

OZONE THERAPY AND LEGISLATION - ANALYSIS FOR ITS REGULARIZATION

(Original written in English)

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ABSTRACT (1st. ed., November 18, 2012)

Ozone therapy is on the agenda and figures attest to its growing importance. Ozone therapy is increasingly practiced in different parts of the world. The existence of more than 40 national and international associations of ozone therapy and more than 26 000 ozone therapists confirm it. However, while ozone was discovered in 1785 by Dutch physicist Martin van Marum (1750-1837) and synthesized in May 1840 by the German chemist Christian Friedrich Schönbein (1799-1868), history has shown that it has been difficult for ozone therapy to have a significant presence on the world's medical agendas. Only Russia, Cuba, Spain and Italy have provisions from the authorities that specify the criteria to be met for practicing ozone therapy. These provisions are analyzed in this study to rule in favor of regularizing ozone therapy, with reference to the measures taken by these countries. Specific points are proposed and a methodology that should be taken into account when developing a strategy that can lead to the regularization of ozone therapy in countries where it is still widely practiced.

ABSTRACT (2nd. ed., May 20, 2015)

Two and a half years has elapsed since the publication of the first edition of this paper in November 2012, although the research started in 2006 and its results were written initially in 2008¹. During nearly 10 years of intensive work developed in favor of the ozone therapy from both the medical and legal fields, results are coming out. This paper pretends to provide a full picture of where is placed the ozone therapy in the legal world and for that reason the intention is to update it to keep the research up to day in conformity with the advances obtained in the legal status of the therapy in different countries.

In the 1st. edition we have written that “history has shown that it has been difficult for ozone therapy to have a significant presence on the world's medical agendas.” Our continued gathering of information, providing advised on legal issues to different national ozone therapy associations, and intervening at different levels to obtain the regularization of ozone therapy in different countries, have permitted to say that the current legal situation of the ozone therapy in May 2015 is much better than before. Currently there are ten countries where the therapy has been regularized and there are other countries where ozone therapy associations are presenting serious and founded proposals before the authorities to obtain the regularization.

Last but not least the scientific foundations of the therapy related to its security and efficacy have been indicated in an ISCO3 paper.²

¹ http://www.aepromo.org/asociados/files/ponencia_mexico.pdf

² ISCO3 - International Scientific Committee of Ozonotherapy. (Madrid, 2012). Ozone Therapy and Its Scientific Foundations. <http://isco3.org/wp-content/uploads/2016/11/Ozone-Therapy-and-Its-Scientific-Foundations-ISCO3-November-18-20121.pdf>

ABSTRACT (3rd. ed., October 9, 2017)

In the first edition of this paper we wrote that Russia, Cuba, Spain (in 15 out of 17 autonomous communities) and Italy (in three regions out of 20) had provisions specifying the criteria to be met for practicing ozone therapy.

In this third edition the number of countries with some type of provision on ozone therapy is not four but twelve. So little by little the therapy of ozone is being appeared in the health agenda of governments. In other countries ozone therapy associations are working with the objective that this therapy may be regularized. We are well aware that still the objective to obtain the regularization in all the countries where the therapy is used, is far away. But before were nothing, in right now the number has increased to 12. And fortunately, in all the other countries, according to our knowledge the practice is widely accepted by the authorities.

The regularization of ozone therapy is one objective, and a very important one. However, once obtained it, the legal work must continue because it is important that the authorities apply the legal provisions in conformity with their spirit and contents. One example occurs right now in Spain where the major autohemotherapy, in two autonomous communities (Madrid and Catalonia), have to be performed according to the procedures applied for the hemodialysis. Legal interpretation that is not shared by Aepromo (Spanish Association of Medical Professionals in Ozone Therapy), which has expressed its oppositions in written medical and legal documents sent to both communities. The interpretation done by Madrid and Catalonia means that ozone therapy medical centers in Catalonia and Madrid have to:

- hire a physician;
- have a specialization in hematology and hemotherapy;
- have two years of experience after getting the specialization title in one or more centers or services of transfusion;
- be appointed as director of the medical center.
- In addition, this physician may delegate his functions in another person.³

The application of art 30 means that medical center must hire a hematology and hemotherapy, specialist and appoints him as director of the center. This situation might oblige the medical center to increase its medical fees to hire the specialist for only signing because he may delegate his functions.

This provision indicates that great lobby power that in Spain have the hematologists to the point that in a national regulation they have managed to be authorized to delegate their functions in third persons.

Keywords: ozone, legislation, ozone therapy, regulation, legal aspects.

³ Royal Decree 1088/2005 (art. 30)

I. INTRODUCTION

Although ozone was discovered in 1785 by Dutch physicist Martin van Marum (1750-1837) and synthesized in May 1840 by the German chemist Christian Friedrich Schönbein (1799-1868), history has shown that it has been difficult for ozone therapy to have a significant presence on the world's medical agendas.

But the gradual, steady and rising use of ozone therapy primarily in Germany and the former Soviet Union starting in the 1960's of the last century has prompted renewed interest in the scientific use ozone therapy in accordance with protocols previously adopted. In the ensuing decades ozone therapy was emerging in various European countries, mainly in Italy, followed by Spain, and then with widespread use in Cuba. China became another country where the therapy started to have importance after being introduced in 2000.

Today we can certainly say that this therapy is increasingly used in many different countries. The investigation conducted has determined that ozone therapy is widely practiced in 50 countries worldwide, with more than 40 national and international associations, plus the International Scientific Committee of Ozone Therapy - ISCO3. (www.isco3.org).

