

1 A. Exactly.

2 Q. Thank you, Mr. Freels.

3 MR. ROSETTI: I have no more questions.

4 THE COURT: Any recross?

5 MR. OLDENBURG: Nothing further, Judge.

6 THE COURT: All right. You can step down.

7 Thank you.

8 THE WITNESS: Okay.

9 (Tape 1, Side 2 of 4 concluded)

10 \* \* \*

11 (Tape 2, Side 3 of 4 begins)

12 MR. ROSETTI: Dr. Marois, would you raise your  
13 right hand, please.

14 - - -

15 DR. PIERRE MAROIS,  
16 being first duly sworn, was examined and testified as  
17 follows:

18 MR. ROSETTI: Please be seated and state your  
19 name.

20 CROSS-EXAMINATION

21 BY MR. ROSETTI:

22 A. Dr. Marois, I'm handing you your direct  
23 testimony.

24 If you would turn to Page 6. I'm just going to  
25 make sure that is the same numbers.

1 A. There are no numbers on mine.

2 Q. All right. Is the signature at the end of the  
3 testimony your signature?

4 A. Yes, it is.

5 Q. Okay. Beyond that is the --

6 MR. ROSETTI: Is the recorder working, Judge?

7 THE COURT: Yes.

8 BY MR. ROSETTI:

9 Q. -- a copy of your curriculum vitae?

10 A. Yes.

11 Q. It is in French?

12 A. It is in French. Sorry.

13 Q. That's okay. I'm going to hand you a copy of  
14 it --

15 MR. ROSETTI: Judge, if it's okay, can he read  
16 in English his curriculum vitae?

17 THE COURT: Do you have any objection to that  
18 translation?

19 MR. OLDENBURG: Unless you --

20 THE COURT: All right. I can read most of it.  
21 I don't have much of an objection but I mean it's not  
22 an official language thing.

23 THE WITNESS: You know, I won't go through  
24 everything. It can be too long. But already in my  
25 deposition, I have made a little resume of what it

1 was.

2 So I was trained in physical medicine. I did  
3 first my medicine in Montreal at the University of  
4 Montreal, was five years of medical studies. And  
5 then I did training in pediatrics and also in  
6 physical medicine in rehabilitation of children for  
7 four and a half years in Montreal.

8 I have been received as a specialist in Quebec  
9 Province in 1979. Also I am a member of the Fellow  
10 of Royal College of Physicians of Canada, which is a  
11 recognition of your specialty everywhere in Canada as  
12 a physician specializing in physical medicine and  
13 rehabilitation with special interest with children.

14 I have been doing a fellowship in other  
15 countries for one year. I stayed in Sweden for three  
16 months and a half. I worked a little bit in England.  
17 I came to the States, Palo Alto University at  
18 Stanford University in Palo Alto. I work in Los  
19 Angelos also. I train there at the Rancho Los Amigos  
20 Center. I train in Toronto and I train in  
21 Minneapolis.

22 I started working with children with cerebral  
23 palsy in 1989 - 1981. Sorry. Since then I have  
24 been practicing mostly at Sainte Justine Hospital,  
25 which is the biggest health center in Canada,

1           pediatric center, which now we are a rehabilitation  
2           facility which is called Marie Enfant Hospital.

3           Now I'm working mostly at Sainte Justine but  
4           also for the rehabilitation center in Province  
5           Quebec, working physically in 20 places with around  
6           25 rehabilitation teams. So I work with about 300  
7           professionals, occupational therapy, physical  
8           therapy, et cetera. And I work also with colleagues,  
9           neurosurgeons, orthopedic surgeons, neurologists, et  
10          cetera.

11          I have been in charge of all the doctors at  
12          Marie Enfant Hospital. At the beginning I was  
13          President of the Medical Board for 19 years. There  
14          was 100 doctors. I've been also involved in many  
15          research practices.

16          If you look at the curriculum vitae, I just  
17          went through very fast some of the areas. There was  
18          one page that is my training, one where I talk about  
19          the training I did in other countries, and the  
20          clinical experience.

