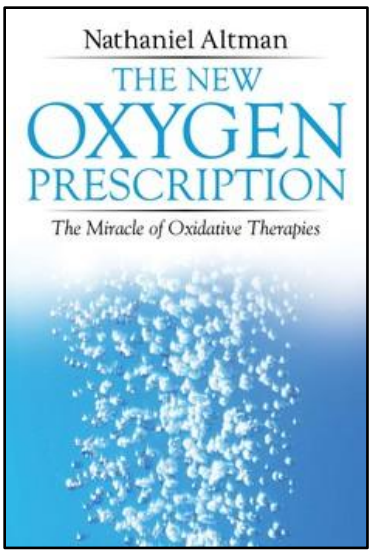
Ozone Therapy: A Solution to the Opioid Epidemic?



By Nathaniel Altman

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Chronic pain has become common in the United States, with approximately 11 percent of the population reporting *daily* pain. Although this percentage is said to have remained fairly constant over the past few decades, intense promotion by the American pharmaceutical industry has led to a dramatic increase in sales of pain medications in recent years. Such medications, known as *analgesics*, are of three types: Analgesics include paracetamol (known in North America as acetaminophen), nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, and opioid drugs like morphine and oxycodone. While most opioids were originally prescribed for treating severe short-term pain connected with surgery or cancer, they are now routinely prescribed for less acute and longer-lasting pain associated with arthritis, back pain, sports injuries, migraines and fibromyalgia.

Sales of prescription opioids quadrupled from 1999 to 2014. Prescription opioid sales totaled over $11 billion by 2010, mostly shared by Endo Pharmaceuticals, Abbott Labs, Johnson & Johnson, Pfizer, Novartis, Covidien, Watson Pharmaceuticals and Purdue Pharma, the private drug company owned by the Sackler family of philanthropic fame. Since its introduction in 1995, Purdue's OxyContin alone has reportedly generated some $35 billion in sales. [1]

Over the course of two decades, Purdue and the other drug companies have paved the way for opioids to become the *go-to* pain treatment medication using a wide range of sophisticated and often misleading marketing and advertising tactics targeted to both doctors and patients. In addition to funding medical research, pharmaceutical companies often pay physicians to represent them within the medical profession, in front of Congress, and to the general public. Lobbying on behalf of the American Pharmaceutical industry has also had a major impact on sales. In 2015 alone, "Big Pharma" coordinated a massive $178,863,490 effort by 1320 lobbyists to protect its interests in Washington. [2]

From 2010 to the present time, opioid misuse and abuse rates have soared. In 2015, the U.S. Department of Health and Human Services estimated that more than 12.5 million Americans misuse opioids, and more than 2 million currently suffer from substance use disorders related to prescription opioid pain relievers. According to the Centers for Disease Control, 53,000 Americans died from opioid overdoses in 2016 and 591,000 had a substance use disorder involving heroin. Almost 100 Americans are dying from

opioid overdose (including heroin) *every single day*. [3] It is estimated that 23 percent of individuals who use heroin today were previously addicted to opioids. The deaths of some of America's most beloved celebrities have been linked to opioids, including Prince, Heath Ledger, Michael Jackson and Elvis Presley. Other well-known celebrities have fought addiction to opioids, including Jamie Lee Curtis, Rush Limbaugh, Courtney Love, Brett Favre, Nicole Richie, Wynona Ryder and Eminem.

By 2013, the annual economic cost of opioid misuse and addiction (including emergency room care, hospital stays, addiction treatment, law enforcement and lost productivity) was over $78 billion, a number that is growing substantially every year. However, the human costs of the opioid epidemic cannot be calculated: family impoverishment, domestic violence, child neglect and abuse, as well as robberies (to pay for drugs), wrecked careers and destroyed lives. Although the U.S. government has declared the opioid epidemic a "public health emergency" many feel that it deserves to be classified as it truly is: a national disaster.

Big Pharma and Federal Government Collusion

Government agencies responsible for health care and health policy in the United States are belatedly looking at ways to reduce so many needless deaths and long-term addiction. While the opioid crisis has been a growing threat since the 1990s, very little has been done to combat it. In July 2017, FDA commissioner Dr. Scott Gottlieb stated that for the first time, pharmacists, nurses, and physicians, would have training made available on appropriate prescribing of opioid medicines, because opioid addiction had become the "FDA's biggest crisis."

