posturing questions.

MR. ROSETTI: Sure.

THE COURT: So I will deny that rule for sequestration and they will be allowed to remain for that purpose.

I am not anticipating that they will be recalled without good cause, you know, as rebuttal witnesses having heard the testimony of the other party. We'd have to address that at that time to determine whether there would be undue prejudice at that point.

MR. ROSETTI: May I go get our witnesses?

THE COURT: Go ahead.

MR. ROSETTI: Thank you, Judge.

THE COURT: All right, Mr. Oldenburg.

MR. OLDENBURG: Judge, we would call Dr. Gary Miller to the stand.

THE COURT: All right. Dr. Miller.

If you will administer the oath, Mr. Oldenburg.

MR. OLDENBURG: Dr. Miller, before you sit down would you raise your right hand.

- -

DR. GARY MILLER,

being first duly sworn, was examined and testified as follows:

THE COURT: All right, Mr. Rosetti, your cross-examination.

MR. ROSETTI: Thank you, Judge.

CROSS-EXAMINATION

BY MR. ROSETTI:

Q. Good morning, Dr. Miller.

A. Good morning.

MR. ROSETTI: May I approach the witness with his testimony?

THE COURT: You may, sir.

BY MR. ROSETTI:

Q. Do you have a copy of your direct testimony?

A. I do but I'll take yours.

Q. Dr. Miller, the CV that you submitted with your direct testimony, that is an accurate account of your educational experience and professional qualifications, correct?

A. Yes, it is.

Q. Should that be updated in any way from when it was submitted?

A. I might need to look at it to see. I'm not sure when that was submitted.

THE COURT: If you would like, I have the exhibits. On the written direct, the exhibits attached have not been addressed, I don't think. I

don't think they were deemed admitted in the Pre-Hearing Order; is that correct? I think they were still subject to objection.

I think there's a copy of -- one of the attachments is the curriculum vitae and that's what you're addressing at this point. I can just hand that to the doctor.

MR. ROSETTI: Thank you.

THE COURT: For purposes of expediting, inasmuch as the direct has been laid, is there any objection to the admission of A and B exhibits for the Petitioner -- for the Respondent into the record?

MR. OLDENBURG: No objection.

THE COURT: Okay. The curriculum vitae, which is marked as Exhibit A, and the evidence report Technology Assessment marked as B are admitted into the record.

MR. ROSETTI: Thank you.

THE COURT: And just so I don't interrupt further, why don't I go ahead and pass over B. I'm assuming that will probably lead into cross-examination on that.

Doctor, I'll just place them here for your convenience.

THE WITNESS: Thank you.

MR. ROSETTI: B is the HBO report?

THE COURT: Yes, sir.

THE WITNESS: The only addition to the CV is a recent position as of January 1st that is not included on this is that of Medical Director for the Georgia Medical Care Foundation, which is a position that was started as of January 1st that I have added to my CV.

BY MR. ROSETTI:

Q. Okay. Now, in reviewing your CV, I didn't see anything on there about experience with hyperbaric oxygen therapy; is that correct?

A. That is correct.

Q. You were asked in this proceeding to assess whether or not HBO therapy was necessary to correctly ameliorate CP or any of its associated conditions?

A. That's correct.

Q. You were asked to do so after the Georgia Medical Care Foundation, which you are now the Medical Director of, issued a denial for that treatment, correct?

A. I'm not exactly sure the procedural situation as to who initially denied the determination, so I don't know that I can answer that question.

Q. Very good.

Do you know when you were contacted to render

an opinion on that issue?

A. It was sometime since the first of the year.

Q. Sometime -- okay.

And pursuant to their request, you performed a literature review?

A. Yes, I did.

Q. Okay. Now, before you did this literature review for the Georgia Department of Community Health's GMCF, had you performed a literature review on hyperbaric oxygen therapy?

A. No, sir, I don't think I had.

Q. Okay. So is it fair to say that prior to being asked by the GMCF to issue an opinion on this issue, you were not particularly well versed in using hyperbaric oxygen therapy for pediatric CP patients?

A. I did have some familiarity with it in that I have practiced pediatric neurology for many years and have been aware of what are accepted treatments in the community for children with CP and other similar conditions. So I did have some familiarity with the situation.

Q. But with respect to actually performing any type of literature review, what was the extent at which you performed such a review for hyperbaric oxygen therapy in the treatment of CP patients?

A. I have not specifically performed a literature review in that area.

Q. Okay. So when the children of CP patients inquired by the efficacy of hyperbaric oxygen therapy in your office, what did you tell them?

A. I told them that at this point I did not feel there was sufficient evidence to recommend this as a treatment for cerebral palsy.

Q. And this advice or this counseling was given without performing any significant medical literature review on the issue?

A. It was given without performing that literature review, although I do read medical journals, I attend neurology meetings, I communicate with my colleagues, so I do feel that I have an understanding of what the current accepted treatment of the condition is.

Q. Okay. The current accepted treatment but not anything specifically relating to CP -- I'm sorry, to hyperbaric oxygen therapy in CP patients?

A. I'm not sure I understand the question.

Q. I'm sorry. I will rephrase it for you, Doctor.

You have an understanding of the generally-accepted treatment protocols established by neurologists in the State of Georgia with respect to the treatment of pediatric CP patients, correct?

A. I would not confine it to the State of Georgia. I think that, for the most part, the accepted methods of treatment are a national acceptance rather than just confined to the State of Georgia.

Q. And, generally speaking, neurologists do not use hyperbaric oxygen therapy for the treatment of pediatric CP patients, correct?

A. That's right.

Q. You had mentioned in your direct testimony that you have privileges at a local hospital which is adjacent to a hyperbaric clinic. Is that Windy Hill?

A. The new facility is actually adjacent to WellStar Kennestone Hospital in Marietta.

Q. Okay. Did you refer any of those patients over to the hyperbaric clinic to inquire about the use of hyperbaric oxygen therapy for the treatment of CP, pediatric CP patients?

A. I have not.

Q. Okay. Once you learned about the hyperbaric clinic adjacent to a hospital at which you have privileges, did you do any research to inquire about the efficacy of the treatment for this particular condition?

