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 PAUL HARCH, 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. PAUL HARCH: YES

Q: Please state your full name.
A: Paul Gregory Harch.

Q: Are you employed?
A: Yes.

Q. In what capacity?
A: I am the director of the Louisiana State University School of Medicine, New Orleans Hyperbaric Medicine Fellowship. I am in private practice as a hyperbaric medicine physician, and work in hospital-based emergency medicine, and freestanding urgent care center.

Q: Please provide a description of your education and work experience.
A: University of California, Irvine 1972-76, B.S. in biology, Phi Beta Kappa, Magna Cum Laude; Johns Hopkins University School of Medicine, 1976-1980, MR.; General Surgery training 1980-82, University of Colorado Health Sciences Center, Denver, Colorado; Radiology 1986-87, LSU School of Medicine, New Orleans and Charity Hospital; National Oceanographic and Atmospheric Administration Physicians' Diving Accident Management Course 9/1987; emergency medicine, diving and hyperbaric medicine practice 1983-present.

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: Since 1983

Q. Are you Board Certified?
A: Yes, in Emergency Medicine by the Board of Certification in Emergency Medicine and in hyperbaric medicine by the American Board of Hyperbaric Medicine.

Q: Are you licensed to practice medicine?
A: Yes.

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

Q: Do you have any experience with hyperbaric oxygen therapy?
A: Yes. I have been practicing and engaged in research in hyperbaric medicine since 1986.

Q: What is hyperbaric oxygen therapy?
A: It is the use of greater than atmospheric pressure oxygen as a drug to treat basic disease processes and their diseases.

Q: Have you received any training with respect to administering hyperbaric oxygen therapy?
A: Yes. I participated in the National Oceanographic and Atmospheric Administration's Physicians' Diving Accident Management course in 1987 and a hyperbaric orientation course in 1986. I have also had direct training by Dr. Keith Van Meter, one of the world's diving and hyperbaric medicine authorities, through my continuous association and practice with him since 1986.

Q: Do you use hyperbaric oxygen therapy in your practice?
A: Yes.

Q: For how long have you been using hyperbaric oxygen therapy?
A: Since 1986.

Q: For what medical conditions do you administer hyperbaric oxygen therapy?
A: For all of the typically reimbursed indications and a wide range of off-label uses, including cerebral palsy, autism, stroke, traumatic brain injury, dementia, residual effects of carbon monoxide poisoning, chronic residual effects of cerebral decompression illness, and a large number of acute and chronic adult and pediatric neurological conditions.

Q: Do you administer hyperbaric oxygen therapy for children who have cerebral palsy (CP)?
A: Yes.

Q: Approximately how many children with CP have you treated with hyperbaric oxygen therapy?
A: In excess of 100 over the last 15 years.

Q: What are the results of the children who received HBOT?
A: 90% demonstrate improvement in function.

Q: Do you catalogue the results?
A: Somewhat. I have begun assembling groups of patients with similar diagnoses, including the different types of CP to evaluate their brain imaging and functional changes. Each patient, however, has a record of the results of treatment in their chart along with a videotape of their abilities before and after HBOT.

Q: Are you familiar with the AHRQ report referenced in the Georgia Department of Community Health's denial of HBOT to Jimmy Freels?
A: Yes.

Q: How are you familiar with this report?
A: I served as a peer reviewer and consultant for the report and was the source of most of the neurological literature that was reviewed.

Q: What is the AHRQ?
A: Agency for Healthcare Research and Quality.

Q: What type of study was sanctioned by the AHRQ?
A: A literature review of hyperbaric oxygen therapy in brain injury, stroke, and CP.

Q: What organization performed the study?
A: The Oregon Health and Science University's Evidence-based Practice Center.

Q: Who was the principal investigator?
A: Marian McDonagh, Pharm.D.

Q: What did the AHRQ study rely upon?
A: The hyperbaric medicine literature that they were able to gather by various means from multiple sources.

Q: Did they perform a complete review of all the literature available to it?
A: No. It was restricted to human studies published in English.

Q: What data was not reviewed by the researchers?
A: Any foreign language literature, animal studies, human studies that did not have clinical outcome measures, case reports, and small case series.

Q: What, if any, significance is there to not reviewing or addressing these studies?
A: The animal studies underpin the human studies and show that HBOT has every reason to have a beneficial effect in human neurology. The exclusion of the international non-English speaking literature prevents the review of potentially very valuable information that is germane to all people with brain injury, not just those who speak a foreign language. Lastly, human studies that evaluated biochemical and other non-clinical

outcomes help explain the underlying science of HBOT in human brain injury and the potential beneficial effects seen in the clinical outcome literature. If there is symmetry and consistency of the scientific studies across the human spectrum, both clinical and biochemical, regardless of the language in which the studies are written, and there are similar positive findings in the animal studies you have a very powerful argument that trumps flaws in any given study and/or its design.

