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MEMORANDUM

TO: Technical Committee on Hyperbaric and Hypobaric Facilities

FROM: Elena Liolin, *Senior Committee Administrator*

DATE: July 14, 2023

SUBJECT: NFPA 99 Proposed Tentative Interim Amendment (TIA) No. 1735
– **Public Comment Review**

The attached Public Comment is being submitted to the Technical Committee for review.

If you wish to change your vote, the change must be submitted through the NFPA online ballot system at the following link: [NFPA Ballot Link](#). If you do not wish to change your vote, no response is necessary.

Please complete the ballot on or before **July 20, 2023, by 11:59 pm ET**.

While completing your ballot, please remember the following:

- **A comment is required for both Question No. 1 and Question No. 2 for the online TIA ballot. Comments must accompany all Negative, Abstaining and Agree votes.**
- **If you vote “Agree” on Question 1, simply add “Agree” to the comment field and if you vote “Agree” on Question 2, insert the applicable letter(s) selections in the comment field which can be found in the Instructions box on the ballot site.**

You must hit SUBMIT to SAVE your work. **Note:** the system session will time you out after 45 minutes; any work not submitted at that time will not be saved! You may return to finish or change your ballot at any time up to the closing date. Ballot comments exceeding 4,000 characters must be submitted in a Word document via email, to Elena Liolin at eliolin@nfpa.org.

The return of ballots is required by the *Regulations Governing the Development of NFPA Standards*.

Attachment: Public Comment(s)

Foran, Rosanne

Comment No. 7
SUPPORT
page 1 of 4

From: Mario Caruso
Sent: Wednesday, July 12, 2023 5:55 PM
To: Shared TIAs
Subject: Comment on Proposed TIA 1735 on NFPA 99
Attachments: Comment on Proposed TIA 1735 on NFPA 99 07-12-23.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good morning,

Attached is my Public Comment related to the above referenced TIA.

Regards,

Mario Caruso, CHT-A, DMT, EMT-P
Senior Consultant | Hyperbaric Consulting LLC
3231 Glenwood Circle – Holiday, FL 34691-2545



Hyperbaric Consulting LLC

"There's No Substitute For Experience!"

July 12, 2023

To: National Fire Protection Association

Re: Comment on Proposed TIA 1735 on NFPA 99

Clarification statement of letter to Restore Hyper Wellness dated May 11, 2022.

The letter has caused some confusion as to what my interpretation of NFPA code language is and what my intent of writing the letter was. Hopefully this statement will clarify this and will provide proper context to what my current position is regarding “soft chambers”.

In the letter I mentioned that soft chambers are not required to comply with the current edition of NFPA 99-14. The reason I made that statement is that 99-14 does not address soft chambers specifically, it addresses multiplace (class A) and monoplace (class B) chambers that by design are considerably different to soft chambers. This makes it impossible for end users of soft chambers to comply with most of what NFPA 99-14 states. The fire risk and the evacuation requirements for soft chambers are drastically different than in monoplace and multiplace chambers. That forces users to come up with their own “standards”. My intent was to correct this by suggesting that changes should be introduced to the current code language to make the use of these devices standardized and ultimately safer.

I believe that the incidents that have occurred involving soft chambers could have been mitigated by having adequate codes that address their fabrication and use. Only by wishing that the thousands of soft chambers currently in use would simply go away is not going to make their use safer, it's only going to force end users to operate without proper guidance and training further contributing to potential incidents. Again, my hope was to be of assistance in making actionable recommendations that would bring soft chamber use in compliance with new and realistic actionable standards and thereby make their use safer. Nothing more.

(Page 1 of 3)

Mario Caruso, CHT-A, DMT, EMT-P
Senior Consultant | Hyperbaric Consulting LLC
3231 Glenwood Circle – Holiday, Florida 34691-2545



Hyperbaric Consulting LLC

"There's No Substitute For Experience!"

My intent was not that soft chambers should not comply with any standards, but that unfortunately current standards are not clear and do not specifically address soft chambers concurrent with their actual fire hazard. My intent was that standards should be written and eventually adopted; that would be a great improvement to what currently must be worked with.

My initial intent was, and it continues to be, that clear actionable language addressing soft chambers should be drafted to standardize their use. This will make their use safer and will give the Fire Marshals (Authorities Having Jurisdiction) clear guidance.

It is unrealistic to expect that these devices will just simply disappear. Soft chambers are FDA approved for altitude mountain sickness and thus may be used with proper medical oversight for off-label, experimental, and research purposes.

Unfortunately, in my opinion, soft chambers should have been addressed by the 99-14 Committee long ago. There are many thousands of these devices currently in use in the US and most likely more will be in use in the future. That is not just my opinion, it is a fact.

My position is that their use should be made safer. Restore Hyper Wellness asked me what they could do to improve safety and I gave my opinion. I was hoping that this would improve the status quo of soft chamber use in the US.

My stance regarding the use of oxygen analyzers was based on two factors, as follows:

1. The soft chamber manufacturers recommend that their devices be compressed only with air and do not address the use of supplemental oxygen.
2. Studies that were done (and submitted to the NFPA) demonstrated that even with the use of supplemental oxygen, the concentration of oxygen did not approach 23.5%.

Of course, if there's a possibility of the oxygen concentration exceeding 23.5%, I would advocate the use of oxygen analyzers.

(Page 2 of 3)



Hyperbaric Consulting LLC

"There's No Substitute For Experience!"

I am not a soft chamber subject matter expert. Obviously there is much, much more to be said regarding the fabrication and use of soft chambers. This letter is certainly not an exhaustive list of all my positions regarding the matter. In the final analysis, my ONLY intent was and is to make the use of these devices safer.

Another fact is that no one exactly knows the effectiveness of air at low pressures. Some credible studies have been done that, for certain selected medical conditions, low pressure air in a chamber may be beneficial. Obviously many more high-level studies need to be done and peer reviewed. That cannot happen by forcing soft chamber users to operate in the shadows. Prohibition does not promote or advance science.

As in my first letter, these opinions are completely my own. I do not imply, nor it should be inferred or assumed that they reflect the opinions of the National Board of Diving and Hyperbaric Medical Technology (NBDHMT), the Undersea and Hyperbaric Medical Society (UHMS), Restore Hyper Wellness, any other agencies that I'm associated with, or any of my esteemed colleagues.

Respectfully submitted,

Mario Caruso

(Page 3 of 3)

Foran, Rosanne

Comment No. 8
SUPPORT
page 1 of 6

From: Shared TIAs
Subject: FW: NFPA 99 TIA 1735 Public Comments
Attachments: Hyperbaric chambers of soft with edits 3-15-2023.pdf; Restore Cryotherapy Mail - Fwd_ Hello.pdf; NFPA 99 CH14 TIA PC - Google Docs.pdf

From: Chris Neal
Sent: Thursday, July 13, 2023 2:53 PM
To: Shared TIAs <STIAs@nfpa.org>
Subject: Fwd: NFPA 99 TIA 1735 Public Comments

Hello,
Please see attached public comment with supporting documents submitted for NFPA 99 Proposed TIA No. 1735.

Chris Neal | Sr. Director, Operations
Restore Hyper Wellness

----- Forwarded message -----

From: Harrington, Greg
Date: Thu, Jul 13, 2023 at 11:37 AM
Subject: NFPA 99 TIA 1735 Public Comments
To: Chris Neal

Chris,

Public comments on the proposed TIA can be sent to tias_errata_fis@nfpa.org. If you'd like to copy me to ensure it's received, that would also be fine. The public comment deadline is today, July 13, 2023. Public comments are circulated to the technical and correlating committees before the ballots are finalized.

If you have any other questions, please don't hesitate to ask.

-Greg

Gregory Harrington, P.E.
Principal Engineer | NFPA
1 Batterymarch Park
Quincy, MA 02169-7471

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Public Comment re: NFPA 99 Proposed TIA No. 1735

There seems to be a belief that Restore misrepresented Tom Costabile's position re: ASME's applicability to soft shell chambers. This is not the case. By way of history, back in March IHA met with Mr. Costabile and he was "supportive" of IHA issuing a statement that there are no standards applicable to soft shell chambers, but that IHA is working with ASME to develop a standard. Mr. Costabile even edited the statement and the attached email reflecting his support. We do not want this to be viewed as Restore misrepresenting anything with respect to ASME's position as what we were told by IHA was exactly what ASME via Mr. Constabile that was agreed to.

Separately, some states are recognizing the distinction in the codes for soft shell chambers that operate at pressures less than 5 psi. On June 28th, for example, a public hearing took place in Atlanta, Georgia whereby a proposed rule was submitted (outlined below) that would essentially exclude soft-wall hyperbaric chambers (<5psi) from the boiler and pressure vessel code.

Accordingly, Restore submitted the TIA in an effort to fill an identified gap in the safeguarding requirements that currently exist in a standard soft-walled mild hyperbaric chamber. We believe ASME recognized it but has since been silenced by other industry players that have fought against this clarification. Efforts are being made to continue the code clarification process. In the meantime, exceptions to soft-walled hyperbaric chambers are being pushed at the legislative level thereby creating a need for NFPA to work with the industry to create a code relevant to these chambers. We continue to urge you to do so.

We look forward to a productive and collaborative relationship with the technical committee through the respected standards process, in pursuit of effective & appropriate technical representation of soft shell chambers in the code.

**RULES OF
OFFICE OF INSURANCE AND SAFETY FIRE COMMISSIONER**

**CHAPTER 120-3
RULES OF SAFETY FIRE COMMISSIONER**

**SUBJECT 120-3-26
RULES AND REGULATIONS FOR BOILERS AND PRESSURE VESSELS**

TABLE OF CONTENTS

Rule 120-3-26-.22 Exceptions

- (1) Boilers and pressure vessels exempted from the requirements of the Safety Act. The following is in addition to the exceptions listed in O.C.G.A. Section 25-15-16.
- (2) Espresso coffee and similar machine boilers, providing these boilers meet the following requirements:
 - a. The boilers shall be manufactured and tested to a National Standard, and
 - b. shall not be more than (3) three U.S. gallons in size, and
 - c. shall not operate more than 15 pounds per square inch, (PSI) and have a safety relief valve set to relieve at or below 15 psig.
 - d. The boiler shall not be repaired by welding.
- (3) Boilers with outlets open to the atmosphere when there are no valves or restriction in the outlet system and pressure cannot rise to above 0 psig at maximum operating condition and temperature cannot rise above 212 degrees Fahrenheit.
- (4) Hot water supply heaters with storage capacity of six gallons or less and 400,000 BTU/hr. or less used for spas or swimming pools with open systems (unrestricted flow) shall meet all requirements of an adopted standard and ASME CSD-1 as applicable for construction, installation, repairs, or alterations.
- (5) Soft-walled hyperbaric chambers for pressures less than 5 psi, and which are composed of an airtight bag which is zipped shut with a person inside and inflated using only ambient air. A soft-walled hyperbaric chamber must have at least two relief valves.

Authority: O.C.G.A. § 25-15-13.

From: Shannon Kenitz
Sent: Monday, June 26, 2023 6:22:51 PM
To: Kathryn Stalmack
Subject: Fwd: Hello

Email between Thomas and I . He changed the things in red and clearly doesn't change that the IHA and ASME are working together.

----- Forwarded message -----
From: **Thomas Costabile**
Date: Tue, Mar 14, 2023 at 10:10 AM
Subject: RE: Hello
To: Shannon Kenitz

Shannon,

Thanks for the note. I fully understand and appreciate your request and approach. As ASME is in the discovery stages it is premature for us to issue a press release. I am Ok and supportive of IHA releasing a statement.

As such I made a few edits to the draft you sent via the attached email.