A. The only inquiry I made, I do have an acquaintance who works at the center and I asked her if they were treating any children with cerebral palsy and

was told that they were not.

Q. And this acquaintance was a --

A. She is a respiratory therapist who works at the center.

Q. A physician?

A. Not a physician. A respiratory therapist.

Q. Okay. Did you contact the physician who operates the center?

A. I have not.

Q. Now, there are some commonly-accepted indications for hyperbaric oxygen therapy, correct?

A. That's correct.

Q. And some of those indications are neurological indications, correct?

A. That's correct.

Q. All right. What are those neurological indications?

A. Well, some may have neurological aspects. For example, carbon monoxide poisoning. I think another indication that it may be useful for is acute cerebral edema.

Q. What else, besides carbon monoxide and acute cerebral edema, would there be a neurological indication for this treatment?

A. Again, it might have -- an associated

implication would be cyanide poisoning.

Q. Of course, presumably you could have a patient with one of these conditions. They could come to your office, correct?

A. Potentially, that's correct.

Q. And has that occurred?

A. It hasn't in quite a few years. I haven't seen any of those conditions in particular.

Q. And when they ask you about hyperbaric oxygen therapy, what will you be telling them, if that --

A. I think for those indications, it would be a consideration as to whether that would be an appropriate treatment or not.

Q. And you base that opinion on what?

A. On the fact that for those particular conditions it has been FDA approved and I think has been examined in the sense that there is evidence that it's helpful for those conditions.

Q. All right. What is that evidence?

A. I haven't really reviewed that evidence for those conditions.

Q. Doesn't this come from a randomized, double-blind control study?

A. Again, I don't know the answer to that.

Q. Okay.

You mentioned I think in your direct testimony that there are certain treatments that are adopted after extensive clinical experience in the medical community. What would be an example?

A. I think the example I gave was treatment of meningitis with antibiotics.

Q. Would you agree that there are physicians who will argue that there is extensive clinical experience demonstrating the effectiveness of hyperbaric oxygen therapy in the treatment of brain-injured children?

A. Well, I think there are physicians who would hold that position.

Q. Neurologists don't use this treatment modality for that particular condition?

A. That's correct.

Q. Even though you were being asked about it by parents that were --

A. Correct.

Q. -- that were coming into your facility and asking you about hyperbaric oxygen therapy?

A. I have some parents who have asked about it, yes.

Q. And just to be clear, nobody has actually ever come to your facility and said they've had experience with hyperbaric oxygen therapy in the treatment of a

brain-injured child or a child with CP and it didn't work?

Nobody came in and said that to you, did they?

A. Again, when you say "nobody," are you talking about physicians or patients or parents?

Q. Well, start with patients.

A. So the question is have --

Q. Has anybody come to your office and said we got a trial of HBOT for my child who has cerebral palsy and they said it didn't work or it didn't do anything for them?

A. Well, yes, I have had that experience.

Q. All right. How often has that occurred when you've had a patient come to your office who's already had hyperbaric oxygen therapy for CP?

A. It's been a rare situation because at least if patients or their families have told me about it, it's been a very rare situation where someone has had hyperbaric oxygen treatment.

Q. Most parents want this for their children, people who bring it up to you?

The parents of children of CP patients, who are CP patients, they bring this up to you because they want this treatment, correct?

MR. OLDENBURG: Object. That would call for speculation.

THE COURT: Response?

MR. ROSETTI: I will rephrase.

THE COURT: All right, you're withdrawing it.

BY MR. ROSETTI:

Q. When parents come to you regarding HBOT, do they express a desire to actually undergo the treatment?

A. I think when they inquire about it, they are interested in any treatment they think might be of benefit to their child, and that applies to any treatment that they might inquire about.

I think that they obviously are interested in anything that they think would benefit their child, and that would apply to other procedures or treatments that they might ask about as well.

Q. Generally speaking, when you have a treatment that's been adopted after clinical -- after extensive clinical experience, you actually have to have the extensive clinical experience for it to be adopted, correct?

A. Are you talking about me personally having the experience or the medical community?

Q. The medical community in general.

The medical community would have to have an opportunity to have extensive clinical experience with the treatment before it could be adopted, accepted without a

randomized, double-blind control study, correct?

A. I think that is potentially a way that treatments can be accepted.

I think in this day and age we're being asked more and more to depend on evidence-based medicine to accept treatments for patients rather than subjective impressions of physicians or just based on our clinical experience which may or may not be accurate.

Q. Because randomized, double-blind control studies are very difficult to perform, correct?

A. I don't know that I would say that as a blanket statement. They may be difficult to perform in some situations.

Q. Okay. Would the treatment of hyperbaric oxygen therapy for CP patients, pediatric CP patients, would they be difficult to perform?

A. I think it would be possible to perform a double-blind, randomized control study.

Obviously it would require a certain amount of effort to enroll patients and adequately randomize them and do that type of treatment, but I think it certainly could be done.

Q. Did you have an opportunity to review the testimony, the direct testimony of Dr. Pierre Marois?

A. Yes, I did.

Q. Did you know that Dr. Marois had followed approximately 800 children with HBOT, who had HBOT?

A. Yes, I saw that in his testimony.

Q. Okay. Kind of a large group of patients for one physician with one diagnosis; is that correct?

A. It is, yes.

Q. And you saw Dr. Marois' report where he testified that over 80 percent of the parents reported improvement after 40 treatments?

A. I saw that in his testimony.

Q. Okay. So are you aware he mentioned that there was significant improvement in gross motor changes?

A. I did read his testimony to that effect.

Q. Okay. And Dr. Marois also utilized a Gross Motor Function Measure to assess and monitor progress?

A. That's correct.

Q. That's an objective measure, isn't it?

A. It is an objective measure.

I would point out that it is being performed and done by the same person who is administering the treatments or recommending the treatments. So in that sense, it is not a blinded assessment.

Q. It's not a blinded assessment but it's a clinical evaluation, and we use clinical evaluations to develop a standard of care over a course of time, isn't

that correct?

A. Well, I think when we start talking about standard of care that may be a different aspect than what we have been discussing so far.

Standard of care to me seems like a different issue than what we are discussing here.

