with reduction of spasticity, improvement in bladder incontinence, improvement in chronic fatigue, increase in muscle spasm, and a decrease in pain. Dr. Guseo felt that the higher oxygen saturation of the blood and tissues after hyperbaric oxygenation combined by the better blood supply of tissues after pulsing electromagnetic field may multiply their effect.

# C. Galvez, M.D., Cuba (presented by E. C. Sanchez, M.D.)

#### Hyperbaric Oxygen in Cuba

In Cuba there are over thirty-three hyperbaric oxygenation centers that deal not only with wound care but also extensive neurology. They have excellent results in cerebral palsy, multiple sclerosis, and strokes. It has been rumored that after Fidel Castro's recent fainting spell, he was rushed to a hyperbaric oxygenation chamber and with a miraculous recovery was able to deliver a four hour speech several hours later.

# Leah Nof, Ph.D. & Raymond H. Cralle, R.P.T., USA

#### **Complimentary Neuro-Rehabilitation**

This presentation stressed the importance of the vestibular system stating that the small organs involved in the vestibular sensation are "the most sensitive of all the sense organs". He also stressed the importance of tactile stimulation and alterations of labyrinth in function will induce changes in positive reaction that can be determined and measured by an analysis of tendon jerks. It was also noted that therapeutic interventions involving head movements are beneficial for comatose and semi-comatose individuals and one reason why

the Horses for Handicapped program has been found to have beneficial effect on muscle tone problems. The talk revolved around the many neuro-rehabilitation approaches for those suffering from neuropathology and the need for caution where there is a tendency for parents to become involved in "systems" requiring ritualistic adherence. There is a need to question centers promoting expensive, short term "intense treatments" that promise rapid unrealistic neuro-developmental All physical, speech, and goals. occupational therapy is not the same. Correction of normal developmental tracts via repetition are essential.

#### Kenneth R. Locklear, CHT, USA The FDA, CMS (formerly HCFA), Insurance Providers, and Hyperbaric Legislation: What Does it All Mean?

Hyperbaric medicine has a volume of supporting documentation to show efficacy in many neurologic conditions such as: Arterial Gas Embolism, CO Poisoning, Cerebral Edema, Near Hanging, Near Drowning, Traumatic Brain Injury, and Asphyxiation. Routing this scientific information in the right direction with the support of the medical community and the general public hopefully will



bring about the element of acceptance of hyperbaric oxygenation as a powerful, objective therapy. Hyperbaric medicine has been making advances in medical research as well as reimbursement and legislative acceptance across the United States and other countries. It was specifically pointed out that the Texas State legislature is making hyperbarics the standard care with House Bill 1676. A new medical association has been formed to specifically deal with the challenges of getting HBOT accepted by the medical mainstream. The International Hyperbaric Medical Association (IHMA) is a not for profit organization supported by research and clinical physicians, nurses, technicians, hospitals, chamber manufacturers, and patients alike to further the ethical and scientific acceptance of Hyperbaric Oxygen You can learn more about the IHMA by visiting their website at: www.ihmaonline.org

Complete proceedings from the Conference are being published by Best Publishing, Co., Book No: B1040 This book will be available in hard cover, PRE-PUBLICATION PRICE \$24.95

PLUS \$4.50 shipping. ISBN: 1-930536-01-1

The 2nd International Symposium for Hyperbaric Oxygenation on Cerebral Palsy and the Brain Injured Child documented the reproducibility of positive effects being seen around the world. Longterm effects were noted and it was obvious that the earlier the intervention took place. the better the results. In Russia and Mexico City, infants are being taken from the delivery room to the hyperbaric chamber within hours. The immediate correction of hypoxia and ischemia may alter a child's life in a very favorable fashion with even a single treatment. The tragic mistake of retrolental fibroplasia and surface oxygen in the premature infant was discussed. Upon withdrawal of oxygen from the preemie, the incidence of cerebral palsy skyrocketed. It was found later that it was not the 40 percent surface oxygen but the early withdrawal from the environment that caused the retrolental fibroplasia. When children were put back into the oxygen environment, the eye disease was reversed. Interesting results were presented regarding different protocols. The Canadian study was reviewed completely and the fact that 1.35 ATA compressed air benefited a certain number of the children was a fortuitous finding. It was pointed out that this in no way negated the positive effects of hyperbaric oxygenation

(the group in which the more seriously ill children were treated) but opened a whole new world. It became obvious that this was not just the increase of oxygen from the 20-21 percent to 28 percent since surface oxygen by mask has been utilized for a number of years, particularly since World War II without any profound neurologic effects. It was of note that the Russian protocol used 1.1 to 1.2 ATA for periods of only twenty minutes. The rationale is based on a change in the hemoglobin red cell membrane and the metabolism of carbon dioxide. This did not adhere to any of the gas laws of physics that had been the gold standard for the rationale of the use of hyperbaric oxygenation in CNS diseases. Side effects throughout the world were minimal with the main problems being in the ear. The reproducibility on a worldwide basis gives credence to the fact that hyperbaric oxygenation is a welldocumented treatment for cerebral palsy and the brain injured child.

