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(1) been proven. The results have not been proven
(2) at this point.

(3) Q. I'm reading from a disclosure of
(4) information required by order of August 22nd,
(5) 2000, that was provided by Respondent's
(6) counsel. One of the rejections says, quote,
(7) there is no sound evidence that has been
(8) presented to these entities to show
(9) affirmatively from a medical standpoint that
(10) the HBOT on the Petitioner has improved his
(11) condition. Is that something that you asked
(12) Dr. Neubauer or Dr. Chelton or Cohen?

(13) A. Cohen. I don't know if he
(14) specifically asked him that or not.
(15) Q. So we don't know whether or not there
(16) was any sound evidence that was presented to
(17) these entities to show that there was some
(18) evidence of its effectiveness?

(19) A. Well, there was to some of them
(20) because some of the reviews said -- Dr.
(21) Trevathan, for instance, said there is no
(22) scientific evidence that Hyperbaric Oxygen
(23) Therapy improves the function of Cerebral
(24) Palsy. He said it is not biologically possible
(25) but plausible. Not biologically plausible and

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(1) in some cases in lab animals elevated oxygen
(2) levels can injure neuronal cells. He said the
(3) SPECT scan and he had reviewed these SPECT
(4) scans. He said the SPECT scan findings can
(5) fluctuate significantly over a period of hours
(6) and improved blood flow to the temporal lobes
(7) can't be said to improve motor function, so he
(8) did, I mean, some of them did specifically look
(9) at the SPECT scans and the results there and
(10) address those things specifically.

(11) Q. Did you find Dr. Trevathan --

(12) A. I beg your pardon?

(13) Q. How -- how did the GMCF find Dr.
(14) Trevathan?

(15) A. We have a panel of physicians and we
(16) work with physicians who network and research
(17) our experts. I can't tell you exactly how we
(18) found him.

(19) Q. Do you know where he is located,
(20) where he practices now?

(21) A. He is the director of pediatric
(22) epilepsy center and the director of clinical
(23) neurophysiology in the midwest. Now, I don't
(24) have his direct address.

(25) Q. It's actually Washington University.

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(1)

(2) A. Okay.

(3) Q. Washington University in St. Louis.

(4) Why would you go all the way there?

(5) Q. Why would we go to St. -- because we
(6) were trying to not leave a stone unturned. We
(7) really were trying to do some serious research
(8) in this area. I mean that's the same reason
(9) that we talked with Dr. Harch. He is not right
(10) here in this area. It's the reason we talked
(11) with Dr. Kelton in Baltimore.

(12) Q. Do you have a date for when you
(13) talked with Dr. Trevathan. I see you have a
(14) log up there with times. Do you have a date?

(15) A. It looks like it was in November. I
(16) don't have the exact date.

(17) Q. That's November 1999, right?

(18) A. Yes.

(19) Q. If an individual forwards you a
(20) request for review, is it not the policy to
(21) inform the individual that it's actually
(22) supposed to run through a physician?

(23) A. Yes, that is what we do.

(24) Q. Did you inform Mr. Freels that a
(25) review was supposed to run through a physician

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(1) or was supposed to be initiated by a physician?

(2) A. Mr. Freels and I talked about that

(3) several times. Yes, we did.

(4) Q. During his first submission to GMCF?

(5) A. I can't give you specific dates, but
(6) I do remember several conversations in which we
(7) spoke about that.

(8) Q. I know you spoke many times to Mr.
(9) Freels on the phone but you don't know whether
(10) or not when you talked about that that was
(11) during the first?

(12) A. I don't know which time we talked
(13) about it.

(14) Q. Okay. I came into possession of a
(15) letter.

(16) (Whereupon, Mr. Rosetti presented the
(17) letter to Mr. Oldenburg)

(18) BY MR. ROSETTI: (Resuming)

(19) Q. I came into possession of this letter
(20) from the Washington University School of
(21) Medicine on their letterhead signed by Edwin
(22) Trevathan, M.D., associate professor of
(23) neurology and pediatrics, director of the
(24) pediatric epilepsy center. It's dated August
(25) 14th, 1999. I'll give you an opportunity to

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(1) review this letter very, very quickly. It's
(2) short.

(3) A. (Reviewing) Okay.

(4) Q. How would you characterize Dr.
(5) Trevathan's opinion of hyperbaric oxygen?

