

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

1 BY MR. OLDENBURG:

2 Q. Dr. Harch, I'm going to try to limit or focus
3 here as much as I can. I don't anticipate taking very
4 long because you have testified before.

5 With regard to -- well, you're familiar with
6 the American Board of Medical Specialty, correct?

7 A. Correct.

8 Q. And that is a global umbrella or grouping for
9 all the medical specialities in the United States?

10 A. Yes.

11 Q. And I know I'm speaking in broad terms and I
12 understand you may have some concerns about that, but that
13 is the group, the ABMS, that generally is the one who
14 board certify physicians, correct?

15 A. It's one of a few groups.

16 Q. Okay. That group, for instance, board certify
17 neurologists, correct?

18 A. Yes, they are one of them that would certify
19 neurologists.

20 Q. And certify -- well, many other specialties,
21 but they don't have a certification for hyperbarics,
22 right?

23 A. No, they do. They have a sub-certification
24 through the America Board of Emergency Medicine and
25 through the Board of Physical Medicine and Rehabilitation.

1 Q. All right. But my understanding, your
2 certification in hyperbarics is not through the ABMS,
3 correct?

4 A. Correct.

5 Q. It's through another American Board of
6 Hyperbaric Medicine?

7 A. Correct.

8 Q. Now, you are familiar with the Undersea and
9 Hyperbaric Medical Society?

10 A. Yes.

11 Q. And that's a group that has been around since
12 about 1967?

13 A. Roughly.

14 Q. And their stated -- well, they describe
15 themselves as a professional medical and scientific
16 organization dedicated to the appropriate application of
17 hyperbaric oxygen therapy?

18 A. I'll take your word for it. You're probably
19 reading from something.

20 Q. I am.

21 You have worked with this group before?

22 A. Correct.

23 Q. Does that, to you, based upon your
24 understanding, is that part of, at least in part, what
25 their involvement is with hyperbaric therapy?

1 A. Yes.

2 Q. Are you familiar with their November 2003
3 position statement entitled "Hyperbaric Oxygen Therapy for
4 Chronic Brain Injury"?

5 A. I believe I am. I've read it. I didn't bring
6 that with me.

7 Q. Okay. Let me see if I can remind it -- are you
8 aware that in this position statement -- well, let me go
9 back.

10 The Undersea and Hyperbaric Medical Society is
11 one of the largest groups or most prominent groups in the
12 study of hyperbaric therapies in the United States?

13 A. Yes.

14 Q. Would you say it's the foremost group who does
15 these types of studies?

16 A. Well, you would have to define "foremost."

17 They're the largest. They were, I believe, the
18 first. They have the largest membership.

19 Q. Okay.

20 In this November 2003 position paper, were you
21 aware that they determined that the data that was
22 available at that time included a number of -- with regard
23 to the use of hyperbaric therapy in brain injury cases,
24 chronic brain injury cases, that the data available
25 included individual case reports, some small case series,

1 and one prospective randomized trial, but the results of
2 the cases suggested a beneficial role but there was no
3 conclusive evidence that found benefit to the hyperbaric
4 oxygen therapy treatment?

5 A. If I could just -- did you say chronic brain
6 injury or --

7 Q. Yes.

8 A. Or brain injury?

9 Q. Yes.

10 A. Chronic.

11 Again, I'll take your word for it. I know the
12 general tone of the article but I don't have it in front
13 of me.

14 Q. Okay. And I'm not trying to fool you, Doctor.

15 A. Sure.

16 Q. Let me show you what is marked as Respondent's
17 Exhibit Number 2 --

18 A. Yes.

19 Q. -- and ask you if you have seen that before?

20 A. I believe I have but I think in a different
21 form.

22 Q. And do you recall that that study found that,
23 specifically with regard to the treatment of children with
24 cerebral palsy, that there was inconclusive or
25 insufficient evidence at that time to say that hyperbaric

1 oxygen therapy would be effective for children with that
2 state?

3 A. Well, yes, they say that there is insufficient
4 supportive evidence to warrant such an endorsement at
5 present.

6 And, I mean, indirectly, it more references the
7 paragraph before which references the ARCH study which
8 mentions cerebral palsy.

9 Q. Right.

10 And the ultimate finding from this group was
11 that the weight of the available information in the
12 literature didn't support the use of HBOT for chronic
13 brain injury, including patients with cerebral palsy?