After taking office, President Trump established the bipartisan *Commission on Combating Drug Addiction and the Opioid Crisis* to look into the opioid problem and make recommendations. On August 10, 2017, President Trump agreed with the Commission's report released a few weeks earlier and declared the country's opioid crisis a national emergency. And on September 1, 2017, Trump nominated Rep. Tom Marino to be director of the Office of National Drug Control Policy, or "drug czar." But just seven weeks later on October 17, Marino withdrew his nomination following reports that he had been the chief architect behind a bill that protected pharmaceutical manufacturers and distributors and crippled the Drug Enforcement Administration's ability to combat the opioid epidemic in the United States. Many feel that such collusion between pharmaceutical companies and lawmakers is nothing less than a criminal conspiracy that should be prosecuted to the full extent of the law.

Ozone Therapy: A Viable Alternative to Opioids

Over the past few years, media focus has concentrated on the role of Big Pharma, money and politics in helping to create the opioid epidemic. On October 30, 2017, *The New Yorker* published an explosive article ("Empire of Pain") about how the Sackler family's promotion of opioids generated billions of dollars and millions of addicts. Such articles are welcome. Yet the mainstream media has ignored one of the safest, most

effective and non-addicting alternative treatments for pain management that has been widely used in Europe, Asia and Cuba for decades: **ozone therapy**.

Ozone is an elemental form of oxygen occurring naturally in Earth's atmosphere. When it occurs in the upper atmosphere, ozone forms a protective layer that absorbs much of the sun's ultraviolet radiation. Ozone can also be artificially produced by passing an electrical charge through a specially-built condenser containing oxygen. Ozone generators produce ozone for many industrial uses, because it can kill harmful bacteria, fungi and viruses. Ozone has long been used to disinfect medical and laboratory equipment, sanitize fruits and vegetables, clean wastewater, purify drinking water and even reduce pesticide residues in fruits and vegetables.

Although ozone gas can be harmful when inhaled, it has many therapeutic effects when used in medical treatment. Ozone's mechanism of actions include inactivation of bacteria, viruses, fungi, yeast and protozoa, stimulation of oxygen metabolism in the body, and activation of the immune system.

Ozone therapy has been utilized in medical practice for over a century, mostly in Western Europe, Russia and Cuba, with a record of over 15 million treatments. In many countries in Europe- including Germany, Italy, France and Spain- it is part of the medical mainstream. When properly administered, ozone therapy s among the safest medical procedures. A German study of 5 million medically administered ozone treatments found that the rate of adverse side effects is .0007 per application, lower than any other type of medical therapy.[4] Ozone therapy has been researched extensively, primarily in Europe, the Middle East, Asia and Cuba. Hundreds of articles have been published in reputable peer-reviewed medical and scientific journals. Many can be found on Pubmed, an online resource maintained by the United States National Library of Medicine.

How does ozone work in the human body? Ozone is a type of superactive oxygen. When it reacts with body fluids like moisture in skin, mucous membranes or blood plasma, it generates a number of chemical messengers (such as antioxidants and polyunsaturated fatty acids) and produces hydrogen peroxide and *reactive oxygen species* or ROS. They, in turn, produce what is known as *transient oxidative stress* and longer-term reactions that strengthen the immune system and increase oxygen delivery to the body's cells. When hydrogen peroxide or ozone break down into these various oxygen subspecies, they contact anaerobic viruses and microbes [i.e. viruses and microbes that have the ability to live without air], as well as diseased or deficient tissue cells. They oxidize these cells while leaving the healthy cells alone.

Because therapeutic ozone works primarily to enhance the body's immune response, it offers a tremendous range of medical applications. According to *The Madrid Declaration on Ozone Therapy* released in June 2015- the first document of its kind to present unified recommendations from the world's leading ozone researchers and clinicians- the following conditions or diseases have been treated successfully with ozone therapy, either alone or in combination with other therapies. Many of these

problems can also respond to hydrogen peroxide- another type of "oxygen therapy"- as well.