R. A. Neubauer, M.D.
Program Coordinator
\* Author's Note: Findings have not been
confirmed by other centers.





# SHAM SCIENCE AND CEREBRAL PALSY: REPORT FROM THE SECOND INTERNATIONAL SYMPOSIUM ON CEREBRAL PALSY AND THE BRAIN INJURED CHILD

By: Kenneth P. Stoller, MD, FAAP

It was the publication in the February 24th (2001) issue of the *Lancet* by Dr. Jean-Paul Collet and colleagues that began the impetuous behind calling together the Second International Symposium on Cerebral Palsy (CP) and the Brain Injured Child. Two of Collet's co-authors, Drs. Pierre Marois and Michel Vanasse spoke about the results of this Canadian study. This controversial randomized multi-center trial treated one group of children with 100% oxygen at 1.75 ATA and the other group of children with compressed air at 1.3 ATA (what Collet calls sham therapy). The study demonstrated that children in both groups improved substantially with respect to gross motor function as well as speech, attention, memory, and functional skills. So, Collet reported back to the Canadian government, who funded the study, and the world media that "hyperbaric oxygen treatment is not better than sham therapy."

Drs. Marois & Vanasse told how Collet had been appointed by the Canadian government to be the principal investigator of this study even though he had no expertise with Hyperbaric Medicine. Furthermore, Dr. Marois said that Collet had announced prior to the inception of the study that he did not believe that hyperbaric therapy could treat nor have any effect on children with CP. Even more disturbing was that Marois said Collet never actually participated in the execution of the study, nor did he examine even one of the children in either treatment arm of the study. Lastly, Dr. Marois stated that Dr. Collet wrote the article that was printed in the *Lancet* without letting either Dr. Vanasse nor himself read it, let alone review it.

I have since learned, from a high placed source, that Dr. Collet was allegedly paid to present the results of this study in the most negative light, put the worst spin on the outcome, and to make sure that no one would hereafter believe that Hyperbaric oxygen therapy (HBOT) had any benefit for children with CP. The obvious motive is that the Canadian government does not want to pay for the treatment of these children, but the real reason is even more pernicious.

If HBOT were accepted into mainstream medicine, it would change the very face of medicine, as we know it today, in many ways. Today, Western medicine divides illnesses into discrete entities and then funnels patients to physicians who are themselves sub-divided into various specialties. So, we have those that specialize only in cancer, cardiac problems, or neurological problems, etc. Everything in medicine has been divided up, and each area has its own territory. What happens with Hyperbaric Medicine is that there is assistance provided to the human body that crosses over into the territory of many, many specialties. Understand, it has been very profitable on many levels to have this separation in medicine, or separation between specialties.

For years, the cigarette industry sponsored research that produced results saying cigarette smoke was not harmful when all the while they knew the hidden truth. So, an industry that sold death, that sold a carcinogenic drug delivery system remains strong and influences many political decisions. Understand that those that try to protect something that is bad, also try to keep from the public that which is good. This is very much about control and power at the highest levels of medical societies as well as governments.

There is a lot of fear in mainstream medicine that HBOT could change the way medicine is practiced forever. Should HBOT, still a relatively unknown area of conventional medicine, ever come to the fore and be embraced by mainstream medicine it would be very threatening indeed to the old guard. So, Dr. Collet and the Canadian government have succeeded for a time in delaying the acceptance of HBOT as a legitimate therapy for CP, but only for a time, because the effects of HBOT for CP will come through. Other research facilities will step forward and counter the negative propaganda generated by Collet at the behest of the Canadian government.

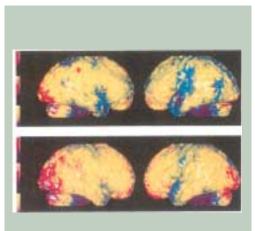
Now, this report would not be complete without addressing the scientific issue of how 1.3 ATA of room air could alter the natural course of CP, because this is the real revelation, albeit it was camouflaged by the negative publicity of Dr. Collet. Collet would have the world believe that 28%

oxygen by mask is equivalent to 1.3 ATA of compressed air, and that this is "good news" for children with CP who will now be spared the hassle of HBOT. The only problem, of course, is that 28% oxygen by mask is not the same as 1.3 ATA of room air. Pressure allows the oxygen to permeate into the cells of the body that would not be possible under normobaric conditions.

