

2019 HOUSE HUMAN SERVICES

HB 1359

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee Fort Union Room, State Capitol

HB1359
1/16/2019
30907

- ☐ Subcommittee
☐ Conference Committee

Committee Clerk: Elaine Stromme by Risa Bergquist

Explanation or reason for introduction of bill/resolution:

For a Medicaid pilot project for hyperbaric oxygenation treatment; to provide for a report to legislative management; to provide an appropriation; and to declare an emergency.

Minutes:

Attachment 1-12

Vice Chairman Rohr: Opened the Hearing for HB 1359.

Representative Dick Anderson, District 6: Introduced HB 1359. (see attachment1) Explained brain injury and recently the results of treatment look much better now. Section one of the bill, right now there is no insurance coverage for this program. They need a clinical study to get the data that would convince them to have insurance coverage. I went to Medicaid but they didn't want to go along with the pilot program since hyperbaric oxygen treatment wasn't approved to treat concussions. We need enough data for a trial to convince the insurance companies to go along with it. In Line 16 of the bill in item one add the word "moderate" instead of "severe" at some time. I also have some information about the appropriations that we might need to start this program. Medicaid helped provide that. (See Attachment 2). (1:50-4:47)

Representative M. Ruby: How many people would benefit from this?

Representative Anderson: I really don't have a specific number. We were just going to treat a limited number to keep the cost down. I would say that 10% of the population has had a head injury or concussion at one time or another. The number is quite large.

Representative M. Ruby: If we are going to have to limit this is it going to be a first come first served or is it a severity issue?

Representative Anderson: We do have some criteria set up in the program, moderate to severe brain injury.

6:00-9:00 Representative Austen Schauer District 13: In support of HB 1359. (See Attachment 3)

9:20 Dr. Daphne Denham: (Refers and explains attachment 1) In support of HB 1359. Explained how hyperbaric oxygen treatment helps brain injury and the budget. We are asking for enough money to treat 30 patients for approximately 40 treatments. (page 4 of attachment 1) There were almost 1200 severe head brain injury patients that Medicaid contributed to and the expenses were over 9 million dollars a year, excluded hospital stay and the physicians visits. As a state we are spending about 7-8 thousand dollars per brain injury. The cost is major for patients on average it's a loss of life time income of 50% and many it's a life time loss of 100%. A major part of the study is not just to treat the patients but to show we will save Medicaid money.

13:25-19:00 Next page is Safety (Page 6 of attachment 1) We follow hospital standards or better. Out of 463 thousand treatments in a 2 year period of time there were minimal complications. Hyperbaric is very safe. It is an FDA approved treatment for 13 indications. With hyperbaric we can increase the oxygen from 500 to 1200% with pressure very similar to flying on an airplane.

Representative Westlund: Have you ever seen any patients suffering from dementia see improvement?

Dr. Daphne Denham: Yes, we have.

Representative Dobervich: You said there are 13 conditions currently approved by the FDA, of those are traumatic Brain Injuries, concussions or depression in that list?

Dr. Daphne Denham: They are not on the list, however one of the improved indications that we are working with is in the acute concussion scenario is what is called a crush injury, or a compartment syndrome. If someone is removed, their arm, there are wraps around the muscles that the blood vessels and the nerves are under, when the muscles start to swell the wrap limits that swelling. So hyperbaric is FDA approved to help reduce that swelling and the inflammatory process that goes with it to protect skeletal muscle and nerves.

Representative Porter: In the Medicare component of this they have a medical necessity in order to use that diagnosis code; can you explain that to us?

Dr. Daphne Denham: The diagnosis code for Medicare is not approved for payment but I spoke to Medicare this past week and to get them to reopen their coverage determination they require enough data on 65-year-old plus patients otherwise they might do a specific limited reexamination of their policy but they need data. That's why this pilot project through North Dakota would be invaluable throughout the United States.

Representative Porter: Are there any insurance companies that currently pay for your services?

Dr. Daphne Denham: FDA indications yes, and we are working with an insurance company for the acute concussions following the work we have already been doing with the Dakota medical foundation. An acute concussion being defined as a 10 days or less from injury.

24:30 Representative Porter: The way the bill is written we are looking at funding a pilot project, if the department isn't able to get the waiver necessary from the federal government

to do it, that would really limit it down to the 335 thousand dollars of state funding. Looking at this as a clinical study to further prove the benefits and the patient outcomes but I don't see that written into the pilot project the way it is written right now.

Dr. Daphne Denham: We have a pilot written up as far as all the protocols as far as publishing in a medical journal if we don't have a placebo control medical journal won't except it. It's unethical to waste that opportunity, that time and the machine and not benefit patients. We want to show that not only will it benefit these patients but also the state of North Dakota.

Representative Porter: Is that written in the way this is set up?

Dr. Daphne Denham: That's the intention.

28:15 Vice Chairman Rohr: You don't think that to be eligible for the federal waiver that you have to look at this as a clinical trial? The inclusion criteria you have here, is there going to be any age limit?

Dr. Daphne Denham: That is correct, and the age limits would be up to you as far as Medicaid providers.

29:30 Bruce Murry, Registered Lobbyist: I am here as a volunteer for Dr. Biberdorf who was unable to attend. (see attachment 4)

30:10 Lonnie Wangen, ND Vets Affairs Commissioner: In my many roles I have learned a lot about hyperbaric, one of the most interesting was a couple of Vietnam vets that went through this and after a week their feet hurt and I thought that was terrible. They said no we haven't felt our feet in years because of diabetes. There was a medical doctor that was in Afghanistan and obtained a traumatic brain injury, he came back, his wife had to care for him, he lost his medical license, he ended up in Florida and start hyperbaric therapy. When I met him he has his license back and was treating patients again and it was a miracle for him it really changed his life.

32:00-41:00 Read testimony of Dr. Edward F. Fogarty: (see attachment 5)

Vice Chairman Rohr: Questions? Further testimony?

41:25-45:10 Hannah Anderson from Leads ND (see attachment 6)

45:25-52:50 Mike Callahan, Valley City: I am an athletic trainer and have been in sports medicine for 25 years my wife and I lost our son January 3rd 2018. Dr. Daphne Denham and I met 6 months to late. We had taken our son to many neurologist, Nero surgeons, Rochester Minnesota twice; that's when they told us he had 15 concussions. My son was left in despair, they tried treating the symptoms, it did not work. I don't need placebo or anything else, when I hear from parents that say I can't believe my daughter/son is back. We spent thousands and thousands of dollars with no answers, after our experience I have sent many kids to Dr. Daphne Denham. I've sent teachers, athletes, this isn't about getting back to athletics for me it's about getting people back to life. They used to tell us if you have a concussion you should go rest for a week, we wouldn't do that for any other injury, it just doesn't make sense. I had

an athlete this year get a concussion, went through the normal protocol of the impact program, we have a base line and then there are follow up and return to play protocols. Kid returns to play and received a second concussion he went down to Dr. Daphne Denham, I am not sure how many treatments he had but after 3 treatments his parents said they couldn't believe the improvements. I asked if I could retest him after all his treatments, his numbers were higher than any base line I had or any return to play post injury test I did. They were much higher.

53:15-55:00 Lisa Anderson, Leads North Dakota: Hannah's Mom (see attachment 7)

55:15-59:45 Lynne Ostrem from Rugby, ND (see attachment 8)

1:00:00-1:03:30 Dianna Alcon, Minot, ND: March 18th 2018 my daughter had a stroke, we were told she would not survive. We spent a month at Trinity hospital and two months in Denver at the rehab hospital there. I had to stay with her night and day because her memory so bad she would get frightened if I left the room. After many months of therapy, speech, OT and PT and home health care we finally started HBOT therapy on January 9th with Dr. Daphne Denham. After her first treatment she told me I didn't have to come back because she wasn't afraid anymore, after third treatment she was able to tell me who the president is, what month it was and what season it was. These are things that were asked everyday while we were in Denver. The week before we started a neurologist asked her these questions and she wasn't able to answer them. After every treatment my husband and I notice improvements. Please pass this bill.

1:03:45- 1:05:00 Jim Nelson, Spokesman for the ND Vets Legislative Council (see attachment 9) Just two things I would like to note about my testimony; (page 3 of attachment 9) this is testimony of veteran that underwent a pilot program by Dr. Harch. There are also tendencies and after a few treatments 10 of those people exhibited no signs of suicidal tendencies. VA calls it "off label" they allow it but they don't pay for it so perhaps this study could get that changed.

Vice Chairman Rohr: Any other testimony? Any Opposed?

1:05:50-1:10:05 Tammy Zachmeier, Utilization Review Administrator for the Medical Services Division in the Department of Human Services: (see attachment 10)

Representative Schneider: After hearing all this testimony, are you willing to work with medical community to break down barriers to be able to provide this treatment and promote some leadership in the state and nation?

Tammy Zachmeier: As health care providers and a nurse myself that is certainly where my heart is, I truly appreciate all of the information we have received today. From a federal stand point, I do not know if federal funds are going to be able to be used for this project. It is important for the committee to understand that, as a department we will gladly help out Representative Anderson and any of these other people in any way we can if the project was to go forward.

Representative Ruby: Do you have an idea of the cost to have this research outsourced?

Tammy Zachmeier: It would depend on the scope of the study. I believe it would be a limited number of people in the initial study, that would help keep the cost under control.

Vice Chairman Rohr: Dr. Daphne Denham has 30 patients planned in her testimony and you have on the fiscal note 500.

Tammy Zachmeier: We have determined that based on the number of brain injuries in the past 5 years in North Dakota. There would be 2500 eligible population and we took only 20% and that is 500. If we are legislated to cover this, it's always been Medicaid history that we would cover all individuals weather they are in this study or not.

Vice Chairman Rohr: Any further questions? Any neutral testimony? We will close this hearing.

Attachments 11-12 where passed out but not addressed.

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee Fort Union Room, State Capitol

HB 1359
2/4/2019
32140

- ☐ Subcommittee
☐ Conference Committee

Committee Clerk Nicole Klamon by Marjorie Conley
--

Explanation or reason for introduction of bill/resolution:

For Medicaid pilot project for hyperbaric oxygenation treatment to provide a report to legislative management, appropriation and to declare an Emergency.

Minutes:

Attachment 1

Chairman Weisz: Opened HB 1359.

Rep. Anderson: Basically the new amendment replaces just about the whole bill because I had a lot of difficulty going through Medicaid Services. I thought visiting with Dr. Denham and Jennifer Clark, we decided to put it through the Department of Health, and running a pilot program through there. There was a beginning date and an ending date. We couldn't decide where we wanted the money to go to so we put parameters in there to hopefully funnel the money to where we thought it would do the best job. I believe Dr. Denham and her treatment center in Fargo, she's figured out the protocol that she has the best results for. That's why the language is the way it is and using that RightEye improvement study seems to show a lot of beneficial results. She will make periodic reports to the budget section and I am not sure what the time frame should be for that. Maybe that should be defined a little better. The whole purpose of this study is to get data that the insurance companies need To make a decision whether to provide coverage for HBO. (Attachment 1)

Vice Chairman Rohr: Who would be the nonprofit entity on Number 2?

Rep. Anderson: I would say the Dakota Medical that Dr. Kramer runs.

Chairman Weisz: Who establishes protocol? The Department of Health?

Rep. Anderson: I would think that the RightEye is basing the protocol.

Rep. Devlin: On the original bill, before the hog house arrived, there was an emergency clause.

Rep. Anderson: I thought about that if it goes through appropriations July 1st.

I know Blue Cross Blue Shield are interested in pursuing this but they are not there yet. I am just trying to get the data because I believe what she is doing works well. It is initially going to save a lot of money and provide some quality of life improvements for a lot of different people.

Rep. Porter: I would just like to make a blanket suggestion to Rep. Anderson on this amendment. On the top, I would overstrike budget section and put legislative management so it goes to one of the interim committees on health. The budget section isn't really going to care how the treatment protocols are working and how things are going. I would definitely make legislative management push this off to one of the health care committees. Sub one I would cross off general fund and put strategic investment fund. The general fund is broke. I would get rid of recognized and make that realized.

Rep. Anderson: I would agree with that. I appreciate Rep. Porter's comments.

Chairman Weisz: Are there any other changes?

Rep. Anderson: I move the recommendations by Rep. Porter. Changing budget section to legislative management both in section one and paragraph 3 changing paragraph one to strategic investment funds and paragraph 3 changing the word recognized to realize.

Chairman Weisz: Everyone understand the amendment?

Rep. Schneider: Seconded the motion.

Voice vote carried.

Chairman Weisz: We have an amended bill in front of this committee.

Vice Chairman Rohr: I move a Do Pass as amended on HB 1359 and rereferred to appropriation.

Rep. Skroch: Seconded the motion to Do Pass as amended on HB 1359.

Rep. Anderson will be the **Carrier**.

Roll Call Vote Yes 12 No 1 Absent 1

HB 1359 passed as amended and rereferred to appropriations.

Hearing closed.

February 4, 2019

DP 2/9/19

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1359

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to provide for a hyperbaric oxygen therapy pilot program; to provide an appropriation; and to provide for a report to the legislative management.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. APPROPRIATION - HYPERBARIC OXYGEN THERAPY PILOT PROGRAM - REPORT TO LEGISLATIVE MANAGEMENT.

1. There is appropriated out of any moneys in the strategic investment and improvements fund in the state treasury, not otherwise appropriated, the sum of \$335,000, or so much of the sum as may be necessary, to the state department of health for the purpose of contracting with a third party to implement a hyperbaric oxygen therapy pilot program, for the biennium beginning July 1, 2019, and ending June 30, 2021.
2. The department shall contract with a local nonprofit entity with experience implementing studies using hyperbaric oxygen for traumatic brain injuries to conduct a pilot program for treatment of moderate to severely brain-injured North Dakotans using an established protocol of hyperbaric oxygen therapy provided by a private entity with experience in treating traumatic brain injury using medical-grade hyperbaric chambers pressurized with one hundred percent oxygen. The goals of the study include demonstrating improvement in brain-eye function using RightEye, significant improvement in quality of life of injured patients, significant improvement in cognitive abilities of injured patients, and financial savings and increased revenues for the state, including possible savings for medical assistance and workers' compensation and a positive impact on income tax revenues. The pilot program design must be established in consultation with a third-party physician.
3. During the 2019-21 biennium, the department shall make periodic reports to the legislative management on the status of the pilot program and whether the goals are being realized."

Renumber accordingly

**2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1359**

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 19.0646.02002

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar
Other Actions: ☐ Reconsider ☐

Motion Made By Rep. Anderson Seconded By Rep. Schneider

Representatives	Yes	No	Representatives	Yes	No
Robin Weisz - Chairman			Gretchen Dobervich		
Karen M. Rohr – Vice Chairman			Mary Schneider		
Dick Anderson					
Chuck Damschen					
Bill Devlin					
Clayton Fegley					
Dwight Kiefert					
Todd Porter					
Matthew Ruby					
Bill Tveit					
Greg Westlind					
Kathy Skroch					

Total (Yes) _____ No _____

Absent _____

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Voice Vote - Motion carried to adopt amendment

**2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1359**

House Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☒ As Amended ☒ Rerefer to Appropriations
☐ Place on Consent Calendar
Other Actions: ☐ Reconsider ☐ _____

Motion Made By Rep. Rohr Seconded By Rep. Skroch

Representatives	Yes	No	Representatives	Yes	No
Robin Weisz - Chairman		x	Gretchen Dobervich	x	
Karen M. Rohr – Vice Chairman	x		Mary Schneider	x	
Dick Anderson	x				
Chuck Damschen	x				
Bill Devlin	x				
Clayton Fegley	x				
Dwight Kiefert	A				
Todd Porter	x				
Matthew Ruby	x				
Bill Tveit	x				
Greg Westlind	x				
Kathy Skroch	x				

Total (Yes) 12 No 1

Absent 1

Floor Assignment Rep. Anderson

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1359: Human Services Committee (Rep. Weisz, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** and **BE REREFERRED** to the **Appropriations Committee** (12 YEAS, 1 NAYS, 1 ABSENT AND NOT VOTING). HB 1359 was placed on the Sixth order on the calendar.

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to provide for a hyperbaric oxygen therapy pilot program; to provide an appropriation; and to provide for a report to the legislative management.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

**SECTION 1. APPROPRIATION - HYPERBARIC OXYGEN THERAPY
PILOT PROGRAM - REPORT TO LEGISLATIVE MANAGEMENT.**

1. There is appropriated out of any moneys in the strategic investment and improvements fund in the state treasury, not otherwise appropriated, the sum of \$335,000, or so much of the sum as may be necessary, to the state department of health for the purpose of contracting with a third party to implement a hyperbaric oxygen therapy pilot program, for the biennium beginning July 1, 2019, and ending June 30, 2021.
2. The department shall contract with a local nonprofit entity with experience implementing studies using hyperbaric oxygen for traumatic brain injuries to conduct a pilot program for treatment of moderate to severely brain-injured North Dakotans using an established protocol of hyperbaric oxygen therapy provided by a private entity with experience in treating traumatic brain injury using medical-grade hyperbaric chambers pressurized with one hundred percent oxygen. The goals of the study include demonstrating improvement in brain-eye function using RightEye, significant improvement in quality of life of injured patients, significant improvement in cognitive abilities of injured patients, and financial savings and increased revenues for the state, including possible savings for medical assistance and workers' compensation and a positive impact on income tax revenues. The pilot program design must be established in consultation with a third-party physician.
3. During the 2019-21 biennium, the department shall make periodic reports to the legislative management on the status of the pilot program and whether the goals are being realized."

Renumber accordingly

2019 HOUSE APPROPRIATIONS

HB 1359

2019 HOUSE STANDING COMMITTEE MINUTES

Appropriations Committee Roughrider Room, State Capitol

HB 1359
2/14/2019
32760

- ☐ Subcommittee
☐ Conference Committee

Committee Clerk: Risa Bergquist by Caitlin Fleck
--

Explanation or reason for introduction of bill/resolution:

A BILL for an Act to provide for a hyperbaric oxygen therapy pilot program; to provide an appropriation; and to provide for a report to the legislative management.

Minutes:

Chairman Delzer: Opened hearing. There is no sunset on it.

Representative Weisz: The 335,000 is for the patients in this 2-year study and the average cost for the full treatment is 10 thousand dollars. So the point of this is to get enough data so the insurances could have enough information so that they would cover it, and also that we could ask the department for a waiver to include that under Medicaid expansion. Currently it is not an acceptable treatment, and there is no reimbursement.

Chairman Delzer: Does it need to be 30 patients?

Representative Weisz: We are not sure how many people we will need, but the rules at Sanford would be that much so that they will cover this. This is largely for traumatic brain injuries, but it's not an accepted practice yet. If it'll work like they say it will, this program would save the state a lot of money.

4:40 Chairman Delzer: Adam, it says that it is a pilot program and there is some reporting, do we need to put a sunset on this as well?

Adam Cronquist, Legislative Council: The money would only be available for this biennium.

Chairman Delzer: We give some transfer authority to the department of human services, would they then be able to transfer this money anywhere else?

Adam: It would be clear from this that the intent would be that it would be used for this program. It may result in an audit finding.

Chairman Delzer: We do give them authority to transfer some things.

Representative Kreidt: Are there facilities in the state that can provide this therapy?

Representative Weisz: Yes there is one in Fargo.

Representative Kreidt: Is that the only one?

Representative Weisz: As far as I know, that is the only one. We also have support from the doctor in UND school of medicine, but I don't believe he does it himself.

Representative Kreidt: Insurance companies don't recognize this as a legitimate procedure?

Representative Weisz: Correct.

Representative Meier: Would the individual in Fargo have proven results?

Representative Weisz: It would depend on the definition of improvement. I do have a lot of testimony in favor of this procedure.

Representative Meier: How long has this doctor been in Fargo?

Representative Weisz: I don't know that answer.

Representative Beadle: The doctor commutes between Fargo and Chicago. There has been some evidence coming out of there too.

Representative Schobinger: Are we doing something that is already out there?

Chairman Delzer: I think that what they are trying to do is quantify the information that is out there, and the Department of human services would give a report on it.

Representative Weisz: There's been a number of people that have had this treatment and it's been a positive treatment for them. However, it isn't currently a recognized treatment so there is no quantified research to go along with it.

Chairman Delzer: Is there anything in the language that restricts it to instate patients?

Representative Weisz: No, I would think that is probably assume.

Chairman Delzer: There may be some rules for that within the department.

No further questions, meeting closed.

2019 HOUSE STANDING COMMITTEE MINUTES

Appropriations Committee Roughrider Room, State Capitol

HB 1359
2/14/2019
32818

- ☐ Subcommittee
☐ Conference Committee

Committee Clerk: Risa Bergquist by Caitlin Fleck
--

Explanation or reason for introduction of bill/resolution:

Adopting amendments.

Minutes:

Chairman Delzer: Bring HB 1359 back up, I have heard a lot of good things about this. I'm not sure about the money side however. Some of the information that I got was that with the traumatic brain injury, some of your vessels close up and they don't get the oxygen they need. So this treatment would allow the vessels to get that needed oxygen.

Representative Beadle: One of the things that they can measure is eye movement, and they track how this therapy can impact eye function.

Representative Kempenich: I'll move a do pass.

Representative Schatz: Second. I have a son with a traumatic brain injury and I really think that we need to support this bill. This bill would have potential to help many different people, not just those with traumatic brain injuries.

Chairman Delzer: I will support the bill as well. How are they going to collect the information?

Representative Beadle: When talking to Dr. Denim, I know one of the things they are doing is trying to get a clinical reporting and coverage for it.

Chairman Delzer: I would hope and expect that this reporting would be similar to the department's.

Representative Monson: If the department has to make the report then it is up to them to get the data.

Chairman Delzer: If everyone is honest and on the record about gathering the data and information and making the report, then I think that is probably okay.

Representative J. Nelson: had we had this bill in our section with the health department, I think that language could have been changed. We also wouldn't have funded it with the

strategic investment and improvements fund (SIFF) funding, instead it would be with the tobacco prevention funding because there are adequate funds in there and they will run out.

Chairman Delzer: I don't think that there would be a difference to anyone if we change that funding source. We already have one motion out, but would they withdraw it?

Representative Kempenich: I'll withdraw my motion.

Representative Schatz: I will also withdraw the second.

Representative J. Nelson: I make a motion to amend by changing the fund that supports this from SIFF funds to the tobacco prevention and control fund.

Representative Meier: Second.

Representative J. Nelson: Should we add a reporting mechanism?

Chairman Delzer: Well if everyone thinks it's ok how it is right now; I can live with that. The department has to give periodic reports, so they must also gather the information.

Voice vote. Motion carries.

Representative Kempenich: Motion for a do pass as amended

Representative Monson: Second.

Roll Call Vote: 20 Yes, 0 No, 1 Absent.

Motion carries.

Floor assignment: **Representative D. Anderson**

Meeting closed.

19.0646.03001
Title.04000

DP 2/15/19
Prepared by the Legislative Council staff for
the House Appropriations Committee
February 14, 2019

PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1359

Page 1, line 6, remove "strategic investment and"

Page 1, line 7, replace "improvements" with "tobacco prevention and control trust"

Renumber accordingly

Date: 2/14/2019
Roll Call Vote #: 1

**2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1359**

House Appropriations Committee

☐ Subcommittee

Amendment LC# or Description: 19.0646.03001

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar
Other Actions: ☐ Reconsider ☐ _____

Motion Made By Representative J. Nelson Seconded By Representative Meier

Representatives	Yes	No	Representatives	Yes	No
Chairman Delzer					
Representative Kempenich					
Representative Anderson			Representative Schobinger		
Representative Beadle			Representative Vigesaa		
Representative Bellew					
Representative Brandenburg					
Representative Howe			Representative Boe		
Representative Kreidt			Representative Holman		
Representative Martinson			Representative Mock		
Representative Meier					
Representative Monson					
Representative Nathe					
Representative J. Nelson					
Representative Sanford					
Representative Schatz					
Representative Schmidt					

Total (Yes) _____ No _____

Absent _____

Floor Assignment _____

Voice Vote/Motion Carries

Date: 2/14/2019
Roll Call Vote #: 2

**2019 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. HB 1359**

House Appropriations Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☒ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Representative Kempenich Seconded By Representative Monson

Representatives	Yes	No	Representatives	Yes	No
Chairman Delzer	X				
Representative Kempenich	X				
Representative Anderson	X		Representative Schobinger	X	
Representative Beadle	X		Representative Vigesaa	X	
Representative Bellew	X				
Representative Brandenburg	X				
Representative Howe	X		Representative Boe	X	
Representative Kreidt	X		Representative Holman	X	
Representative Martinson	X		Representative Mock	A	
Representative Meier	X				
Representative Monson	X				
Representative Nathe	X				
Representative J. Nelson	X				
Representative Sanford	X				
Representative Schatz	X				
Representative Schmidt	X				

Total (Yes) 20 No 0

Absent 1

Floor Assignment Representative D. Anderson

Motion Carries

REPORT OF STANDING COMMITTEE

HB 1359, as engrossed: Appropriations Committee (Rep. Delzer, Chairman)
recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends
DO PASS (20 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). Engrossed HB 1359
was placed on the Sixth order on the calendar.

Page 1, line 6, remove "strategic investment and"

Page 1, line 7, replace "improvements" with "tobacco prevention and control trust"

Renumber accordingly

2019 SENATE HUMAN SERVICES

HB 1359

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee
Red River Room, State Capitol

HB 1359
3/12/2019
Job # 33573

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

For Medicaid pilot project for hyperbaric oxygenation treatment: to provide a report to Legislative management, appropriation and to declare an emergency.

Minutes:

Attachments # 1-6

Madam Chair Lee opens the hearing on HB 1359.

(00:25-03:20) Representative Dick Anderson, District 6 introduces HB 1359 and gives a brief overview.

(02:05) Representative Anderson: Right now I think human services spends about 10 million dollars a year on treating brain injuries and the way I am looking at this; it will reduce that quite a bit. There is just one other thing I would like to mention, originally I had an emergency clause on it and then when I had to re-write it I forgot to put the emergency clause back on. If you guys could put that on I would appreciate it because Dr. Denham has people who are waiting to be treated and the sooner, we get started the better data we will get.

(3:20) Senator Anderson: Tell me why this treatment isn't being run by a regular clinical trial rather than us funding it and doing it in the state of North Dakota.

Representative Anderson: The FDA does not approve of this, and they wanted to have a placebo in the test and how do you put a placebo in a hyperbaric treatment. I think Dr. Denham could answer that better than I can. We have also found out that in Europe it has worked for MS (multiple sclerosis) and it does work for dementia as well.

Senator Anderson: My concern is here; we have a lot of anecdotal stories. Typically, in medicine we like to see things proven and reproducible before we start paying for them and that is why the FDA hasn't approved it yet. We are dealing with the marijuana bills in this committee and of course there are hundreds of anecdotal stories about how it helps and there are some clinical trials that proves that certain constituent chemicals of the marijuana plant are good for certain things but there are a lot of other hoaxes that are perpetrating people because we are pretending things are good for ailments that they are really not.

Representative Anderson: You will hear testimony today from people and I hope they can convince you. I think sometimes the FDA and the federal government are a little slow on reacting to things and I think we have a chance here that is going to be unique for the rest of the country to follow and I think we are going improve a lot of people's lives and that is why it is important. This bill is kind of under the radar and maybe that is the way it should be until we get it passed but I'm sure after you hear all the testimony, you will be convinced like I was.

Madam Chair Lee: Have you had any inputs from the insurance companies?

Representative Anderson: Yes, I have and I think Dr. Denham are working with the insurance company. We are making strides right now because of the evidence that we are seeing I think they are seeing also. One of the insurance companies did tour the clinic so I think they have their eyes open somewhat too.

Madam Chair Lee: The 335,000 that is coming from the tobacco fund, is that taking any funding away from any other program that is currently funded through that source?

Representative Anderson: I probably couldn't tell you, that would be an appropriations question. You know appropriations works, unless you are there all the time you just don't know.

Senator Clemens: Is this the clinic in Fargo that you are talking about?

Representative Anderson: Yes, it is. I think the clinical in Fargo is using medical grade equipment and I think Dr. Denham has found a protocol that works because hyperbaric oxygen treatment is not new but somehow she has figured it out to make it work and has spent a lot of time doing that.

Senator Clemens: I think the hospital in Jamestown are doing some of this too correct?

Representative Anderson: I think they are doing some of it but I think they don't have the medical grade chambers like there are in Fargo. I believe the clinic in Fargo is probably the only area in the state where you can do the medical grade equipment if I am right.

Senator Clemens: The location in Fargo, I see the bill talks about non-profits so this is obviously a non-profit?

Representative Anderson: We set the language up the way we did to run it through the Dakota Medical foundation. We want a third party looking at the results and tried to make the data so that the insurance companies will accept it and that is what we are up to here.

Madam Chair Lee: Can you elaborate a little bit on Dakota Medical Foundations involvement?

Representative Anderson: No, not really.

Madam Chair Lee: I just wondered if they are viewing it as one of the studies they would get involved with or are they just the fiscal agent.

Representative Anderson: I think basically they are going to be a fiscal agent.

Senator Hogan: As a pilot project, do you see this as meeting all the standards for research and evidence that the FDA would need so that you could it verifiable because those are very strict protocols.

Representative Anderson: I'm not sure about that, if I can get the insurance companies to accept it, that is what I am up to. I am not that familiar with the FDA I just know that sometimes the federal government drags their feet on a lot of things.

Senator Hogan: But they have standards for evidence on research and I just wondered if that was your expectation.

Madam Chair Lee: The FDA's protocol for drugs for example, first it is tested in the lab, the next level the drug is tested on healthy people, and the third level is it is tested on people with the condition which it is supposed to treat. It isn't supposed to be released to the rest of us until it is demonstrated to be safe and effective. There really is a reason for the protocol that they make sure what comes to us is safe and effective and worthy of use so bypassing some of that could be an inappropriate risk.

Representative Anderson: Your sitting in the hyperbaric oxygen chamber, everyone needs oxygen. It is not pharmaceutical, there are no surgeries involved, and from what I see the results are fantastic. The risk to me is very low, I have a lot of confidence in Dr. Denham. I think if you can get someone that was at a level here after a brain injury and get them back up to here, what a wonderful thing that would be for a lot of people.

Senator O. Larsen: Did this legislation move any quicker because of the Trump administration signing off on the legislation for right to try now?

Representative Anderson: I really can't answer that. I see a chance to get my foot in the door and that is what I am trying to do here. If the data shows that it works than it will be a wonderful difference for a lot of people.

(13:28-15:35) Representative Austen Schauer, District 13. Testifying in support of HB 1359. Please see **Attachment #1** for written testimony.

Representative Schauer: If you have friends whose children have suffered a concussion, it is a horrible situation and you don't know what to do and then the affects linger. Fargo has an opportunity for you to take a look at. Yes, the results have not been determined long-term but on short-term, they are there.

Senator Hogan: Did you look at the BIRI (Brain Injury Research Institute) institute and did they have any input on this treatment?

Representative Schauer: I did not look that deeply.

Senator Hogan: Or whether they confirm that this is a viable treatment.

Representative Schauer: I did not look at that specifically no.

Madam Chair Lee: Have you or Representative Anderson had any contact with Rebecca Quinn who runs the Brain Injury Network?

Representative Schauer: I have not.

Representative Anderson: I am on the Brain Advisory Council and Dr. David Biberdorf is the one who helped me understand what this clinic was all about.