It is testified by the figures of existing ozone therapists. The number of existing ozone therapists already exceeds 30 000, placing Germany as the first country with 11 000 practicing health professionals. China is next in number with 5 000. Then Russia is third with 3 500, followed by Italy with 3 000 professionals.⁴

I.1 Authorities and ozone therapy

Examples of the widespread use of ozone therapy abound, to the extent that health authorities in various countries have had to comment on it.

Argentina

At the express request of the Medical College of the Santa Fe Province in Argentina, AEPRMO presented a legal brief on ozone therapy on September 5, 2011.

Brazil

The City Council of the City of Cajamar, in the Brazilian state of Sao Paulo, approved a decision asking the Prefecture to offer ozone therapy in the city health facilities. The Prefecture of Nova Lima in the State of Belo Horizonte has also developed projects for the application of ozone therapy.⁵

⁴ Roberto Quintero Mariño. Annex, Statistical Table in paper of Velio Bocci et al. (2011). "Oxygen-ozone therapy is at a cross-road". Revista Española de Ozonoterapia. Vol.1, no 1, pp. 74-86.

<http://www.revistaespañoladeozonoterapia.es/index.php/reo/article/view/8/20>

⁵ http://www.aboz.org.br/Web/secoes_site.asp?id=1 (pág. Consultada 26-2-2012)

México

The Ministry of Health of the State of Jalisco (SSJ) advised patients to check whether the doctor was trained and certified in the practice of ozone therapy, and if the technical equipment used was certified by the Federal Commission Against Risks Health (Cofepris). It emphasized that

"People must understand that [ozone therapy] is not a cure all, however it does have its benefits as any therapy." It noted that "there is increased risk that the patient may fall into the hands of inexperienced people who do not know this type of treatment and may actually cause more problems than benefits."⁶

Tlaxcala, capital of the state of the same name in México, in its 2010 Municipal Administration Government Report proudly stated that they had been using ozone therapy.⁷

The municipality of San Pedro Cholula, Puebla State in México, decided to include ozone therapy in its services for seniors. The municipality also stated that such therapy had been practiced in the state for over ten years.⁸

Peru

The mayor of the province of Huamanga, Amilcar Huanchuari Tueros, who is also physician, uses ozone therapy whenever necessary with his patients.⁹

The Municipal Polyclinic of the San Miguel District in the Lima urban area is providing in its Pain Therapy Service ozone therapy in different type of treatments.¹⁰

Spain

A report by the autonomous community of Andalusia in 2006 indicated that in Spain "Increasing diffusion of this technology in recent years confirms that citizens are more interested in ozone therapy. The Health Technology Assessment Agency of Andalusia (AETSA) indicates from May 2005 on a non negligible percentage of citizen telephone calls (12 171, 7%) have been on ozone therapy."¹¹

The Canary Islands asked AEPROMO (Spanish Association of Medical Professionals in

⁶ Ernesto Cisneros Madrid, Departamento de Regulación de Insumos y Servicios de Salud de la Secretaría de Salud en Jalisco (SSJ). El Occidental, 12 de septiembre de 2011.

<http://www.oem.com.mx/eloccidental/notas/n2224638.htm>

⁷ Informe de Gobierno de la Administración Municipal correspondiente al ejercicio 2010. Tlaxcala, viernes 17 diciembre 2010

http://www.e-consulta.com/tlaxcala/index.php?option=com_content&task=view&id=20885&Itemid=131

⁸ 21 de Octubre de 2011, <http://www.aquiespuebla.com/salud/avances/8391-salud>

⁸ 23-9-2011. <http://www.diariodesevilla.es/article/deportes/1071622/calloway/nuevo/refuerzo/para/plaza.html>

⁹ http://www.diariolavozdehuamanga.com/noticias/index.php?option=com_content&view=article&id=5040:alcalde-de-huamanga-asiste-a-paciente-con-tratamiento-de-ozonoterapia&catid=20:local&Itemid=67

¹⁰ <http://larevista.aqpsoluciones.com/2012/05/18/campana-medica-gratuita-en-policlinico-de-san-miguel/> Page consulted on May 19, 2012

¹¹ Vidal Serrano Silvia y Hermosilla Gago Teresa. "Efectividad clínica de las intervenciones con Ozono". Sevilla: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía; Madrid: Ministerio de Sanidad y Consumo, 2008, p. 16

Ozone Therapy) in February 2012, to enumerate the basic requirements that medical facilities should have to practice ozone therapy.

It is worth indicating that ozone therapy is implemented in 22 Pain Treatment Units of the Spanish public health sector.¹²

I.2 Elite sport and ozone therapy

More often ozone therapy is used in the field of elite sport in some countries.

The professional basketball team Cajasol Civic Banking in Seville, Spain has used ozone therapy to treat medically Joan Sastre, one of its most important players, for a bulging disc, since

"the success of this technique is based on the same properties of ozone, which is analgesic, antiseptic and water-repellent".¹³

After Sastre's successful recovery the medical team decided not to operate on him because

"ozone and corticosteroids, according to experts, should solve a problem that dragged on for a couple of months, when a sore leg indicated that the problem came from the lower back."¹⁴

In November 2011 the team announced that the player had undergone a significant improvement in his back injury, given the

"good response to treatment of infiltration and ozone therapy that has been done in recent weeks, to solve the problems experienced since the preseason because of a bulging disc in his back."¹⁵

The national football team of Venezuela has used medical ozone on their players, so they could play at high altitudes like the capital of Bolivia which is over 3650 meters above sea level or in Quito at 2850 meters. Ozone therapy

"will help us, we will strengthen the resilience to recover faster. At high altitude breathing is different and choking may occur (...) It seeks to introduce ozone therapy into the blood stream of players to improve their circulation and increase the capacity of the blood in transferring oxygen through the body."¹⁶

¹² I Sánchez P. et.al. Unidad de tratamiento de dolor: estándares y recomendaciones. 69 (Madrid: Ministerio de Sanidad, Política Social e Igualdad.

http://www.msssi.gob.es/organizacion/sns/planCalidadSNS/docs/EERR/Unidad_de_tratamiento_del_dolor.pdf, 2011).

