

The FDA & Ozone Treatment in the USA

Author: Dr Julian Holmes, February 2007.

I have been asked by a number of Dentists and Physicians in the USA to put together the legal argument why ozone treatment is, in my opinion, legal in the USA. I have argued in the past that although the FDA may have the right to approve, or not-approve of a particular medical or dental device, the FDA's approval is not actually necessary before that device can be used in a clinical setting.

Doctors in New York and many other states now practice some form of ozone therapy under the health freedom laws. As of 1998, the following states have such protection: Alaska, Colorado, Georgia, Nevada, New Mexico, New York, North Carolina, Oklahoma, Texas, Washington and Minnesota. Naturopaths in Canada and America have always used ozone.

I cannot find any up-to-date information to tell me if additional states have introduced these laws. I would add that the legal system would take into consideration the use of technologies that were available across the entire USA, and they would have to take into consideration the volume of research and publications from Europe, South Africa, Cuba, Russia and the USA.

Perhaps the best known case that set the scene in the USA is that of Dr Robert Atkins, director of the Atkins Center for Complementary Medicine in New York. Dr Atkins had his licence revoked by the FDA for treating patients with ozone. In 1993 his successful court case against New York State to regain his license resulted in the passing of a law permitting physicians to use ozone and other non-FDA-approved techniques. Many of the battles to get such therapies recognised are recorded in the award-winning 1993 documentary *Ozone and The Politics of Medicine* produced by Geoffrey Rogers of Threshold Film, Vancouver, B.C, which is available on video.

In an interview in 1994, Dr Robert Atkins said; "If there's a voodoo doctor who is getting good results, I want to know how he's doing it," says Atkins. "That's the difference between me and other people. Good results warrant a serious look-see. I don't care if it is voodoo." In 1993 New York State demurred and temporarily suspended Atkins's license for using ozone on a breast cancer patient. Judge Greenfield later ruled that the state health commissioner had acted capriciously and arbitrarily and restored Atkins's license five days later. A shocking miscarriage of justice, according to Atkins. "I just didn't think they would pick on people who practice medicine at our level of excellence".

I have reproduced the Judgement from Judge Greenfield, as it is an important indicator on the court's interpretation of the law, and this has never been challenged since 1993. The court upheld the right of the patient to seek and receive treatment that may not be considered 'main-stream', and upheld the principle of choice. This can be interpreted as the court upholding the right of the clinician to use any device or product that offers a safe treatment modality that may, or may not, have FDA approval.

Studies from Europe (Abu-Salem *et al*, 2003; Baysan and Lynch 2001; Holmes, 2003; Holmes and Lynch, 2003) have shown conclusively that the use of ozone in dental care is effective as a non-destructive method to manage decay and its destructive effects. The use of ozone has been shown to be the ideal way to manage anxiety of patients – young and old - and their carers (Dahnhardt *et al*, 2003; Domingo *et al*, 2004).

The effects of ozone reduce tooth destruction in routine preparation (Clifford, 2004; Holmes, 2004; Holmes and Lynch, 2004) and ozone reduces the time and the cost of dental care (Domingo and Holmes, 2004; Johnson *et al*, 2003) and raises the practice income. In Endodontics, ozone is effective against *Enterococcus faecalis* (Chang *et al*, 2003).

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Professor Velio Bocci from Milan University (1994) has emphasised that the potential toxicity of O₃ should not preclude its employment for medical, dental & veterinary purposes. This statement has been echoed by thousands of health professionals who use ozone in clinical practices around the world, and millions of patients that have been treated. The results of these studies show that ozone reduces the necessity for filling materials of unknown long-term potential toxicity.

I hope this allows you to make your own informed decision whether or not to incorporate ozone technologies into your health care program in your clinic.

With regards, Dr Julian Holmes.

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JUDGE GREENFIELD'S HISTORIC DECISION

"...The court finds...that directive [suspending Atkins's license]...to be **arbitrary, capricious, and overbroad**. From the facts, it appears that Dr. Atkins has over 5,000 patients, 10 of whom are receiving the disputed treatment of ozone therapy for cancer, including Mrs. Coy....

"In the absence of any hearing, I don't see how the Commissioner can jump to the conclusion that the administering of ozone therapy, which evidently is practiced with approval in other jurisdictions, itself constitutes an imminent danger to the health of patients in the state of New York, without more scientific evidence produced.

"That seems to me to be a hastily arrived at conclusion. **Patients of course have the right to choose a mode of treatment, or indeed to choose non-treatment, if they are adults capable of arriving at a decision for their own reasons.** Of course, there are many cases where patients have refused treatments which are medically indicated, in which the overwhelming number of physicians would say are necessary. Here, we have what is evidently a disputed method of treatment as to its effectiveness and I am not aware that there was any showing that the administration of that therapy does in fact present an imminent danger, even though it might be ineffective; but that is not the status on which this order has proceeded.

Individual complaints are treated in medical malpractice actions, not all of which result in suspensions; and certainly it would be very rare or unknown for a doctor to be totally barred from the practice of medicine because of an allegation of negligence. In this case she was not turned out into the street to wander about by herself. So, at worst you would have a debateable condition as to whether or not hospitalization was called for.

Counsel for petitioner has indicated there may be some element of vindictiveness involved in issuing the summary suspension order prior to the hearing. Certainly we are not going to permit a person's right to contest charges in a legal forum to restrict rights that he otherwise has. That would be to approve the practice of a new kind of legal medicine that you might call "cryo-forensics," i.e., it would have an extreme chilling effect on litigation.

It does seem to me that the reaction of the Commissioner under the circumstances presented here was overly vigorous and overly broad, and so the court will direct that the summary suspension order be vacated pending the scheduled hearing before Mr. Justice Tom.

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