Madam Chair Lee: So what has Rebecca Quinn had to say about this?

Representative Anderson: She hasn't said a lot; we did have people there in the council who agreed that this was a bill worth pursuing so that is what it is.

(18:30-00:00) Dr. Daphne Denham, testifying in support to HB 1359. Testimony is as follows: Thank you for the opportunity to discuss this bill. If I may just clarify somethings, Jamestown does have hospital grade chambers and are affiliated with the hospital. Typically, it is a hospital rule not to use hyperbaric chambers for non-FDA approved indications. That is why the study would be very difficult to be done in a hospital affiliated hyperbaric centers. At one-time cerebral edema or brain swelling was an FDA approved indication for the use of hyperbaric treatment. There was an article in 2006 it is called the Polemics of Hyperbaric Medicine, it was thought to be because of the cost in the hospital at that time, the cost of a treatment was about 2,000 dollars and since then Medicare has brought the cost of treatment down for hospitals and the cost of treatment up for outpatient centers so it is becoming more equivocal for providing FDA approved indications in a private center versus a hospital as far as Medicare and insurance reimbursements.

(20:30) Senator K. Roers: So the brain edema used to be FDA approved indication and it no longer is and you believe the reason it no longer is was because the cost ratio was off?

Dr. Denham: The cost and politics. The gist of the article written by Dr. Richard Neubauer who many felt to be the grandfather of hyperbaric for the brain he felt, was a very political move so I will share that article with you but, there are 13 indications for hyperbaric medicine currently and one of those indications is a compartment syndrome or a crush injury, and by definition that is nerve damage currently by definition to an arm or a leg after a crush, the muscle swells so much that the fascia limits it so the nerves are damaged. If you re-examine that definition and replace skull for fascia, a concussion or any traumatic brain injury fits that very same definition. We are actively working with a private insurance company; this bill is for moderate to severe brain injuries. What I have been doing for the past three and a half years aggressively is treating acute concussions meaning patients who may or may not have required an ER visit are discharged from the ER and are not thought to have a severe brain injury and in your packet for the pilot program (please see Attachment #2) we discuss that for this bill they will be at one point classified by a physician in their hospital records somewhere as a moderate to severe brain injury. The work that I have done in Fargo with the help of the Dakota Medical Foundation, they set up the Concussion Care Initiative, a

private donor put money into that. Patients anywhere in North Dakota and western Minnesota could come with a concussion, again a different brain injury from what we are talking about, could come and were treated at no charge to the patient we billed the Dakota Medical Foundation Medicare rates for that treatment so that Medicare gets the cheapest treatment rate. In that data we have found that an average of only three treatments is needed to completely resolve symptoms and that repair is sustainable and by coming to Fargo we have objective evidence with the Right Eye tool that is now FDA approved as a concussion diagnostic tool. I say all of that to say, we are making an enormous leap for acute concussions and private insurance are extremely interested and now doing a pilot program, I owe them a little bit more data by the end of this week for them to hear by the end of this month and we will know if they are going to take on the pilot for the acute concussions. What we are asking now because moderate and severe brain injuries are much more difficult to treat, take more treatment, and would be more funding than I could do myself. Prior to coming to Fargo I treated acute concussions at no charge to the patient in my clinic in Northbrook, but the reason to come to Fargo was to work with Dr. Biberdorf and the Right Eye to have objective evidence because we don't have concussion diagnostic tool until the Right Eye was just approved. By asking for this money for the moderate to severe, doing the same type of research and during my seven years of surgical residency I did two years of research in the lab. I am used to doing research that was under a university, we are expecting to get IRB (Institutional Review Boards) approval through the University of North Dakota and patients will be evaluated objectively outside of the clinic to show the improvement for this bill. We should be doing that quality level of research but there is not a placebo for hyperbaric, you waste enormous time and money, and patients know whether or not their ears pop, if their ears don't pop then they know that they didn't get a treatment. Some studies have used air that has increased the pressure but that is the whole concept of increasing the pressure, when you fly on an airplane by increasing the pressure you increase the oxygen that goes into any mammalian system and therefore it was not an inactive placebo so those studies are flawed by saying that they were placebo studies when they weren't.

(26:03) Madam Chair Lee: What I would like to ask, is if you could put in writing the information that you just provided because I only see the information on the product itself not any written testimony.

Senator K. Roers: When you were talking about with the acute, you said three treatments

Dr. Denham: On average.

Senator K. Roers: Yes, on average but how quick are those?

Dr. Denham: Ideally, within four to five hours which follows the compartment syndrome protocol.

Senator K. Roers: Three in one day?

Dr. Denham: Correct

Senator K. Roers: Do you know what the average healing time is for the untreated versus what you are seeing?

Dr. Denham: An article came out in September demonstrating that a clinic in Boston had about 161 acute concussions that presented within the first ten days of their injury and at 28 days, 58% of those patients still had symptoms. We are seeing patient's symptom free on average in three to four days. A lot of patients may get a concussion on Friday night, we treat them Saturday twice, Sunday twice, and they are back in homeroom Monday morning as if nothing ever happened. The data on the academic need of concussions is that 14% still need academic help at a year and we got these kids in and doing well. The last two pages of the right hand side of the packet are the Right Eye test. This was from a 31-year-old who was six years out from a moderate to severe brain injury so this is data for that would apply to the bill we are talking about. If you compare the two, the score when he presented, his brain health score was a 38 and if you look at the marker he is way in the yellow headed to the red. In three weeks his brain health score exceeded the functional level, he was up to 79. The right eye device, a patient sits in front of a computer screen with their chin on a rest and the device picks up each individual eye as they track the same marker on the screen and that is why we get a red for the right and a blue for the left but if you look at his circular tracking he should be tracking on this black dotted line and he is completely off. What is so important certainly for the kids is that the horizontal tracking is essentially reading, and these kids are not able to read and they say that their vision is blurred or their eyes hurt and often times it is dismissed. We for the first time unlike other studies have true objective evidence, this gentleman who was six years out cannot change in three weeks what he presented with statistically impossible, so we have objective evidence for this study and is not placebo driven because of there not being a good placebo. I put some cartoons in here just to explain how hyperbaric works because so many people question how it works. I think what is most important and what we as physicians have appreciated is number 3 "after a brain injury, there is a lot of brain inflammation" and if you skip past number 4 "research ties, inflammation to post concussive symptoms" and I believe that is what we are seeing and what animal models support the reason for hyperbaric working but we are not going to take brain biopsies of humans after hyperbaric, because of the blood brain barrier we won't just be able to draw a blood test and get appropriate inflammatory markers, and with the objective eye evidence it almost doesn't matter at this point. We in medicine say if you watch ten people come out of an airplane with a parachute do you really have to do the study that the parachute helped them. At some point yes, the FDA requires all of these things and I think it is perfectly appropriate but private insurance looks at money savings. Private insurance covers inflammatory bowel disease and some other hyperbaric treatments that are not FDA approved so the significance of this bill is to gather the data for private insurance to look at this and say yes, this is a safe treatment and it is going to save us thousands. The budget of what we are asking for and I apologize this is on 2018 numbers, 2019 Medicaid gave hyperbaric centers a pay raise in the G code but honestly since we used this budget my sincere hope is that we are going to come in under budget based on the treatment numbers needed, standard of care, and all the research is based on 40 treatments per individual to potentially 80 but by acknowledging the inflammatory response and what I have been working on for three and a half years we are not seeing that using the protocol that we have developed. Perhaps the most important thing is the page cost to the patient, for every 15 point IQ increase it translates to about 20,000 dollars a year of income. One of the data points that we really want to look at is the potential to get patients with a moderate to severe head injury either not requiring as much care and medical expense but my sincere hope is that we shift them from a tax burden to a tax payer. That is what several other studies have shown

with military veterans. We are not addressing veterans in this study but it is out sincere hope that this study helps the VA to recognize, they have been ignoring the opportunity for a very long time. I did print out the protocol that we would take patients with a moderate to severe brain injury and do appropriate objective measures, pre-treatment my preference would be most of those objective measures are done outside of my office except the Right Eye, they can't fake that test nor can we manipulate that data. We obviously want to be extremely diligent in making sure that this is safe, well tolerated, and making progress. I would prefer that their objective testing be done elsewhere. I didn't go through all of my sheets, I tried to oversimplify everything.

(36:00) Madam Chair Lee: In addition to traumatic brain injuries, are these treatments also beneficial to someone who has had a stroke or another kind of brain injury?

Dr. Denham: In Israel they did a beautiful stroke study and they did not enroll any patient in the stroke study until they were at least six months out from their stroke so that they were not clouded with what patients could gain within the first six months. They did a cross over study designed, which is sometimes accepted by the FDA, in that half the patients waited an additional six months and had ongoing standard of care, the other half had hyperbaric treatments and had a statistical improvement in multiple modalities that they tested. After six months the standard of care were crossed over and they made the same as a whole statistically improved quality of life ability to do their ADL's (activities of daily living) etc. There was no difference for that stroke study that some patients waited an additional six months that shows that we can heal brain injuries even in a delayed fashion.

Madam Chair Lee: Is there any regression from the improvement over a longer period of time for either the stroke victim or for someone who has had a concussion or another brain injury?

Dr. Denham: I know for the acute concussions we are not seeing regression and we are actually seeing that they are less at risk of the next concussion because I know they would be coming back if they were concussed and they are not coming back, and that has been three and a half years since I started this. The chronic injuries however, there are some patients based on previous protocols that need six months to a year to come back for a few treatments. Dr. Paul Harch out of Louisiana has the most data on that and he refers to it as an oil change. Dr. Harch and I go two different ways when we talk about protocols and with what I have seen with the acute concussions and the anti-inflammatory response, we have walked that back for patients with chronic brain injury and that is the protocol that others will testify to and most of them know exactly when they get the treatment that is the most anti-inflammatory.

Madam Chair Lee: The money that you are talking about here, is this because the grant is running out from the private donor and you want to move on or is this additional? Talk to me about the money please.

Dr. Denahm: Through the Dakota medical foundation we originally had 100,000 dollars and then an anonymous donor donated another 50,000 dollars but we treated acute concussions. They needed to present within seven days and be walking and talking out of the hospital. What we are asking for as far as funding are the patients who present to the emergency room

unconscious and have a Glasgow coma scale of 12 or less, many of those have severe brain injuries that they are in a coma for a month and learn to walk and talk again. We are trying to add to that or just finish that off depending on the duration from their injury and from the data I have been looking at, much of that is due to this inflammatory response. Every cell in the body is within vessel range to get oxygen but after an injury there is brain death but there are swollen cells that are not able to get enough oxygen to function as brain cells but they are still alive. It is as if you were gainfully employed and took a massive pay cut, you could still feed the family but there are no frills. What hyperbaric does especially in the acute setting is to take away the swelling and to allow all of those cells that are still alive to regain full function. The inflammatory response is pulling oxygen away from these already necessary or under nourished brain cells and that is why we see such a dramatic change in patients when we turn off that inflammatory response which is why my protocol is different than other protocols.

Madam Chair Lee: Have you explored grant funding or partners among any of the national partners that might be likely supporters of this or why are you coming to this state, since we don't generally get in the research funding areas?

Dr. Denham: I met Dr. David Biberdorf on January 18, 2018 and we opened July 23, 2018 if that tells you how desperately I wanted to find somewhere where we could do the research and with Dr. Biberdorf and the Right Eye data have objective data. I was so tired of these kids getting dramatically better and going back to their concussion doctor who had to clear them to play per the high school rules or per their club's sport rules and they were told that all of that was just relaxation, hyperbaric doesn't do anything and Dr. Denham is doing is not okay, then the kids would get in the care from that appointment and the kid says to his mom "I can still go can't I, I feel so much better". How horrible is that for the kids in that area so I would tell the kids it is not your job to convince physicians that hyperbaric works, so the opportunity to leave that scenario when I knew it worked but we had the world against us to an opportunity that we can continue to do treatments with no costs to the patient so we got a true idea of what each patient needed. We have enormous amounts of data that we need to get put together but as of now I am so busy in the clinic I haven't had time to do that but we are working on getting someone data and just to do data so that we can extend the hours of the clinic.

Madam Chair Lee: That means that you haven't applied for grants in any other place, that was the question.

Dr. Denham: We have through some others, I have tried to work with some other national institutes but again, they are not interested and if you look some people have interior motives for patients not getting better it is a shame to say.

Senator Hogan: Could you tell us what your academic background is and have you had any published national research?

Dr. Denham: Yes, I trained as a general surgeon from 1993-2000 and I did two years of basic science research looking at inflammatory markers in pancreatitis which is part of the reason the inflammation means so much to me and I have several national publications presented at several national meetings but that was 20 plus years ago. We even published

a change of standard of care article on the approach to parathyroid surgery making minimally invasive parathyroid surgery standard of care and the article that I published was looking at the cost effectiveness of it.

Senator Hogan: Can you tell me a little bit about you IRB, I was pleased you are getting an IRB approval from UND (University of North Dakota) Medical School. Can you tell me who you are working with and how that process would work?

Dr. Denham: Dr. Biberdorf is part of the adjunct faculty at UND and he has been working with Dr. Tom Petros and we do have IRB for the retrospective publication of the acute concussion work that we are doing and we will get IRB for this particular pilot project.

Senator K. Roers: Can you tell me when you are talking about the Glasgow coma scale of 12 etc. How do you intend to get you referral source, how do you make sure that people know about your trial and also making sure you're not getting people who are self-selective?

Dr. Denham: That will be an issue but that is why having objective evidence. Someone who walks into the clinic and is talking and able to do a job, how do we know that they were a moderate to severe brain injury? We would need to have hospital records and I want to talk to their therapists or preferably have a third party talk to their therapists so that their therapists don't know that they are getting hyperbaric, they are doing everything they can but there is just a hump they can't jump over. We recently got an e-mail for an infant that was severely injured that I would like to potentially be our first patient so that is why I changed it to age appropriate things. It is going to be word of mouth and word of mouth is extremely effective in Fargo.

Senator K. Roers: Have you tried working with the healthcare systems in Fargo and/or the NRI (National Research Institute)?

Dr. Denham: Through Dr. Biberdorf, he is part of the brain injury committee here in North Dakota and most people on that committee are aware of it, we have reached out to the other healthcare systems. When I first got here we had multiple open houses for physicians to come in and see and certainly if we are successful with this pilot and the pilot through private insurance, we will be targeting again the referral source.

Senator Anderson: If you could provide us with some links to the study that you mentioned that said hyperbaric wasn't any good and also if we have your IRB in electronic format I would like to look at that.

Dr. Denham: Well we haven't written the IRB for this yet.

Senator Anderson: Do you have a problem with the authorization of funding being based on your receiving the IRB for the study?

Dr. Denham: No.

(51:40-55:53) Jim Nelson, Legislative Director for the North Dakota Veterans Legislative Council. Testifying in support of HB 1359. Please see **Attachment #3** for written testimony.

Senator Anderson: The study that is being designed here, how do you see that relating with the veterans and their injuries.

Jim Nelson: Basically the way we looked at it was a concussion is a concussion. Whether you get it from a bomb, gun blast, car accident, or football injury. We see the possibility that the VA would acknowledge this if the effects are indeed as we believe they are and as another avenue for them to take a harder look. We see the same thing in a lot of our Vietnam veterans that have went for years undiagnosed and untreated and this is a possibility to eliminate that epidemic of 20 plus suicides a day.

Senator O. Larsen: We have kind of two parallels of the PTSD treatment one with the medical marijuana and the other with this new coming issue. Is your group going to team together and do research to see what these two are going to be doing with your group? Has that been brought forward at all?

Jim Nelson: Not to my knowledge.

(58:13-1:14:43) Nicole Rude and her son Payton Rude, hyperbaric patient. Testifying in support of HB 1359. Written testimony was provided and e-mailed to the committee after the hearing on HB 1359. Please see **Attachment #4** for written testimony.

Nicole Rude: We are here today in support of HB 1359 and for you to understand why we are here and where we come from is to understand our backstory for the last three years of Payton's post concussive symptoms. Along with this I want to give you my background too, I was a kindergarten teacher at the West Fargo Kindergarten Center. I have stayed home to take care of our four children and I have adjunct at Minnesota State University Moorhead in the Education Department, I have a Masters in Curriculum and Instruction and my Bachelor's degree in two areas of special education. I am currently University Supervising, supervising student teachers. As Payton has struggled through his post concussive pieces, I have definitely noticed the behavioral pieces that go along with that and more importantly those educational pieces that have played into that role of Payton getting ready and back into school.

Payton Rude: I have had four concussions. My first concussion was in a basketball game three years ago now, the second one was in physical education class in middle school just diving for a volleyball, and the third one was last year in December a basketball hit my head and about a year ago in may I got hit by a pool noodle.

Nicole Rude: So to understand the significance of all those multiple concussions, those concussions all four happened within two years. When Dr. Denham was talking about the inflammation on the brain a child should have been able to withstand being hit in their right temple by a pool noodle but the inflammation in his brain you can't see a brain injury which I think is an important thing to recognize too. Although he was cleared and we were trying to get him back into school, we were doctoring with Mayo Neurology, they were like let him be

a kid but, just that simple impact of a pool noodle created another concussion. I took him down to visit with the baseball coach who is also a varsity football coach who I asked if he thought that I should take Payton in and he looked at me and said "Nicole here's the deal, a kid looks like that on our football field, we have the ambulance on the field hauling him in. You need to go now to the ER." In my head it is a pool noodle, tell me I'm wrong this isn't another concussion but, it was. Now to kind of line that up, there have been many doctor appointments along that, with the first concussion it was around the time that I was actually going through cancer treatments so when he talked about having headaches and not sleeping well, we were all stressed out. Six months later when he had the second concussion in P.E. (physical education) class we went to the ER, a week later we went back in because he still couldn't even have a curtain open in the house and he said that he just needed to get back to school and get back in routine. His words are slurring, so as a parent that is not cool to hear your child and know that it is his brain. Nine months later we were still not able to get back into school full time so we started doctoring with Neurology at Mayo. At the Mayo appointment about nine months post his second concussion he was referred for various therapies, one including that his balance was off for physical therapy. He would have been starting physical therapy two weeks after that appointment, we took off for the four of July week and he broke his leg. It wasn't just a simple break, we were in our camper and he rolled his ankle which rolled with enough force and broke the bone up here also. We really feel that was because of his vision and balance being off. The cast comes off and we are back in Mayo in October for another re-check. His leg still has pain, but we start physical therapy. By December the physical therapists are ready to cancel him because she can't make progress with him. Multiple tests, MRI's, X-ray's, he is now diagnosed with CRPS (complex regional pain syndrome) which is a disorder that his brain was recognizing pain that is necessarily not there. What Payton felt, every day, every step, even if air or water touched his leg, so now we have a third concussion on top of this, we are back to Mayo with this referral for CRPS. In 2018 we went to Mayo six different times for treatment of post concussive, CRPS, and then most recently digestion issues. Along with that we have also had issues with digestion track with the May concussion he had, September we visited with the neurologist about his stomach not feeling well and in October he had to miss a few days because he couldn't get out of bed. At Mayo they did a lot of different testing to rule out many different diagnoses and at the end the doctor there felt that it was also brain related. Payton has had so many therapies to be able to count, with his CRPS diagnoses his neurologist actually took him out of school for the rest of the year. Post concussive symptoms that Payton has had, I will let him read those to you.

Payton Rude: I have had headaches from the concussions, vision issues, balance issues, dizziness, body temperature control, nausea, fatigue, sensitivity to light and sound, slurred speech, and memory loss. I was just overwhelmed with all the symptoms I was having. I also was feeling depression and anxiety.

Nicole Rude: And I am going to say the one that you skipped because I know it is hard for you, Payton has also had a lot of suicidal thoughts too. Part of that not only comes with the post concussive piece of that and I know that you had also touched on that with our military families but when that brain isn't thinking clearly and there is inflammation and you have all of these other pieces that you're not able to do, life feels pretty desperate at points. We were actually on two different time on this journey, asked to put him in an inpatient hospital at the advice of one time with a social worker and another time with a psychologist and along with

the psychologist recommendation out psychiatrists said absolutely not, this is a brain injury if we put him in there, we need to keep him at home where we can control environment as long as you can keep him safe. The medications that he has been on has also caused some of those symptoms that go along with that. Along this journey he has been on 14 different types of medication. Let me talk about the school piece, in sixth grade he missed 98 days without full attendance, in seventh grade he had 25 days without full attendance, and for the second half of the year he had a home bound tutor. He was in a 504 education plan and has had 54 days this year so far that are not full attendance because mostly for appointments. To understand the insurance costs of that, our insurance company has been close to 100,000 dollars for his therapies and treatments and our out of pocket is nearing 15,000 dollars along with the fact of travel and my work piece being cut don't drastically to be at home taking care of him.

Payton Rude: We went to go see Dr. Biberdorf at the hyperbaric clinic. I didn't really know what was going to happen, I just thought it was going to be another eye appointment. He gave me the right eye test and it was very low in the dysfunctional region and with that he recommended doing hyperbaric treatments to help with the eye functioning and with that the scores from that improved.

Nicole Rude: If you look down here, this is what Dr. Denham was talking about with the reading piece. Payton struggled with the horizontal tracking and along with that vertical tracking is taking notes from the board and down to your paper. In those areas Payton was at the 35th percentile. Looking at educational data that 35th percentile is when we would do remediation on any child. His score was in the 47th overall eye health which is in the dysfunctional range. After doing one week of hyperbaric, he had ten treatments and at the end of that week his tracking had improved and he was in the 71st percentile. Here in his horizontal tracking he now went to 95th percentile, so from 35th percentile then one week of treatment and one week of post treatment he is now in the 95th percentile. His eye functioning went to 72%. Two weeks after that we went back for another eye test and his overall eye functioning was now at 88%, which means for Payton this is a huge gain. He is a very smart and studious student, we at one point were seeing a neuro psych because his words were slurring and he said that Payton is in the genius level but we still saw this discrepancy and gap so how do we get him back to where he was? When Dr. Denham talked about that pay check, that is the thing as a parent I saw slipping away. I saw this kid that was going to be very successful and yet I saw a kid who couldn't start the microwave. His first day after treatment he was able to go back to Skyzone (a trampoline park) and now he is playing drums again, playing outside, and really his symptoms are gone. I just want you to imagine the possibilities of a kid, that they are able to show his visual tracking is at a 16th grade, he was only tracking at a 10th grade with his visual tracking prior to the hyperbaric.

(1:14:50-1:18:18) Hannah Anderson from Leeds, North Dakota. Testifying in support of HB 1359. Please see **Attachment #5** for written testimony.

(1:19:08-1:21:30) Lisa Anderson from Leeds, North Dakota. Testifying in support of HB 1359. Please see **Attachment #6** for written testimony.

Senator O. Larsen: We have two therapies that we are looking at. Is that other therapy from the medical marijuana something that you have thought about?

Lisa Anderson: I haven't done the research. I run the support group for the brain injury survivors in Devils Lake and I know there are a couple of them there who are interested in that but I personally haven't done any of the research for medical marijuana.

Senator O. Larsen: This therapy that she is doing will this continue for a lifetime or as long as the Right Eye testing comes back good?

Lisa Anderson: Dr. Denham said that she didn't believe that Hannah would need any additional treatment unless she received a concussion or had another brain injury, which the possibility of having another brain injury increases after they have had a brain injury.

(1:23:53-1:24:31) Vicki Bitner, Resident of Fargo, providing testimony from a **patient Bruce A. Hendrickson.** Please see **Attachment #7** for written testimony.

Senator Anderson: I don't know if you want to close the hearing but we need to hear from the health department.

Madam Chair Lee: We can get that later.

Senator K. Roers: Blue Cross said that they are still waiting for data to make a decision on which way they are going.

Madam Chair Lee: There are interest in each of those places because they want to support good things that are going on too but there has to be some process in the whole thing.

Madam Chair Lee closes the hearing on HB 1359.

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee Red River Room, State Capitol

HB 1359
3/12/2019
Job # 33590

- ☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

For Medicaid pilot project for hyperbaric oxygenation treatment: to provide a report to Legislative management, appropriation and to declare an Emergency.

Minutes:

No Attachments

Madam Chair Lee opens the discussion on HB 1359.

(00:10-04:18) Senator Clemens describes his tour of the hyperbaric facility of Dr. Denham. Senator Clemens explained that the facility was a nice and clean facility. Senator Clemens was not impressed with the technicians that there were on staff, there were two technicians that were manning the hyperbaric chamber and Senator Clemens said they “did not seem professional”. During the time of his tour Senator Clemens and Representative Schauer had a conversation with Dr. Denham and one thing that stood out to Senator Clemens during the conversation and that was the feeling of Dr. Denham being “desperate” for income and does not feel that the committee should be funding her business.

(04:20) Senator K. Roers: I learned that Blue Cross had sent something to me saying that they have not accepted this concept for a pilot, they are waiting for the data from Dr. Denham and she has not been providing it in a timely fashion. Blue Cross is interested in her results, they asked for her data and that is where it stands. They support the evidence and what the veterans are after but, there isn't enough evidence for insurance coverage, she shows promising progress but she needs to get her data together to us before we can pilot. It's not that the insurance companies are against this, it is that they are asking her to follow a path and it's not happening. I would agree with your final statement; I feel like they are asking the government to basically subsidize her business which I don't agree with.

Senator Anderson: The only way I would vote for this is if we considered an economic development project for North Dakota. There are a lot of people around the country working on this and there are trials underway. In spite of the anecdotal evidence, I have never been one to base medical decisions on anecdotal evidence even with the marijuana issue, this may help some people, we haven't heard from the people who didn't help. Without some more research, it is unusual to see a program that was FDA approved and then for some reason is not. I don't even know how that process works. The only time I know of when some

drug or treatment falls off of the FDA approval list is when there is injury to people. They don't generally pull it because it doesn't work once it is approved.

Senator K. Roers: And she said it had to do with politics as well.

Senator Anderson: Politics might affect the state of North Dakota or Illinois or some other but politics isn't going to affect a federal program I don't believe unless the president's son was in a competing business of something but generally not. I would want to do a little more research before I thought we should fund a study, its North Dakota getting into the clinical trial business and that is a dangerous road to go down because there are a lot of different things that we could be in trials about and we could fund. It is a dangerous precedent to establish even though we think this might help some people but there are a lot of things that might help some people.

(07:30-08:02) (Inaudible)

(08:04) Senator Clemens: She also stated when we were in that tour, she was telling us that treatments were about 175 dollars for typical treatment and they could do a couple a day. After three or four treatments they were done so you're looking at less than 1,000 dollars for a lot of the cases that she was referring to so its not a real expensive hardship either.

Senator Anderson: You talked about Jamestown and I don't know we could touch base with Jamestown and see what they say. Obviously they thought it was worthwhile to buy a couple of these chambers.

Senator K. Roers: I can give you a little clarity on that. In Fargo at Sanford we have hyperbaric oxygen as an option for the FDA approved purposes and so Jamestown also has them for wound healing and other things like that but not for this purpose so I think it is just her utilization that is different not the facility that is any different.

Madam Chair Lee: Alex (Intern), could you google Dr. Denham for us. Im just curious about her medical background.

Senator K. Roers: She didn't answer that question very clearly either, her medical background. She jumped straight to certain things but she didn't say where she went to school or where she did her residency or any of that. Dr. Biberdorf I know the name but I don't know who it is.

Madam Chair Lee: He has two brothers, one of whom is the guy who was a state official that manages oil and this brother must be an ophthalmologist not an optometrist. This guy's name was Dave and Bob, the one you and I know. I would think that he is a highly credible guy by knowing the family.

(11:10-11:40) The committee goes over the medical credentials of Dr. Denham that the Senate Human Services Intern found.

Senator Clemens: I was just going to mention, I think that after I went through her clinic I got a little interested and googled Jamestown and they are into this hyperbaric quite a bit, but I'm sure they aren't doing any more than what they would in Fargo.

Senator O. Larsen: When they are doing that eye testing is that an optometrist?

Senator K. Roers: What is interesting is his professorship or adjunct is with the Department of Psychology at UND (University of North Dakota) which I remember my psych classes learning a lot about the eye and brain so I guess its not completely un heard of.

(13:23-13:40) Dr. Denham still holds active licenses in Illinois and has never been disciplined. (information supplied by the Senate Human Services Intern)

Senator K. Roers: So this is from the FDA's site "hyperbaric oxygen therapy doesn't be misled. No hyperbaric oxygen therapy has not been clinically proven to cure or be effective in the treatment of cancer, autism, or diabetes but do a quick search on the internet and you will see all sorts of claims for these and other diseases for which the device has not been cleared or approved by the FDA. Involves breathing oxygen in a pressurized chamber, has clear hyperbaric chambers for certain medical uses such as treating decompression sickness suffered by divers. Patients may be unaware that the safety and effectiveness of hyperbaric oxygen treatments have not been established for these diseases and conditions including: HIV/AIDS, Alzheimer's, Asthma, Bell's Palsy, Brain injury, Cerebral Palsy, Depression, Heart Disease, Hepatitis, Migraine, MS, Parkinson's, Spinal Cord Injury, Sports Injury, and Stroke. Thirteen uses have been cleared by the FDA they include treatment of: Air or Gas Embolism, Carbon Monoxide Poisoning, Decompression Sickness, and Thermal Burns" Those are some of the thirteen it doesn't list all of them.

Madam Chair Lee: If I had something as exciting as this could be I think I would figure out a way to get the data together so that I could apply for grants because then it would be exciting for somebody.

Senator K. Roers: I move a **DO NOT PASS** on HB 1359.
Seconded by Senator Anderson

ROLL CALL VOTE TAKEN

5 YEA, 1 NAY, 0 ABSENT

MOTION CARRIES

Senator K. Roers will carry HB 1359 to the floor.

Madam Chair Lee closes the discussion on HB 1385.

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee Red River Room, State Capitol

HB 1359
3/13/2019
Job #33635

- ☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

Relating to abandoned infants at certain locations.

Minutes:

No Attachments

Madam Chair Lee: We had some very interesting testimony in the morning but the afternoon discussion wrapped a bit around other sources of funding and I spoke this morning with Pat Traynor. A little back ground there yes, they are handling Gary Tharaldson's contribution to that project and they are willing to help her. After our conversation I said the data is the issue because she has it and Pat said too he knows she has it, it just isn't in any organized form at all so I said we had two issues that came through really in the afternoon. One is, the data are not organized and presented in a way to make it possible to apply for grants. I said, a gentleman was here who is one our advocates for the medical marijuana issue and in about three minutes he found six places that there would be opportunities for grants. The second is, the tobacco funds are 241,000 dollars already in the hole so there isn't any money in the fund, it's all in your books Justin (Senate Human Services Clerk) put it in, I got it from Alan Knutsen what the request already are for the money there. The third is, should the state really be in the business of directly funding research projects. If the research universities for example, they get the funding for research which has been requested, I could see her having her ducks in a row by that time, because DMF is going to help her with that, applying for a grant from UND for example in conjunction with the medical school could do this and he agreed that would be the proper place for it to go. I have to talk to Dick Anderson which Senator K. Roers did last night and told all about what is going on but I want to make sure I touch base with him as well. It is not that we reject the importance or the value of what she is doing but that is kind of where we came from. State funding is opening a Pandora's box; we just weren't comfortable. How many requests would we have next session? We cannot evaluate grants, they are professionals who do that and good work recognized by everybody, data has to be lined up and if Pat can help her which he said he would, then she can apply both in and out of state for grants that are available so this can continue. He said there is resistance from providers who do not want to refer who feel that they have a protocol in place for trauma treatment for concussion treatment and that everyone isn't ready to leap on board with this. Well, it isn't proven yet and that is part of the deal. This just may be a work in progress and it would be really interesting to see how this goes, it seems to be pretty effective

for the ones who came and talked to us but we are back at anecdotes again. I am open to further discussion about that if somebody has comments to offer at this point.