Also I will send you via a separate email a copy of the ASME procedure and form for the development of a new standard. When convenient please call me to discuss.

With regards,

Tom



Thomas Costabile P.E.

Executive Director / CEO

ASME

11757 Katy Freeway, Ste 1500

Houston, TX 77079-1733

ASME HQ

2 Park Avenue, 7th Floor

New York, NY 10016-5990

USA

From: Shannon Kenitz
Sent: Monday, March 13, 2023 4:21 PM
To: Thomas Costabile
Subject: Hello

WARNING: This Message Came From Outside of ASME. Do not click on links or attachments unless you know the content to be safe.

Hi Thomas,

I was wondering if ASME / You would be willing to put out a statement regarding the chambers while we work on the new committee for soft walled chambers.

It could be a joint statement from IHA and ASME or ASME alone - this is a draft that one of our medical advisory board members started.

It would really help the IHA to be able to communicate this to Fire departments across the board.

Hyperbaric chambers of soft-wall composition, that have been evaluated and granted an FDA 510 (k), are cleared for home and clinic use with an exceptional safety record. The soft-wall chamber models are designed to operate with a consistent air exchange (Flow-Through Method), ensuring no gas pooling. Moreover, the addition of an oxygen concentrator does not increase the risk of combustion, nor does it pose any danger to the patient or attendant. Hyperbaric chambers that operate with mild-pressure do not fall under the purview of ASME-PVHO regulations, as These models are not operating with high pressure and 100% medical oxygen administration. As of today ASME has no set standards with softwalled chambers however, we are working with the International Hyperbaric Association (IHA) to form a new ASME committee that will set standards for the soft walled chambers.

If you have any questions regarding soft walled chambers please contact us at the contact information below.

XXXXXXXXXXXX
ASME

XXXXXXXXXXXX
IHA

--
Shannon Kenitz
Executive Director

Hyperbaric chambers of soft-wall composition, that have been evaluated and granted an FDA 510 (k), are cleared for home and clinic use with an exceptional safety record. The soft-wall chamber models are designed to operate with a consistent air exchange (Flow-Through Method), ensuring no gas pooling. Moreover, the addition of an oxygen concentrator does not increase the risk of combustion, nor does it pose any danger to the patient or attendant. Hyperbaric chambers that operate with mild-pressure do not fall under the purview of ASME-PVHO regulations, as These models are not operating with high pressure and 100% medical oxygen administration. As of today ~~ASME has no set~~ there are no standards ~~with for the manufacture and operation of~~ soft-walled chambers. ~~however, we are working with the~~ The International Hyperbaric Association (IHA) is working with the American Society of Mechanical Engineers (ASME) compiling research, industry participation and general interest in development of a standard to form a new ASME committee that will set standards for the soft walled chambers.

If you have any questions regarding soft walled chambers and are interested in participating, please contact IHA ~~us~~ at the contact information below.

~~XXXXXXXXXX~~
~~ASME~~

XXXXXXXXXX
 IHA

Foran, Rosanne

Comment No. 1
OPPOSE

From: Dan Christopher
Sent: Sunday, June 18, 2023 10:17 AM
To: Shared TIAs
Subject: Comment on Proposed TIA 1735
Attachments: Proposed_TIA_1735_NFPA_99.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Good Morning,

I am **opposed** to TIA 1735. All pressurized chambers should meet NFPA and PVHO code. All sections should apply to all chambers. It has been clearly demonstrated that patient harm can occur from just 1.5-2psi pressure change. It is not safe to create a category of hyperbaric chamber (or bag) that doesn't need to meet all aspects of NFPA fire and safety code. By doing this, you are creating potential for future patient harm (and patients have already been harmed in these kinds of chambers). Safety first. ALWAYS.

Daniel Christopher MSN, RN, CHRNC
Vice President, HBO Training & Education

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From: [Melnyczenko, Andrew R., CHT](#)
To: [Shared TIAs](#)
Subject: Comment on Proposed TIA
Date: Tuesday, June 27, 2023 9:26:45 AM
Attachments: [SC Comments on NFPA TIA 1735 \(Final\).pdf](#)
Importance: High

Comment No. 2
OPPOSE
page 1 of 10

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CAUTION: Always use caution when opening attachments. Make sure you know the sender and are you expecting one.

To: **Secretary, NFPA Standards Council,**

On behalf of the Hyperbaric Oxygen Safety Committee of the Undersea and Hyperbaric Medical Society (UHMS), I'd like to formally submit a public comment related to the recent Tentative Interim Amendment proposal number 1735, submitted on June 6, 2023.

The enclosed document contains the consensus views of the UHMS HBO2 Safety Committee.

We would appreciate any feedback that you are able to share. If there is need for clarity on any of the enclosed statements, please do not hesitate to reach out to me.

We appreciate your consideration of this important matter.

Sincerely,

Andrew Melnyczenko, BSHCA, CHT
Chair, HBO₂ Safety Committee, UHMS

Andrew Melnyczenko, BSHCA, CHT

Technical and Safety Director – Hyperbaric and Altitude Medicine, Division of Public Health, Infectious Diseases, and Occupational Medicine

Mayo Clinic
200 First Street SW
Rochester, MN 55905
[mayoclinic.org](https://www.mayoclinic.org)

Date: 6/27/2023
From: UHMS HBO₂ Safety Committee
RE: **Comments regarding NFPA 99 Proposed Tentative Interim Amendment (TIA) No. 1735**

Introduction

The following statements reflect the consensus views of the UHMS HBO₂ Safety Committee related to the recent Tentative Interim Amendment proposal number 1735, submitted on June 6, 2023.

Summary

1. Wherever NFPA 101 is applied, all hyperbaric chambers (including soft sided mild hyperbaric chambers) are subject to the requirements of NFPA 99, Chapter 14. Where soft sided mild hyperbaric chambers are used, it would be considered Category 3 hyperbaric care, which is appropriate to the inherent risks of using this type of equipment.
2. Compliance with ASME PVHO-1 is required in NFPA 99, Chapter 14. Soft sided mild hyperbaric chambers can exceed 2 psi, and are therefore included in the scope of ASME PVHO-1. In addition, ASME PVHO-1 applies to all pressure vessels for human occupancy and does not exempt those filled with air or any other breathable gas. The American Society of Mechanical Engineers has made no statements to the contrary.
3. There is no emergency nature to this TIA. Soft sided mild hyperbaric chambers have existed for at least 20 years, and the technology is not new. These devices, like other hyperbaric chambers, carry inherent risk, and must meet the existing standards that have kept the public safe for decades.
4. The use of oxygen concentrators as identified in the TIA proposal carry the inherent risk of an oxygen-enriched atmosphere greater than 23.5%. The FDA has warned that oxygen concentrators are not to be used with soft-sided chambers. [Hyperbaric Oxygen Therapy: Get the Facts | FDA](#)
5. The use of soft sided mild hyperbaric chambers does not come without risk. On June 10, 2011, a young man asphyxiated inside a soft sided mild hyperbaric chamber that utilized an oxygen concentrator. [Sparks v. Oxy-Health, LLC](#)

Conclusion

We confidently stand upon the existing codes and standards that address hyperbaric chambers. These are developed over many years, consistently validated, reviewed, and revised through industry feedback, specialist evaluation, and focused research programs. The existing codes apply to soft sided mild hyperbaric chambers, therefore **the UHMS HBO₂ Safety Committee does not endorse the adoption of Tentative Interim Amendment (TIA) No. 1735.**

Respectfully,

The UHMS HBO₂ Safety Committee

Defendant replies in-kind to plaintiffs' response without objection to plaintiffs' various new legal theories, thereby constructively amending the complaint.⁷ Defendant argues that the "apparent manufacturer" doctrine is inapplicable to the instant matter and further maintains its strenuous objection to the causative element of each of the Estate's substantive product liability and UDPA claims.

STATEMENT OF FACTS

A. Hyperbaric Chambers

"Portable mild hyperbaric chambers" are enclosures that are inflated and allow the occupant to experience higher than normal atmospheric pressure. (Patel Decl. ¶4). The Vitaeris 320 generally, and the Chamber specifically, is a "portable mild hyperbaric chamber," described as a "cylindrical, soft-shelled enclosure that receives continuous fresh air through a valve at one end." (*Id.* ¶¶4–5). The air is pumped through a hose, secured to the chamber body by a "quick disconnect" valve. (*Id.* ¶5). The valve itself is manufactured by Colder Products, a non-party, and is a "push button" disconnect, rather than a threaded-style connector. (*Id.*; *see also* Natoli Dep. 139:13–15). As fresh air continuously is forced into the chamber through one end, two valves at the opposite end

Presson's husband, ("Jack Presson Dep.," DE 69-15), a list of autism conferences attended by defendant (DE 69-21); treatment notes from one of Jarred's doctor visits, (DE 69-26); various brochures for the chamber and a competitor chamber, the SOS Hyperlite ("Chamber Brochure," DE 69-29; "SOS Hyperlite Brochure," DE 69-36); the 2002 American Society of Mechanical Engineer's Pressure Vessel for Human Occupancy ("ASME–PVHO") safety standards (DE 69-33); the FDA's product classification for hyperbaric chambers (DE 69-35); a declaration executed by plaintiff Amy Sparks, dated November 26, 2014, (Sparks Decl., DE 69-32); various articles regarding the efficacy of the treatment of autism by hyperbaric oxygen therapy ("IHA, Autism and Its Growing Hyperbaric Movement," DE 69-38; "FDA, Hyperbaric Oxygen Therapy: Don't Be Misled," DE 69-39), as well as the Sheriff's Report detailing the Cumberland County, North Carolina, Sheriff's Department's investigation into Jarred's death (Sheriff's Report, DE 69-28, 81).

⁷ Because plaintiffs raised new legal theories unobjected to by defendant in briefing on summary judgment, the court will consider the complaint constructively amended. *See United States v. Cochran*, 79 F. Supp. 3d 578, 583 (E.D.N.C. 2015) ("[P]arties [may] constructively amend the complaint by, for example, . . . addressing a theory of liability in their summary judgment briefs.") (quoting *Interstate Petroleum Corp. v. Morgan*, 249 F.3d 215, 227 (4th Cir. 2001)) (internal quotations omitted).

expel carbon dioxide and excess fresh air (“release valves”). (See Patel Decl. ¶5). The Vitaeris 320 also ships with an air compressor to deliver air into the chamber. (See Lewis Memo at 4).

The quick disconnect valve is the only avenue through which fresh air is delivered into the otherwise air-tight enclosure. (See Oxy-Health Dep. 95:18–24, 104:11–105:4). In the event the quick disconnect valve becomes disengaged, or the air compressor supplying air to the occupant malfunctions, the release valves no longer expel excess carbon dioxide. (Id. 105:4–21; see also id. 108:5–10). In the event that occurs, carbon dioxide will build up in the Vitaeris 320 over time, as the occupant respires. (Id. 108:5–21). There is no alarm to alert the occupant to the accumulation of carbon dioxide. (Natoli Dep. 270:13–23).

