

The Pressure Point

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58th Annual Meeting: Keeping the Palsy in Cerebral Palsy

The AACPDM Report

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By: KP Stoller, MD & David Freels, writer, *Hyperbaric Medicine Today*

In the Fall of 2004, the **American Academy of Cerebral Palsy and Developmental Medicine (AACPDM)** held its annual conference in Los Angeles. Dr. William Oppenheim, a pediatric orthopedic surgeon at UCLA's Cerebral Palsy Clinic, a member of the AACPDM's Board of Directors and Second VP, announced that his IRB had been approved at UCLA and that his study to treat children with cerebral palsy with hyperbaric oxygen would commence shortly.

Interestingly, the AACPDM has a history of presenting negative opinions on the use of HBOT for CP. At the September, 2000 AACPDM annual meeting, Dr. Jean Paul Collet presented findings from the second Canadian study on HBOT for CP (http://ucp.org/ucp_generaldoc.cfm/1/4/24/24-6608/1522). Both groups of children receiving hyperbaric treatment improved yet Collet claimed the 100% oxygen group's improvements were no better than the "placebo" group, even though Collet had no placebo (or control) group. When *The Lancet* finally published Collet's paper nearly six months later (*Lancet*. 2001 Feb 24;357(9256):582-6), it was conditional upon Collet removing all references to placebo.

Both groups of children had 15% improvements in GMFM scores, so Collet was correct; there was no statistical difference between the two groups. Actually, it is impossible to determine exactly how much both groups improved because none of the data from the Collet trial has ever been reviewed (or even seen) by any of the investigators.

Prior to the Collet study done in Quebec, no CP children (or adults) had ever experienced improvement from a placebo in any other placebo-controlled trial for any cerebral palsy treatment or therapy. Also prior to Collet, no one had even claimed improvement from a placebo in CP.

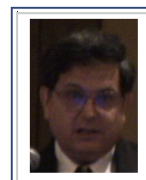
AACPDM, 2004: "I'm not familiar with hyperbaric chambers" – Oppenheim.



UCLA Neuropsychiatric Institute

UCP/UCLA investigators Oppenheim and Fowler (PhD in Physical Therapy) are not known for speaking favorably on the use of Hyperbaric Oxygen Therapy for CP. (Fowler was identified by the UCLA IRB as being the principal investigator; however, she has denied that she is the PI). Neither Oppenheim nor Fowler have experience with hyperbaric medicine, and Oppenheim so stated during his presentation at the conference. His lack of familiarity of the field was evident when he pointed to pic-

'Neither Oppenheim nor Fowler have experience with hyperbaric medicine...'



Top right: Oppenheim
Bottom right: Fowler



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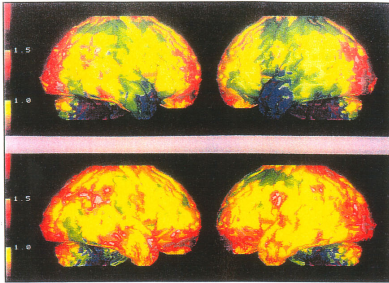


FIGURE 1

Treatment Protocol			
	Sea Level	Mild HBO	Traditional HBO
ATA	1.0	1.3	2.0 – 3.0
PSIG	0	4.7	14.7 – 29.4
FSW	0	11	33 – 66
O ₂ Concentration	21%	24%	100%

Scans such as these from Dr. Heuser's office provide concrete evidence of change in the brain after even a few treatments.

"Introduction to Alternative and Complementary Therapies in Cerebral Palsy." (see <http://www.aacpdm.org/resources/2004AnnualMeetingProgram.pdf>)

The course description states "parents and patients involved with chronic diseases are frequently attracted to therapies, which by their very definition remain unproven. Such therapies are pursued with or without medical supervision, supported by a belief system nurtured by anecdotal experiences, Internet chat rooms, or at times 'caring' practitioners of various 'arts.'" And, "A brief introduction to alternative medicine will be followed by discussions of specific therapies in terms of scientific rationale, the targeted group of patients, costs, risks and potential benefits. Included will be passive therapies such as Hyperbaric Oxygen Treatment..."

In one of the slides Oppenheim showed, during his presentation, he was critical of Gunnar Heuser, MD, Ph.D, who is an Assistant Clinical Professor of Medicine at UCLA, who in the late 1960's was Chief of the Neurophysiology Program at the UCLA Neuropsychiatric Institute. Oppenheim disdainfully pointed out that Heuser had given low pressure hyperbaric air and shown that this caused changes to take place in the brain as documented by a SPECT scan.