(6) A. Well, I would say it's pretty
(7) opinionated. He's pretty firm in his belief
(8) that it's not helpful. I don't know Connie
(9) Willis. I don't -- this is the first time I've
(10) seen that letter.

(11) Q. If you had known an individual had
(12) such strong negative feelings about the use of
(13) Hyperbaric Oxygen Therapy in brain injured
(14) children would you have contacted him to get an
(15) objective opinion?

(16) A. We are looking for an objective
(17) opinion. We contacted many experts in the
(18) field, not just the one. If we were looking
(19) for somebody -- if we had been trying to find
(20) somebody with just a negative opinion we
(21) certainly wouldn't have gone to Dr. Neubauer.
(22) We were making every effort to get the most
(23) objective review that we could get.

(24) Q. When you asked Dr. Neubauer you
(25) didn't ask him whether or not he thought it --

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(1) The reason she is testifying is because
(2) Judge Schroeder issued the order saying
(3) that the Department had an obligation to
(4) put on testimony regarding the efforts it
(5) made in evaluating this claim. I don't
(6) think Ms. McKenzie has been qualified as
(7) an expert to be able to review the
(8) materials or give an opinion regarding
(9) those materials and that is really outside
(10) the scope of relevance to her testimony at
(11) all.

(12) THE COURT: Mr. Rosetti?
(13) MR. ROSETTI: She is representing the
(14) Department and the Department is charged
(15) with the obligation of reviewing these
(16) types of requests. She stated that she
(17) had personal involvement with the
(18) investigation on this claim. She said she
(19) did it along with Dr. Chelton and with Dr.
(20) Cohen. There was an awful lot of
(21) testimony that she offered on direct that
(22) talked about things that happened within
(23) that review, but because of the
(24) circumstances she is a representative of
(25) the Department obviously that is something

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(1) whether he thought it worked, you asked him if
(2) it was the accepted medical practice at this
(3) point.

(4) A. Because that was our charge. That is
(5) what we were sent to review.

(6) Q. Well, isn't that pretty obvious from
(7) the fact that nobody had ever seen a review
(8) like that so you became personally in this
(9) because it was not standard medical practice to
(10) perform Hyperbaric Oxygen Therapy on brain
(11) injured children at that point?

(12) A. It did become obvious right away that
(13) that was not the standard of practice.

(14) Q. That was the only basis on which you
(15) were reviewing this claim?

(16) A. Whether this is medically necessary
(17) and part of medical necessity in the way that
(18) we determine it by standard is -- is that the
(19) experts in the field say yes, this is a medical
(20) necessity. It's a . . .

(21) Q. Have you reviewed that packet?

(22) A. Yes.

(23) Q. What did you think?

(24) MR. OLDENBURG: Judge, I think I'm
(25) going to have to object to that question.

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(1) that needs to be addressed by virtue of
(2) the order that was issued by Judge
(3) Schroeder. I'm just asking her as part of
(4) that review process and being intimately
(5) involved with this review including
(6) speaking with the Petitioner's father on
(7) many occasions what she thought about the
(8) -- what she thought about the appeal
(9) packet.

(10) THE COURT: Let me review your
(11) testimony. You have said that you were
(12) part of the review team. Were you part of
(13) the analysis or --

(14) THE WITNESS: No, I made no decision.
(15) I was not part of the decision making
(16) process, but I was part of the directing
(17) getting input from experts in the field
(18) and but I was not --

(19) THE COURT: So you were not the
(20) person -- I mean, while you reviewed the
(21) documents you were not reviewing it as an
(22) expert. You were simply reviewing them
(23) for the submittal and then referring them
(24) to the experts for review?

(25) THE WITNESS: We have board certified



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WASHINGTON · UNIVERSITY · IN · ST · LOUIS
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Pediatric Epilepsy Center
St. Louis Children's Hospital

Department of Neurology
and Neurological Surgery

August 14, 1999

Tiny Willis
Atlanta, GA

RE: Hyperbaric oxygen treatment for children with various forms of brain injury

Dear Tiny:

As we discussed by phone, there is a lot of 'hype' regarding hyperbaric oxygen treatment for brain injury in children. However, there is no scientific data to suggest that it is effective.

There is a great deal of scientific literature related to mechanisms of brain cell death/damage and recovery (or plasticity). Based upon all of this data, there is no reason to believe that hyperbaric oxygen would be helpful in assisting the natural process of plasticity. The notion that it could 'wake up' damaged areas of brain is frankly scientifically silly.