The negative publicity generated by Dr. Collet is galvanizing many physicians who are now coming forward to present the truth. One of these physicians is Dr. Michael Uszler, Director of the Nuclear Medicine Department, UCLA Medical Center-Santa Monica. He showed the symposium the SPECT scan (SPECT isotopes cross the blood brain barrier and measure metabolic activity in the brain as well as perfusion.) of a child's brain before and after treatment with 1.3 ATA of compressed air objectively documenting "the beneficial effects of slightly pressurized air."

Left unanswered by Drs. Marios and Vanasse was why they allowed the *Lancet* to publish their names as co-authors on Collet's article knowing Collet was distorting the study's findings. Nevertheless, it took courage for them to come forward with the truth.

Dr. Stoller is a Board Certified Pediatrician and founder of Simply Hyperbarics in New Mexico. (www.simplyhyperbarics.com)



SPECT scan of child's brain before and after mild hyperbaric therapy. Top is before; bottom is after (yellow means perfusion).



#### Presentation of the Richard A. Neubauer, MD Award for Excellence in Hyperbaric Medicine in Pediatric Neurology July 26, 2001

Presented by Mr. Edward Nemeth & Mr. Kenneth Locklear

The presentation of this award was bestowed to Dr. Pierre Marois at the 2nd International Symposium for Hyperbaric Oxygenation in Cerebral Palsy and the Brain-Injured Child. The award was presented by Mr. Edward Nemeth & Mr. Kenneth Locklear on behalf of Rebecca Nemeth and Friends of Rebecca (www.littlestangel.com) and the International Hyperbaric Medical Association (www.ihmaonline.org). This award is to honor Dr. Neubauer for his untiring contributions to the field of HBOT and neurology, and to Dr. Pierre Marois for his constant defense of his research in the field of HBOT and cerebral palsy. Dr. Marois has demonstrated the vigilance and excellence that have been inherent throughout Dr. Neubauer's work in Pediatric Neurology.

Mr. Edward Nemeth:

I believe I speak for every parent here in conveying the great appreciation and respect to Dr. Neubauer for his dedicated life's work to help our children. Despite the overwhelmingly adverse scientific and medical environment, he stayed the course in belief of the facts of his clinical observations, regardless of the consequences. He preserved and conducted himself to the ideals of his Hippocratic Oath.

In fact, I think we can all say that none of us would be here caring for our children as we do, if were not for his efforts. Personally, despite all the successes we have had with our daughter Rebecca's physical therapies; I know that she would not have achieved her current abilities without the hyperbaric oxygen treatments she has received from Dr. Neubauer.

To put these efforts and this historical moment in perspective for future generations, the "Friends of Rebecca" and the newly formed International Hyperbaric Medical Association (IHMA) have established a small, but prestigious commemoration.

To explain to everyone who the "Friends of Rebecca" are; they are all of our children who suffer from CP, and other brain injuries; all of our littlest angels who have the purest love in their hearts, and greatest appreciation in their souls.

"Friends of Rebecca" and the IHMA are proud to announce the first annual presentation of the Richard A. Neubauer,

The Richard A. Nouhawer M.D. Award

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JULY 26, 2011

MD Award for Excellence in Hyperbaric Medicine in Pediatric Neurology.

To properly commemorate this honor, and adequately bestow the respect and appreciation earned by every award winner; we commissioned an artist to create a truly unique and symbolic work of art. The award sculpture shows how each annual winner affects the lives and hopes of their patients, as well as others far removed from their research and practice.

I am honored to present the First Annual Richard A. Neubauer Award for Excellence in Hyperbaric Medicine in Pediatric Neurology to Dr. Marois for Pierre his outstanding contributions in completing a foundational study determining the efficacy of hyperbaric oxygen therapies for cerebral palsy and brain injured patients. Further, we greatly appreciate his tireless presentation of the true results of this research.

Dr. Marois, this award is presented on behalf of all our children who have benefited from your work as well as on behalf of the children that will be helped in the years to come.

Dr. Marois, with the greatest appreciation from every parent here today, and those not able to be present, thank you!

#### Kenneth Locklear

This Richard Neubauer Award for Excellence and Perseverance in Hyperbaric Medicine and Neurology is presented to Dr. P. Marois in part by the International Hyperbaric Medical Association for your

outstanding contributions and tireless defense of your research in cerebral palsy.

We would also like to honor you with this award and thank you for your selfless devotion and vigor to defend the integrity of your work at a time when the scientific community refused to see it. On behalf of the International Hyperbaric Medical Association and all of the patients effected by your work, thank you and Congratulations.

