

BEFORE THE OFFICE OF STATE ADMINISTRATIVE HEARINGS
STATE OF GEORGIA

JIMMY FREELS, a minor by and :
Through DAVID FREELS, his :
Father, : DOCKET NUMBER:
 : OSAH-DCH-LOC-0615259-44-Teate
Petitioner, :
 :
DEPARTMENT OF COMMUNITY :
HEALTH, :
 :
Respondent. :

DIRECT EXPERT TESTIMONY OF DR. GARY MILLER

COMES NOW the Department of Community Health, Respondent in the above-styled matter, and respectfully submits the direct expert testimony of Dr. Gary Miller pursuant to the Court's Order dated January 27, 2006.

By submitting the testimony of Dr. Miller herein, the Respondent is in no way admitting or conceding that it has the burden of proof with regard to any issue addressed by Dr. Miller's testimony. Rather, pursuant to OSAH Rule 7(1)(d), Petitioner, as a potential recipient of a public assistance benefit, bears the burden as to all issues.

1.

Q. Please state your name and occupation.

A. Gary M. Miller. I am a physician specializing in Pediatric Neurology.

2.

Q. By whom are you employed?

A. I am self-employed, practicing with Pediatric Neurology of Georgia.

3.

Q. How long have you been a physician practicing in the area of pediatric neurology?

A. I finished my residency in 1983 and have been a practicing pediatric neurologist for the twenty-three years since.

4.

Q. Please provide your educational background.

A. I completed my undergraduate studies at UNC-Chapel Hill. I then graduated Duke University Medical School in 1977. I completed my pediatric and neurology residency at the University of Colorado Medical Center in Denver from 1977 to 1983.

5.

Q. Are you certified to practice medicine by the State Board of Medical Examiners in Georgia?

A. Yes.

6.

Q. In what areas of medicine are you board certified?

A. I am board certified in Pediatrics and Neurology with special competence in child neurology.

7.

Q. What must one do to become board certified in pediatric neurology?

A. I was required to complete an approved residency program, pass a written exam, and an oral examination.

8.

Q. Have you written articles for research journals?

A. Yes.

9.

Q. Please provide examples of your scholarly works.

A. Please refer to my Curriculum Vitae for a complete listing. I have published one study regarding brain malformation in children and one study regarding immunological aspects of brain tumor treatments.

10.

Q. Are the works listed focused on one particular area of medicine?

A. Most of my works are related to aspects of neurology.

11.

Q. Have you published any articles or other works relating to the treatment or study of brain injuries, particularly in children?

A. I have engaged in controlled trials of possible neuroprotective agents in stroke and head trauma patients.

12.

Q. Have you done any other work, research, or study relating to brain injuries?

A. I have frequently been asked to testify as a medical expert in cases regarding cerebral palsy or brain injuries in children. I have testified by deposition or at trial for both plaintiffs and defendants.

13.

Q. Have you done any work, research, or study regarding the effects of oxygen on the brain?

A. Other than my medical training, I have extensively reviewed the available medical literature regarding the effects of both oxygen and lack of oxygen on the brain.

14.

Q. Have you done any work, research, or study regarding the effects of oxygen on brain-injured subjects?

A. I have reviewed the available medical literature on the subject.

15.

Q. Attached hereto as Exhibit "A" is a copy of your Curriculum Vitae. Is it a true and correct copy and is it up-to-date?

A. Yes.

16.

Q. Please describe the condition of Cerebral Palsy ("CP").

A. Cerebral Palsy is a clinical condition characterized by abnormalities of muscle tone, function, and movement due to a non-progressive injury to the brain. The condition is presumed to originate before or at the time of birth.

17.

Q. What is spastic quadriplegia?

A. Spastic quadriplegia is a condition of spasticity or stiffness of all four limbs. Spastic quadriplegia represents one of the more severe forms of CP.

18.

Q. In your practice, do you treat children with CP?

A. Yes.

19.

