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Low-Pressure Portable Hyperbaric Chambers: The Pandora's Box of Hyperbaric Oxygen Therapy

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On August 8, 2000, the US Food and Drug Administration (FDA) cleared the first of eight low-pressure, portable fabric hyperbaric oxygen therapy (HBOT) chambers, based upon the Gamow Bag, which was developed for the treatment of acute mountain sickness. Since then, these types of hyperbaric chambers have become endemic.

When I learned of the FDA's decision, I called the FDA's Deputy Director of Compliance for devices at the time and stated that the FDA has just opened Pandora's Box.

At the time, I did not appreciate how prophetic that statement was. Why should anyone worry about the fact that there are a lot of inflatable "altitude sickness" hyperbaric chambers in the USA? Inflatable hyperbaric chambers are cleared by the FDA only for the treatment of acute mountain sickness and they are not FDA cleared for use with 100% oxygen. They are designed to be used with compressed air in order to treat one specific condition. The maximum pressure that they can achieve is the equivalent of about 12 feet of sea water or 3–5 pounds per square inch (PSI), or a maximum of 1.4 atmospheres absolute (ATA). By comparison, "hard sided" hyperbaric chambers provide treatments at 2 ATA (33 fsw) or greater. While there is a lot to be said about this issue, I am going to focus on the issues relevant to safety and compliance with legal requirements.

There are two engineering and operational safety codes that relate specifically to the design, fabrication, testing, installation and operation of clinical hyperbaric chambers: the American Society of Mechanical Engineers' Pressure Vessels for Human Occupancy Code (ASME PVHO-1) and the National Fire Protection Association's NFPA 99, Fire Safety Code for Health Care Facilities.[1,2] More specifically, the hyperbaric requirements of NFPA 99 require that all clinical hyperbaric chambers comply with the requirement of the ASME PVHO-1 Code. The FDA formally recognizes these two codes when evaluating a new hyperbaric chamber system for clearance via the Premarket Notification Process or FDA 510k submission, yet the FDA has cleared several companies that produce these low-pressure, portable fabric hyperbaric chambers even though they do not meet the code requirements that they formally recognize.

Why Compliance Matters

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None of the low-pressure, portable fabric hyperbaric chambers is compliant with ASME PVHO-1 or NFPA 99. Why does that matter?

Eleven states have statutes that mandate compliance to ASME PVHO-1 for any clinical hyperbaric chamber in operation in their respective state. They are Arkansas, California, Delaware, Georgia, Hawaii, Minnesota, North Carolina, Oregon, Tennessee, Washington, and Wisconsin.[3] Accordingly, in those states, it is against the law to provide clinical hyperbaric oxygen therapy using a device that does not meet this safety code. So, if there are these states in which hyperbaric chamber must comply with ASME-PVHO-1, why are dozens, if not hundreds, of these chambers being used for clinical hyperbaric oxygen therapy treatment in each of these states?

The explanation is very simple: the authority having jurisdiction (AHJ: state/local fire marshal, state pressure vessel inspector, etc.) does not know these chambers are operating in their jurisdiction. If a hospital or doctor's office wishes to install a traditional hyperbaric chamber (such as from Sechrist, Perry, PAHI, Fink, etc.) they must have a piping permit. This permit is reviewed and approved by the local fire marshal's office so he/she knows that a clinical hyperbaric chamber is coming into their jurisdiction.

All of these low-pressure, portable fabric chambers are shipped to a facility in 3–5 boxes by FedEx, UPS, etc., totally bypassing the fire marshal. They can be assembled and operational in less than 30 minutes. The local AHJ cannot provide oversight of chambers that he/she does not know exist. However, as only one example, once the state fire marshal of Georgia learned of their state's statute, he started coordinating a statewide initiative to stop the use of these chambers for clinical hyperbaric services across the state of Georgia.[4]

Unfortunately, not all states and/or jurisdictions have adopted NFPA 99 as a mandatory code. In the absence of mandating NFPA 99, many jurisdictions have adopted either the International Fire Code or the International Building Code. Each of these alternative codes make direct reference to complying with NFPA 99 and its specific requirements for hyperbaric facilities. The same endorsement is found in NFPA 101, Life Safety Code which is adopted in all 50 states. Therefore, in my opinion, both ASME PVHO-1 and the hyperbaric chapter of NFPA 99 have become a national requirement. In other words, all states must comply with the relevant part of NFPA 99 when it comes to the equipment used to provide clinical hyperbaric treatments.