"He thinks this proves something," Oppenheim said, and further went on to inform the audience that the SPECT scan was taken by someone from UCLA, but not at UCLA. This statement was meant to put down the physician who

tures of the UCLA chamber and said the 'pillows' in the chamber were there so when patients fainted they would not injure their heads.

Yet, since Collet's 2000 appearance, every subsequent AACPDM annual meeting has featured a CME (Continuing Medical Education) course taught by Drs. Oppenheim and Fowler, which specifically discourages the use of HBOT for cerebral palsy children:

had cooperated with Heuser by taking the SPECT scans.

Unbeknownst to Oppenheim, J. Michael Uszler, MD, who had taken these SPECT scans, was sitting in the audience. He is Medical Director of the Nuclear Medicine Department, UCLA Medical Center, Santa Monica which is a satellite of the UCLA Medical Center in Westwood. This must have been the kernel of truth in Oppenheim's prevaricating presentation since technically UCLA Medical Center Santa Monica is not in Westwood.

Oppenheim: "We're all left—to prove them [HBOT] not true."

At his 2003 presentation, Dr. Oppenheim stated "Now having said that this is not evidenced-based medicine doesn't mean that it's not actually true. Because, just because you can't prove something is true doesn't in fact mean that it isn't true. And, in a way, "we're all left... to prove them (HBOT) not true, which is sort of the opposite of the scientific method." (Each CME course was recorded and may be purchased from Job Conference Recording Services, telephone 202-269-2000.)

Interestingly, the only part of the 2003 CME course that was not recorded was Dr. Fowler's presentation on HBOT and some of the floor responses. The 2003 meeting was held in New Orleans and attended by *Hyperbaric Medicine Today* editor Ken Locklear and Dr. Paul Harch.

AACPDM, 2002: HBOT is dangerous.

Mr. Locklear said, "Believe me, we were the only pro-hyperbaric people in the entire building. They started off [talking about] the 77 deaths from fires in the last century and I was the first one to speak and asked them if they could please quote any of the fires in North America. They all whispered among the panel and came back and said, 'No, but that doesn't mean it doesn't happen all over the world, everywhere else.' They laughed, so then pretty much the whole room started to laugh. Then Dr. Harch spoke, and I thought okay, well, we're on the record. So I went and bought the tape, of the audio transcript. [They said] 'We're sorry. That one's messed up, and it doesn't start until halfway through.'"

While the 2002 recording missed Locklear's comments, it did include the audience response from Dr. Harch who disputed claims that HBOT is dangerous. Harch also pointed out other inaccuracies in Dr. Fowler's presentation, particularly her failure to disclose both groups of children improved in the Collet trial.

AACPDM, 2003: HBOT is dangerous.

Despite Dr. Harch's assurance of HBOT safety during his 2002 personal appearance to AACPDM members, in her 2003 AACPDM presentation, Dr. Fowler repeated her 2002 claims that HBOT for CP is dangerous.

Rather than contact Dr. Harch or other practitioners, she instead relied solely on information posted on the Undersea and Hyperbaric Medical Society (UHMS) website, primarily UHMS position papers on HBOT for chronic brain-injury and multiple sclerosis.

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AACPDM Continued...

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She asked, "Is there evidence for use in cerebral palsy?" Then answered, "There was a report by our society [AAPCDM] and United Cerebral Palsy Research and Education in 1999 that there was no biological basis for use in cerebral palsy."

Fowler quotes Essex.

Dr. Fowler finished her talk on HBOT with extensive quotes from the Essex article (Hyperbaric oxygen and cerebral palsy: no proven benefit and potentially harmful), published in March, 2003 by the official AAPCDM journal, *Developmental Medicine and Child Neurology* (DMCN). The Essex article hinges on Collet, which was re-published by Hardy as Neuro-psychological effects of hyperbaric oxygen therapy in cerebral palsy. [also in DMCN (2002 Jul;44(7):436-46)].

Hardy's first sentence is "We conducted a double-blind placebo study to investigate the claim that hyperbaric oxygen treatment (HB02) improves the cognitive status of children with cerebral palsy (CP)."

Essex's first sentence is "Any good pediatrician will point out to parents of a child with cerebral palsy (CP) that their child's brain damage is fixed and cannot be altered."

In reference to the Collet and Hardy articles, The AAPCDM website (aacpdm.org/library/topTenArticles2002.html), states, "These two studies by the same group demonstrate that hyperbaric oxygen does not improve functioning compared with placebo in children who have cerebral palsy. Many Internet sites advocate the use of hyperbaric oxygen, and some insurance companies will even pay for it."