¹³ 23-9-2011. <http://www.diariodesevilla.es/article/deportes/1071622/calloway/nuevo/refuerzo/para/plaza.html>

¹⁴ 13-10-2011 <http://www.diariodesevilla.es/article/deportes/1087565/sastre/no/sera/finalmente/operado.html>

¹⁵ 17-11-2011 <http://www.europapress.es/deportes/baloncesto-00163/noticia-baloncesto-joan-sastre-cajasol-banca-civica-experimenta-importante-mejoria-lesion-espalda-20111117184402.html>

¹⁶ 21-9-2011 <http://www.el-nacional.com/noticia/1838/2/Vinotinto-en-la-altura.html>

I.3 Courts and ozone

Physicians who practice ozone therapy have also been brought to the courts and the information has had an impact on the media.

Argentina

An Argentine newspaper in 2009 had a headline entitled: "A woman died during ozone therapy".¹⁷ But then the autopsy showed that the person had died of a subdural hematoma. According to the medical-legal considerations

"cranial hematoma is vital, recent and consistent with falling and banging against a hard surface..., establishing that the use of medical ozone gas was not considered as a factor in the autopsy."¹⁸

Brazil

The Justice had to force a Sao Paulo hospital to practice ozone therapy to a patient. In his decision the judge authorized a doctor with his medical group to enter the hospital along with the necessary medical equipment to treat a patient with ozone therapy, as long as it was necessary.¹⁹

Spain

A private hospital with an insurer company had to compensate a patient with 180 000 Euros in 2009 because of an infection acquired in the hospital operating room during an operation on "four spaces in the lumbar spine by rhizolysis and ozone."

It must be stated however, that the complaint filed by the patient and the payment of compensation were not due to ozone therapy because "the civil liability lawsuit filed by the patient was based on 'medical malpractice.'" This point was supported by the experts who pointed out that the damage done to the patient was due to "the existence of a bad medical care during the operation."

Neither the patient through his attorney, nor medical experts who served in the process questioned the medical therapy of ozone. In addition the medical intervention was made without collection of the "informed consent for the ozone therapy operation, but only informed consent for anesthesia."²⁰

I.4 Research and ozone

There is a widely accepted view that research should be a matter of priority in ozone

¹⁷ <http://www.clarin.com/diario/2010/01/09/sociedad/s-02116417.htm> page accessed January 17, 2010

¹⁸ Nuevo Diario de Salta, Salta, Argentina, January 19, 2010

http://www.nuevodiariosalta.com.ar/diario/archivo/buscar_resultados.asp page accessed January 20, 2010

¹⁹ Régis Rodriguez Bonvicino, 1ª. Vara Civil, Foro Regional XI Pinheiros, Tribunal de Justiça do Estado de São Paulo. 17 fevereiro 2011

²⁰ <http://www.europapress.es/madrid/noticia-ruber-internacional-indemnizara-180000-euros-paciente-infeccion-hospitalaria-20091210163040.html> page accessed December 11, 2009

therapy, as in the vast majority of medical fields and for the general improvement of human knowledge.

Researchers devoted to the issue of ozone are unanimous in indicating that the field still needs much more research, knowing that it is endless. The meager financial support provided for the investigation of ozone therapy is quite small compared to the work that needs to be done and this constitutes a serious challenge for randomized and controlled research. However ozone therapy research is carried out in different parts of the world.

In 2010 the first meta-analysis occurred that took into account the results of 20 clinical studies on the applications of ozone in the herniated disc. The results showed that ozone was effective and extremely safe.²¹ A second meta-analysis was released in 2012 in a high impact factor journal, which analyzed the results of eight studies and four randomized clinical trials.²²

Meta-analysis investigations have great value as scientific evidence because they are not the result of a single research but put together mixed results. For the first time, the value of ozone therapy was established following criteria from evidence based medicine. In lumbar disc herniation: 1) for paravertebral ozone therapy, the level of evidence was II-1 and the grading of recommendation was I-B; 2) for intradiscal ozone therapy, the level of evidence was II-3 and the grading of recommendation was I-C.

The Spanish newspaper ABC reported on the research that was advancing in the Hospital Doctor Negrín of Las Palmas, Canary Islands

"(...)as the effectiveness of ozone therapy to address some diseases has been tested [the current research aims]to contrast the efficacy of treatments of a herniated disc with ozone compared to traditional surgery. Bernardino Clavo, oncologist of the Dr. Negrín University Hospital, told EFE that ozone therapy is already effective in treating sicknesses such as arthritis, cancer, or necrosis, so now it is time to certify its validity for the treatment of disc hernia."²³

The number of clinical studies on ozone therapy has increased dramatically. While only two trials were recorded in the database in 1997, by 2007 the number had risen to 243.²⁴

After consulting three different sources (cochranelibrary / MedLine / Clinicaltrials gov²⁵) on September 24, 2017 the estimate accumulated number of ozone therapy clinic

²¹ Jim Stepan, Thomas Meaders, Mario Muto and Kieran J. Murphy. A Metaanalysis of the Effectiveness and Safety of Ozone Treatments for Herniated Lumbar Discs. *J Vasc Interv Radiol* 2010; 21:534–548

²² Francisco N. De Oliveira Magalhaes, MD, Luciana Dotta, MD, Andre Sasse, PhD, Manoel J. Teixeira, MD, PhD, and Erich T. Fonoff, MD, PhD. "Ozone Therapy as a Treatment for Low Back Pain Secondary to Herniated Disc: A Systematic Review and Meta-analysis of Randomized Controlled Trials". *Pain Physician* 2012; 15:E115-E129 • ISSN 2150-1149

²³ 19-1-2011. <http://www.abc.es/agencias/noticia.asp?noticia=658763>

²⁴ L. Re, G. Martínez-Sánchez, G. Malcangi, A. Mercanti, V. Labate. Ozone Therapy: a Clinical Study on Pain Management. *International Journal of Ozone Therapy* 7: 37-44, 2008.