Senator Hogan: You know I spent an hour on the phone with Pat Traynor as well. I was very clear about exactly those same concerns in the pre-conversation before I heard what you said. The lack of research and one of my biggest concerns was the lack of partnership and relationship with key players whether it be the medical school or healthcare providers. It is too isolated and way too independent. I have my niece who is the head of the PTSD research for the veteran's hospital association based out of Austin University and I forwarded her this and she said, okay it is out there. She looks at all types of scientific issues and we will look at it. It is interesting because it is a total lack of integration that made me nervous. Most research is so collaborative with research.

Senator Clemens: I don't negate the technology and the fact that shit is probably helping is, the problem I am having with this is, I toured the facility which I told you yesterday, I sensed that there is some desperation and the fact that we would be funding the business enterprise, that is what I don't like about it. I'm not opposed to hyperbaric but that is the issue I'm having.

Senator Anderson: I talked to Representative Anderson this morning and of course he is convinced that it works for these concussion protocols and he is just trying to get some additional money to serve more people. I don't think the state of North Dakota should be in the business of funding these investigational studies and I have an additional concern as I'm not sure this study that she is doing meets the qualifications of a real clinical trial. She talked about getting IRB approval and so forth but we could always put the funding contingent on that approval but still mostly IRB approval is protection of the patient who is going into the study not so much the study design or what is going to come out of it. I'm just uncomfortable with us funding clinical trials on a case by case basis like this and that is what I told Representative Anderson.

Madam Chair Lee: I appreciate Representative Anderson so much, he has worked so hard on this, he is committed to it and I just think that he is a wonderful guy and im glad he cares enough to work this hard on it.

Senator Hogan: Did you have any opportunity to get any feedback from the Health Department?

Madam Chair Lee: I meant to ask that last night. The three physicians that are the advisory council for the Health Department, I mentioned it to them but I did not ask them to comment specifically on this particular thing. I did not inquire to the department. We seem to have enough reasons to not do it. We left the vote open for you, if you would like to vote on it.

Senator Hogan: I am totally comfortable with voting YES on a DO NOT PASS (Absent vote is reflected on Job # 33590 which was a final vote of 5 YEA, 1 NAY, 0 ABSENT)

Madam Chair Lee: I think we are pretty much on the same page, I'm sure no one has changed their mind overnight.

Madam Chair Lee closes the discussion on HB 1359.

2019 SENATE STANDING COMMITTEE MINUTES

Human Services Committee Red River Room, State Capitol

HB 1359
3/14/2019
Job # 33771

- ☐ Subcommittee
☐ Conference Committee

Committee Clerk: Justin Velez

Explanation or reason for introduction of bill/resolution:

For Medicaid pilot project for hyperbaric oxygenation treatment: to provide a report to Legislative management, appropriation and to declare an Emergency.

Minutes:

Attachments #1-3

Madam Chair Lee: I had visited with doctor Winn and we chatted this morning about the possibility of looking at the university research appropriations. You were up to that speed. I have told everyone this, individually you all said that we had real concerns about this bill and ironically everyone's reservations were the same about giving state funds this is opening a Pandora's box and she doesn't have the data for the application. I got some e-mails last night from a house member saying it was going to be hard time finding the money for the behavioral health programs in 2012 if we don't talk about this again, well that is unconstitutional and immoral in my book.

Senator Anderson: I think we should report that as an ethics violation.

Madam Chair Lee: It is an ethics violation. I talked to Senator Hogan and Pat Traynor. We learned they were the fiscal agent for Gary's money and it turns out that Gary is willing to provide additional support. When I told pat that the presentation had been less than sterling from Dr. Denham because we didn't have data and we looked at grants and told him about the guy from the medical marijuana group that googled and found multiple grants that could be submitted for topics like that. This is a popular topic right now. Pat said he would have someone help her get her data in order. Rebecca Quinn was being blamed by house member for sabotaging this. She did not say anything to me that would be anything but supportive of addressing this problem. It is just a rumor mill run amuck. She sent a message to me today about helping Dr. Denham with her data and research and also find another source of funding. So we have Dakota Central that is going to assist her but she is going to have to be a part of the solution and Rebecca Quinn is going to as well. In the mean time I visited with Dr. Wynne again and last message which I did forward to all of you but in her report she made it clear that the money is just for treatments. Now I have to call Dr. Wynne back because he said that if we appropriate dollars to UND because of the medical school, to a research university for the dedicated purpose of exploring treatments for serious brain injury. That would be ok but there has to be a faculty person attached to it. What you see in front of

us is where we were until we found out that she was only going to use the money for additional treatments and I talked to Dr. Wynne and he said no we can't do that, so that is where we are. In addition to the house members who are mad at me and collectively us but I'm a big girl and I don't care because I am angry about the response to this and they also went to the governor, he had a discussion with the governor about whether or not this is appropriate and he said yeah we are kind of on the same page and he understands why we have this position. So, I am bringing this back to you but I am only one person on this committee. You would all agree that we had a lot of discussion and collaboration with her and everybody came up with the same conclusion that this wasn't ready to roll and she needs to be a part of that. Now we have both Rebecca Quinn and Pat Traynor that will assist her with that project. We cannot be directly sending state dollars to a private provider for treatment of a condition or disease, and that is Dr. Wynne's point as well as Senator Wardner's and Senator Holmberg's not just me. So if you have any big differences of opinion with this, I have a very short time to address this because Senator Holmberg will want this in his committee if we are going to hook it up to the university system on Monday. I think we probably come back to the point we were at when we finished the discussion in committee which is, we probably did the right thing in the first place, but I am asking if you want to go forward with some different kind of legislative process here because I see this here that can informally have done privately between Rebecca and Pat Traynor and Dr. Denham to get her things together, apply for grants, to get the support of Gary Tharaldson for funding.

Senator Anderson: I am a little confused are you telling me that this would satisfy the people in house?

Madam Chair Lee: I haven't even talked to the people in the house about it because by the time we had this all put together we found out that we got the message from her saying that she will only use it for additional treatments, that is what she wants the money for.

Senator Anderson: We could pass this and unless she wants to go along with the research project. I am in favor of a research project if the proper project is designed and the IRB approval is given, I don't have a problem with that. I was in favor of the 45 million dollars for research at the universities and this could one of them. I wouldn't even be opposed to putting all the money that dick put in there and see what happens but 100,000 dollars isn't much.

Madam Chair Lee: That wasn't a suggestion that was a pretty firm request from the head of appropriations. I don't have any debate with that, you have to have a little skin in the game. It could be from Gary Tharaldson or from wherever they want to go.

Senator Clemens: I'm opposed to any money being approved by this committee. I'm a little upset about this now. I think we are being given the run around by her and its irritating she doesn't cooperate with an offer and then we come back and I don't think we have to be trying to convince her to be going with this program so, I'm a no on this.

Senator Anderson: It is not unusual for us to do legislation to make other people happy or to get their votes. I have a bill in house human services which they voted 8-5 do not pass and then agreed to bring it back to give me an opportunity to fix it so they might be happy with it. It isn't unusual that we do that but my bill isn't contingent on what we do here. if we can come up with a solution that gets peoples votes and accomplishes something for the

state. The e-mail that Senator Lee eludes to, I wouldn't be opposed to turning that in, that is a current ethics violation if somebody did that.

Madam Chair Lee: I got it, do you want it?

Senator Anderson: That is clearly a violation right now and I would be opposed to turn that in but, that is a different issue. You know what we are trying to do here is accomplish something and a research study is fine with me, I don't have a problem with your position either.

Madam Chair Lee: I don't think that the university should be the ones that have to come up with the matching funds, I think that she is the one who has to come up with the matching funds.

Senator Anderson: Or whoever.

Madam Chair Lee: Our intern has done a great job on this but that has to be matching or there is no question that appropriations won't consider it. It says to UND school of medicine for a study and the funds appropriated maybe spent and the university provides two dollars of matching funds from non-state sources but I don't think that they should be the ones who have to hustle the money is my point. She and Pat Traynor and whoever else.

Senator Anderson: Someone else can volunteer the money that is not unusual we were just talking about when we didn't get the money to build the addition to Sudro hall well legislature said they would authorize you to spend the money but you have to raise it from outside sources so we did that, the 39 million dollars that was used to build that addition all came from outside sources.

Senator O. Larsen: Even though I guess I heard that she's only going to use it for patients or whatever when the funding source is there and they can only get money from research it'll be pretty quick but it'll sink in that I have to use my patient for research and I think she will come around to it.

Senator Hogan: if I hadn't seen particularly the traumatic brain injury young women from Leeds who I have known for six or eight years maybe, I think this does have some viability. I think in that sense it seems like a reasonable compromise. I shared your concerns when I voted no but the fact that there was not a real research plan and I think that would guarantee this and would ensure this. I kind of like this.

Madam Chair Lee: I don't think anybody in the committee was not impressed with the fact that there is an impact there but the fact that anybody thinks they can threaten me or intimidate me into doing anything tells me they don't know much about me, I'm just saying. I'm here to bring it to you or I would have said forget this a long time ago this afternoon. I am not unwilling to discuss whatever it is that you would like to discuss. I absolutely understand Senator Anderson's point and if it's done in a way that can be appropriate, I think Dr. Wynne will be interested in the research part of it but I want that private money to be raised by private people and I don't think that UND should have to be doing it so, somehow we have to make that very clear.

Senator Anderson: I can remember; does it make any difference if we voted for or against the bill if we are going to move reconsideration?

Madam Chair Lee: We all voted against it so anybody, Senator O. Larsen voted for it so he can't make the motion. You now have copies of the emails that I got from Dr. Denham (**Attachment #1**) and from Rebecca Quinn (**Attachment #2**).

Senator Anderson: I'll move **reconsideration** of HB 1359.
Seconded by Senator Hogan

VOICE VOTE TAKEN
MOTION CARRIES TO RECONSIDER.

Madam Chair Lee: Do you feel that the language is tight enough as we have it? I would also like to Alex (Senate Human Services Intern) on the fine job of putting this together (**Attachment #3 Christmas tree bill**) because she had to do it kind of on the fly.

Senator Anderson: This language to me, in spite of being mad about what happened, it's easy for me to put that aside because I have been in this legislative business for a little while.

Madam Chair Lee: So have I.

Senator Anderson: I believe, had this bill come to use with this language we probably would have supported it. I'm willing to move a **DO PASS** on this amendment.
Seconded by Senator K. Roers

Madam Chair Lee: May I ask one thing? If we change the word "provides" to "receives" two dollars of matching funds from non-state sources on the second page, line 15. How would you feel about that change? That way they are not responsible for providing it but they can accept it. Would you be willing to consider that in your amendment?

Senator Anderson: That's what I meant.

Madam Chair Lee: I heard that, I'm pretty sure.

Senator K. Roers: I'll tell you I'm also upset but I do agree, had this come this way I think the concerns that we had, would have had a different conversation because the things that we were so opposed to was appropriating dollars directly to her and this does provide a way through and theoretically it could be someone other than her, so I think that is something I can live with. However, I don't believe I can carry the bill and not share my frustration at the same time.

Madam Chair Lee: We may not be able to share it on the floor but we can express our concerns.

Senator K. Roers: I'm just saying I might not be able to hold the distain in.

Senator O. Larsen: As we were dealing with this I think that my own shortcomings that, my grammar and spelling are horrible but, my ideas are amazing. So this idea, if we can get passed all of the bad grammar and the spelling the idea is amazing because we are stumbling over ourselves with the medical marijuana and the new therapy. If we can get rid of migraines without having to go get my medical marijuana card and be hooked on that for a lifetime. I see this as a parallel avenue to that and I really like the idea that there is no name attached to it so maybe Jamestown and Fargo will get excited about it. I didn't want the idea to die, the idea is amazing.

Madam Chair Lee: I don't think anybody did, I think we just felt that what was being proposed was wrong.

Senator Anderson: Some hospital might say I would like to partner with the University of North Dakota and we use (inaudible) chambers.

Madam Chair Lee: Except those aren't the high intensity ones I don't think.

Senator Clemens: Senator Anderson mentioned, and I was thinking it earlier too. Let's say Jamestown. I know they are not involved with the high level brain injury but could they still do the study?

Madam Chair Lee: They could apply, but didn't we learn that those chambers that she is using are high intensity. It's a stronger concentration isn't that what she said? Senator K. Roers is shaking her head, well then I misunderstood that so they are all the same right?

Senator O. Larsen: The big difference with that is the concentration level in that eye chart thing, that is what they are using as the key. If the oxygen level and the pressure isn't quite there, then they stick them back in for an adjustment.

Senator Anderson: She expressed using that right eye coordination as her test. Now we don't say anything about that here. The researcher at the University of North Dakota might decide that is or is not a validation of success in this thing and of course if a researcher is going to do that, the right eye doc can't be associated with her clinic it has to be someone else, and she did mention that she would rather have an optometrist or ophthalmologist outside of her doing that right eye thing because she realized that when her employee is doing that it is questionable. The University of North Dakota wouldn't allow you to do that with your own person that you employ, it would have to be someone else doing that validation. I'm comfortable with the universities approach to this and I would be surprised if she ended up being the one.

Madam Chair Lee: Well the original draft did talk about the right eye in more details and Alex and I worked on that a little bit and I said we need to get that detail out of there.

Senator K. Roers: When I build policies for my workplace, we purposely don't use brand names so I remember in that bill thinking, this sounds like a brand name, granted its FDA approved but it made me think that so I'm glad that it isn't in this draft.

Madam Chair Lee: There was much more detail than the original one that had come out so. Any other discussion on the motion to amend?

Senator Clemens: Looking at this new bill here, it just refers to treating brain injuries so there is not a level here of what type of brain injury this has to go to. Earlier in the discussion we were saying that Jamestown doesn't do high level.

Madam Chair Lee: But the medical school gets to decide what level of intensity. That is why it's not there, it's an intentional thing unless you're not comfortable with that.

Senator Anderson: Obviously we pass it this way and if we get it passed on the senate floor, the conference committee may not agree and we may be in conference committee forever if they don't agree to that.

Madam Chair Lee: Appropriations may not agree with us in the senate.

Senator Anderson: They may not. Of course we don't say where the money comes from either, this is just general fund money now.

Madam Chair Lee: Jon Nelson told me that it was seven million in it at the beginning that is why they put it in there, everybody else wants it. I knew you would be logical and bring me back to reality. I think you would have been equally frustrated and annoyed with the incidents of the last 20 hours or so because it has been so inappropriate and ridiculous and the gossip and trash talk that was coming from the house was so absolutely unacceptable that why would they think that I would want to anything even the least bit cooperative and collaborative. It's only because I am surrounded by all these noble people now that have convinced me that I have to go forward with this because it's a good goal in the end so thank you, to the committee. Anyone else wants to talk before we vote on the amendment which includes the change to instead of "provides" to "receives"?

Senator Anderson: Before we proceed to the vote, do we need to make any change in the title of the bill based on the way.

Madam Chair Lee: Yes, we don't need to report to legislative management.

Senator Anderson: Ok, so whatever my motion is I will include fixing the title.

Madam Chair Lee: Everyone comfy with those changes?

ROLL CALL VOTE TAKEN
6 YEA, 0 NAY, 0 ABSENT
MOTION CARRIES TO ADOPT AMENDMENT.

Senator Anderson: I will move **DO PASS, AS AMENDED, AND REREFFER TO APPROPRIATIONS.**

Seconded by Senator Hogan

ROLL CALL VOTE TAKEN

Senate Human Services Committee

HB 1359

3/14/2019

Page 7

6 YEA, 0 NAY, 0 ABSENT

MOTION CARRIES DO PASS, AS AMENDED, REREFFER TO APPROPRIATIONS.

Senator Anderson will carry HB 1359 to the floor.

Madam Chair Lee closes the hearing on HB 1359.

March 14, 2019

Handwritten:
3/14/19
LOD

PROPOSED AMENDMENTS TO REENGROSSED HOUSE BILL NO. 1359

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to provide for a study of the efficacy of hyperbaric oxygen therapy; and to provide an appropriation.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. UNIVERSITY OF NORTH DAKOTA SCHOOL OF MEDICINE AND HEALTH SCIENCES STUDY- HYPERBARIC OXYGEN THERAPY. During the 2019 -21 biennium, the university of North Dakota school of medicine and health sciences may design and implement a study of the efficacy of hyperbaric oxygen therapy in treating brain injuries.

SECTION 2. APPROPRIATION. There is appropriated out of any moneys in the general fund in the state treasury, not otherwise appropriated, the sum of \$100,000, or so much of the sum as may be necessary, to the university of North Dakota school of medicine and health sciences for the purpose of a study of hyperbaric oxygen therapy, for the biennium beginning July 1, 2019, and ending June 30, 2021. The funds appropriated in this section may be spent only to the extent the university of North Dakota school of medicine and health sciences receives two dollars of matching funds from nonstate sources for each one dollar provided from the general fund."

Renumber accordingly

Date: 3/12/19
Roll Call Vote #: 1

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1359

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☐ Do Pass ☒ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar
Other Actions: ☐ Reconsider ☐ _____

Motion Made By Sen. K. Roers Seconded By Sen. Anderson

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee	X		Sen. Kathy Hogan	X	
Sen. Oley Larsen		X			
Sen. Howard C. Anderson	X				
Sen. David Clemens	X				
Sen. Kristin Roers	X				

Total (Yes) 4 5 No 1

Absent 0

Floor Assignment Sen. K. Roers

If the vote is on an amendment, briefly indicate intent:

Date: _____
Roll Call Vote #: _____

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1359

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment ☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☒ Reconsider ☐

Motion Made By Sen. Anderson Seconded By Sen. Hogan

[illegible]

Total	(Yes)	No
100	50	50

Absent

Floor Assignment

If the vote is on an amendment, briefly indicate intent:

Motion Carries

Date: 3/14/19
Roll Call Vote #: 2

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1359

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: 19.0646.04001

Recommendation: ☒ Adopt Amendment
☐ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar
Other Actions: ☐ Reconsider ☐

Motion Made By Sen. Anderson Seconded By Sen. K. Roers

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee	X		Sen. Kathy Hogan	X	
Sen. Oley Larsen	X				
Sen. Howard C. Anderson	X				
Sen. David Clemens	X				
Sen. Kristin Roers	X				

Total (Yes) 6 No 0

Absent 0

Floor Assignment _____

If the vote is on an amendment, briefly indicate intent:

Date: 3/14/11
Roll Call Vote #: 3

2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1359

Senate Human Services Committee

☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☒ As Amended ☒ Rerefer to Appropriations
☐ Place on Consent Calendar

Other Actions: ☐ Reconsider ☐ _____

Motion Made By Sen. Anderson Seconded By Sen. Hogan

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee	X		Sen. Kathy Hogan	X	
Sen. Oley Larsen	X				
Sen. Howard C. Anderson	X				
Sen. David Clemens	X				
Sen. Kristin Roers	X				

Total (Yes) 6 No 0

Absent 0

Floor Assignment Sen. Anderson

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1359, as reengrossed: Human Services Committee (Sen. J. Lee, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** and **BE REREFERRED** to the **Appropriations Committee** (6 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Reengrossed HB 1359 was placed on the Sixth order on the calendar.

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to provide for a study of the efficacy of hyperbaric oxygen therapy; and to provide an appropriation.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. UNIVERSITY OF NORTH DAKOTA SCHOOL OF MEDICINE AND HEALTH SCIENCES STUDY- HYPERBARIC OXYGEN THERAPY. During the 2019 -21 biennium, the university of North Dakota school of medicine and health sciences may design and implement a study of the efficacy of hyperbaric oxygen therapy in treating brain injuries.

SECTION 2. APPROPRIATION. There is appropriated out of any moneys in the general fund in the state treasury, not otherwise appropriated, the sum of \$100,000, or so much of the sum as may be necessary, to the university of North Dakota school of medicine and health sciences for the purpose of a study of hyperbaric oxygen therapy, for the biennium beginning July 1, 2019, and ending June 30, 2021. The funds appropriated in this section may be spent only to the extent the university of North Dakota school of medicine and health sciences receives two dollars of matching funds from nonstate sources for each one dollar provided from the general fund."

Renumber accordingly

2019 SENATE APPROPRIATIONS

HB 1359

2019 SENATE STANDING COMMITTEE MINUTES

Appropriations Committee Harvest Room, State Capitol

HB 1359
3/26/2019
Job # 34236

☐ Subcommittee
☐ Conference Committee

Committee Clerk: Rose Laning and Alicia Larsgaard

Explanation or reason for introduction of bill/resolution:

A BILL for an Act to provide for a study of the efficacy of hyperbaric oxygen therapy.

Minutes:

Attachments: 0

Legislative Council: Adam Mathiak

OMB: Stephanie Gullickson

Chairman Holmberg: Called the committee to order on HB 1359.

Former **Senator Pete Naaden:** Came in to the committee room for a visit.

(1:45) Representative Dick Anderson, District 6, Bottineau, Renville & McHenry Counties

This is pilot program for getting a study or data and hopefully getting insurance coverage for severe and moderate brain damaged individuals. The clinic in Fargo has been working with Blue Cross Blue Shield on getting a program for acute, which is minor concussions through sports related injuries. I am looking for a pilot project to get the data for severe to moderate brain injury victims that have probably been living with the injury for a series of years. The appropriation sum of \$335,000 would treat approximately 30 patients with 40 treatments. That is \$11,000 per person. Working with Dr. Denham, I have found out that she's treated people up to 10 times, 2 times a day. Some people have fully recovered. There are others who have more severe damage. I don't know how many treatments they would need. We basically put it up to 40 treatments for those individuals. I am not sure if you understand what hyperbaric treatment does. You're put into a chamber of pressurized oxygen. It will go up to two atmospheric pressures. They use a right eye brain scan function to monitor the results of the treatment. It's liked you have a clogged fuel line. You can start a diesel tractor up on idle. The only way to get the brain to function fully, would be to get the oxygen flow going back to the cells. It's like cleaning out the fuel line and making sure the fuel is flowing to the brain cells. In a brain injury, there is inflammation and a chemical reaction. In a lot of cases, the cells do not die. The oxygen flowing between the cells is restricted. Through this clinic in Fargo, they have found a way to get that airway open again. The results are amazing. We spend about \$10 M in Medicaid services and the Human Service Department per year in dealing with people who have had a brain injury. I am very positive that this would reduce

this quite a bit. I am just looking for a pilot project to get the data so we can prove the results. I do not know if people have any questions about the right eye exam or not.

(5:18) Senator Mathern: Thank you for your work on brain injury. The Senate committee amended this bill so that it no longer provides payment for treatment. It provides \$100,000 for the school of medicine to do research and attest to the outcomes of these treatments. I am wondering if you're asking the bill to be amendment or do you support it as is.

Representative Anderson: Dr. Denham has found a protocol that works. There are hyperbaric chambers all over the country. Over her years of research, she found one system that works. The way the language was, it basically leaves the door open to someone else. I want the language funneled through her clinic. I know, from talking to people on the federal level, that this is coming for the vets. It is a great opportunity for our state and the city of Fargo to have this there. I know it works. When I went to the clinic, I visited with the people who were getting treatment. I am sold on it. The way the language was changed in the Senate, this would open it up to someone else's protocol and I think we need to have a test where the results are positive.

(7:33) Senator Poolman: The bill was also amended to ensure that it is \$2 matching funds from not state sources for each dollar that is allocated. Does the University of North Dakota have partners in mind for the \$2?

Representative Anderson: I don't know. I was not involved with that amendment. I just went to appropriations on the House side and told them what I needed. They came up with this.

Bruce Murray, Executive Director, Association of Community Providers

My board has given me permission to volunteer with this effort. If this goes to conference committee, and any drafting or research ideas were to be necessary, I'd be most happy to assist. There might be ways to accomplish some of these goals through demonstration projects, vouchers, etc.

Representative Austin Schauer, District 13, West Fargo

I have been to clinic in Fargo twice. I visited between 15 and 20 patients. The results are phenomenal. The evidence is there and it will either push this forward, or it won't. I would highly recommend that we go with the pilot program. I was very disappointed with what the Senate Committee did. We need to go forward with this pilot program.

Chairman Holmberg: You are confident that if we pass this and it goes to conference committee, those rough edges would be able to be smoothed out?

Representative Schauer: There are some rough edges, as you know. This is an opportunity for us to help people. I think we all know someone with an adolescent who has undergone a concussion. This treatment that Dr. Denham has come up with is helping people.

Senator Wanzek: You said you were visiting with patients and their families. What is a common cost for people to get this hyperbaric service?

Representative Schauer: With help of the trainer and the Dakota Medical Foundation, along with a Gary Tharaldson, for adolescents, the cost is zero. For adults, it is about \$250 - \$270 a session. Each session is about 45 minutes in which you go into the chamber. The effects are like you are landing in an airplane and you're yawning.

Senator Wanzek: We've come a long way in recognizing the significance of a head trauma. Back in my day, they just rubbed some salts on your nose and told you to get back in there.

Senator Robinson: We have folks in my district who have contacted me on this bill. My wife also went to Fargo visited the clinic. We had friends who had a son with multiple concussions and they were doing everything to save their son. They lost him. They were here a few weeks ago when the bill was on the House side. They are pleading with us to give this pilot a chance. They are convinced that this might have saved their son. Thank you, Representative Anderson, for your work on this bill. I think there is potential here. We owe it to the folks who are searching and struggling for an answer.

Representative Schauer: I talked to a Navy veteran. He was to the point of suicide in September of 2018. He underwent treatment in October and for the next two months he said it's night and day. How can we walk away from people like that?

Senator Poolman: Do we have a history of doing this for other conditions? What is the history of picking a condition and paying for people's treatment and using that as a data collection type of pilot?

Representative Anderson: I cannot answer that. You have a couple suggestions where it's been done before.

Bruce Murray: During the time I worked with protection and advocacy, there were legislations for Russell Silver syndrome. There were some supplemental food therapies that were very disease specific that were emerging treatments at the time. Those were funded successfully. There is some precedent for it. I think there are other ways to do it that aren't quite so experimental. It can be more of a demonstration project or a voucher system that could be worked out in a conference committee.

Representative Anderson: I have some information on the cost of a treatment and other things that could be provided. They are in my iPad and need to print them out.

Senator Dever: I am not sure to what extent hyperbaric treatment is delivered elsewhere in ND. I understand there was a doctor here in Bismarck that did it several years ago. It seems to me that a study may yield results that already exist. If they exist, then why do we need the pilot program rather than just taking the information that already exists and advance the argument that there should be some coverage of it?

Representative Anderson: Hyperbaric has been around for many years. The protocol that Dr. Denham was partially by accident. It is different than anyone else's. She is currently working with an insurance company and they are going ahead with the protocol. They wanted her to release her protocol and she is protective of it. She spent 3-5 years on it. I sat in a chamber for a while and it is like going up and down in an airplane. They use the right eye

brain function exam and they figure out the pressure point and the times it triggers the brain to start working again. There was one gal who took two treatments a day after she was in an accident. She started on a Monday and by Wednesday, she said she could tell she is feeling better. By Friday, she said she was the best she has felt in a 11 years. Instead of working part time, she's working almost full time now. With the right eye brain function data she uses, they come in with a concussion and they have them draw circles in a horizontal line. A person with a concussion can usually not do that because their eyes are not working together. After treatment, they are able to have a vast improvement over what their first test was. After 2-3 days of treatment, there are dramatic results. After this treatment, the majority of kids are back in school within a week. I know it's been around for years, but she's found a system that works.

Senator Dever: I can understand her being protective of her protocol. If we're being asked to provide money to create a pilot program using that protocol. Is she going to extend that to others?

Representative Anderson: Her goal is to get this going so it is an option to treat. She just hopes she can be a consultant and wants to get her protocol established in other areas. When she handles a patient, you can tell in her eyes that she wants this to move forward. It's not about her. It is about her protocol being used.

Chairman Holmberg: Anyone else looking to give us further information?

Chairman Holmberg: Closed the hearing on HB 1359. We can sit on this or pass it so it can go to the conference committee to iron out the rough edges.

Senator Wanzek: Moved Do Pass on HB 1359.

Senator Bekkedahl: Seconded the motion.

**A Roll Call Vote Was Taken: 14 yeas, 0 nays, 0 absent
Motion Carried.**

The bill goes back to the Human Services Committee and Senator Anderson will carry the bill.

Date: 3-26-19Roll Call Vote #: 1

**2019 SENATE STANDING COMMITTEE
ROLL CALL VOTES**
BILL/RESOLUTION NO. 1359

Senate Appropriations Committee☐ Subcommittee

Amendment LC# or Description: _____

Recommendation: ☐ Adopt Amendment
☒ Do Pass ☐ Do Not Pass ☐ Without Committee Recommendation
☐ As Amended ☐ Rerefer to Appropriations
☐ Place on Consent Calendar
 Other Actions: ☐ Reconsider ☐ _____

 Motion Made By Wanzek Seconded By Bekkedahl

Senators	Yes	No	Senators	Yes	No
Senator Holmberg	✓		Senator Mathern	✓	
Senator Krebsbach	✓		Senator Grabinger	✓	
Senator Wanzek	✓		Senator Robinson	✓	
Senator Erbele	✓				
Senator Poolman	✓				
Senator Bekkedahl	✓				
Senator G. Lee	✓				
Senator Dever	✓				
Senator Sorvaag	✓				
Senator Oehlke	✓				
Senator Hogue	✓				

Total (Yes) 14 No 0Absent 0Floor Assignment Human Services - Anderson

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

HB 1359, as reengrossed and amended: Appropriations Committee (Sen. Holmberg, Chairman) recommends **DO PASS** (14 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). Reengrossed HB 1359, as amended, was placed on the Fourteenth order on the calendar.

2019 CONFERENCE COMMITTEE

HB 1359

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee Fort Union Room, State Capitol

HB 1359
4/11/2019
34721

☐ Subcommittee
☒ Conference Committee

Committee Clerk: Nicole Klamann

Explanation or reason for introduction of bill/resolution:

A BILL for an Act to provide for a study of the efficacy of hyperbaric oxygen therapy; and to provide an appropriation.

Minutes:

--

Chairman Anderson: Opened hearing

Senator Lee: We had no objection to effective treatment as a result of hyperbaric oxygen therapy, that is not the problem here at all. The constitution in a limited law provision does not permit state money to be given directly to any entity. I thought I had a copy in my desk drawer and didn't so I will make sure you get a copy.

This is why I've visited with a variety of people including Dr. Josh Winn at the medical school and he understood that as well. He suggested away that we could do this. Instead, give money to the University on a research project on hyperbaric oxygen therapy and having a supervising physician, an oversight by someone to be a neutral party. They may then see to it that the research being done the way it needs to be for proper consideration for grants. Also, visiting with majority leader Wardner and appropriations chair Homberg they thought the way to do it was \$100,000 in state money with a 2 to 1 private match. I visited with Pat Trainor several times with Dakota Medical Foundation and I know he's firmly behind this as well. In concept, we are as well but financing is the issue. It's not the therapy, it's the financing. Also, we found other grants which the application to be made but it's got to be in the proper form.

He suggested money to the University They thought the way to do it was 100,000 state money with a 2 to 1 match.