21          I have been working mostly with cerebral palsy  
22          since 1981 in many areas in many clinics. It's all  
23          hospitals settings or rehabilitation settings. I've  
24          seen in consultation more than 50,000 -- I've made  
25          more than 50,000 consultations in cerebral palsy so

1 far.

2 I have been following more than 3,000 children  
3 with cerebral palsy and actively following now about  
4 1500 children with cerebral palsy. That's the most  
5 important part of my work.

6 I have been -- there is a Section IV, which is  
7 the presentation. It is all the -- it is all part of  
8 the presentation that I did in the symposium,  
9 Congress meetings, on many subjects, mostly on  
10 cerebral palsy: What is cerebral palsy; the  
11 treatments of cerebral palsy; the new treatments that  
12 we have proposed with time.

13 I have put together the first clinic in North  
14 America in the world. I did rhizotomy in children  
15 since, and we were the only clinical team that was  
16 doing that surgery for five years in North America.  
17 Since then everywhere in the states it has been used.  
18 So we really were the first one to do that.

19 And I did also a lot of research in  
20 neuromuscular disease, muscular dystrophy.

21 Finally, the last research I have been doing  
22 were mostly with HBOT starting in 1998.

23 So just a little -- Section IV is all the  
24 publications, symposiums, conferences I've been doing  
25 in many places.

1 I've been teaching also medicine with all the  
2 students of medicine, but mostly all the residents,  
3 the doctors who want to specialize in physical  
4 medicine and the rehabilitation mostly in children.  
5 Doctors come from other countries that come and stay  
6 at Sainte Justine Hospital with me. And I am still  
7 teaching medicine today.

8 What else? I have been, you know, I receive  
9 research funds for many researches: Neuromuscular  
10 disease, rhizotomy, and more recently with HBO  
11 treatment. I have also administered the Vexper,  
12 Section VI.

13 I was president of Medical Board for 19 years.  
14 I was also vice-president of the Administration  
15 Consulate at one hospital for six years. I was  
16 member of the Executive of College of Physicians of  
17 Canada for some time. I am still part of many  
18 communities of research communities.

19 CROSS-EXAMINATION

20 BY MR. OLDENBURG:

21 Q. All right. Thank you.

22 Dr. Marous?

23 A. Marois.

24 Q. Marois. I apologize if I struggle with that.

25 A. I'm sorry. I am bad for my English. We speak

1 French all the time in Quebec.

2 Q. My name is Mark Oldenburg. We have not met  
3 before.

4 A. Okay.

5 Q. You are not board-certified in hyperbaric  
6 medicine, correct?

7 A. No.

8 Q. Is there any such board certification in  
9 Canada?

10 A. I don't know.

11 We don't use the term "board-certified" in  
12 Canada. That is not the way it is worded. You are a  
13 member of the College of Physicians when you are a  
14 specialist. But no, there is no board certification in  
15 Canada. That is the equivalent.

16 Q. Okay. You do indicate in your direct testimony  
17 that you're board-certified in physical medicine in  
18 Canada?

19 A. Yes. But, yes, it is the equivalent of  
20 board-certified. It means you have the certification.  
21 It's not board -- it is -- you have done your exams and  
22 you are certified to practice.

23 Q. I understand.

24 But as part of any board certification type of  
25 thing, there is no such certification in Canada for

1 hyperbaric medicine?

2 A. I don't know that there is such a certification  
3 like that.

4 No, I am not -- you know, I don't have a  
5 certification in hyperbaric medicine.

6 Q. Okay. With regard to the study you have been  
7 involved in with Dr. Vaness?

8 A. Varnasse.

9 Q. Varnasse.

10 To date, that study has not been published,  
11 correct?

12 A. Which one?

13 Q. If you have your direct testimony, it's the  
14 one --

15 A. Because I've been involved in three studies  
16 with Dr. Varnasse.

17 Q. All right.

18 A. The last -- the retrospective study?

19 Q. I'll just show you what we're talking about  
20 here.

21 It's on the last page of your direct testimony  
22 here. I'm sorry.

23 A. Oh, okay.

24 Q. Beginning at the very top.

25 A. Okay.



1 Q. Just so we are clear, it indicates -- the  
2 question is: Have you been involved in any recent  
3 studies?

4 Your answer is yes. I, along with  
5 Dr. Varnesse, are participating in the publication article  
6 about a retrospective study of HBOT and the treatment of  
7 cerebral palsy.