In 2000, Hyperbaric Technologies, Inc. (“HTI”), the chamber’s manufacturer, applied for and received market clearance for the Vitaeris 320 from the Food and Drug Administration (“FDA”) through the FDA’s § 510(k) clearance procedure.⁸ (FDA 510(k) Clearance; Patel Decl. ¶6). The

⁸ The Vitaeris 320 is a Class II medical device. Medical devices regulated by the FDA fall into one of three categories or “classes.” See Walker v. Medtronic, Inc., 670 F.3d 569, 572 (4th Cir. 2012). A Class I device is one “for which general controls, such as labeling requirements, are sufficient to provide reasonable assurance of their safety and effectiveness.” Id. (quoting 21 U.S.C. § 360c(a)(1)(A)(I)) (internal alterations, citations, and quotations omitted). Class II devices include such devices as powered wheelchairs and surgical drapes, and are subject to heightened oversight mechanisms, such as “performance standards” and “postmarket surveillance.” Id. (quoting 21 U.S.C. § 360c(a)(1)(B)). Class II devices are “either useful in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health or that present a potential unreasonable risk of illness or injury.” Id. (quoting 21 U.S.C. § 360c(a)(1)(C)) (internal alterations, citations and quotations omitted). A Class III device “require[s] the highest level of federal oversight.” Id. “Class III devices are those for which the general controls regulating Class I devices and the specific controls that regulate Class II devices are deemed insufficient to ensure safety and effectiveness.” Id.

When bringing the chamber to market, HTI sought FDA approval through the FDA’s 510(k) clearance process. See 21 C.F.R. §§ 807.87, 807.92, 807.93. (describing the requirements for 510(k) clearance). The Supreme Court has described the 510(k) process as a “limited form of review,” Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996), as compared to the more substantial “pre-market approval” (“PMA”) process applicable to new devices. See id. at 478–79 (“The § 510(k) process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours. . . . The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly.”) (internal alterations and quotations omitted); Walker, 670 F.3d at 572–73 (describing the PMA process). “If the FDA concludes on the basis of the § 510(k) notification that the device is ‘substantially equivalent’ to a pre-existing device, it can be marketed without further regulatory analysis.” Lohr, 518

Vitaeris 320 was cleared only for the treatment of “acute mountain sickness,” a relatively rare condition that affects climbers who are exposed to altitudes in excess of 8,000 feet. (Patel Decl. ¶6; Workman Decl. ¶28). However, despite not being “cleared” for the treatment of autism, such use is a recognized “off-label use” in certain medical communities. (Kartzinel Dep. 33:4–34:14). Use of a hyperbaric chamber for the treatment of autism requires a prescription. (See id. 35:2–9).

B. The Sparks Family’s Experience with Hyperbaric Oxygen Therapy

Plaintiffs are the mother and father of Jarred Sparks, a 19 year old autistic man who asphyxiated inside a hyperbaric chamber on June 10, 2011. Jarred was diagnosed with autism in 1994. (Amy Sparks Dep. 35:24–25). Sometime prior to November 2005, plaintiff Amy Sparks learned about the purported ability of hyperbaric oxygen therapy (“HBOT”) to treat or reduce the symptoms of autism. (Id. 74:18–75:8). Sometime thereafter, in connection with a recommendation from Jarred’s treating physician, Jerry Kartzinel, Jarred began HBOT at “Creation’s Own,” a clinic in Melbourne, Florida. (Amy Sparks Dep. 59:14–25, 69:13–25; Bradstreet Dep. 54:23–24). Jarred’s treatments at Creation’s Own were intermittent, ideally once every three to four weeks, but realistically once every few months. (Amy Sparks Dep. 77:4–12). During the treatments Jarred first used a Vitaeris 320, but later switched to a “hard sided” chamber. (Id. 126:1–6). Due to the distance between the family’s home in North Carolina and the clinic, Jarred also began receiving treatment at A Small Miracle, a clinic in Goldsboro, North Carolina, offering certain services, including HBOT, to children and adults with special needs, owned by Jack and Janet Presson. (See Amy Sparks Dep. 77:14–21, 127:4–22; see also Agreement to Purchase). At A Small Miracle, Jarred was treated using a Vitaeris 320. (See Amy Sparks Dep. 123:16–21). Jarred’s treatments at Creation’s

U.S. at 478. “[D]evices that enter the market through § 510(k) [are] never . . . formally reviewed . . . for safety or efficacy.” Riegel v. Medtronic, Inc., 552 U.S. 312, 323 (2008) (internal quotations omitted).

Own and A Small Miracle overlapped, but Jarred was last treated at Creation's Own on July 1, 2008.

(Bradstreet Dep. 69:2–15).

During his treatments at Creation's Own, Jarred rarely was left alone while inside the hyperbaric chamber. Usually, plaintiff Amy Sparks remained in the room, (Amy Sparks Dep. 94:12–16), and a technician employed by Creation's Own frequently was in the room during the course of a 60 minute treatment session. (Id.; Kartzinel Dep. 57:16–58:14). During treatments at Creation's Own two to three technicians were responsible for monitoring five hyperbaric chambers, (Bradstreet Dep. 36:5–16), and were checking on the patients in the chamber at least three times per hour. (See Kartzinel Dep. 74:19–75:12). In addition, during treatments, either Jarred's father, Robert Sparks, or one of his siblings always accompanied him into the chamber. (Amy Sparks Dep. 96:3–13). Similarly, during Jarred's treatments at A Small Miracle, one of the company's employees would “come and go” throughout the duration of the treatment. (Id. 127:4–22).

Beginning in December 2006, for a period of approximately 10 months, the physician-owner of Creation's Own, Jeff Bradstreet, allowed the Sparks family to borrow a Vitaeris 320 for temporary use in their home. (Amy Sparks Dep. 80:8–81:25). Bradstreet shipped the Vitaeris 320 to the Sparkses in North Carolina. (Id.). However, Bradstreet did not include with the shipment any instructions on proper use of the chamber. (Id. 155:4–19). Despite not receiving any instructional material, the chamber was used. (See Robert Sparks Dep. 202:8–203:6).

On February 5, 2011, the Sparks family purchased the Chamber from A Small Miracle. (Agreement to Purchase). The Chamber was the same Vitaeris 320 Jarred had been using during his treatments at A Small Miracle, and had been purchased by A Small Miracle from a third party distributor, that in 2005 had purchased the Chamber from defendant. (Amy Sparks Dep. 123:16–24;

Agreement between A Small Miracle and Vita 02; Patel Decl. ¶15; see also Distributorship Agreement).

Prior to the purchase of the Chamber, the Sparks family had been planning to purchase a hyperbaric chamber for some time. (See Amy Sparks Dep. 137:1–11). In 2009, Amy Sparks attended a “Hope for Autism” conference in Charleston, South Carolina. (Amy Sparks Decl. ¶4). At this conference, she met a representative, employed by defendant, who was touting the efficacy of HBOT, and in particular the efficacy of the Vitaeris 320, in treating the symptoms of autism. (See id. ¶5). The representative distributed an article entitled Autism and Its Growing Hyperbaric Movement, which represented that HBOT had beneficial effects for the autistic brain. (Id. ¶10). This experience affirmed the family’s desire, and specifically Amy Sparks’s desire, to purchase a hyperbaric chamber for Jarred’s use. (Amy Sparks Dep. 307:13–22, 314:14–315:13).

Prior to receiving the Chamber, Amy Sparks reached out to Kartzinel, who wrote Jarred the required prescription. (See Amy Sparks Dep. 137:1–11). On February 5, Jack Presson brought the Chamber to the Sparkses’s home and set it up in the upstairs. (Jack Presson Dep. 65:3–67:23; Amy Sparks Dep. 137:25–138:7). Given their experience with the Vitaeris 320 generally, the Pressons provided the Sparkses no training on how to use the Chamber, with the exception of the oxygen concentrator, an after-market component which the Sparkses had never used before. (Jack Presson Dep. 65:3–67:23; Amy Sparks Dep. 137:1–138:7). The oxygen concentrator was an external device that worked as the name implied, by increasing the oxygen concentration in the air inside the Chamber. (See Reference Manual at 36; see also Amy Sparks Dep. 83:7–24). The Pressons delivered with the chamber the Reference Manual, providing instructions on how to use the Chamber properly. (Amy Sparks Dep. 154:2–5). However, no member of the Sparks family ever

read the manual. (See Amy Sparks Dep. 154:2–21; Robert Sparks Dep. 34:4–25; Dylan Sparks Dep. 64:19–65:5).

When using the Chamber, a consistent pattern was followed involving use at night, roughly every other day. (See Robert Sparks Dep. 202:8–23). On evenings when Jarred was to receive HBOT, the family would wait for him to go to bed and after a few hours would wake him up and guide him to the Chamber. (Id. 204:4–205:9). Treatments typically lasted 2–3 hours, but at times lasted up to 6 hours. (Id. 203:10–13, 205:3–6). Usually, the last person in the Sparks family to go to bed would wake Jarred up to get him out of the Chamber. (Id. 205:3–6). The Sparkses never were told to limit the amount of time Jarred spent inside the Chamber explicitly. (Id. 203:20–204:1). Jarred always used the oxygen concentrator, (Amy Sparks Dep. 186:22–24), notwithstanding a label on the chamber body and FDA warning in the Reference Manual to the contrary. (See Concentrator Label; Reference Manual at 36). When the Chamber was in use, the release valves and air compressor could be heard downstairs, despite the Chamber’s location upstairs. (Robert Sparks Dep. 217:11–23; Dylan Sparks Dep. 109:8–14).⁹

C. The Incident

Jarred’s body was discovered June 10, 2011, at approximately 3:00 a.m.. (Dylan Sparks Dep. 93:2–9). Earlier that evening, at approximately 10:00 p.m., Jarred’s brother, Dylan, helped Jarred into the Chamber. (See id. 98:14–24, 104:6–10). Jarred laid in the Chamber and Dylan zipped him in. (Id. 104:6–10). At that time, the air compressor was attached to the Chamber and it was inflating properly. (Id. 104:6–19). After sealing Jarred in the chamber, Dylan turned the

⁹ The same pattern was followed in the family’s use of the Vitaeris 320 borrowed from Creation’s Own. (Robert Sparks Dep. 202:13–23).

lights off, closed the door, and left the room. (Id. 91:22–92:8). Dylan had no trouble closing the door, (id. 112:24–113:2), and went to bed around 11:00 p.m. (Id. 91:22–92:8).

While Dylan was helping Jarred get into the chamber and thereafter, plaintiff Amy Sparks, a teacher, was downstairs filling out report cards for her students. (Amy Sparks Dep. 202:4–18). Robert Sparks was out of town, in Raleigh. (Dylan Sparks Dep. 96:16–25). Sometime after Dylan had gone to bed, plaintiff Amy Sparks fell asleep while working. (Amy Sparks Dep. 202:21–24). When she woke up, plaintiff Amy Sparks, concerned for Jarred, went upstairs to check on him. (Id. 202:24–203:11). She found the Chamber partially deflated despite the fact that the air compressor, which should have been providing fresh air into the chamber, was running. (Id.). At that time, plaintiff Amy Sparks discovered Jarred. (Id.).

Plaintiff Amy Sparks cried for Dylan, waking him up. (Dylan Sparks Dep. 92:9–18). Immediately thereafter, Dylan called 911 to request an ambulance. (Id.). While on the phone, the 911 operator instructed Dylan to pull Jarred’s body out of the Chamber and perform CPR. (Id. 92:9–93:1). Dylan stopped performing CPR only when emergency medical assistance arrived a few minutes later. (Id.). Dylan did not notice whether the quick disconnect valve was attached to the Chamber at that time. (See id. 141:7–142:18).