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# DIVING

#### Freestanding HBOT Facilities And Federal Health Care Program REIMBURSEMENT: A FUTURE CHALLENGE FOR PROVIDERS

By: Corrine Parver, Lynne DeSarbo and Danielle Schonback\*. rates from private payors; further expanding

Currently, hyperbaric oxygen therapy ("HBOT") services provided freestanding health care facility are not separately covered or reimbursed under Medicare Part B. Without such federal health care program reimbursement, the future provision of HBOT provided in these facilities may be in jeopardy. Patients who do not have private insurance or sufficient funds would be compelled to choose the hospital setting for such services.<sup>1</sup> Thus, the need for providers in freestanding facilities to consider joining in an effort for gaining federal reimbursement of HBOT in that setting may be necessary, to preserve the ability of beneficiaries to seek treatment provided there under the umbrella of federal health care program coverage and payment criteria.

Given that federal health care programs do not, at present, cover or reimburse freestanding facilities for HBOT services, a collective effort to form a coalition of HBOT freestanding facilities dedicated to promoting common goals would work to advocate for such reimbursement gains.

the types of conditions covered under HBOT; and maintaining quality services within the profession of HBOT providers.

A strong advocacy effort can help bring this critical issue to the attention of federal policy makers. Lobbying is an essential tool in educating legislators and regulators, alike, about how HBOT can be provided with the same quality of patient care in freestanding facilities as in a hospital setting, and how federal program coverage and reimbursement can assist HBOT freestanding facilities to meet their patients' needs. The formation of a coalition of freestanding facilities to advocate for federal reimbursement for HBOT services can fulfill this role. Other industry groups, such as the Hyperbaric Oxygen Therapy Association ("HOTA"), advocate parallel interests; at present, however, no coalition specifically represents the unique interests of freestanding facilities. Given that, the nature of the immediate problem calls for action specifically by freestanding facilities to participate in efforts to seek federal health care program coverage

representation both at the federal and local levels. Recently, significant progress in state governments has occurred in that regard, resulting in an expansion of the use of HBOT for neurological conditions. For example, the Texas legislature recently enacted legislation (HB 1676)<sup>2</sup>, scheduled to take effect on September 1, 2001, which will ensure that persons with traumatic brain injuries have access to HBOT. The Texas "grassroots" lobbying effort increased awareness, applied pressure on state legislators, and helped to support enactment of this law.

successful with consistent, united and strong

Similarly, a national-based coalition of freestanding HBOT facilities undoubtedly could help educate legislators and regulators alike that HBOT is a well-recognized, viable therapy in that setting, one that improves the daily quality of life for patients. Dickstein, Shapiro, Morin, & Oshinsky LLP is prepared to coordinate coalition activities in collaboration with existing freestanding HBOT facilities.3 Such a coalition would promote mutually useful dialogues with high-level policy decision-makers on Capitol Hill and at the U.S. Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"), the Office of the Inspector General ("OIG"), and with other influential public and private health care officials.

Leveraging experience and expertise to advocate on behalf of freestanding HBOT facilities and coalition members will increase the opportunities for securing adequate public and private coverage and reimbursement of HBOT furnished in freestanding facilities. However, such an initiative will not be nearly as promising without the collaboration and participation of freestanding HBOT facilities in a coalition effort, designed specifically to advance these health care policy goals.

Other coalition initiatives and reimbursement for PERBARIC also could include HBOT provided in seeking adequate reimbursement Lobbying can Clinical & Mobile Multiplace Systems prove v e r y www.oxytank.com Fax: 813-932-5392 Email:drmichael@mindspring.com Built & Sold in the USA Comfortable Convenient Affordable Six Seat Safe & Secure Indoors Delivered & Installed Outdoors

• Corrine Parver, Esq., is a partner in the Washington, D.C., office of Dickstein, Shapiro, Morin, & Oshinsky LLP; Lynne DeSarbo, Esq., is an associate in the law firm's Health Law Services Practice; Danielle Schonback, second-year law student at the Washington College of Law, American University, is a Summer Associate at the firm. For further information about the coalition's efforts, contact Ms. DeSarbo at (202) 861-9182 or DeSarboL@dsmo.com

(Footnotes)

1 Presently, Medicare reimbursement for HBOT is available if services are Presently, Medicare reimbursement for HBOT is available if services are provided in a hospital, either on an inpatient or outpatient facility basis, or "under arrangement" with a hospital. In the hospital setting, Medicare reimbursement includes a facility charge and a charge for physician supervision for HBOT treatments for 14 covered conditions. Facility reimbursement is included as part of the inpatient hospital prospective payment system ("PPS") diagnosis related group ("DRG"), if provided during an inpatient stay. Outpatient hospital PPS reimbursement based on ambulatory payment classifications ("APCs") replaced cost-based reimbursement for outpatient services. HBOT is included as a "new technology" APC. technology" APC.

Tracas' Senate Business and House Insurance Committees signed the bill

The Firm's Health Law Services Practice presently represents a freestanding HBOT facility