The AAPCDM webmaster is William Oppenheim (www.aacpdm.org/committees/currentofficers.htm).

Fowler ignores the Essex rebuttal by Marois.

Just as Dr. Fowler failed to make a full disclosure of the facts in her 2002 presentation, she also failed to fully disclose all the facts in her 2003 presentation. The 2003 meeting took place September 10-13. The September, 2003 issue of *Developmental Medicine and Child Neurology* (DMCN) included a letter of rebuttal to not only Essex but in essence, also to Collet and Hardy.

The rebuttal letter's author was Dr. Pierre Marois, and beginning on page 646, he writes about the improvements that occurred with both groups of children in the Collet/Hardy trial:

"In the *Lancet* study, the children in both treatment arms (1.75 ATA with 100% oxygen and 1.3 ATA with 21% oxygen) improved an average of ten times more during the two months of HBO treatment than dur-

ing the three months follow-up when medications and ancillary physical and speech therapies were restarted."

And, "Dr. Essex does not attempt to qualify the improvements that were measured in our study. It is important to state that everyone who was involved agreed that they were statistically and clinically very significant. Statistics never reveal the whole picture. During this study we have seen many tremendous functional improvements. At an age where we did not expect any dramatic changes, some children started to walk, to speak, or to sit for the first time in their lives. The motor changes that were seen and measured with the GMFM, were greater, more generalized, and were obtained in a shorter period of time than most of the improvements found in any other studies of recognized conventional therapies in the treatment of children with CP."

DMCN Publisher: Marois's Rebuttal at 2003 Meeting.

It would have been difficult for Dr. Fowler to miss the Marois rebuttal letter, particularly at the 2003 AAPCDM meeting. According to DMCN Marketing Director Susan Sole (personal communication), AAPCDM membership automatically includes a subscription to DMCN. Electronic subscriptions of the September, 2003 issue could also be downloaded from the Internet beginning in early August, 2003. In addition, DMCN maintains a large, centrally-located booth at every AAPCDM meeting where the most recent issues of the journal are freely distributed.

DMCN Managing Editor Michael Pountney stated (personal communication) copies of the September, 2003 issue of *Developmental Medicine and Child Neurology* were freely available at the September, 2003 AAPCDM meeting.

Other AAPCDM Members against HBOT

Dr. Oscar Papazian and Dr. Israel Alfonso of Miami Children's Hospital, speakers at the 2003 AAPCDM annual meeting (see www.aacpdm.org/resources/2003AnnualMeetingProgram.pdf) published Hyperbaric oxygen treatment for children with cerebral palsy [*Rev Neurol.* 2003 Aug 16-31;37(4):359-64], which is a review of the published literature.

Their abstract states, "The authors and the Advisory Scientific Committee of the American Academy of Cerebral Palsy and Developmental Medicine agreed that the positive results in both groups were due to a participation effect."

It's unknown how the AAPCDM Advisory Scientific Committee concluded there was a "participation effect." The actual clinical investigators of the Collet trial have never been allowed to evaluate or even see this data.

Besides Collet, there is no reference to a "participation effect" occurring in another cerebral palsy study—just as there is no placebo effect in any other CP study either—except Hardy.

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An Interview with Dr. Jolly from Whitaker Wellness Center

In order to best serve our readers, The International Hyperbarics Association recently met with Dr. Donald Jolly from the Whitaker Wellness Center in Newport Beach, California, and asked him a few questions regarding the center's practice of hyperbaric medicine. Here is his insightful interview:

IHA: Dr. Jolly, how did you first get involved in hyperbaric medicine?

DR: I first got involved with Hyperbaric Medicine in 1980 when Cardinal Maximilian de Firstenburg from the Vatican called me and asked me if I'd help with a hyperbaric project.

Cardinal de Firstenburg asked if I would come there and meet with him and some other people who were working on using hyperbarics in the missionary field. He also wanted me to call some of my contacts from Europe—doctors—and I did. I put together a group of doctors to help set up some missionary work with hyperbarics. And so I saw astonishing things. That's how I first got involved.

I saw really astonishing things. Afterward, I started working with David Hughes, Dr. Hughes, from England. He was, actually from Scotland, but he established an institute there in England. He was there for quite a while.

Anyway, I brought him to the United States, and we established a research institute here. He worked with Richard Neubauer for quite a while and many other physicians that were open-minded.

In the United States, we were doing things in the 80s that people are just recognizing now. It was kind of fun. Of course, we were all 'witch doctors'—according to everybody else.

IHA: What was the name of the institute?

