

**EXTRACT**  
August 17, 2011  
ABME

Ozone Therapy The Credentials Committee recommended that the physician be notified that the Board does not regulate specific practice procedures; therefore, the Board chooses not to make a recommendation regarding the use of ozone therapy in the physician's private practice. However, the Committee recommended that the physician be cautioned that the non-FDA approved procedure is experimental and investigational, and that the Board would be concerned should any patient complaints be received related to the use of ozone therapy. The motion was adopted without objection.



ALABAMA STATE BOARD OF MEDICAL EXAMINERS

LARRY D. DIXON, EXECUTIVE DIRECTOR

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August 24, 2011

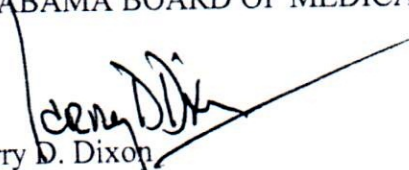
Dear Dr. :

At its meeting August 17, 2011, the Alabama Board of Medical Examiners considered your correspondence of July 19, 2011, in which you requested permission from the Board to use Ozone in your medical practice.

The Board instructed me to notify you that the Alabama Board of Medical Examiners does not regulate the specific practice procedures conducted in a physician's office; therefore, the Board chooses not to make a recommendation concerning the use of Ozone therapy in your medical practice. However, the Board also instructed me to make you aware that, due to the experimental and investigational nature of the non-FDA approved therapy, the Board would be extremely concerned should any patient complaints be received related to the use of Ozone therapy.

Thank you for contacting the Board regarding this matter and for your thoroughness in providing information related to your request.

Yours sincerely,  
ALABAMA BOARD OF MEDICAL EXAMINERS

  
Larry D. Dixon  
Executive Director

LDD/atd

07/19/2011

Alabama State Board of Medical Examiners  
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Dear Dr. Gifford:

I am an Anesthesiologist, who recently opened a pain management clinic in \_\_\_\_\_, Alabama.  
*Phenix City Pain Management* [1810 Stadium Drive, Phenix City, Al 36867; 334-664-1969].

I am writing this letter to the Alabama State Board of Medical Examiners, to bring to your attention a successful technique for the treatment of chronic pain – Ozone therapy.

I recently had a long discussion with Mr. Herb Bobo at the Alabama Board of Pharmacy. It is my understanding that Mr. Bobo frequently serves as a liaison to the Alabama State Board of Medical Examiners. I wanted to find out from Mr. Bobo since some states decided to allow the use of Ozone, how should I proceed to seek its approval in Alabama. Mr. Bobo contacted Ed Munson, who recommended I send a letter to the Board requesting permission to use Ozone in my practice.

My education and medical training and are as follows:

1. College – Illinois Institute of Technology, Chicago, Illinois. 1980
2. Medical School - Loyola University, Chicago, Illinois. 1984
3. Residency - Illinois Masonic Medical Center, Chicago, Illinois. 1987
4. Fellowship Year-University of Illinois, Chicago, Illinois. 1988 The Chairman was Dr. Alon Winnie. I studied Interventional Pain Management for 6 months, and 6 months of Cardiac Anesthesia training.

As part of my Continuing Medical Education, earlier this year, I went to the Daradia Pain Clinic in Calcutta, India, where I observed Ozone in use. I met Dr. Guatam Das, the Director of the Daradia Pain Clinic. He is an Examiner of the Fellow of Interventional Pain Practice Society.

While at the Daradia Pain Clinic, I interviewed numerous clinicians and observed the routine use of Ozone to treat chronic pain. I had the opportunity to interview the patients before and after their

treatments. I did not observe any complications and the patients were satisfied with their previous and current treatments. Of course my experience is "observational" at this time but the efficacy and safety is clearly documented in the literature.

I have signed up for "Ozonotherapy Certification Course, and Beginning Prolozone," which will be held 9/22-25/11. Also "Advanced Prolozone" on 4/23-24/12. These are given in Reno, NV. by Frank Shallenberger MD.

Ozone has historically had many uses. Ozone was first used in Germany around the 1880's. Most of the original published work was lost due to the bombing of Germany in World War I and in World War II. Ozone was used to accelerate wound healing and for the treatment of pain. In the 1950's a new method of generating Ozone was developed that gave precise control to the concentration delivered. Its use in medicine has dramatically taken off since this advance. Since Ozone is a gas that should not be inhaled, the Ozone generators on the market have a safety mechanism to destroy and render harmless any Ozone generated but not used.

Ozone is currently used in many other countries: Barbados, Bulgaria, Cuba, The Czech Republic, France, Germany, Greece, Israel, Italy, Japan, Malaysia, Mexico, Poland, Romania, Russia, Slovakia, Switzerland, Turkey, United Arab Emirates and Ukraine. Specifically, The Cuban Government recently built an Ozone Research Facility just outside of Havana complete with a hospital.

Although it is not FDA approved, Ozone is approved for use by Medical Doctors as an alternative medication in 13 states: Alaska, Arizona, Colorado, Georgia, Minnesota, New York, New Jersey, North Carolina, Ohio, Oklahoma, Oregon, South Carolina, and Washington. I hope to get Alabama added to the list. Ozone is also recognized and approved by Homeopathic and Naturopathic Boards in these additional states, California, Connecticut, Florida, Hawaii, Idaho, Indiana, Illinois, Kansas, Louisiana, Montana, Nevada, New Mexico, Pennsylvania, Texas, Utah, Virginia, and Wisconsin.

