BEFORE THE OFFICE OF STATE ADMINISTRATIVE HEARINGS
STATE OF GEORGIA

JIMMY FREELS, a minor by and through DAVID FREELS, his father, Petitioner,	)	Docket No.: OSAH-DCH-LOC-0615259-44-Teate
v.	)	
DEPARTMENT OF COMMUNITY HEALTH, Respondent.	)	

DIRECT TESTIMONY OF PIERRE MAROIS, M.D.

DO YOU SWEAR THAT THE TESTIMONY YOU ARE ABOUT TO GIVE IS THE TRUTH, THE WHOLE TRUTH, AND NOTHING BUT THE TRUTH SO HELP YOU GOD AND UNDER PENALTY OF PERJURY?

DR. PIERRE MAROIS: YES

Q: Please state your full name for the record.
A: Pierre Marois.

Q: Are you employed?
A: Yes.

Q. In what capacity?
A: I am a physician specializing in pediatric Physical Medicine and Rehabilitation.

Q: Please provide a description of your education and work experience.
A: I did all my medical studies (5 years) at the Montreal University School of Medicine then I trained for 4 and a half years for a residency in pediatrics and Physical Medicine and Rehabilitation.

After being board certified in Physical Medicine in Canada in 1979 (Fellow of the Royal College of Physicians) I did a one year fellowship in pediatric rehabilitation at the University of Karolinska(Sweden), at the University of Toronto, at Stanford University (Palo Alto), at Rancho Los Amigos (Los Angeles) and three rehabilitation centers in Minneapolis.

Since 1981 I have worked mainly at Ste-Justine University Hospital (pediatric hospital) in Montreal which is the biggest mother-child health center in Canada. I am also working in 4 Rehabilitation centers in the Province of Quebec and with more than 20 rehabilitation teams, mainly with children and families of children with cerebral palsy. I have done more than 50,000

consultations in cerebral palsy and I am actively following more than 1,500 children with this diagnosis.

I have put together the first rhyzotomy team in C.P in the world and at Ste-Justine Hospital, in 1982 we were the first team in North America to do a selective dorsal rhyzotomy in C.P. Since 1987, this is a treatment used in children with C.P. everywhere in North America. I was involved in many research studies on neuromuscular diseases and cerebral palsy and in 1998 initiated the first published pilot study on Hyperbaric Oxygen Therapy(HBOT) in cerebral palsy. I then started the coordination of the first double blind study on the same subject, eventually published in the Lancet in 2002.

I regularly teach medicine and I have given numerous local, national or international lectures on the treatment of Cerebral Palsy, including HBOT, as well as on many rehabilitation topics, bio-ethics etc.

I have been the president of the Medical Board of Marie-Enfant Hospital for 19 years, President of the Humanization of Health care committee at Ste Justine and member of many other administrative or ethics committees.

Q: Is the attached CV a fair and accurate description of your education and work experience?
A: Yes.

Q. For how long have you been practicing medicine?
A: 30 years.

Q: Is your license to practice medicine in good standing?
A: Yes.

Q: In your professional experience, have you had occasion to treat pediatric cerebral palsy (CP) patients?
A: Yes. More than 80% of my work is dedicated to the treatment of cerebral palsy.

Q: What type of treatments have you offered pediatric CP patients?
A: All the recognized or promising therapies including: Surgeries (orthopedic and neuro-surgical), oral medications, physical therapy, occupational therapy, speech therapy, psychological therapy, orthoses and adaptative devices, Botox and Phenol injections, baclofen pumps, horseback therapy, HBOT, and neurostimulators.

Q: Do you have any experience with hyperbaric oxygen therapy?
A: Yes, since 1998.

Q: What is hyperbaric oxygen therapy?
A: It is a very simple treatment consisting of breathing pressurized oxygen at above sea level pressure. It is generally given in a pressurized chamber.

Q: Have you received any training with respect to administering hyperbaric oxygen therapy?

A: Yes, I did a training with Dr. Eric Kindwall. I am trained to administer HBOT but it never was my intent to administer such a treatment. I did this training to better understand the treatment I was doing research on. I never administer or supervise HBOT.

Q: Do you use hyperbaric oxygen therapy?
A: I do not treat anyone with this treatment or directly use hyperbaric oxygen therapy.
I treat patients with cerebral palsy, recommending any treatments that would be needed to improve their function, their autonomy, and the comfort of my patients. With the positive research done on C.P and HBOT, I often recommend or suggest HBOT. The treatments are generally done in private clinics. I do not work with those clinics but evaluate the progress of the children receiving any kind of treatment, including HBOT.

Q: For how long have you been doing research or following patients receiving hyperbaric oxygen therapy?
A: Since 1998

Q: For what medical conditions do you recommend hyperbaric oxygen therapy?
A: I recommend HBOT in many neurological conditions.

Q: Have you followed and evaluated children who have cerebral palsy (CP) and that have been treated with HBOT
A: Yes.

Q: Approximately how many children with CP have you followed that have been treated with hyperbaric oxygen therapy?
A: Approximately 800.

Q: What are the results of the children who received HBOT?
A: Most children had permanent improvements after 40 treatments.
More than 80% of the parents reports positive changes in cognition, communication gross motor and fine motor function. We have evaluated with objective standardized testing more than 350 children and have measured impressive gross motor changes in the vast majority of them (more than 65%). The cognitive changes are even more frequent. The positives changes seem to be permanent as we have 7 years follow-up on many children.

Q: Do you catalogue the results?
A: We did catalogue the results on more than 350 children.