²⁵ <http://onlinelibrary.wiley.com/cochranelibrary/>
<http://clinicaltrials.gov/ct2/home>

researches up to 2017 would be 292, of which 279 have ended and the remaining 13 are still underway.

At present the new regulations for clinical trials establish that the results should be available in public databases. At this time the public database of clinical studies from the National Institutes of Health, U.S. records the following 21 researches in progress:²⁶

1. Implication of Two Doses of O₂-O₃ Upon the Pain Alleviation in Patients with Low Back Pain (Egypt).
2. Methylene Blue and Ozone in Early Sepsis. (Egypt)
3. Variable Approaches of Intradiscal O₃-O₂ Injection (Egypt)
4. Effect of Ozone Gel on Treatment of Chronic Periodontitis. (Egypt)
5. The Effect of Epiduroscopy and Ozone Therapy in Patients With Failed Back Surgery Syndrome (Brazil)
6. Ozone Therapy in Endodontic Practice, in Vivo Study (Brazil)
7. Clinical Trial to Evaluate the Efficacy and Safety of the Use of Ozone Versus Sunflower Oil in Treating Diabetic Foot (PHIOZO0110) (Brazil)
8. Ozone Therapy in the Treatment of Digital Ulcers in Patients with Systemic Sclerosis (India)
9. Local Application of Ozone Gas for Infected Ulcers (India)
10. Clinical Effects of Ozone Therapy in Cervical Disc Hernia (Turkey)
11. Ozone Therapy for Masticatory Muscle Pain (OTMMP) (Turkey)
12. Ozone Therapy as an Adjunct to the Surgical Treatment of Peri-implantitis. (Turkey)
 13. A Trial of Percutaneous Lumbar Discectomy Combined with Ozone for Treatment of LDH (China)
 14. Efficacy of Medical Ozone Therapy in Patients with Chronic Hepatitis B (China)
 15. The Effect of Ozone Therapy for Lumbar Herniated Disc (Spain)
 16. Ozone Therapy in Patients on Waiting List for Surgery Due to Disc Herniation: Prospective, Post-authorization Study (O3HDCIRUGIA) (Spain)
 17. Intraarticular Ozone Therapy for Pain Control in Osteoarthritis of the Knee (Israel)
 18. Safety and Effectiveness Study of the AO-1000 Device to Treat Contained Herniated Discs (Canada)
 19. Healozone Study to Evaluate the Safety and Efficacy of the Use of Ozone for Management of Dental Caries (United States)
 20. Study on the Effects of Oxygen-ozone Therapy on Back Pain in Subjects Aged 65 or Older (O₂-O₃) (Italia)
 21. Grand Autohemo-Therapy with Oxygen-ozone on Patients With Hypertonia (HAB) (Germany)

Dr. Bernardino Clavo summarized the research difficulties due to lack of financial support as follows:

<http://www.ncbi.nlm.nih.gov/pubmed>

²⁶ <http://clinicaltrials.gov/ct2/home>

"Working in this field of medicine is 'very difficult' because there is no industry support, and also because 'ozone is very cheap' but 'not available in pills.' He added that the 'ozone is not a drug and 95 percent of the research done in medicine is based on drugs', promoted by large pharmaceutical companies." ²⁷

"Ozone is inexpensive and, unlike conventional medications, it is not patentable and it cannot be conveniently packaged and marketed... The main role of ozone therapy is not to replace pharmacotherapies but to improve the clinical results that they can offer in several diseases. ... If ozone is presented as a potential partner (rather than a threat) would ozone therapy receive support from the pharmaceutical industry, at least in setting-up clinical trials teams? Perhaps not; and, as such, other ways to continue ozone-research need to be explored." ²⁸

ISCO3 (International Scientific Committee of Ozone Therapy) is contributing to the research. Up to now this committee, since its foundation on 2010, has issued more than 50 papers (all of them in English and a few ones have been translated into Spanish). Spanish) in the following subjects:²⁹

Global reference document: The Madrid Declaration on Ozone Therapy

Good clinical practice papers

Clinical Applications

Laboratory Analytic

Reference Documents for Recognition and/or Regularization of the Ozone Therapy by the Health Authorities

Continuing Education on Ozone Therapy

Forms & Templates

Pioneers of the Modern Ozone Therapy

It is worth remembering that ISCO3 documents are only recommendations which may become source of guiding and reference to all those who practice ozone therapy. However, it is up to each ozone therapist to follow or not the recommendations issued by ISCO3.