DR: Hyperbaric Research Institute—Hyperbaric Oxygen Research Institute.

IHA: Where was that located?

DR: In England and also one in San Bernardino, California and in Mexico.

At our facility in Mexico, it was strictly research. We didn't treat any patients. Dr. Hughes had many research ideas and we wanted to pursue them. It was easy for him because he had many friends down in Mexico. In this way, we had a lot of help.

IHA: Right. So you probably didn't have as many regulations as you do here?

DR: No, right, absolutely.

IHA: So what made you decide to get your first chamber?

DR: Well the research institute was when we bought the first hyperbaric chamber. That was in the 80s—mid 80s.

IHA: You have a big unit back there, it wasn't that one?

DR: No, no, we bought a unit from England, it was a different one, totally different. We brought that one from England. We brought it here specifically for starting research projects.

So we had one in England and one in San Bernardino, where we were, and then we had one in Mexico.

IHA: So you got them all at

the same time?

DR: We got them all from England. Actually, originally they came from Scotland, from Aberdeen. Aberdeen is a place where there are many divers and diving schools and hyperbarics—it's a pretty big place for hyperbarics and diving.

They make these chambers we have here in Aberdeen.

IHA: What brand?

DR: Hyox. Divex, I think is the company's name.

IHA: Divex?

DR: But the chamber is called Hyox. It's getting pretty popular. They are very civilized chambers—they are wonderful. But, of course, the kind we first bought from them were just decompressive-type chambers like the white one there—small.

IHA: I see, the one person type.

DR: Well, actually you can fit two people easily, but we usually only treated one. We put an attendant in

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Dr. Jolly stands in front of the center's many chambers manufactured by Sechrist and Divex (Hyox).

An Interview with Dr. Jolly

(Continued from page 4)

sometime, but only one person at a time was treated.

IHA: Would you please describe the hyperbaric facility at Whitaker Wellness Center? And also, what aspect of hyperbaric medicine does this center specialize in?

DR: O.K. We have seven physicians here. And patients come from all over the country as well as from the local area, for various reasons. Patients come by recommendation, whenever the physicians feel that hyperbaric would be in order or helpful; they prescribe it.

Primarily, the regular conditions of wounds, osteomyelitis, osteo necrosis, and radio necrosis, some infections; we sometimes treat people with bad skin grafts. Also, if the physicians feel that the chamber can help other things, they send them.

And we sometimes have neurological problems that we treat. Sometimes we assist in detoxing—if they're in a detox program. And sometimes people are just hypoxic and we treat them and help them. They sometimes go home with oxygen to use.

We treat some stroke patients, but not a lot. We don't believe in treating stroke patients, unless they are involved in a complete program of physical therapy. We like also for some people to incorporate a mineral therapy. If people really work hard, we see very good results. Very good results.

IHA: You mean patients? Their participation?

DR: Yes. If they come here and they think all they have to do is sit in the chair in the chamber and write a check, then my estimation is, they are not going to improve much. But if they are willing to buy into the fact that they are the ones involved in creating their healing—all we are doing is creating an atmosphere in which their bodies can heal them—and they work hard with their physical therapists and they do their exercises, and they hydrate properly and they don't eat a bunch of garbage—we don't like them to eat a lot of sugar and not a lot of diet products—we like them to take some supplements—they do very well.

We have a man here now, who is doing well. His attitude has changed. I think sometimes when people become hypoxic, it puts them in a situation where they become prone to depression. But this man comes here regularly with his caregiver, and his life is changing, right before our eyes, everyday. His attitude is getting better, his range of motion is increasing. He's very adamant about his therapy and his exercise. He wants to get better, and he's getting better. And that's exciting. Very exciting.

We've had three patients in the last three months who have been in incredible pain. One man, a Vietnam Veteran, has suffered for 37 years. Absolutely

no relief. 37 years. He has titanium in his arms, his shoulders—and just a mess, really.

We have another young man, 30 who's been in pain for about 4 years, and throwing up every day— incredible neurological problems as a result of an accident.

And another one 22 years, old from Canada, who— [has had] pain for 7 years since he was 15. He had to quit school because he couldn't function, couldn't sleep because of his pain.

And all three of these patients had intensive hyperbaric therapy, along with [their other] therapy and the whole routine of our diet. And I tell you, miracles beyond miracles.

And the man, Thomas Ryan, the war veteran—is so incredible. I just talked to him the other day, and he's doing so well, he's so happy.

And Jason the young man, the 30 year old—it's just incredible—he hasn't been vomiting since therapy.