They include spinal diseases, including herniated disc and spondylolysis; orthopedic diseases and localized osteoarthritis; painful disorders of musculoskeletal soft tissue; gonoarthrosis; pathologies of the tendons (including tennis elbow and jumper's knee); carpal tunnel syndrome; diabetes, diabetic foot and diabetic-related ulcers; chronic fatigue syndrome and fibromyalgia; Ménière's disease*;* advanced ischemic diseases and lower limb arterial ischemia; age-related macular degeneration; dental cavities, particularly in children; ostromyelitis; pleural emphysema; abscesses with fistula, infected wounds, bedsores, ulcers and burns; acute and chronic infectious diseases, including hepatitis, HIV-AIDS, herpes, papilloma virus infections, nail fungus, candida, giardia and athlete's foot. Ozone therapy has also been prescribed to help treat cancer-related fatigue (to be integrated with conventional cancer treatment) and asthma. Individual researchers have also found these therapies to be effective in treating cancer, hepatitis, Alzheimer's disease, emphysema and Parkinson's disease.[5] Therapeutic ozone and hydrogen peroxide have also become increasingly popular among dentists and veterinarians.

How is Ozone Administered?

The three primary methods of ozone delivery to treat pain have been administered to literally millions of patients. When utilized according to established protocols by certified practitioners, ozone is among the safest of medical therapies:

1. Major Autohemotherapy (MAHT), which involves removing about one half pint of blood from the patient, adding ozone and oxygen to the blood, and infusing the blood back to the patient. It becomes, in essence, a type of "auto-vaccine." MAHT is used primarily to treat systemic disease, but can be effective in other conditions as well.

2. Rectal insufflation, in which ozone and oxygen is administered as an enema. The ozone/oxygen mixture first reacts with the large intestine and beneficial chemical reactions follow. Its scope of treatment is similar to MAHT.

3. Intra-articular injection, which call for a mixture of ozone and oxygen to be injected directly into a joint, such as the finger, elbow, shoulder or knee. Other treatments involve injections into or between the vertebrae. Intra-articular injections have been found to be very effective in treating many pain-related syndromes that Americans suffer from today connected to arthritis, sports injuries, sciatica and lumbar pain.

Ozone's Two Pathways: Relieving Pain while Treating the Underlying Cause

Although physicians have long focused on ozone's ability to treat disease, a beneficial "side effect" of ozone therapy is its ability to reduce pain.

One of the earliest North American findings related to ozone and pain reduction took place in Canada during AIDS trials conducted by the Canadian Department of Defence in 1990, when the analgesic effects of ozone were discovered unexpectedly. Capt. Michael E. Shannon, M.D., who coordinated the study (Shannon later served as Deputy Surgeon General of Canada) said, "Inadvertently, we discovered that this particular type of therapy has an incredible effect, a very pronounced effect in managing pain. It has a very potent analgesic effect."[6]

In addition to treating systemic health problems like heart disease, hepatitis and diabetes, medical ozone has been used successfully to treat joint pain and other types of pain primarily in Europe- where laboratory and clinical research in ozone therapy are sponsored by the government and medical schools- for over forty years. But here in the United States, oxygen therapies like ozone and hydrogen peroxide are recognized as "experimental" and physicians have been discouraged to use them. There is also little or no funding for ozone research due to opposition from Big Pharma that has a powerful influence over government health policy and funding for university research.

A study by researchers of the University of Ancona in Italy and Cairo University in Egypt focused on understanding the mechanism behind ozone's proven clinical ability to reduce pain. Fifty-two patients suffering from shoulder, cervical, and low back pain were chosen for this study, and each received subcutaneous injections of oxygen and ozone.