Chairman Anderson: Do you understand my bill or the way it was wrote?

Senator Anderson: I don't know that we have questions however to take state money and pay for any form of medical treatment for anyone is different than what we use to do. We have autism vouchers, we have brain injury vouchers, all of which you have to qualify for to pay for your care under Medicaid or whatever else. It would be very unusual for us to take a

pot of money and say we are going to directly pay for care for anything. Regardless of whether it works or whether it doesn't. It might even be an approved therapy, that we know works. We still are not going to take money and pay for it directly. That's where we are coming from.

Chairman Anderson: Senator Anderson, I guess I have a slight disagreement with that. We fund the Dept. of Commerce a huge amount of money every session and they end up funding projects all over. So I don't think this is really unique in doing that.

Senator Roers: Representative Anderson, we are funding the Dept. of Commerce and they decide but I think the problem with this is there is no one else that could even apply for the money. It's one person that is even eligible. Whereas the Dept. of commerce will put out a call for a request for proposal to decide how to divvy out the money. I think this is the challenge here, talking about 1 provider.

Chairman Anderson: I will agree, we are talking about one provider but her data which I gave to you and she continues to collect it. Whatever she's doing works well and I'm not sure anyone else could do it with her protocol, this is why I wanted to funnel the study to her.

Senator Roers: We've only heard the good stories.

Chairman Anderson: I provided some information for your review. I've heard cases of people saying it didn't work, but she may not have been given all the data.

Senator Lee: Then she would be the only person to qualify for the University of ND Medical School and Research when they call for proposals. In which case, it would be a scientifically supervised properly done research project. We don't also know the long term impacts. It doesn't matter to me what the science or the data is. I'm talking about the process and want to do it correctly. The process has to be done the way proper medical research is done.

Chairman Anderson: Currently the money goes through Dakota Medical Foundation, they handle the grant.

Senator Lee: But that is private, I don't care what you do privately.

Chairman Anderson: Is that a problem sending the money through the Dakota Medical Foundation?

Senator Lee: We can't give money to Dakota Medical Foundation either. Unless it's made available to everybody. Constitutionally this is inappropriate.

Chairman Anderson: I've been told numerous times that money has been issued to fund studies.

Senator Lee: They can do whatever they want Representative Anderson, we can't constitutionally have tax dollars going directly to an entity. We do not fund direct care for diabetics. The other important thing, we have insurers who are very interested in seeing

what is going on but they cannot look at reimbursing any of this treatment for anybody of their insured and same with Medicaid if we don't have the proper longitudinal studies type proposals in order to have proper research project. Which can be done through that UND proposal. I would think they would be happier not being involved with a state project to avoid the who gets how much of what ever conversation.

Senator Anderson: If this were a Dept. of commerce program to do medical research for business developments, then I could see or maybe we could give grants for business development. The problem I have is paying for funds directly. Let me give you a quote I have a fellow in my church coffee every Sunday morning. His grandson went to this clinic and they provided him a free hyperbaric oxygen treatment as a result of a concussion he got in wrestling. He thought it helped, at least short term, obviously there was only short term after the thing happened. I said to that constituent, "So then the State of ND spend money to fund those treatments directly?" He said, "Of course not!" and that's kind of the way I feel about it.

Chairman Anderson: Senator Anderson, I've talked to Dr. Denim several times about the cases where the data wasn't there. Some probably had more than one concussion and some of them received 1 treatment and left. So it's not a thorough test. The one's that have gone there several times and had the recommended treatments have done very well.

Senator Anderson: Here I want to reinforce what Senator Lee said; we are not talking about a treatment and whether it works or whether it doesn't. We are talking about what ND should be doing with people's money. We feel like paying directly for care for somebody in these situations, whatever the ailment or treatment is, is not appropriate way to go about it.

Rep Schneider: Did the Senate explore the possibility of a pilot project or some of the things we see within the Dept. of Human Services where money goes to a nonprofit organization such as Dakota Medical foundation might be to have a pilot project on brain injury and treatment for it. Would that be a possibility to explore? How do we get money to 211 for instance. It's thru Human Services to a nonprofit entity to run a particular program that nobody else runs.

Senator Lee; The 211 example is where there are criteria that have to be met and it's a contract, providing after hours call answering for example. Everybody within the state that makes a call to 211. It's no different than any other approved provider that has a contract to provide those services. Whether it's an intermediate for SIIF Facility and it's no different from any approved provider that is qualified for reimbursement that has a contract to provide those services. This doesn't qualify, it hasn't gone through that. Let's go back to FDA research levels. If when looking at a drugs, they are doing their lab work. A petri dish process, then it moves to animals, then it moves to healthy adults, then it goes to adults or children that have the condition. There is a protocol that is important in this whole thing. I think the enthusiastic support you have already for Dakota Medical Foundation, would provide far fewer strings but will have a hard time using taxpayers money. The Dept. of Human Services does not entertain grant opportunities. They have particular services that have to be done, they write up what it takes to do that and the people that want to do it will offer their services. First Lake is the only one in the case of 211 then that is the one who is likely to get the contract.

Chairman Anderson: I did try to go through Medicaid to start with. The amount of money needed, I had no chance. So I went back to find the minimum amount to get the insurance data was needed for moderate to severe concussions. Dr. Denim is working on acute, all the data shows it works. I'm trying to get the moderate to severe part of the equation. I don't have a problem going through UND Medical School, but I want the money to be funneled through Dakota Medical Foundation and I'm up front about that, and get to Dr. Denim. What she is doing appears to be working better than what anyone else is doing.

Senator Roers: I think the challenge we have is the goal where this can become FDA approved and sent through insurance. Sending it through a proper research study, she will get accreditation the correct way and then the ability to help so many more people. We are trying to help her, we are not here trying to hurt this research project. We trying to make it work and have the a credibility to be able to help so many more people by doing it in a valid research methodology.

Chairman Anderson: If we went through the Dakota Medical Foundation, what is the time frame to get the information collected? I know I was told yesterday that she can't get any more people in there than she has now. They are going to expand that place greatly. It's the people that believe in it and I don't think they would be coming back if it didn't work.

Senator Roers: I apologize upfront as my next question may sound rude, but does she really need our money?

Chairman Anderson: She's only testing acute. She needs a group of people that have had concussions for a number of years. So that is the data she's working for. I'm not working with any of the acute cases. I'm trying to get the data. A lot of people with concussions are on Medicaid. I know a couple in Rugby that can't go there because they don't have the money. Right now we spend a lot of money per year on head injuries and this would reduce it.

Senator Roers: The intent behind my question was really to say, if she doesn't have capacity to care for any more patients, we could give her all the money in the world and that doesn't change her capacity.

Chairman Anderson: The capacity is coming. Right now ND spends ten million dollars a year on head related injuries and services and I know this would reduce it by half. I could go through UND Medical School but Pat Trainor is used to working on this and I would like the money to go through Dakota Medical Foundation and that is how it's worded.

Senator Lee: Of the 2 million Mr. Therelson is giving, at least 1.3, by the assets of her clinic they will be providing this care. They will assemble this data because right now it's the equivalent of an electronic shoebox because she is so busy. The process needs to be followed, better outcomes for the patient. It takes some time to get to the 4th quarter of the football game.

Chairman Anderson: I know she's had issues with the data, however she's upgrading that now.

Senator Lee: Then she will be ready to go and able to apply for other grants. Pat has told me we are going to help her with the data and grant applications. Then everything will fall into place but not overnight. This way all the insurers and Medicaid will cheerfully pay for better outcomes for the patient, lower costs in the treatment and ultimately everybody wins.

Rep. Schneider: Why was the money cut down and additional barriers added, two for one match?

Senator Lee: Appropriations was never going to approve the original amount. We had to have the match and go through the medical school in order for it to go through the Senate.

Chairman Anderson: I'm committed to this and will find a way.

Chairman Anderson: Closed meeting

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee Fort Union Room, State Capitol

HB 1359
4/16/2019
34779

☐ Subcommittee
☒ Conference Committee

Committee Clerk: Nicole Klamann

Explanation or reason for introduction of bill/resolution:

A BILL for an Act to provide for a study of the efficacy of hyperbaric oxygen therapy; and to provide an appropriation.

Minutes:

Chairman D. Anderson: Opened the Conference committee hearing on HB 1359. I've been involved with traumatic brain injury since 2011. I've worked with several people who have suffered, one you met Hannah Anderson. There are several others as well, you've not met. When I first got involved with Hyperbaric, I asked to go through the facility. I talked to a bronc rider, he said he'd been kicked in the head so many times he could no longer stay at his ranch without a treatment. Explained other situations. They all seemed to show great improvement. This started when an individual I worked with didn't have insurance and that is what got the ball rolling. I've been accused of being a part of the clinic, and I am not. I know you don't like the funding mechanism in this. It's in Appropriations on the house side in SB 2012. Any comments?

Senator J. Lee: I think we've made it clear since the beginning, we are not saying this is an effective treatment. The appropriate thing is to make sure that the information is put together in an appropriate scientific manner so that the insurers including Medicaid are willing to support it. They are watching this. The whole program ought to be moving towards that kind of approval. There isn't any question we are anxious to see how this will work. We hope it will work for everyone in the best way possible. However, the Appropriations group is done with it on our side. They would not look at anything over \$100,000 in the match with a program that went to the Medical schools. With a \$2 million grant and less interest in providing additional state money. It would be at the most \$100,000 with a 2-1 match and done through the medical school as done in the original proposal. The research must be done in order for it to be proper.

Chairman D. Anderson: I agree, get the data so the insurance accepts it. As far as the money amount goes, I tried for the minimum amount of money that would work to get the data. Maybe it is not the proper way to fund it but I had no other way to fund it. I tried to go through Human Service budget, and that didn't work. Maybe I would have been better off

going to the Department of Commerce. Now this late in the process, I am going to have to do what I'm going to do. It will go to Appropriations. I know Rep. Tveit is being treated for West Nile virus and she is improving. This works, I know it works.

Senator J. Lee: I am not trying to speak for my colleagues.

Rep. D. Anderson: I know we have to have the data, that was the whole purpose going here is to get the insurance company to cover it. I think we spend \$10 million a year on traumatic brain services and I don't see that we get much benefit from it. Why we don't try to fix the problem and hopefully we would save money there. I would like to see having a good policy, better outcomes and save money and I think this will do it so that is why I am pursuing it.

Senator Anderson: My feelings are pretty much the same as Senator Lee's. No problems with the treatment or outcomes and no question it works in many cases. The problem lies in the funding of this, and we do not fund them directly. The way it was in the Senate it sounded like there was some private donors who would step up through the University of North Dakota and the study that would reach the research criteria that they would set is the best way to get it published. Once it is published like other studies has been it begins to get the insurance companies to pay for it as a regular treatment. We did not see in the Senate that they had the data together or the institutional review board to get things ready.

Chairman D. Anderson: In that hearing the last thing I heard was 11:30 am the Senate requested some data and we agreed to get you some data but you voted a do not pass out of the committee on the same day.

Senator J. Lee: We voted on it right away not because of the data not being acceptable but because of the funding mechanism here. Not whether or not it works. There are a lot of people that are interested in this. There is a process. The insurance and Medicaid, CMS, aren't going to approve it because we think it is a good idea it has to be done because there is process that is followed. We thought with UND being involved we thought was a good recommendation. We altered it and changed it. I don't recall a do not pass. What we sent to you was with UND and \$100,000 and a 2-1 match because that what Appropriations said they would do. It still can be put together to make this acceptable to the payers. It is a bad idea to be sending money directly to any individual for any particular cause.

Chairman D. Anderson: That may be correct but I know we have done it numerous times. Such as in the oil business we sent some for pipeline studies. It's on the record.

Senator J. Lee: But it is not a medical thing. It is different for medical procedures. It doesn't go to an individual where this is talking about giving money directly to a physician. This is an enormous Pandora's box, never mind the constitutionality. Funding directly to an individual for any cause, we cannot be going there.

Chairman D. Anderson: I understand your point. However, I do believe we should be a leader in the state especially with the Congressional delegation coming to Fargo next week.

Rep. Schneider: In both of your discussions can we conceive any idea to marry a research component to Dakota Medical Foundation.

Senator J. Lee: I visited with Pat Traynor, Dakota Medical Foundation and they understand the importance of that. His board is primarily physicians and business people who are connected and they get it. That is a good involvement and they are very supportive of exploring this opportunity. But I think it's way better to stay at the private side than government involvement.

Rep. Schneider: Is there a way that the Dakota Medical Foundation could pull in a research component rather than go through UND?

Chairman D. Anderson: They will go through UND, I already talked to them about that. I know how important the data is. My whole goal here is to get the insurance companies get on board.

Senator Roers: You say there is no problem going with UND. So where is the problem now?

Chairman D. Anderson: To make sure the research goes through Dr. Denham's clinic because her protocol is working best.

Senator Roers: From what I understand, she's the only one that qualifies. So I'm struggling to see where the disagreement is. I feel we are more on the same page than before. What change could be made from the way the Senate passed it out that would make you feel more comfortable with this?

Chairman D. Anderson: I would have to just look for money and investors. I have a hard time asking people for money when I think the state should show some leadership here.

Rep. Devlin: Is there any chance the Senate would increase the \$100,000 to a more acceptable level for the House? Would the Senate increase that to \$250,000?

Senator Anderson: I have no problem with trying an increased amount but Senator Lee is the one that went before the Senate Appropriations committee with this.

Chairman D. Anderson: Then if we get close I will talk to Pat Traynor and others to get the money. Any way we can make it work that is what I want to do.

Senator J. Lee: What are they doing with the \$2 million?

Chairman D. Anderson: The way it was set up it originally it got \$335,000 she thought she could treat 30 patients up to 40 treatments. That is what it was based on and it was about \$11,000 per patient is what the funding was. I do believe in Hanna Anderson's case she only had 10 treatments. So Dr. Denham may be able to treat 60 or 70 patients with that amount of money.

Senator J. Lee: And you don't see the problem with the money going into treatments and not putting some of it into what we are talking about here.

Chairman D. Anderson: No, the data has to go to the UND Medical Foundation. I did ask Dr. Wynne how much it would cost and he didn't know exactly what they would need. He does want us to come down and visit with him.

Senator Roers: If we went to Appropriations with half of the \$335,000 that was in there originally and would just have a 1-1 match instead of a 2-1 match. That would be \$167,500. Would that be better?

Chairman D. Anderson: \$200,000 would be better and then it would be easier to get the rest of it. Talk to appropriations and see what you can come up with.

Senator Anderson: I am willing to make a motion that we would change the dollar amount and leave everything else the same. I make a motion to say that the Senate would recede and further amend to \$200,000.

Rep. Devlin: Seconded.

Senator Roers: I wonder if we don't want to word that as not to exceed 200,000 with a 2 to 1 match. So if they don't get an exact \$400,000 match they can still go up to the whatever the match is or they needed. Once UND finds out what it will cost them it might change the parameters to what it would cost to conduct a study.

Chairman D. Anderson: I will have to try to get a matching amount for whatever they need to cover their data collection from grants hopefully. The way it is now it says the sum of \$100,000 or so much of the sum as necessary so it is already there. We just are changing it from \$100,000 to \$200,000. Any further discussion?

Roll call vote for the Senate recede from Senate amendments and amend from \$100,000 to \$200,000. **Yes 4 No 2 Absent 0.**

Motion fails.

Senator Roers: I can make a motion to accede and further amend to \$150,000 instead of \$200,000. Motion dies for lack of a second.

Chairman D. Anderson: We could meet again.

Senator J. Lee: I would like to see another meeting and see if we can find another pathway here. Maybe we could explore a voucher program to help people who cannot afford this treatment and be able to access Dr. Denham's system.

Senator Roers: one of the differences I see between the current programs that we have and the ones you are proposing is they are all generally medically accepted treatments and this is not. I think we need to get this concept that we have seen benefit people be generally medically accepted and then vouchers may be a conversation down the road.

Senator J. Lee: Could there be a pilot medical project on this?

Senator Roers: I believe the chairman tried to do all of those routes and none of those were available for this program.

Chairman D. Anderson: People who have traumatic brain injury are not at the same level at getting services as someone with a disability. They are in a category all by themselves and I was talking with some people and they just don't know what to do. If we could get them treated maybe it wouldn't be an issue. There are a lot of families out there with no place to go. We will meet again. Meeting adjourned.

2019 HOUSE STANDING COMMITTEE MINUTES

Human Services Committee Fort Union Room, State Capitol

HB 1359
4/17/2019
34819

☐ Subcommittee
☒ Conference Committee

Committee Clerk: Jeanette Cook by Donna Whetham

Explanation or reason for introduction of bill/resolution:

A bill relating to program management for residents of the life skills and transition center and regional crisis support services for individuals with an intellectual or developmental disability; relating to the assessment of intellectual or developmental disabilities; and to provide for a report to the legislative management.

Minutes:

--

Rep. D. Anderson: Opened the Conference Committee on HB 1359. Yesterday we were talking about adding additional money. Did you come up with a figure or anything you wanted?

Senator J. Lee: I did visit with someone in Appropriations and I don't think we will be getting any more money. With the \$2 million dollars and other support they should be able to make it. It would move along much more quickly than if the state is involved.

Rep. D. Anderson: I did talk to Pat Traynor and he isn't enthused about getting grant money and I talked a few people from the insurance industry and they are still trying to get more data from Dr. Denham. I think the big hang up is over protocol. This will go to the appropriations committee and we will probably have to go from there.

Rep. Devlin: I don't think we will settle this anywhere between here so I will move that the **House accede to the Senate amendments on HB 1359.**

Rep. Schneider: Seconded.

Roll Call Vote: Yes 5 No 1 Absent 0. Motion carries.

House carrier is Rep. D. Anderson. Senate carrier is Senator J. Lee.

Rep. D. Anderson: Meeting adjourned on HB 1359.

Date: 4/16/2019
Roll Call Vote #: 1

**2019 HOUSE CONFERENCE COMMITTEE
ROLL CALL VOTES**

BILL/RESOLUTION NO. HB 1359 as (re) engrossed

House Human Services Committee

- Action Taken** ☐ **HOUSE accede to Senate Amendments**
☐ **HOUSE accede to Senate Amendments and further amend**
☐ **SENATE recede from Senate amendments**
☒ **SENATE recede from Senate amendments and amend as follows**
- ☐ **Unable to agree**, recommends that the committee be discharged and a new committee be appointed

Motion Made by: Senator Anderson Seconded by: Rep. Devlin

Representatives	4/11	4/16		Yes	No		Senators	4/11	4/16		Yes	No
Chairman D. Anderson	h	h		X			Senator J. Lee (Chairperson)	h	h			X
Rep. Devlin	h	h		X			Senator Anderson		h		X	
Rep. Schneider	h	h		X			Senator Roers	h	h			X
Total Rep. Vote				3	0		Total Senate Vote				1	2

Vote Count Yes: 4 No: 2 Absent: 0

House Carrier _____ Senate Carrier _____

LC Number _____ of amendment

LC Number _____ of engrossment

Emergency clause added or deleted

Statement of purpose of amendment

To amend to increase \$100,000 to \$200,000.

Motion failed.

Date: 4/17/2019
Roll Call Vote #: 1

**2019 HOUSE CONFERENCE COMMITTEE
ROLL CALL VOTES**

BILL/RESOLUTION NO. HB 1359 as (re) engrossed

House Human Services Committee

- Action Taken** ☒ **HOUSE accede to Senate Amendments**
☐ **HOUSE accede to Senate Amendments and further amend**
☐ **SENATE recede from Senate amendments**
☐ **SENATE recede from Senate amendments and amend as follows**
- ☐ **Unable to agree**, recommends that the committee be discharged and a new committee be appointed

Motion Made by: Rep. Devlin Seconded by: Rep. Schneider

Representatives	4/17			Yes	No		Senators	4/17			Yes	No
Chairman D. Anderson	x				X		Senator J. Lee (Chairperson)	x			X	
Rep. Devlin	x			X			Senator Anderson	x			X	
Rep. Schneider	x			X			Senator K. Roers	x			X	
Total Rep. Vote				2	1		Total Senate Vote				3	0

Vote Count Yes: 5 No: 1 Absent: 0

House Carrier Rep. D. Anderson Senate Carrier Senator J. Lee

LC Number _____ of amendment

LC Number _____ of engrossment

Emergency clause added or deleted

Statement of purpose of amendment

Motion carried.

REPORT OF CONFERENCE COMMITTEE

HB 1359, as reengrossed: Your conference committee (Sens. J. Lee, Anderson, K. Roers and Reps. D. Anderson, Devlin, Schneider) recommends that the **HOUSE ACCEDE** to the Senate amendments and place HB 1359 on the Seventh order.

Reengrossed HB 1359 was placed on the Seventh order of business on the calendar.

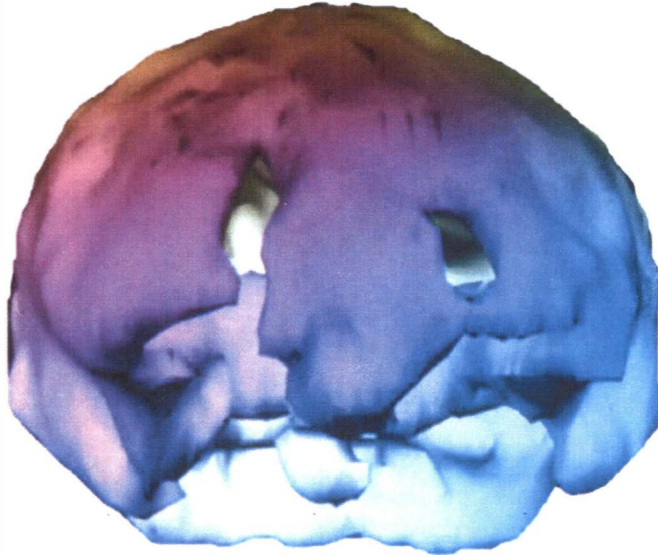
2019 TESTIMONY

HB 1359

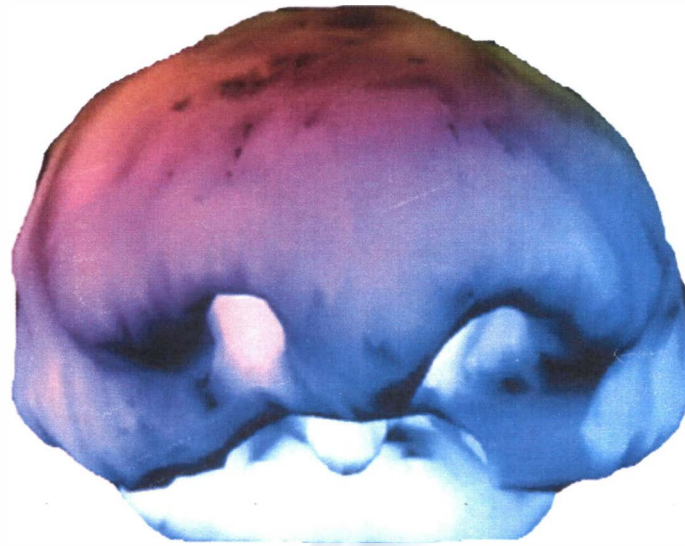


Non-Healing Wound of the Brain

Physical Abuse - 9 years after Injury - 21 y. female



Pre-HBOT 1.5



Post-HBOT 1.5

No wound will heal without oxygen!

What is the difference between the diabetic non-healing foot wound and the non-healing brain injury? Essentially nothing. FDA has already approved HBOT for 3 kinds of non-healing wounds and 3 neurological injuries!

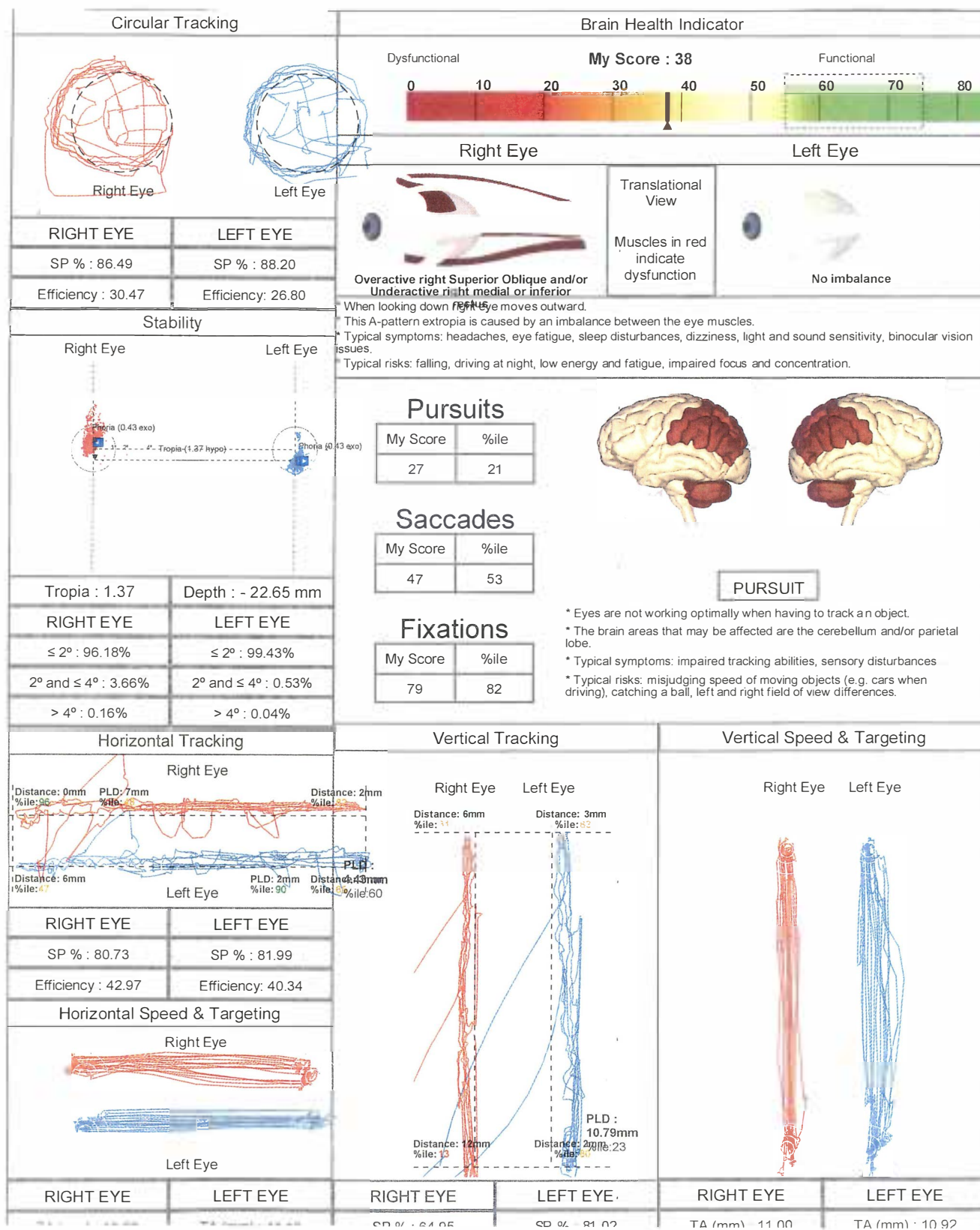
HB 1359 A#1 pg. 1
Y16/19



HB 1359
Att 1 1/16/19 pg. 2

31 year old SIX years out from multiple concussions. Suicidal.
He was tearful when we discussed how bad his brain-eye function was, but HBO can help.

Repeat RightEye was 18 days later, after 20 HBO treatments. His brother was tearful over the repeat as he had seen the improvements and willingness to live and be involved in life again.



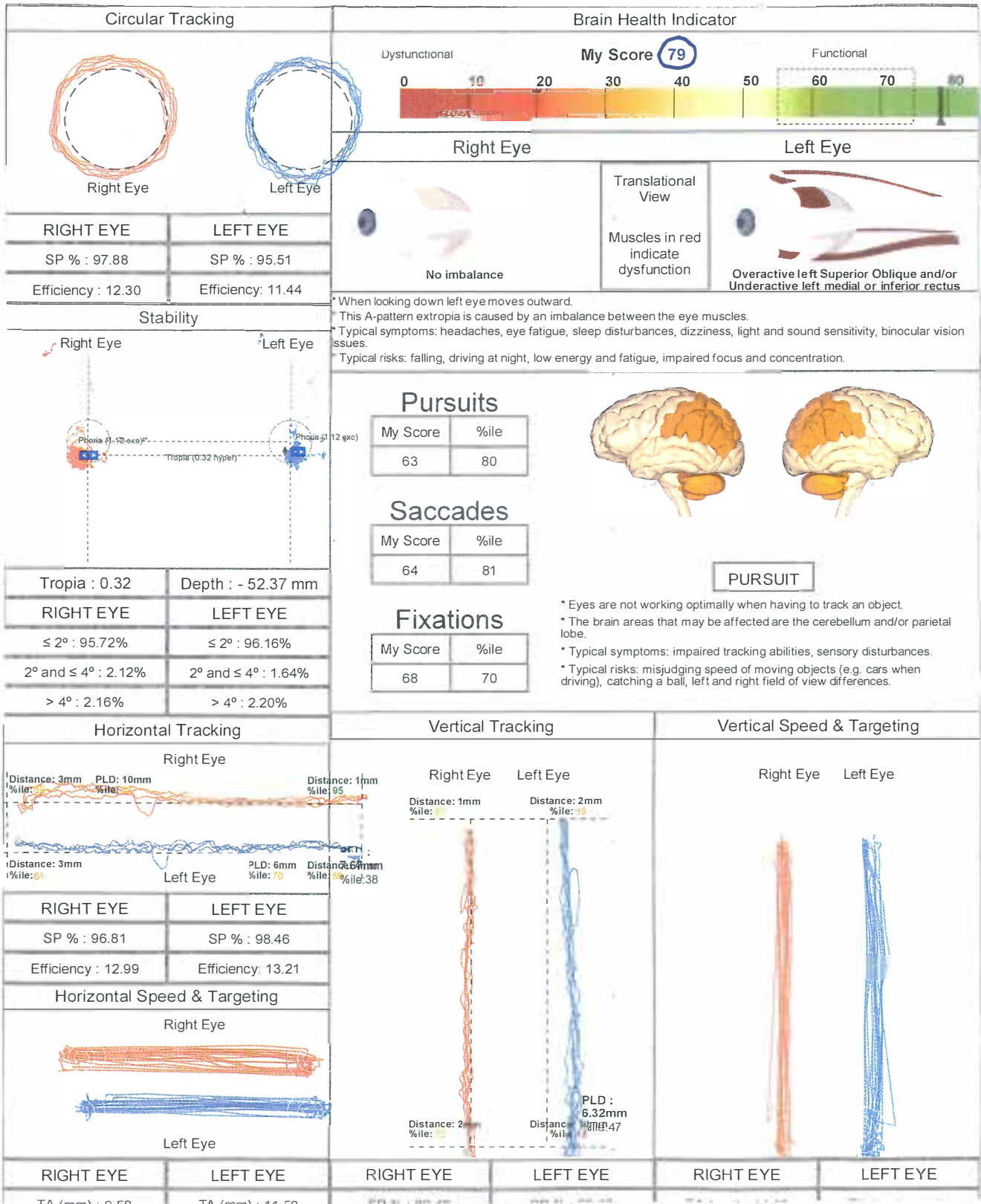
HB 1359
1/16/19
A+1 Pg. 3



LESSONS LEARNED: Even 6 years later, HBO can help.