8 A. Yes. That has -- it has not been published  
9 yet.

10 Q. All right. And to date that work has not yet  
11 been subject to peer review; is that correct?

12 A. Yes, that's correct.

13 Q. And was that a double-blind study?

14 A. No, it was not.

15 It was a retrospective study done with children  
16 with cerebral palsy --

17 Q. I understand.

18 A. And I think some too on HBOT treatment.

19 Q. I understand.

20 Has the article actually been written and  
21 accepted for publication yet?

22 A. Not yet. We are adjusting that. We will be  
23 presenting those results at the international symposium  
24 next month. It will be also presented in a neurological  
25 international symposium in Spain this fall.

- 1 Q. And then only after that is presented will it  
2 be subject to peer review --
- 3 A. Yes.
- 4 Q. - and commented on by your peers?
- 5 A. Yes.
- 6 Q. You have extensive clinical experience in  
7 treating children with cerebral palsy; would you agree  
8 with that?
- 9 A. Yes.
- 10 Q. Would you also agree that generally-accepted  
11 treatment protocols for children with cerebral palsy would  
12 include physical therapy?
- 13 A. Sure.
- 14 Q. Occupational therapy?
- 15 A. Sure.
- 16 Q. Speech therapy?
- 17 A. Yes.
- 18 Q. Medication, if indicated?
- 19 A. Yes.
- 20 Q. Do you prescribe medications for treating  
21 children with CP?
- 22 A. Sure.
- 23 Q. Would those include Baclofen and Botox  
24 injections?
- 25 A. Yes.

1 Q. Do you actually perform the Botox injections  
2 yourself?

3 A. No, I don't do that.

4 Q. You have someone else do that?

5 A. Yes. I don't have the time to do that.

6 Q. The goal of these types of treatments that I've  
7 just mentioned - the physical therapy, the occupational  
8 therapy, the speech therapy, and the medications - the  
9 goal is to increase the function of the child, correct?

10 A. The goal is to -- it depends.

11 Botox, it's mostly to treat their spasticity.  
12 Sometimes it will improve function and sometimes it will  
13 just improve their comfort or release the pain or just it  
14 will be easier for the parents to take care of them.

15 But with physical therapy, also the main  
16 purpose is to have mobility but also can improve function.

17 Same with occupational therapy and the speech  
18 therapy, increasing their ability to speak and to walk or  
19 to use their hand better.

20 Q. I need you to do me just a little bit a favor  
21 and if you could just speak a little more loudly.

22 A. No problem.

23 Q. I'm sure these guys would like to hear, too.

24 So that use of these therapies, would you  
25 agree, is to assist in -- well, preventing complications

1 would be one thing, correct?

2 A. Yes.

3 Q. But it would also be to try to assist or  
4 prevent or to promote development in the child?

5 A. Exactly.

6 Q. And by using these type of treatments, you may  
7 see improvement in gross motor skills?

8 A. Yes. You can see improvement in gross motor  
9 skills. And there have been curves that have been done to  
10 really show how it's going with the therapies.

11 In fact, the curves are called GMFM SES curves.

12 Can I use this?

13 Q. If you need to explain your answer.

14 A. Yes, because it's very important to understand.

15 This is something that --

16 Q. I can't see it.

17 A. Thank you.

18 Okay. That is zero. GMFM is the Gross Motor  
19 Function Measurement. It is used in cerebral palsy. It  
20 is used in all developmental problems in children. It  
21 measures the function of children.

22 Usually with a child, we reach one of the  
23 percents at the age of five. Okay. So that's one, two,  
24 three, four, five. Normal child is like that.

25 A child with CP, there are five curves. A

1 little one, two, three, four, five. One is the child that  
2 is least cerebral palsy, least involvement. Little five  
3 is very handicapped children.

4 So level one is like that; level two like that;  
5 level three; level four; five. What we see there is, yes,  
6 with therapy, we see -- because all the children are  
7 treated -- we see a lot of improvement in the first year  
8 of life, like normal, but you have a plateau that is  
9 attained more and more quickly if you have a big  
10 involvement.

