

To: dfreels@mindspring.com  
From: David Freels <dfreels@mindspring.com>  
Subject: Not our last communication  
Cc:  
Bcc: Philip\_James, Harch.all  
X-Attachments:

>Mr. Freels,  
>  
>It is clear to me that we will not agree on the issue of hyperbaric oxygen  
>in the treatment of brain injury. However, I do believe that it is  
>important to back-up what we do in medicine with evidence. All too often  
>treatments we all thought and hoped would work, when placed under the  
>microscope of rigorous clinical trials work no better than nothing - or  
>worse do more harm than good. The examples of these sorts of optimistic  
>therapies proven later to not work are too numerous to count. They were  
>not accepted and praised by idiots. Rather, very bright people have been  
>fooled by the hope that something would work and that hope then clothed in  
>something that looked good but later was ineffective - or worse dangerous.  
>  
>I agree that there should be more research on brain injury and brain damage  
>in children. In fact, I am spending a considerable percentage of my time  
>doing just that - so that we can do a better job someday helping the kids  
>who need help most.  
>  
>I cannot let your poorly-informed comments about the lack of pediatric  
>clinical trials in children with epilepsy go unanswered, as I spend (and  
>have spent over the past 10 years) a considerable amount of my time  
>participating in these studies. To give you a rough idea of the volume of  
>research on the topic, I've attached a list of references of published  
>clinical trials on anti-epileptic drugs (some of which I have personally  
>participated in as an investigator) taken from a manuscript that I'm  
>preparing on a specific aspect of the methods we use for these types of  
>trials. The list is not exhaustive, but as you can see from the reference  
>list (especially those that are in bold that specifically relate to  
>children), your claim that there are no clinical trials published on  
>anti-epileptic drugs in children is far from correct.  
>  
>If you look carefully at the literature on hyperbaric oxygen and brain  
>injury and cerebral palsy in children, you will find that there are a  
>couple of clinical trials published - both show no effect compared to  
>placebo or a placebo-like therapy. Also, there are reports published (like  
>in Pediatrics last fall) of significant adverse events in children who have  
>had hyperbaric oxygen therapy. I am certainly not the only person who  
>knows about the brain who believes that hyperbaric oxygen therapy should  
>not be done in kids until and unless clinical trials prove efficacy and  
>safety. A major medical society for hyperbaric oxygen specialists has  
>recently published similar recommendations.  
>  
>I do not ask that you agree with me Mr. Freels. Only that you understand  
>that I am not a villain, and that I do my very best (although I admit not  
>enough) to help the same children for whom you have deep emotions. I have  
>had now almost 20 years experience as a physician, and during that time  
>I've seen many families lose all they have paying money for therapies that  
>don't work. I find this quite sad, especially when therapies we know do  
>work for specific disorders can't find adequate funding from agencies like  
>Medicaid. We must be careful with resources and direct them towards  
>therapies proven to be effective and safe - a goal easily stated but  
>difficult to achieve.  
>  
>You obviously believe that hyperbaric oxygen is helpful. I disagree. One  
>of us is right, and one of us is wrong. There are no objective data for

>either of us to prove our position. I suggest that you write your  
>congressman and insist that funding be established for a randomized  
>clinical trial of hyperbaric oxygen be conducted on children like yours.  
>Then I suggest that you refuse to pay for such treatment until the trial is  
>completed. Ofcourse since you believe it works, you should be happy to  
>have your child participate in the clinical trial.  
>  
>Then when the trial is completed, if it is found to work, then I'll be  
>happy to say I was wrong. Will you do the same if the trial proves it  
>doesn't work?  
>  
>Until such a trial is completed, this will end our discussion.  
>  
>I wish you and your child all the best,  
>  
>Edwin Trevathan, M.D., M.P.H.  
>Attachment converted: Big Mac:references childhood AED trials (WDBN/MSWD) (0002B543)

Thank you for the references. I quickly reviewed them but didn't see anything that disputed the findings on SPECT-scan imaging. That's what I'm primarily interested in.

I'm also interested in your thoughts and comments on the work of Roger Denays utilizing SPECT-scan imaging in cerebral palsy.

As someone who has many years experience in clinical trials, surely you are aware that the first rule in creating a placebo for a double-blind controlled study is that by definition the placebo can have absolutely no effect.

With this mandate, what would be the placebo in a double-blind controlled study for hyperbaric oxygen since oxygen could not be used as placebo?

Surely you are also aware that the majority of drug studies are primarily funded by the drug companies who will recoup their investment once they have a patent. Surely you also know that as soon as they get FDA approval, they quickly market their new product with as much off-label use as possible.

Who would pay for a study on hyperbaric oxygen in children? There's nothing to get a patent on--the agent is oxygen.

Witness the prescribing methodology in pediatric neurology.

This practice destroys lives and destroys brains.

Also on Windfield Circle is a young man named Elliot Stein whose mother came home one day when he was six and found him asleep on the couch. She couldn't wake him so she took him to the emergency room where the physician decided he must have had a seizure and prescribed Dilantin, and he's been on it ever since.

Today he struggles with daily living, hygiene, and finding his purpose and direction in life. At the same time he has an incredible sense of humor and a skill for mathematics that borders on genius.

But he's never had a seizure.

Is any of this your fault? No. That's just the way it is--mainly because the gas laws of physics and the molecular properties of oxygen utilization by the body are not part of any standard medical curriculum at any American medical school--which is pretty ironic considering there's no healing or health or life without oxygen.

Hyperbaric oxygenation should be the first thing taught on the first day of medical school. It is the efficient and effective method of delivering oxygen to the body--it is the most fundamental of fundamentals.

Yet you view it as quackery just like 99.9% of all physicians simply because you don't know anything about it, and some redneck in Tucker, Georgia is trying to help you learn something about it.

If you're truly interested in the truth then don't let this be our last communication.

Dr. Trevathan, this is not rocket science, actually maybe it is--but even if it is, it's not that hard once you sit down and look at it. Look, I was a Theatre and English major in college. Professionally I write advertising for ad agencies. If I can figure this out so can you.

I am going to email you a pdf file of Chapter 2 from The Textbook of Hyperbaric Medicine. It explains how it works.

In the meantime, attached is the rebuttal to the Pediatrics article. I have contacted a number of the physicians who authored the original article to ask their opinions on the rebuttal, but no one has the courage to discuss it.

I would be interested in your thoughts.

Reference #11 from the rebuttal: 11. Harch PG. Hyperbaric Oxygen Therapy in acute Neurological Indications. 7th Annual Advanced Topics Course in Hyperbaric Medicine, Richland Memorial Hospital, Columbia, South Carolina. April, 1998. Available in text and on videotape from the Department of Hyperbaric Medicine, Richland Memorial Hospital.

I have a copy of this video presentation that I would be more than happy to share with you. I'll send you a copy next week.