Q: Have you been involved with designing any studies related to using HBOT to treat CP patients?
A: I initiated and I have been involved in the design of the first pilot study on CP and HBOT published in 1999 in the Undersea and Hyperbaric Society Journal as well as in the double blind study published in The Lancet in 2002.

Q: How many children were involved in the 1999 study?
A: 25.

Q: What were the results of the testing?
A: We saw important changes in the gross motor function as well as on the reduction of spasticity.

Q: How did you determine "improvement?"
A: We used standardized objective measurements, the GMFM for gross motor function, Asworth scale for spasticity, and a questionnaire for the parents.

Q: Are you familiar with the Collet Study on the effectiveness of HBOT for CP patients?
A: Yes, I am one of the principal co-authors.
Q: Did you have any involvement with the Collet Study?
A: Yes. I initiated it. I, along with Dr. Vanasse, the chief neurologist at Ste Justine designed the protocol. I participated in the recruiting of the patients and in the formation and the training of the professional team (more than 50 doctors and therapists). I also created a temporary Hyperbaric clinic (for the duration of the research) for which we had to hire 25 persons (doctors, technicians, nurses, inhalo therapist etc,).We were then able to treat 65 children at this center every day under close medical supervision. I received from the Government of Quebec a 1.4 million dollar grant to do this study, but eventually the coordination of the study was given to the F.R.S.Q., the official government research organization who named one of its associates, Dr. Collet to direct the research.

Q: Did the Collet study follow the recommended protocol?
A: No.

Q: How did the protocol vary from the one established by you and Dr. Vanasse?
A: We recommended three groups. One group to receive HBOT at 1.75 times normal pressure at sea level. The second group was to receive air at 1.3 times normal pressure, and the third group was to be a pure control group. This last group would receive no increase in pressure. However, this last group was not utilized in the Collet Study, so there was no "control group."

Q: Why did you and Dr. Vanasse design the protocol for the study with the third "control group"?
A: The middle group in our originally designed protocol, the group receiving air at 1.3 ATA air, actually received a low dosage of HBOT. The only way to distinguish the results was to have a true control group that received absolutely no HBOT effect.

Q: What was the significance of the change in protocol?
A: This was a huge mistake because there was no true control group. Both remaining groups were treated with HBOT with the only difference being the dosage. Both groups improved significantly but it was then hard, without the control group, to conclude that the impressive results were the sole effect of HBOT. Without the last group, the study only compared different dosages of the same treatment.

Q: Since there was improvement in both groups, what did the study conclude?

A: The researchers had no choice but to postulate that either both treatments were effective or that the mere act of participating in the study had a positive effect. The clinicians involved in the study could not support the latter conclusion, which was scientifically dishonest because the improvements measured in this study were more impressive than all those measured with recognized therapies. Experience taught us there had never been that level of improvement in CP children prior to the study and it was dishonest to conclude it was attributable solely to a participation effect.

Q: What observations did you make concerning the results of the Collet study?
A: We (most of the principal researchers and clinicians involved in the study) had to face the problem of interpreting the results without the true control group. All the clinicians involved in the study were by-passed, and Collet who had no knowledge or experience with HBOT or CP decided to interpret the results by himself. His conclusion was that the improvement was a placebo effect, an ironic finding since there was no true placebo group.

Q: Did you concur with Collet's conclusions?
A: No. There was a big dispute over his interpretation of the results.

Q: How was the study published?
A: Even though there was a dispute, Collet sent the article to The Lance who after many exchanges of letters accepted to publish it " provided that all references to the term placebo was removed"

Q: How could there be any reference to a placebo effect in that study?
A: Even when the article was published, Collet and the FRSQ, in the official governmental communiqués, falsified the title and the conclusion of the article to make everyone believe that the results of the study showed that the improvements were secondary to placebo effect. In fact we have all the evidence to show that the improvements were the effect of both treatments administered with lower pressures.

Q: Do you have an opinion for why both groups in the Collet study showed improvement?
A: Yes. I have seen or participated in many research studies involving CP. Many articles have been published on the improvements obtained by "conventional" and recognized therapies, measured with the same evaluation tools that we used on the same type of patients. I have never seen more impressive results that those we have measured with HBOT. If the amount of improvements we have observed are a participation effect then we should close down every rehabilitation center in the world. The only plausible explanation is that both treatments were effective and the issue more a matter of identifying a more standardized dosage.

Q: In your opinion, can HBOT correct or ameliorate the underlying problems causing CP in children?
A: Yes.

Q: Have you been involved in any recent studies?
A: Yes, I along with Dr. Vanasse are preparing the publication of an article about a retrospective study on HBOT in the treatment of cerebral palsy.

Q: What methods did you use to gather data?
A: We followed and evaluated 118 children affected with CP and treated with HBOT, receiving 30 to 40 treatments with 100% oxygen at 1.5 ATA. Fifty one children received one series of treatment (mean 39 treatments), 40 children received two series (32.8 treatments) and 27 children received three or more series of HBOT. These children were then evaluated by a Gross Motor Function Measurement (GMFM) done before and after each series of treatments.

Q: What were the results?
A: After the first series of treatments, a mean improvement of 3.96% of the GMFM was measured in the 118 treated children with 69 (58.5%) having an improvement of 2.5% or more. The amount and rate of improvement was higher or equal to those published with any recognized treatment in CP. Further improvements of 3.09% and 1.77% in the GMFM were seen in patients who had a second and third series of treatments.

Q: What conclusions did you draw as a result of the data collected?
A: The data confirmed previous findings. It confirmed HBOT could be a valuable treatment for CP, even many years after the neurological damage was sustained.

Q: Based on your experience in treating CP patients with other therapeutic measures, and with HBOT, do you believe HBOT can correct or ameliorate the condition causing the disease?
A: Yes.