DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

August 23, 2013

Cecilia A. Mouton, MD
Executive Director
Louisiana State Board of Medical Examiners
P.O. Box 30250
New Orleans, LA 70190-0250

Re: *Hyperbaric Oxygen Therapy Treatment Centers*

Dear Dr. Mouton:

FDA's Center for Devices and Radiological Health (CDRH) has become aware of the use of hyperbaric oxygen chambers to treat a range of serious medical conditions for which the device has not been FDA-cleared or approved. Some of the claims being made by treatment centers offering hyperbaric oxygen therapy (HBOT) pose serious potential safety concerns. According to complaints we have received and websites that promote these uses, HBOT is being promoted to treat a variety of conditions that have not been cleared or approved, including:

- Asthma
- Autism
- AIDS/HIV
- Cancer
- Diabetes
- Heart Disease
- Migraine
- Parkinson's Disease
- Stroke

The FDA has cleared hyperbaric oxygen chambers for the following uses:

- Air or Gas Embolism
- Carbon Monoxide Poisoning
    - Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
- Gas Gangrene (Clostridial Myonecrosis and Myonecrosis)
- Crush Injury, Compartmental Syndrome and Other Acute Traumatic Ischemias
- Decompression Sickness
- Arterial Insufficiencies
    - Central Retinal Artery Occlusion
    - Enhancement of Healing in Selected Problem Wounds
- Severe Anemia
- Intracranial Abscess
- Necrotizing Soft Tissue Infections
- Osteomyelitis (Refractory)

- Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
- Compromised Grafts and Flaps
- Acute Thermal Burn Injury

The FDA does not regulate the practice of medicine, but is concerned that patients treated with HBOT for non-cleared conditions, especially in place of treatment options with established safety and effectiveness, may experience a lack of improvement or worsening of their existing condition(s). Patients may not be aware that the safety and effectiveness of HBOT has not been established for use in these condition(s).

The hyperbaric chamber operator is typically trained to operate the chamber and recognize signs and symptoms of injuries caused by pressure changes and how to respond, but is not typically trained in the treatment of the disease or condition.

Please share this information with the health care providers that you license and look closely at any complaints you may receive related to the treatment of patients with HBOT. The FDA recently posted a Consumer Update, Hyperbaric Oxygen Therapy: Don't Be Misled (http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm364687.htm), which urges patients to discuss HBOT directly with their health care providers to determine whether it is an appropriate treatment option. The FDA encourages you to inform your constituents about the potential risks of using HBOT for the conditions listed above for which these devices have not been cleared or approved.

Hyperbaric oxygen chambers are prescription devices, and we have received numerous complaints related to the sale of these devices to patients without a prescription. We have also received numerous complaints regarding their use in facilities not operated by a licensed physician. We would encourage your organization to work with these establishments to ensure they are in compliance with state and local regulations.

Additionally, any information that you can provide that may help us better understand this issue would be greatly appreciated. If you have any information about these or other issues that have come to your attention, please contact FDA's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV, or 800-638-2041, or 301-796-7100. You can also submit an adverse event report to FDA's MedWatch, FDA's information and adverse events reporting program.

Sincerely,

Kimber C. Richter, M.D.

Kimber Richter
Supervisory Medical Officer
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration