UNDERSEA & HYPERBARIC MEDICINE

A Critical Look at Soft-Sided and Hard-Sided "Mild" Hyperbaric Chambers – Risks, Regulations, and Ethical Oversights

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ABSTRACT

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Soft-sided hyperbaric chambers, as well as some hard-sided (mild) hyperbaric chambers, which are low-pressure, hyperbaric chambers that are typically designed for operational pressures of 3-5psi, have gained popularity in recent years. They are marketed as safe and effective for various conditions but lack compliance with critical regulatory and safety standards and codes. This raises concerns regarding patient safety, the validity of manufacturers' claims, and the ethical obligations of medical professionals and regulators.

This manuscript examines the risks, regulatory gaps, and ethical implications of using soft-sided fabric chambers, as well as hard-sided (mild) hyperbaric chambers, focusing on their failure to meet FDA clearance, NFPA 99 & NFPA 101 codes, and ASME-PVHO standards.

A comprehensive review of regulatory guidelines, safety reports, and marketing practices was conducted, supplemented by illustrations of adverse events linked to the use of these devices. Ethical principles, including beneficence, non-maleficence, and informed consent, were applied to analyze the responsibilities of manufacturers, healthcare providers, patients, and regulators.

These chambers are often marketed with misleading claims about their efficacy and safety. Their non-compliance with FDA clearance, as well as not following industry standards and safety codes increases the risk of patient harm, including otic and pulmonary barotrauma, suffocation, fire hazards, structural failure, and, in extreme cases, death. Regulatory oversight remains inconsistent, allowing manufacturers to exploit loopholes. Furthermore, ethical concerns arise when patients are not fully informed of the limitations and risks of these devices.

The widespread use of these hyperbaric chambers poses significant safety and ethical challenges. Stricter enforcement of regulatory standards and codes, transparent marketing practices, and ethical accountability from healthcare providers and manufacturers are essential to protect patients and uphold public trust in medical technologies.

Keywords: fire or explosion; mild hyperbaric treatment; hyperbaric oxygen; hyperbaric oxygen treatment; soft-sided, hard-sided

INTRODUCTION

The use of soft-sided "mild" hyperbaric oxygen (HBO_2) chambers in wellness clinics and spas across the United States and worldwide has surged in recent years. These chambers, as well as their hard-sided counterparts in these same settings, are marketed with claims that they can reduce inflammation and pain associated with conditions such as arthritis

and diabetic neuropathy, as well as claims that it can alleviate symptoms of chronic fatigue syndrome, fibromyalgia, and cancer, among others. Additionally, they are said to increase mitochondrial production, improving energy, sleep, and stamina. Supporters also claim that these chambers can alleviate neurological disorders, including migraines, multiple sclerosis, Alzheimer's disease, and Parkinson's disease, among other conditions. [6,10,13]

However, the rapid proliferation of these devices creates grave safety, regulatory, and ethical concerns that must not be overlooked. Soft-sided chambers are not FDA-cleared for most of the advertised uses[14], nor are they compliant with standards and codes like ASME-PVHO-1[4] and NFPA 99[19]. This lack of compliance, as well as misleading health claims, present a significant and unacceptable public health risk.

Soft-sided hyperbaric chambers are inflatable devices that were initially designed for emergency treatment of acute mountain sickness, which remains their only FDA-cleared use.[14] Unlike their medically appropriate hard-sided counterparts, which deliver 100% oxygen at controlled high pressures, soft-sided chambers, as well as hard-sided "mild" hyperbaric chambers, administer only ambient air, typically composed of 20-21% oxygen, and are used at significantly lower pressures. However, due to the need for enriched oxygen environments, wellness centers, spas, and even private homes have increasingly turned to oxygen concentrators. These devices augment the oxygen level in the breathing gas mixture, which is then delivered via nasal cannulas or oronasal masks to the patient. As a result, the oxygen concentration in these settings can inadvertently increase above 21%, likely exceeding 23.5%, an elevation that could lead to catastrophic consequences.[11,19] Despite their medical limitations, these devices are increasingly being used off-label in wellness clinics, spas, and private homes for therapies that lack scientific validation.