Q: Do you believe the results of the AHRQ study are valid?
A: No. It is invalid and incomplete.

Q: Why not?
A: The authors did not have a facile understanding of the science of HBOT, they did not evaluate the science of the studies, and they did not interpret them in a composite manner. Instead, their analysis can best be termed accounting in medicine. It was a rigid scoring of internal and external validity criteria that is devoid of an understanding of the underlying science and nuances of HBOT in brain injury, stroke, and cerebral palsy. For instance, the CP part of the report did not dissect the somewhat contradictory and confusing conclusions in the Collet study where the Collet authors note that motor improvements (gross motor functional measures and PEDI-Pediatric Evaluation of Disability Inventory) cannot be explained by a learning effect while the multiple improvements (including motor) of the children in the study can be explained by a parent participation effect. They opine that the parent participation effect is due to the environment of parents who "were particularly motivated and supported in their hope by anecdotal (sic) reports"...and the "context of the intervention" which "was a source of positive communication with other children and with parents." They note that "such an environment has been reported to accelerate intellectual, emotional, and social development." The reference for this last quote is a book entitled Personality: Theory and Research. While I have not read this book it does not appear by title to deal with objective motor findings in children and is cited by the Collet authors as a substantiating document for issues related to intellectual, emotional, and social development. In other words, the objective scientifically measured motor improvements of both hyperbaric groups of patients in the Collet study can't be explained by a learning effect, but can be explained by a parent participation/environmental effect which has been reported to accelerate non-motor improvements, NOT motor improvements. This is non-sensical.

Essentially, we have a study where two different hyperbaric oxygen doses caused durable objective improvements in children at a far faster rate than ever before seen in the treatment of CP. However, the authors attributed it to a placebo effect caused by the parents and children participating in an atmosphere of good cheer inside a submarine like vessel. This conclusion is contradictory and ludicrous by itself, but when we understand the science of hyperbaric oxygen therapy in chronic wound states that has shown that HBOT is a trophic drug that causes tissue growth through actions on the DNA of cells in damaged areas of the body the studies become a consistent body of information that shows a benefit of HBOT in CP. The AHRQ Report did not understand these facts about HBOT in chronic conditions.

Finally, the AHRQ Report was incomplete. It was originally supposed to address the use of SPECT with HBOT in brain injury. SPECT findings could have added another

layer of proof to their analysis because brain blood flow and metabolism are coupled in normal brain and chronic brain injury and metabolism determines neurological function. Studies with positive changes in SPECT brain imaging would have bolstered the studies with clinical outcomes.

Q: Is the Collet Study the study referenced in the AHRQ report as the only randomized controlled study?
A: Yes.

Q: Are you familiar with the Collet Study?
A: Yes.

Q: How are you familiar with the Collet Study?
A: I was in contact with some of the co-authors before they performed their pilot study that led to the Collet study and was instrumental in getting them to make sure they performed 40 HBOT's on the children in the Collet study. I tried unsuccessfully to get them to change the control group to a sham pressurization, a true control, and the HBOT group to 1.5 ATA/60 minutes per treatment instead of the 1.75 ATA they used.

Q: What protocol was used to create the study?
A: 1.75 ATA pure oxygen for the HBOT group and 1.3 ATA air for the control group.

Q: Do you agree with this protocol?
A: No.

Q: Why not?
A: The control group was not a true control group which was designed to eliminate a placebo effect. The children in the control group did not get a placebo treatment, i.e., a parent participation effect. Instead, they received a 30% increase in oxygen with each treatment. Since oxygen is not inert a 30% increase in oxygen could not be a placebo. The HBOT group received forty 1.75 ATA oxygen treatments, a dose that was higher than what I and others had shown to be effective in the treatment of CP and a dose that had never been used before in the treatment of CP.

Q: What does the Collet Study show?
A: That two pressure protocols cause significant durable improvements in children with CP.

Q: Since 2000, have you had occasion to be involved with Jimmy Freels' medical treatment?
A: Yes.

Q: What was the nature of your involvement?
A: I evaluated him and reviewed his case in 2000, then re-evaluated him again in 2004 with HBOT and SPECT.

Q: Was he sent for a pretreatment testing?
A: Yes.