Q. Okay.

Generally a treatment is utilized after extensive clinical experience demonstrates its efficacy; is that correct?

A. It may or may not been.

Again, I think we are going more and more to depending on evidence-based medicine results of research studies that are done in a controlled, randomized fashion rather than just accepting treatments based on clinical experience.

Q. Extensive clinical experience?

A. Be that extensive or not, that it's a study that has been peer-reviewed, examined by other physicians and determined that that experience or the results that they are reporting can stand the test of scrutiny from other physicians.

Q. But there are instances where we are using treatments, where we are using them for -- where they have become used because of extensive clinical experience with

those treatments?

A. There are --

Q. -- showing their efficacy. I apologize.

A. There are situations like that that I gave the example of meningitis. I think you would have a very hard time at this point convincing someone that we should do a placebo-controlled study of meningitis to see if antibiotics work.

So there are situations where I think the evidence of efficacy is overwhelming enough over the years that those studies are not required or indicated and I don't think this situation is one of those.

Q. But there are other indications, there are other treatments that are being prescribed without the value of what you just described, overwhelming results from a broad range of sources, extensive clinical experience?

A. I think we would have to look at specific situations to say what is the evidence that a particular treatment or recommendation works.

Q. Okay. You certainly would admit that Dr. Marois has more experience in treating pediatric CP patients with hyperbaric oxygen therapy than yourself, correct?

A. That's correct, since I do not have that

experience of treating the patients directly.

Q. Okay.

You also mentioned that observation or open-label studies are more reliable if the condition is actually a static condition, correct?

A. That's correct.

Q. Would you agree that CP is more or less a static condition?

A. I think it's been considered static in the sense that it is not progressive in terms of deterioration.

Certainly most children with CP do make improvements over the years because of the situation where childrens' brains are growing and developing just like in any normal child.

Q. Over the long term that would be the case, but spontaneous improvement generally not, correct?

A. They may undergo spontaneous improvement even in a short time span and that this improvement may not be a gradual, continuous type of improvement. But there are times I think when children with CP make, over a short period of time, make substantial improvements for reasons we don't fully understand.

Q. Spontaneous improvements may occur, may occur regularly in CP patients?

A. I think it's not unusual to see that over the course of following these children.

Q. Just so I'm clear, and this may be a matter of semantics, but just because something hasn't been proven effective by virtue of a randomized, double-blind control study or by extensive clinical testing doesn't mean it doesn't work, correct?

A. I think that's correct. I think the answer may be that we don't know whether it works or not if it hasn't been adequately studied.

Q. All right.

So we are not necessarily saying that hyperbaric oxygen therapy for Jimmy Freels doesn't work, correct?

A. I think what I'm saying is that based on the evidence that we have, we can't say that it does work.

Q. And your direct testimony referred to one study using pressurized oxygen versus pressurized room air in CP patients. Is that the Collet study?

A. Yes.

Q. All right. That was the study that was the basis for the AHRQ report which is Exhibit B to your testimony, correct?

A. I don't think that one study was the total basis of their report or conclusions. I think they

reviewed all the available literature that was available to them.

Q. All the available literature?

A. Well, I have read some discussion of that, that it was available literature in the English language --

Q. In the English language?

A. -- regarding human subjects. That it wasn't based this single randomized control double blind study. It was --

Q. To be clear --

A. It was more than that.

Q. To be clear, the AHRQ report actually excluded all studies relating to animals, correct?

A. Correct.

Q. And your direct testimony talked about the value of animal studies, correct?

A. There may be value in animal studies for sure.

Q. And those were excluded by the AHRQ report.

The AHRQ report also excluded any studies that were not published in English, correct?

A. That's correct.

Q. Are you aware of studies that are published in other countries that are not published in English?

A. There are. Sure.

Q. Have you reviewed those?

A. There was only one that I reviewed, an English abstract of one study that had been published in Spanish.

Q. Let me be clear then, and I don't know how many there are but of all the studies performed that were published in a foreign language, you reviewed the abstract of one?

A. Correct.

Q. Did you read the animal studies?

A. I did not.

Q. Just the studies that were contained in the AHRQ report?

A. I reviewed their conclusions as well as some other material where extensive reviews of the literature had been done.

Q. Did you review all of the underlying studies that were relied upon by the AHRQ report?

A. No, I didn't.

Q. Just the conclusions in the report basically?

A. And I did review the Collet study.

Q. You did?

A. Yes.

Q. Are you familiar with Dr. Marois?

A. I saw that he was one of the authors on that study.

Q. One of the principal authors on that study.

You define a placebo or a control as a group being given convincing but harmless and effective substitute for treatment; is that correct?

A. I don't remember the exact terminology but --

Q. Does that sound --

A. That sounds correct.

Q. Okay. The Collet study didn't have a control group, did it?

A. It had a control group of sorts. You can argue about whether that was a satisfactory control group or not.

Q. Did either group have -- did either group not get hyperbaric oxygen therapy?

A. If we can call it a control group received pressurized air as the placebo.

Q. Would you agree that that is simply a lower dosage of hyperbaric oxygen therapy?

A. It is a lower dose of oxygen therapy slightly above atmosphere pressure of room air.

Q. It's hyperbaric oxygen therapy at a reduced dosage, is it not?

A. I suppose it depends on how you define "hyperbaric oxygen."

When I think of hyperbaric oxygen therapy, I presume that they are using supplemental oxygen, not just

room air.

I think one of the comments about that issue was that if you look at the oxygen saturation produced by pressurized air at 1.3 atmospheres that you could achieve that same saturation just by having the patient inhale oxygen without pressurization without having to do the hyperbaric treatment.

Q. Both groups, you will agree, at least received increased oxygen in pressurized conditions?

A. I think that's a fair statement.

Q. And you read Dr. Marois' testimony; we talked about that earlier.

And, of course, his report, this is really just a matter of dosing, that report, isn't it, Collet?

A. I don't know that I can say it is just a matter of dosing.

Q. Because really all we're dealing with is two different dosages of hyperbaric oxygen therapy?

A. Well, that was not the conclusion that the primary author on the paper reached, and I think other physicians who have reviewed it have reached different conclusions.