To contribute to the ongoing research ISCO3 has set up the "Ozone Therapy International Library". It keeps updated a library with all published and presented papers on ozone therapy. It contains more than 2586 scientific publications, books and papers. The data base is growing-up day by day. Almost everything related to ozone therapy may found in this library or at least indications where is possible to get it. It is an online and of free access library.³⁰

²⁷ 19-1-2011. <http://www.abc.es/agencias/noticia.asp?noticia=658763>

²⁸ Bernardino Clavo, Norberto Santana-Rodriguez. Are we ready for a medical ozone challenge? Journal of Experimental and Integrative Medicine. 2012; 2(3): 189-191. doi: [10.5455/jeim.170612.ed.014](https://doi.org/10.5455/jeim.170612.ed.014). <http://www.ejmanager.com/mnstemps/4/4-1338413059.pdf?t=1352029085>

²⁹ <http://isco3.org/officialdocs/>

³⁰ <http://isco3.org/>

I.5 Prohibition and prosecution of ozone therapy

There have been cases where ozone therapy practice is not allowed and / or health professionals have been the subject of administrative or judicial investigation. Even ozone therapy equipment has been confiscated by the authorities. The examples are varied and have been occurring in different countries.

Spain

The Autonomous Community of Madrid in Spain from 2006 until March 9, 2009 banned the practice of ozone therapy in outpatient private clinics. Initially by a purely verbal order then the community was obliged to put it in writing on May 20, 2008. During the term of the ban, ozone therapists had been inspected and were prohibited from practicing ozone therapy; follow-up inspections were made to verify that they were complying with the ban. They were warned that in case of non-compliance with the order, they would be subject to punitive measures and / or precautionary measures in accordance with current legislation (Law 12/2001 of December 21, Art. 144).

In its letter of 20 May 2008 the Community of Madrid formalized its prohibition policy saying

"In general, the topical administration of ozone carries no special effects, and can be performed in private facilities, however in the case of the application of ozone therapy through invasive methods many accidents have been described, which prevent authorization in such centers (...) The available evidence on treatment with ozone therapy is insufficient to recommend its widespread use."³¹

The ban remained in effect until March 9, 2009 when it was not only lifted but its practice was authorized and regularized in private outpatient clinics.³²

Brazil

Dr. Heinz Konrad who introduced ozone therapy in Brazil in 1975, was indicted five years later by the Regional Council of Medicine of the State of Sao Paulo for spreading a therapeutic method "unofficially recognized" and therefore was in violation of sections of the current code of ethics. However, the plenary of the Regional Council ruled that ozone therapy had not violated the ethical code.³³

Then a group of doctors reported him to the same Regional Council of Medicine of the State of Sao Paulo arguing that ozone therapy only served to make an economic profit, and that the medical treatment did not appear in the "respectable medical literature" and

³¹ Madrid. Comunidad de Madrid, Consejería de Sanidad, Dirección General de Ordenación e Inspección, Subdirector General de Autorización y Acreditación, Enrique Alexandre Royo. Letter of May 20, 2008 addressed to a Roberto Quintero Mariño. www.aepromo.org, members area, legislation, Spain.

³² Madrid. Comunidad de Madrid, Consejería de Sanidad, Dirección General de Ordenación e Inspección. Director General de Ordenación e Inspección, Manuel Molina Muñoz. Letter of March 9, 2009 addressed to AEPRMO. www.aepromo.org, members area, legislation, Spain.

³³ Konrad Heinz, "Considerações a respeito da legalidade da ozonioterapia no Brasil", 2009. Document sent by the autor to Roberto Quintero.

that his procedure was not ethical or legal. After two years of facing disciplinary proceedings the council closed the case.³⁴

Egypt

As pioneers, the Egyptian Ministry of Health in December 1999 regularized the practice of ozone therapy. Despite the progress achieved, the regularization ended in February 2008 when the practice was banned in private centers, due to the significant economic slowdown that pharmaceutical companies were experiencing because some pharmaceutical products were less purchased due to the effectiveness of ozone therapy.³⁵

United States

In California the FDA (Food and Drug Administration) seized 79 ozone generators from the Applied Ozone Systems Company on January 30, 2010.³⁶

I.6 Legal delay and ozone therapy

The foregoing description of events in different parts, for or against the practice of ozone therapy is indicative of the importance that therapy is acquiring.

However, the increasing use of ozone therapy and medical advances are not on par with regulatory developments. Despite the legislative intent that countries may have, in the vast majority of cases, for reasons of various kinds, laws cannot or do not want to go at the pace of innovative development that scientific advances show. The spectrum policy is overdue on what should be legislated, to the extent that it may even become an obstacle to scientific progress in the area of health.

Spanish legislators were well aware of this finding when the preamble of the General Law of Health noted that:

““It is indeed an easily verifiable historical fact that the answers of government authorities to challenges brought by the people on health problems have always been behind the changing needs without reaching them. Health structures have always been inadequate for the needs of each succeeding period of time.”³⁷

The "easily verifiable historical fact" referred to by the Spanish legislators, can be applicable to many countries around the world for observing the gap between the

³⁴ Konrad Heinz, "A história do ozônio medicinal no mundo e no Brasil", 2009. Document sent by the autor to Roberto Quintero.

³⁵ Dr. Nabil Mawsouf. Interview with Roberto Quintero, June 4, 2010.

³⁶ <http://www.news-medical.net/news/20100130/US-Marshals-seize-unapproved-ozone-generators-from-Applied-Ozone-Systems.aspx>, pág. consultada 5-2-2010

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm199322.htm>

Page accessed February 18, 2010

³⁷ Ley 14/1986, de 25 de abril, Ley General de Salud, Boletín Oficial del Estado (BOE), España, 102/1986 del 29/4/1986. Preámbulo.

advancement of ozone therapy and the policies developed by health authorities. In fact very few countries have been interested in providing ozone therapy with minimum legal coverage.

II.FOR THE REGULARIZATION OF OZONE THERAPY

II.1 To regulate or not to regulate

In general terms two lines of thought on how to address the issue of ozone therapy within a legal framework can be established to be recognized as a valid therapy and therefore be accepted by the authorities, judges, insurance companies, patients and society in general.