The medical use of Ozone has an excellent safety record. In fact, it is unprecedented in modern medicine. There are no allergic reactions to Ozone. Ozone is inexpensive. It is produced from medical oxygen at the time of use. In a gaseous phase, Ozone has a half-life of 20 minutes. In general, the free radical oxygen molecule, oxidizes the products of inflammation, and then oxygenates the area. Ozone activates the body's own anti-oxidants and free radical scavengers. It reduces the formation of inflammatory mediators such as prostaglandins, and thus exerts its effect as an anti-inflammatory agent. One of the main effects of the injection of Ozone is to raise the pH and increase arterial blood flow thus allowing physiologic normalization of the area and promotion of healing.

Due to its anti-bacterial, anti-fungal and anti-viral properties it has a very impressive safety record. In fact, Ozone is used world-wide to purify drinking water. It was also used to sterilize dental and surgical instruments. Another safety feature is that Ozone is only made of Oxygen, it is O<sub>3</sub>, and therefore, there are no allergic reactions to it.

Contraindications for the use of Ozone are very few. They include active bleeding from any site, active/uncontrolled hyperthyroidism, and G-6-PD deficiency. Pregnancy is listed in all articles, but according to the literature, Ozone does not cause any untoward effects if used during pregnancy.

I am interested in using Ozone for pain management. I propose to inject it as a gas intra-muscular into the para-spinal muscles, and occasionally inject into the disc itself, for the treatment of disc disease. The literature reports success rates of around 75%, and it can be repeated easily, as need be. The literature and the clinic in India report pain relief lasting 9-15 months. Another benefit to Ozone therapy is that if it does not work, no bridges have been burned; the patient can go on to other therapies, such as surgery. The Ozone will have had no negative effects.

Neurosurgeons and Orthopedic Surgeons who treat disc disease with discectomies, disc replacements and fusions, report variable results. The cost is high, it is very invasive and complications are not uncommon. The need for a second surgery at another time is also very common. Disabled patients with Failed Back Syndrome are very common in Pain Clinics.

I also propose to inject Ozone intra-articularly as a gas into the large joints: knee, shoulder, and hip. When I use it intra-articularly I will also use Pulsed Radio Frequency, set to a maximum temperature of 42\* C. Tissue destruction starts at 45\*C. The Orthopedic Literature as of late has changed in regards to the efficacy of knee arthroscopies for strictly inflammatory causes. ((Reference; American Academy of Orthopedic Surgeons, Clinical Guidelines 2008, Treatment of Osteo-arthritis of the knee, (non-arthroplasty.) Recommendation #18.)).

Ozone has a few other uses in Interventional Pain Management such as intra-muscular for trigger point injections, but the vast majority of its use would be as I already mentioned. Here in greater detail is how Ozone would be used in a knee, and intra-muscular into the para-spinal muscles for disc disease. The procedures are very simple and straight forward.

#### Group 1

1. Patients who have inflamed or arthritic knees and are not, at this time, candidates for total knee replacement. Patients that are too young, too frail, or are just afraid of a Total Knee Replacement.
  - a. A radio frequency (RF) probe will be placed intra-articularly and pulsed RF will be delivered with a maximum temperature of 42°C. The probe goes thru a cannula.
  - b. After 15 minutes of pulsed RF, 8 to 10 mls of Ozone (30 mcg per cc of medical grade oxygen) would be injected into the joint via the cannula already in place.
  - c. Most existing protocols recommend repeating the above procedure weekly for a total of 5 injections.
  - d. The existing literature reports success rates averaging around 75%. Success would be measured by a decrease in narcotic use by 50%, and subjectively, by patient satisfaction.
  - e. The shoulder and hip joints would be treated similarly.
  - f. The Ozone treatment does not take the place of a total knee replacement.
  - g. Ozone used in this way is designed to be anti-inflammatory.
  - h. Decrease in pain (and medication), and increase in function are the goal.
  - i. This results in a reduction in narcotics and also a reduction in the number of visits to the physician's office. Patients have less time off work, and a higher quality of life, due to less pain and greater mobility.

Group 2

1. Patients who have disc disease: from rupture of the innermost layer of the anulus fibrosis, on thru full thickness rupture of the disc with extrusion.
2. A 25-gauge 1½ inch needle will be placed about 1 inch lateral to the spinous process on both sides, at the level of the diseased disc. Two more 25-gauge 1½ inch needles will be similarly placed at the disc above and at the disc below. A total of six needles are placed. The depth is just posterior to the lamina, this can be verified by use of a C-Arm.
  - a. One ml of Preservative Free Lidocaine 1-2% will be injected into each needle.
  - b. Then, five mls of Ozone (30 mcg per cc of medical grade oxygen) will be injected into each needle and the needle is then removed. A total of 30 cc of Ozone will be injected.
  - c. A series of 5, weekly injections generally will be performed.

In general, if the patient does not receive good pain relief after the second injection then it is considered a failure. The duration of pain relief in both groups is generally reported to be 9-15 months.

Ozone is very inexpensive and readily available, that is a double edged sword. There is no possibility of a patent and therefore, there is no possibility of any pharmaceutical company funding a clinical trial in preparation for FDA approval. Ozone carries the stigma of an "orphan drug" and as a result there are not and will not be large, double-blind, prospective studies in the literature. A large portion of the Ozone literature is comprised of anecdotal case studies and self-funded clinical trials. Despite this limitation, thirteen states have approved the use of Ozone in patient care. I plan to contact the Medical and Pharmacy Boards in these states to determine how they oversee the medical use of Ozone and what uses have been authorized.

I would like the Board to consider, possibly with the input from the Alabama State Board of Pharmacy, approval for the medical use of Ozone in Alabama for at least the treatments I have briefly outlined above. After all, my practice is no different from those of the other thirteen states wherein the use has been approved. I am very willing to have the Board monitor my practice and in fact will gladly pay for any expense that would incur.

Thank you for your time and consideration.

Sincerely, \_

Encl.: Diskette containing numerous articles and references on Ozone.