And Christopher, who is 22 has a new life. Totally new life. He's coming back in a week and a half for his 3rd trip, and we think that will be the end this whole ordeal for him. He's now able to sleep, where before he never slept.

His mom and father were terribly worried about him. He couldn't go to school, he couldn't think, he couldn't read, he couldn't sleep until he was totally exhausted. Then he would pass out. And that would always be during the day. He would pass out and get up around 6 o'clock when it was dark. Then, he would have only 3 to 4 hours of sleep and couldn't function. Now he is doing beautifully. It's incredible.

So those are the kinds of things I enjoy. And Every week we have something new at the clinic.

And then of course, we do use hyperbarics as an adjunctive therapy for heart patients, who are doing EECF. (Enhanced External Counter-Pulsation (EECF) is a non-invasive, very low risk, outpatient treatment that has been proven to relieve acute angina and lessen the effects of Congestive Heart Failure (CHF) for 8 of 10 patients tested.) But, if we can oxygenate them dramatically before the EECF, then they have more benefit as the plasma is oxygenated in the chamber.

The plasma is 85% of the blood volume—85%! Only 15% of your blood is getting oxygen, under [normal atmospheric] breathing circumstances. Even if you're breathing 100% pure oxygen, 15% gets oxygenated. The chamber changes this totally because you oxygenate 100% of your blood volume. So by putting a patient in the chamber and then doing EECF with them, it's magnificent.

IHA: You do foot and diabetes work, too?

DR: Yes, we specialize in that. Lots of foot work. It's one of the approved accepted forms of hyperbaric medicine. But we don't deal with insurance companies. We do courtesy billing, if patients request. But,

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An Interview with Dr. Jolly

(Continued from page 5)



With a variety of chambers to suit patients' needs, The Whitaker Wellness Centers accommodates patients with many ailments.

mostly insurance companies refuse cover anything.

IHA: In your own words—you may have already touched on this—just for the readers, would you describe how hyperbaric oxygen therapy works?

DR: It works the same way carbon dioxide is dissolved into Coca Cola at the Coca Cola factory. There is pressure, the physical law, that wherever pressure is in an environment, that pressure will cause whatever gas is in that environment to dissolve in whatever liquid is the environment.

So, we're not Coca Cola, we're blood and body fluids. If the body is in the chamber and the chamber is producing the pressure, and the gas present that you breathe is 100% medical grade oxygen, then the pressure causes the oxygen to dissolve into the body fluids—into the blood especially. The blood is the most important, and then the plasma. So that's how it happens. It's very simple.

IHA: What was the most memorable success you recall in your hyperbaric career.

DR: There are too many. There are too many. A woman from Arizona received her sight back. This woman was blind as a bat, and on her way back to Arizona in the car, she started reading signs. She got her sight back—and a part of Lisa was still there—I didn't know how permanent this would be, but this was years ago.

A very prominent man here in Southern California, a

business man, received his hearing back. Amazing. The man got his hearing back, and is no longer deaf. Those are magnificent things.

A little child has been treated and is coming back from what I call a sort of death because he had meningitis and was in a coma. He's really coming back little by little. His brain function is magnificent. Absolutely magnificent.

His conversational skills are incredible. His body still is falling behind, but coming little by little. When he was in a coma, doctors wanted to let him die. They told the parents that it would be best for the child to die. And the parents would have nothing to do with it. Today, he's doing well. I'm just pleased.

IHA: Is this a current patient?

DR: Yes, he's still a patient. Things like this happen all the time. It's not like you can find which one is the most exciting. Sometimes people walk who haven't walked—stroke victims!

But it's not easy—this is very difficult. I never want to give the opinion that this is something that happens just because you go into the chamber. There's a whole synergism that is necessary, and a lot of it is attention for the patient—the patient's attitude, where the patient is coming from, how much they're willing to work.

I believe, much of their recovery depends on how much love there is in their life. I believe that. In my own small way, I see that and sense it. When there's a lack of love in their life, their recovery is slow. Their attitude also matters. It might be faith—their faith in life. Both of those things. They're very, very important.

IHA: That's good advice too.

What do you feel would help to forward Hyperbaric Oxygen Therapy forward as a mainstream medicine?

DR: I think one of the most important things to do is to push people—the drug companies are already doing this. The drug companies are advertising their

drugs to the people and the people are going to the doctors and pushing for those drugs.

I think we have to push awareness of hyperbarics through programs through news articles, through specials, through documentaries, through health shows, talk shows—any method at all to get the word out that the people must push. And we, who are in the business must push, with the legislators, and people who have an open mind. With the insurance companies, we have to prove that what we can do is helpful, and ultimately can save them some money.