Although pain among patients was relieved, the focus of this study was on how pain was mediated with ozone. The researchers concluded that the analgesic mechanism of ozone involves two important steps:

1. A short-term mechanism that may correspond with the direct oxidation on biomolecules.

2. A long-term mechanism that may involve the activation of anti-oxidant pathways. [7]

I mentioned earlier that one of the major methods of treating joint pain involves intra-articular injections containing small amounts of ozone and oxygen, either alone or with other therapeutic substances. Medically, it is known as either *regenerative injection therapy* (RIT) or *proliferative therapy*. An American variation, known as *Prolozone Therapy,* was developed by Frank Shallenberger M.D. and is taught to physicians through the American Academy of Ozonotherapy. In RIT, ozone gas is injected directly between the joints, primarily those of the painful knee, elbow, finger or shoulder, or between or into the vertebrae. Intra-articular injection has been used primarily by physicians in Europe, Asia and Cuba to treat rheumatoid arthritis, knee arthrosis, rheumatism, sciatica, traumatic knee disorders, lumbar disc pain and other joint diseases.

A major controlled clinical trial on oxygen-ozone therapy to treat pain from a herniated lumbar disc was done at Bellaria Hospital in Bologna, Italy, and reported in the *American Journal of Neuroradiology* in 2003. Six hundred patients suffering from

herniated discs were treated with a single session of oxygen-ozone therapy. The first group of three hundred (Group A) was given only ozone. In addition to ozone, the other half (Group B) received a corticosteroid and an anesthetic.

Both groups were evaluated six months later. In Group A, treatment was a success (i.e., excellent or good outcome) in 70.3 percent and considered a failure in the remaining 29.7 percent of patients. In Group B, treatment was successful in 78.3 percent and a failure in 21.7 percent. The researchers concluded that the combined use of ozone and steroids provides the best results and added: "Oxygen-ozone therapy is a useful treatment for lumbar disc herniation that has failed to respond to conservative management." [8]

An article in *Medical Hypothesis* addressed the safety and effectiveness of RIT in treating painful ligaments and joints. The authors wrote that ozone dissolves in body fluids and immediately reacts with biomolecules that generate messengers responsible for biological and therapeutic activities. They continued, "The results are an anti-inflammatory response, which also results in a similar trophic [promoting cellular growth or survival] reaction to that of RIT. It is logical to expect that combining these two modalities [RIT plus minor or major autohemotherapy] would result in enhanced healing and therefore improved clinical outcomes."[9]

Other types of pain- especially pain caused by migraines and fibromyalgia- are treated with major autohemotherapy (MAHT) and rectal insufflation. Both are often used for a wide variety of systemic health problems, including arterial circulatory disorders, general immunoactivation, adjuvant cancer therapy, diabetes and hepatitis A, B and C. While not popular among Western practitioners, Russian doctors often favor ozonated saline, which is infused into the patient.

How Oxygen-Ozone Treatment Works: Disc Pain

Disc pain is said to affect almost 80 percent of the world's adult population. When it comes to treating disc pain, oxygen-ozone gas is normally given via an injection into the herniated disc. A needle delivers the treatment directly to the disc, and it reduces the volume within the disc. This is due to the oxidation of proteoglycans, which are proteins found within the gel-like center of the disc. When disc volume is reduced, the pressure on nerves is also reduced. This, in turn, lowers the amount of pain. When it comes to treating symptoms exacerbated by chronic pain, ozone is believed to act as a type of "chemical acupuncture" or "reflex therapy."

Writing in the journal *Pain Physician,* Vahid Eslami, M.D. and Vafa Rahimi-Movaghar, M.D. of the Tehran University of Medical Sciences in Iran outlined the four major ways that oxygen-ozone injections are successful in treating herniated intervertebral disc (HID) disorders:

1. Ozone has an effect on the inflammatory cascade by altering the breakdown of arachidonic acid to inflammatory prostaglandins. As a result, by reducing the inflammatory components, there is a subsequent decrease in pain.

2. Herniation can impinge on the venous and arterial flow and cause phlebostasis and arteriostenosis, which leads to a serious hypoxemia of the area. By applying the ozone to the herniated site, hyper-oxygenation of the area occurs, which reduces the pain by direct and indirect mechanisms.

3. This mechanism of action is the direct effect of the ozone as a rapid and strong oxidizing agent. The ozone molecule breaks down some of the glycosaminoglycan chains in the nucleus pulposus and reduces their ability to hold water, thereby diminishing the size of the herniation and subsequently contributing to pain relief.