11 So with a child that are at level five, for  
12 example, the plateau usually is reached around the age of  
13 two or three.

14 So it's, it's right to say that with therapies  
15 you improve, but there is curves that have been determined  
16 and accepted throughout the world that show how this  
17 improvement is made. It's not like this. It's mostly  
18 quite progressive. And at one point when you attain the  
19 age of three, four, five, you have a plateau and you don't  
20 expect much improvement, even with physical therapy or OT.

21 So you're statement is true that you improve,  
22 but much more when you're younger.

23 Q. And this improvement that you would hope to see  
24 through using the therapy that is outlined, that would  
25 apply to both fine and gross motor skills, correct?

1 A. Yes.

2 Q. And as well as --

3 A. This group was made with gross motor, but you  
4 would expect that it's about the same with more --- there  
5 is no curves of fine motor.

6 Q. And would you also hope to achieve through the  
7 use of these therapies some sort of increase in cognitive  
8 development as well, if there is a cognitive impairment?

9 A. Not specifically with physical therapy or  
10 occupational therapy.

11 With time, with a lot of stimulation program or  
12 any stimulation with the child, yes, it will improve  
13 cognitively. That is a rule with normal people, human  
14 beings.

15 Q. Now, with regard to patterning -- you're  
16 familiar with that term, of course?

17 A. Yes.

18 Q. And the activities that Mr. Freels described  
19 during his testimony, would that be consistent with your  
20 understanding of what patterning activities are?

21 A. Yes.

22 Q. Do you recommend to the parents of patients  
23 with children with CP that they engage in patterning  
24 activities?

25 A. We don't use that kind of therapy in Canada.

1 There is some groups, little groups where they use it.

2 It's not part of our usual treatments, no.

3 Q. Why not?

4 A. I have not seen any big studies done with that.

5 The involvement in families is incredible. It  
6 is -- you know, most of the time it will be hours and  
7 hours and hours every day. And we have seen other  
8 therapies that most of the time have better or faster  
9 results.

10 But, you know, I have not seen a single study  
11 that was really showing improvements. But I have some  
12 patients that went to Philadelphia and some parents  
13 reported changes.

14 You know, we don't recommend. It's not easily  
15 accessible in Canada. And it's so much of a burden for  
16 time with the family that we don't recommend it.

17 Q. And the parents that went to Philadelphia  
18 describing to you, you know, changes or improvements that  
19 occurred, that would just be anecdotal evidence, correct?

20 A. Yes.

21 Q. And no -- with regard to patterning activities  
22 as a recommended therapy, to your knowledge there have not  
23 been any double-blind, randomized control studies?

24 A. With patterning?

25 Q. With patterning, correct?

1           A.     No.

2                     It would be -- in fact, it would be almost  
3     unfeasible because you would have to consider every type  
4     of cerebral palsy and to be double blind with therapies  
5     like that you could not do that. So, you know, I would  
6     not expect anyone publish any time, especially like that.

7           Q.     Even taking away whether there's been a  
8     double-blind, randomized control study, to your knowledge  
9     there haven't been any studies that recommend patterning?

10          A.     No.

11          Q.     Now, you would agree, would you not, that doing  
12     double-blind, randomized control studies is one of the  
13     best ways for the medical community to accept or  
14     develop -- move to accepting a particular therapy,  
15     correct?

16          A.     Certainly one of the best ways when possible.  
17     But the problem is that in many areas of work and in  
18     medicine, you couldn't do that. If you were using double  
19     blind studies to prove every treatment that we were doing,  
20     you know, we would stop doing medicine.

21                     It is not more than ten percent of the  
22     treatment that we use to be -- that I have been through  
23     double-blind, placebo control studies, and in my work in  
24     cerebral palsy I don't know any double blind placebo  
25     control studies that are showing -- that have been done in



1 physical therapy, occupational therapy, rhizotomy, Botox,  
2 whatever I prescribe. So we would shut down every  
3 rehabilitation center in North America who rely on  
4 double-blind, placebo-controlled studies.

5 Q. Would you agree with Dr. Miller's statement  
6 that the medical community is, for lack of a better word,  
7 being forced to move to have more double-blind,  
8 randomized, customized studies before they accept a  
9 particular therapy modality?