14 A. The ARCH study?

15 Q. This particular paper. --

16 A. Okay. This particular paper, yes.

17 Q. That's all the questions I have, Dr. Harch.

18 THE COURT: Mr. Rosetti?

19 MR. ROSETTI: May I review this?

20 REDIRECT EXAMINATION

21 BY MR. ROSETTI:

22 Q. Dr. Harch, is the hyperbaric oxygen therapy for
23 chronic brain injury the only study that you've had an
24 opportunity to review?

25 A. That paper?

1 Q. Yes.

2 A. Oh, no.

3 Q. Are there any other studies which document
4 other studies relating to hyperbaric oxygen therapy and
5 its use in CP or for CP patients, rather?

6 A. Yes, CP and chronic brain injury.

7 Q. And which -- what other studies do you rely
8 upon?

9 A. The ones that Dr. Marois mentioned, the eight
10 studies. There are additional studies in symposia and
11 then there is a larger range of studies on both chronic
12 injury and acute brain injury throughout both the
13 English-speaking and non-speaking medical literature.

14 Q. And you're familiar with those studies?

15 A. Very well, yes.

16 Q. And personally reviewed them all?

17 A. Yes, at one time or another.

18 Q. Okay. What conclusions would you draw from
19 reviewing those studies?

20 A. I disagree with the conclusions that both the
21 UHMS and ARCH have come to.

22 Q. And why is that?

23 A. Pardon me?

24 Q. Why is that?

25 A. Well, for a variety of reasons.

1 As I mentioned in my testimony, this ARCH study
2 is incomplete, it's inadequate, and I think it's invalid.
3 But they didn't do a complete review, and I don't think
4 they understood the science of the articles that they were
5 reviewing.

6 In addition, there are statements in there that
7 are contradictory to a certain extent. They have made
8 statements that, for instance, they believe that
9 pressurized air was responsible for the beneficial effects
10 they saw in cerebral palsy in the Collet study. And if
11 you believe that, then you turn around and make a
12 conclusion that there is insufficient evidence to say that
13 hyperbaric treatment caused an improvement, it seems
14 contradictory to me.

15 Q. Is that because administration of air at
16 pressurized conditions is a form of hyperbaric oxygen
17 therapy?

18 A. Correct.

19 Q. What other studies do you usually rely on?

20 A. Well, I rely on a preponderance of the
21 evidence: Case reports, case series, animal studies, the
22 non-English-speaking literature that's been translated,
23 symposium articles, and then English speaking articles in
24 journals, English speaking articles.

25 Q. What conclusion do you draw from those various

1 sources?

2 A. The preponderance of evidence supports the use
3 of hyperbaric oxygen in cerebral palsy and in other
4 chronic and acute brain injury and, in fact, exceeds the
5 level of evidence for many of the indications that the
6 Undersea and Hyperbaric Medical Society has put on their
7 accepted indications list.

8 Q. Like what?

9 A. Intracranial abscess is one of the best
10 examples. It was approved based on 13 cases published in
11 the literature, five cases that were called from the open
12 body of the UHMS meetings four years in a row that were
13 never published, and a sixth case that they came up with
14 privately.

15 Q. And how do you know this?

16 A. Because I was very closely monitoring this, and
17 when the indication was added in 1996, the wording of it
18 was that we now have 19 cases against the backdrop of
19 progressively decreasing mortality in intracranial
20 abscess.

21 But you really can't apply statistics to this.
22 But we will apply statistics and we come up with
23 significance; therefore, it should be approved.

24 Well, the reason was that the proponent of it
25 was the ex-president of the Undersea and Hyperbaric

1 Medical Society and also a committee member.

2 Q. Now, it --

3 A. It does not meet scientific scrutiny.

4 Q. Mr. Oldenburg actually brought up this report,
5 the "Hyperbaric Oxygen Therapy for Chronic Brain Injury"
6 report, where it -- did it necessarily conclude that
7 hyperbaric oxygen therapy was ineffective for the
8 treatment of CP?