Since September 2021, it has been discovered that there are hundreds, if not thousands, of non-compliant and low-pressure, portable fabric hyperbaric chambers that are being illegally exported to the US from Argentina, Austria, Canada, China, Germany, Peru, and South Korea. It is likely that other countries are producing them

that we do not even know about. These chambers have not been cleared for use in the U.S. by the FDA and none meet the aforementioned safety codes. There are at least 10 US companies that are known to be contributing to this illegal activity by distributing them. These companies are also in violation of US customs regulations related to the importation of medical devices into the US. With limited exceptions, these chambers are not being logged on shipping manifest as hyperbaric chambers but as an "inflatable bag with oil-less compressor," etc.[5] To be clear, it is not just the use of these chambers for clinical hyperbaric treatment which is illegal (under medical safety laws), but the importation/distribution of them is also illegal under different laws.

In light of the above, who are the customers for these illegal portable chambers? The manufacturers and U.S. distributors are targeting chiropractors, naturopathic doctors, functional medicine physicians, wellness centers, spas and lay people. Many of these individuals or practices are promoting the use of these low-pressure, fabric chambers for the treatment of mainstream hyperbaric indications (eg, diabetic foot ulcers, late effects of radiation), as well as for "off-label" uses such as persistent COVID-19 symptoms, cancer, etc. Neither the facilities nor the manufacturers mention the fact that these low-pressure chambers cannot achieve a therapeutic dose of oxygen for any of the recognized hyperbaric indications. This misleading omission may lead patients to believe that they are receiving a medical treatment when in fact, they are not. Keep in mind that patients are also likely paying cash for these treatments.

What the FDA Requires

It is important to note that the FDA specifically prohibits the use of oxygen cylinders or oxygen concentrators with these low-pressure, portable fabric hyperbaric chambers. Despite this, virtually every one of these chambers are being sold with oxygen concentrators. Unfortunately, even though the pressures achieved by these inflatable devices is insufficient to provide medical benefit, it is sufficient to make them very dangerous in terms of fire risk.

To the FDA's credit, they are aware of the way these chambers are being promoted and used. The FDA has actually issued two consumer warnings urging the public to not be misled about unproven claims of efficacy and the potential dangers of these inflatable devices.[6] In its most recent warning, the FDA even recommended that patients seeking hyperbaric treatment do so in a legitimate hyperbaric facility that has been accredited by the Undersea & Hyperbaric Medical Society (UHMS). I endorse that recommendation by the FDA. (By full disclosure, before my retirement from the UHMS, I managed the Society's clinical facility accreditation program.)

With regard to chiropractors, there are 19 states that have medical practice acts that prohibit chiropractors from administering oxygen, using hyperbaric chambers or both. My preliminary search revealed that in every one of the 19 states in which it is prohibited, there are chiropractors actively offering "hyperbaric oxygen" treatments with inflatable devices. If a cursory internet search is sufficient to demonstrate widespread disregard of these laws, it is likely that the problem is much bigger than we know.

There is a large "wellness company" that has over 130 locations in close to 30 states. The company offers hyperbaric oxygen therapy as a treatment for various maladies. *None* of the chambers in operation at these locations is code compliant with either ASME PVHO-1 or NFPA 99. That is just one national company—there are others. Additionally, there are at least 300 independents centers[7] that are offering treatment in these illegal chambers across the nation—and those are just the ones that have been discovered!

Conclusion

There are many, many practitioners advertising that they offer "hyperbaric oxygen therapy" but using equipment that is not cleared for use by the FDA at all, or if cleared for use by the FDA, is only cleared for the treatment of altitude sickness. None can be legally pressurized with oxygen. Depending on the state and the practice act of the clinician, the practitioner may be at risk of the loss of their professional license and in violation of several laws. None of these chambers meets current safety codes.

What can you do to help put the lid back on Pandora's Box? First, know your community. Learn those centers that might be promoting the use of inflatable chambers which may not comply with recognized codes and standards. Then, do not be afraid to open a dialogue with your local fire marshal.

Next, if you have not already done so, establish a relationship with the local first responders, who would be the first to arrive at any facility offering hyperbaric oxygen therapy, including your own facility. Many of these professionals have never seen a hyperbaric chamber before and are not aware of the medical or fire problems they may be called upon to manage in relation to them. The NFPA requires an annual "worse-case scenario" fire drill to be conducted. To optimize that drill for everyone, involve the local first responders. You will improve the safety of your own facility, and you can also educate your local fire marshal and fire fighting community as to the possible existence of unsafe operations.

Finally, for those of you who reside in one of the 11 states with mandatory ASME-PVHO-1 laws on the books, engage your state fire marshal and pressure vessel

inspector (usually under the Labor Department) and let them know if there is a known or suspected center operating these illegal chambers. The sad reality is that if there is a catastrophic event at one of these illegal operations, the impact will not be limited to the unfortunate people involved. Legitimate hyperbaric operations will be impacted by the negative press and subsequent patient fear.

Remember that the laws are on your side. For those of you who would like to discuss that matter further, please do not hesitate to contact me at wtworkman@aol.com

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