Three weeks and twenty treatments saved the life of a very capable person.

Many people have better than "Functional" brain-eye coordination.



pg 3

HB 1359
A# 1
1/16/19

Budget:

HBO treatment using acute concussion protocol

G0277	\$85(2)	\$170
-------	---------	-------

99183	\$107	<u>\$107</u>
-------	-------	--------------

\$277 per tx (Medicare rate)

20-40 treatments @ \$277 is \$5,540 - \$11,080

30 patients, 20-40 treatments each patient

\$166,200 - \$332,400

HB 1359

Att'

1/16/19 pg. 5

Cost to Patient

Each 15 point IQ increase translates to about \$20,000 in income.

Persons who suffer from a single mTBI have a **future lifetime income loss of 50%.**

(Matched to themselves and their non-injured counterparts, matched for education, intelligence, etc., Gamboa, Chicago School of Economics)

45% will be unemployed 2 years post injury

33% will have "anger" issues rising 56.7% with co-morbid depression.

14.9% will become substance abusers.

H B 1359

1/16/19

AH1

Pg. 6

Safety

HBO is a safe procedure.

The United States Air Force School of Aerospace Medicine did a longterm follow-up study of 563 patients, each of whom had more than 20 daily HBO therapies of 90 minutes of oxygen breathing at 2.4 ATA. The follow up period was six months to eight years. *No chronic or late effects due to HBO were seen.* Cataracts occurred in only two patients (a poorly controlled diabetic and a 67 year old man on high dose steroids).

Diversified Clinical Services did an analysis of adverse events in all their centers for 2009-2010. They examined 340 hospital-based outpatient wound centers, 89% treating only FDA approved indications.

Monoplace Chamber Adverse Events Associated with Hyperbaric Oxygen Treatment (Tx)

	Total events in 2 years	AE per 10,000 Tx
Number of treatments	463,293	
Complications	1870	40
Ear Pain	928	20
Confinement anxiety	407	8
Hypoglycemic event	244	5
Shortness of breath	112	2
Seizure	88	2
Sinus Pain	66	1
Chest pain	25	1

Split by year:

In 2009 there were 916 adverse events reported for 207,479 treatments in 7,871 patients, rate **0.44%**

In 2010 there were 954 adverse events reported for 255,814 treatments in 9,396 patients, rate **0.37%**

Pg 6

HB 1359 AH1
1/16/19

Incidence of the 10 Most Common Complications (in Surgical Patients)

Complication	No. of Patients Affected	Incidence, %
Death	128	2.70
Other miscellaneous	101	2.17
Wound Infection	88	1.89
Readmission	74	1.59
Urinary tract infection	65	1.40
Pneumonia	60	1.29
Dysrhythmia or arrhythmia	55	1.18
Other gastrointestinal complication	52	1.12
Other vascular complication	40	0.86
Respiratory failure	37	0.79

<https://jamanetwork.com/journals/jamasurgery/fullarticle/212419>

The Polemics of Hyperbaric Medicine

Richard A. Neubauer, M.D.

William S. Maxfield, M.D.

Early History

The history of modern hyperbaric medicine dates back to around 1620, when Drebbel developed a one-atmosphere diving bell. Forty years later, Boyle and Gay-Lussac formulated the General Gas Law.

The modern age of hyperbaric medicine began in 1937, when Benke and Shaw used a hyperbaric chamber to treat decompression sickness (DCS).

It was not until 1955 that interest awakened in using hyperbaric oxygenation therapy (HBOT) for conditions other than DCS. That year, Churchill-Davidson began to use oxygen therapy in a hyperbaric chamber to treat radiotherapy-induced damage in cancer patients. In 1956, Boerema of Holland performed the first reported heart surgery in a hyperbaric chamber. In 1962, Sharp and Smith of Scotland were first to treat carbon monoxide poisoning by HBOT. In 1965, Perrins in the United Kingdom showed the effectiveness of HBOT in osteomyelitis. In 1966, Saltzman et al. in the United States showed the effectiveness of HBOT in stroke patients. In 1970, Boschetty and Cernoch of Czechoslovakia used HBOT for multiple sclerosis. In 1971 Lamm of West Germany used HBOT for treatment of sudden deafness. In 1973, Thurston showed that HBOT reduces mortality in myocardial infarction.¹

The Undersea Medical Society was formed in the United States in 1967, and added hyperbaric to its name in 1986.

Forgotten Breakthroughs

Most physicians have never heard of these breakthroughs. HBOT has been called the Cinderella of modern medicine. With no large pharmaceutical interest to nurture and protect it, hyperbaric medicine languished.

Since it was not taught in medical schools, knowledge about HBOT was restricted primarily to the fields of diving and aerospace medicine—small niches in the medical community. Even the simple fact that pressure increases the concentration of oxygen in tissues is not widely appreciated. There are no pharmaceutical representatives to offer “free” Continuing Medical Education on the gas laws. In addition, HBOT reaches across all medical specialties and doesn’t readily fit into one of the compartments into which medicine has been balkanized since the end of World War II.

In the early 1970s, George Hart, M.D., was asked to chair a committee formed by the Social Security Administration to decide what should and shouldn’t receive reimbursement for HBOT therapy. He was a naval officer at the time and received an order from his commanding officer to make sure that “stroke” did not appear as a covered indication, even though there was mounting evidence that HBOT worked for treating stroke patients.² The explanation was that it would bankrupt the U.S. Treasury if all the stroke patients in the United States wanted to receive HBOT for neurorehabilitation.

Insurers tend to focus on immediate costs, and often fail to consider long-term savings from a given therapy. For example, the fact that HBOT prevents 75 percent of all major amputations that would otherwise be necessary for diabetic wounds, with all the collateral costs and effect on quality of life, could not be factored into the decision about coverage of HBOT for diabetic foot wounds. The fact that the treatment worked was considered, but not the fact that it is cost-effective.

For a time, cerebral edema was a covered indication, and neurological injury was being successfully treated. This condition was, however, later removed from the Medicare coverage list—as a consequence, it is rumored, of a conflict between two scientists.

In 1980, when the authors formed the American College of Hyperbaric Medicine (ACHM) to foster the ethical advancement and expansion of hyperbaric medicine, it appeared that hyperbaric medicine might be ready to make a major breakthrough. B.H. Fischer, M.D., a tenured professor at New York University, became the principal investigator of a study funded by the Multiple Sclerosis (MS) Society. The MS Society in the United States had great difficulty accepting the results of the work Dr. Fischer had completed, and multiple revisions were required to weaken the conclusions sufficiently to satisfy the editors of the *New England Journal of Medicine*.³

In a double-blind controlled study of patients with advanced chronic disabilities, Fischer found significant improvement in objective measurements, and the treatment effect persisted for at least one year. For reasons hard to explain, this study was never followed up, despite the positive results, and the treatment languished for lack of financial support and sponsorship. Indeed, Fischer lost his position, and his chamber was destroyed.

In 1983, the year that Fischer’s study was published, we became founding board members of the American Board of Hyperbaric Medicine.

HB 1359

AH1

pg. 9

1/16/19

Hyperbaric Oxygen Therapy

What is it?

Breathing 100% oxygen in a pressurized chamber/vessel



These are medical grade chambers. Physician supervision is required.

These are not the soft sided/bag/zipper chambers professional players buy off the internet.

HB 1359

1/16/19 pg. 10

AH1

How does it work?

Hyperbaric oxygen therapy does 4 basic things:

1. Hyper-oxygenates the tissues to allow them to repair
2. Decreases swelling
3. Turns off inflammation
4. Stimulates new blood vessel, and new cell growth, including brain cells

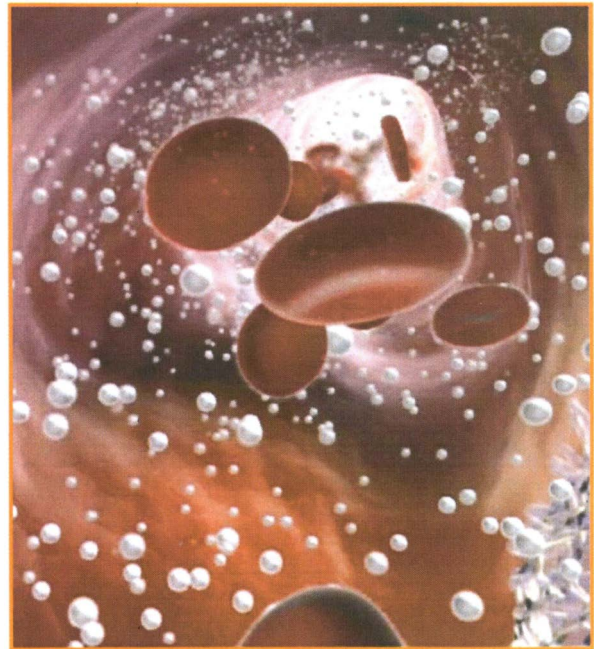


HBOT: It's About Oxygen Saturation

The body's liquids are saturated with more oxygen, helping areas with compromised circulation.



Before HBOT



After HBOT

Image Courtesy of Dr. Stoller

We increase the amount of oxygen in the liquid part of blood by 500-1,200% based on the protocol for injury.

(as demonstrated by the white bubbles)

HB 1359

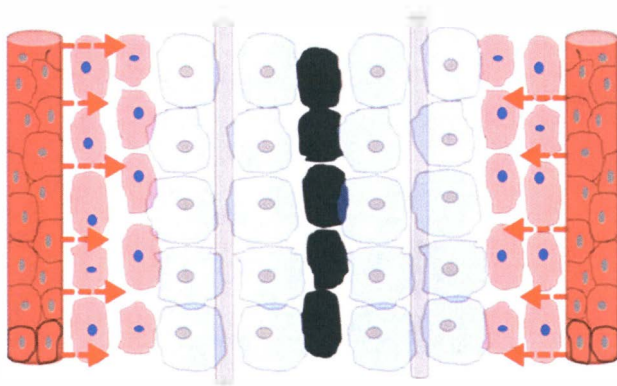
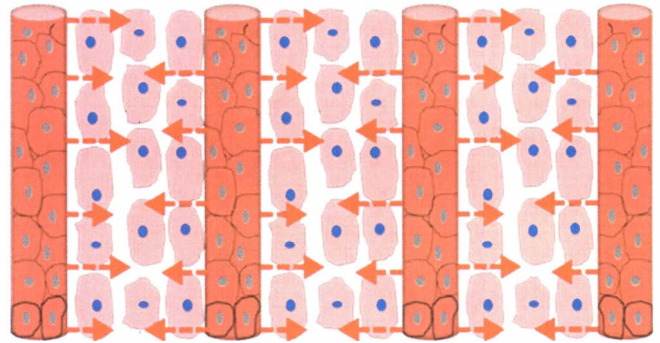
A#1

Pg. 11

1/16/19

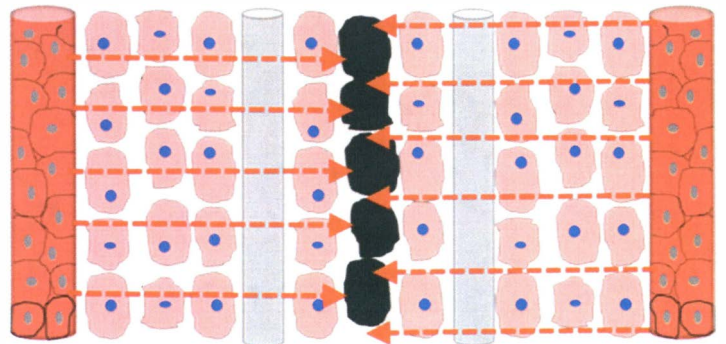
1. Hyperbaric Oxygen Therapy gets oxygen to damaged tissue to allow them to repair

Normally, all cells are close enough to a vessel to get oxygen.



After a trauma the tissue is damaged and some cells cannot get the oxygen they need, especially to repair themselves. Injured cells in blue and dead cells in black.

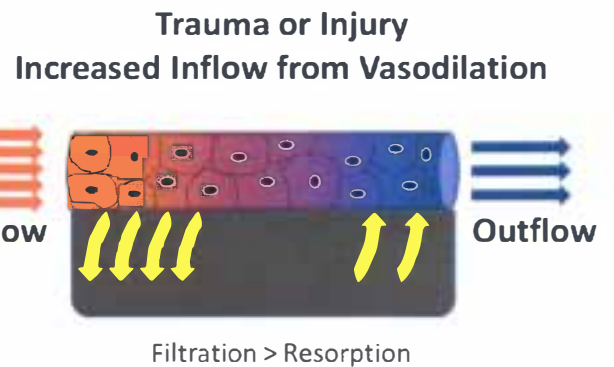
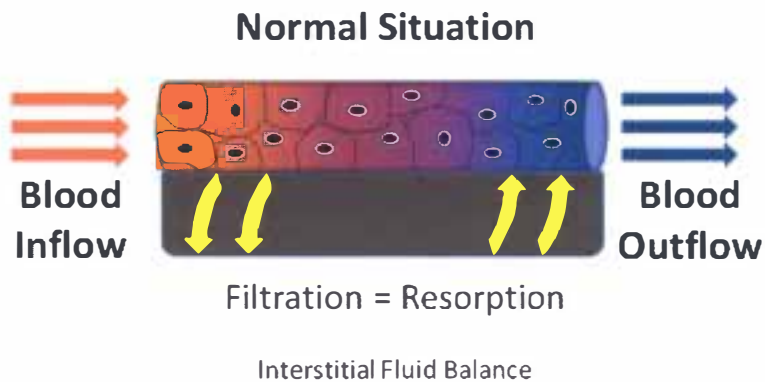
Under hyperbaric conditions, oxygen gets to the injured cells and lets them repair.



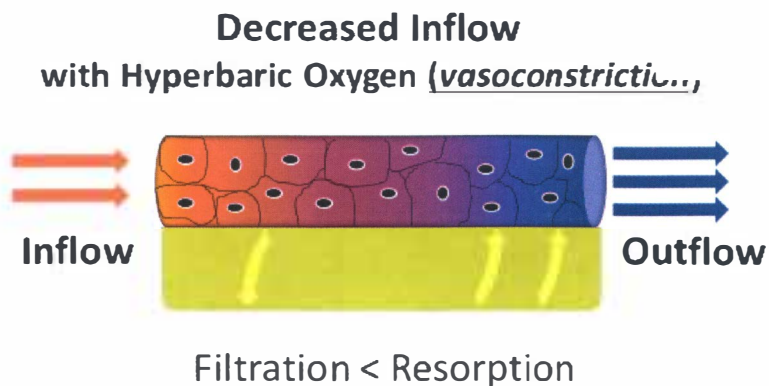
HB 1359 PG. 12
1/16/19 AH1
2. Hyperbaric oxygen therapy decreases swelling

Normally fluid in equals fluid out. After trauma, increased fluid in, therefore swelling.

With hyperbaric, less fluid in, therefore less swelling.



Swelling



20-30% Reduction in Swelling

But we still have tissue oxygenation

HB 1359

1/16/19

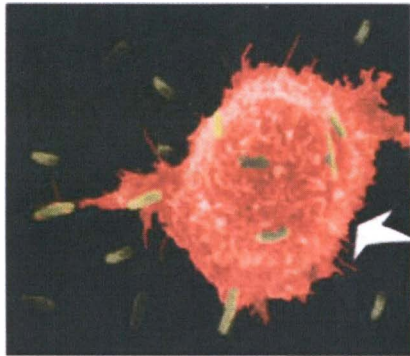
A#1

pg. 13

3. HBO mitigates the inflammatory response

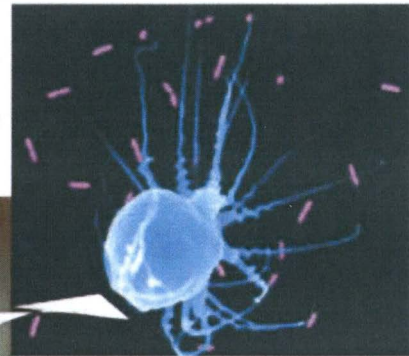
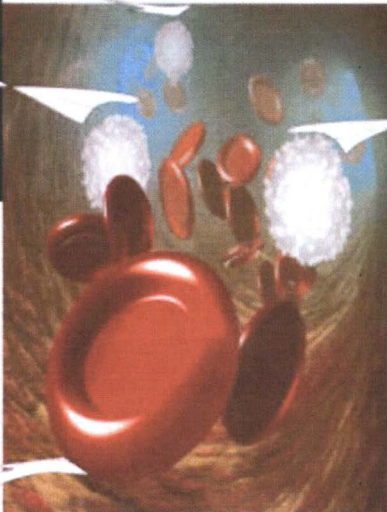
“Under HBO conditions, all the body’s clear fluids carry oxygen, thereby eliminating the need for the inflammatory response.”

Immune and Defense System Amplified by HBOT



When activated, some large white cells become “Big Eaters” (*macrophage*) and reach out and swallow invading pathogens. These cells also have a potent ability to give off growth factors (*EPG*) after they have cleaned up the dead pathogens and other debris. The *EPG* help replace damaged body cells. **These macrophage require up to 24 X O₂ to perform efficiently.**

Immune and defense white cells (leukocytes) patrol through the body ready to react to invading pathogens. **When activated they require up to 24 X O₂ to energize.**



When activated, some large white cells become “poisoners” (*phagocytes*) and use reactive oxygen species (ROS) - free radicals - to brew up the most effective poison for that particular pathogen. This process is called *phagocytosis*. As the invading pathogens are broken apart, macrophage complete the clean up of cellular debris.

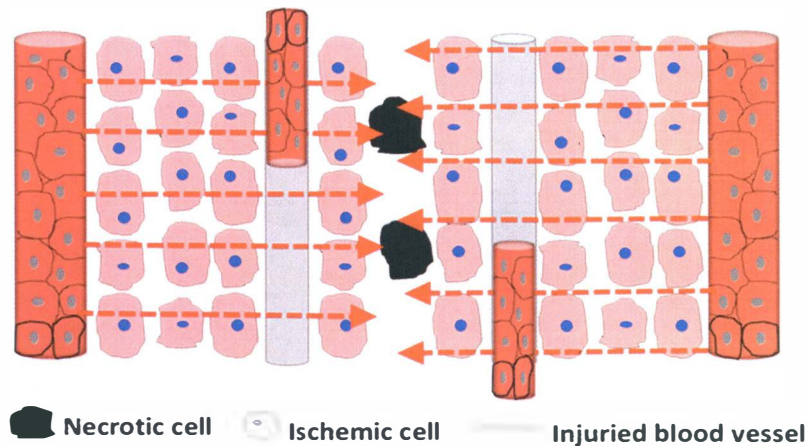
Red blood cells (erythrocyte) - RBC - are the only oxygen carrying cells under normal circumstances. When extra oxygen is required to activate immune response, blood vessels enlarge in process called inflammation (to set on fire) to allow more RBC to deliver O₂ to energize white cells.

Under Hyperbaric Oxygen Therapy (HBOT) conditions, all of the body’s clear fluids carry oxygen, thereby eliminating the need for the inflammatory response.

4. Hyperbaric oxygen therapy stimulates the growth of new blood vessels and new cells.

HBO works for chronic injuries. FDA approved for diabetic foot ulcers, chronic bone infections, etc. due to the ability to grow new blood vessels and new cells.

After several hyperbaric treatments, new blood vessel growth begins, restoring more normal blood flow, as demonstrated to the left. Surrounding cells are able to begin to remove/repair the tissue.



HB 1359 pg. 15
1/16/19
A#1

Refer to #3: HBO turns off inflammation. Therefore, it does not matter how long ago the concussion was, we are seeing great responses to stopping post-concussion symptoms.

Research Ties Inflammation To Post-Concussion Symptoms

Paul Stone | May 11, 2015



Researchers at McMaster University in Canada have found evidence supporting the belief that inflammation is an underlying factor facilitating symptoms of traumatic brain injuries.

The study published in *Brain, Behavior, and Immunity* may help explain why those with mild brain injuries, or even injury to other parts of the body, experience from significant post-concussion-like symptoms such as headaches, dizziness, and cognitive impairment.

According to the findings, individuals with a specific genetic change related to a certain inflammatory protein are particularly likely to have a poorer and more prolonged recovery from brain injury.

Rather than a concussion, we'd like to propose a unifying umbrella term of post-inflammatory brain syndromes or PIBS," said Michel Rathbone, M.D., Ph.D., professor of medicine for McMaster's Michael DeGroote School of Medicine and a lead author of the study.

He continues to suggest that the new findings will encourage researchers to explore new lines of research into post-concussion symptoms so that physicians may be able to treat post-concussion-like symptoms even when there is no obvious brain injury.

The author concluded the results may also provide hope for individuals suffering from cognitive dysfunction after major injuries or trauma, as they may benefit from similar treatments as those with brain injuries.

"This research opens many doors for so many different patients. We are excited to be starting a totally new approach to the field, and we look forward to making a difference for the patients of the future."



[concussion](#) [inflammation and TBI symptoms](#) [post-concussion symptoms](#) [post-concussive syndrome](#) [TBI and inflammation](#) [traumatic brain injury](#)

www.traumaticbraininjury.net/research-ties-inflammation-to-post-concussion-symptoms/

HB 1359
AH 2
1/16/19

Safety

We are a hospital grade center.

HBO is a very safe procedure.

The United States Air Force School of Aerospace Medicine did a long term follow-up study of 563 patients, each of whom had more than 20 daily HBO therapies of 90 minutes of oxygen breathing at 2.4 ATA. The follow up period was six months to eight years. No chronic or late effects due to HBO were seen. Cataracts occurred in only two patients (a poorly controlled diabetic and a 67 year old man on high dose steroids).

Diversified Clinical Services did an analysis of adverse events in all of their centers for 2009-2010. They examined 340 hospital-based outpatient wound centers, 89% treating only FDA approved indications.

Monoplace Chamber Adverse Events Associated with Hyperbaric Oxygen Treatment (Tx)

	Total events in 2 years	AE per 10,000 Tx
Number of treatments	463,293	
Complications	1870	40
Ear Pain	928	20
Confinement anxiety	407	8
Hypoglycemic event	244	5
Shortness of breath	112	2
Seizure	88	2
Sinus Pain	66	1
Chest pain	25	1

Split into years:

In 2009 there were 916 adverse events reported for 207,479 treatments in 7,871 patients, rate 0.44%

In 2010 there were 954 adverse events reported for 255,814 treatments in 9,396 patients, rate 0.37%

HB 1359 1/16/19
AH 2

Department of Human Services
Medical Services Division
Medicaid Services for Individuals with TBI

	CY 2017	CY 2018	Total
Hospital Services	\$785,620.78	\$712,276.03	\$1,497,896.81
Physician Services	\$97,360.67	\$81,974.52	\$179,335.19
Institutional Services ¹	\$4,495,720.33	\$4,662,229.79	\$9,157,950.12
Waiver Services ²	\$4,552,583.44	\$4,466,303.17	\$9,018,886.61
Other Services	\$123,045.66	\$187,751.45	\$310,797.11
Total Paid Amount ³	\$10,054,330.88	\$10,110,534.96	\$20,164,865.84

¹ Institutional Services includes nursing facility, swing bed, and ICF.

² Waiver Services includes services provided under one of ND Medicaid's 1915(c) home and community based waivers.

³ 1,196 individuals received Medicaid services in either one or both years.

HB 1359
AH 2
1/16/19

Budget:

HBO treatment using acute concussion protocol

G0277 \$85(2) \$170

99183 \$107 \$107

\$277 per tx (Medicare

rate)

**20-40 treatments @ \$277 is \$5,540 -
\$11,080**

30 patients, 20-40 treatments each patient

\$166,200 - \$332,400

HB 1359
AH 3
1/16/19

Good morning Mr. Chairman and members of the Human Services committee.

Thank you for your time and service.

My name is Austen Schauer, a Representative from West Fargo, District 13.

It is my honor to speak in support of a **Medicaid Pilot Project** for Hyperbaric Oxygen Treatment, **House Bill 1359**.

I have toured the Hyperbaric Oxygen Treatment Center or HBO in Fargo **twice**.

I was extremely impressed with **Dr. Daphne Denham** and her team which includes an Optometrist from UND who helps with diagnosis.

Dr. Denham is a surgeon by trade but moved into the study of hyperbaric treatment after her daughter suffered a **serious concussion** in 2015.

Dr. Denham's protocol is different from other Oxygen treatment facilities. The results according to client testimony have been **outstanding**. The emphasis is to **reduce inflammation** in the brain after a concussion occurs. This reduction of swelling can also be used to treat other injuries.

Much of Dr. Denham's work is with adolescents. HBO treatment in Fargo has proven to help young people recover from the lingering effects of a concussion. Currently, the HBO Clinic in Fargo is offering free treatment to adolescents. This is made possible through the gifting of hotel developer Gary Tharaldson in partnership with the Dakota Medical Foundation.

HB 1359

A#3

1/16/19

Page 2

HBO treatment has also proven to help veterans suffering from Post-Traumatic Stress Disorder and depression. It has also helped clients who continue to suffer from past brain injuries.

Recently, I was at Sanford Hospital in Fargo waiting to visit a friend. I was on the phone talking to Rep. Dick Anderson about hyperbaric treatment. A man in the waiting room approached me and said he overheard my conversation. He wanted me to know how Hyperbaric treatment has helped him. He said he was assaulted in 2005 and suffered a serious brain injury. He said he's had little relief over the years until undergoing hyperbaric treatment. He said it has **changed his life.**

We are asking you Mr. Chairman and members of the Human Services Committee to provide help for those suffering from concussions and other brain injuries by supporting **HB 1359.**

Thank you Mr. Chairman and I am open to questions.

HB 1359
AH 21
1/16/19

Testimony for HB 1359 – Hyperbaric Oxygen Treatment

My name is Dr. David H. Biberdorf. I am an optometrist who has practiced in Grand Forks, North Dakota for over 30 years where I subspecialize in vision development, vision therapy and neuro-optometric rehabilitation. I also collaborate in research at the University of North Dakota with Dr. Dmitri Poltavski investigating the ability of oculomotor and electrophysiological diagnostics to predict past history of concussion. Our research has been published in the Journals *Vision Research*, *Brain Injury*, and *Optometry and Vision Science* and has been cited in the *Journal of NeuroSurgery* and *Journal of Neuro-Ophthalmology* (see references below).

In the concussion world, new research is challenging the traditional approach to concussion management of “rest until symptoms resolve”. It suggests, in fact, that prolonged rest adversely affects the pathophysiology of concussion. Unwittingly perhaps, this “wait and see” approach can delay the institution of effective therapies for acute concussion and may be detrimental to recovery. Although the current management of concussions calls for targeted interventions with therapies such as vision therapy, vestibular therapy, and cognitive therapy for symptoms that do not resolve, these interventions can cause symptoms to become protracted and exacerbated from the lack of brain energy available for optimal rehabilitation. Hyperbaric oxygen treatment early on after head injury could potentially shorten the duration of acute concussion symptoms, speed up return-to-learn, return-to-play and return-to-work time delays and augment the rehabilitative benefits that targeted therapies for post-concussion syndrome currently provide.

On January 14, 2018 I attended a meeting organized by a group of scientists, physicians, engineers, and philanthropists who had a vision. That vision was the establishment a hyperbaric oxygen clinic in Fargo North Dakota for the purpose of treating patients who were suffering with acute concussions and post-concussion syndrome using off-label Hyperbaric Oxygen. A surgeon from the Chicago area by the name of Dr. Daphne Denham was in attendance who had vast clinical experience with hyperbaric oxygen treatment of acute and chronic concussions. This group hoped to utilize my expertise in oculomotor and visual processing to help determine the overall efficacy of hyperbaric oxygen treatment for brain injury.

Historically, efficacy studies of hyperbaric oxygen have relied on symptom surveys and neuro-cognitive measures before and after hyperbaric oxygen treatment. Because the visual system is so extensively involved in the brain’s functional processes, it is quite sensitive to any altered neurological function. Objective measures of eye movements, focusing mechanism, pupillary dynamics, and perceptual processes are now being used as evidence-based biomarkers for brain injuries and interventional therapies.

Intrigued by the possibility that hyperbaric oxygen may reduce brain inflammation, prevent the metabolic concussion cascade and induce neuroplasticity, I agreed to loan this hyperbaric clinic over \$200,000 in diagnostic ophthalmic equipment and to volunteer my time to collect evidence-based outcome data to explore the efficacy of hyperbaric oxygen treatment of concussion. Using FDA-approved eye tracking technology, I have been gathering data of acute and chronic concussed patients receiving treatments at the hyperbaric clinic in Fargo, North Dakota since August of 2018.

HB 1359

1/16/19

A#4

So far, there is clear clinical evidence of a more rapid improvement of oculomotor performance and reduction of symptoms for the majority of participating patients: more than one would otherwise expect using a “wait and see” approach. Additional data from a prospective clinical trial to include such measures as pupillary dynamics, accommodative dynamics, vergence dynamics, visual evoked potentials, electroencephalography and perceptual-motor diagnostics will be needed to better understand the mechanisms behind hyperbaric oxygen treatment on brain functions and the potential it may have for lowering the overall cost of health care for brain injured patients.

The infrastructure to investigate promising new clinical trials using hyperbaric oxygen is now in place in the state of North Dakota. I would like to encourage the ND State Legislature to support the funding of a Hyperbaric Oxygen Medicaid Pilot Project for the benefit of its head injured citizens, their families and those involved with their health care support services.

Thank you for your time and consideration of HB 1359.

Dr. David H. Biberdorf
Grand Forks, ND

References

Poltavski D.V., Biberdorf D, Petros T. Accommodative Response and Cortical Activity During Sustained Attention. May 2012 *Vision Research* 63:1-8.

Poltavski D. V, & Biberdorf D, (2014). Screening for Lifetime Concussion in Athletes: Importance of Oculomotor Measures. *Brain Injury* 28(4), 475-485.

Poltavski D, Lederer P, Cox L, Visually Evoked Potential Markers of Concussion History in Patients with Convergence Insufficiency. *Optometry and Vision Science*: July 2017 - Volume 94 - Issue 7 - p 742–750.

Collins M, et al. Statements of Agreement From the Targeted Evaluation and Active Management (TEAM) Approaches to Treating Concussion Meeting Held in Pittsburgh, October 15-16, 2015. *Neurosurgery* 79:912–929, 2016.

Venura R, Jancuska J, Balcer L, Galetta S, Diagnostic Tests for Concussion: Is Vision Part of the Puzzle? *Journal of Neuro-Ophthalmology* 2015;35:73–81.

HB 1359

A#5

1/16/19

January 16, 2019

Testimony to House Human Services

HB 1359

Hyperbaric Oxygen Therapy

Dr. Edward F. Fogarty

This is the testimony of Dr. Edward F. Fogarty of Bismarck, North Dakota regarding any bill under consideration of the North Dakota Legislature that involves the use of hyperbaric oxygen therapy for neurological injury, specifically but not limited to its use in U.S. Veterans.

Firstly, I am grateful to North Dakota Veterans Affairs Commissioner Lonnie Wangen for speaking these words on my behalf to the legislative members assembled today. My testimony regarding the issue of hyperbaric medicine for our citizens is based upon over a decade of medical imaging analytics and validation of the results of this intervention with my academic medicine colleagues at the Louisiana State University, led by Paul G. Harch, MD.