9 A. No, I believe it was said insufficient
10 evidence. Again, I'd have to read it. It's been a while.

11 Q. And the evidence they relied upon was, among
12 other things, was the Collet study?

13 A. And the ARCH report.

14 Q. How does that compare with regard to the
15 evidence of the indication you just described?

16 A. There is far greater evidence in both cerebral
17 palsy -- and I'll give you another example.

18 The ARCH report on acute, severe traumatic
19 brain injury they ignored and did not interpret the
20 science of the studies. And I tried to point this out to
21 them because I was a peer reviewer, technical consultant
22 on the project in one of their sources of literature, and
23 in the conversation after my peer reviews, one of the
24 authors told me that regardless of what I had to say about
25 it they would not change their conclusions, meaning my

1 scientific argument was irrelevant to them.

2 Well, I subsequently have had this published in
3 the archives of Physical Medicine Rehabilitation two
4 months ago and it was specifically to their publication of
5 part of this ARCH report.

6 Q. You heard the testimony earlier from Dr. Miller
7 with regard to the 1989 study?

8 A. Yes. The SPECT study?

9 Q. Yes.

10 Have you seen comparable studies since 1989?

11 A. Yes. There are a series of studies in the
12 literature on SPECT imaging in cerebral palsy, and the
13 preponderance of evidence is that the physical findings in
14 the children correlated with the perfusion deficits in the
15 brain.

16 Q. Are there any deficits -- I'm sorry. Are there
17 any deficiencies in the study referenced in Dr. Miller's
18 work -- I'm sorry, testimony?

19 A. Well, some. It's on an old, insensitive
20 scanner for one.

21 Number two, it's difficult to specifically
22 localize an area of function along the electrical axis
23 such that when you look for perfusion deficits on a
24 machine like that, they are usually looking for large
25 areas of deficit.

1 And to have spasticity, for instance, let's say
2 in the right leg, you can have a problem anywhere above
3 the spinal cord level. So up through the brain stem, the
4 midbrain, the basal ganglia, white matter, all the way to
5 the cortex.

6 And essentially what they were, I believe in
7 the Talberg study, primarily looking at were cortical
8 perfusion deficits. I will have to review it in detail.

9 But all I'm saying is that you can injure the
10 axis some place and not necessarily register it as a large
11 focal defect. And, again, the preponderance of the study
12 shows that there's generally correlation.

13 Q. Between SPECT imaging --

14 A. Between functional findings and perfusion
15 deficits in the brain.

16 Q. Thank you.

17 RE-CROSS-EXAMINATION

18 BY MR. OLDENBURG

19 Q. Dr. Harch, you disagree with the Collet study?

20 A. I disagree with their conclusion and their
21 interpretation of the data.

22 Q. You disagree with the ARCH report?

23 A. Yes, I do.

24 Q. And you disagree with the --

25 A. The UHMS.

1 Q. Yes, the Undersea and Hyperbaric Medical
2 Society, 2003 position statement?

3 A. Which is based on the ARCH report, yes.

4 Q. Right.

5 Now, to your knowledge, there have been no
6 double-blind, randomized custom studies of the use of HBOT
7 in cerebral palsy kids, correct?

8 A. Say that again.

9 There have been no --

10 Q. Double-blind, randomized custom studies with
11 regard to the efficacy of HBOT in kids with cerebral
12 palsy?

13 A. Well, yes. That is what the Collet study was.

14 Q. All right. Other than the Collet study?

15 A. I believe the Sethy study in India was a
16 randomized prospective controlled study. I'd have to look
17 to see if it's double blind.

18 Q. Do you have a copy of that in your reports?

19 A. I do. It's in my suitcase.

20 Q. Let me just ask some questions about it?

21 A. Yes.

22 Q. Do you know when that was done?

23 A. In 2003 or '04 it was published.

24 Q. And to your knowledge, has it been subject to
25 peer review?

1 A. I believe the Indian Journal of Occupational
2 Medicines peer review, but I don't know for certain.

3 Q. Let me show you what Mr. Rosetti gave me and
4 ask you if that's a copy of that article?

5 A. Yes, that's it.

6 Q. And you reviewed the protocols used in that
7 particular study?

8 A. Yes, because I gave it to the author.

9 Q. Did they follow your protocol?

10 A. Pretty much.

11 Q. What did they deviate from?

12 A. Well, let's see. One-and-a-half atmospheres
13 twice daily five days a week for four weeks, 40 sessions.
14 That is exactly what I have done.