In addition, the safety and efficacy of soft-sided chambers, as well as their hard-sided "mild" counterparts, which are also being used in wellness clinics, spas, and even private homes, have come under increased scrutiny.[5,8,12-14,16-17,21-22,24-29] These devices lack FDA clearance for most of their advertised uses, and their failure to meet established fabrication standards as outlined by ASME-PVHO-1 and safety codes as outlined by the NFPA raises some profoundly serious concerns.[4,19,20] While the FDA has cleared soft-sided chambers for the treatment of acute mountain sickness[14,28], their use beyond this scope is not supported by rigorous clinical evidence, despite growing claims of many wellness and beauty applications. This off-label usage, coupled with unsubstantiated health claims, is a growing trend that not only misleads consumers but also steers patients away from proven, evidence-based medical treatments.[6,8,10,13,14,21,23]

WHAT ARE THE REGULATORY BODIES AND WHAT ARE THEIR RESPONSIBILITIES?

In 1976, the U.S. Food and Drug Administration (FDA) placed hyperbaric chambers under Class II medical-device oversight.[7] This classification obliges manufacturers to obtain FDA clearance through the 510(k)-pre-market notification process, which requires submission of detailed design specifications, performance data, and safety documentation. As part of the review, applicants must stipulate the device's intended indications for use and acknowledge its status as a prescription device. Consequently, hyperbaric chambers may be marketed or operated only when a licensed healthcare professional has issued a valid prescription. The FDA regulates both the oxygen used in Hyperbaric Oxygen Treatment (HBO_2 Treatment) and the hyperbaric chambers, which are generally a tube large enough to hold one person or a vessel (chamber) that can accommodate more than one person. As of July 2021, the FDA has only cleared the use of HBO_2 for the following indications[14]:

- Air and gas bubbles in blood vessels
- Anemia (severe anemia when blood transfusions cannot be used)
- Burns (severe and large burns treated at a specialized burn center)
- Carbon monoxide poisoning
- Crush injury
- Decompression sickness (diving risk)
- Gas gangrene

- Hearing loss (complete hearing loss that occurs suddenly and without any known cause)
- Infection of the skin and bone (severe)
- Radiation injury
- Skin graft flap at risk of tissue death
- Vision loss (when sudden and painless in one eye due to blockage of blood flow)
- Wounds (non-healing, diabetic foot ulcers)

The National Fire Protection Association (NFPA) is a trusted source of safety knowledge. For more than 125 years, it has helped solve some of the planet's most challenging safety problems. To remain relevant for over a century as a knowledge and information organization, the NFPA has continually evolved its scope of expertise—from fire prevention, wildfire preparedness, and electrical safety to hazardous materials, community risk reduction, and public safety.[2]

For hyperbaric oxygen (HBO) facilities, the most relevant enforcement authorities are typically state and local fire marshals. Before the 2015 edition, NFPA 99 primarily addressed hyperbaric facility construction requirements. The 2015 edition expanded the scope significantly to encompass both construction and daily operational aspects. This shift represents a critical change, empowering local fire marshals with direct oversight of a facility's ongoing operation and maintenance, thereby enhancing safety and compliance.

The National Fire Protection Association 99 compliance is not universally mandated across all jurisdictions and states within the United States. This means enforcement varies by location, making it essential for facility operators to understand their local requirements.

The National Fire Protection Association 101, the Life Safety Code, is also a crucial code that significantly affects hyperbaric facilities and has been adopted in all 50 states. It addresses fire safety requirements for buildings with public occupancy, including offices, theaters, and shopping centers.

The importance of NFPA 101 cannot be overstated because, since the 2000 edition, it includes provisions that reference and endorse compliance with the hyperbaric facility requirements outlined in NFPA 99. This creates a pathway for NFPA 99 requirements to become enforceable even in jurisdictions that haven't specifically adopted NFPA 99. Essentially, NFPA 101 serves as a "backdoor" mechanism that can make hyperbaric safety codes legally binding through its universal adoption, significantly expanding the reach and enforceability of hyperbaric facility safety requirements across the United States.

The American Society of Mechanical Engineers serves a broad engineering community through quality learning, the development of standards and codes, certifications, research, conferences and publications, government relations, and other outreach efforts.

The ASME PVHO-1 standard provides requirements for the design, fabrication, inspection, testing, marking, and stamping of pressure vessels for human occupancy, having an internal or external pressure differential exceeding 2 psi. This Standard also provides requirements for the design, fabrication, inspection, testing, cleaning, and certification of piping systems for PVHOs. A PVHO is a pressure vessel that encloses a human being within its pressure boundary while it is under internal or external pressure that exceeds a 2psi differential pressure. PVHOs include, but are not limited to, submersibles, diving bells, personnel transfer capsules, decompression chambers, recompression chambers, hyperbaric chambers, high altitude chambers, and medical hyperbaric oxygenation facilities. This does not include nuclear reactor containments, pressurized airplane and aerospace vehicle cabins, and caissons.[4]