Q: What testing?
A: In 2000 it was for recommendations on further treatment and to see if a repeat SPECT brain scan was necessary. On the second occasion it was to see how much additional HBOT would be needed.

Q: When was he sent for a SPECT Scan?
A: In 2000 I told his father that there was no need for an additional SPECT at that time. In 2004 I recommended that he be evaluated with SPECT before and after a single HBOT.

Q: Why was a SPECT Scan ordered prior to any treatment?
A: I ordered it to see how much injury was still evident in the brain and whether a single HBOT could impact that injury.

Q: What, if any, treatment was administered to Jimmy Freels after the April 5, 2004 SPECT Scan?
A: He underwent a single HBOT and then a repeat SPECT scan.

Q: How was it administered?
A: 1.25-1.33 ATA/60 minutes.

Q: What was done after HBOT was administered?
A: The patient was videotaped during the HBOT and then underwent repeat SPECT scan of the brain.

Q: Why was another SPECT Scan administered?
A: To see if a single HBOT treatment could favorably change brain blood flow and metabolism

Q: What were the results?
A: The baseline scan was abnormal and the repeat scan was noticeably improved. In addition, and most importantly, the father and my technician reported that the patient's clinical condition was improved both in the chamber and after the treatment. He was very talkative, had improvement in his lower extremity spasticity, and improvement in right hand and arm motor function.

Q: Did you draw any conclusions about the efficacy of HBOT based on these results?
A: I concluded that Jimmy Freels would benefit from additional HBOT.

Q: Why did you conclude Jimmy Freels would benefit from additional HBOT?
A: Because of the patient's clinical improvement and improvement on SPECT brain imaging following a single HBOT.

Q: Could any conclusions be drawn about whether HBOT would correct or ameliorate Jimmy Freels CP?
A: Yes.

Q: What conclusion could be reached?
A: HBOT could definitely ameliorate his condition. It may also partially correct the underlying problem.

Q: Why did you reach this conclusion?
A: Because the patient physically improved and the imaging simultaneously improved.

Q: Is there any question as to the reliability of SPECT Scan imaging?
A: There is no question that SPECT is a reliable technique for measuring brain blood flow and indirectly metabolism.

Q: What is the reason for Jimmy Freels' increased brain blood flow from April 5, 2004 to April 6, 2004?
A: The hyperbaric oxygen had a beneficial effect on his brain blood flow and metabolism.

Q: Is it your opinion that Jimmy Freels' CP has been corrected or ameliorated as a result of being administered HBOT?
A: Yes.

Q: Is there any reason to believe Jimmy Freels will continue to experience correction and amelioration of his physical condition with administration of additional HBOT?
A: Yes.

Q: Why did you reach this conclusion?
A: Because he has responded to it in the past and after 4 years he and his SPECT scans show that they can benefit from additional HBOT. In addition, we know that HBOT works by stimulating growth and repair hormones and upregulating the cell receptors for growth and repair hormones. There is every reason to believe that this is the mechanism active in Jimmy Freels' brain with additional HBOT.

Q: Can you form an opinion within a reasonable degree of medical certainty as to whether HBOT has already partially corrected and ameliorated Jimmy Freels' CP?
A: Yes.

Q: What is that opinion?
A: That it has.

Q: What is the basis for that opinion?
A: The first SPECT scan performed on Jimmy Freels before any HBOT shows, among other abnormalities, a blood flow defect in the anterior lateral left frontal lobe. This area corresponds to Broca's Area 44 on anatomical imaging such as MRI and CT and is the area of the brain that subserves speech motor function. Jimmy Freels was severely speech impaired at the time of this scan. So, in essence, we have a CP child who has minimal speech and who has the corresponding deficit in brain blood flow and metabolism on brain blood flow imaging in the exact anatomical area of the brain

responsible for speech. The child then undergoes hyperbaric oxygen therapy and has a noticeable improvement in speech. A repeat SPECT brain blood flow scan after the hyperbaric oxygen therapy when the child has improved speech shows an improvement in brain blood flow to the previous defect that corresponded to the speech deficit.

Five years after the original SPECT brain scan while the child has improved, but still limited, speech a repeat SPECT brain scan in 2004 on a higher resolution scanner shows a lesser defect in the speech motor area, indicating that hyperbaric oxygen therapy has partially corrected the defect in speech and brain blood flow responsible for speech. After a single HBOT the patient shows additional improvements in blood flow to the speech area on SPECT scan repeated after this HBOT and simultaneously shows improvement in his speech, indicating that HBOT can further improve/ameliorate and possibly correct the speech deficit in this child.

Paul G. Harch, M.D.