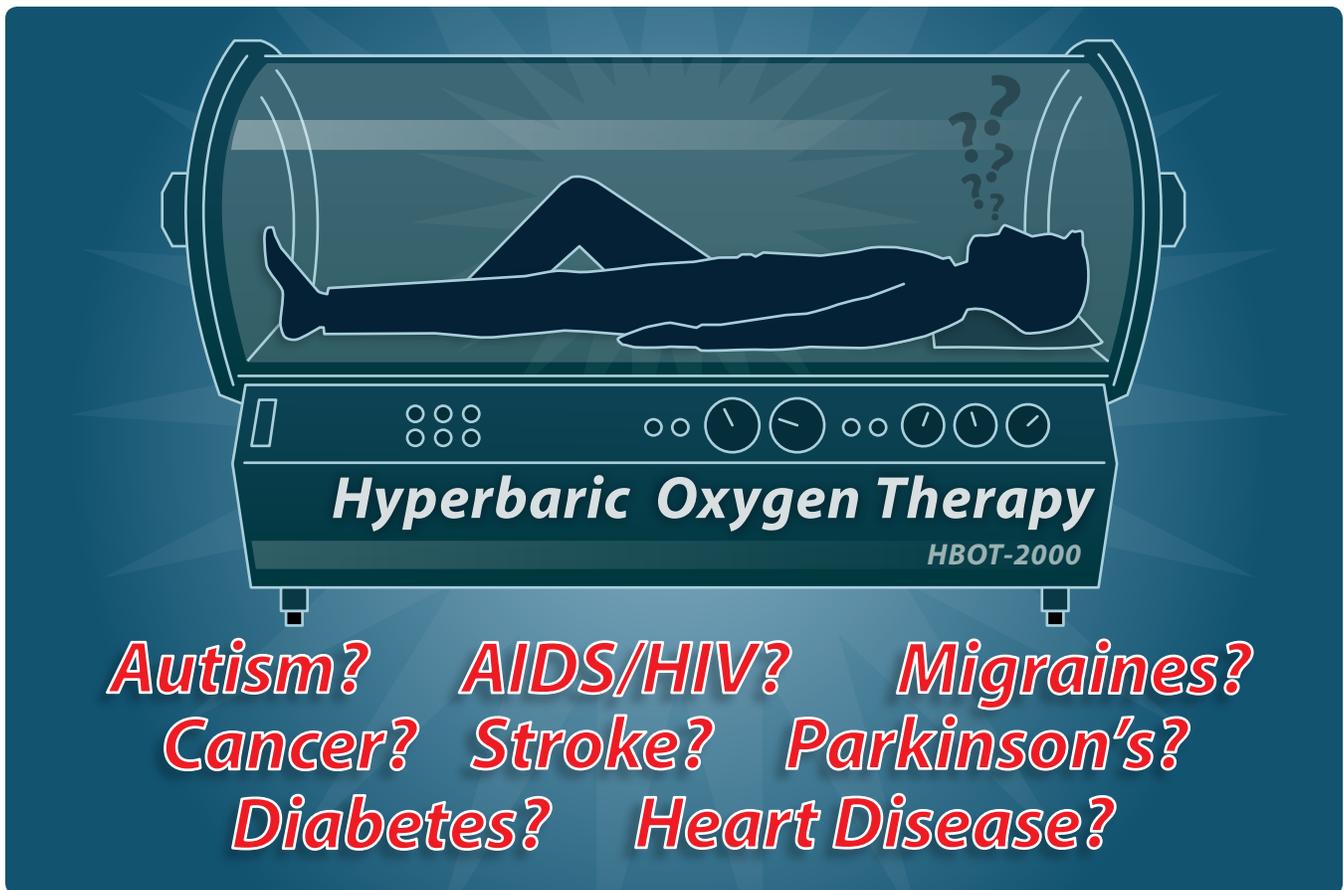


Hyperbaric Oxygen Therapy: Don't Be Misled



No, hyperbaric oxygen therapy (HBOT) has not been clinically proven to cure or be effective in the treatment of cancer, autism, or diabetes. But do a quick search on the Internet, and you'll see all kinds of claims for these and other diseases for which the device has not been cleared or approved by FDA.

HBOT involves breathing oxygen in a pressurized chamber. The Food and Drug Administration (FDA) has cleared hyperbaric chambers for certain medical uses, such as treating decompression sickness suffered by divers.

HBOT has not, however, been proven to be the kind of universal treatment it has been touted to be on some Internet sites. FDA is concerned that some claims made by treatment centers using HBOT may give consumers a wrong impression

that could ultimately endanger their health.

"Patients may incorrectly believe that these devices have been proven safe and effective for uses not cleared by FDA, which may cause them to delay or forgo proven medical therapies," says Nayan Patel, a biomedical engineer in FDA's Anesthesiology Devices Branch. "In doing so, they may experience a lack of improvement and/or worsening of their existing condition(s)."

Patients may be unaware that the

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safety and effectiveness of HBOT has not been established for these diseases and conditions, including:

- AIDS/HIV
- Alzheimer’s Disease
- Asthma
- Bell’s Palsy
- Brain Injury
- Cerebral Palsy
- Depression
- Heart Disease
- Hepatitis
- Migraine
- Multiple Sclerosis
- Parkinson’s Disease
- Spinal Cord Injury
- Sport’s Injury
- Stroke

Patel says that FDA has received 27 complaints from consumers and health care professionals over the past three years about treatment centers promoting the hyperbaric chamber for uses not cleared by the agency.

How HBOT Works

HBOT involves breathing oxygen in a pressurized chamber in which the atmospheric pressure is raised up to three times higher than normal. Under these conditions, your lungs can gather up to three times more oxygen than would be possible breathing oxygen at normal air pressure.

Patel explains that your body’s tissues need an adequate supply of oxygen to function. When tissue is injured, it may require more oxygen to heal. “Hyperbaric oxygen therapy increases the amount of oxygen dissolved in your blood,” says Patel. An increase in blood oxygen may improve oxygen delivery for vital tissue function to help fight infection or minimize injury.

Hyperbaric chambers are medical devices that require FDA clearance. FDA clearance of a device for a specific use means FDA has reviewed valid scientific evidence supporting that use and determined that the device is at least as safe and effective as another legally U.S.-marketed device.

Thirteen uses of a hyperbaric chamber for HBOT have been cleared by FDA. They include treatment of air or gas embolism (dangerous “bubbles” in the bloodstream that obstruct circulation), carbon monoxide poisoning, decompression sickness (often known by divers as “the bends”), and thermal burns (caused by heat or fire).

What are the Risks?

Patients receiving HBOT are at risk of suffering an injury that can be mild (such as sinus pain, ear pressure, painful joints) or serious (such as paralysis, air embolism). Since hyper-

baric chambers are oxygen rich environments, there is also a risk of fire.

“If you’re considering using HBOT, it’s essential that you first discuss all possible options with your health care professional,” Patel says. “Whatever treatment you’re getting, you need to understand its benefits and risks. Your health care professional can help you determine which treatment is your best option.”

In addition, any problems experienced with these devices can be reported to MedWatch (www.fda.gov/Safety/MedWatch/default.htm), the FDA safety information and adverse events reporting program. 

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