The synergy between NFPA 99 and ASME PVHO-1, along with NFPA 101's overarching safety codes, creates an unparalleled foundation for safety and quality in hyperbaric medicine. NFPA 99 meticulously governs the operational environment of hyperbaric facilities through requirements for fire-rated construction, fire hazard mitigation, oxygen handling protocols, ventilation systems, and emergency procedures to ensure safety in oxygen-enriched environments.[19] NFPA 101, the Life Safety Code, provides additional critical safety requirements that apply to all healthcare facilities, including those housing hyperbaric chambers.[20] Meanwhile, ASME PVHO-1 provides the structural backbone of hyperbaric safety by defining precise requirements for the design, fab-

rication, inspection, and testing of pressure vessels for human occupancy. The standard extends to associated piping systems, ensuring every component is certified for human safety.[4]

Together, these standards and codes form a comprehensive framework that, while they don't guarantee safety, greatly increase the ability to protect human life and reinforces public trust in hyperbaric technologies by striving for excellence at every level.

THE RELEVANCE OF ASME STANDARDS TO HYPERBARIC OXYGEN TREATMENT

The safe and effective application of hyperbaric oxygen treatment (HBO_2) relies heavily on the structural integrity and mechanical reliability of the pressure chambers used in treatment. These chambers are categorized as pressure vessels, subject to elevated internal pressures and enriched oxygen atmospheres that introduce both mechanical and combustion risks. The engineering standards established by the American Society of Mechanical Engineers (ASME) form the basis for ensuring the safety, durability, and regulatory compliance of such equipment in clinical and industrial environments.[4]

Founded in 1880, ASME has been instrumental in the development of standards for pressure systems. Most notably, the ASME Boiler and Pressure Vessel Code (BPVC)—first published in 1911—remains the principal framework governing the design, fabrication, inspection, and certification of pressure vessels worldwide. The BPVC provides rigorous guidelines for materials selection, welding, stress analysis, nondestructive examination, and quality assurance. Hyperbaric oxygen chambers, being subjected to repeated cycles of pressurization and depressurization, fall directly within the scope of this code. Adherence to the BPVC significantly reduces the risk of structural failure, pressure-related injury, and oxygen-induced fire or explosion.[4]

In addition to the general requirements of the BPVC, ASME has developed a specialized standard titled Pressure Vessels for Human Occupancy (PVHO). The PVHO-1 code, first issued in 1981 and updated periodically, provides focused safety criteria for enclosures designed to be occupied by humans under internal pressures exceeding ambient atmospheric pressure (ASME). This includes hyperbaric chambers, manned submersibles, decompression chambers, and related structures. The PVHO-1 standard addresses not only the mechanical integrity of these vessels but also their ergonomic design, viewport materials and configurations, pressure relief systems, and cyclic fatigue performance. These provisions are essential in a clinical context, where the reliability and long-term performance of HBO_2 chambers directly affect patient safety and therapeutic efficacy.[4]

The application of ASME standards in hyperbaric medicine is further reinforced by the requirements of accreditation bodies such as the Undersea and Hyperbaric Medical Society[3], the National Board of Boiler and Pressure Vessel Inspectors[9], and the U.S. Food and Drug Administration, all of which emphasize code compliance in the manufacture and operation of medical-grade hyperbaric systems.

Given the intrinsic hazards associated with elevated oxygen concentrations and compressed gas environments, strict adherence to ASME's engineering and safety principles is non-negotiable[4]. The integration of BPVC and PVHO standards into the design and regulation of hyperbaric chambers represents not only a legal and technical obligation, but also a foundational aspect of ethical patient care.

While adherence to pressure vessels for human occupancy (PVHO) standards is crucial, it does not guarantee absolute safety. However, compliance demonstrably reduces the risk of hyperbaric system failures[3]. This principle applies equally to adherence to NFPA 99, the standard for health care facilities, which includes specific provisions for hyperbaric facilities. NFPA 99 addresses both the initial construction and ongoing operation and maintenance of these specialized environments. By establishing comprehensive requirements for design, construction, testing, inspection, and operational procedures, NFPA 99 contributes significantly to mitigating risks associated with hyperbaric systems. Full compliance with NFPA 99, along with other relevant PVHO and safety codes, strengthens the overall safety profile of a hyperbaric facility, protecting both patients and staff. Though the possibility of unforeseen events can never be entirely eliminated, diligent adherence to established standards and codes rep-

resents the most effective approach to minimizing potential hazards and fostering a culture of safety within the hyperbaric environment. Implementing robust safety protocols and adhering to these established guidelines remain critical for ensuring the well-being of all individuals involved.[3,4,19,20]

The promise of portable hyperbaric oxygen treatment has a dark undercurrent: recurring incidents tied to soft-sided chambers, and even some hard-sided chambers that evade the fabrication standards of ASME-PVHO-1 and NFPA safety codes, reveal a chilling lack of regulation and reliability. Fires, explosions, mechanical failures/zipper failures, and suffocation deaths paint a grim portrait of the risks involved when these devices bypass the rigorous clearances, safety standards, and codes upheld by the FDA, NFPA 99, NFPA 101, and ASME-PVHO-1.