At around 5:30 a.m., officers from the Cumberland County, North Carolina, Sheriff’s Department arrived. (See Sheriff’s Report). The officers were the first people to point out that the quick disconnect valve had become disengaged from the Chamber. (Dylan Sparks Dep. 141:7–142:18; Amy Sparks Dep. 245:22–246:11). At approximately 8:15 a.m., detectives from the Sheriff’s Department asked Dylan to set up the Chamber as he had the night before. (Sheriff’s Report at 7). When the Chamber was inflated, the quick disconnect button, the feature that

disengages the quick disconnect valve, was pressed against a book shelf near the head of the Chamber. (Id.). Upon closer inspection, a detective discovered that the book shelf had depressed the button and that the hose would become fully disengaged with only a slight disturbance. (Id.). Specifically, when the detective touched the hose it “fell to the floor and the [C]hamber started deflating.” (Id.). Earlier in the evening, other investigators observed that when the hose was disconnected from the Chamber, the hissing noise produced by the hose sounded similar to the hissing noise of the properly functioning chamber, and that the hose being disconnected made the air compressor much louder. (Id. at 3–4). After the investigators left, several of the family’s friends removed the Chamber from their home. (Amy Sparks Dep. 245:11–23). Based on the investigators event recreation, the Sparks family believes Jarred shifted while in his sleep, pressing the quick disconnect button against the book shelf and dislodging the quick disconnect valve. (See id. 247:7–15).

D. Defendant’s Relationship with HTI

HTI manufactured the Vitaeris 320. (Patel Decl. ¶3). Defendant was the exclusive distributor of certain hyperbaric chambers manufactured by HTI, including the Vitaeris 320, from 1999 until 2009. (See Distributorship Agreement; Patel Decl. ¶¶3, 6). There was no corporate overlap between the companies. (Patel Dep. ¶7).

Defendant, in its capacity as distributor, received certain chamber “bladders,” representing the portion of the Vitaeris 320 into which the patient is placed during the course of HBOT, in bulk and repackaged those bladders, along with other components including an air compressor, as a unified product sold as the Vitaeris 320. (See Patel Decl. ¶10). The air compressors shipped by defendant under the Oxy-Health brand were shipped to defendant by Brenner-Fielder, a third party,

Foran, Rosanne

Comment No. 3
OPPOSE

From: Carl Jackson
Sent: Wednesday, July 5, 2023 2:26 PM
To: stds_admin
Cc: Shared TIAs
Subject: NFPA 99 TIA 1735 Public comment

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Standards Council,

I am emailing to add public comment to NFPA 99 TIA 1735.

I wish to comment to strongly oppose all changes proposed to 14.1.3.4; 14.1.4; 14.1.4.1 and 14.1.4.2. I also strongly oppose the addition of 14.4.

I make the following statements as reason to oppose TIA 1735:

The TIA states that soft-sided mild hyperbaric chambers do not fall under the purview of ASME-PVHO-1 regulations: This is incorrect. All pressure vessels for human occupancy capable of 2psi or greater fall under ASME-PVHO-1.

The TIA is not an emergency measure and time should be taken to seriously consider the proposal.

The proposed changes would create a patchwork of regulations for hyperbaric oxygen therapy, making it difficult for patients to know which chambers are safe and effective.

Best regards,

Carl Jackson
Hyperbaric Technologist and Safety Director

Foran, Rosanne

Comment No. 4
OPPOSE
page 1 of 7

From: Guy Richards
Sent: Wednesday, June 21, 2023 9:32 AM
To: stds_admin <stds_admin@nfpa.org>
Subject: TIA 1735 - OPPOSED

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

To the Secretary of NFPA99, Ms Dawn Michele Bellis

Dear Ms Bellis,

TIA 1735 OPPOSED

I have served as a volunteer member of the ASME PVHO Committee for over 20 years and wish to address several misleading or wholly incorrect statements made in substantiation of this TIA.

In no respect am I speaking for or on behalf of ASME or PVHO as these are my own personal comments.

The TIA states the following:

"Substantiation: This TIA request is to fill an identified gap in the safeguarding requirements that currently do not exist in a standard for soft sided mild hyperbaric chambers within NFPA Chapter 99. 1) There is an identifiable gap now that ASME has stated hyperbaric chambers that operate with mild-pressure do not fall under the purview of ASME-PVHO regulations as 2) these models are not operating with high pressure and 100% medical oxygen administration. 3) As of today, there are no standards for the operation of soft-sided chambers. This gap in the code has prevented a large proportion of clients from accessing this potentially beneficial treatment. This change provides requirement to populate Category 4 and creates 4) a new specific section for lower hazard chambers. Emergency Nature: The proposed TIA intends to accomplish a recognition of an advance in the art of safeguarding property of life where an alternative method is not in current use or is unavailable to the public. 5) ASME has recently created an identifiable gap in the NFPA Chapter 99 code now that the organization has stated hyperbaric chambers that operate with mild-pressure do not fall under the purview of ASME-PVHO regulations as these models are not operating with high pressure and 100% medical oxygen administration. As of today, there are no standards for the operation of soft-sided chambers within chapter 99. It is urgent that the reserved section of Category 4 within chapter 99 is populated to create safeguarding requirements. Please see all uploaded documents for a detailed bases supporting the emergency nature of this TIA to require prompt action."

1. To my certain knowledge there has been no such statement from ASME or ASME PVHO that mild pressure soft sided bags do not fall under the purview of ASME PVHO-1, nor has there been any change of Scope which states that ALL pressure vessels for human occupancy with a pressure exceeding 2 psi fall within its remit. Therefore, there is NO IDENTIED GAP covering soft sided bags.
2. These soft sided bags do not usually use 100% medical Oxygen but custom and practice within this industry over the past 10 years has been for Oxygen concentrators to be supplied separately, feeding to breathing masks or nasal prongs used by the occupant. This causes a significant fire hazard from Oxygen enriched air both inside and outside the device.

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3. This statement that soft sided bags do not fall under the purview of ASME-PVHO regulations is again factually incorrect, as ASME PVHO-1 applies via its Non-Mandatory Appendix E and its accompanying matrix specifically for their consideration. At least five similar Cases have been approved over the past ten years covering both low and high pressure soft sided bags.
4. There is no evidence for these lower pressure, soft sided bags being safer. There have been seven Manufacturer and User Facility Device Experience (MAUDE) incidents reported to the FDA involving such bags and at least one fatality. There may have been more such incidents as many of these bags are NOT FDA 510K pre-market notified for any indication other than altitude sickness and there is therefore no obligation on the manufacturer to report any accidents. I attach the original report upon which ASME PVHO-1 based its 2-psi pressure differential within its Scope.
5. This is again factually incorrect as to my certain knowledge, ASME has not made any such statement that "there are no standards that apply to soft sided bags". On the contrary, at a PVHO meeting in 2022, attended by myself and representatives of a soft sided bag manufacturer and a representative body for that industry, the PVHO committee outlined the pathway for obtaining a PVHO-1 Case for their soft sided bags under the scope of the ASME PVHO-1 Standard and its Non-Mandatory Appendix E.

On a general point.

Accidents WILL happen causing serious injury or deaths when companies seek to carve out exceptions to best practice and accepted safety standards and I vehemently oppose any efforts by vested interest groups to do so.

Two recent examples I will mention where PVHO-1 Standards were ignored include:

1. Lehi UT, May 2023 when an incorrectly designed acrylic window in a non-FDA 510k hyperbaric chamber failed at 2.8 ATA – seriously injuring two occupants and
2. The Titan submersible diving to 4,000 metres – again not built to ASME PVHO-1 Standards, currently out of contact near the Titanic wreck, with five souls on board, currently missing, presumed dead.

PVHO-1 current Scope is appended below:

1-2 SCOPE

1-2.1 Application

This Standard applies to all pressure vessels that enclose a human within their pressure boundary while under internal or external pressure exceeding a differential pressure of 2 psi (15 kPa). PVHOs include, but are not limited to, submersibles, diving bells, and personnel transfer capsules, as well as decompression, recompression, hypobaric, and hyperbaric PVHOs.

In conclusion I believe that the request to exempt these soft-sided bags from PVHO-1 and in this instance NFPA99 standards, is both hazardous and sets an extremely poor precedent.

ASME PVHO-1 set its 2-psi limit based upon sound medical data from 1995. Further information suggests that serious barotrauma may be caused by rapid decompression from even 1.6 psi. Therefore, I fail to see how soft sided bags operating at 5 psi could be described as a) being outside of PVHO-1's Scope and b) be safe, due to the frequent reports of jammed zippers, poor air quality, lack of medical supervision and failures in their pressure boundaries.

I trust that the NFPA99 after due consideration of this poorly substantiated TIA 1735 will reject it in its entirety.

Sincerely



Guy Richards MA. CChem, FRSC. NEBOSH

International ATMO, Inc.

Richard D. Heimbach, M.D., Ph.D.
C.J. Cutrone, C.H.T.
Paul J. Sheffield, Ph.D.
Mathew J. Brakora, M.D.

Comment No. 4

OPPOSE

page 3 of 7

MEMORANDUM

TO: Jack Maison, PhD
Chairman, ASME, PVHO Committee; [REDACTED]

FROM: Paul J. Sheffield, PhD

INFO: Richard Moon, MD; President UHMS; [REDACTED]
Dave Desautels; Chm, UHMS Safety Committee; [REDACTED]

DATE: April 24, 1995

SUBJECT: ASME-PVHO Question: What is the pressure range near sea level where physiological problems are minimal

The Problem: At the last ASME PVHO Committee meeting, you tasked me to ask the UHMS to define the pressure range near sea level where physiological problems are minimal. The purpose of the question is to define the range of pressures that ASME-PVHO should identify in the construction codes for pressure vessels (both altitude and diving) that are designed for human occupancy. The results reported herein is a consolidation of responses from UHMS members concerning the hyperbaric environment. Colonel Tom Workman queried the AsMA concerning the altitude environment and will report separately.

Effects of Rapid Decompression: The severity and consequences of pressure vessel failure depend on the rate of decompression and the pressure range over which it occurs. The physiological effects of rapid decompression are primarily barotrauma (due to gas expansion), and decompression sickness (due to evolved gases). Barotrauma can result from pressure changes in the middle ears, sinuses, gastrointestinal tract and lungs. Decompression sickness can manifest itself as bends pain, chokes, neurologic impairment, paralysis, chokes, or circulatory collapse. The life-threatening disorders are lung rupture and severe decompression sickness.

Summary of Results: Figure 1 summarizes the reported minimum pressure changes that have resulted in a physiological problem. The respondents to this inquiry assumed the worse-case scenario in which a PVHO vessel fails catastrophically.

Barotrauma: Basically, no known barotrauma results from a pressure change of less than 2 fsw. The middle ear and sinuses normally clear automatically during decompression. But, if the person has an ear or sinus block, barotrauma can result in pain from pressure changes of 2-4 fsw (Fife, Personal communication). Farmer (1990) reported that rupture of the ear drum can occur at a pressure change of between 120-300 mmHg (4.3 - 17.4 fsw). However, catastrophic failure of the

hyperbaric chamber poses the greatest threat to the lung. Lung barotrauma that results in arterial gas embolism has been reported at pressure changes as little as 6 fsw (Fife, Personal communication). Malhotra and Wright (1960) using primates as experimental animals, showed that during a decrease in ambient pressure by more than about 50 mmHg (3.5 fsw; 0.1 atm), the gas expanding within the alveoli may rupture into the circulation, the interstitial tissues, or the pleural space. Ascent to the surface following respiration of gas under pressure holds the same hazard for man. Elliott (1995, personal communication) has treated a severe neurological decompression illness following blow up from less than 8 feet. Elliott and Kindwall (1982) reported that death has occurred following ascent from as shallow as 7 ft (1.2 ata).

Decompression Sickness: Decompression sickness can result if the individual is decompressed following exposure to pressure for long enough duration. It is unusual unless the individual has been exposed to a pressure greater than 33 fsw (2 ata), but it has been reported after surfacing from 17 feet after a saturation exposure of greater than 25 hours (Fife, Personal communication).

Recommendations: The general view of the respondents was that, for the purpose of establishing standards, it would seem most appropriate to select a pressure differential that would prevent a life threatening disorder, such as lung barotrauma.

References:

1. Clarke JM (1995) Personal communication
2. Elliott, DH (1995) Personal communication
3. Elliott DH & Kindwall EP (1982) Manifestations of the decompression disorders, In: PB Bennett & DH Elliott, Physiology and Medicine of Diving. Philadelphia: WB Saunders, p 469.
4. Farmer, JC (1990) Ear and sinus problems in diving, In: AA Bove and JC Davis, Diving Medicine, Philadelphia: WB Saunders, p 206
5. Fife, CA (1995) Personal communication
6. Malhotra, MC & Wright CAM (1960) Arterial air embolism during decompression and its prevention. Proc R Soc, B 154, 418-427.

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Figure 1. REPORTED MINIMUM PRESSURE CHANGE THAT RESULTED IN A PHYSIOLOGICAL PROBLEM UPON SURFACING

Pressure Change (fsw) (psi)		Physiological Problem	Signs or Symptoms
2	1	None	None
2-3	1-1.5	Ear & sinus barotrauma	Pain
4	2	Ear barotrauma	Ruptured ear drum
6	3	Lung barotrauma	Emphysema Pneumothorax Arterial gas embolism
7	3.5	Lung barotrauma	Death due to arterial gas embolism
17	8.5	Decompression sickness (after a saturation exposure)	Pain Central nervous system effects Paralysis

1994/95 UNDERSEA AND HYPERBARIC MEDICAL SOCIETY
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FAX -

e-mail -

Foran, Rosanne

Comment No. 5
OPPOSE
page 1 of 13

From: John Feldmeier
Sent: Monday, July 10, 2023 9:55 AM
To: Shared TIAs
Subject: Comment on Proposed TIA 1735 on NFPA 99
Attachments: EPSON213.PDF; Rationale for 2.0 PSI.pdf; EPSON214.PDF

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

To: The Secretary of the Standards Council
NFPA

Dear Sir or Madam,

Please see my comments on the NFPA 99 Proposed TIA 1735. These are presented as public comments on the proposed TIA 1735 Amendment.

Along with my remarks you will find 2 supporting documents.

One relates to the long-standing determinations of minimum pressures from which a rapid loss of pressure has the potential to cause serious injuries.

The other is an article published in The Bexar County, TX Medical publication explaining the risks inherent in the operation of "Mild Hyperbaric" chambers.

Your consideration of these documents is appreciated.

Sincerely,

John J. Feldmeier, D.O.

Date: 8 July 2023

To: NFPA, Secretary of the Standards Council

From: John J. Feldmeier, D.O., FACRO, FUHM

Past President of the Undersea and Hyperbaric Medical Society (UHMS)

Current Co-Chairman of the UHMS FDA Liaison Committee

Current Co-Chairman of the UHMS Research Committee

Experienced Hyperbaric Physician since 1980

Re: **Comments Regarding NFPA Part 99: Proposed Interim Amendment (TIA) No. 1735**

Introduction: This amendment proposes that a special “carve out” be offered to purveyors of so-called “Mild Hyperbarics.”

Summary:

1. “Mild Hyperbaric” units have sprung up in the U.S. and internationally over the past 10 years. They are often located in store fronts, wellness centers and health spas. Mild hyperbaric sessions are often not prescribed and overseen by licensed physicians. Oxygen concentrators are frequently used in these units. Mild hyperbaric centers often deliver their “therapy” to a vulnerable group including children and the elderly for conditions that have no support in medical literature. They will also treat conditions known to be amenable to mainstream hyperbaric oxygen pressures with oxygen in adequate doses including both treatment pressures and adequate oxygen supplementation (95% or higher O₂ containing breathing mix). The purveyors of this “mild” exposure base their treatment on medical literature and experience using adequate pressures and oxygen content supported by publication and accumulated experience. This is akin to providing drug therapies at doses of less than 10% of the recommended amount.
2. Already one young man has died from asphyxia at home when undergoing treatment in a “Mild Hyperbaric Chamber” which was unattended. Also in Great Britain, a diver with decompression illness was treated in a “Mild Hyperbaric Chamber” without resolution. Eventually, this diver was treated at a mainstream certified chamber at adequate doses with good result. The delay in appropriate treatment could have resulted in permanent disability or even death.
3. Organized medicine, at the level of the American Medical Association and local Medical Societies in Texas, New York and Bexar County, TX, at its annual meetings, has passed resolutions decrying these “mild” practices and noting both the ineffectiveness and dangers of “Mild Hyperbarics.” Additional efforts are underway in CA, PA and NC for the

local medical societies to propose and approve similar resolutions. In the state of Texas, two "mild hyperbaric" units under the practice of dentists have been shut down by the medical license board because the practice of medicine (namely hyperbaric medicine) was being conducted by non-physicians.

4. Main stream hyperbaric medicine has been utilized for carefully studied disorders in the U.S. and Europe for nearly 60 years. It arose from military and industrial diving experience. Its hallmark has been safety with minimal accidents. In fact, the UHMS Safety Committee has researched the issue and NO chamber that has been certified by the PVHO has had a failure in the U.S. The PVHO (Standards for Pressure Vessels for Human Occupancy) has been a standing committee of the ASME (American Society of Mechanical Engineers) since 1977, and the ASME actually began its oversight of pressure vessels in 1915.
5. To date, the NFPA has intended its standards for hyperbaric chamber design and operation to include any chamber with an internal pressure over a value over one atmosphere. The ASME after consideration and experience of potential injuries resulting from possible explosive chamber decompression chose internal pressures above 2.0 PSI gauge pressure to be their threshold for establishing standards. This threshold was shown to be a pressure at which a chamber occupant suffering a rapid decompression could experience life threatening damage to the lungs (pneumothorax) See attachment.
6. The current "Mild Hyperbaric" community mostly treats at pressures of 1.4 ATA (atmospheres absolute) or below. In terms of gauge pressure this would be approximately 6.0 PSI, exceeding by a large margin the pressures capable of causing severe bodily harm. Many "mild" centers are also using oxygen enhancement typically with O₂ concentrators. Please recall that the FDA requires that a physician prescribes and oversees the administration of oxygen at any pressure. Since both hyperbaric chambers and oxygen concentrators are Class II Medical devices, their combined use must be cleared by the FDA in addition to clearance of each individually. The NFPA is well aware that an oxygen enhanced environment at any ambient pressure increases the likelihood and severity of a fire.
7. The importance of appropriate and careful testing and certification of pressure vessels has been re-emphasized by two recent events. All five occupants of the Titan submersible operated by Ocean Gate were lost in late June when this vessel was crushed at depths of greater than 13,000 feet of sea water while attempting to explore the wreckage of the Titanic. In mid-May two occupants of an uncertified hyperbaric chamber operating at what has been reported as 2.8 ATA pressure experienced an explosive decompression when one of its view ports was inadequate to withstand this pressure and failed. Complete details have not been released, but we are told that one of the occupants experienced bilateral pneumothoraces (collapsed lungs) and the other occupant suffered a ruptured ear drum. Although neither of these vessels were employed in "Mild Hyperbaric" treatments, neither had certification by NFPA99 or ASME PVHO-1 or FDA.
8. "Mild Hyperbarics" proponents have requested "the carve out" excluding them from ASME and NFPA standards based on the reduced pressures used and reduced oxygen supplementation used. As discussed above, there is no quality published medical literature supporting the efficacy of such treatments. Also, as discussed above, rapid

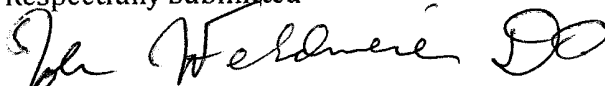
explosive losses of pressure can result in serious injury to the chamber occupant and any close-by observers in immediate proximity to the chamber, even at the reduced pressures at which the "mild" community operates.

9. It is important to note that the vast majority of chambers used for "Mild Hyperbarics" are not cleared by the FDA, nor do they meet the standards of the NFPA or the ASME. Most of these non-compliant chambers are being constructed outside the U.S. In some cases they enter the U.S. in piecemeal fashion to avoid recognition by inspecting governmental entities at the port of entry. They are then assembled after entry. In some cases, the "Mild" community has employed a soft sided chamber known as the Gamow bag to deliver their underdosed version of hyperbaric oxygen. Note that the Gamow Bag is no longer in production but other soft-sided designs similar to it are in production and use. This device is FDA cleared but ONLY FOR MOUNTAIN SICKNESS and is not certified for use with any level of supplemental oxygen. The Canadian equivalent of our FDA has banned the use of this chamber and all "Mild Hyperbaric" chambers in all of Canada.

Conclusions:

For the above reasons supported by attachments and as Co-chairman of the UHMS FDA Liaison Committee, I urge the NFPA to continue their appropriate and well considered standards for the construction and operation of **ALL** hyperbaric chambers. The Technical Committee of the ASME, in our considered opinion, recently took the appropriate stand to continue to include all pressure vessels used for human occupancy to any vessel exceeding 2.0 PSIG (approximately 1.14 ATA or 5 feet of sea water).

Respectfully Submitted



John J. Feldmeier, D.O.

2 enclosures

When It's Better to Be Under More Pressure

By John J. Feldmeier, DO, Jayesh B. Shah, MD, John S. Peters, FACHE

The medical discipline of clinical hyperbaric medicine had its origins in the 1960s with seminal work done in both Holland and the United States. One of the early applications employed hyperbaric oxygen delivered in large chambers configured as operating theaters. By operating under pressure and delivering significantly increased oxygen doses to the patient, open-heart surgery was possible because the enhanced hyperoxemia permitted a tolerance to a longer period of asystole than would be possible for patients operated at normal surface pressures.¹ Once heart and lung machines became available, there was no need for surgery under pressure. The very first application of hyperbaric or recompression treatment was its application to the treatment of decompression sickness (commonly known as the bends) and other diving injuries.² This treatment is still the definitive intervention for decompression sickness and injury due to rapid changes in pressure for divers, including traumatic air embolism also known as barotrauma.

In the intervening years, hyperbaric oxygen has evolved to be a studied and effective therapy for many disorders, often as an adjunct to the primary treatment (See Table 1. for the list of accepted indications). These applications are based on a large body of supporting literature and research, much of it level-1 evidence. Some in other medical disciplines still think of hyperbaric oxygen as an "alternative medicine." It is certainly an unusual medical treatment because it does not come as a pill or capsule nor is it delivered intravenously. Hyperbaric oxygen has been recognized as a medical subspecialty by both the American Board of Preventive Medicine and the American Board of Emergency Medicine both of whom offer board-certification in this discipline. Hyperbaric oxygen is most commonly employed now for non-healing wounds in the lower extremities of individuals with diabetes and delayed complications of therapeutic radiation. In both of these applications, hyperbaric oxygen can often permit avoidance of major disfiguring and disabling surgeries. Randomized controlled trials sup-

Table 1

Undersea and Hyperbaric Medical Society Accepted Indications for Hyperbaric Oxygen⁴

Hyperbaric Treatment of Air or Gas Embolism: Current Recommendations.	As primary treatment along with supportive measures
Arterial Insufficiencies including Central Retinal Artery Occlusion and Selected Problem Wounds.	As adjunct to other established treatments
Carbon Monoxide Poisoning.	As primary treatment along with supportive measures
Clostridial Myonecrosis (Gas Gangrene).	As adjunct to surgery and antibiotics
Compromised Grafts and Flaps	As adjunct to surgery and antibiotics
Acute Traumatic Ischemias	As adjunct to surgery and antibiotics
Decompression Sickness.	Primary Treatment
Delayed Radiation Injuries	As adjunct to other treatments
Sudden Sensorineural Hearing Loss	Along with steroids
Intracranial Abscess	As adjunct to surgery and antibiotics
Necrotizing Soft Tissue Infections	As adjunct to surgery and antibiotics
Chronic Refractory Osteomyelitis	As adjunct to surgery and antibiotics
Severe Anemia	As temporizing measure until normal hematogenesis is adequate in selected patients
Thermal Burns	As adjunct to surgery and antibiotics

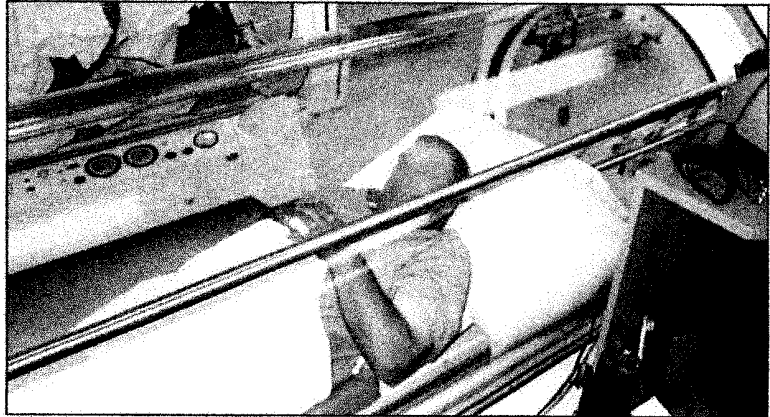
port its application in both these pathologies. One mark of its acceptance is the declaration that hyperbaric oxygen should be considered an intervention supported by Level 1 evidence published in the article laying out clinical guidelines by the American Society of Colon and Rectal Surgeons for the treatment of chronic radiation proctitis. Most third-party payers including Medicare will reimburse for hyperbaric oxygen treatments for the indications provided in Table 1.

The Undersea and Hyperbaric Medical Society (UHMS) has been the premier professional organization for the hyperbaric medicine community for over 50 years. This organization seeks to provide support for education, research and communication, and offers a forum for continuing education and exchange of the latest updates at its national and regional meetings. The UHMS has conducted a practice accreditation program for 20 years that seeks to promote high standards of practice within the hyperbaric medicine community. Hyperbaric oxygen is a unique treatment that offers unique benefits in certain cases but also introduces unique concerns regarding safety in this very specialized environment involving high pres-

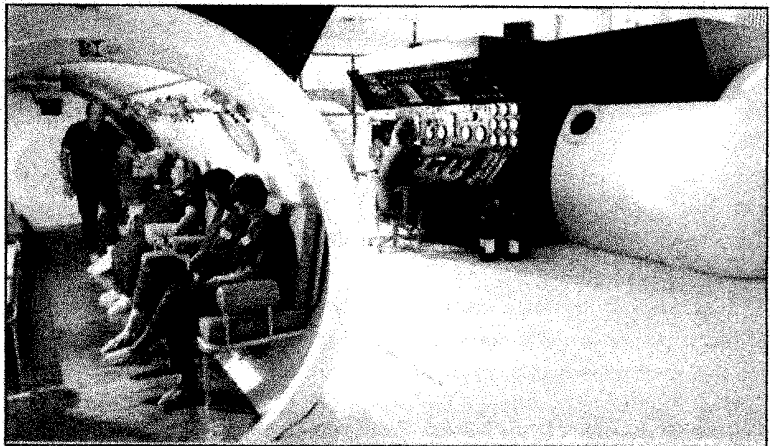
tures, high oxygen content and the attendant risk for both fire and explosive decompression. It is vital that the equipment involved in treatment, especially the pressure vessel itself, be designed, manufactured, installed and maintained to the highest standards. This requires adherence to established hyperbaric design and operational standards provided by the NFPA (National Fire Protection Association) and the American Society of Mechanical Engineers Safety Standards for Pressure Vessels for Human Occupancy (ASME PVHO-1). Perhaps, most importantly the chambers should be cleared in accordance with the Pre-Market Notification Process (FDA 510k) by the FDA.

Over the past decade or so, "mild hyperbaric" facilities have proliferated in the U.S. and internationally. These "mild hyperbaric" centers are mostly located in Spas, Wellness Centers, and even shopping center store fronts. They are not being operated as medical facilities or even doctors' offices. They frequently operate with minimal or no physician involvement. Staff are often inadequately trained. Many, if not most, employ pressure vessels to deliver mild hyperbaric "treatment" that fail to meet the safety standards of the NFPA or ASME and frequently they are not FDA cleared. Many use zip-up chambers made of non-rigid material very much akin to a canvas bag. Some of the soft-sided chambers have FDA clearance for the treatment of acute mountain sickness but are not cleared for the range of disorders scientifically supported by the UHMS (Undersea and Hyperbaric Medical Society) and are not cleared when combined with oxygen. Even more recently we have seen rigid chambers manufactured in other countries and exported to the U.S. in parts and pieces to be assembled. In this piecemeal fashion, these uncleared chambers are often not detected by inspectors and pass into the country to be used without FDA awareness. Standard, main stream hyperbaric medicine requires treatment most often at ambient pressures of 2.0 to 3.0 ATA (atmospheres absolute) with oxygen delivery at those pressures exceeding 95% of the breathing gas mix. The "mild" hyperbaric facilities typically treat their patients - more prop-

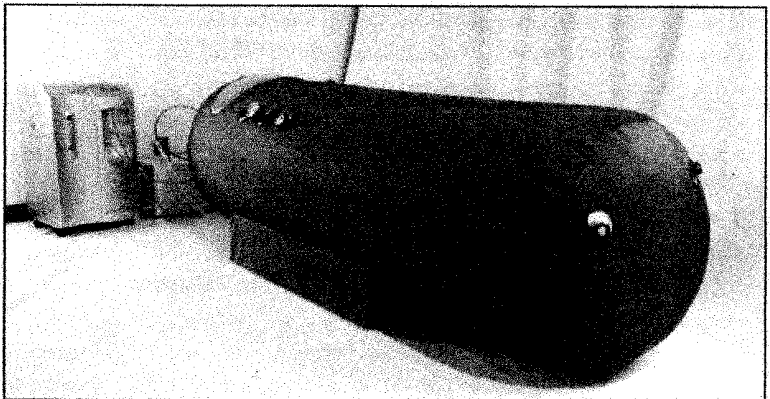
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Class B Monoplace FDA-approved Chamber



Class A Multiplace FDA-approved Chamber. The door is sealed for treatment.



This photo shows a soft-sided chamber typical of chamber used for "mild hyperbarics." This type of chamber can only be approved by the FDA for the treatment of mountain sickness. The photo also shows an oxygen concentrator which is not approved for usage with hyperbaric treatments.

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erly clients, at pressures of 1.4 ATA or lower. While many “mild” centers treat with compressed air only, some “mild” facilities attempt to increase the oxygen concentration for patients in their noncleared chambers and compound safety issues by adding oxygen concentrators. The oxygen concentrators employed are themselves often imported without 510K clearance. Since both hyperbaric chambers and oxygen concentrators are classified as Class 2 medical devices, they have to be reviewed and cleared individually and in any joint usage.

In websites and promotional brochures, some of these facilities have intentionally usurped the large body of published scientific articles reporting the results of standard and properly dosed and delivered hyperbaric oxygen. These include the 14 indications listed in Table 1. The mainstream hyperbaric community, as does the FDA, considers hyperbaric oxygen to be a “drug.” As such, it must be delivered by prescription in adequate doses with proven protocols to be effective. Ineffective treatments can delay the appropriate application of hyperbaric oxygen. Just recently, in Great Britain, a diver was treated for decompression sickness (the bends) ineffectively in a “mild” hyperbaric facility. The diver did not have resolution with the “mild” treatment and subsequently required retreatment at a standard hyperbaric recompression/hyperbaric facility. Severe, improperly treated decompression sickness can result in death for the diver if treatment is inadequate or delayed.

“Mild hyperbaric medicine” centers are targeting a vulnerable population of patients with disorders for which there is no established role for hyperbaric oxygen at any pressure in any treatment protocol. Desperate parents will pay large sums of money to these centers to treat children with cerebral palsy, autism or other unproven, often neurologic indications. “Mild hyperbarics” is portrayed as an innovative new therapy. Another vulnerable group includes stroke patients who may be months or years post stroke. Although the treatment of stroke patients with hyperbaric oxygen has been and continues to be studied, this treatment is investigational and not reimbursed by health insurance carriers. Therefore, when treated in unsafe chambers and with ineffective doses, these patients accumulate a substantial debt with virtually no hope of improvement.

Both the American Medical Association (AMA) and the Bexar County Medical Society have approved resolutions calling for a cessation of “mild hyperbaric” treatments. As you may know, the Bexar County resolution was recently communicated to the Texas Medical Board (TMB). The TMB took prompt action to issue a cease-and-desist order to two “mild hyperbaric” activities in state. Each were operated by dentists. These operations were shutdown based on the determination that these individuals were practicing medicine without a medical license.

In summary, “mild hyperbaric” advocates and providers offer a du-

plicitous presentation to their potential clients and regulators. On one hand, they claim that their chambers need not adhere to the long-established standards for safe design and operation required for clinical hyperbaric installations because of the “mild” doses delivered at pressures just slightly elevated above sea level pressure. On the other hand, they attempt to convince their potential customers that these mild pressures will be as effective as the established higher pressures combined with essentially 100% oxygen offered by mainstream hyperbaric facilities. All too often, the current “mild hyperbaric” operators promote their therapy to vulnerable populations for unproven indications. Until and unless, these “mild hyperbaric facilities” comply with all appropriate safety regulations and select appropriate treatment pressures and protocols along with safely delivered and approved oxygen delivery systems to treat scientifically supported disorders, they should be required to cease and desist treatments. The delivery of hyperbaric medicine is the practice of medicine. Non-physicians must not be permitted to deliver this very specialized medical treatment without the involvement, prescription and oversight of properly trained and licensed physicians. Nurses and staff working under the direction of trained and preferably board-certified physicians must be adequately trained to understand and respond to their patients’ unique hyperbaric environment and their patients’ reactions and special needs in this environment.

Physicians of the UHMS would gladly welcome new colleagues to our discipline if indeed they were committed to practice safe and effective hyperbaric oxygen treatments. As it now stands, we are a discipline which aims to police itself and seeks to support safe and effective treatments by professional and technical staff who are prepared and trained to deal with the unique complications that can occur in the hyperbaric realm and do so with greater frequency when the treatments are improperly delivered.

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30192320Table 1.

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John J. Feldmeier is the retired Chairman of Radiation Oncology at the University of Toledo Medical Center. He is board-certified in both Radiation Oncology and Hyperbaric Medicine. He is a Past President of the Undersea and Hyperbaric Medicine Society (UHMS). He currently serves as Co-chairman of that Society's Research Committee and Chairman of its FDA Liaison Committee.



Jayesh B. Shah is Immediate Past president of the American College of Hyperbaric Medicine and serves as medical director for two wound centers based in San Antonio, Texas. In addition, he is president of South Texas Wound Associates, San Antonio. He is also the past president of both the American Association of Physicians of Indian Origin and the Bexar County Medical Society and is currently on the Texas Medical Association Board of Trustees.



John S. Peters is the Executive Director of the Undersea and Hyperbaric Medical Society (UHMS). He is a board-certified healthcare executive and a Fellow of the American College of Healthcare Executives (ACHE). He has spent over thirty years in the undersea and hyperbaric medicine field, originally in the acute care setting and later leading teams to success in several different organizations involved in the Specialty.