One line of thought is posed by the urgent need to equip ozone with the requirements that allow its practice within a previously determined legal framework.

The other line of thought is the one which proclaims that it is best not to stir the waters and therefore not come face to face with the authorities. To approach them may have negative consequences as the authorities may decide to ban the practice. The best, according to this line of thought, is to continue working in a more or less underground way.

This research was carried out in order to support the work being done in different parts of the world, so that ozone therapy, sooner than later, would be widely recognized and accepted by the competent bodies. In our view, it is necessary that the building of ozone therapy is constructed on solid foundations at both the medical and the legal levels because any health administrative action against ozone may cause the collapse of what has been built so far.

The regularization must serve the patient, as he or she will be the first to benefit; the health professionals who apply it; the companies and the laboratories that manufacture and distribute various equipment and materials necessary for the use of medical ozone; the health authorities so that they can fulfill their role in managing the medical practice; and the general public to know that there is a regularized and beneficial therapy.

To this end we invite the national associations of ozone therapy to take the necessary steps to request the competent state body to recognize the practice of ozone therapy. One of the measures to be taken is to compile a scientific, medical and legal document to present to the authorities. The recognition process is slow, complex and difficult. But we must take the first step.

Valuable support is in the "Declaration of Madrid on Ozone Therapy " which its first edition was adopted at the "International Meeting of Schools of Ozone Therapy ", held at the Royal National Academy of Medicine in Madrid on June 3 and 4, 2010 under the

auspices of the Spanish Association of Medical Professionals in Ozone Therapy (AEPROMO).

The second edition of the Declaration was approved by ISCO3 on May 10, 2015 and officially presented at the “International Meeting of the Madrid Declaration on Ozone Therapy” held at the Royal Academy of Medicine in Madrid on June 12th, 2015, under the auspices of ISCO3 (International Scientific Committee of Ozone Therapy) and the administrative and logistical support of AEPROMO (Spanish Association of Medical Professionals in Ozone Therapy). The declaration is available in 11 languages so far.³⁸ The official version is the English one.

The "Madrid on Ozone Therapy" is the first and document of consensus in the global history of ozone therapy, and has become the only document of ozone therapy truly international and greatly accepted in the world.

The Declaration already states a specific objective regarding the legal status of therapy by indicating in its sixth conclusion the following:

“To encourage the different associations to work in their own countries where ozone therapy has not yet been regularized to get it properly regularized and therefore to enjoy a legal status.”

For this purpose, as stated in the Declaration itself, it should be noted that

"Ozone therapy is a ‘medical act’ and should be practiced by medical personnel and implemented with a scientific rigor”.³⁹

The Declaration is the guiding and working document of ISCO3 and it is a living document. This committee has the responsibility of updating it every five years, to keep it in accordance with the scientific research on ozone therapy conducted in the entire world. The next update will be in 2020. And as it had been done for the 1st and 2nd editions ISCO3 will make an international call asking ozone therapists around the world to provide their suggestions, comments and proposals for the updating. Based on them and the internal inputs provided by the members of the committee, ISCO3 shall approve the 3rd edition in 2020.

III. COUNTRIES THAT HAVE REGULARIZED THE PRACTICE OF OZONE THERAPY

Despite the time elapsed since the discovery of medical ozone so far, very few countries have decided to include it into their legal structures. However, it is worth emphasizing

³⁸ Printed Versions: English, Spanish.

Electronic Versions: Arabic, French, German, Greek, English, Portuguese, Spanish, Japanese, Russian, Italian, and Turkish. <http://isco3.org/madrid-declaration-on-ozone-therapy-2nd-edition-2/>

³⁹ Madrid Declaration on Ozone Therapy, ISCO3, 2nd. ed. 2015, annex, item 5.

that in all countries where it is practiced today, if there is no legal backing, ozone therapy is widely tolerated. The tolerance has greatly facilitated the daily work of health professionals, and the patients have benefited from the practice of good therapy. Although the tolerance for ozone therapy has to be considered as highly satisfactory, it is not sufficient. It is necessary to establish minimum rules for the practice of ozone therapy, so all actors involved know in advance what to expect.

Currently Greece, Ukraine, Italy (3 regions), China, Russia, Spain (15 autonomous communities), Cuba, Oman, United Arab Emirates (1 Emirate: Dubai), Portugal, Turkey and Brazil (in dentistry), in total twelve countries, have laws, or decrees, or administrative regulations, or judicial decisions, or guidelines or letters from the health authorities, which are specifically related to the practice of ozone therapy.

As pioneers, the Egyptian Ministry of Health in December 1999 regularized the practice of ozone therapy. Despite the progress achieved, the regularization ended in February 2008 when the practice was banned in private centers, due to the significant economic slowdown that pharmaceutical companies were experiencing because some pharmaceutical products were less purchased due to the effectiveness of ozone therapy.⁴⁰

III.1 GREECE - Pioneer in the regularization of ozone therapy in the world (1991 and 2014)

In the first edition of this paper in 2012 we had written that Russia had been “the first country in the world to adopt legal decisions on ozonotherapy”. But new research obliged us to write in the 2015 second edition that Ukraine appeared to be “the first country of the world to have passed provisions specifically related on ozone therapy in 2001.” However, new research permits to say the Greece actually is the first country to have adopted provisions on ozone therapy, before than Ukraine and Russia.

Greek Presidential Decree 157 of 1991⁴¹ on the "Increase in remuneration derived from medical visits, as well as medical and dental practices" establishes a list of therapies and what should be charged for each one.