Q. How many children have you treated with CP?

A. The treatment of children with CP is a regular part of my practice and I see these patients on a weekly basis. Therefore, over the years I have seen and treated hundreds of children with CP.

20.

Q. Do any of the children you treat have spastic quadriplegia?

A. Yes.

21.

Q. As a result of your training and your work, are you familiar with the medically accepted standards and practices in the United States with regard to treating children with CP?

A. Yes. It is a routine part of my practice.

22.

Q. As a result of your training and your work, are you familiar with the medically accepted standards and practices in Georgia with regard to treating children with CP?

A. Yes, the standards and practices are relatively consistent throughout the country.

23.

Q. What is the generally accepted treatment protocol for a child with CP?

A. Typical therapies include physical therapy, occupational therapy, and speech therapy as indicated. Spasticity may be treated by medications such as baclofen or botox injections. Overall management and assessment may include adaptive appliances and corrective surgeries for orthopedic complications.

24.

Q. Presently, is CP a curable disease?

A. No.

25.

Q. If CP is not curable, what is the goal of the treatment protocol that you have described?

A. To maximize the child's potential for function. There is usually some improvement noted due to normal brain growth and development, thus the therapies are both to promote normal development and prevent complications.

26.

Q. What types of improvements are possible with a CP child by following the generally accepted treatment protocol?

A. Improvements may be seen in all areas of impairment, including gross motor, fine motor, and speech functioning. If there is cognitive impairment, this may improve as well.

27.

Q. Do you typically see these sorts of improvements in your patients over time?

A. Yes.

28.

Q. How are these improvements measured?

A. Both by serial examinations and by formal assessment tools such as standardized testing.

29.

Q. Do you use both objective and subjective measures?

A. Yes, both may be important. Obviously, objective measures of functional improvement are more reliable than subjective measures.

30.

Q. Is it possible for dead or lost brain cells in humans to regenerate?

A. Not with our present level of understanding.

31.

Q. What is "patterning" as that term relates to the treatment of children with CP?

A. Patterning therapy is a technique using patterned movements of the extremities to try to promote brain development.

32.

Q. Is patterning a generally accepted treatment for children with CP?

A. No.

33.

Q. Are you familiar with Hyperbaric Oxygen Therapy ("HBO" or "HBO Therapy")? If so, how are you familiar with it?

A. I am familiar with HBO Therapy. The therapy has been available for many years for certain conditions. In fact, there is a hyperbaric center located adjacent to one of the hospitals where I work. I have also sometimes been asked by parents in my practice about its efficacy for treating CP.

34.

Q. Were you asked by the Georgia Medical Care Foundation to perform an evaluation as to whether HBO Therapy is necessary to correct or ameliorate CP in children?

A. Yes.

35.

Q. What specifically were you asked to do with regard to this evaluation?

A. I was asked to do a current medical literature review regarding published studies of HBO Therapy in treating CP. I was also asked to review the documents produced at the previous hearing of this matter and to also review and consider the testimony of the Plaintiff's experts in making my evaluation. Finally, I was asked to formulate an opinion as to whether HBO Therapy is necessary to correct or ameliorate CP or any of its associated conditions or symptoms.

36.

Q. Are there certain illnesses or conditions that may be effectively treated with HBO Therapy?

A. Yes. HBO Therapy is used to treat decompression illness, carbon monoxide poisoning, gas gangrene, certain types of wounds and infections, and other various conditions.

37.

Q. How is it generally determined that a particular treatment or therapy is safe and effective for a given condition?

A. Some treatments have been well established with respect to efficacy over many years; the treatment of bacterial meningitis with antibiotics, for example. Others are established by double-blind, randomized, placebo controlled studies. Certain treatments and medications may be approved by the FDA after their evaluation. Peer review is an essential part of the process, and certain treatments may be adopted after extensive clinical experience has been obtained in the medical community. Safety is usually evaluated in clinical studies, may be determined in initial open-label or observational studies, and is further defined after widespread usage is adopted.

38.