4. The stimulation of fibroblastic activity by ozone will result in the initiation of the repair process by stimulating collagen deposition. [10]

Ozone injections to treat joint and back pain are generally more effective than autohemotherapy, which focuses on diseases that affect the body as a whole. According to Dr. Velio Bocci, Professor Emeritus of Physiology at the University of Siena in Italy, "…The use of ozone [injections] in orthopedics has witnessed a far swifter success than the practice of ozonated autohemotherapy for systemic dysfunction: such a discrepancy can be explained by the rapid disappearance of pain achievable in most cases after a single intradiscal injection of ozone, even if further studies are necessary to demonstrate the persistency of effects of ozone therapy over time." [11]

Ozone: A Promising Cure for Migraine Headaches

Approximately 14 percent of the population suffers from this pathology with a peak incidence between 25 and 55 years of age. In addition, migraine headache is very common in children and adolescents, particularly among teenagers whose prevalence is estimated around 8-23 percent.

A Russian study conducted by Dr. S. A. Kotov conducted a randomized clinical trial to see whether ozone therapy can help relieve symptoms of migraine. Sixty-eight adult migraine sufferers were chosen for this study: forty patients received eight to nine infusions of ozonated saline solution at a concentration of 1,200 μg/l, and a control group of twenty-eight received infusions of saline without ozone.

The intensity of headache, expressions of anxiety, state of vessels in the brain, and other biochemical indices were evaluated. Dr. Kotov found that there was a 25 percent overall improvement among the patients receiving ozone as compared to the controls. He concluded: "In 59% of the patients the attacks were absent during 3–5 months after ozone therapy, less intensity of headache was observed after their relapse. Improvements in the patients coincide with changes in biochemical parameters."[12]

A 2016 Italian clinical study published in the *Journal of Pain and Relief* reported two case histories of individuals whose migraines disappeared completely after ozone therapy. One case was a ten year old boy who suffered daily headaches for two years.

After 17 days of treatment via rectal insufflations (two treatments a week), the patient reported an increased sense of wellness and a significant reduction of headache episodes, which completely disappeared immediately after the treatment cycle. Six months after the end of the therapy, the patient reported to have experienced no more than two headache episodes in a month.

The other patient was a 51-year old female schoolteacher suffering from frequent migraine headaches accompanied by panic attacks. The doctors at the pain clinic administered major autohemotherapy once a week for 18 weeks. At the end of the eighth infusion, the patient reported a complete disappearance of headaches, reduced fatigue at the end of the day, improved mood (especially upon waking) and a greater ability to concentrate. The doctors concluded, "The efficiency of ozone therapy in the treatment of headache is appropriate to be evaluated in further clinical studies with a greater number of patients." [13]

While the majority of headaches are caused by tension and do not require medical intervention, roughly 20 percent of the population experience incapacitating headaches that resist medical treatment. Refractory migraines are those that continue persistently despite aggressive attempts to manage them, including medical, behavioral, and alternative modes of treatment.

A novel study was undertaken by Dr. Bernardino Clavo and his colleagues at the Chronic Pain Unit, Research Unit, and the Departments of Radiation Oncology and Neurology at the Dr. Negrin University Hospital, Las Palmas, Spain, along with Dr. Velio Bocci of the Department of Physiology at the University of Siena, Italy.

Five patients were chosen for this study. All had suffered from severe/persistent headache that did not respond to standard headache management (including 5-HT1 agonist triptan drugs). Patients were treated with ozone therapy in the form of major autohemotherapy. The procedure involved venous blood drawn into a sterile single-use glass bottle containing anticoagulant, gently mixed with an equal volume of an ozone-oxygen gas mixture, pre-filtered through a sterile 0.20-lm filter and slowly re-infused back into the donor patient via the antecubital vein in the arm.

Outcomes were measured by analgesia requirements, days of sick leave due to headache, number of headache events, and pain intensity according to the visual analogue scale (VAS). Outcomes were recorded at three time points: pre-ozone therapy, post-ozone therapy, and before the last follow-up (mean: 64.6 – 36.8 months).