In my role as the Chairman of Radiology at the University of North Dakota School of Medicine, I have had the opportunity to teach a number of our state's veterans who have served the country prior to matriculating into our state's medical school. Many of these students and their classmates have had the opportunity to see the powerful effects of hyperbaric medicine through our review of cases from LSU which allow me to show them the physics of imaging as well as the gas law physics of pressure vessels. Many of these cases document profound improvement in both imaging findings and clinical status.

Having spent over a decade working with LSU researchers on this critical issue for our nation's veterans. I am most grateful to the network of North Dakotans who first connected me to Dr. Harch in 2007. Our research publications in this arena of innovation have helped define the art and science of this powerful medicine. It has been an incredible privilege to help advance the science while advocating for this intervention for our veterans.

Based on all of the imaging changes documented in the medical literature in the use of HBOT for brain injury, there should be no doubt that it is highly efficacious. In October of 2017, Israeli researchers published the first MRI proof of white matter tract regeneration in brains treated with HBOT for TBI. That same month our LSU/UND team of researchers published a statistically significant decrease in suicidal ideation with the use of hyperbaric medicine in a portion of the LSU Phase 1 Safety trial participants. The regenerative effect of HBOT implied by the imaging findings in the LSU Phase 1 Trial published in the Journal of Neurotrauma in 2012 has virtually been confirmed by Shari Efrati, MD and his colleagues in Israel. In 2007, a study by led by Dr. S Thom at University of Pennsylvania showed stem cells are released after 10 hours of hyperbaric therapy. Many other studies show the impactful biological effects of gases under pressure in humans and animals. Internationally, there are many who recognize the University of North Dakota's leadership in the credible proof of concept documented by imaging for the brain healing effects of Hyperbaric Medicine.

My journey into this realm of research started by seeing recoveries of severely brain injured patients by the artful clinical practice of Dr. Harch. Until late 2006, I had never seen anything like this physician's work in all of my medical training and across the tens of thousands of cases I had interpreted over the years in clinical radiology. His work should be on the nightly news for its incredible breakthroughs, but it's not-it's too disruptive. The science we have pioneered has been disparaged for not having placebo controls or for simply being case reports-astounding results but no funding for larger studies to add to the world's understanding of a ubiquitous effect on all species injury recovery speed. What I have come to learn over the last decade of investigation in this arena is that there has been a terrible misinterpretation of the concept of a placebo in hyperbaric medical research. This has propagated the dismissal of these innovations. This is an important issue for legislators to understand as the use of a biological active placebo is misleading and ultimately costly for society and our taxpayers.

There is a history of placebos from one era of medicine being discovered as biologically active in another, and thus unethical. This changes the whole landscape of an area of study and renders old interpretations of research null and void in many instances. Hyperbaric medicine is not primarily a 'drug' based specialty. It is a device based specialty. In device based specialties like surgery, interventional radiology or interventional cardiology it is difficult to justify the expense of a "fake" or sham procedure. A truly ethical placebo should have the highest of safety indexes and lowest of costs while having no biological activity. The history of the misuse of biologically active placebos in hyperbaric medicine will probably make everyone who's been

H0 1359
A715 1/16/19

paying attention to this line of research for the last few years quite upset.

In 2001, a groundbreaking study on children with cerebral palsy was published in the Lancet. The researchers used hyperbaric air therapy at 30% more than we are experiencing right now as a placebo. That is the same dose that was shown to be biologically active in Eden Carlson's recovery from severe brain injury, which Dr. Harch and I published in July of 2017. All of the studies in our veterans outside of those published by the LSU team have used the same biologically active placebo. Because air under pressure is almost as helpful as oxygen under pressure, these "controlled" studies end up treating a lot of people with 2 good but slightly different interventions for the brain. Study after study shows remarkable improvement in so many of these parameters of neurological injury in both the "sham" and the experimental group that are continually discounted as a strange "intention to treat" type of effect or some other truly bizarre explanation for how the neurologically injured are making amazing strides across incredibly short windows of time. Pressurized oxygen at 21% or at 100% accelerates all sorts of biological fence mending.

From my perspective as a long-standing "observer" of medical practice through imaging, we have lost a lot of time on a simple misunderstanding that started a long time ago. It is time to turn the tide on this progressive misuse of our resources. There is little point in looking back for you as legislators except to understand you now have a powerful knowledge point to discuss with others who disparage this powerful medicine. Misinterpreted shams from pundits in academic medicine have left a lot of the wounds of the

HB 1359
AHS
1/16/19

brains of our military family members untreated. I can assure you that the next 20 years will be a revolutionary time where the real “decade” of the brain will manifest through this simple concept of healing. As a state, we are quickly becoming the national leadership in real brain healing on the ground. This is mainly because we have a number of insightful supporters of a special physician in Fargo named Daphne Denham, MD. These civic leaders are seeing with their own eyes in Fargo that placebo controlled studies have diverted the nation’s attention from real healing with hyperbarics. It’s an open secret that we can do this without breaking the bank in North Dakota, it’s time to show the world small places can still do great things.

As an educational Basecamp, check out HBOT.COM for more information.

Ted Fogarty, MD
Chair, UND Radiology

SELECTED MEDIA/RESEARCH HIGHLIGHT:

Pediatric Hyperbarics

<https://www.usatoday.com/story/news/nation-now/2017/07/20/toddlers-brain-damage-reversed-treatment-after-near-drowning/496134001/>

HB 1359
Att 6 1/16/19

Testimony
Human Services Committee
January 16, 2019

Good morning, Chairman Weisz and members of the committee. My name is Hannah Anderson from Leeds, ND. I am here today, to testify in favor of House Bill 1359, and to explain how hyperbaric oxygen therapy has made a difference in my life.

On November 12, 2007, I was in a nearly fatal car accident, where I suffered a traumatic brain injury along with other injuries. After 3 months in different hospitals, I relearned how to breath again on my own, without the use of any machines, I also learned how to talk, and how to walk on my own. My traumatic brain injury, however, left me with issues that I have struggled with daily for the past 11 years. My short term memory is very poor, I am tired all the time and just getting through the day is exhausting. I suffer with headaches every day and am on medications to help me get through the day and then take medications to help me sleep at night. I am easily overwhelmed in large groups of people and struggle to follow conversations. I become irritated when this happens.

Due to the great support that I had, I was able to graduate high school and even got my Associate Degree from Trinity Bible College in Ellendale, ND. I am currently working part time at the Minnewaukan Public School as a paraprofessional and living at home with my parents.

HB 1359
A#6 1/16/19

My mom heard of other brain injury survivors doing Hyperbaric Oxygen Therapy in Fargo, so she started doing research on it. We decided, as a family, that it might be a good thing for me to try. I was willing to try almost anything that would help get rid of the headaches that I had every day. We were not sure if HBOT would do anything for me because it had been 11 years since my traumatic brain injury. We were not given any promises, or any false hopes.

HBOT turned out to be the best thing I could have done. On day one, I was tired from my sessions, just like they said that I might be. On Day 3, halfway through the treatments, I felt as if my brain fog was lifting. I thought brain fog was something I would have to live with the rest of my life. It was also interesting to me that the headaches were much less severe than I had previously had. Also after the 3rd day, or 6 treatments, I was able to go out to supper with 5 other people. At that supper, I was able to concentrate on the menu and choose my own meal. I was able to keep up with the conversation the entire evening and according to my mom, I responded appropriately to questions throughout the evening. By the time I was finished with my 10 treatments in 5 days, I felt like my brain injury almost didn't exist.

It was only last week that I was in Fargo, having HBOT treatments. I went to work on Monday, and didn't become overwhelmed with everything that was going on at the school, and all the kids that needed help. I have not had a headache since last week, which is so amazing. I have more energy

HB 1359
A#6 1/16/19

than I have had in 11 years. I wish I could have had this treatment along time ago, because the sooner I would have tried this therapy post injury, the sooner I could have felt less exhausted and had fewer headaches. I used to just drag through each 4 hour shift and come home exhausted. These last two days at work have actually been fun because of the amount of energy I've had.

Thank you for your time and your consideration of House Bill 1359. If you have any questions, I will be happy to try and answer them for you.

Hannah Anderson
6081 58th Ave NE
Leeds, ND 58346
701-351-6747 (cell)
701-466-2561 (home)

HB 1359

Att 7

1/16/19

Pg. 1

Testimony
Human Services Committee
January 16, 2019

Good morning, Chairman Weisz and members of the committee. My name is Lisa Anderson from Leeds, ND. I am here today, to testify in favor of House Bill 1359, and explain why I support this bill.

You heard my daughter, Hannah's story, and how Hyperbaric Oxygen Therapy made a difference in her life. It is my belief that HBOT has made a tremendous difference in the quality of Hannah's life. It helped her to focus better, it has helped her balance and it has helped with her fatigue. We are amazed at the difference 10 Hyperbaric Oxygen Treatments made for Hannah.

Hannah's insurance company has paid over half a million dollars in benefits since 2007, for Hannah's medical expenses. Hannah's father and I have paid over \$ 50,000 out of pocket since 2007, for Hannah's medical expenses. It is my firm belief that if Hannah had received HBOT years ago, not only would everyone have saved thousands of dollars, but Hannah's quality of life would have been so much better. These figures do not include food, motel or mileage for any of the medical trips that we have made with Hannah.

In closing, I would like to thank you for your time, and for your thoughtful consideration of HB 1359. HBOT can make a huge difference in the life of a brain injury survivor. Please vote in favor of this pilot program for brain injury survivors. Not only will it potentially save the State of ND money, it will give brain injury survivors a better quality of life. If you have any questions for me, I will be happy to try and answer them. You can reach me at:

Lisa Anderson
6081 58th Ave NE
Leeds, ND 58346
701-739-6912 (cell)
701-466-2561 (home)
lisa.anderson@gondtc.com

1/16/19

Human Services Committee – HB 1359 - January 16, 2019

Good morning, Chairman Weisz and members of the committee.

My name is Lynne Ostrem from Rugby, ND. I am here today, to testify in favor of House Bill 1359, and explain why I support this bill.

My son is David Folden. David was finishing up Chiropractic School in Iowa when he sustained a traumatic brain injury in November 2011. We were told David would not survive, and if he did, the prognosis was grim; he would be wheelchair bound and unresponsive. David overcame those odds and learned how to eat, talk and walk again. David and his family returned to North Dakota in August 2012. I can't even begin to come up with a dollar amount that has been spent for medical care, out of pocket expense, and lost wages of family members that provide informal support for David since November 2011.

David continues to struggle with the long term side effects of traumatic brain injury; which include persistent headaches, seizures, short term memory deficits, and mood swings. In addition to his prescribed medications, David was taking Tylenol or Ibuprofen every 4 hours daily and even with that, some days he still had a "slight headache". David's last labs showed elevated liver and kidney levels which his Primary Care said is probably due to the Tylenol and Ibuprofen, but we did not want to introduce narcotics for pain.

David started doing Hyperbaric Oxygen Therapy in Fargo in mid/late December. After his 4th treatment he asked me, "Do you think I'm getting better?" I asked him what he thought. David's response was, "My headaches are not as bad and I feel like my brain is so much clearer." David being able to verbalize and notice an improvement was enough for me to want to continue treatments for David and tell others of how it helped David.

So far, David has had a total of 7 treatments and no longer complains of headaches. There are other improvements I have witnessed:

- 1.) David can now set a timer and remembers what the timer was for – he doesn't need to write a note as a reminder what the timer was for.
- 2.) David is more relaxed and content – which is unusual for a frontal lobe brain injury. David recently attended a meeting with me. He was walking up to people he didn't know and initiating conversation – he usually isolated himself and was on his phone/iPad.
- 3.) When he finishes a task he will seek me out and let me know he is done and asks what he can do to help next.
- 4.) The amount of time needed to remember things in the short term has reduced. Previously, we would still have dry erase boards up for months reminding him it was a new year.
- 5.) His caregivers have noticed an improvement in memory and mood – they didn't know he was doing HBOT.

In closing, I appreciate your time and your consideration of HB 1359. I believe HBOT can make a difference in the life of a brain injury survivor. I have already seen the positive effects for my son. Improvements for survivors would have a multitude of ripple effects for family members, potential future medical costs but the most important item is allowing our ND Brain Injury Survivors a better quality of life. Please vote in favor of HB 1359. If you have any questions for me, I will be happy to try and answer them.

Lynne Ostrem
5693 Hwy. 3 South
Rugby, ND
701-208-1051
ostrich@gondtc.com

HB 1359—Pilot project for hyperbaric oxygenation treatment

Chairman **W. B. B. B.** and members of the committee my name is Jim Nelson and I represent the ND Veterans Legislative Council. I serve as its Vice President and Legislative Director. The Veterans Legislative Council is made up of the top officers from the American Legion, AMVETS, Disabled American Veterans, Veterans of Foreign Wars and the Vietnam Veterans of America. We are here today to support this bill.

A pilot control study of veterans with mild traumatic brain injury (TBI) or persistent post-concussion syndrome (PPCS), with or without post-traumatic stress disorder (PTSD) has found significant improvements in TBI and PPCS with PTSD symptoms, neurological exam, memory, IQ, attention cognition, depression, anxiety, quality of life and brain blood flow following hyperbaric oxygen treatment.

Simultaneously and most importantly, subjects experienced a significant reduction in suicidal ideation and anxiety, this is probably the most significant finding of the study given the current suicide epidemic in and out of the military. Dr. Paul Hatch, Clinical Professor and Director of Hyperbaric Medicine at LSU Health New Orleans School of Medicine along with Dr Edward Fogarty Chair of Radiology at the UND School of Medicine. Dr Hatch writes "The PTSD symptom reductions in PTSD symptoms in a four-week period with any reported diagnoses of blast induced PPCS and PTSD."

The improvements include a discontinuation or decreased dosage of psychoactive medications, continued to increase over the six-month post-traumatic period. Dr. Fogarty writes "Mild traumatic brain injury, persistent post-concussion syndrome and post-traumatic disorder are epidemic in the United States Iraq and Afghanistan war veterans. The only effective treatment of the combined diagnoses that is available and well-studied is via these chambers.

HB 1359
AH 9
1/16/19 pg 2

Thirty active duty or retired military men and women 18-65 with on more mild-to-moderate blast TBIs characterized by loss of consciousness that a minimum of one year old and occurred post 9/11 participated in the study. 10 of 12 patients who expressed suicidal ideation prior to treatment did not express suicidal thoughts after treatment. Of the patients who indicated significant anxiety before treatment, 75% were no longer anxious after treatment.

I have attached the testimony by one the participants experience with the study VA officials have acknowledged that the new use of hyperbaric oxygen therapy and are pairing it with new research efforts by the VA and military in treatments. As such they have given it a "off label" or unauthorized designation. This designation means the veteran must pay for it use

We are excited bill because is could well be an avenue for the VA and military in changing the designation and we ask for your support of this bill by a do pass.

I will attempt to answer any questions.

HB 1359
AH 9
1/16/19
Pg. 3

Hyperbaric Oxygen Therapy Has Helped Beat TBI/PTSD, Veteran's Testimony

Sat, 08/31/2013 - 14:33 | Visitor (not verified)

Veteran Testimony - One of the first five treated in the TBI/PTSD HBOT Pilot Trial

The following is a testimony of one of the first five veterans treated by Dr. Harch with HBOT for TBI and PTSD. This veteran was referred by a compassionate Army doctor who was unsuccessful with other treatments. His story is typical of the ability of HBOT to positively change the trajectory of a brain-injured individual's life and literally give people back their lives. It is also the foundation of the Oklahoma HBOT legislation for veterans and the [National Grassroots Movement for HBOT](#) in the treatment of veterans that was launched by Rainey Owens in Texas. We hope you enjoy his story and realize that he is the rule, not the exception.



I sustained a Traumatic Brain Injury (TBI) in April 2003 when an ammunition bunker in Iraq was detonated within close proximity to my location. The concussion was tremendous and the negative effects immediate. Later on, after brain surgery to fix some damaged blood vessels, the disabilities became even more evident. Then, on March 1, 2007, I was in my home when an F4 tornado torn the place apart all around me. The sudden pressure changes from that event left me literally unable to cope with life. Everything was so confusing, overwhelming and frustrating. I would seek out the darkest areas of our rebuilt house and sit in confused agony for hours at a time. Often, not remembering what I had done earlier in the day, much less the events of the days before. I hardly knew what month it was and was completely unaware of the day of the week or the time of day.

Prior to my Hyperbaric Oxygen treatment beginning in June 2008, by Dr. Harch, I found myself living in a daily fog that was later diagnosed as Post Traumatic Stress Disorder. Everything from my ability to think to my impatient, misery/depression filled interaction with my family and friends, to writing and reading was affected by this PTSD fog. My frustration levels were extremely high. My family life was compromised to the point of my wife feeling as though she had an adult child in the house and my son didn't think I was very fun either! I was living in daily frustration with not being able to think clearly, sleeping on and off through out the day and generally, not having the capability to work or interact for very long with others. I was miserable. Knowing who I was before the TBI/PTSD, yet dealing with what I had become was depressing. I simply couldn't get myself out of that hole the head injury had caused.

Literally, during the first two Hyperbaric Oxygen Therapy treatments, I found parts of my brain waking up and the fogginess becoming less intrusive. By the time I finished 80 treatments, I had rediscovered the ability to enjoy reading a book again for the first time in five years! Writing this simple statement would have taken me three or four hours before treatment but now, a matter of fifteen minutes. I have high hopes of working full time after my medical retirement from the Army and most importantly, my wife and son still come up to me on occasion and just hug me.. They then mention how happy they are to have their husband and father back. I also found myself able to sleep again and feel refreshed!

I still struggle with various issues, some cognitive and some physical, but I'm so very grateful that the Lord placed Dr. Harch in my path to recovery. Dr. Harch and his staff are some of the most dedicated, sincere and hard working medical professionals I've ever been treated by. The quality of life improvements I've seen since being treated by Dr. Harch have made the difference between an existence of sitting at home, too confused and frustrated to LIVE, and a life with hope, patience and most importantly, a reduction in the daily fog of brain injury. Hyperbaric oxygen therapy has helped me to find my motivation and desire for life again. Also, since I am able to process better, the following four months at the Shepherd Center were much more productive!

For those who suffer with the fog and depression of TBI/PTSD, you will know how tremendously important those kinds gains are.. For the family members of those who suffer with this type of injury, the smiles and happiness from my wife and kids are testimony enough to know how much this treatment has given me back my life. God Bless!!



The Administrative Committee on Veterans Affairs (ACOVA) is responsible for the organization, policy, and general administration of all veterans' affairs in North Dakota. The Administrative Committee is comprised of 15 voting members, each appointed by the Governor, representing the five major patriotic veteran organizations in the state.

Each year, the Governor is to appoint one member from a list of two names submitted by the following North Dakota veteran organizations: American Legion, Veterans of Foreign Wars, Disabled American Veterans, AMVETS, and Vietnam Veterans of America. The ACOVA is also comprised of three nonvoting members who are to serve in an advisory capacity - the North Dakota Adjutant General, the Center Director of the Federal Veterans Affairs, and the Executive Director of Job Service of North Dakota. The Governor also appoints the ACOVA's Chairman and Secretary.

The ACOVA has several activities they monitor on behalf of the Governor and the state's veterans.

North Dakota Veterans Home:

The ACOVA appoints a seven member governing board for administration of the North Dakota Veterans Home located in Lisbon, ND. It assists in creating the management and not in the day to day management of the Veterans Home.

Post War Trust Fund:

The veterans' postwar trust fund (PWTF) is a permanent trust fund of the state of North Dakota and consists of moneys transferred or credited to the fund under NDCC 37-14-14 and other laws. All income received from investments is to be utilized only for programs of benefit and service to veterans or their dependents, and all income earned in a biennium is appropriated to the (ACOVA) on a continuing basis.

ND Department of Veterans Affairs:

The committee shall appoint the commissioner of the department of veterans' affairs. The commissioner of veterans' affairs shall serve as the executive secretary for the subcommittee. The commissioner has no vote in the affairs of the sub-committee.



HB 1359 AH9
1/16/19 pg 4



*Who We Are
and What We
do for Veterans*

HB 1359
995
1/16/19

A# 9



*FIVE ND Patriotic Organizations
31,000 Members Statewide
5,456,000 Members Nationwide*

What is the difference between the NDVLC and the ACOVA? The acronym NDVLC stands for the North Dakota Veterans Legislative Council and is a Non-Governmental Council comprised of the five principal veteran organizations in the state of North Dakota. Their purpose is to discuss and develop a unified consensus on veteran issues. ACOVA stands for the Administrative Committee on Veterans Affairs which is responsible for the organization, policy, and general administration of all veterans' affairs in North Dakota.

The ND Veterans Legislative Council is made up of three members from each of the following five ND Veterans' Patriotic Organizations; The American Legion, Veterans of Foreign Wars, Disabled American Veterans, AMVETS, and the Vietnam Veterans of America.



*ND Disabled American Veterans
5,000 North Dakota Members, 11 Local Chapters
1.2 Million Members Nationwide*



*ND Veterans of Foreign Wars
7,715 North Dakota Members, 54 Local Posts
1.7 Million Members Nationwide*

The NDVLC was established to bring veterans organizations together in a united effort on behalf of all veterans and dependents. It is meant to provide a practical means through which the Veterans organizations throughout the state may effectively contribute to the betterment of all veterans.

The three major responsibilities of the Legislative Council are to sponsor and monitor legislation that affects veterans and their dependents, monitor all general programs for veterans including hospital benefits, employment programs, social programs and finally to establish a system of public relations for veterans.

No member of the Legislative Council may hold concurrent membership on the Administrative Committee on Veterans Affairs. The three representatives from each Veterans organization shall be the Department



*ND American Veterans
2,800 North Dakota Members, 14 Local Posts
290,000 Members Nationwide*



*ND Dept. of the American Legion
15,050 North Dakota Members, 215 Local Posts
2.2 Million Members Nationwide*

Commander, the Department Adjutant, and one other representative. Each member has one vote. The office of president, vice-president, and secretary/treasurer are elected from within these voting members.

The members are volunteers and do not receive salaries for performing their duties as outlined in the organizations by-laws. The third segment of the Council is the Legislative Committee. Two members are appointed from each of the veterans organizations and a committee chairman. They are appointed for two years. They should be from the Bismarck area so they may attend hearings on bills affecting the veterans.

The Legislative Council's main function is drafting, monitoring, and seeking sponsors for veterans legislation. It is not an administrative body. Administration and implementation of veterans laws is the function of the ACOVA.



*ND Vietnam Veterans of America
435 North Dakota Members, 10 Local Chapters
66,000 Members Nationwide*

HB 1359

Pg. 6

1/16/19

AH9

2019 Veteran Legislation



ND Department of Veterans Affairs Budget

- Return 2 of 3 Staff positions
- Remove Federal Funding Mandate
- Training & Outreach funding
- Grant database update

Stand Down Funding \$5,000

- Serving vulnerable veterans

Service Dog Grants \$50,000

- ND veterans with PTSD

DAV Transportation Van \$18,600

- ½ cost to purchase 1 van

National Service Officer Grant \$150,000

- 3 grants at \$50,000

ND Department of Veterans Affairs

- Accept and expend funds. FH Coin

ND Department of Veterans Affairs

- Work with all entities

ACOVA & Post War Trust Fund

- Set investment goals & objectives

ND Veterans Legislative Council

- Name change in NDCC

Military Retirement Pay

- Exempt from ND income tax

ND Income Tax Check off

- Donate to Post War Trust Fund

ND Veterans Affairs File Access

- Clean up verbiage

ND Assn. County & Tribal Service Officers

- VA disabled qualify for ND Grant & Loan
- CVSO accreditation to include NDDVA
- Veterans Preference remove resident and wartime. Add Guard and Reserve.

HB 1359 A#9

pg. 7

Members of the North Dakota Veterans Legislative Council 2018

President: Karen Meier ND AL
Vice President Jim Nelson AMVETS
Secretary: Ronald Matthews ND AL

Member Organizations:

ND American Legion

Karen Meier 701-595-3717 bgkjmeier@restel.com
Ronald Matthews 701-293-3120 adjutant@ndlegion.org
Glenn Wahus 701-842-2093 gwahus@gmail.com

ND AMVETS

Wayne Krueger 701-793-6022 harleymillionaire@gmail.com
Keith Peterson 701-871-0208 peteronkeith96@yahoo.com
James Nelson 701-400-5635 jimnelson73@yahoo.com

ND DAV

Joe Hall 701-328-5048 joehall.DAV@outlook.com
Larry Holweger 218-779-048 cholweger@gra.midco.net
Steve Benson 218-991-2366 stephenjoebenson@hotmail.com

ND VFW

Bill Tuff c701-261-2144 bltuff@aol.com
Darcy Medicine Stone 701-880-217 darcywilfred1944@gmail.com
Wayne Paulson 701-838-8470 vfwnd@minot.com

ND VVA

Dan Stenvold 701-284-6426 troy@polarcomm.com
Russ Stabler 701-306-2659 palkid@aol.com
Larry Young 701-786-3494 yohound50@yahoo.com



HB 1359
A#10
1/16/19 pg. 1

Testimony

House Bill 1359 – Department of Human Services

House Human Services Committee

Representative Weisz, Chairman

January 16, 2019

Chairman Weisz and members of the House Human Services Committee, I am Tammy Zachmeier, Utilization Review Administrator for the Medical Services Division in Department of Human Services (Department). I am providing testimony today regarding the Department's opposition to House Bill 1359.

The Medicaid Utilization Review staff is responsible for making coverage decisions for medical treatment and services. This involves researching and assuring that the treatment is consistent with generally accepted professional medical standards, reviewing literature for evidence-based practices, reviewing coverage determinations by other payers, reviewing Medicare's national and local coverage determinations, and researching for approval of a medical device by the U.S. Food & Drug Administration (FDA).

Medical Services defines coverage parameters for specific services and may limit coverage to a specific diagnosis when appropriate. Hyperbaric Oxygenation Treatment (HBOT) is covered by ND Medicaid for conditions such as carbon monoxide poisoning, infection of skin or bone causing tissue death, nonhealing wounds such as diabetic foot ulcers, radiation injury, and arterial gas emboli. The use of HBOT is covered for these

conditions because they are approved by the FDA and accepted professional medical practices.

The Department opposes House Bill 1359 for the following reasons:

- The treatment is not consistent with generally accepted professional medical standards.
- Medicare does not pay for HBOT for traumatic brain injury (TBI). There are no national or local coverage determinations.
- The FDA has not approved HBOT for TBI.

In addition, while we have sought guidance, we do not have specific approval from the Centers for Medicare and Medicaid Services (CMS) whether we will receive federal funds for payment of claims for HBOT for TBI. Also, it is uncertain if there is potential Department liability for covering a service that is not consistent with accepted professional standards and not approved by the FDA.

House Bill 1359 appears to require the Department to conduct research, analyze data, and report results. The Department does not employ experts in conducting research. If the Department is directed by legislation to cover HBOT for TBI, the Department can report information on expenditures for the treatment and related services; however, reporting on treatment outcomes would have to be outsourced. Given the number of ND Medicaid recipients with a diagnosis of TBI, and the scope of data collection and expertise that would be required with a contractor, the proposed appropriation of \$335,000 in House Bill 1359 would be insufficient. The Department estimates a fiscal impact of \$4,898,550 for the 2019-2021 biennium (\$2,449,275 federal funds; \$2,449,275 state funds).

HB 1359
AH10
1/16/19 Pg. 3

This concludes my testimony and I would address any questions that you have.

Estimate per person

Total Eligible Population*	Utilization Rate**	Estimated population for service			
2500	20%	500	2019 - 2021 Biennium		
500	20%	100	Used the average of SFY 2017 and SFY 2018 new cases		
Services / Treatment plan					
	Reimb. Code	Rate as of 1/2019	Units	Total	Note
Exam	CPT 99204	\$ 161.84	1	\$ 161.84	30 minute sessions, two per day, 20 hours of treatment, 5 days a week for 4 weeks
Hyperbaric oxygen under pressure, full body chamber	G 0277	\$ 84.65	40	\$ 3,386.00	
Physician attendance and supervision of hyperbaric oxygen therapy	99183	\$ 107.42	20	\$ 2,148.40	
Follow up post-treatment exam	99214	\$ 106.35	1	\$ 106.35	
Visual Field Exam	92082	\$ 48.37	2	\$ 96.74	
Neuropsychological testing	96118	\$ 97.26	2	\$ 194.52	
				\$ -	
Travel***		\$ 0.53	6,668	\$ 3,534.04	
				\$ -	
Subtotal Average cost per recipient^				\$ 9,627.89	

Total estimate for 2019-2021 Biennium

	Total	State	Federal	Population Served
2019 - 2021 Biennium^^	\$ 4,898,550.00	\$ 2,449,275.00	\$ 2,449,275.00	500

*Total population was calculated using claims data from ND Medicaid members with the following diagnosis codes: ICD 9: 850.0 – 854.19; ICD 10: S06.0X0A - S06.9X9A, S06.0X0S - S06.9X9S, F07.81.

**It is estimated that 20 percent of patients with an eligible diagnosis would participate in treatment.

***The estimates are based on all patients receiving treatment in Fargo. There is also a hyperbaric oxygenation treatment provider in Jamestown, but currently that provider only treats patients with non-healing wounds.

^Estimates are based on the service being available statewide to Medicaid members who meet the qualifying criteria. If availability of services were limited to a specific geographic area, fiscal estimates would change and ND Medicaid would need to apply for a waiver from the Centers for Medicare and Medicaid Services (CMS) to implement the services with a limited (not statewide) population. Developing the waiver application and receiving waiver approval from CMS would delay implementation of services.

^^Estimates do not include any study-related costs, including reporting on treatment outcomes.

HB 1359 Att 11
1/16/19 Pg 1
Before concussions

out going
always busy
loved getting together with family + ~~friends~~ friends

Concussions + before treatment

Grades were going down
Cared less about everything
showed up late to family holidays
Turned into a alcoholic
Depression got worst
Didn't think anyone cared
woke up every day hating the world
hide in my room all day

After treatment

feel amazing
care about everything I use to
Im out going
Im hanging out with friends + family
Over all just couldn't be happier with
where I am right now after treatments

HB 1359 AH 12

1-3-19

1/16/19 Pg 1

To Whom it May Concern:

Our child was involved in a sports related collision with another child that resulted in a severe brain concussion. Prior to the injury our child was a very active, quick witted, happy-go-lucky child and was also participating in the gifted and talented services at school.

After the collision we did make a hospital visit in which the diagnosis was a brain concussion. The doctors prescribed no school attendance, nausea medication, no screen time, low light and lots of brain rest. We did keep our child out of school for approximately five days and strictly followed the doctor's recommendations. A repeat trip to the doctor resulted in a clearance to go back to school on a restricted basis. Our child, who was very eager to get back to school, went and quickly found out that the body and brain were not ready. The following conditions developed: headaches, extreme fatigue, dizziness, inability to concentrate, sensitivity to light, unable to produce words when trying to speak and the inability to read for more than five minutes without the words blurring together. Prior to the concussion, this child would read a 200-300 pg. book in 1 day. Life had without question changed dramatically following the concussion. Most days resulted in a nap/break a couple times a day during the school day or a phone call saying our child needed to go home for the day. Our child also suffered insomnia and horrible "zinging" pains in the temples in the evening resulting in little to no sleep. Our child was begging for help.

We went back to our pediatrician and emergency room a few more times in the 5 weeks post-concussion period. Our emergency room doctor did refer us to a physician that specializes in concussions. The specialist told us it would take time and physical therapy before we would notice any significant changes. We were told said it would take between 3-9 months to recover from the concussion.