10 A. It's a trend, but it is also a contested trend.  
11 I'm not -- I'm not (inaudible)

12 It would be in a -- the best world would be to  
13 do that if we can. But, you know, even Botox, which we  
14 are recommending and that has been recommended in North  
15 America in CP for about ten years, we wrote a prescription  
16 for that, you know. It was recommended before there was a  
17 single study every published for Botox, and it was paid by  
18 most insurance companies and by the health care system  
19 much before there was not double blind placebo control  
20 study but even a (inaudible) pilot study.

21 So, yes, the state-of-the art would be to have  
22 those kinds of studies but it is not the reality right  
23 now. Not at all.

24 Q. You would also agree with me, would you not,  
25 that it is important to have peer review as part of any

1 study which may recommend a new type of therapy? I'm just  
2 not talking about with children with CP but any type of  
3 therapy. Peer review is an important part of that  
4 process?

5 A. It is much better, yes, but even with big  
6 journals, like Development and Child Neurology Journal,  
7 which is the biggest journal in cerebral palsy, it is  
8 always not peer-reviewed. But, you know, yes, I'm sure it  
9 would be better.

10 But, again, most treatments that are used have  
11 not been through even peer-review studies.

12 Q. And would you also agree with me that simply  
13 having clinical experience is not sufficient to the  
14 medical community to accept a particular therapy for  
15 treatment?

16 A. Sure. It is -- you need more than that.

17 But in the case of HBOT, many people have  
18 clinical experience. There have been, you know, eight or  
19 nine studies so far that have been published or present  
20 and you can count, you know, hundreds and hundreds of  
21 children in those studies. All those studies were  
22 positive. Not a single one didn't show any results. So  
23 all the studies were positive so far.

24 Q. I think you've commented on this, but some of  
25 the studies which have been performed, even in your

1 opinion, have not been very well done, correct?

2 A. Yes.

3 Q. And even with regard to the Collet study in  
4 which you were involved, you don't think that was done  
5 properly?

6 A. In fact, there was a big mistake right in the  
7 beginning when Dr. Collet decided to remove the control  
8 group.

9 Q. And having a control group is very important?

10 A. It makes --

11 Q. If you don't mind, let me finish my question  
12 just so we're clear. I don't mean to interrupt.

13 But you would agree that having a control group  
14 is very important in being able to determine the efficacy  
15 of any treatment or therapy?

16 A. It is much easier to input the results when you  
17 have a control group.

18 And the Collet study, though the results were  
19 so important, changes with the GMFM were so important,  
20 they were far more important than with any other studies  
21 that were done on CP children evaluating the effect of any  
22 recognized therapies that, you know, it was -- we could at  
23 least reach some conclusion that the changes were  
24 statistically and clinically very, very significant, and  
25 at the end of the study we had, you know, some control

1 just beyond the (unintelligible) of the study.

2 Q. You worked directly with Dr. Collette?

3 A. What?

4 Q. Dr. Collette, isn't that his name?

5 A. Dr. Collet.

6 Q. Collet. You worked directly with him on this  
7 particular study?

8 A. Indirectly. Not directly.

9 I had built the protocol with Varnasse in the  
10 beginning and that was a protocol that was accepted in all  
11 ethics and scientific communities.

12 But Dr. Collet was appointed by the government  
13 to direct that research and he removed the control group  
14 and then, you know, we didn't work much together.

15 Q. Now, do you know Dr. Collet's qualifications?

16 A. Yes.

17 Q. And is he a qualified physician in Canada?

18 A. He doesn't have the right to practice in  
19 Canada. He has the right to do research in Canada. So he  
20 is not a member of the College of Physicians in Canada.

21 He's a pediatrician that came from France and  
22 he's assigned mostly to do studies on medication. But he  
23 was assigned by the government to direct that study.

24 Yes, he has absolutely no experience in CP and  
25 no experience in HBOT.

1 Q. But the government of Canada appointed  
2 Dr. Collet --

3 A. The government --

4 Q. Let me just finish.

5 The government of Canada appointed him?

6 A. The government of France Quebec through their  
7 organization, research organization that is called "Fonds  
8 de la recherche en sante du Quebec." So it was not the  
9 minister that appointed him but a research organization of  
10 Province of Quebec, not of Canada.

