**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](http://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](http://(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](http://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 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](http://(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 FDAs “substantial equivalency” standard. Restore markets provision of hyperbaric *oxygen* (my emphasis) therapy.([www.restore.com](http://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 Fi02 of just 36%. [(www.oxygenconcentratorstore.com](http://(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](http://www.macypan.com/catalogue-of-hyperbaric-oxygen-chamber.pdf) retrieved July 27, 2022; [www.hyperbaricpro.com](http://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.