One month before ozone treatment began, the median number of severe headache episodes was 20 a month, with 80 reported episodes over six months before the ozone therapy began. One month after ozone therapy sessions concluded, zero events were reported. After six months, zero severe headache events were reported. The VAS scores also recorded a large decrease in headache pain in general. In the six month period before the study, 60 percent of the patients had to take time off from work due to headache pain. A follow-up after five years after ozone therapy, patients reported no sick

days due to headache pain. All patients stopped using triptan drugs, primarily used to treat migraine and cluster headaches.

The researchers concluded, "Ozone therapy decreased headache episodes and pain severity over a protracted period." They added, "This novel approach is effective and merits further research."[14]

Ozone: A Cure for Fibromyalgia?

Fibromyalgia is a chronic disease affecting over five million Americans. Its exact cause is unknown but is believed to involve psychological, genetic, neurobiological, and environmental factors. Although generalized pain is considered to be the primary symptom, many other associated symptoms are common, especially sleep disturbance, chronic fatigue, anxiety, and depression.

A pilot study was undertaken by researchers at the Universities of Granada and Almeria in Spain along with scientists from the Ozone Research Center in Cuba to evaluate the effectiveness and tolerability of ozone therapy by rectal insufflation as an add-on therapy in fibromyalgia management.

A total of 36 patients diagnosed with fibromyalgia (33 women and 3 men) were recruited for this study. They received 24 sessions of ozone therapy during a 12-week period. At each session, the administered dose of ozone was 8mg (200mL of gas, at a concentration of 40 μg/mL). Ozone sessions were given five days a week during the first two weeks, twice a week from weeks 3–6, and weekly from weeks 7–12. A Fibromyalgia Impact Questionnaire was the main measure of outcome, and was administered when the study began and at weeks 4, 8, and 12. Secondary outcome measures, administered at the beginning and end of the study included the Pittsburgh Sleep Quality Index, the Beck Depression Inventory, the State and Trait Anxiety Inventory, and the SF-12, the abbreviated form of the Short Form Health Survey. Adverse reactions to treatment were also recorded.

The researchers found that the total scores of the Fibromyalgia Impact Questionnaire decreased significantly during the study period, with the decrease being observed in the first four weeks of the study. Significant improvement was also seen both in depression scores and in the Physical Summary Score of the SF-12. Most of the positive effects of ozone therapy had to do with a reduction of physical symptoms, but depression was reduced in 47 percent of the patients. Transient meteorism (distention of the abdomen due to air or gas in the intestine) after ozone therapy sessions was the most frequently reported side effect, and impacted approximately 36 percent of the patients at some point during treatment.

The researchers concluded that "At the dose and number of sessions used in this study, ozone therapy by rectal insufflation seems to be beneficial for physical symptoms and depression of fibromyalgia."[15]

In *The New Oxygen Prescription*, I cover a wide variety of clinical research into how ozone and hydrogen peroxide can treat musculoskeletal problems, including arthrosis, herniated disc pain, lumbar sciatic pain, spondylolsys, joint pain and Prolozone therapy, mandibular osteomyelitis, osteoarthritis, osteoporosis, rheumatoid arthritis, TMD/TMJD pain, failed back surgery syndrome, migraine and fibromyalgia.

Summing Up: Benefits of Oxygen-Ozone Treatment

Besides providing a shorter recovery time and lower complication rate than surgery, ozone therapy can eliminate the need for opioids and other pain medications for many pain-related problems. Benefits of oxygen-ozone therapy include:

- It is minimally invasive.
- It is an outpatient procedure that requires no hospital stays.
- It takes little time to administer.
- It costs much less than drugs or surgery.
- It is a relatively pain-free procedure.
- There are no adverse side effects.
- It will not lead to addiction.

Why Isn't Oxygen-Ozone Therapy More Widely Used in the United States?