Hyperbaric oxygen 'tanks' are very expensive, and there are few proven effective uses. Therefore, as Dr. Evans mentions in the enclosed email, there are several hyperbaric oxygen centers 'looking for a home'. It is these centers' financial need that seems to be driving the marketing that is without any reasonable scientific basis.

We all understand that parents of children with serious neurological problems will do anything to help their children. Often they are the victims of hype because of their best intentions.

Based upon my review of the available data, and the opinions of child neurologists from around the world, I doubt any qualified child neurologist is likely to put his or her name on anything that supports the use of hyperbaric oxygen for the purpose sought by your friend. In my opinion it is unethical for any neurologist to support hyperbaric oxygen use in this situation outside a fully funded clinical trial. In other words, if your friend finds a qualified physician investigator who is willing to perform hyperbaric oxygen therapy free (including all related expenses) as part of a controlled clinical trial designed to objectively assess the effects of the treatment, then participation in such a clinical trial should be considered.

Pediatric Epilepsy Center
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Hyperbaric Oxygen therapy
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Charging for a treatment with absolutely no proven efficacy is unethical, and no insurance company should pay for such therapy.

There are many exciting areas of basic research in neuronal plasticity (recovery from injury) and neuroprotection (prevention of neuronal injury). However these areas of basic research will not likely lead to proven therapies in children for a few years (at least). In my opinion, hyperbaric oxygen has no reasonable chance of being a true breakthrough therapy and in theory could have long-term adverse consequences. Therefore we are not willing to expose our patients to a therapy with possible risks and no reasonable chance of efficacy. We do anticipate the development of protocols to test more promising therapies over the next few years.

I realize that this is not the answer sought by your friends, but nevertheless I wish them well.

Yours sincerely,



Edwin Trevathan, M.D., M.P.H.
Associate Professor of Neurology & Pediatrics
Director, Pediatric Epilepsy Center

Enclosure

Date: Sat, 14 Aug 1999 00:00:01 -0500
From: Automatic digest processor <LISTSERV@Waisman.Wisc.Edu>
Subject: CHILD-NEURO Digest - 12 Aug 1999 to 13 Aug 1999 (#1999-200)
Sender: Child Neurology Mailing List <CHILD-NEURO@Waisman.Wisc.Edu>
To: Recipients of CHILD-NEURO digests <CHILD-NEURO@Waisman.Wisc.Edu>
Reply-to: Child Neurology Mailing List <CHILD-NEURO@Waisman.Wisc.Edu>

There is one message totalling 32 lines in this issue.

Topics of the day:

1. Hyperbaric oxygen treatment

Date: Fri, 13 Aug 1999 11:23:05 +0100
From: Andrew Lloyd Evans <andrew@CUSUM.DEMON.CO.UK>
Subject: Hyperbaric oxygen treatment

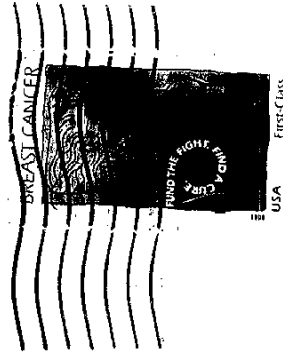
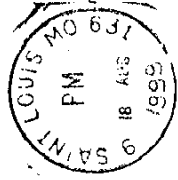
In the UK this has been offered for children with cerebral palsy in the private sector for some time. It is estimated that as many as 450 children in the UK may have been treated in this way. It has been heavily marketed by a vocal parent support group. As usual, there is no proper research trial and the 'successes' are anecdotal. As I understand it, the treatment was used initially for the bends in divers and for carbon monoxide poisoning where it is useful, and then for multiple sclerosis where it was found to be ineffective. I think it has also been tried in stroke and found to be ineffective. There are therefore a few hyperbaric chambers looking for a home. There seems to be no clear scientific rationale for the treatment and it is difficult to imagine that one is 'waking up' unused areas of brain long after the damaging event is finished. There is certainly a down side to the treatment since children may be afraid to go in the tank. Parents may need to go in with them. One of my patients had her mother go in with her and her mother needed myringotomies for middle ear disease! Children may also get painful ears related to the pressure changes. The majority of paediatricians/ paediatric neurologists involved with cerebral palsy in the UK would not support this as a treatment option.

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End of CHILD-NEURO Digest - 12 Aug 1999 to 13 Aug 1999 (#1999-200)

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