11 Q. And you believe that the -- well, there is no  
12 question that Dr. Collet did not follow the protocol which  
13 you designed, correct?

14 A. Yes.

15 Q. And you ultimately would disagree with the  
16 conclusions he reached that were published in The Lancet?

17 A. No. The conclusion that was published in The  
18 Lancet is that -- and you can read, you can read exactly  
19 the editorial of The Lancet when it was published.

20 It says: The researcher is supposed to relate  
21 that either of the treatments were equally effective or  
22 the mere act of participating in a trial that promoted  
23 communication with other motivated children in Paris had a  
24 positive effect. Either way the results are --

25 I co signed this article, but at the same time

1 it showed that the participation effect doesn't stand --  
2 in all the clinic -- with all the clinicians that were  
3 involved in this research project, no one agreed with  
4 that. But we had to say that because we didn't have any  
5 control group.

6 If we had a control group, we would have proven  
7 that the HBO was effective. But without any control  
8 group, the only two hypotheses that could stand were those  
9 two.

10 The problem is that Dr. Collet lost  
11 communication after that. I come to see the article we  
12 signed. He says it was a placebo effect. It could not be  
13 placebo effect, there was no placebo group in the  
14 treatment, in the study, and even the word "placebo" was  
15 not allowed to be used in the publication.

16 The Lancet specifically asked Dr. Collet to  
17 remove the word "placebo" and never use it. So then  
18 Dr. Collet is saying it was a placebo effect. So almost  
19 everyone disagrees, the researchers involved in the study.

20 Q. They disagree with Dr. Collet?

21 A. Interpretation of the article.

22 Q. And he was the one who wrote the article,  
23 correct?

24 A. He is the one who mainly wrote the article.

25 Q. He wasn't the one that probably did the

1 writing, there were others involved?

2 A. Yes.

3 Q. His conclusion that the -- that there wasn't  
4 sufficient evidence that the use of the hyperbaric oxygen  
5 therapy really assisted the patients with cerebal palsy,  
6 correct?

7 A. His own conclusion.

8 Q. Correct?

9 A. It was not the conclusion of the research. It  
10 was the conclusion of the article.

11 Q. Yes. The article was published. That was the  
12 conclusion, that there was no substantive -- sufficient  
13 evidence.

14 A. Yes. Showing we show go and do more research.

15 Q. Exactly.

16 Now, why did you allow your name to continue to  
17 be associated with that article if you disagreed with it?

18 A. I don't.

19 Again, I disagree with what Dr. Collet --  
20 Dr. Collet's interpretation of the article. I don't  
21 disagree with the -- mainly with the article.

22 The article was stating that it could be the  
23 two treatments that were collective and that we should do  
24 more research to prove that. That has been my position at  
25 that time, and since then, you know, I've seen 500 more

1 children treated with HBOT and I have seen more research  
2 done by the U.S. Army, by Cornell University, by Galveston  
3 University, by a study that was done in India, and  
4 everyone sees changes in exactly the same way we do.

5 Q. You're familiar with the Agency for Healthcare  
6 Research and Quality.

7 A. I know the name of the agency but I'm not  
8 really familiar with their work.

9 Q. Well, are you aware that one of their roles is  
10 to improve the quality and the safety of health care in  
11 the United States?

12 A. Sure.

13 Q. And have you reviewed the paper which  
14 Dr. Miller testified about that is attached and is  
15 admitted as an exhibit to this entitled "Hyperbaric Oxygen  
16 Therapy for Brain Injury, Cerebral Palsy and Stroke"?

17 A. I have seen some of the conclusions they  
18 reached, yes.

19 Q. You have not reviewed the whole paper?

20 A. No, no, no.

21 Q. All right.

22 A. Some -- only some segments.

23 Q. Okay. You are aware --

24 A. You know, for me it's quite positive.

25 Q. You're aware that the conclusion of that paper



1 was that it was difficult to interpret the use of HBOT in  
2 CP patients because of the --

3 A. The lack of control group.

4 Q. -- the lack of a control group, right?

5 A. Yes.

6 Q. Right.

7 And you don't disagree with that?

8 A. I don't disagree with that.

9 But they also say that in their opinion the  
10 main hypothesis that could be reached or attained is that  
11 both treatment were equally effective. They also say  
12 that.