The most harrowing example is the 2009 fire in Florida, which claimed the lives of a 4-year-old boy and his grandmother. According to CBS News Miami, the fire was believed to be traced to a static charge in a hard-sided chamber, where the elevated oxygen concentration became a tinderbox. The resulting fire engulfed the chamber almost instantly, leaving no chance for survival.[16] While the chamber in question was hard-sided, the lesson is universal: oxygen-rich environments amplify fire risks exponentially, making any design, maintenance, and operational flaw potentially fatal.

Failures in soft-sided hyperbaric chambers, though underdocumented, are more common than some might suspect. Adverse events that are reported are cataloged in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database. For instance, on December 29, 2015, a soft-sided chamber exploded during depressurization. As a nurse initiated the pressure release, the chamber violently ruptured, ripping the zipper off and expelling a cloud of "white dust" due to rapid decompression. This incident left both the patient and the nurse understandably shaken. This underscores the need for greater awareness and investigation into the frequency and causes of such incidents.[12]

June 18th, 2017, saw another incident reported in the MAUDE Database in which the chamber's "big window" exploded under full pressure, leading to rapid deflation. While no one died, there was an unknown injury to the user, and the implications are alarming: compromised materials and insufficient testing can lead to catastrophic failures.[12]

Also, given that the MAUDE database's data collection is confined to the most recent 10-year period, it is reasonable to infer that the actual number of adverse events or occurrences surpasses those currently cataloged within the system.[12]

Further underscoring the potential for adverse events, a soft-sided hyperbaric chamber rupture, accompanied by an explosion, occurred in India in September 2024. Information concerning this incident, supported by visual evidence from the individual's home security camera, was disseminated through the National Board of Diving and Hyperbaric Medical Technology's monthly Newsletter of November 2024.[18]

Further investigation into the hyperbaric chamber market reveals profound implications for regulatory oversight and patient safety. Data from commercial directories, specifically Volza's U.S. Hyperbaric Chamber Importers database, indicates a substantial number of unregistered market participants: 27 active importers currently sourcing devices from 23 suppliers. A critical finding is the complete absence of U.S. Food and Drug Administration (FDA) registration for these importing entities as medical device manufacturers. Correspondingly, the imported hyperbaric chambers have not undergone the rigorous FDA clearance process required for medical devices marketed in the U.S.[15] This situation highlights a significant gap in market surveillance, allowing for the potential proliferation of unvetted devices that do not meet established safety, efficacy, or manufacturing quality standards, which is a paramount concern for the hyperbaric medical community.

Soft-sided chambers have also suffered zipper malfunctions in multiple other reports. These incidents are not benign quirks; they are failures that can potentially trap users in deflated chambers, risking suffocation. A March 28th, 2017, complaint filed with the FDA's MAUDE Database described repeated zipper failures at "standard operating pressure of 1.3ata". The only fix offered was a zipper repair kit, and the owner was told to fix the issue on their own.[12]

The horror of suffocation becomes all too real when chambers malfunction. In 2011, a 19-year-old man in North Carolina suffocated when the air hose of a soft-sided chamber detached during his session. The parents later claimed that he had been left unattended for several hours. This death, as highlighted in Sparks v. OxyHealth, LLC, No. 5:13-CV-00649 (District Court, E.D.N.C. Sept. 12, 2013), demonstrates a tragic failure in both equipment design and procedural safeguards.[25]

Even when suffocation does not lead to fatalities, air supply malfunctions expose users to grave danger. This inherent risk is compounded by the fact that the FDA, through its regulatory framework and public warnings, effectively prohibits the use of oxygen concentrators with these unapproved soft-sided hyperbaric chambers for medical treatment, a use deemed non-compliant, unsafe, and illegal.[14] For example, in 2018, a user reported that their oxygen concentrator, part of such an unapproved setup, began rumbling loudly before shutting off entirely, leaving the occupant gasping for air. When they contacted the chamber manufacturer, the company allegedly denied responsibility, offering no repair or replacement, further highlighting the unregulated nature and inherent dangers of these products.[12]