Q. Did the report state that there was a placebo?

A. I don't think they used the terminology of "placebo."

Q. Do you want to review the report to see if there was the term "placebo" used?

A. I will take your word for it if you say that that's in this report.

Q. You don't know?

A. I don't remember whether they specifically called it a placebo.

Q. Okay.

Dr. Marois' testimony was that there was no placebo; is that correct?

A. I read that in his testimony, yes.

Q. Okay. So we are not really dealing with a true randomized, double-blind control study in that context, correct?

A. I think we are dealing with a double-blind, randomized study, perhaps not a placebo-controlled study.

Q. Okay. Have you ever been personally involved in a study regarding hyperbaric oxygen therapy?

A. No, I haven't.

Q. Are there other considerations involved in creating a double-blinded study for hyperbaric oxygen therapy in the treatment of CP patients?

A. I think the main consideration would be, in terms of blinding the patient, that they would have an awareness if they were exposed to pressurization in the

chamber.

Q. When you read the Collet study, one of the things that it talked about was that the group that received the higher dosage of hyperbaric oxygen therapy actually had ear problems because they were brought up at such a fast level to coincide with the lower level, correct?

A. I recall that they did have a higher incidence of ear problems in the hyperbaric oxygen group. I don't know about the second part of that in terms of the rapidity of pressurization.

Q. Do you know how fast they were able to bring those patients up to the desired pressure?

A. No, I don't.

Q. They were brought up at the same time, at the same amount of time, correct?

A. I don't know.

Q. You don't know.

When you read the Collet study were there -- the overall conclusion was that it didn't work, correct?

A. When you say that "it didn't work" --

Q. That hyperbaric oxygen therapy didn't improve these patients' conditions, correct?

A. The conclusion was that their conditions improved but that there was no difference between the

group that was treated with hyperbaric oxygen and the group that was treated with pressurized air.

Q. Okay. So everybody who was receiving the treatment -- higher dosage, lower dosage -- was improving?

A. That's correct.

Q. It doesn't sound like anybody was getting any worse from the treatment?

A. In terms of their cerebral palsy, that's correct.

Q. Doctor, let's clarify questions 52 to 54, if we could.

Let's just clarify questions 52 through 54. Do you have them in front of you?

A. Yes, I do.

Q. You would agree that there was no reason to believe that artificially induced increased blood flow can increase brain function.

Is it your testimony that hyperbaric oxygen therapy artificially induces increased blood flow?

A. I think this is related to the findings on the SPECT scans is what this was relevant to.

Q. Okay. So your testimony isn't that hyperbaric oxygen therapy somehow artificially induces increased blood flow?

A. Sir, would you repeat the question?

Q. Is it your testimony that hyperbaric oxygen therapy artificially induces increased blood flow?

A. That would not be my testimony, correct.

Q. You just really (inaudible) to the SPECT imaging?

A. Correct.

Q. You relied on the AHRQ report in reaching your conclusion that hyperbaric oxygen therapy is not -- will not correct or ameliorate Jimmy Freels' condition; is that correct?

A. That was one of the factors that I relied on.

Q. What else did you rely on?

A. Reviewing other literature, including other reviews that had been done of the subject.

Q. Okay. But principally you relied on the AHRQ report?

A. I don't know that --

Q. Which is a comprehensive report of most of the available literature on the subject, correct?

A. That's correct.

I don't know that I would say principally. I think, again, I gave weight to other reviews that I reviewed as well.

Q. I'm sorry, Doctor. I didn't -

A. I said I don't know that I would say that I

principally relied upon that report in formulating my opinions. It was one of the things that I relied upon.

Q. What were the other things that you relied upon again?

A. The review of the Collet study.

Q. Okay.

A. I also reviewed a summary statement that was done by the Aetna Insurance Company where they had done a similar type of review of the literature regarding whether they would cover hyperbaric oxygen for cerebral palsy.

Q. Is that included in your submission -- as part of your testimony today?

A. It is not included in that testimony.

Q. What is included is the AHRQ report?

A. Yes.

Q. Would you turn to Page 5 of that report.

A. You may have to provide it to me.

Q. Excuse me.

THE COURT: Go ahead.

BY MR. ROSETTI:

Q. Okay. Page 4 of the report.

In the AHRQ report, Page 4 of the report talks about conclusions with respect to hyperbaric oxygen therapy in the treatment of CP patients.

Do you see that sub-heading on that page?

A. Under "cerebral palsy"?
Q. Yes.
A. Yes, sir.
Q. What does that report conclude?
A. That there is insufficient evidence to determine whether the use of hyperbaric oxygen improves functional outcomes in children with cerebral palsy.
Q. And what does it continue to say?
A. Do you want me just to read --
Q. Just that paragraph.
A. The results of the only truly randomized trials were difficult to interpret because of the use of pressurized room air in the control group. As both groups improved, the benefit of pressurized air and of hyperbaric oxygen therapy at 1.3 to 1.5 atmospheres should both be examined in future studies.
Q. Thank you, Doctor.
And so that report, according to what you just read, is actually saying that --
A. That the --
Q. -- that we should look at the distinction between 1.3 and 1.5 atmospheres, that it's inconclusive because both groups improved?
A. I don't think the conclusion is that it's inconclusive just between those two groups.

I think their conclusion is that it's inconclusive whether hyperbaric oxygen therapy improves cerebral palsy.

Q. Would you defer to the direct testimony of one of the principal authors of that study with regard to what that study actually demonstrates?

A. I will ask you to clarify. When you say "that study," are you talking about the AHRQ or the --

Q. The Collet study.

A. -- or the Collet study.

Q. Yes.

Would you defer to one of the principal authors of the Collet study with respect to what that study actually shows?

A. I don't think I would at this point because I it's clear that there is disagreement between some of the principal authors on the study as to what the conclusions of that study are.

Q. Certainly one of the principal authors of that study would have far more involvement with it than one who reviewed it after being asked by the State to review it, correct?

A. That's correct.

But I think we would, in that situation, need to give weight to all the people involved in the study and

not necessarily one more than the other.

Q. And we have one here?

A. Correct.

Q. All right.

Now, in reviewing your CV, I saw no reference whatever to SPECT imaging, correct?