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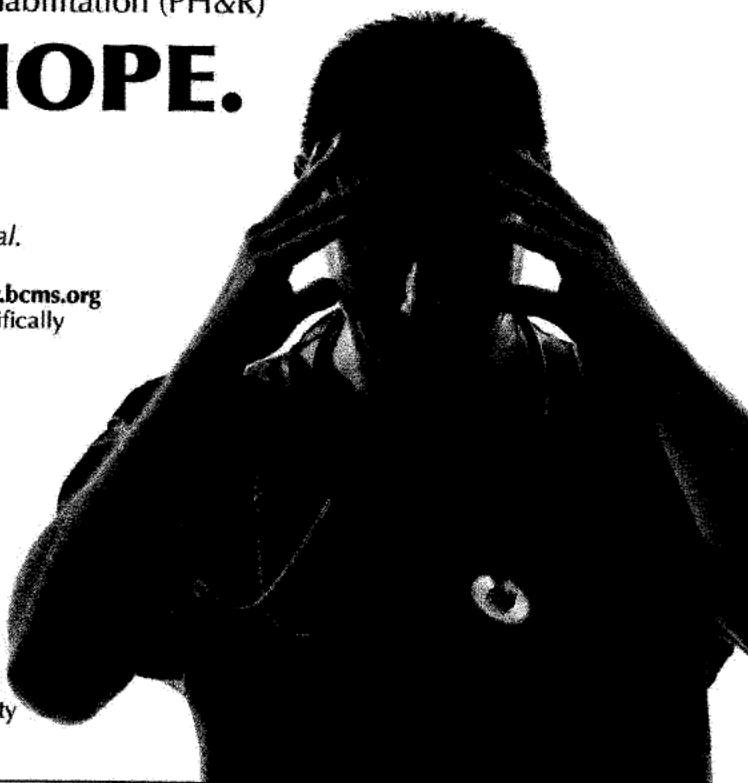
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C.J. Cutrone, C.H.T.
Paul J. Sheffield, Ph.D.
Mathew J. Brakora, M.D.

Comment No. 5
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MEMORANDUM

TO: Jack Maison, PhD
Chairman, ASME, PVHO Committee; [REDACTED]

FROM: Paul J. Sheffield, PhD

INFO: Richard Moon, MD; President UHMS; [REDACTED]
Dave Desautels; Chm, UHMS Safety Committee; [REDACTED]

DATE: April 24, 1995

SUBJECT: ASME-PVHO Question: What is the pressure range near sea level where physiological problems are minimal

The Problem: At the last ASME PVHO Committee meeting, you tasked me to ask the UHMS to define the pressure range near sea level where physiological problems are minimal. The purpose of the question is to define the range of pressures that ASME-PVHO should identify in the construction codes for pressure vessels (both altitude and diving) that are designed for human occupancy. The results reported herein is a consolidation of responses from UHMS members concerning the hyperbaric environment. Colonel Tom Workman queried the AsMA concerning the altitude environment and will report separately.

Effects of Rapid Decompression: The severity and consequences of pressure vessel failure depend on the rate of decompression and the pressure range over which it occurs. The physiological effects of rapid decompression are primarily barotrauma (due to gas expansion), and decompression sickness (due to evolved gases). Barotrauma can result from pressure changes in the middle ears, sinuses, gastrointestinal tract and lungs. Decompression sickness can manifest itself as bends pain, chokes, neurologic impairment, paralysis, chokes, or circulatory collapse. The life-threatening disorders are lung rupture and severe decompression sickness.

Summary of Results: Figure 1 summarizes the reported minimum pressure changes that have resulted in a physiological problem. The respondents to this inquiry assumed the worse-case scenario in which a PVHO vessel fails catastrophically.

Barotrauma: Basically, no known barotrauma results from a pressure change of less than 2 fsw. The middle ear and sinuses normally clear automatically during decompression. But, if the person has an ear or sinus block, barotrauma can result in pain from pressure changes of 2-4 fsw (Fife, Personal communication). Farmer (1990) reported that rupture of the ear drum can occur at a pressure change of between 120-300 mmHg (4.3 - 17.4 fsw). However, catastrophic failure of the

hyperbaric chamber poses the greatest threat to the lung. Lung barotrauma that results in arterial gas embolism has been reported at pressure changes as little as 6 fsw (Fife, Personal communication). Malhotra and Wright (1960) using primates as experimental animals, showed that during a decrease in ambient pressure by more than about 50 mmHg (3.5 fsw; 0.1 atm), the gas expanding within the alveoli may rupture into the circulation, the interstitial tissues, or the pleural space. Ascent to the surface following respiration of gas under pressure holds the same hazard for man. Elliott (1995, personal communication) has treated a severe neurological decompression illness following blow up from less than 8 feet. Elliott and Kindwall (1982) reported that death has occurred following ascent from as shallow as 7 ft (1.2 ata).

Decompression Sickness: Decompression sickness can result if the individual is decompressed following exposure to pressure for long enough duration. It is unusual unless the individual has been exposed to a pressure greater than 33 fsw (2 ata), but it has been reported after surfacing from 17 feet after a saturation exposure of greater than 25 hours (Fife, Personal communication).

Recommendations: The general view of the respondents was that, for the purpose of establishing standards, it would seem most appropriate to select a pressure differential that would prevent a life threatening disorder, such as lung barotrauma.

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Figure 1. REPORTED MINIMUM PRESSURE CHANGE THAT RESULTED IN A PHYSIOLOGICAL PROBLEM UPON SURFACING

Pressure Change (fsw) (psi)		Physiological Problem	Signs or Symptoms
2	1	None	None
2-3	1-1.5	Ear & sinus barotrauma	Pain
4	2	Ear barotrauma	Ruptured ear drum
6	3	Lung barotrauma	Emphysema Pneumothorax Arterial gas embolism
7	3.5	Lung barotrauma	Death due to arterial gas embolism
17	8.5	Decompression sickness (after a saturation exposure)	Pain Central nervous system effects Paralysis

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Foran, Rosanne

Comment No. 6
OPPOSE
page 1 of 8

From: Dick Clarke
Sent: Monday, July 10, 2023 11:05 AM
To: Shared TIAs
Subject: Comment on Proposed TIA 1735 on NFPA 99
Attachments: COMMENT ON TIA JULY 2023.pdf; Attachment.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

To Whom it May Concern.

Please find attached my Public Comment related to the above referenced TIA.

Respectfully,

Dick Clarke, President
National Baromedical Services
National Board of Diving & Hyperbaric Medical Technology
9 Richland Medical Park, Suite 440
Columbia, SC 29203, USA

Re: **Comment on Proposed TIA 1735 on NFPA 99**

I write to OPPOSE the above-referenced TIA.

To argue my opposition, I offer a critique of several documents that have been submitted in support of the proposal. In doing so I will demonstrate that their collective assertions demonstrate a profound lack of knowledge of cited codes and standards, involve factually incorrect statements, illustrate ignorance of fundamental fire safety, and include what appear to be purposely misleading assertions. The sum of all of this is that, in effect, these documents effectively argue against TIA 1735.

The *“International Hyperbarics Association”* letter dated April 17, 2023, is a case in point. Within it is a statement that the soft-sided chamber has been evaluated and granted an FDA 510 (k) and cleared for home and clinic use. While the FDA recognized that a predicate device existed (Gamow Bag), nowhere does the FDA indicate that it is cleared for home and clinic use, nor cleared for the many scientifically unsupported indications for which the IHA advocates. This same letter adds that *“the addition of an oxygen concentrator does not increase risk of combustion”*. This clearly demonstrates that these chambers are being used outside the scope of the FDA’s substantial equivalency standard and the incredulous assertion that use of oxygen does not increase risk of combustion nor pose any danger to patients or attendants.

The most cursory of on-line searches will readily identify long appreciated authoritative evidence to the contrary. For example, Wood MH, *et al.* (Process Safe Environ Prot. 2021;153:278-288) state that *“even a small increase in the oxygen level in air to 24% can create a fire hazard. In an oxygen-enriched environment, materials become easier to ignite and fires burn hotter and more fiercely than normal air”*. The IHA letter further demonstrates this organization’s complete misunderstanding or ignorance of relevant codes by its statement that *“mild-pressure” chambers “do not fall under the purview of ASME-PVHO regulations, as these models are not operating with high pressure and 100% medical oxygen administration”* and they add *“As of today, there are no standards for the manufacture and operation of soft-walled chambers.”* In fact, the cited ASME-PVHO-1 standard applies to *all* pressure vessels that enclose a human within their pressure boundary while under internal or external pressure exceeding a differential pressure of 2 psi (15 kPa) and make no reference to a chamber’s atmosphere. It is abundantly clear, therefore, that this standard extends to the soft-walled mild pressure chamber. Further, NFPA-99 represents a long-standing “operation” standard. So, indeed, standards clearly exist for the soft-walled chambers to meet.

The letter’s final statement that the IHA has been working with ASME to develop a soft-walled chamber is at best economical with the truth. The IHA did approach the ASME in 2022 to demand they issue a separate standard “within three months” to allow soft-walled chambers to be certified as being compliant. Litigation was threatened if this did not occur. The ASME board declined to issue this standard and indicated the existence of a “case code” process for any chamber design application to meet its engineering requirements.

A second document intended to support the TIA represents an equally flawed interpretation of prevailing codes and standards. Its conclusions are at odds with the facts and the opinions of recognized experts on hyperbaric safety, hyperbaric technology, as well as others who serve on related authoritative committees. This document was commissioned by Restore Hyper Wellness, a PE-owned operator of lifestyle facilities that include soft-walled hyperbaric chambers and authored by Mr. Mario Caruso. The concern regarding Mr. Caruso’s flawed interpretations, views, and recommendations was grave enough that the Undersea

and Hyperbaric Medical Society suspended his standing as a UHMS hyperbaric facility surveyor and disciplinary action is underway against Mr. Caruso by a related certifying body.

Mr. Caruso stated that Restore Hyper Wellness (RHW) hyperbaric operations are not required to comply with NFPA 99, Chapter 14. This is wholly incorrect. His assertion is based, in part, on an incorrect analysis that RHW offers *therapeutic* not *medical* treatment. RHW chambers acquired from OxyHealth LLC are marketed and sold as a “medical model of the Gamow bag” and “for medical use”. This assertion that RHW provides therapeutic not medical care fails at every turn. The FDA, National Cancer Institute and other authoritative organizations make it abundantly quite clear that therapeutics is an intertwined branch of medical science. This same definition exists within federal trade regulations and legal case law (see attachment). Mr. Caruso incorrectly further argues that RHW chambers operate below 1.4 ATA/5.88 psi so not within the scope of NFPA. In accordance with **NFPA 99 2021 1.1.12* Chapter 14 (Hyperbaric Facilities) “...design and operation of hyperbaric chambers...at gauge pressures from 0 psi to 100 psi)**. He also incorrectly states that the Undersea and Hyperbaric Medical Society deems pressures below 1.4 do not constitute hyperbaric medical treatment when their pressure standard is one that exceeds 1.0 ATA. This UHMS position does not, however, represent an authoritative code or standard.

Mr. Caruso adds to his ignorance of prevailing codes, standards, and operational features by his assertion that NFPA again does not apply “*because the compressors that they (RHW) are using to supply air to the chamber is (sic) not a medical gas supply*”. The type of compressor used does not determine whether it is a hyperbaric chamber or not. Chambers do not have to be compressed using medical air. Air-filled chambers are to be compressed using air that meets CGA Grade E requirement, with no condensable hydrocarbons for Class B-monoplace chambers. He rather incredulously adds that RHW compressors “*simply compress the room air (21% oxygen, 78% nitrogen, 1% other gases)*” as if this is something unique to their compressor type. This is how ALL air is produced to pressurize ALL air-filled chambers.