These documented incidents reveal a critical public health concern: soft-sided hyperbaric chambers, as well as other low-pressure "mild" chambers, operate outside established regulatory frameworks, creating significant, unacceptable safety risks that extend beyond isolated cases. The systematic circumvention of essential safety standards and codes, including NFPA 99 and ASME PVHO-1, represents a fundamental breakdown in medical device oversight. This regulatory deficit is particularly concerning given these devices' use of pressurized environments and enriched oxygen, conditions that require strict safety protocols and engineering controls to prevent catastrophic failures.[4,19,20] The proliferation of these non-compliant devices in wellness centers, retail establishments, and private residences, often without proper emergency protocols or qualified personnel, represents an urgent public health challenge. This situation is exacerbated by aggressive marketing campaigns targeting vulnerable populations seeking treatment for serious medical conditions, despite the devices' lack of FDA clearance for such applications.[14] The current regulatory framework has proven insufficient to address this expanding problem, as manufacturers exploit regulatory gaps by marketing these devices as wellness products rather than medical devices, thereby evading crucial safety oversight.[15] The disparity between established safety codes, fabrication standards and current practices in the field represents a significant threat to public health and safety that demands immediate intervention. Without comprehensive regulatory reform and enhanced enforcement mechanisms at both federal and state levels, the risk of serious injuries and fatalities will likely increase as these devices continue to proliferate. This situation necessitates a coordinated response from regulatory authorities, medical professionals, and public health officials to establish and enforce appropriate safety standards and codes and prevent the distribution of potentially hazardous devices.

REGULATORY CONCERNS: NFPA 99, NFPA 101 & ASME PVHO-1

The NFPA 101, known as the Life Safety Code, is another critical safety code that hyperbaric facilities must follow.[20] This code, adopted in all 50 states, provides comprehensive requirements for building safety and fire protection in healthcare facilities and other public occupancies. Since its 2000 edition, NFPA 101 has included specific provisions that reference and endorse compliance with the hyperbaric facility requirements outlined in NFPA 99, effectively creating an additional mandatory layer of safety compliance even in jurisdictions that haven't specifically adopted NFPA 99. One key concern with soft-sided chambers is that they fail to meet the safety codes outlined in NFPA 99, which explicitly addresses healthcare facilities and hyperbaric oxygen treatment, as well as NFPA 101's building safety requirements. NFPA 99 outlines the necessary fire and safety protocols for hyperbaric chamber operation, while NFPA 101 ensures the facility itself meets crucial safety codes for public occupancy.[19,20] Together, these codes create a comprehensive safety framework that soft-sided chambers consistently

fail to meet in the following areas:

- Oxygen Fire Risk: Soft-sided chambers present significant fire hazards due to their non-rigid construction and the unauthorized use of oxygen concentrators to create oxygen-enriched environments. These devices frequently incorporate oxygen concentrators to supplement ambient air, potentially elevating oxygen concentrations above 23.5%, a threshold recognized as creating significant fire risk in pressurized environments.[8,19,23] This practice not only violates FDA clearance specifications but also contravenes fundamental safety codes for oxygen-enriched atmospheres.[8,14,23,28] NFPA 99 states that all hyperbaric chambers, regardless of classification, must be electrically grounded - a requirement that soft-sided chambers fundamentally cannot meet.[19] Additionally, when oxygen concentrations exceed 23.5%, as routinely occurs when these chambers are integrated with oxygen concentrators, NFPA requires chamber occupants themselves to be grounded, presenting another critical safety violation.[19] The combination of elevated oxygen concentrations with non-fire-resistant materials and the absence of fire suppression systems creates conditions conducive to rapid oxidation and potential combustion events. Oxygen, when present in high concentrations, is an accelerant and can lead to rapid flash fires and explosions. NFPA 99 explicitly states that chambers used for oxygen treatment are to meet stringent fire safety codes. While fire suppression systems are currently only required for Class A (multiplace) chambers, NFPA 99 establishes comprehensive fire safety codes and emergency procedures that these soft-sided chambers cannot meet. Furthermore, these chambers lack the necessary smoke detection/alarm systems and other critical safety features required for safe operation in oxygen-enriched environments. These requirements are further reinforced by NFPA 101's comprehensive fire safety provisions, which establish additional requirements for facility-wide fire protection systems, emergency egress, and fire-resistant construction - none of which are typically present in facilities operating soft-sided chambers.[19,20]
- Pressure Vessel Integrity: While properly constructed hard-sided chambers that comply with ASME PVHO-1 standards are designed to provide greater structural integrity than soft-sided chambers[4], compliance with safety codes and standards does not guarantee absolute safety. This was dramatically illustrated in May 2023 when a hard-sided chamber in Lehi, Utah experienced a catastrophic viewport failure during operation. The chamber's glass window burst while pressurized to 27 psi, sending hand-sized shards of glass into the air and causing serious injuries to two occupants, with one person rendered unconscious. Despite the manufacturer's claims of "medical grade" construction, the chamber lacked proper NFPA code compliance and showed no evidence of meeting ASME PVHO-1 fabrication standards.[22] Notably, this incident, which should have been reported to the FDA by the manufacturer as required by law, remains unreported in the FDA's database. Soft-sided chambers present even greater risks as they fundamentally lack the basic structural integrity to safely handle hyperbaric pressures. The absence of compliance with fabrication standards outlined in ASME PVHO-1 creates an inherently dangerous situation where chamber failure is not just possible, but probable. This risk is further compounded when facilities fail to meet NFPA99 & NFPA 101's codes for proper building construction and safety systems, a hazardous scenario exacerbated by chambers that contravene ASME-PVHO-1 fabrication standards, thereby profoundly elevating the risk of catastrophic failure. The combination of substandard construction and lack of safety protocols creates an environment where catastrophic failures become increasingly likely.[4,19,20]
- Lack of Regulatory Oversight: Soft-sided chambers, as well as some hard-sided chambers, are typically marketed for wellness rather than medical purposes and are not FDA-cleared for medical use beyond acute mountain sickness.[8,14,23,28] This lack of regulatory oversight compounds safety concerns, as these devices frequently operate in settings devoid of medical supervision, proper staff training, and established emergency procedures. Furthermore, these facilities consistently fail

to meet both the operational safety codes of NFPA 99, and the building safety codes set forth by NFPA 101. Adding to these concerns, the growing presence of soft-sided chambers in the marketplace has raised significant alarm within the hyperbaric community.

The UHMS Consumer Warning[8] emphasizes that soft-sided hyperbaric chambers, like their hard-sided "mild" counterparts, must adhere to strict safety regulations. According to the integrated codes and standards of NFPA 99, NFPA 101, and ASME PVHO-1, these chambers must meet specific design, operational, and facility safety criteria to ensure safe operation. The warning highlights the use of non-compliant chambers that are not registered with the FDA, do not meet the comprehensive safety codes of NFPA 99 and 101, do not meet the fabrication standards of ASME-PVHO-1, and are constructed outside of the U.S. to avoid scrutiny.[8] It also underscores the tragic incidents related to these non-cleared devices. These cases reinforce the risks associated with unregulated hyperbaric oxygen treatment and demonstrate the critical importance of adherence to all applicable fabrication standards and safety codes to protect users.

The increasing prevalence of cease-and-desist orders issued to wellness clinics utilizing soft-sided hyperbaric chambers underscores the severity of the safety and compliance concerns associated with these devices. Across states like North Carolina, Idaho, and Georgia, regulatory agencies and fire marshals have acted, citing violations of critical codes like NFPA 99 and ASME PVHO-1.[17,24,29,30] These orders are not arbitrary but rooted in documented risks, including fire hazards, deflation-related suffocation, and improper emergency planning. For example, in Idaho, the State Fire Marshal has implemented enforcement actions through cease-and-desist orders, citing violations of Section 609.1 of the International Fire Code (IFC).[17,24] While the IFC does not establish hyperbaric-specific guidelines, it explicitly endorses compliance with the hyperbaric provisions outlined in NFPA 99, a requirement similarly reflected in the Uniform Building Code. These regulatory notices specifically address the fundamental inability of soft-sided chambers to meet safety codes, particularly regarding fire suppression systems and alarm protocols. Furthermore, under Idaho Code, Title 41, Chapter 2, Section 41-254(3)[24], hyperbaric facilities must demonstrate compliance with both ASME PVHO-1 standards and NFPA 99 requirements, including comprehensive fire safety protocols. These enforcement actions illuminate a systemic failure among wellness center and spa operators to prioritize essential safety measures over commercial interests, thereby creating potentially life-threatening conditions for patients.