A. That's right.

Q. You're a member of the American Academy of Neurology?

A. Yes.

Q. Does the American Academy of Neurology have a statement with respect to expert witness testimony, a standard?

A. I think they do have some standards.

Q. Are you familiar with them?

A. I am generally familiar with them.

Q. Does your familiarity include anything relating to testifying as to matters for which you do not have direct competency?

A. My recollection of what it says is that you should confine your testimony to your field of specialty.

Q. And to be clear, your field of specialty does not include SPECT imaging?

A. My field of specialty is pediatric neurology of which SPECT imaging may be a component of that.

You're correct in the sense that I don't interpret SPECT scans, but I do have a familiarity with it because it is a technique that is used in evaluating pediatric neurology patients.

Q. Including CP patients?

A. Correct.

Q. For what purpose?

A. It has been used predominantly in that population for evaluation of seizure localization.

Q. It's also been used to determine the efficacy of HBOT, correct?

A. It has been purported to be used for that. I think that's an issue of some dispute.

Q. What experience, what training have you had in SPECT imaging?

A. No particular training, other than my involvement, again, using it for evaluating epilepsy patients.

Q. Do you review SPECTS personally?

A. I look at the scans when we are evaluating a seizure patient with SPECT scanning.

Q. And what training do you have in reviewing that scan?

A. Again, my experience and training is simply what I have obtained through my practice. I don't have

any specific training in interpreting SPECT scans.

Q. You're familiar with Dr. Usler's testimony? You were able to take a look at Dr. Usler's direct testimony?

A. Yes, I did.

Q. Were you able to attend the first, second or third symposiums on cerebral palsy and brain injury at which Dr. Usler was a speaker?

A. No, I was not.

Q. You're not familiar at all with what was presented at those symposiums?

A. No.

Q. Are you familiar with what the American Academy of Neurology Physicians as with respect to what neurologists should know about major neuro-imaging modality?

A. I don't know what you're referring to in terms of any particular document or statement that they've made.

Q. Are you familiar with the American Academy of Nuerology's resident core curriculum for neuro-imaging modalities?

A. Not specifically, no, I'm not.

Q. Are you aware that the American Academy of Neurology now recommend that in order to obtain practical experience in a given modality, the minimum number of

studies that should be performed and interpreted under supervision is 150?

A. I am not familiar with that number. I think that refers to physicians who are going to formally interpret imaging studies.

Q. Are you not interpreting imaging studies?

A. I am not interpreting SPECT scans in a formal way where I render an independent report.

Q. Just you come in and you see them, you see the aesthetics of them, but do you know the distinction between SPECT imaging machines or --

A. The only familiarity I have with it in my practice is in the context of evaluating patients for localization of epilepsy, and this is usually done in a multi-disciplinary setting where we have a number of people who are there reviewing all the data.

Q. Oh.

It's true, though, that SPECT imaging is actually used as an intravenously injected amount of a radioactive substance, correct?

A. Yes.

Q. All right.

The tracer can only be taken up by a functioning cell, isn't that correct?

A. I think that's correct.

Q. A functioning cell.

If a tracer in the first scan is not present in the cells but is present in the second scan, wouldn't you agree that there's a restoration of regional brain function in those cells?

A. I think in terms of brain functioning it obviously indicates that there was blood supply to that area and that a cell took up the tracer that was not metabolically active prior to that.

Q. So it was not metabolically active prior to it, and then the second scan shows the tracer taking in the cell meaning that it would have to be metabolically active in the second scan?

A. I think, again, that is a relative term because the SPECT scanning is a relative study. It doesn't give absolute numbers. So it means that there was some increased activity in that cellular population where uptake is seen in the second scan.

Q. Increased cellular activity as maybe not increased cellular activity?

A. I think that's the way I would define it.

Q. Okay.

Cellular functioning?

A. I think cellular function, it may indicate some increased cellular function. It still doesn't tell us

that there's any increased brain function. It's certainly not increased function in the patient.

Q. You'd correlate the findings with what we see clinically, correct?

A. I'm sorry, the question?

Q. You would correlate the findings from the SPECTS with what you see clinically in the patient, correct?

A. I think that's a reasonable statement, yes.

Q. I mean, it does have value. By itself you would need the clinical correlation, but the scan has value?

A. I don't think that there is a great deal of evidence that those kind of scans have value in assessing a patient's functional capabilities, especially in a situation like cerebral palsy.

Q. But the brain function -- you have to have brain function in order to have clinical function, correct?

A. That's correct.

Q. And brain function improves, there is more areas of brain function, more cells are functioning, metabolizing the tracer from one scan to the next; that is improvement, isn't it?

A. Well, not necessarily.

For example, the situation that we see with epilepsy patients, you, on the preliminary scan, may see an area of tissue that's not functioning, at least based on the SPECT scan which is felt to be the focus of their seizure disorder. If you then do a SPECT scan following a seizure, you see increased localization of tracer in that area.

So, in the same sense, they're we are seeing increased metabolic activity in an area of the brain. It doesn't mean that that area is functioning better. In fact, in that situation, it's just the opposite; it occurs in response to an epileptic seizure.

Q. For epilepsy, not for CP?

A. I think the issue that we're talking about is whether the changes on the SPECT scan can predict whether the patient is going to have increased functional capabilities or not, and I think that evidence is not there based on my review of things.

Q. But the SPECT scan actually demonstrates that the underlying requirement, that there be increased cellular function; is that, correct?

A. I would go back to what I said earlier, that it indicates an increased blood supply to that area and that some cells are taking up the tracer. For example, we don't know necessarily are those neuronal cells, are they

supportive cells, glia cells.

Q. They are taking up the tracer. More cells are taking up the tracer. More cells are metabolizing the tracer. And you must have function.

As you said, you must have the underlying cellular functioning in order to have any kind of clinical function to have the underlying cellular function.

A. You must have that, but I still would suggest that it's not a sufficient condition then to say that that implies improved function in the patient.

Q. Right. You might want to correlate it with what the patient is saying clinically or what the family is saying clinically in this context?

A. I think I would need more rigorous proof than what the patient or the family is saying.

Q. More proof than underlying cellular improvement coupled with the family coming in and telling you that they're doing better?