But we have to push—we have to give information to

(Continued on page 7)

“There's a whole synergism that is necessary, and a lot of it is attention for the patient—the patient's attitude, where the patient's coming from, how much they're willing to work.”

An Interview with Dr. Jolly

(Continued from page 6)

the people—not force them, but give information so that people talk about hyperbarics and seek it from their doctors. I'm getting prescriptions now from Kaiser, and that's pretty amazing.

IHA: Kaiser?

DR: They'll write on the prescription, "Kaiser cannot pay for this therapy", but they're sending people. Here.

IHA: They know it's the right protocol?

DR: Yes. Yes. I had a horrific thing with Kaiser. Maybe this is one of the great things that has happened. There was this boy who had necrotitis and facitis in his finger. I think at 7:30 or so in the morning, he got this finger wound. By 4 o'clock in the afternoon, it was crimson red, and they were going to amputate. His mom called Kaiser in hysterics, and they wouldn't listen to her about hyperbarics. She could have taken him out of AMA care, but the family didn't know their options. It was, after all, against medical advice to do so.

But anyway, I put together a team of people—physicians who went there and met with them. We tried to see what benefit hyperbaric would have on necrotitis and facitis. But the Kaiser physicians were just obstinate as could be.

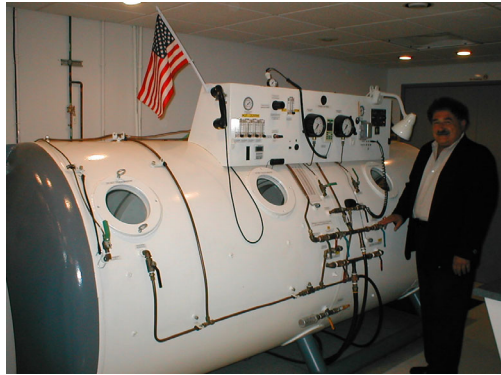
We were—pretty nice. We were factual—"This will work, here is the paperwork," "haven't you read it," "it's in the journals," "what's wrong?"

And so they said, "Well, we don't condone that. We don't condone experimental therapies."

And then, we made some remarks to counteract that. To make a long story short, I told them that I'd called a news conference, here in the parking lot, and that we were going to let the media take this information because this callousness was unacceptable.

They [Kaiser] asked for 10 minutes time, and came back with their answer: "Well, we've approved Eric for hyperbarics."

Seven treatments—7 treatments—knocked the necrotitis and facitis out! The boy's name is Eric Stowell. He's willing to tell the world that hyperbarics has saved his arm and probably his life.



Dr. Jolly admits that there are many costs involved in maintaining a comprehensive center such as the Whitaker Wellness Center

"I think we have to push awareness of hyperbarics through programs through news articles, through specials, through documentaries, through health shows, talk shows—any method at all to get the word out that the people must push.

And we, who are in the business must push, with the legislators... and insurance companies... and ultimately save them money."

IHA: Wow. What a story! Well, is there anything else you would like to say?

DR: Just that I hope that people will really be fired up about getting the word out. I think we all have to be missionaries. We have to go and preach the good news. And this is good news. Also, we have to have more chambers and competition. Competition will bring the price down. The cost must come down.

Our price is very competitive—we have a lot of patients, a lot of treatments, and we work with them. But, we have to pay our bills. It's an expensive place to run.

IHA: How many chambers do you have here?

DR: We have—{counts}—6. 2 are Sechrist, 3 Hyox, and the big one. That's a lot of money. We have a big room in the back, and another part of the building full with compressors, filters and coolers and air dividers... and then another room with oxygen equipment—regulators and all those things.

These things are necessary. We must also maintain it—thousands of dollars for upkeep.

The maintenance crew comes from Scotland to service these chambers. Every year it must

be done. The people from Sechrist come and they take apart everything, the tubes, and put all new fittings. They take apart all the dials and put it back together again.

IHA: That's their annual maintenance?

DR: Yes, that's very expensive.

IHA: Well, thank you for this glimpse into your hyperbaric centers. Thank you.

DR: You're welcome. Glad I could help.