The documented history of tragedies involving these devices, including fatal fires and suffocation incidents, underscores the incredibly urgent need for stronger oversight and universal compliance with established safety codes and fabrication standards. While the requirements do not extend to private residences, the Idaho State Fire Marshal recommends that even home-use devices meet ASME PVHO-1 standards, emphasizing the fundamental importance of these safety protocols in all settings. The fact that such devices have already contributed to tragedies, including barotrauma, fatal fires, and suffocation incidents, underscores the urgent need for stronger oversight and compliance measures.

Canada has taken regulation a step further. In October 2019, Health Canada issued a warning regarding soft-sided chambers, stating that these unauthorized medical devices are dangerous. They highlighted that the chambers are being advertised to treat various medical conditions such as autism, cerebral palsy, and migraines, and that their use for these purposes could pose serious health risks, including death.[26] Then again in November of 2020, Health Canada issued another warning, this time not only warning Canadians about the risks of using unlicensed soft-sided hyperbaric chambers as they did in 2019, but that the Department had continued to take action to remove these products from the market and to respond to complaints.[27]

In early 2020, Health Canada seized six unlicensed soft-sided hyperbaric chamber units from distributors in the Province of Quebec, and in September 2020, the department seized three more unlicensed soft-sided hyperbaric chamber units from a distributor in Alberta.[27]

A particularly concerning aspect of this regulatory inconsistency is exemplified by a specific manufacturer whose chambers, while banned from sale and use within Canadian borders under Health Canada's strict regulatory framework, continue to manufacture these devices within Canada for export to other markets. This paradoxical situation, where a product is deemed too dangerous for use in its country of manufacture yet is still produced for distribution elsewhere, highlights the urgent need for international regulatory harmonization and more stringent oversight of medical device manufacturing and exportation. This regulatory disconnect not only undermines public health but also raises serious ethical concerns about the manufacturing and distribution of medical devices known to pose safety risks in their country of origin.[1,27]

Further, in the United States, as of June 2022, Arkansas, California, Delaware, Georgia, Hawaii, Minnesota, North Carolina, Oregon, Tennessee, Washington, and Wisconsin have adopted statutes that mandate any clinical HBO_2 chamber operated within their state to comply with ASME PVHO-1.[30] The uneven adoption of these standards and codes highlights a serious regulatory gap that puts patients at risk.

The ethical implications surrounding the marketing and use of soft-sided hyperbaric chambers are profound. Despite the devices' lack of FDA clearance for most conditions advertised, ranging from chronic pain to neurological disorders, [6,10,13] they are frequently promoted with unsupported health claims. This misinformation not only exploits vulnerable individuals seeking alternative treatments but also undermines public trust in legitimate medical therapies.

Operators often blur the line between wellness and medical treatment, failing to disclose the significant differences between soft-sided chambers and medically approved HBO_2 systems. Ethical practice demands transparency and adherence to evidence-based medicine, yet many prioritize financial gain over patient welfare. Such practices mislead consumers and contribute to a broader erosion of accountability within the alternative health sector. Regulators, medical professionals, and advocacy groups are responsible for combating these deceptive tactics and protecting patients from avoidable harm.

The American Medical Association's (AMA) recent adoption of Resolution D-270.986, "Oppose Unsafe Use of 'Mild Hyperbaric Therapy'" represents a crucial step in the right direction towards addressing this issue. Through this resolution, the AMA has committed to several key actions:

- Educating the Public: They will support efforts to inform consumers that many medical therapies promoted directly to them have not undergone rigorous evaluation for safety and efficacy by the FDA.
- Collaborating with Regulators: Crucially, the AMA resolved to collaborate with federal and state regulators, including the FDA, Federal Trade Commission (FTC), state medical boards, and state attorneys general.
- Investigating and Taking Action: This collaboration is also aimed at working together to close facilities offering "mild hyperbaric treatment" until these facilities adopt and adhere to all established safety regulations, follow the established principles of the practice of hyperbaric oxygen under the prescription and oversight of a licensed and trained physician, and ensure that staff are appropriately trained and compliant with applicable safety regulations.[21]

This comprehensive approach by the AMA, which brings a powerful medical voice to the regulatory table and aims to both educate the public and target deceptive practices, is highly encouraging. However, while commendable, this initiative alone will likely not suffice. More robust, proactive, and adequately resourced oversight is necessary to truly curb the proliferation of these dangerous products and practices. Regulatory bodies often face challenges with funding, manpower, and the speed at which new, unproven therapies emerge and are marketed. A sustained, multi-faceted effort involving legislative action, increased regulatory enforcement, and continuous public awareness campaigns will be essential to protect vulnerable patients from serious health risks, including death, associated with these unvalidated treatments.