A. I think when we're trying to assess this type of treatment that that's the gist of what we're talking about; that we need more objective proof that there is a benefit.

Q. At this point you're managing patients. That is what a pediatric CP practice is, right?

You're managing, you're trying to find ways to

gradually increase levels of function and keep patients comfortable, right?

A. That's correct.

Q. We are not restoring them completely. We are trying to -- that's what a pediatric CP practice is is to try to find ways to make patients comfortable and find levels of improvement. There is no cure, as you said?

A. That's correct. I think the goal is to try to maximize their potential and maximize their functional levels.

Q. So when you see these types of studies out there demonstrating parents coming in and saying these things work for their children, SPECT scan imaging saying there is increased cellular functioning, regional brain functioning -- you've been doing this a long time, Doctor, did you ever think about sending one out, a patient out for this treatment?

A. I would say I certainly have considered it, but I think my conclusion in reviewing this recently and my previous conclusion has been that there isn't sufficient evidence or efficacy to warrant recommending it as a treatment.

Q. Instead Botox injections, right? Things like Botox injections are being used, correct?

A. That is one of the treatments that's being

used.

Q. Short-term, right? Botox doesn't have any long-term effects on the muscles, does it?

A. Its benefit is -- in terms of relaxing the muscle it's short-term.

Q. Temporary. Because there certainly haven't been any long-term studies on the efficacy of using Botox on pediatric CP patients?

A. That's what I was going to say. There hasn't been a long-term study to see if that can carry over into long-term improvement.

Q. You use it though. It's used in the pediatric CP practice, correct?

A. Yes.

Q. Rhizotomy, what's that?

A. That's a surgical procedure that's done to try to lesson the spasticity in CP patients.

Q. An orthopedic procedure?

A. Either orthopedic or neurosurgical.

Q. You've recommended those?

A. I would say if that's a consideration then I would refer them to someone to assess whether they thought it would be helpful.

That's not something that I would recommend myself without confirmation from another physician.

Q. So you would recommend them over to an orthopedist?

A. No. Generally there are pediatric neurologists in town here who specialize in that aspect of treatment. So I would have them evaluated by them.

The same really for Botox injections. I don't do those myself, so I would refer them for an evaluation to determine if they thought that would be a helpful treatment.

Q. In your practice what actual treatment do you provide for CP patients?

A. You mean do I provide personally?

Q. Correct.

A. As far as hands-on personally, I don't do Botox or Rysotomies, so it would be requesting those evaluations by other physicians or referring them for therapies, PT/OT, speech therapy.

Q. You're just sort of a point-of-contact physician?

A. Right, to manage their care, refer them to the appropriate providers to provide those services.

Q. Okay. And you hear a lot of positive reports coming from all over the place about hyperbaric oxygen therapy. Nothing verified, of course, in a randomized, double-blind control study, but all of these various

reports from both in the United States and outside the United States, correct?

A. I would not say that that's true.

I would have to say that I don't hear in my day-to-day conduct of my practice a lot of comments or questions about hyperbaric oxygen.

Q. With regard to what the SPECT scan images from, and let me clear about this -- when we're talking about the SPECT images in this case, we're talking about the two SPECT scan images from 1999, before and after SPECT images, and then the two SPECT images performed in 2004.

Would you defer to Dr. Usler who, of course, is board-certified in nuclear medicine as to what those SPECTS actually demonstrate?

A. I think I would defer as far as the interpretation. I don't argue with the fact that you can look at those scans and see that there's a difference. I think the issue in my mind is can you then translate that into saying that it represents any kind of improved function in the patient.

In that sense I don't think I would defer to a radiologist to make that determination.

Q. Did you read Dr. Usler's testimony?

A. Yes, I did.

Q. Dr. Usler's testimony, am I correct,

Dr. Usler's testimony referred to regional brain function and not to functional outcomes in a particular patient?

A. I think that's correct.

Q. And his conclusion was that regional brain function improved in Jimmy Freels' both 1999 studies, the two 1999 studies and the two 2004 studies, correct?

A. I think that was his conclusion.

Q. Dr. Usler testified on direct that improved regional brain function is necessary for the underlying amelioration of Jimmy Freels' condition. Do you disagree with that?

A. Could I have you ask the question one more time?

Q. Yes. Sure.

If in order to have increased clinical function you have to have increased brain function, and Dr. Usler is interpreting the SPECT scans to demonstrate increased brain function, would you agree that that is an underlying requirement for correcting or ameliorating Jimmy Freels' CP?

A. I think I would agree with the statement that increased brain function would be necessary to correct or ameliorate his condition.

I don't think I can agree with the conclusion that the changes on the SPECT scan indicate that it is

correcting or ameliorating his condition.

Q. I knew there was a reason why I didn't want to be a scientist or a doctor. This stuff is always a little bit much.

But what you're saying is not that there isn't increased cellular function. What you're saying is you just can't correlate it to clinical functioning?

A. I think strictly looking at the SPECT scans, it would suggest that there is some type of increased blood flow or function in that particular area of the brain. It doesn't mean that that results in any increased functional capability of the brain or increased functional capability of the patient.

I would go back to the previous example of the SPECT scans in epileptic patients show increased activity, increased blood flow. It does not in any way correlate with any improvement with the way the brain is functioning or the way the patient is functioning.

Q. With regard to CP, though, which is why we're here, you can't make that same conclusion, can you?

A. I would look at it from the opposite standpoint. I don't think you can look at those changes on the SPECT scan and --

(Tape 1, Side 1 of 4 concluded)

* * *

(Tape 1, Side 2 of 4 begins)

BY MR. ROSETTI:

Q. We know that there -- we know that these reports, again deferring to Dr. Usler, we know that these reports show -- well, these scans show increased regional brain function, correct?

A. Regional brain function in the sense that there is some activity there that's increased from what it was before.

Q. And then it would simply be a matter at this point of correlating it with clinical findings, or at least it would be important to correlate it with clinical findings?

A. I think that's the ultimate question. And if I could, just from one of Dr. Harch's chapters that was provided as part of the documents in this case, he says, and this is picking up in the middle of the sentence: Whether the degree of improvement in brain blood flow post-HBO treatment is predictive of the magnitude of subsequent functional outcome are all unknown.