For more information about therapies at The Whitaker Wellness Institute, please call 800.488.1500

Membership Fee Schedule

- | | | |
|----------|---|------------------------------|
| 1 | Prime Corporate Membership | \$15000/yr |
| | <i>Benefits include Voting Participation at meetings; voting rights for state and federal level political lobbying campaigns; full access to the graphic art design department (i.e. editing of literature, pamphlets, posters, and your organization newsletter); receipt of IHA monthly newsletter, 'The Pressure Point,' and submission of feature articles and prime ad space; and networking with fellow doctors, access to member studies and reference literature.</i> | |
| 2 | Medical Directors | \$1000
(Lifetime) |
| | <i>Medical Directors (upon approval): Benefits include Voting Participation at meetings, study participation and publishing, speaker sponsorships, receipt of monthly IHA newsletter 'The Pressure Point,' graphic design and editing services for office literature, prime features in newsletter and ads, and travel benefits.</i> | |
| 3 | Corporate Membership | \$500/yr |
| | <i>Benefits include graphic art design work and editing of literature, pamphlets, posters, and your organization newsletter; receipt of IHA monthly newsletter, 'The Pressure Point,' submission of feature articles and prime ad space; and networking with fellow doctors, access to member studies and reference literature.</i> | |
| 4 | Provider Membership (non-equity) | \$500/yr |
| | <i>Hyperbaric Clinics and Health Centers; patient referrals, member to member hyperbaric reimbursement, study participation and publishing, speaker sponsorships, graphic design and literature editing services for provider's own literature, receipt of monthly IHA newsletter, as well as features in IHA newsletter articles and ads.</i> | |
| 5 | General Membership (non-equity) | \$10/yr |
| | <i>Benefits include access to member referrals, receipt of IHA monthly newsletter 'The Pressure Point,' article submittals, and member to member hyperbaric reimbursement.</i> | |
| 6 | Participating Membership/ (non-equity) | \$Free |
| | <i>Benefits include access to general membership benefits and IHA literature. Participating members are available to work on given IHA projects, and may be asked to travel on behalf of the Association to medical shows, symposiums, and meetings.</i> | |



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International Hyperbarics Association

Application for Membership

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CERTIFICATION

In making this application to the **International Hyperbarics Association**, and if I am accepted, I agree to abide by all of its rules, regulations and policies as these may be promulgated from time to time.

My membership fee of (select one): \$10 (general) OR \$500 (Provider)
is attached to this application.

*(Please make checks payable to **International Hyperbarics Association**)*

Executed on _____ at _____
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IHA use only	Membership No.
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AACPD Continued

(Continued from page 3)

Murray Goldstein, D.O., M.P.H., is medical director of the United Cerebral Palsy Research and Educational Foundation, and is medical consultant to the United Cerebral Palsy Associates of the United States.

He is recognized internationally as a leader in the clinical, scientific and administrative aspects of disorders of the nervous system. His present focus is developmental brain injury and cerebrovascular disease.

Goldstein to the FDA: In CP, Anecdotal Evidence Enough

Perhaps most surprising of all is the effort by UCP to initiate and finance the proposed HBOT study at UCLA. According to Dr. Murray Goldstein, Medical Director of the UCP Research and Educational Foundation, such a study is unnecessary when something has been found to help more than just one cerebral palsy child.

Dr. Goldstein was the guest speaker at an April 24, 2001 meeting of the Food and Drug Administration's (FDA) Pediatric Subcommittee of the Center for Drug Evaluation and Research (see <http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3744t2.rtf>). The specific purpose of the meeting was to determine dosage in a drug used off-label for CP children.

“Even without a randomized, double-blind, placebo-controlled trial, there was consensus agreement the drug worked. The moderator stated, “The efficacy is not the question in this situation. We have a therapy that we know is efficacious that we know is being used. It’s the dose. It’s the ethics of how do we conduct a trial in a population so we can determine the correct dose.”

Just like Hyperbaric Oxygen Therapy, physicians are now prescribing the drug off-label based on nothing more than anecdotal evidence. According to the official FDA transcript, Dr. Goldstein said, “Whether we like it or not, these studies are going on all over the country. They’re going on in physicians’ offices, in clinics all the time with very biased populations and with very biased observers. They’re trying to do their clinical job, and doing it well.”

Goldstein: Parents most scrupulous observers.

Just like Hyperbaric Oxygen Therapy, where parents are pushing for HBOT reimbursement based upon observed

improvements in their own children, Dr. Goldstein concurs that parents are experts at observing improvements in their children, “I urge you to incorporate the use of the parents even though they are obviously biased. Thank God they’re biased. On the other hand, I have learned by working with them that they are often the most scrupulous observers of what is happening to their children, and the rest of us who plug in every now and then and take a look and plug out again don’t really understand the natural history of what’s going on with that child in its day-to-day involvement and interaction. So, parents are superb observers. Sometimes they scare the hell out of me with the conclusions they come to, but they’re good observers.”