We discussed how our child, our family, our child's school, and our finances were going to handle the next 2-7 months. Our child was a changed person and honestly miserable. Our family life and schedule were 100% reactive to the "condition" of our child at this point.

At the point of week 7, with very little change from week 1, our child had really only learned to cope with the symptoms when the reality was that there really was no-to-very-little improvement. At this point, when in a discussion with a family member, the family member had remembered hearing a news story about a new clinic in the Fargo area that was using hyperbaric therapy to treat concussions and how it offered a solution to patients suffering with concussion symptoms. Hearing this was a breath of fresh air since waiting was not working for us or our child. This new information took a day or two to sink in since it was not something that we had heard come out of the mouth of any of the countless physicians that we had been in contact with since this had happened. Upon reading a few articles and letting it sink in we decided that we would see if it would work for our child. We consulted our insurance to see if it was covered under the plan we were on and it was not. Now the choice was if we wanted to still pursue this treatment it was going to be with out of pocket costs. It took another few days and no change in the post-concussion "new normal" with now zinging pains in our child's temples and one of us

HB 1359 AH12 1/16/19

parents up with our child for long periods during the night. This was all that we needed to convince us that we were going to try anything to try to offer our child some relief.

We reached out to Healing Hyperbaric clinic in Fargo and set up an evaluation and a few appointments. This, for us, was a huge decision due to the fact that it was 200 miles from our home. There would be out of pocket cost and my spouse or I would be missing work along with our child missing even more school. With where we were at, we needed this to work as it was honestly our last-ditch effort before completely accepting the "new normal".

We went, did the eval and saw first hand what the problems were with our child's eyes and what our child was struggling with. Our child's eyes were inconsistently working together and motor skills were greatly delayed when even compared to myself. We did do a treatment and the following day did two more treatments.

That evening we went home got ready for bed and the next morning two things happened, our child woke up and stated that it felt good to have slept the entire night without waking up and waking up with no headache. These two things for us were major milestones. Seeing this improvement, it made my child and me eager to go for a few more treatments no matter the costs or time as we had finally found something that was working, or at least took the edge off of the "new normal". After two more treatments we went back home and had a much better experience with much less "new normal". The next time that we went back to Fargo we saw an eye specialist and he also confirmed that our child's eyes were not working well together. Glasses that were to help the eyes work together were prescribed and we did another round of treatments. We went back home and ordered the glasses. Following these treatments, we could see major improvements in our child as so did the as teachers, other family members and all the people that had been around our child lately. The glasses showed up and our once voracious reader returned and could read without the page blurring and did not give up on reading after only a few minutes. We did return for another round of treatments and discussed what had been happening with the doctor. From this point and following a few more treatments and getting a pair of glasses we have never looked back and I would say that our child is back to, or very near, the former self, no "new normal" for us. We are thankful that our family member saw a news story about a new clinic in our state for wound and concussion treatment. We had a family member in the right place at the right time. This therapy worked for our child. My number one wish is that we had found it sooner than week 7 or 8. When I look at the after-insurance costs to our family that we had from all of the hospital visits that didn't work compared to the costs of what did work with hyperbaric therapy, it is a no brainer to pursue the hyperbaric therapy. The near immediate change proves that it works. I am still asking myself why; when this therapy works, why isn't a hospital that should have every means and option at its disposal not using this. I am fearful that the reason we were not introduced to this therapy by our hospital is merely due to the fact that it does not have an insurance code that can be tied to it. Thank goodness for people like my child, that there are doctors who believe in the therapy, see its results every day, have not given up on it and persevere through all obstacles to make it available to patients like my child. Please help the other people suffering from concussions and make this option available with an insurance code so that others can stop living their "new normal".

Sincerely,

A thankful family

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1359

Page 1, line 1, after "A BILL" replace the remainder of the bill with "to provide for a hyperbaric oxygen therapy pilot program; to provide an appropriation; and to provide for a report to the budget section.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. APPROPRIATION - HYPERBARIC OXYGEN THERAPY PILOT PROGRAM - REPORT TO BUDGET SECTION.

1. There is appropriated out of any moneys in the general fund in the state treasury, not otherwise appropriated, the sum of \$335,000, or so much of the sum as may be necessary, to the state department of health for the purpose of contracting with a third party to implement a hyperbaric oxygen therapy pilot program, for the biennium beginning July 1, 2019, and ending June 30, 2021.
2. The department shall contract with a local nonprofit entity with experience implementing studies using hyperbaric oxygen for traumatic brain injuries to conduct a pilot program for treatment of moderate to severely brain-injured North Dakotans using an established protocol of hyperbaric oxygen therapy provided by a private entity with experience in treating traumatic brain injury using medical grade hyperbaric chambers pressurized with one hundred percent oxygen. The goals of the study include demonstrating improvement in brain-eye function using RightEye, significant improvement in quality of life of injured patients, significant improvement in cognitive abilities of injured patients, and financial savings and increased revenues for the state, including possible savings for medical assistance and workers' compensation and a positive impact on income tax revenues. The pilot program design must be established in consultation with a third-party physician.
3. During the 2019-21 biennium, the department shall make periodic reports to the budget section on the status of the pilot program and whether the goals are being recognized."

Renumber accordingly

Good morning Madam Chair Judy Lee, from the great community of West Fargo, and members of the Senate Human Services committee.

My name is Austen Schauer, a Representative from District 13, the heart of West Fargo.

It is my honor to speak in support of **House Bill 1359** calling for a **Therapy Pilot Project** for Hyperbaric Oxygen Treatment.

I have toured the Hyperbaric Oxygen Treatment Clinic in Fargo twice and was **amazed** by what I saw and what I learned.

The number of people suffering concussions in this country each year is staggering. The Brain Injury Research Institute (BIRI) suggests it's anywhere from 1.6 million to 3.8 million, most happening in youth sports.

Here is what the BIRI suggests when you receive a concussion:

- Seek medical attention right away.

That's good advice, but the reality is most victims are sent home, told to rest up for a few days and then resume normal activity.

But what happens if the effects of a concussion (headache, listlessness) linger for weeks, months? Is there help?

The answer is yes, and it is happening right now in Fargo with the backing of the Dakota Medical Foundation and lead donor Gary Tharaldson.

Page 2

Dr. Daphne Denham runs the Fargo clinic. She is a surgeon by trade but moved into the study of hyperbaric oxygen treatment after her daughter suffered a **serious concussion** four years ago.

Her protocol is different from other treatment facilities and the results have been **outstanding**. The emphasis is to **reduce inflammation** in the brain.

Much of Dr. Denham's work is with adolescents but oxygen treatment is also proving to be effective with **veterans** and others who've experience **Traumatic Brain Injuries**.

We are asking you, Madam Chair Judy Lee and members of the Senate Human Services Committee, to **provide help** for those suffering from concussions and other brain injuries by supporting this pilot program in **House Bill 1359**.

Thank you for your time and I am open to any questions you may have.

Hyperbaric Oxygen Therapy

What is it?

Breathing 100% oxygen in a pressurized chamber/vessel



These are medical grade chambers. Physician supervision is required.

These are not the soft sided/bag/zipper chambers professional players buy off the internet.

How does it work?

Hyperbaric oxygen therapy does 4 basic things:

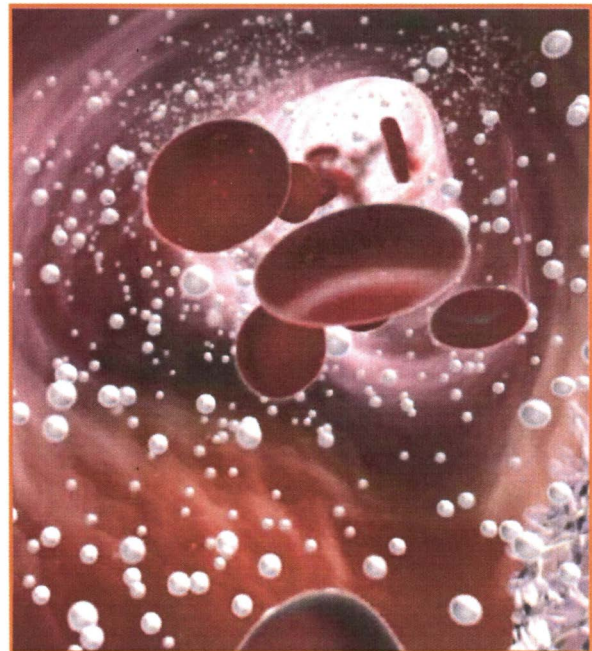
1. Hyper-oxygenates the tissues to allow them to repair
2. Decreases swelling
3. Turns off inflammation
4. Stimulates new blood vessel, and new cell growth, including brain cells

HBOT: It's About Oxygen Saturation

The body's liquids are saturated with more oxygen, helping areas with compromised circulation.



Before HBOT



After HBOT

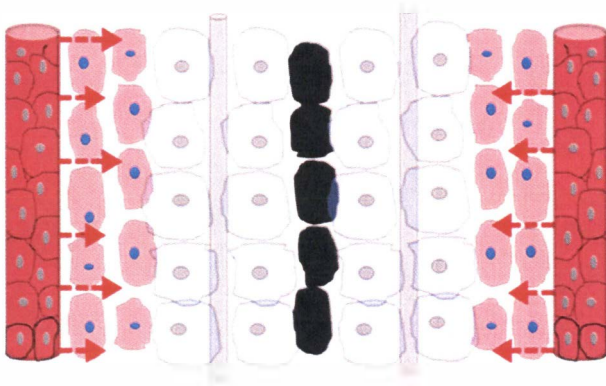
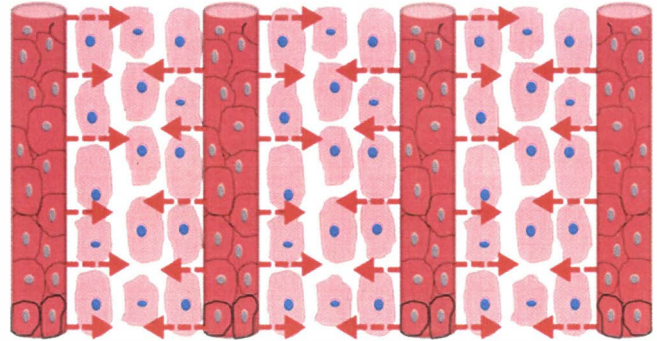
Image Courtesy of Dr. Stoller

We increase the amount of oxygen in the liquid part of blood by 500-1,200% based on the protocol for injury.

(as demonstrated by the white bubbles)

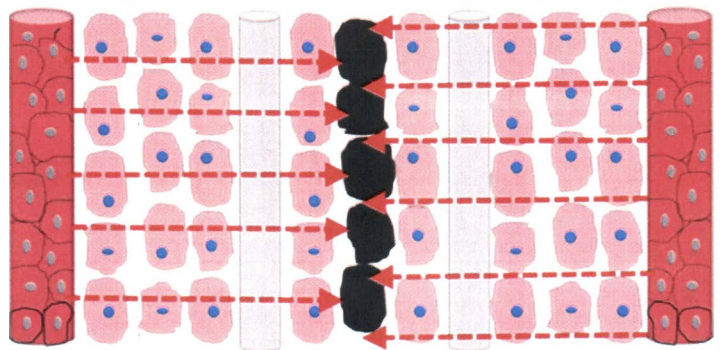
1. Hyperbaric Oxygen Therapy gets oxygen to damaged tissue to allow them to repair

Normally, all cells are close enough to a vessel to get oxygen.



After a trauma the tissue is damaged and some cells cannot get the oxygen they need, especially to repair themselves. Injured cells in blue and dead cells in black.

Under hyperbaric conditions, oxygen gets to the injured cells and lets them repair.

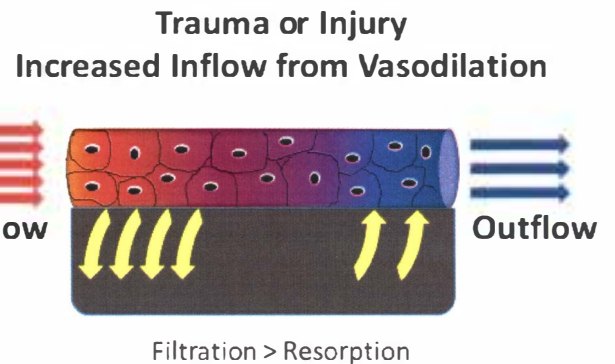
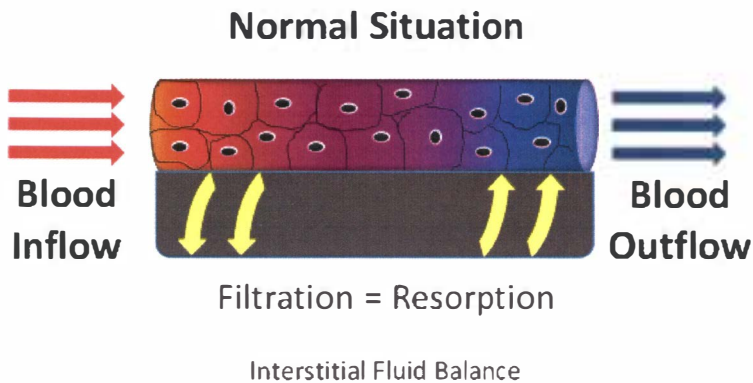


HB 1359
3/12/19
#2 pg. 4

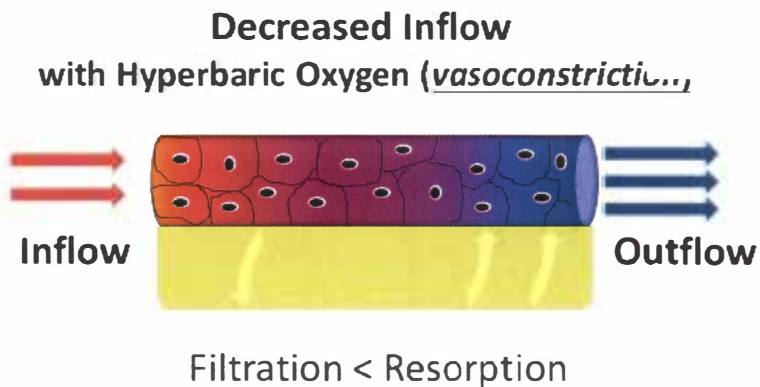
2. Hyperbaric oxygen therapy decreases swelling

Normally fluid in equals fluid out. After trauma, increased fluid in, therefore swelling.

With hyperbaric, less fluid in, therefore less swelling.



Swelling



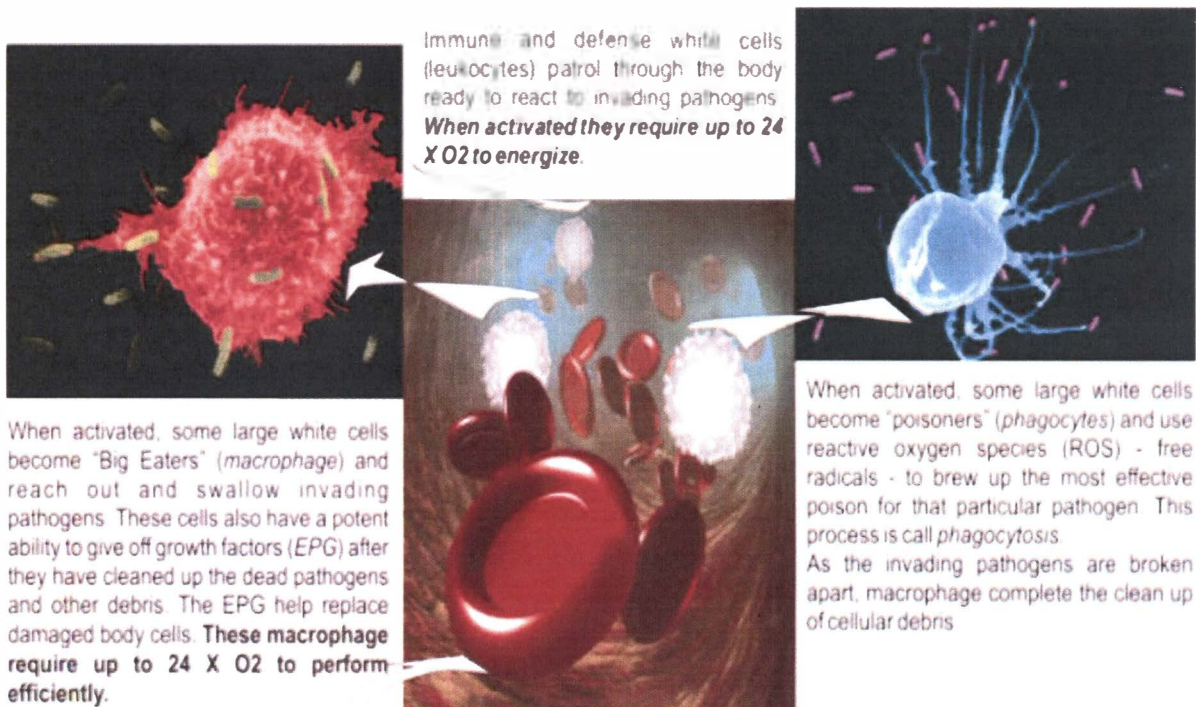
20-30% Reduction in Swelling

But we still have tissue oxygenation

3. HBO mitigates the inflammatory response

“Under HBO conditions, all the body’s clear fluids carry oxygen, thereby eliminating the need for the inflammatory response.”

Immune and Defense System Amplified by HBOT



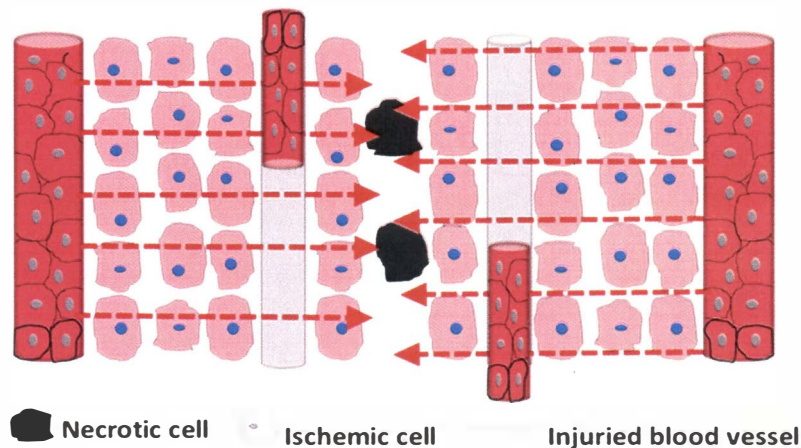
Red blood cells (*erythrocyte*) - RBC - are the only oxygen carrying cells under normal circumstances. When extra oxygen is required to activate immune response, blood vessels enlarge in process called inflammation (to set on fire) to allow more RBC to deliver O₂ to energize white cells.

Under Hyperbaric Oxygen Therapy (HBOT) conditions, all of the body’s clear fluids carry oxygen, thereby eliminating the need for the inflammatory response

4. Hyperbaric oxygen therapy stimulates the growth of new blood vessels and new cells.

HBO works for chronic injuries. FDA approved for diabetic foot ulcers, chronic bone infections, etc. due to the ability to grow new blood vessels and new cells.

After several hyperbaric treatments, new blood vessel growth begins, restoring more normal blood flow, as demonstrated to the left. Surrounding cells are able to begin to remove/repair the tissue.



Refer to #3: HBO turns off inflammation. Therefore, it does not matter how long ago the concussion was, we are seeing great responses to stopping post-concussion symptoms.

Research Ties Inflammation To Post-Concussion Symptoms



Researchers at McMaster University in Canada have found evidence supporting the belief that inflammation is an underlying factor facilitating symptoms of traumatic brain injuries

The study, published in *Brain, Behavior and Immunity*, may help explain why those with mild brain injuries—or even injury to other parts of the body—experience from significant post-concussion-like symptoms such as headaches, dizziness, and cognitive impairment.

According to the findings, individuals with a specific genetic change related to a certain inflammatory protein are particularly likely to have a poorer and more prolonged recovery from brain injury.

Rather than a conclusion, we'd like to propose a unifying umbrella term of post-inflammatory brain syndromes or PIBS," said Michel Rathbone, M.D., Ph.D., professor of medicine for McMaster's Michael DeGroote School of Medicine and a lead author of the study.

He continues to suggest that the new findings will encourage researchers to explore new lines of research into post-concussion symptoms so that physicians may be able to treat post-concussion-like symptoms even when there is no obvious brain injury.

The author concluded the results may also provide hope for individuals suffering from cognitive dysfunction after major injuries or trauma, as they may benefit from similar treatments as those with brain injuries.

This research opens many doors for so many different patients. We are excited to be starting a totally new approach to the field, and we look forward to making a difference for the patients of the future.



Budget:

HBO treatment using acute concussion protocol

G0277	\$85(2)	\$170
-------	---------	-------

99183	\$107	<u>\$107</u>
-------	-------	--------------

\$277 per tx (Medicare rate)

20-40 treatments @ \$277 is \$5,540 - \$11,080

30 patients, 20-40 treatments each patient

\$166,200 - \$332,400

Cost to Patient

Each 15 point IQ increase translates to about \$20,000 in income.

Persons who suffer from a single mTBI have a **future lifetime income loss of 50%.**

(Matched to themselves and their non-injured counterparts, matched for education, intelligence, etc., Gamboa, Chicago School of Economics)

45% will be unemployed 2 years post injury

33% will have "anger" issues rising 56.7% with co-morbid depression.

14.9% will become substance abusers.

Circular Tracking

RIGHT EYE	LEFT EYE
SP % : 97.88	SP % : 95.51
Efficiency : 12.30	Efficiency : 11.44

Stability

RIGHT EYE	LEFT EYE
Tropia : 0.32	Depth : - 52.37 mm
RIGHT EYE	LEFT EYE
≤ 2° : 95.72%	≤ 2° : 96.16%
2° and ≤ 4° : 2.12%	2° and ≤ 4° : 1.64%
> 4° : 2.16%	> 4° : 2.20%

Horizontal Tracking

RIGHT EYE	LEFT EYE
SP % : 96.81	SP % : 98.46
Efficiency : 12.99	Efficiency : 13.21

Horizontal Speed & Targeting

RIGHT EYE	LEFT EYE
TA (mm) : 9.58	TA (mm) : 11.59

Brain Health Indicator

Dysfunctional: 0 10 20 30 40 50 60 70 80 Functional

My Score 79

Right Eye

No imbalance

Left Eye

Overactive left Superior Oblique and/or Underactive left medial or inferior rectus

When looking down left eye moves outward
This is A-pattern: exotropia is caused by an imbalance between the eye muscles
Typical symptoms: headaches, eye fatigue, sleep disturbances, dizziness, light and sound sensitivity, binocular vision issues
Typical risks: falling, driving at night, low energy and fatigue, impaired focus and concentration

Pursuits

My Score	%ile
63	80

Saccades

My Score	%ile
64	81

Fixations

My Score	%ile
68	70

PURSUIT

- Eyes are not working optimally when having to track an object.
- The brain areas that may be affected are the cerebellum and/or parietal lobe.
- Typical symptoms: impaired tracking abilities, sensory disturbances.
- Typical risks: misjudging speed of moving objects (e.g. cars when driving), catching a ball, left and right field of view differences.

Vertical Tracking

RIGHT EYE	LEFT EYE
SP % : 80.48	SP % : 88.46

Vertical Speed & Targeting

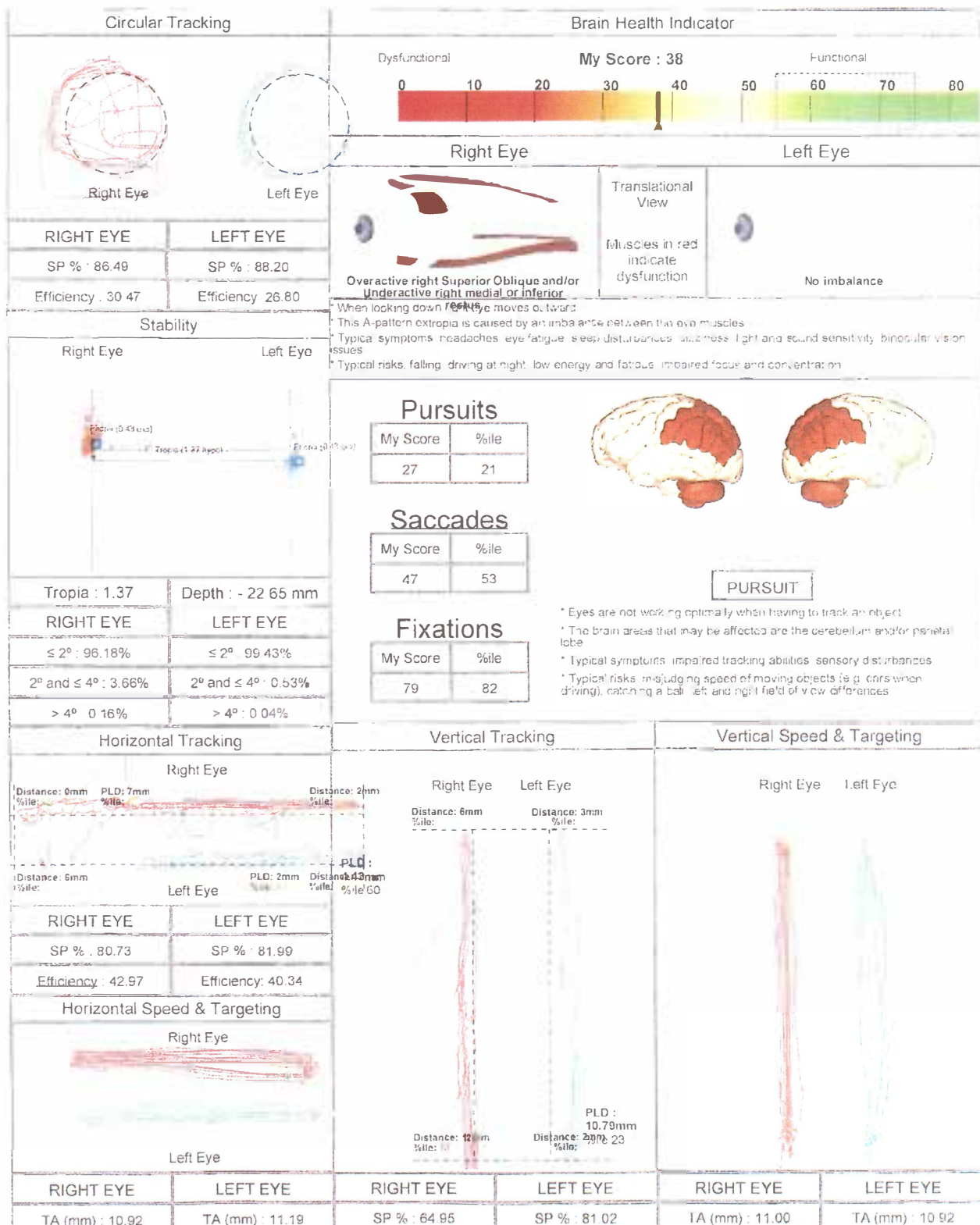
RIGHT EYE	LEFT EYE
TA (mm) : 14.68	TA (mm) : 16.04

HB 1359
3/12/19
#2 pg. 11



31 year old SIX years out from multiple concussions. Suicidal.
He was tearful when we discussed how bad his brain-eye function was, but HBO can help.

Repeat RightEye was 18 days later, after 20 HBO treatments. His brother was tearful over the repeat as he had seen the improvements and willingness to live and be involved in life again.





Hyperbaric Oxygen Therapy Pilot Program for Moderate to Severe Traumatic Brain Injury

Protocol:

1. Patient presents to Healing with Hyperbarics of North Dakota.
 - a. Patient with documented previous moderate to severe traumatic brain injury by any previous physician. [Glasgow Coma Scale 12 or below at some point]
2. Focused History and Physical Exam
 - a. History
 - i. Document Quality of Life issues
 - ii. Document current functional status
 1. Activities of daily living
 2. Age appropriate Cognitive tests
 3. RightEye exam
 4. Other age appropriate assessment tools as indicated
 - b. Assess for safety to have hyperbaric oxygen (HBO) treatment
 - i. Blood sugar check if diabetic
 - ii. Any suspicion of inability to tolerate pressure
 1. Tympanic membrane dysfunction
 2. Any implantable device that cannot be removed and/or is contraindicated
3. Traumatic brain injury hyperbaric oxygen protocol
 - a. Protocol used over past 3 years
 - b. Patient treated daily or twice a day as patient's and clinic's schedule allows
4. Repeat functional status performed after 10 treatment intervals by objective personnel
5. Follow up patient at 1 and 3 month post completion of HBO treatment; reassessed to document status

Exclusions:

1. Patients not medically cleared for HBO
2. Patients unable to tolerate pressure in the chamber

Data Collection:

1. All data will be kept in the office
2. De-identified data will be reported back to demonstrate progress with the study
3. Institutional Review Board (IRB) approval will be obtained through University of North Dakota
4. Results will be published and/or used to initiate other pilot studies for private insurance to assess cost-effectiveness of using HBO for moderate to severe brain injuries
5. Anticipated results:
 - a. Patients will demonstrate improved Quality of Life
 - b. Patients will demonstrate improved functional status
 - i. Activities of daily living
 - ii. Age appropriate Cognitive tests
 - iii. Neuro-ocular function as demonstrated by RightEye
 - c. Patients may demonstrate change in employment or potential change (for the better)
 - d. Patient's medical expenses will be followed to assess if decreased due to improvements deemed to be due to HBO

HB 1359—Pilot project for hyperbaric oxygenation treatment

A pilot control study of veterans with mild traumatic brain injury (TBI) or persistent post-concussion syndrome (PPCS), with or without post-traumatic stress disorder (PTSD) has found significant improvements in TBI and PPCS with PTSD symptoms, neurological exam, memory, IQ, attention cognition, depression, anxiety, quality of life and brain blood flow following hyperbaric oxygen treatment.

Simultaneously and more importantly, subjects experienced a significant reduction in suicidal ideation and anxiety, this is probably the most significant finding of the study given the current suicide epidemic in and out of the military. Dr. Paul Harch, Clinical Professor and Director of Hyperbaric Medicine at LSU Health New Orleans School of Medicine along with Dr Edward Fogarty Chair of Radiology at the UND School of Medicine. Dr Harch writes “The PTSD symptom reductions in PTSD symptoms in a four-week period with any reported diagnoses of blast induced PPCS and PTSD was noted.”

The improvements include a discontinuation or decreased dosage of psychoactive medications, continued to increase over the six-month post-traumatic period. Dr. Fogarty writes “Mild traumatic brain injury, persistent post-concussion syndrome and post-traumatic disorder are epidemic in the United States Iraq and Afghanistan war veterans. The only effective treatment of the combined diagnoses that is available and well-studied is via these chambers.

Thirty active duty or retired military men and women 18-65 with on more mild-to-moderate blast TBIs characterized by loss of consciousness that a minimum of one year old and occurred post 9/11 participated in the study. 10 of 12 patients who expressed suicidal ideation prior to treatment did not express suicidal thoughts after treatment. Of the patients who indicated significant anxiety before treatment, 75% were no longer anxious after treatment.

I have attached the testimony by one the participants experience with the study

VA officials have acknowledged that the new use of hyperbaric oxygen therapy and are pairing it with new research efforts by the VA and military in treatments. As such they have given it a “off label” or unauthorized designation. This designation means the veteran must pay for it use

We are excited with this bill because it could well be an avenue for the VA and military in changing their designation and we ask for your support of this bill

I will attempt to answer any questions.