Q. Has HBO Therapy for children with CP been subjected to these vetting processes that you have described?

A. The study of HBO Therapy for children with CP has been very limited. Most of the available information is of observational studies, with little or no peer review. The methods for evaluating the children post-treatment are usually not blinded and sometimes poorly defined. Diagnostic information regarding the subjects is usually lacking, which is especially important since the entity of cerebral palsy may have many etiologies. To my knowledge, there has been only one published double-blind, controlled study of HBO therapy. In that study, one of the study groups received pressurized oxygen, whereas the control group received only pressurized room air. The study authors found no difference in improvement when the controls were compared to the children receiving HBO Therapy.

39.

Q. Are you familiar with the Agency for Healthcare Research and Quality (“AHRQ”)?

A. Yes. AHRQ is a Federal agency within the Department of Health and Human Services. AHRQ is charged with improving the quality, safety, efficiency, and effectiveness of health care in the United States.

40.

Q. Attached hereto as Exhibit “B” is a report titled Hyperbaric Oxygen Therapy for Brain Injury, Cerebral Palsy, and Stroke (“the Report”) prepared by and for AHRQ. Are you familiar with that Report?

A. Yes.

41.

Q. Did you review and rely on the Report as part of your evaluation of HBO Therapy in treating children with CP?

A. Yes, I did.

42.

Q. Does the Report comprehensively survey and summarize the known clinical trials of HBO Therapy in treating children with CP?

A. Yes.

43.

Q. In the previous hearing that you were not a part of, testimony was given by Dr. James Carroll regarding the importance of randomized, controlled, double-blind clinical studies in determining the efficacy of any treatment for cerebral palsy or any other condition. Could you briefly describe your understanding of a randomized, controlled, double-blind clinical study?

A. "Randomizing" refers to efforts to remove selection bias from the subjects studied. Patients should be assigned to treatment or control groups randomly, not selectively. Several factors may need to be controlled for, however, such as age, sex, severity of illness, socioeconomic status, and the like. "Double-blinding" attempts to eliminate bias in both the subjects and the investigators. Neither the subjects nor the investigators should be aware of whether the subject is receiving the treatment or a placebo. "Placebo controlled" means that some subjects will receive the actual treatment, others will receive what appears to be the treatment, but is not. Those subjects in the latter group are given a convincing, but harmless and ineffective substitute. The study then reaches its conclusions by comparing the outcomes in the treatment group with the control group.

44.

Q. Do you agree that randomized, controlled, double-blind clinical studies are vital in determining the efficacy of treatments or proposed treatments for medical conditions?

A. Absolutely.

45.

Q. What other sorts of study models might one construct to study the efficacy of a given medical treatment?

A. Observational or open-label studies may provide valuable information, especially with regards to safety and risks. These studies are more reliable if the condition is truly static, and not expected to change on its own. Also, animal studies are often done initially to determine features of a treatment, including risks.

46.

Q. In your opinion, what variety of study model would produce data upon which firm conclusions could be reached regarding the efficacy of HBO Therapy in treating CP?

A. It is clear that randomized, controlled, double-blind studies that are published in a peer reviewed journals would produce the most reliable data.

47.

Q. To your knowledge, have any randomized, controlled, double-blind studies been conducted for the treatment of CP in children using Hyperbaric Oxygen Therapy?

A. Again, the one study that I previously mentioned using pressurized oxygen versus pressurized room air in CP patients found no difference in outcomes between the two. That is, according to the published article, both the treatment group and the control group improved similarly. My research has revealed no other randomized, controlled, double-blind studies indicating that HBO Therapy has any effectiveness in treating CP in children.

48.

Q. Based on your own knowledge, and based on the study results set out in the Report, does HBO Therapy improve functional outcomes in children with CP?

A. We do not have any convincing evidence for this. According to Report, there is insufficient evidence to determine whether the use of HBOT improves functional outcomes in children with cerebral palsy.

49.

Q. Is HBO Therapy an FDA-approved treatment for CP in adults or children?

A. No.

50.