“I urge you to incorporate the use of the parents even though they are obviously biased.”—Goldstein

Goldstein: Interventions Should Address Pathologies, Not Symptoms

“Even though we’re looking at one approach to solving the clinical issue, we are not approaching the pathological issue at all by this approach. So, one has to be extremely careful that we realize that we’re proposing to address symptoms rather than the basic pathology which raises other kinds of issues about whether there are pharmacologic approaches to addressing the basic pathological entity.”

These remarks to the FDA were about the off-label use of Robinul to control drooling. Known side effects include extreme constipation, to the point where children wind up in the emergency room because their bodies cannot eliminate toxic wastes. This was discussed at the same meeting, yet no one stated Robinul is dangerous.

One of the most well-known and universal side effects of HBOT—reported by almost all parents—is an almost immediate reduction and near elimination of drooling.

Goldstein: When endpoint is absolute, no blinding.

According to Dr. Goldstein, the existing anecdotal evidence constitutes a trial, and any further research doesn’t need blinding. If there’s no need of blinding, then there’s no need of a placebo either.

Said Dr. Goldstein, “I would like to, if I may, address the issue of blinding. When the endpoint is absolute and the natural history is well known, you really don’t have to blind even though blinding is a beautiful gold standard to attempt to approach, but it isn’t necessarily the law of the Medes and Persians. If you have a treatment and you give it to one person and the person recovers, it’s a miracle. If you give it to two people and they both recover, it’s a trial.”

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AACPDM Conclusion

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United Cerebral Palsy Funding an HBOT Study Designed To Fail?

According to the most internationally recognized experts in the use of HBOT to treat CP children, the UCP/UCLA protocol is purposely flawed and can produce nothing but the results its biased investigators want it to produce.

Are the UCP/UCLA investigators objective? Since 2001, Drs. Oppenheim and Fowler, have taught a CME course to their peers against the use of HBOT for CP. The information taught has not been factually accurate.

At the same time, the Medical Director of UCP has gone on record with the FDA regarding what constitutes enough research for CP treatments when weighed against accumulated anecdotal evidence. Dr. Goldstein's standard for a manufactured pharmaceutical

is somehow different than the standard for the pharmaceutical known as Hyperbaric Oxygen Therapy.

Is United Cerebral Palsy Funding an HBOT Study Designed To Fail?

Dr. Marois has stated, "There are few experts in hyperbaric medicine who are experts in CP and vice-versa. It is then very easy to mislead almost anyone in the scientific community..."

UCLA IRB Approves the UCP/AACPDM CP Study

Why would investigators who are so clearly biased against the use of HBOT for CP want to do a study of same?

Oppenheim told the 58th AACPDM conference that his IRB had been approved; however, he refused to provide Dr. Harch a copy of the same when asked.

Oppenheim further stated that he was not doing a study to determine whether HBOT was efficacious in treating children with CP. He said he was doing a study to determine whether using PET scans was able to determine changes in the brain after HBOT.

CP HBOT Objective:

"We're all left... to prove them (HBOT) not true, which is sort of the opposite of the scientific method."

—Oppenheim

But if that is really Oppenheim's intention, then why do the study using children?

Oppenheim has already publicly stated that his intention is to disprove HBOT as being efficacious for treating children with CP: "We're all left... to prove them (HBOT) not true, which is sort of the opposite of the scientific method."

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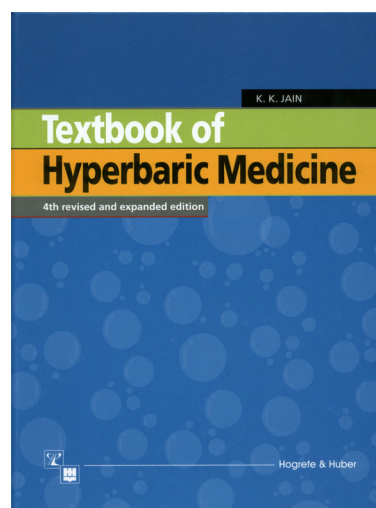
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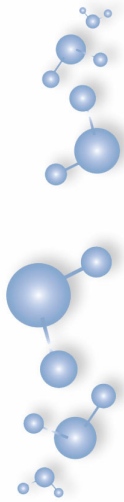
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discussion board**



The International Hyperbarics Association is a coalition of doctors, parents, patients, corporate chamber-industry professionals, hyperbaric center owners, and above all members who are committed to the cause of medical hyperbarics.

Our members come to us from all geographical areas with one common goal— to share their knowledge and information regarding the latest hyperbaric news.

Our driving force is our members, who are committed to do all we can “to give life to the world.”

— “Mundo vitam dare”



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