His final discounting of NFPA is his statement that RHW locations are not considered hyperbaric facilities as defined by NFPA Chapter 3.3.80. Once again, this is incorrect. Namely: **NFPA 3.3.80 Hyperbaric Facility. Building, structure, or space used to house hyperbaric chambers and auxiliary service equipment for medical applications and procedures at pressures above normal atmospheric pressure. (HYP)** To not recognize RHW chambers exist in a *space* as defined above and referencing back to the lack of any distinction between *therapeutic* and *medical* is again without factual basis.

Mr. Caruso’s misinterprets the ASME PVHO-1 code standard. As published, under **SCOPE 1-2.1 This standard applies to all pressure vessels that enclose a human within their pressure boundary while under internal or external pressure exceeding a differential pressure of 2 psi (15kPa)**. Soft-shell chambers are not included with the **1.3 Exclusions** so there is nothing within this standard that would warrant the opinion that it is not applicable to soft-shell chambers “*in the way there are used by Restore Hyper Wellness locations*”.

The statement that an oxygen monitor is only necessary when the atmosphere inside the chamber reaches an oxygen level of 23.5% or higher is counter intuitive at best. How would one know when this level has been reached/exceeded during RHW practice of delivery of 95% oxygen in the absence of an oxygen monitor? It is surely indisputable that there must be some zone within the chamber that is well above this 23.5% threshold.

Elsewhere in Mr. Caruso's letter is a general and disturbing sense of arguing the reduction/elimination of long-established safety standards and well-accepted operational policies and recommendations. The two recent (2023) pressure vessel failures resulting in serious injuries (Utah) and five deaths (North Atlantic), neither of which were designed and manufactured to established codes should serve as a stark object lesson for those who seek to discount adherence to prevailing codes and standards.

The work commissioned by RHW and undertaken by Page is sufficiently generic, is lacking in verifying references and incorrectly states they do not believe the mHBOT (soft-sided) chamber is required to comply with NFPA 99 "by definition". Page adds that NFPA 99 includes requirements for oxygen-enriched atmospheres are not applicable for the mHBOT utilized by RHW as if this somewhat preempts this chamber type from all NFPA 99 standards. Page notes in one section that chamber clients/occupants are delivered with oxygen by a nasal cannula, elsewhere it states by oxygen mask. In their testing scenarios it should be one of the other analyzed unless they tested both delivery system types, which did not appear to be the case. I saw no information as to the take-off point of the in-chamber sample line. In one test scenario an oxygen mask was worn, in the other it was placed alongside the client/occupant. As 95% oxygen flowed at 4 lpm it is inconceivable that there would not be a level greater than the 23.1% highest level reported, if assessed at these locations. Simple gas physics dictates this.

All of this serves to limit confidence in Page as a sufficiently knowledgeable resource in the context of hyperbaric delivery system codes and standards, and so too its findings and conclusions.

Finally, there is certainly nothing suggestive of an emergency nature associated with this proposal. This soft-sided chamber type has been in use in the USA for more than a decade. Those who choose to use it do so in an entirely elective setting of home, private clinic, or office. And there is no present code gap, as asserted.

Respectfully submitted.

Dick Clarke, CHT-A

Columbia, SC

Dick Clarke

Public Comment Regarding NFPA 99-2022

I wish to express opposition to the proposal that so called mild hyperbaric chambers are therapeutic not medical in their purpose, involve minimal fire and other risks so should not be held accountable to current NFPA 99 Chapter 14 standards. I likewise oppose the proposal that this chamber type be assigned to the currently reserved Category 4 within NFPA 99 14.1.3.4.

These inflatable chambers are manufactured and marketed as *medical* (my emphasis) devices. For example, OxyHealth, a mild hyperbaric chamber supplier to Restore (and the company on whose behalf this proposal has been generated) and other customers, notes that *"We made a medical model of the Gamow Bag for medical treatment"*. (My emphasis) *"Our chambers are utilized by over 3,000 physicians and have been used to treat hundreds of thousands of patients"* (www.oxyhealth.com retrieved July 21, 2022). OxyHealth adds that *"These are Class II medical (my emphasis) devices, which require a prescription from a licensed physician"*. Clearly, then Restore and others are acquiring medical devices.

The Federal Drug Administration defines medical devices (therefore this chamber type) as, *inter alia*, *"intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease..."*. (Is the Product a Medical Device? U.S. Food and Drug Administration 2018-11-03). The World Health Organization holds a largely identical albeit more precise view, in that a medical device is *"intended by the manufacturer to be used, alone or in combination, for a medical purpose"* (my emphasis). (www.who.int/home/health-topics/medical-devices#tab-tab_1)

With reference to "therapeutic", The National Cancer Institute defines this term as having to do with treating disease and helping healing take place. (www.cancer.gov/publications/dictionaries/cancer-terms/def/therapeutic) It is a long-held view elsewhere that *"therapeutics is a branch of medical science."* (Merriam-Webster Dictionary 11th Ed.) (My emphasis)

The argument that Restore offers therapeutic not medical services and suggests a clear distinction between the two, also fails on legal grounds. Established case law

(Travenol Laboratories vs. United States Court No. 89-08-00469, 1993), cites several authoritative sources extending back over three quarters of a century, noting therapeutic as deemed to represent treatment of an illness or disease (Random House College Dictionary 1988); pertains to treating or curing disease (Taber's Cyclopedic Medical Dictionary 1957), having medicinal or healing properties (Blakiston's New Gould Medical Dictionary 1956), and a branch of medical science dealing with treatment of disease (Funk & Wagnalls New Standard Dictionary 1942). (Again, my emphasis)

The Court of International Trade, a U.S. federal agency that adjudicates civil actions relating to U.S. Customs and trade laws and frequently cited in medical product disputes, defines therapeutic *"as its purpose of complete or partial elimination of disease"*. Therapeutics is, therefore, explicably intertwined within delivery of medical care. To state otherwise is a poorly research argument, one that belies authoritative medical opinion and established case law.

As previously noted, and consistent with other such manufacturers, OxyHealth's mild hyperbaric chamber is a medical device manufactured and promoted for medical purposes. It is surely principal remit of this committee to assess chamber design and design intent, construction, installation and compliant operation, rather than any given end-user's thoughts on how they may choose to use it.

The regulatory basis (FDA Section 510K) for marketing mild hyperbaric chambers is that they are substantially equivalent to the Gamow Bag and with *"Intended Use: To provide mild hyperbaria (sic) for the treatment of Acute Mountain Sickness (AMS) and its associated mild symptoms"*. Readily apparent upon the most cursory of internet searches is that this chamber type is proposed as treatment on behalf of the desperate, gullible and vain, and I use the term treatment loosely as it is an undoubted exercise in futility, for anything but AMS. And these chambers are frequently found in the most un-clinical of settings.

Multiple occupancy utilization is not uncommon, another FDA violation, and one company manufacturers a four-person capability. (www.medicalexpo.com/prod/shanghai-bangyi-industrial/product-301208-1026794.html retrieved July 22, 2022).

Air-filled Class A hyperbaric chambers incorporate an oxygen delivery system that is an essential closed loop, with excess oxygen eliminated via the breathing circuit directly to chamber and building exteriors, and the chamber's atmosphere

constantly monitored to confirm safe and effective exhausting. In these inflatable chambers, excess oxygen and the initially delivered oxygen if the mask is not worn, flows directly into the mild hyperbaric chamber (an inboard dump in the vernacular of the diving industry) in violation of NFPA 99 and further violation of the FDA's "substantial equivalency" standard. Restore markets provision of hyperbaric *oxygen* (my emphasis) therapy. (www.restore.com retrieved July 20, 2022). They attempt to do so by using a medical grade oxygen concentrator, one capable of producing approximately 95% oxygen, and limiting its rate of delivery to 4 lpm. So, while this is seen to produce an FiO_2 of just 36%. (www.oxygenconcentratorstore.com retrieved July 22, 2022) it must not distract from the fact that 95% oxygen is entering the chamber to generate this degree of alveolar gas exchange. From a purely therapeutic perspective, and I understand this not to be within this committee's remit, when a suggested mask option involves placing it adjacent to rather than directly on an occupant, it is difficult to imagine there being even a modicum of enhanced oxygen delivery. All of this serves to question the veracity of Restore, and others, as legitimate providers of hyperbaric oxygen therapy and clearly fails its accepted definition. (Hyperbaric Oxygen Therapy Indications 14th Edition Moon RE Editor. ISBN: 978-1-947239-16-6 2019)

The Restore commissioned 2021 analysis (the study design, conduct and reporting of which is sufficiently flawed that I and others have little confidence in its conclusions) of chamber oxygen concentration indicated an increase of barely 1% above normal atmospheric content. It was unclear where the sample point was but obviously nowhere near the oxygen inlet site, where it would have measured in the order of 95%, so, by definition, an ***oxygen enriched atmosphere***. This essential cone of heightened oxygenation is concentrated immediately adjacent to various battery powered electrical and electronic devices occupants are permitted and even encouraged to take into the chamber.

There is nothing to prevent other users from employing higher flow rates and alternative oxygen delivery systems, such as liquid Dewars or high-pressure gas cylinders. Accordingly, oxygen delivery rates are prone to increase, so too the extent of the oxygen enriched atmosphere. All of this with no knowledge of the chamber's actual oxygen concentration. Further concerning from a safety standpoint is again the chamber's exhaust flowing directly into the room, occupants invariably wear unapproved clothing, and being permitted to take into

this chamber cell phones, laptops, tablets, ventilation fans and “walkie-talkie” communication devices, all in direct violation of NFPA standards and hyperbaric safety norms.

Despite the fact this chamber type incorporates a low operational pressure, accommodation of each occupant’s air containing bodily spaces is required during pressure changes. There remains, therefore, an inherent albeit minor risk of ear and sinus barotrauma. A more serious risk is associated with sudden uncontrolled chamber decompression secondary to failure of the fabric hull. Even at 1.4 ATA/6-psig, this chamber’s type’s apparent upper operating limit, inadequate lung ventilation during such an event can result in life-threatening cerebral arterial gas embolism. A devastating such injury occurred from ascent of less than 2 psig. (Benton PJ, *et al.* Aviation, Space, & Environmental Medicine 1996;67(1):63-64) The patient’s resulting brain injury was promptly diagnosed and successfully treated in large part because of the onsite presence of trained and knowledgeable personnel. My understanding is that the use of these chambers within the business sector lacks such trained and knowledgeable personnel. It is absolutely the case during in-home use. Even more concerning, at least two mild hyperbaric chamber manufacturers promote the ability to operate the chamber from within, obviating the need for anyone to be present outside. (www.macypan.com/catalogue-of-hyperbaric-oxygen-chamber.pdf retrieved July 27, 2022; www.hyperbaricpro.com retrieved July 27, 2022).

Just last week the American Medical Association formally opposed the use of mild hyperbaric facilities *“unless and until effective treatments can be delivered in facilities with appropriately trained staff including physician supervision and prescription and only when the intervention has scientific support or rationale...”*. (AMA Policy Finder Legislation and Regulation “Oppose Unsafe Use of “Mild Hyperbaric Therapy” D-270.986 2022). This authoritative body joins many others in taking a dim view as to the legitimacy of the mild hyperbaric chamber as a medical therapeutic device, short of acute mountain sickness.

This committee is urged to reject both proposals. To do otherwise would give an essential green light for further indiscriminate medical, operational and safety behaviors and place the NFPA in direct conflict with the FDA, the Undersea and Hyperbaric Medical Society and now that of the AMA.

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