Ozone therapy is included in the chapter of Vascular Surgery (epigraph II): Intra-arterial Ozone Therapy (section 48) and External Ozone Therapy (Section 62). It means that these two procedures that use medical ozone were authorized because both were included in the list of medical practices and the price to be charged for them.

Later, it seems that the practice of ozone therapy for painful musculoskeletal syndromes and only for hospital use was authorized.⁴²

⁴⁰ Dr. Nabil Mawsouf. Interview with Roberto Quintero, June 4, 2010.

⁴¹ FEK (Diario Oficial Griego), 30 de abril 1991, páginas 1033 y 1034

⁴² We have not found which governmental body issued this authorization nor its date.

<http://codesfordoctors.gr/ICD10-search->

Then another step forward of great significance took place. The Minister of Health on August 29, 2014⁴³ made official the decision that had been adopted by the Central Health Council (KE.S.Y, for its acronym in Greek) "on the method of ozone therapy". In accordance with this decision Greece extended the spectrum of the application of ozone therapy to all specialties and diseases in both the public and private sectors. The Minister of Health makes explicit reference to the inclusion of ozone therapy in the FEK (Greek Official Journal) 157 / A / 1991 relating to medical methods; In addition, it points to major and minor autohemotherapy, to intramuscular and intraarticular ozone injections, specifying that

"they are globally known methods, that they are not only applied in lymphatic diseases, but are proposed and recommended for all medical specialties, providing better results and without side effects for the patient ." To practice it requires that "the person who is responsible for its application has to be a good connoisseur of such medical practice."

In this way ozone therapy in Greece is authorized to apply it in all specialties and diseases, both in the public and private sector. Requirement: Whoever applies it "has to be a good connoisseur of such medical practice."

III.2 UKRAINE (2001 and 2014)

Ukraine appears to be the second country of the world to have passed provisions specifically related on ozone therapy in 2001 and which still are in force.⁴⁴ A new updated document "Guidelines" was issued in 2014.⁴⁵

The 2014 "Guidelines" 51 pages long document includes the following titles: Introduction, therapeutic effects of ozone therapy, methods of ozone therapy, the use of ozone therapy in various diseases, indications and contraindications to apply ozone therapy, ozone therapy equipment, and conclusions.

The Guidelines states that medical ozone is easy to use, reduces mortality and the

ICD.php?searchType=3&query=%CE%9F%CE%96%CE%9F%CE%9D%CE%9F%CE%98%CE%95%CE%A1%CE%91%CE%A0%CE%95%CE%99%CE%91

⁴³ [ΑΔΑ: 7Γ10Θ-Θ78]ΑΔΑ: 7Γ10Ζ-Ζ78 . Admission by the Minister of Health of decision No. 21 adopted in the plenary session 246 / 25-06-2001 of the Central Health Council (KE.SY Directorate of Development of the Health Unit, Ministry of Health and General Directorate of Services of Health, Directorate General of Health Services, Athens, 29-8-2014, Protocol No. Y4a (oik.75108

https://www.google.es/search?q=%CE%91%CE%94%CE%91+7%CE%9310%CE%98-%CE%9878&rlz=1C1PRFB_enES493ES493&oq=%CE%91%CE%94%CE%91+7%CE%9310%CE%98-%CE%9878&aqs=chrome..69i57.399j0j7&sourceid=chrome&es_sm=93&ie=UTF-8&gws_rd=ssl

⁴⁴ Medical Ozone Guidelines. Ministry of Health of Ukraine, Health Services of Department. Guidelines, Kiev, 2001. Non official translation made by Aepromo (Spanish Association of Medical Professionals on Ozone Therapy) from Ukrainian into English. www.aepromo.org, members area, legislation, other countries.

⁴⁵ Medical Ozone Guidelines. Ministry of Health of Ukraine, Centre for Scientific Medical Information and Patent and License Work. Guidelines, Kiev, 2014. Non official translation made by Aepromo (Spanish Association of Medical Professionals on Ozone Therapy) from Ukrainian into English. www.aepromo.org, members area, legislation, other countries.

degree of disability. It adds that ozone therapy provides a faster clinical effect; lower doses of drugs, reduces the duration of hospital treatment and the frequency of recurrent hospitalizations. It improves the quality of life of patients. The medical ozone has a strong therapeutic effect. It enumerates and explains in great detail the different accepted methods of application of the therapy, adding what are the indications and contraindications for its use.

It analyzes the requirements of ozone therapy generators, the conditions for test equipment medical ozone generators. It classifies medical ozone generator in first and second class.

Actually the “Guidelines” is a manual for practicing ozone therapy. To our knowledge is the only country that through an official document provides detail information, directives, proposals and instructions on ozone therapy.

III.3. ITALY (2003, 2006, 2007, 2009)

The Italian legal analysis requires a review of national and regional government regulations; and court decisions on ozone, which have reviewed government regulations owing to appeals lodged by health professionals before the judiciary.

Out of 20 Regions that the country has, three have regularized the ozone therapy, being the first one Lombardy Region in 2003.

III.3.1 Government regulations

The Superior Council of Health under the Ministry of Health, in a 2004 letter to the Minister of Health to respond to a request from the Federazione Italiana di Ossigeno-Ozono Terapia (FIO), stated that it had reinforced

“The hypothesis that some serious side effects, verified through the years (for example, deaths from air emboli, and vagal crises) are not specific but rather attributable to negligence, incompetence or procedural errors, and not to the presence of ozone in the mixture.”