13 Q. Do you use SPECT scans in your treatment of  
14 receiving patients?

15 A. We have been using SPECT scanning for about  
16 three or four years. So the first studies were not done  
17 with SPECT scanning. And the last study we did  
18 recently -- in fact, it's a retrospective study, about 40  
19 of the 120 children had SPECT scanning, and all those  
20 SPECT scans were interpreted by a neuroradiologist at  
21 Sainte Justine Hospital.

22 In fact, what we have seen is that in all the  
23 studies we did so far, the pilot study, the double-blind  
24 study, and now this study, is about 65 to 70 percent of  
25 the children would improve the GMFM, in terms of the Gross

1 Motor Function, and about 80 percent of the children  
2 improve clinically in terms of cognition.

3 With the SPECT scanning, we are seeing that,  
4 you know, around 60 percent of the children show  
5 improvement in the SPECT scanning. And sometimes children  
6 improve clinically without changing -- with SPECT scan,  
7 but I've never seen a change in SPECT scan with the  
8 children with CP with no clinical change. All the  
9 children that had SPECT scan changes in their pre-post  
10 HBOT all have clinical change at the same time.

11 Q. And, again, the basis of your testimony is  
12 based -- is your clinical experience with the treatment of  
13 the children under HBOT?

14 A. Yes. Sure.

15 I never interpret the SPECT scan. The doctors  
16 who interpret the SPECT scan don't have any clues about  
17 the clinical progress of the children anyway. So I just  
18 put that together and we see that there is a correlation  
19 between the two.

20 Q. And other than that clinical correlation, would  
21 you agree that there are no studies that you know of that  
22 have been published that directly relate an increased  
23 blood flow in the SPECT scan to increased physical  
24 functioning or to increased functioning of the patient?

25 A. I cannot answer that. I don't know.

1 Q. You are just not aware of any?

2 A. No.

3 Q. Thank you.

4 MR. OLDENBURG: That's all the questions I  
5 have, Judge.

6 THE COURT: Anything on redirect?

7 MR. ROSETTI: Just a few.

8 REDIRECT EXAMINATION

9 BY MR. ROSETTI:

10 Q. I like charts.

11 The chart that you have brought up there, the  
12 left arch is 100 percent GMF --

13 A. That is GMFM.

14 Q. And what is that?

15 A. That is the Gross Motor Function Measure. It  
16 is the measure that is used in every -- almost every study  
17 that's done with children with cerebral palsy because it  
18 is quite objective. It is not things you ask the children  
19 to do he never did before and is getting better with time.  
20 You just observe a child and what he's capable of doing  
21 and it's very precise.

22 Q. What is the role -- what is the role of the  
23 charting that you used with respect to the studies that  
24 you performed under the Collet study? What did you  
25 utilize?

1           A.     We utilized the GMFM.

2           Q.     You did?

3           A.     Just like all the studies done in cerebral  
4 palsy. And with the Collet study, we did have  
5 improvements, quite impressive improvements.

6                     In fact, if we have a chart here, it's like all  
7 the studies that were done using GMFM. It's a comparison  
8 of changes of Gross Motor Function Measure. It's GMFM  
9 with children with cerebral palsy. And, you know, most  
10 studies that were done were intensive physical therapy,  
11 physio-rhizotomy and intensive physical therapy,  
12 electrical stimulation, Baclofen, Botox, and all  
13 recognized therapies with children with cerebral palsy.

14                    You have a rate of change, a rate of progress  
15 of, you know, most of the time it is less than .5, .6.  
16 Sometimes you can reach .8 percent per month. Okay. And  
17 that's a GMFM change, .8 percent a month.

18                    And in the Collet study, the rate of  
19 improvement was double that. It was 1.5 and 1.45, and so  
20 it was twice the -- whatever had been publicated.

21           Q.     1.5 for one group?

22           A.     1.5 percent per month in one group and 1.45  
23 percent per month in the other group. And when we did the  
24 pilot study, it was 4.9 percent a month.