15 Q. And how big was the subject group?

16 A. Hold on. That was the review of the
17 literature. Let me look at their exact protocol.

18 No. They actually did 1.75 atmospheres for 40
19 sessions once a day six days a week, so it's a little
20 different than what I had done.

21 And your other question was?

22 Q. I think my question was whether they followed
23 your protocol?

24 A. No, that is not the exact protocol.

25 Q. My second question was the -- the size of the

1 case study.

2 A. Okay. 30 subjects, 15 in each group.

3 Q. Is that a sufficient number in your opinion as
4 a medical professional to make a determination as to
5 whether this therapy can correct or ameliorate CP?

6 A. In conjunction with other studies, I believe it
7 is.

8 Q. Just with regard to this study itself, is that
9 a sufficient case size to make that determination?

10 A. We don't -- well, it's hard to answer that like
11 that.

12 Let me say this. It is a -- it has
13 statistically significant findings with this positive --
14 with this small sample size and as such it's a stronger
15 piece of data.

16 You would like to see larger numbers overall
17 upon which to base decisions, but taken --

18 Q. How big a number would you like to see?

19 A. I would like to see maybe 100, a couple hundred
20 patients with consistent results.

21 Q. Okay. That's all I have. Thank you,
22 Dr. Harch.

23 THE COURT: Recross?

24 MR. ROSETTI: Very briefly, Judge.

25 FURTHER DIRECT EXAMINATION

1 BY MR. ROSETTI:

2 Q. When --

3 MR. OLDENBURG: I think it's re-redirect,
4 Judge.

5 THE COURT: I'm sorry.

6 BY MR. ROSETTI:

7 Q. When you review a study like that, do you
8 review it in a vacuum or do you review it against other
9 evidence?

10 A. You review it against all of the evidence.

11 Q. And does it have value based on comparisons of
12 the other evidence available?

13 A. Very much so.

14 Q. And what is that value?

15 A. It's entirely consistent with every other study
16 that has been published.

17 Q. Thank you.

18 A. And it has a rigorous design.

19 Q. Thank you, Doctor.

20 FURTHER CROSS EXAMINATION

21 BY MR. OLDENBURG:

22 Q. Well, it's not consistent with the ARCH report,
23 correct?

24 A. The ARCH report claims not sufficient evidence.
25 But, in fact, the evidence in the Collet study, upon which

1 they largely base their conclusion, in fact shows a
2 statistically significant improvement in both groups of
3 children with two hyperbaric doses. So it is consistent
4 with that.

5 Q. But it is not consistent with the conclusion
6 reached in the ARCH report?

7 A. Well, it is inconsistent -- it is not
8 consistent with their misinterpretation of it.

9 Q. All right.

10 A. Let's say that.

11 Q. All right.

12 A. They've got a contradiction. They in fact said
13 that the improvement seen in the hyperbaric air group they
14 believe was due to the hyperbaric air exposure. So there
15 is significant improvement there.

16 They claim there is not sufficient evidence for
17 them to recommend as a treatment to all physicians.

18 Q. They're not willing to recommend it. This
19 Indian study is.

20 (Tape 2, Side 3 of 4 concluded)

21 * * *

22 (Tape 2, Side 4 of 4 begins)

23 THE WITNESS: To say that -- you know, if I can
24 read their study, I believe it's insufficient
25 evidence that hyperbaric oxygen has an effect on

1 children with cerebral palsy, acute traumatic brain
2 injury, and stroke.

3 BY MR. ROSETTI:

4 Q. Do you feel that the results of the study
5 actually demonstrate sufficient evidence?

6 A. Yes.

7 THE COURT: Anything on recross?

8 THE WITNESS: At least in CP and traumatic
9 brain injury. I'm sorry.

10 THE COURT: I'm sorry, I interrupted you
11 myself. But nothing further on redirect?

12 MR. ROSETTI: No.

13 THE COURT: And no recross, correct?

14 MR. OLDENBURG: No.

15 THE COURT: Sir, you can step down.

16 MR. ROSETTI: Call Dr. Usler.

17 THE COURT: Dr. Usler.

18 MR. ROSETTI: Raise your right hand.

19

20 **DR. J. MICHAEL USLER,**

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

23 MR. ROSETTI: Please state your name.

24 THE WITNESS: My name is officially J. Michael
25 Usler, M.D.