

1 posturing questions.

2 MR. ROSETTI: Sure.

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

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

12 MR. ROSETTI: May I go get our witnesses?

13 THE COURT: Go ahead.

14 MR. ROSETTI: Thank you, Judge.

15 THE COURT: All right, Mr. Oldenburg.

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

18 THE COURT: All right. Dr. Miller.

19 If you will administer the oath, Mr. Oldenburg.

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

22

23

DR. GARY MILLER,

24

being first duly sworn, was examined and testified as

25

follows:

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

3 MR. ROSETTI: Thank you, Judge.

4 CROSS-EXAMINATION

5 BY MR. ROSETTI:

6 Q. Good morning, Dr. Miller.

7 A. Good morning.

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

10 THE COURT: You may, sir.

11 BY MR. ROSETTI:

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

13 A. I do but I'll take yours.

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

18 A. Yes, it is.

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

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

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

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

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

8 MR. ROSETTI: Thank you.

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

13 MR. OLDENBURG: No objection.

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

18 MR. ROSETTI: Thank you.

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

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

25 THE WITNESS: Thank you.

1 MR. ROSETTI: B is the HBO report?

2 THE COURT: Yes, sir.

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

9 BY MR. ROSETTI:

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

13 A. That is correct.

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

17 A. That's correct.

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

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

24 Q. Very good.

25 Do you know when you were contacted to render

1 an opinion on that issue?

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

3 Q. Sometime -- okay.

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

6 A. Yes, I did.

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

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

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

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

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

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

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

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

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

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

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

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

21          Q.     I'm sorry.  I will rephrase it for you, Doctor.  
22                 You have an understanding of the  
23 generally-accepted treatment protocols established by  
24 neurologists in the State of Georgia with respect to the  
25 treatment of pediatric CP patients, correct?

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

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

8           A.     That's right.

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

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

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

18          A.     I have not.

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

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

1 was told that they were not.

2 Q. And this acquaintance was a --

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

5 Q. A physician?

6 A. Not a physician. A respiratory therapist.

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

9 A. I have not.

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

12 A. That's correct.

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

15 A. That's correct.

16 Q. All right. What are those neurological  
17 indications?

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

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

25 A. Again, it might have -- an associated



1       implication would be cyanide poisoning.

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

5           A.     Potentially, that's correct.

6           Q.     And has that occurred?

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

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

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

14          Q.     And you base that opinion on what?

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

19          Q.     All right. What is that evidence?

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

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

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

25          Q.     Okay.

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

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

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

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

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

15          A.     That's correct.

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

18          A.     Correct.

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

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

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

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

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

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

5 Q. Well, start with patients.

6 A. So the question is have --

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

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

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

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

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

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

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

1 THE COURT: Response?

2 MR. ROSETTI: I will rephrase.

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

4 BY MR. ROSETTI:

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

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

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

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

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

22 Q. The medical community in general.

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

1 randomized, double-blind control study, correct?

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

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

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

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

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

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

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

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

25 A. Yes, I did.

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

3 A. Yes, I saw that in his testimony.

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

6 A. It is, yes.

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

10 A. I saw that in his testimony.

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

13 A. I did read his testimony to that effect.

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

16 A. That's correct.

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

18 A. It is an objective measure.

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

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

1 that correct?

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

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

7 Q. Okay.

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

11 A. It may or may not been.

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

17 Q. Extensive clinical experience?

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

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

1 those treatments?

2 A. There are --

3 Q. --- showing their efficacy. I apologize.

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

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

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

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

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

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



1 experience of treating the patients directly.

2 Q. Okay.

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

6 A. That's correct.

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

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

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

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

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

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

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

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

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

11          Q.     All right.

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

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

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

20          A.     Yes.

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

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

1 reviewed all the available literature that was available  
2 to them.