THE PATH FORWARD: REGULATORY AND ETHICAL ACCOUNTABILITY

As soft-sided hyperbaric oxygen treatment (HBO_2 Treatment) chambers continue to proliferate across wellness clinics, spas, and homes in the United States, critical steps must be taken to safeguard public health and ensure that consumers receive safe, effective treatments. Addressing the regulatory gaps and misinformation surrounding these devices requires a collaborative approach. The following actions are essential:

1. Stronger Regulatory Oversight: Regulatory bodies such as the FDA, OSHA, local fire marshals, and local health departments must prioritize the enforcement of existing safety standards and codes and consider updating regulations to reflect the evolving landscape of wellness centers, spas, and the growing use in private homes. Studies show the importance of rigorous oversight in the healthcare industry; soft-sided chambers, as well as hard-sided "mild" chambers, must adhere to the same standards and codes as other medical devices that carry risk.
2. Increased Consumer Education: Public awareness campaigns must be launched to educate consumers on the potential risks of using soft-sided and hard-sided (mild) hyperbaric chambers outside of their cleared scope. Many individuals are unaware that these devices lack FDA clearance, fail to comply with critical NFPA codes (such as NFPA 99 and NFPA 101), and do not adhere to the ASME-PVHO-1 standard. Furthermore, their use is associated with unproven claims and operates entirely outside the robust safety frameworks these specific clearances, codes, and standards are designed to provide. Educating the public will help curb the spread of misinformation and ensure that patients make informed decisions based on facts, not marketing tactics. With clear guidance, consumers will better understand the incredibly dangerous risks associated with these unregulated devices.
3. Transparency in Wellness Clinics: The continued operation of wellness clinics and spas offering soft-sided and hard-sided "mild" hyperbaric oxygen treatments is unacceptable given their equipment's lack of FDA clearance, non-compliance with established fabrication standards and safety codes, and the inherent risks. Many of these establishments, regardless of intent, mislead patients about the safety and efficacy of these treatments. Strict regulatory action, not just transparent labeling and informed consent is essential to protect consumers and prevent unethical practices within the wellness industry.
4. Enhanced Research and Clinical Trials in Safe Environments That are Strictly Regulated: While some claim there are benefits of soft-sided and hard-sided mild hyperbaric chambers, such as improved recovery from injuries or alleviation of chronic conditions like fibromyalgia, scientific research on the long-term efficacy and safety of these devices is sparse. More funding and rigorous clinical trials should be directed at assessing these devices' effects in controlled settings. Using these devices for unapproved conditions can be unethical and harmful without substantial evidence. Comprehensive, peer-reviewed research will provide the clarity consumers and regulators need to make evidence-based decisions.

DISCUSSION

In conclusion, the proliferation of soft-sided and hard-sided "mild" hyperbaric chambers in wellness centers, spas, and private homes represents an urgent public health crisis that demands immediate and decisive regulatory intervention. These devices, operating outside established standards and codes, pose an unacceptable risk to public safety and must be addressed through aggressive enforcement action. The evidence clearly demonstrates that these chambers cannot meet the rigorous safety codes and standards established by NFPA 99, NFPA 101, and ASME PVHO-1, making their continued operation fundamentally dangerous and ethically indefensible. Regulatory authorities must take immediate action to shut down facilities operating these non-compliant devices. This should include implementing severe penalties for violations, including

substantial fines, immediate cessation orders, and equipment confiscation. While some jurisdictions may lack specific statutory requirements for compliance with all safety codes, the documented risks and fatalities associated with these devices justify aggressive intervention under general public safety provisions. The path forward requires zero tolerance for non-compliant operations. Any facility offering hyperbaric oxygen treatment must be required to demonstrate full compliance with all applicable safety standards and codes, maintain proper FDA clearance, and must operate under physician and trained medical staff oversight. Regular inspections must be mandatory, with significant consequences for violations. These requirements, while stringent, reflect the minimum necessary safeguards for a therapy involving pressurized oxygen environments. The current situation, where unregulated devices proliferate under the guise of "wellness" services, represents a fundamental failure of public health protection that must be corrected. These devices and facilities cannot be made compliant through minor modifications or operational adjustments, as their basic design and construction render them inherently unsafe for human occupancy. The only acceptable solution is their complete removal from the market. Healthcare providers, regulatory authorities, and public health officials must unite in opposition to these dangerous devices. This includes active reporting of non-compliant facilities, public education about the risks, and support for enforcement actions against operators. The cost of inaction can be measured in preventable injuries and deaths and is simply too high to allow these dangerous practices to continue.

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