AB 1359
3/12/19
#3 Pg. 2

Hyperbaric Oxygen Therapy Has Helped Beat TBI/PTSD, Veteran's Testimony

Sat, 08/31/2013 - 14:33 | Visitor (not verified)

Veteran Testimony - One of the first five treated in the TBI/PTSD HBOT Pilot Trial

The following is a testimony of one of the first five veterans treated by Dr. Harch with HBOT for TBI and PTSD. This veteran was referred by a compassionate Army doctor who was unsuccessful with other treatments. His story is typical of the ability of HBOT to positively change the trajectory of a brain-injured individual's life and literally give people back their lives. It is also the foundation of the Oklahoma HBOT legislation for veterans and the [National Grassroots Movement for HBOT](#) in the treatment of veterans that was launched by Rainey Owens in Texas. We hope you enjoy his story and realize that he is the rule, not the exception.



I sustained a Traumatic Brain Injury (TBI) in April 2003 when an ammunition bunker in Iraq was detonated within close proximity to my location. The concussion was tremendous and the negative effects immediate. Later on, after brain surgery to fix some damaged blood vessels, the disabilities became even more evident. Then, on March 1, 2007, I was in my home when an F4 tornado torn the place apart all around me. The sudden pressure changes from that event left me literally unable to cope with life. Everything was so confusing, overwhelming and frustrating. I would seek out the darkest areas of our rebuilt house and sit in confused agony for hours at a time. Often, not remembering what I had done earlier in the day, much less the events of the days before. I hardly knew what month it was and was completely unaware of the day of the week or the time of day.

Prior to my Hyperbaric Oxygen treatment beginning in June 2008, by Dr. Harch, I found myself living in a daily fog that was later diagnosed as Post Traumatic Stress Disorder. Everything from my ability to think to my impatient, misery/depression filled interaction with my family and friends, to writing and reading was affected by this PTSD fog. My frustration levels were extremely high. My family life was compromised to the point of my wife feeling as though she had an adult child in the house and my son didn't think I was very fun either! I was living in daily frustration with not being able to think clearly, sleeping on and off through out the day and generally, not having the capability to work or interact for very long with others. I was miserable. Knowing who I was before the TBI/PTSD, yet dealing with what I had become was depressing. I simply couldn't get myself out of that hole the head injury had caused.

Literally, during the first two Hyperbaric Oxygen Therapy treatments, I found parts of my brain waking up and the fogginess becoming less intrusive. By the time I finished 80 treatments, I had rediscovered the ability to enjoy reading a book again for the first time in five years! Writing this simple statement would have taken me three or four hours before treatment but now, a matter of fifteen minutes. I have high hopes of working full time after my medical retirement from the Army and most importantly, my wife and son still come up to me on occasion and just hug me.. They then mention how happy they are to have their husband and father back. I also found myself able to sleep again and feel refreshed!

I still struggle with various issues, some cognitive and some physical, but I'm so very grateful that the Lord placed Dr. Harch in my path to recovery. Dr. Harch and his staff are some of the most dedicated, sincere and hard working medical professionals I've ever been treated by. The quality of life improvements I've seen since being treated by Dr. Harch have made the difference between an existence of sitting at home, too confused and frustrated to LIVE, and a life with hope, patience and most importantly, a reduction in the daily fog of brain injury. Hyperbaric oxygen therapy has helped me to find my motivation and desire for life again. Also, since I am able to process better, the following four months at the Shepherd Center were much more productive!

For those who suffer with the fog and depression of TBI/PTSD, you will know how tremendously important those kinds gains are.. For the family members of those who suffer with this type of injury, the smiles and happiness from my wife and kids are testimony enough to know how much this treatment has given me back my life. God Bless!!

Dear Senators,

On Tuesday, March 12th, my son, Payton Rude, and I (Nicole Rude) had a chance to speak in favor of Bill 1359 regarding the hyperbaric oxygen treatment (HBOT).

We are writing to continue to urge our support for Bill 1359 for the funding of hyperbaric oxygen treatment so that this treatment opportunity can continue to help more individuals with brain injuries in the future.

Payton received ten treatments of hyperbaric treatments in early February. This has been the only thing that finally allowed Payton to feel himself again after nearly three years of pain, therapies, and various appointments. This treatment alone has been a life changer for him!

Since receiving hyperbaric treatment, Payton is finally symptom-free from post-concussive syndrome. He has been able to perform in school, and complete all assignments and computer work like a normal student without the accommodation of his 504 education plan. He is fresh and alert in the morning and even has stamina to make it through the whole day.

According to the Right Eye vision test, Payton's vision has had dramatic results in horizontal tracking (used for reading) from the 35%tile pre-treatment to the 95%tile one week after HBOT. His overall vision score was a 42, in the dysfunctional range, prior to HBOT. Three weeks after receiving treatments, Payton's overall vision score was at an 80, which actually puts his vision in the exceptional range. Payton's vision scores have continued to show gains over the past month, telling us that his brain is continuing the healing process even after the hyperbaric treatment ended. However, Payton didn't need a test to tell us these results. He knows his eyes are better because they finally "don't hurt" while reading.

During our testimony, we shared that Payton had four concussions in two years with MANY post-concussive symptoms. Some of these even included complications such as digestive issues, and a broken ankle and leg, which turned into a painful disorder call CRPS (Complex Regional Pain Syndrome). In our testimony, we mentioned his medical costs have been reaching \$100,000 in insurance expenses and also nearly \$15,000 out of pocket expenses. When considering the cost of HBOT to the cost of various other therapies, it only makes sense to use this as a first line of healing for concussions and inflammation on the brain versus the managing of concussion symptoms.

Payton has missed a LOT of school over the past three years due to therapies and post-concussive symptoms, including five months in which he received homebound education services last school year. We outlined this during the testimony to help point out the expense of his brain injury to his education, in addition to the school district.

Thank you for your time at the hearing and listening to us share our long journey to recovery, which lead us to finally finding hope and healing in hyperbaric oxygen treatment.

Sincerely,
Payton Rude (13 year old patient)
Nicole Rude (mother from West Fargo)

Testimony
Human Services Committee
March 12, 2019

Good morning, Chairman Lee and members of the committee. My name is Hannah Anderson from Leeds, ND. I am here today, to testify in favor of House Bill 1359, and to explain how hyperbaric oxygen therapy has made a difference in my life.

On November 12, 2007, I was in a nearly fatal car accident, where I suffered a traumatic brain injury along with other injuries. After 3 months in different hospitals, I relearned how to breath again on my own, without the use of any machines, I also learned how to talk, and how to walk on my own. My traumatic brain injury, however, left me with issues that I have struggled with daily for the past 11 years. My short term memory is very poor, I am tired all the time and just getting through the day is exhausting. I suffer with headaches every day and am on medications to help me get through the day and then take medications to help me sleep at night. I am easily overwhelmed in large groups of people and struggle to follow conversations. I become irritated when this happens.

Due to the great support that I had, I was able to graduate high school and even got my Associate Degree from Trinity Bible College in Ellendale, ND. I am currently working part time at the Minnewaukan Public School as a paraprofessional and living at home with my parents.

My mom heard of other brain injury survivors doing Hyperbaric Oxygen Therapy in Fargo, so she started doing research on it. We decided, as a family, that it might be a good thing for me to try. I was willing to try almost anything that would help get rid of the headaches that I had every day. We were not sure if HBOT would do anything for me because it had been 11 years since my traumatic brain injury. We were not given any promises, or any false hopes.

HBOT turned out to be the best thing I could have done. On day one, I was tired from my sessions, just like they said that I might be. On Day 3, halfway through the treatments, I felt as if my brain fog was lifting. I thought brain fog was something I would have to live with the rest of my life. It was also interesting to me that the headaches were much less severe than I had previously had. Also after the 3rd day, or 6 treatments, I was able to go out to supper with 5 other people. At that supper, I was able to concentrate on the menu and choose my own meal. I was able to keep up with the conversation the entire evening and according to my mom, I responded appropriately to questions throughout the evening. By the time I was finished with my 10 treatments in 5 days, I felt like my brain injury almost didn't exist.

It was 9 weeks ago that I was in Fargo, having HBOT treatments. I went to work the following Monday, and didn't become overwhelmed with everything that was going on at the school, and all the kids that needed help. I have not had any migraines over the last 9 weeks, which is so

amazing. I have more energy than I have had in 11 years. I wish I could have had this treatment along time ago, because the sooner I would have tried this therapy post injury, the sooner I could have felt less exhausted and had fewer headaches. I used to just drag through each 4 hour shift and come home exhausted. These last 9 weeks at work have actually been fun because of the amount of energy I've had.

Thank you for your time and your consideration of House Bill 1359. If you have any questions, I will be happy to try and answer them for you.

Hannah Anderson

6081 58th Ave NE

Leeds, ND 58346

701-351-6747 (cell)

701-466-2561 (home)

HB 1359
3/12/19
#6 pg.1

Testimony
Human Services Committee
March 12, 2019

Good morning, Chairman Lee and members of the committee. My name is Lisa Anderson from Leeds, ND. I am here today, to testify in favor of House Bill 1359, and explain why I support this bill.

You heard my daughter, Hannah's story, and how Hyperbaric Oxygen Therapy made a difference in her life. It is my belief that HBOT has made a tremendous difference in the quality of Hannah's life. It helped her to focus better, it has helped her balance and it has helped with her fatigue. We are amazed at the difference 10 Hyperbaric Oxygen Treatments made for Hannah.

Hannah's insurance company has paid over half a million dollars in benefits since 2007, for Hannah's medical expenses. Hannah's father and I have paid over \$ 50,000 out of pocket since 2007, for Hannah's medical expenses. It is my firm belief that if Hannah had received HBOT years ago, not only would everyone have saved thousands of dollars, but Hannah's quality of life would have been so much better. These figures do not include food, motel or mileage for any of the medical trips that we have made with Hannah.

In closing, I would like to thank you for your time, and for your thoughtful consideration of HB 1359. HBOT can make a huge difference in the life of a brain injury survivor. Please vote in favor of this pilot program for brain injury survivors. Not only will it potentially save the State of ND money, it will give brain injury survivors a better quality of life. If you have any questions for me, I will be happy to try and answer them. You can reach me at:

Lisa Anderson
6081 58th Ave NE
Leeds, ND 58346
701-739-6912 (cell)
701-466-2561 (home)
lisa.anderson@gondtc.com

HB 1359
3/12/19
#7 pg. 1

I am reading this with the permission of Bruce A. Hendrickson of Kindred, ND. In his words, this is a true-life experience with a happy ending.

The knowledgeable and professional staff at Healing with Hyperbarics of North Dakota are eager to assist you and very helpful. They answer questions and concerns you may have and help to determine if hyperbarics is right for you. I know firsthand and am sharing my experience with you as a living testimony. Hyperbarics is simple and effective. It is safe and the quick results give why to what is true.

On January 24th, 2017 I bumped my head and thought, "that will leave a mark!" This was not the first time, but it turned out to be the beginning of a long road to recovery. The emergency room was unable to detect a concussion and sent me home to treat shingles. I was told that if your body goes through trauma, shingles may occur. In my case, the laceration on the upper left side of my skull was the starting place for the shingles to activate. They spread across the upper left side of my face, swelling my left eye totally shut. The combination of the concussion and shingles left me in unbearable pain.

Six months later I was stumbling and confused. The hospital told me I had post-concussion syndrome. Therapists worked with me and taught me a new way to conduct my life. They said "write down everything. Take deep breaths, slow down and learn to accept this. It is a long process with no guarantee of returning to your old self. Accept your new normal and be happy." Because of the amount of time that had passed I was encouraged to apply for disability for income. That was not going to happen. I was 57 years old and loved my work. I wanted to find my OLD self.

A close friend shared information about the new hyperbarics clinic in Fargo. Two weeks later I made the call for an appointment. I explained my situation and asked a lot of questions. I told them how my current situation had me feeling helpless and hopeless. I was encouraged to come in for a few treatments and see how I felt.

On August 20, 2018 I had my first treatment. The 30-mile ride home after my first treatment was breath of fresh air! I noticed a huge difference in my right eye. I could see as far as the eye can take you. Next, I turned my head for to the left with ease. I had complete range of motion with no discomfort. I was completing a series of thoughts in a row. The thing I had missed most was happening. That night I was in less pain from my year and a half head ache.

I have had a total of 16 treatments and had not had a headache in 6 months. My train of thought is very near before the injury.

Although insurance will not cover hyperbaric treatment, I believe it should. Time will tell, for me, but dollar for dollar, it was worth every cent. As for the hospital and the money spent by me and our health insurance, I would still be paying with little or no progress to show for it.

Had I had a treatment sooner after my injury, I may have not even needed more than the 1st 5 treatments.

Please investigate hyperbarics for yourself. It could be you or a close friend who needs it. The treatments are safe, fun with the movies and the best bang for your buck.

Let Healing with Hyperbarics of ND and their friendly, professional staff put YOU back in control of your own life.

Sincerely,

Bruce A. Hendrickson

Senate Human Services – HB 1359 – March 12, 2019

Good morning, Chairman Judy Lee and members of the committee.

My name is Lynne Ostrem from Rugby, ND. I am in support and in favor of House Bill 1359, and will explain why I support this bill.

My son is David Folden. David was finishing up Chiropractic School in Iowa when he sustained a traumatic brain injury in November 2011. We were told David would not survive, and if he did, the prognosis was grim; he would be wheelchair bound and unresponsive. David overcame those odds and learned how to eat, talk and walk again. David and his family returned to North Dakota in August 2012. I can't even begin to come up with a dollar amount that has been spent for medical care, out of pocket expense, and lost wages of family members that provide informal support for David since November 2011.

David continues to struggle with the long term side effects of traumatic brain injury; which include persistent headaches, seizures, short term memory deficits, and mood swings. In addition to his prescribed medications, David was taking Tylenol or Ibuprofen every 4 hours daily and even with that, some days he still had a "slight headache". David's last labs showed elevated liver and kidney levels which his Primary Care said is probably due to the Tylenol and Ibuprofen, but we did not want to introduce narcotics for pain.

David started doing Hyperbaric Oxygen Therapy in Fargo in mid/late December. After his 4th treatment he asked me, "Do you think I'm getting better?" I asked him what he thought. David's response was, "My headaches are not as bad and I feel like my brain is so much clearer." David being able to verbalize and notice an improvement was enough for me to want to continue treatments for David and tell others of how it helped David.

So far, David has had a total of 7 treatments and no longer complains of headaches. There are other improvements I have witnessed:

- 1.) David can now set a timer and remembers what the timer was for – he doesn't need to write a note as a reminder what the timer was for.
- 2.) David is more relaxed and content – which is unusual for a frontal lobe brain injury. David recently attended a meeting with me. He was walking up to people he didn't know and initiating conversation – he usually isolated himself and was on his phone/iPad.
- 3.) When he finishes a task he will seek me out and let me know he is done and asks what he can do to help next.
- 4.) The amount of time needed to remember things in the short term has reduced. Previously, we would still have dry erase boards up for months reminding him it was a new year.
- 5.) His caregivers have noticed an improvement in memory and mood – they didn't know he was doing HBOT.

In closing, I appreciate your time and your consideration of HB 1359. I believe HBOT can make a difference in the life of a brain injury survivor. I have already seen the positive effects for my son. Improvements for survivors would have a multitude of ripple effects for family members, potential future medical costs but the most important item is allowing our ND Brain Injury Survivors a better quality of life. Please vote in favor of HB 1359. If you have any questions for me, I will be happy to try and answer them.

Lynne Ostrem
5693 Hwy. 3 South
Rugby, ND
701-208-1051
ostrich@gondtc.com

NDLA, S HMS - Velez, Justin

From: Lee, Judy E.
Date: Wednesday, March 13, 2019 2:19 PM
To: -Grp-NDLA Senate Human Services; NDLA, S HMS - Velez, Justin; NDLA, Intern 02 - Carthew, Alexandra
Subject: FW: HB 1359

Info from Rebecca Quinn, the brain injury expert from the Center for Rural Health

Senator Judy Lee
1822 Brentwood Court
West Fargo, ND 58078
home phone: 701-282-6512
e-mail: jlee@nd.gov

-----Original Message-----

From: Judy Lee <judylee1822@gmail.com>
Sent: Wednesday, March 13, 2019 2:17 PM
To: Lee, Judy E. <jlee@nd.gov>
Subject: FW: HB 1359

***** CAUTION: This email originated from an outside source. Do not click links or open attachments unless you know they are safe. *****

-----Original Message-----

From: Quinn, Rebecca <rebecca.quinn@und.edu>
Sent: Wednesday, March 13, 2019 9:57 AM
To: Judy Lee <judylee1822@gmail.com>
Subject: Re: HB 1359

Senator Lee,

First, let me say thank you for the brain injury definition bill. I like to believe somewhere June is smiling down pleased that we could finally fix it.

In regards to the hyperbaric, the official stance from the medical school and the advisory council is that there is insufficient scientific evidence to support it. Currently, no other states are funding it as a treatment and there is very limited scientific evidence. Almost all of the evidence is anecdotal and done by a few promoters/researchers. I personally have concerns regarding state funds going to supporting this type of independent research and about the methods of how individuals will be screened, selected, and supported during the process.

With the medicinal marijuana, I was able to point to the number of states that allow it and it is not for the state to pay for the treatment, only allowing it to happen. I feel the hyperbaric differs in not having other states precedent and allowing state appropriated dollars to fund the treatment.

Please let me know if you have any other questions.

Rebecca Quinn

> On Mar 12, 2019, at 10:17 AM, Judy Lee <judylee1822@gmail.com> wrote:

>

> This bill promotes the hyperbaric chamber as treatment for brain injuries.
What are your comments about this?

>

> Judy Lee

> 1822 Brentwood Court

> West Fargo, ND 58078

> Phone: 701-282-6512

> Cell: 701-238-1531

> e-mail: judylee1822@gmail.com

>

HB 1359
3/14/19
#1 Pg.1

Lee, Judy E.

From: pat traynor <ptraynor@dakmed.org>
Sent: Thursday, March 14, 2019 11:52 AM
To: Lee, Judy E.
Subject: HB 1359

Follow Up Flag: Follow up
Flag Status: Completed

CAUTION: This email originated from an outside source. Do not click links or open attachments unless you know they are safe.

I wanted you to see this. Thanks for all you do for others Judy! Pat

Sent from my iPad

Begin forwarded message:

From: Daphne Denham <denham2468@gmail.com>
Date: March 14, 2019 at 11:02:39 AM CDT
To: pat traynor <ptraynor@dakmed.org>
Subject: HB 1359

Pat,

Thank you for your help with HB 1359. There were some things that came up at the committee meeting that I feel I should clarify and further articulate what we are trying to accomplish.

We know hyperbaric works. The Olympic cyclist who committed suicide 2 months after a concussion has troubled me greatly. She could be my 23-year-old graduate student who is an overachieving athlete that would not be happy not being able to overachieve. But we can TREAT that, that is what DMF helped us show.

I am not sure that I made clear that what DMF helped with was the pilot on ACUTE or "fresh" concussions for student athletes. By definition a concussion is a MILD traumatic brain injury with a Glasgow Coma Scale of 13 or better....the "walkie talkies" as we say. Prior to my treating these acute concussions in Northbrook, IL, there was no protocol. I took an existing protocol and developed what we use today, with my knowledge of inflammation of the brain. I funded this acute concussion protocol development from my clinic and DMF assisted with further development with the RightEye. The RightEye test was recently FDA approved as a test for concussions. It is an objective measure demonstrating the effects of the treatment of the concussion after HBO. No one else is doing what we are doing, and we now have 8 months of data using this device. To date we have treated more than 300 acute concussions, 104 under DMF with RightEye data and this data is incredible.

What HB 1359 seeks to fund is a pilot for MODERATE TO SEVERE traumatic brain injury, defined as a Glasgow Coma Scale of 12 or less. Any pilot participant/patient needs the GCS of 12 or less documented at any time in their history, from another physician. We do not have much data on this group, certainly not enough to apply for a grant. What we do have, that no one else has, is my protocol for this group of patients. Again, I took a standard protocol, applied what I know from brain inflammation, and have changed it. We have treated only a few patients who would be classified in this more severe category,

HB 1359
3/14/19
#1 pg.2

and they came to the committee hearing to passionately tell their story. After HBO treatment they have returned to a much more normal life with no more headaches and much improved cognition and energy. The committee heard from Hannah Anderson and Payton Rude.

We plan to have UND involved and gain their approval for the scope and design of the pilot. This will ensure we have credible data for future grants. The money from HB 1359 will only fund treatments. No additional funding for the testing, for a research person etc. We are trying to keep the ask to only fund the treatments. It is just a plus that we plan to use it to get private insurance companies to see the benefit to then pick up the pilot, just as we are doing with the acute concussions.

Big picture, we are asking that North Dakota fund treatments. We then will use the data we collect as a result of these treatments to demonstrate to private insurance companies that it is cost-effective for them to take a more pro-active treatment approach for moderate to severe head injuries using hyperbaric oxygen.

I would like to clarify my experience in research as a physician. I am well-published in not only cytokine/inflammatory marker research, but also in a cost-effective study that changed the standard of care for parathyroid surgery. Amazingly, what I am doing for brain injuries is a unique combination of these two. With HB 1359 North Dakota has a real opportunity to lead the nation to change the standard of care for moderate to severe brain injuries, something that is long overdue, and for those who are suicidal, we have an opportunity to show them we can make them better.

Happy to discuss further at anytime.

Daphne

Daphne W. Denham, MD FACS FACCWS
Healing with Hyperbarics of North Dakota, PLLC
4487 Calico Drive South, Suite B
Fargo, ND 58104
(701) 532-2426
(701) 532-2427 fax

HB 1359
3/14/19
#2 pg.1

Lee, Judy E.

From: Quinn, Rebecca <rebecca.quinn@und.edu>
Sent: Thursday, March 14, 2019 9:38 AM
To: Lee, Judy E.
Subject: Re: HB1359

CAUTION: This email originated from an outside source. Do not click links or open attachments unless you know they are safe.

Senator Lee,

To provide clarification, the email was from Representative Nelson to me expressing his disappointment with me for my role in the bill failing. I was simply letting Dr. Wynne know so he could be aware of Rep Nelson's concerns.

Thank you for providing the additional information. I also feel that the treatment is promising and look forward to future outcomes. To move from a promising practice to evidence based is a hard step and I think it wonderful that DMF is working with them. I also would be more than happy to help in identifying other funding opportunities and assist in any ongoing support of their goals.

Thank you,

Rebecca Quinn

Mar 13, 2019, at 9:54 PM, Lee, Judy E. <jlee@nd.gov> wrote:

I'd be happy to explain. Jon Nelson had nothing to do with it failing. Neither did I.

The presentation was convincing about the impact of the treatments for brain injuries. However, Dr. Denham apparently has data, but has not done anything to organize it so that it can be presented as any kind of grant application.

Also, the tobacco fund from which the money was supposed to come, according to the bill, is already \$241,000 in the hole because of requests, so the funding is not available there.

Dakota Medical Foundation is supportive of her effort, thanks to a donation from Gary Tharaldson, which is great! I spoke with Pat Traynor, head of DMF, this morning, and he is enthusiastic about the project also. We discussed the challenges, and he is going to assist Dr. Denham in assembling her data to make it useful and also probably assist with preparation of grant applications.

While we were discussing it in the committee, an observer checked online and found at least 6 potential grantors which would be likely places for such a request to be directed. This is a popular topic right now, because of all of the concerns about concussions from sports injuries as well as other causes. The committee is optimistic that there will be additional sources of funding.

But one of the biggest factors is that the state of ND cannot be directly funding research, especially when, at this point, it does not meet the requirements of any application for grants. The legislature may appropriate money to the 2 research universities, and then the application, if properly prepared, can be presented to UND's Center for Rural Health or the Medical School, for example, when they are considering research possibilities.

HB 1359
3/14/19
#2 pg. 2

We want her project to succeed, and the people who testified in its favor were very convincing. But it is inappropriate governance for the state to directly support such projects. The protocol for grant applications is, as I understand, pretty consistent from one grantor to another, and all require certain documentation. When that is available, there will be opportunities for her to receive funding, we are confident.

In the meantime, her treatments are not terribly expensive, and private pay patients can continue to have treatments.

It was interesting to me that every other committee member quietly came up to me after the hearing and individually expressed his or her reservations. Each of us thought we were the only ones, and we all had the same concerns. The end does not justify the means, and there will be other routes to success.

Judy Lee
1822 Brentwood Court
West Fargo, ND 58078
Phone: 701-282-6512
e-mail: jlee@nd.gov

On Mar 13, 2019, at 5:00 PM, Quinn, Rebecca <rebecca.quinn@und.edu> wrote:

CAUTION: This email originated from an outside source. Do not click links or open attachments unless you know they are safe.

Sorry, I forwarded this to you. I meant to send it to Judy Solberg so she could update Dr. Wynne.

Rebecca Quinn

Begin forwarded message:

From: "Nelson, Jon O." <jonelson@nd.gov>
Date: March 13, 2019 at 1:58:12 PM CDT
To: Rebecca Quinn <rebecca.quinn@med.und.edu>
Subject: HB1359

Rebecca: I am trying to find out why the Senate Human Services Committee voted to give HB1359 a Do Not Pass recommendation. I hear you oppose the bill and had some influence on that decision. If true, I am VERY disappointed to hear this. Several of my constituents feel this treatment has given their loved ones the most success they can remember and Rep. Anderson has spent a great deal of time and energy on this effort. He has been a great supporter of Brain Injury as well in the past. Please respond with your opinion.

Jon

Sent from my iPhone

Representatives D. Anderson, Mock, Schauer, Schneider

Senators Burckhard, Kreun, Robinson

- 1 A BILL for an Act to provide for a hyperbaric oxygen therapy pilot ^{research project} program; to provide an
 2 appropriation; ~~and to provide for a report to the legislative management.~~

3 **BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:**

4 **~~SECTION 1. APPROPRIATION - HYPERBARIC OXYGEN THERAPY PILOT PROGRAM -~~**
 5 **~~REPORT TO LEGISLATIVE MANAGEMENT.~~**

- 6 1. ~~There is appropriated out of any moneys in the tobacco prevention and control trust~~
 7 ~~fund in the state treasury, not otherwise appropriated, the sum of \$335,000, or so~~
 8 ~~much of the sum as may be necessary, to the state department of health for the~~
 9 ~~purpose of contracting with a third party to implement a hyperbaric oxygen therapy~~
 10 ~~pilot program, for the biennium beginning July 1, 2019, and ending June 30, 2021.~~
 11 2. ~~The department shall contract with a local nonprofit entity with experience~~
 12 ~~implementing studies using hyperbaric oxygen for traumatic brain injuries to conduct a~~
 13 ~~pilot program for treatment of moderate to severely brain-injured North Dakotans using~~
 14 ~~an established protocol of hyperbaric oxygen therapy provided by a private entity with~~
 15 ~~experience in treating traumatic brain injury using medical grade hyperbaric chambers~~
 16 ~~pressurized with one hundred percent oxygen. The goals of the study include~~
 17 ~~demonstrating improvement in brain-eye function using RightEye, significant~~
 18 ~~improvement in quality of life of injured patients, significant improvement in cognitive~~
 19 ~~abilities of injured patients, and financial savings and increased revenues for the state,~~
 20 ~~including possible savings for medical assistance and workers' compensation and a~~
 21 ~~positive impact on income tax revenues. The pilot program design must be established~~
 22 ~~in consultation with a third party physician.~~

1 3. During the 2019-21 biennium, the department shall make periodic reports to the
2 legislative management on the status of the pilot program and whether the goals are
3 being realized.

4 **SECTION 1. UNIVERSITY OF NORTH DAKOTA SCHOOL OF MEDICINE AND**
5 **HEALTH SCIENCES - HYPERBARIC OXYGEN THERAPY STUDY.** During the 2019-
6 21 biennium, the university of North Dakota school of medicine and health sciences
7 may design and implement a study of the efficacy of hyperbaric oxygen therapy in
8 treating brain injuries.

9 **SECTION 2. APPROPRIATION -HYPERBARIC OXYGEN THERAPY STUDY –**
10 **MATCHING FUNDS.** There is appropriated out of the general fund in the state treasury,
11 not otherwise appropriated, the sum of \$100,000, or so much of the sum as may be
12 necessary, to the university of North Dakota school of medicine and health sciences for
13 a study of hyperbaric oxygen therapy, for the biennium beginning July 1, 2019, and
14 ending June 30, 2021. The funds appropriated in this section may be spent only to the
15 extent the university of North Dakota school of medicine and health sciences provides *reviews*
16 two dollars of matching funds from nonstate sources for each one dollar provided from
17 the general fund.

NDLA, Intern 09 - O'Neill, Seth

From: Roers, Kristin
Sent: Thursday, April 11, 2019 3:15 PM
To: NDLA, Intern 09 - O'Neill, Seth
Subject: Fwd: Special laws

Kristin Roers, BSN, RN

Begin forwarded message:

From: "Lee, Judy E." <jlee@nd.gov>
Date: April 2, 2019 at 4:49:38 PM CDT
To: -Grp-NDLA Senate Human Services <ndlashumserv@nd.gov>, "NDLA, S HMS - Velez, Justin" <shms@nd.gov>, "NDLA, Intern 02 - Carthew, Alexandra" <intern2@nd.gov>
Cc: "Wardner, Rich P." <rwardner@nd.gov>, "Raymon Holmberg (holmbergforsenate@gmail.com)" <holmbergforsenate@gmail.com>
Subject: FW: Special laws

I had discussed the hyperbaric issue with John Bjornson today, and he had Chris Joseph put together the information below about the "special laws" section of the Constitution which would likely be an impediment to directly funding Dr. Daphne Denham and her brain injury program.

The Appropriations Committee will see the original language in 2012 now, because they have been moving it around in the House.

Senator Judy Lee
1822 Brentwood Court
West Fargo, ND 58078
home phone: 701-282-6512
e-mail: jlee@nd.gov

From: Joseph, Christopher
Sent: Tuesday, April 2, 2019 4:36 PM
To: Lee, Judy E. <jlee@nd.gov>
Subject: Special laws

Good afternoon Senator Lee,

This email is in response to your inquiry regarding local or special laws in reference to House Bill No. 1359. Article IV, Section 13, of the Constitution of North Dakota prohibits the Legislative Assembly from enacting a local or special law and from indirectly enacting a local or special law by the partial repeal of a general law.

The legal definition of a local or special law is: "a law that applies to a particular place or especially to a particular member or members of a class of persons or things in the same situation but not to the entire

class and that is unconstitutional if the classification made is arbitrary or without a reasonable or legitimate justification or basis.”

The North Dakota Supreme Court has held that a special law is one which relates only to particular persons or things of a class, as distinguished from a general law that applies to all things or persons of a class. The Supreme Court has held the test for a special law is not what the law includes, but what the law excludes, and the courts look to see whether a statute excludes any within the class to which the law applies.

Although the North Dakota Supreme Court has considered challenges to legislation based on the local law prohibition, case law indicates it is difficult to prevail on those challenges.

If you need additional information or have any questions, please do not hesitate to contact our office.

Sincerely,

Christopher S. Joseph
Legal Counsel
North Dakota Legislative Council
600 East Boulevard Ave
Bismarck, ND 58505
(701) 328-2916
cjoseph@nd.gov