With hundreds of clinical studies showing that oxygen-ozone injections are a low-risk and high-reward treatment for joint and back pain, you may wonder why they aren't readily available in the United States. Oxygen therapies like ozone have been proven in both clinical trials and regular medical practice to be safe and effective in Europe, Australia, China, India and Cuba. Although an estimated 15,000 European practitioners legally use ozone therapy, the number of physicians using ozone in North America is small, due in part to the fact that information about therapeutic ozone is not provided in medical schools. The medical establishment does not advocate the use of ozone therapies and often discourages or prevents licensed physicians from using them. In the United States, physicians have been threatened with having their licenses revoked if they administer ozone to their patients. Clinics have been closed down and practitioners have been threatened with jail.

A major reason for this lack of interest in ozone therapies has to do with money and profit: ozone is *non-patentable*, has the ability to treat a wide range of health problems through various types of applications. It is also easy and inexpensive to produce and utilize in a medical setting. There are simply no financial incentives to incorporate ozone into traditional money-driven medical practice. Ozone therapy poses a real threat to the continued dominance of the medical establishment: the pharmaceutical industry, medical centers and physicians who are accustomed to providing expensive drugs, surgery and other complex medical procedures for the treatment of acute and chronic pain.

Medical ozone forms the "cutting edge" of a new healing paradigm for treating pain. It is a safe, effective, inexpensive and *non-addictive* form of medical therapy. As more people discover the value of these therapies, there will be greater consumer demand. As more health care consumers and their physicians become acquainted with the value of therapeutic ozone, it will become a valuable part of mainstream medical therapy.

Advocates of alternative therapies are continually amazed that oxidative modalities like ozone therapy have made up part of the medical mainstream in many European countries and in Cuba for decades, yet are still viewed as "experimental" and "unproven" in North America. The medical literature is replete with well-researched peer-reviewed articles that testify to the safety and effectiveness of these therapies in a wide range of medical applications. Government funding for further research is essential, and it's time to demand it.

The fact that these therapies have not been objectively studied and evaluated—let alone approved—by the U.S. Food and Drug Administration is a slap in the face to health care consumers who need access to inexpensive, safe, and effective methods to prevent disease, improve their health and reduce or eliminate pain. To continually neglect a promising healing modality—especially one that is accepted in other countries and already used on millions of patients—is nothing short of criminal, especially in light of the current opioid epidemic, a national tragedy.

Over the years, the government has responded to demands for change, albeit reluctantly. Pressure from consumers has finally brought about new FDA dietary recommendations and has made non-Western modalities like acupuncture legally accepted in the United States. Can pressure from health care consumers who demand FDA evaluation and approval of oxidative therapies produce similar results?

NOTES

[1] Marie Theres Jacobs, "Adverse Effects and Typical Complications in -Ozone-Oxygen Therapy," *Ozonachrichten* 1982, no. 1:193–201.

[2] Patrick Radden Keefe, "Empire of Pain," *The New Yorker*, XCIII: 34 (October 30, 2017): 34.

[3] Visit www.opensecrets.org. Search for the term "pharmaceuticals / health products" for more recent articles on this topic.

[4] "Opioid Overdose: Understanding the Epidemic," https://www.cdc.gov/drugoverdose/epidemic/index.html.

[5] International Scientific Committee on Ozone Therapy. *The Madrid Declaration on Ozone Therapy*, 2nd edition (Madrid: International Scientific Committee on Ozone Therapy, 2015), 27–28.

[6] M.E. Shannon, interview in *Ozone and the Politics of Medicine* (Vancouver: Threshold Films, 1993).

[7] Lamberto Re et. al., "Clinical Evidence of Ozone Interaction with Pain Mediators," *Saudi Medical Journal* 32, 12 (2011), 1363-67.

[8] C. F. Andreula et al., "Minimally Invasive Oxygen-Ozone Therapy for Lumbar Disc Herniation," *ANJR American Journal of Neuroradiology* 24, no. 5 (May 2003): 996–1000.

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[14] B. Clavo et al., "Long-Term Improvement in Refractory Headache Following Ozone Therapy," *The Journal of Alternative and Complimentary Medicine* 19, no. 5 (2013): 453–458

[15] Javier Hidalgo-Tallón, et. al., "Ozone Therapy as Add-on Treatment in Fibromyalgia Management by Rectal Insufflation: An Open-Label Pilot Study," *The Journal of Alternative and Complementary Medicine* 18 (2012): 1–5.