Q. What sorts of activities can result in increased blood flow in the brain?

A. A variety of situations, including physical or mental activity, increased tissue activation such as that occurring in seizures, increased temperature, inflammatory changes, and certain drugs such as nitrates or persantine.

51.

Q. So does blood flow in the brain follow mental or physical activity?

A. It often does.

52.

Q. Is there any reason to believe that the reverse is true? In other words, if increased blood flow can be artificially induced by means of HBO Therapy or some other

method, is there any evidence to indicate that this will lead to increased brain functioning or activity?

A. No, not to my knowledge.

53.

Q. Is there any evidence to indicate that increased blood flow to the brain, and thus more oxygen to the brain, can repair damaged, diseased or decayed brain cells?

A. No, not to my knowledge.

54.

Q. Is there any evidence to indicate that increased blood flow to the brain can correct or ameliorate the scarring of brain tissue associated with CP?

A. No.

55.

Q. Attached hereto as Exhibit "C" is a series of SPECT scan images for Jimmy Freels that have been authenticated by stipulation. These images purport to be taken just prior to Jimmy Freels receiving HBO Therapy. Do you recognize these images?

A. Yes, I reviewed the images in performing my evaluation.

56.

Q. Attached hereto as Exhibit "D" is a second series of SPECT scan images for Jimmy Freels that have been authenticated by stipulation. These images purport to be images produced shortly after Jimmy Freels received HBO Therapy. Do you recognize these images? Yes, I reviewed the images in performing my evaluation.

57.

Q. Please explain your understanding of what a SPECT scan is and what it purports to image.

A. "SPECT" scan is an acronym for Single Photon Emission Computerized Tomography. SPECT scans image relative blood flow in the various parts of the brain.

58.

Q. What does the phrase "blood perfusion" mean?

A. That term relates to the provision of blood supply to tissue.

59.

Q. Does a SPECT scan image brain functioning or metabolism?

A. No.

60.

Q. Are scans available that do measure brain functioning or metabolism?

A. Yes.

61.

Q. What scans are available that do or can measure brain functioning and metabolism?

A. Functional MRI and MRI spectroscopy measure certain aspects of brain metabolism. Currently, there are no reliable methods for imaging brain function per se.

62.

Q. To your knowledge, were any of these other types of scans produced by the Petitioner as part of this review?

A. Not to my knowledge.

63.

Q. It is clear that in the SPECT scan images produced after Jimmy Freels underwent HBO Therapy, his brain appears smoother and fuller. Does improvement in the appearance or aesthetics of the SPECT scan image in any way indicate an improvement in brain function?

A. No.

64.

Q. Do the SPECT scan images of Jimmy Freels' brain, before and after HBO Therapy, in any way indicate that he has regenerated brain cells or brain matter?

A. No.

65.

Q. How do you explain the apparent “fullness” of Jimmy Freels’ brain in the SPECT scans taken after HBO Therapy?

A. A SPECT scan does not measure brain matter, only blood flow. The scans for Jimmy Freels indicate some change in the blood flow patterns of the brain after HBO Therapy, but these scans do not tell us anything about the functioning capability of his brain.

66.

Q. Do the SPECT scan images of Jimmy Freels’ brain, before and after HBO Therapy, in any way indicate that his cerebral palsy has been corrected or ameliorated?

A. No. Certainly I think no one would offer the position that his condition has been corrected. To determine if a procedure is effective in ameliorating a condition like CP that may show improvements spontaneously or due to other interventions, an appropriate study in a large number of subjects is necessary.

67.

Q. Do the SPECT scan images of Jimmy Freels’ brain, before and after HBO Therapy, in any way indicate that any conditions or symptoms associated with his cerebral palsy have been corrected or ameliorated?

A. No, they only indicate a change in blood flow patterns.

68.

Q. What other factors, treatments, or activities may lead to improved cognitive improvements and physical functioning in a CP patient?

A. Traditional therapies as previously described, spontaneous improvement due to brain growth and natural development, and the continued intense interactions with the parents and caregivers. Interestingly, researchers have described a “participation effect,” where subjects often improve simply due to participating in a study. In fact, the participation effect may account for the improvement seen in both the treatment and control groups in the one controlled study I have discussed previously.