25                    So the rate of improvement and the amount of

1 improvement was at least equal or most of the time much  
2 faster, much bigger than everything that had been measured  
3 in cerebral palsy.

4 Q. And when you -- when you refer -- you don't  
5 actually perform hyperbaric oxygen therapy in your  
6 practice?

7 A. I don't perform HBO therapy. I don't. I work  
8 with clinics.

9 Q. You send them out to somebody else?

10 A. Like I send people to have Botox injection or I  
11 send them to surgery or I send them to rhizotomy or for  
12 medication. That is the same thing. It is done in a  
13 private clinic and they do it with them.

14 Q. And you're sending them out in conjunction with  
15 other therapies?

16 A. Yes.

17 Q. Not just hyperbaric --

18 A. For sure because the work -- they don't work  
19 exactly the same way.

20 Conventional therapy, like I said, improve  
21 progressively more function, the use -- you know, the  
22 shortening of the muscles, things like that. But that is  
23 the only therapy, HBO, that I have seen changing  
24 cognition, communication, gross motor function, treating  
25 spasticity, all the aspect of brain function. So it

1 change really the course of the progress of the children.

2 I showed you what is natural with therapy with  
3 the children, but in the course of Collet study and the  
4 other studies what we show is that --

5 Q. Doctor, the other studies, what do those show?

6 A. The other pilot study we did in Montreal too,  
7 it was published in the journal and the recent study we  
8 did is that we can see children that are there suddenly  
9 have a big jump in their gross motor function.

10 And then after a while, without HBO therapy,  
11 they just go on the curve again and then they have a jump  
12 with new therapy. Some children have change  
13 (unintelligible) with those of cerebral palsy. It has  
14 never been shown by any other therapy so far.

15 Q. Just to clarify, you were signatory to the  
16 Collet study?

17 A. Sure.

18 Q. And you agree with what was published in The  
19 lancet?

20 A. With most of it. There is part of the  
21 discussion that, you know, I don't really fully agree.  
22 But the main article and the big conclusion where we  
23 should do more research and there are two hypotheses, yes.

24 Q. The first hypothesis is simply a matter -- what  
25 was the firstly hypothesis again?

1 A. That both treatments were equally effective.

2 Q. Okay. And the second?

3 A. Is that it is a participation effect.

4 But the participation effect, you know, has  
5 never been shown with any children with cerebral palsy so  
6 far in any studies. And if it was a participation effect,  
7 how can you explain huge improvement, twice, three times,  
8 four times bigger than what we had with recommended  
9 therapies.

10 All those studies with recommended therapies  
11 had all participation effect probably but that accounts  
12 for a very small improvement and still in the Collet study  
13 there might be a participation effect that could not be  
14 accounted -- that could not be accounted for, the whole  
15 progress that is much faster than any other recognized  
16 therapy.

17 Q. A lot of your patients are receiving hyperbaric  
18 oxygen therapy, a lot of your CP patients are?

19 A. Yes.

20 Q. And how do they do with that?

21 MR. OLDENBURG: I am going to object to the  
22 relevance of that, Judge.

23 THE COURT: Response?

24 MR. ROSETTI: Well, I think his response will  
25 be relevant to the extent that I think it goes to --

1 we are talking about pain for hyperbaric oxygen  
2 therapy here in Georgia. I would like to see how all  
3 of these individuals --

4 THE COURT: I think I'm going to sustain the  
5 objection.

6 MR. ROSETTI: All right. I don't have any more  
7 questions.

8 THE COURT: Any recross?

9 MR. OLDENBURG: No, Judge. Thank you.

10 THE COURT: Thank you, Dr. Marois. You can set  
11 those there.

12 Mr. Rosetti, your next witness?

13 MR. ROSETTI: Will be Dr. Paul Harch.

14 Judge, can we take a five-minute break?

15 THE COURT: Surely.

16 (Recess taken)

17 MR. ROSETTI: Doctor, raise your right hand,  
18 please.

19

20 DR. PAUL G. HARCH,

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

23 MR. ROSETTI: Please state your name.

24 THE WITNESS: Dr. Paul Gregory Harch.

25 CROSS-EXAMINATION