And I think that's my point, that we don't know.

Q. We need to correlate clinically?

A. And I think at this point that hasn't been done, that there hasn't been appropriate studies done to

determine if the changes that we see on a SPECT scan --

Q. How about --

A. Wait. Sir, may I --

Q. I'm sorry.

MR. OLDENBURG: He continues to interrupt the witness. The witness is entitled to complete his answer.

BY MR. ROSETTI:

Q. Go ahead, sir.

A. I've lost my train of thought, but the point is that the appropriate studies haven't been done to be able to say that findings like you're describing on a SPECT scan have any correlation with clinical function in a patient.

Q. You know that we have SPECT scan imaging showing increased regional brain function in Jimmy Freels both in 1999 and 2004 and we have reports of increased clinical function?

A. I think that goes back to the essence of this case in terms of trying to establish how do we determine in a treatment like this if there is a relationship between the treatment and improved clinical function.

I don't think you can look at one patient and make a determination that that's what resulted in his improvement.

Q. In this case we're looking at one patient.

He's not the only patient who has received hyperbaric oxygen therapy with this diagnosis, and he's not the only patient that has received SPECT scan imaging, and he's not the only patient who has been studied, correct?

A. That is correct.

Q. The other studies that you reviewed, besides the Collet study, did any of them show that the children did not improve with HBOT?

A. I am trying to think back in terms of studies that were published.

Again, the Collet study is the only randomized control study that has been done. The others were observational or anecdotal studies and in those I think they had indicated that children improved, but they were not done in a controlled fashion.

MR. ROSETTI: Judge, could I have a moment?

THE COURT: Go ahead.

MR. ROSETTI: Thank you.

BY MR. ROSETTI:

Q. When you reviewed the Collet study, in that study it spoke of comparing the results of HBOT for CP children versus the results from other studies for other modalities used; is that correct?

A. I don't recall that part of it.

Q. Do you recall where they compared the results with the GMFM, that objective measure that's used against other treatment modalities it utilized?

A. At this moment I don't specifically recall that comparison.

Q. Did you actually see the SPECT imaging that was performed in this case?

A. Yes, I did.

Q. Did you notice the areas where there was actual improvement in regional brain functioning?

A. I would say I noticed areas where there was a change in the appearance of the scan in terms of increased tracer uptake.

Q. In other words, areas where the cells function to the extent they could accept the tracer, metabolize the tracer?

A. That's been the presumption.

Again, I don't know that that's well-established. I think we've obviously discussed it. It indicates some change in activity in the tissue in that area.

Q. Does it show what area of the brain there was most improvement?

A. I think it was in the left temporal area.

Q. The area that deals with speech?

A. Correct.

Q. Did you also note in Dr. Harch's testimony about areas of functional improvement in Jimmy Freels?

A. I noted that there was an indication that his speech had improved.

There was another paper that was provided in the materials in the initial application that to some extent addressed that issue. I thought I had included it here but I didn't.

It actually indicated in looking at SPECT scans in CP children that they had been unable to make that kind of correlation that abnormalities on SPECT scans could not be correlated with --

Q. To what do you --

A. -- functional areas.

Q. To what study are you referring?

A. It's in the packet of things that were provided and I thought I had brought it but I'm not seeing it at the moment.

Q. Your attorney is handing me "Cerebral Blood Flow Abnormalities in Cerebral Palsy Children with Normal CT Scan"?

A. And if you would read the last paragraph of their conclusions.

Q. This is a CT scan?

A. With normal CT scans. They were looking at SPECT scans in CP kids who had normal CT scans.

Q. This is from 1989.

MR. OLDENBURG: I only have one copy, Judge.

THE COURT: Go ahead.

THE WITNESS: Well, this was one of the papers that was provided in the initial application to support the application. And their conclusion is that --

MR. ROSETTI: I am going to object to that testimony because I don't know if that's actually the case. I just don't think he has the basis to testify on that particular issue.

MR. OLDENBURG: You can look at the fax line.

THE COURT: Look at what, sir?

MR. OLDENBURG: I'm sorry. The fax line on that came from Mr. Freels.

MR. ROSETTI: I don't know that that means anything. It came to the partner. What it means, it just might be literature. I don't know that that is --

THE COURT: You're asking him to testify to a document that's not in the record; is that correct?

MR. ROSETTI: I am not asking him. He's

testifying --

THE COURT: You just gave him the document.

MR. ROSETTI: He's referencing a document. I don't know if it's in the record or not.

THE COURT: He's giving testimony that it was part of the original -- but your objection is that it was not part of the original, but it's not established in the record that it was part of the original one.

MR. ROSETTI: I don't know if it is or isn't, Judge. I don't have the original. I don't know that he can testify to it either.

THE COURT: You can testify to the foundation for laying it.

Is that a document that was identified in the Pre-Hearing Order or was it part of the --

MR. OLDENBURG: That is part of the submission made by Mr. Freels at the very outset of this case.

THE COURT: That would be part of the record.

MR. OLDENBURG: Correct.

THE COURT: It is not specifically referred to as an exhibit.

I'm going to go ahead and I -- I mean, we're not establishing -- I mean, this is part -- he's saying it's part of the record and it is part of

regional brain function as a result of that demonstration of increased blood flow?

A. I think it -- I don't -- I don't know exactly what his definition of regional brain function is.

There is some change in function there. That doesn't necessarily imply that it's a beneficial function to the brain.

Q. But there's increased cellular function in the brain?

A. I don't know that I can say increased cellular function, but I think there is a change in function in that particular region of the brain.

Q. Change in function.

Is there less or more function?

A. I don't know that I can answer that.

Q. All right.

MR. ROSETTI: Judge, subject to recross, I don't have any further questions at this time.

THE COURT: Redirect, Mr. Oldenburg?

MR. OLDENBURG: Thank you, Judge. I'm going to be very brief.

REDIRECT EXAMINATION

BY MR. OLDENBURG:

Q. Dr. Miller, are observational or anecdotal studies sufficient to the medical community to determine

regional brain function as a result of that demonstration of increased blood flow?