3 Q. All the available literature?

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

6 Q. In the English language?

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

10 Q. To be clear --

11 A. It was more than that.

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

14 A. Correct.

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

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

18 Q. And those were excluded by the AHRQ report.

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

21 A. That's correct.

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

24 A. There are. Sure.

25 Q. Have you reviewed those?

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

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

7           A.     Correct.

8           Q.     Did you read the animal studies?

9           A.     I did not.

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

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

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

17          A.     No, I didn't.

18          Q.     Just the conclusions in the report basically?

19          A.     And I did review the Collet study.

20          Q.     You did?

21          A.     Yes.

22          Q.     Are you familiar with Dr. Marois?

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

25          Q.     One of the principal authors on that study.

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

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

5           Q.     Does that sound --

6           A.     That sounds correct.

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

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

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

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

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

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

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

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

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

1 room air.

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

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

10 A. I think that's a fair statement.

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

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

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

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

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

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

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

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

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

5 Q. You don't know?

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

8 Q. Okay.

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

11 A. I read that in his testimony, yes.

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

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

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

19 A. No, I haven't.

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

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

1 chamber.

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

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

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

14 A. No, I don't.

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

17 A. I don't know.

18 Q. You don't know.

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

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

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

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



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

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

5 A. That's correct.

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

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

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

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

14 A. Yes, I do.

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

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

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

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

25 A. Sir, would you repeat the question?

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

3 A. That would not be my testimony, correct.

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

6 A. Correct.

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

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

12 Q. What else did you rely on?

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

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

17 A. I don't know that --

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

20 A. That's correct.

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

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

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

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

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

5 A. The review of the Collet study.

6 Q. Okay.

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

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

13 A. It is not included in that testimony.

14 Q. What is included is the AHRQ report?

15 A. Yes.

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

17 A. You may have to provide it to me.

18 Q. Excuse me.

19 THE COURT: Go ahead.

20 BY MR. ROSETTI:

21 Q. Okay. Page 4 of the report.

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

25 Do you see that sub-heading on that page?

1 A. Under "cerebral palsy"?

2 Q. Yes.

3 A. Yes, sir.

4 Q. What does that report conclude?

5 A. That there is insufficient evidence to  
6 determine whether the use of hyperbaric oxygen improves  
7 functional outcomes in children with cerebral palsy.

8 Q. And what does it continue to say?

9 A. Do you want me just to read --

10 Q. Just that paragraph.

11 A. The results of the only truly randomized trials  
12 were difficult to interpret because of the use of  
13 pressurized room air in the control group. As both groups  
14 improved, the benefit of pressurized air and of hyperbaric  
15 oxygen therapy at 1.3 to 1.5 atmospheres should both be  
16 examined in future studies.

17 Q. Thank you, Doctor.

18 And so that report, according to what you just  
19 read, is actually saying that --

20 A. That the --

21 Q. -- that we should look at the distinction  
22 between 1.3 and 1.5 atmospheres, that it's inconclusive  
23 because both groups improved?

24 A. I don't think the conclusion is that it's  
25 inconclusive just between those two groups.

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

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

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

9           Q.     The Collet study.

10          A.     -- or the Collet study.

11          Q.     Yes.

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

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

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

23          A.     That's correct.

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

1 not necessarily one more than the other.

2 Q. And we have one here?

3 A. Correct.

4 Q. All right.

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

7 A. That's right.

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

10 A. Yes.

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

14 A. I think they do have some standards.

15 Q. Are you familiar with them?

16 A. I am generally familiar with them.

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

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

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

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

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

5           Q.     Including CP patients?

6           A.     Correct.

7           Q.     For what purpose?

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

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

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

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

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

19          Q.     Do you review SPECTS personally?

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

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

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

1 any specific training in interpreting SPECT scans.

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

5 A. Yes, I did.

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

9 A. No, I was not.

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

12 A. No.

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

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

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

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

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



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

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

6 Q. Are you not interpreting imaging studies?

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

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

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

17 Q. Oh.

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

21 A. Yes.

22 Q. All right.

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

25 A. I think that's correct.

1 Q. A functioning cell.

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

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

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

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

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

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

22 Q. Okay.

23 Cellular functioning?

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