69.

Q. From a medical standpoint, do CP patients respond favorably, for example, to physical and speech therapies? To restate, can these therapies correct or ameliorate CP?

A. I think these traditional therapies can ameliorate CP, but not correct it. There is no cure for CP.

70.

Q. Do children with CP respond favorably to the interaction with and the attention of their parents?

A. Absolutely.

71.

Q. Is it possible for a child with CP to naturally experience functional improvements in speech and motor skills as they mature, even without receiving medical treatment of any kind?

A. Yes.

72.

Q. If a CP child is receiving HBO Therapy, in addition to speech therapy, physical therapy, patterning instruction, and other treatments, and if that child were to exhibit some cognitive improvements or improvements in physical functioning, would it be possible to attribute those improvements to the HBO Therapy alone?

A. No. Assuming there is improvement, it would not be possible to attribute that improvement to any one therapy alone. This is precisely the sort of thing that properly constructed studies attempt to control. The goal of such studies is to control for all other likely influences to determine whether a specific treatment is effective for a specific condition.

73.

Q. So, to be clear, in the example above, would it be possible to attribute those improvements in any measure to HBO Therapy in light of the other concurrent therapies?

A. No.

74.

Q. Are any negative effects or risks associated HBO Therapy?

A. Risks include ruptured eardrums, air embolism, seizures, neurologic deterioration, aspiration, and pulmonary complications including respiratory failure.

Chamber fire, of course, is also a risk given the use of pure oxygen which is highly flammable.

75.

Q. Please explain the physiology of an embolism and how that might occur through exposure to HBO Therapy.

A. An embolism is a situation where foreign material (in this case pressurized oxygen) enters the vascular system and travels downstream. The embolus may interfere with the normal flow of blood to the affected organ or tissue.

76.

Q. Please explain how someone might experience lung damage from receiving HBO Therapy.

A. In some cases, aspiration with associated pneumonia has been observed. Also, rupture of lung airways may provoke pneumothorax. Increased oxygen requirements have occurred in some patients receiving this treatment.

77.

Q. Please explain how someone may experience vision loss as a result of HBO Therapy.

A. An air embolus may occlude retinal arteries, resulting in ischemia (loss of blood flow) to the eyes.

78.

Q. What is oxygen toxicity?

A. Oxygen toxicity is a term for the adverse effects associated with exposure to high levels of oxygen, which may be either acute (e.g., seizures) or chronic (e.g., neurologic deterioration).

79.

Q. To your knowledge, do any medical texts, journals, or other scholarly publications on which a practicing physician might rely support the use of HBO Therapy for the treatment of CP?

A. Not to my knowledge.

80.

Q. Are you aware of any medical texts, journals, or other scholarly publications that describe HBO Therapy as necessary to correct or ameliorate CP or any of its associated symptoms?

A. No.

81.

Q. To your knowledge, do any board certified physician within the state of Georgia use HBO Therapy to treat CP in children or adults?

A. I am not aware of any neurologists who use or recommend it. I cannot speak for all physicians, but in my 23 years of practice in neurology, I have never seen it recommended by another physician.

82.

Q. Is using HBO Therapy to treat CP an accepted medical practice within the state of Georgia?

A. No.

83.

Q. In your opinion, is HBO Therapy a medically necessary treatment for CP or any condition or defect associated with it?

A. No.

84.

Q. In your opinion, does HBO Therapy correct or ameliorate CP or any condition or defect associated with it?

A. No.

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VERIFICATION OF DR. GARY MILLER

Personally appeared before me, the undersigned officer duly authorized to administer oaths, Dr. Gary Miller, who, being duly sworn, deposes and states that he has read the foregoing "Direct Expert Testimony of Dr. Gary Miller" and states that the facts contained therein are true and correct to the best of his knowledge and belief.



Dr. Gary Miller

Sworn to and subscribed before

Me this 8th day of June,

2006.



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