A. I think it -- I don't -- I don't know exactly what his definition of regional brain function is.

There is some change in function there. That doesn't necessarily imply that it's a beneficial function to the brain.

Q. But there's increased cellular function in the brain?

A. I don't know that I can say increased cellular function, but I think there is a change in function in that particular region of the brain.

Q. Change in function.

Is there less or more function?

A. I don't know that I can answer that.

Q. All right.

MR. ROSETTI: Judge, subject to recross, I don't have any further questions at this time.

THE COURT: Redirect, Mr. Oldenburg?

MR. OLDENBURG: Thank you, Judge. I'm going to be very brief.

REDIRECT EXAMINATION

BY MR. OLDENBURG:

Q. Dr. Miller, are observational or anecdotal studies sufficient to the medical community to determine

if hyperbaric oxygen therapy can correct or ameliorate cerebral palsy?

A. I don't think they are.

Q. Is the use of extensive clinical experience sufficient for the medical community to determine if hyperbaric oxygen therapy can correct or ameliorate cerebral palsy?

A. No, I don't think it is.

Q. Is the fact that Dr. Marois has seen 800 patients and treated cerebral palsy patients is my understanding and treated them with some results of, I believe, 80 percent is what he says, is that sufficient for the medical community to determine that hyperbaric oxygen therapy is sufficient to correct or ameliorate cerebral palsy?

A. At this point I don't think it is. I don't think those results have been published or made available to the general medical community to try to determine if that is sufficient evidence.

Q. You indicated that you had reviewed a Spanish study or an English abstract of a Spanish study. What were the findings of that particular study, do you recall?

A. It was, as in some of these others, a review of the literature and a review of studies. They didn't provide any independent data but their conclusion was the

same, that at this point there isn't sufficient evidence to justify its use and this was -- they also gave a statement from the South African Undersea and Hyperbaric Society that they did not recommend the use of hyperbaric oxygen for treatment of cerebral palsy based on their review.

Q. Let me show you -- let me show you, Dr. Miller, what I have marked as Respondent's Exhibit Number 1, Judge, for the record.

Is that the article that you were discussing with Mr. Rosetti during your previous cross-examination?

A. Yes, it is.

Q. And what is the title of that article?

A. "Cerebral Blood Flow Abnormalities in Cerebral Palsy Children with a Normal CT Scan."

Q. Is it your understanding that that document was submitted by David Freels, the Petitioner in this case, or on behalf of his son who is the Petitioner in this case?

A. That is my understanding.

Q. Is this one of the documents that you have reviewed as part of your work in forming your opinions in this case?

A. Yes, it is.

Q. Did you review that article?

A. Yes, I did.

Q. Does that article indicate - let me see that -- on the fax line at the top that it came from David Freels?

A. Yes, it does.

Q. In the -- well, can you summarize the conclusions of that article as relates to your work in regards to this case?

A. I think specifically addressing the issue of the SPECT scans and what those findings mean, they did notice areas of decreased profusion in the brain in these children and their conclusion was that there was a relatively poor concordance observed between the clinical finding and the expected location of the low flow area.

Q. In your work in this case, Dr. Miller, did you review any other articles that would have been published subsequent to this article, Respondent's Exhibit Number 1, which I believe as Mr. Rosetti pointed out was from 1989?

A. With specifically regards to SPECT scanning, I did not.

Q. In your discussions in your direct testimony and your cross-examination, you're making a distinction or are you making a distinction between increased brain function and increased function of a patient when looking at SPECT scans and reviewing additional blood flow?

A. Yes, I am making that distinction.

I think my opinion is we don't really know what these changes on the SPECT scans mean with respect to how that effects the function of the patient.

Q. And would the fact that a SPECT scan shows increased blood flow or brain function, and then there's anecdotal evidence that a patient has some change in function, is that sufficient in the medical community to show that a particular therapy was sufficient to have caused that change in the patient's function?

A. No, I don't think it is.

Q. To your knowledge, Dr. Miller, have there been any randomized, double-blind control studies to make the assumption or come to the conclusion that from review of a SPECT scan showing increased blood flow and brain function that that can relate directly to increased function in the patient?

A. I'm not aware of any.

Q. Thank you.

MR. OLDENBURG: That's all the questions I have of Dr. Miller.

THE COURT: All right. Mr. Rosetti, recross?

RECROSS-EXAMINATION

BY MR. ROSETTI:

Q. Getting back to this article referenced "Cerebral Blood Flow Abnormalities in Cerebral Palsy

Children with a Normal CT Scan," do you know the type of scan that was actually used?

A. I don't. If it was published in 1989, I'm sure it wasn't as technologically advanced as what's available today.

Q. Are you familiar with studies that have been performed on the same topic since 1989?

A. I am not aware of any.

Q. Did you do any research on that after receiving this study?

A. No, I didn't.

Q. Thank you, Doctor.

THE COURT: Dr. Miller, you can step down at this time.

THE WITNESS: Thank you. Do you need this back?

THE COURT: Yes. Actually, this is just an additional copy. What I do need is Exhibit D.

Actually, part of -- you had introduced the document but it was not ruled upon for admission. Was there any objection to Petitioner's Exhibit 1 -- I mean, Respondent's Exhibit 1 being admitted into the record?

MR. ROSETTI: No.

THE COURT: All right, that's admitted into the

record as Respondent's Exhibit 1.

MR. OLDENBURG: Judge, actually there are C and D attached to this.

THE COURT: Attached as well.

MR. OLDENBURG: Attached to this as well as the photocopies of the SPECT scans. For the record, we would move to have those admitted.

THE COURT: Make sure they are identified.

MR. OLDENBURG: The last four or five pages.

THE COURT: Just for the record then, C and D, you indicated you had no opposition to those being admitted?

MR. ROSETTI: No, Your Honor.

THE COURT: Respondent's C and D. So we have those admitted.

At this time we will take a ten-minute break and resume. It's my understanding, Mr. Oldenburg, this is your only witness to call?

MR. OLDENBURG: Correct, Judge. We will rest.

THE COURT: You will rest. And then we will move with the case in rebuttal.

MR. ROSETTI: Great. Thank you.

(Recess taken)

THE COURT: Okay. We are back on the record after a recess. We will begin now with the case in