In a "Consensus Conference" in 2006, gathered under the coordination of the Higher Institute of Health, technical and scientific public body of the Italian National Health Service under the Ministry of Health, representatives from academia, hospitals, the Società Scientifica di Ossigeno Ozono Terapia (SIOOT), and the Rome Province College of Physicians to explore the possibility that ozone could play a role in the treatment of disc herniation lumbociatalgias by paravertebral intramuscular injection within properly regulated and precise specifications.⁴⁶

⁴⁶ Conferencia de Consenso, Presidente Santilli Valter, Oxígeno-ozono terapia en el tratamiento de las lumbociatalgias por hernia discal con técnica inyectiva intramuscular paravertebral, Instituto Superior de Sanidad, Roma, 20 noviembre 2006. Informes ISTISAN 08/9, ISSN 1123-3117.

In its recommendations the "Consensus Conference" specified when ozone therapy could be used:

"For the treatment of sciatica for herniated disc non eject, it is recommended to follow as first choice, therapeutic interventions internationally coded, as indicated by the main international guidelines (...)

"After a month of conservative therapy, it is indicated that sending the patient to the surgeon when the severe and disabling sciatica, continues without improvement or with deterioration. Before a month of conservative therapy it is recommended sending the patient to the surgeon only if there is neurological deterioration, or if the pain is severe and resistant to any conservative treatment."

But if

" (...) the patient, due to the clinical condition (severe comorbidity, serious deficiencies that contraindicate organ surgery) or by personal choice does not wish to undergo surgical therapy, or in cases of non-response to medical therapy oxygen-ozone therapy intradiscal or intraforaminal or by intramuscular paravertebral injection may be used for pain control."

It advises to obtain the written informed consent of the patient:

"In the consent form it must be stated that the practice of oxygen-ozone therapy via intramuscular paravertebral still has no sure evidence of efficacy according to the criteria established by the Evidence Based Medicine."

It recommends acting according to a standard protocol

"(...) during the implementation of the therapy with oxygen-ozone via intramuscular paravertebral (...) to follow a standard protocol described by SIOOT [Societa Scientifica di Ossigeno Ozono Terapia] [it could be perfectly extended to any other scientific organization of ozone therapy]".

It states that the physician should act according to his/her own responsibility, knowledge and belief, performing the medical practice of ozone therapy fulfilling basic requirements regarding training, the equipment and conditions of the facility, and acting in accordance with therapeutic protocols.⁴⁷

III.3.2 Italian Regions

Lombardy Region (2003)⁴⁸

<http://www.iss.it/publ/rapp/cont.php?id=2173&lang=1&tipo=5&anno=2008>

⁴⁷ Recommendations. Consensus conference. Lumbar paravertebral intramuscular injection of oxygen-ozone in radicular pain caused by herniated lumbar disc. Istituto Superiore di Sanità. Rome, November 20, 2006. Informes ISTISAN 08/9, ISSN 1123-3117. pp. 30 y 31

<http://www.iss.it/publ/rapp/cont.php?id=2173&lang=1&tipo=5&anno=2008>

⁴⁸ Regione de Lombardia. Lucchina Carlo, Director General, Regional Board, General Health Directorate,

The Region of Lombardy (Milan capital) based on a decision of the Regional Administrative Court (TAR) of Lazio of September 26, 1986 and referring to the Ministerial Circular of December 31, 2002, on ozone therapy, indicates the following concerning the use of private medical services:

"[The circular] does inhibit and therefore does not interfere with the activity of therapeutic practice with the use of oxygen- ozone therapy performed by outpatient private clinic services; (...)

"It is considered in turn:

"That for the ambulatory practice, the informed consent shall be obtained from the patient undergoing the procedures of oxygen- ozone therapy;

"That all equipment used for treatment have obtained the CE certification, as required by Executive Decree 48/97;

"That the practice of oxygen- ozone therapy must not be performed in such places as beauty and fitness centers .

"It is further recommended that appropriate training courses be organized for physicians who practice oxygen- ozone therapy."

On the use of ozone therapy in public centers it said the following:

"Regarding the use of oxygen- ozone therapy in accredited facilities or under contract with the Regional Health System, it specifies that the therapeutic indication for intradiscal injection, quoted in the Ministerial Circular, has to be interpreted in the broader sense and thus not as referring exclusively to the intradiscal injection, but including the operating equipment provided in the Guidelines already identified by the Italian Scientific Society for Oxygen- ozone Therapy. It shall be understood as including, therefore, the operational procedures relating to ozone intramuscular injections, paravertebral, intraforaminales, periganglionares and episacrales."

Emilia-Romagna Region (2007)⁴⁹

In 2007 the Emilia-Romagna Region in northeastern Italy (capital Bologna), said that the practice of the ozone therapy is exclusively the responsibility of the physician who performed it.

Marche Region (2009)⁵⁰

A note from the Marche Health Service in 2009, makes a significant clarification about the practice of ozone therapy in private outpatient facilities.

"1. The practice of O.O.T. [Oxygen- ozone therapy] can be performed in private

Region of Lombardy. Fax of March 11, 2003 sent to various health organizations and to the Police Directorate for Health Protection (NAS) of Lombardy. www.aepromo.org. Members area, legislation, other countries.

⁴⁹ Regione Emilio-Romagna. Sciarrone Franca, Dipartimento di Sanità Pubblica, Servizio Sanitario Regionale Emilio-Romagna, Parma, 20-9-2007. International Journal of Ozone Therapy, World Federation of Oxygen-Ozone Therapy (WFOOT), volume 7 No. 1, April 2008.

⁵⁰ Regione Marche. Ruta Carmine, Servizio de Salud, Región Marche, Prot. N. 107395/S04/CR, Ancona, 23 de febrero de 2009. Document sent to Police Directorate for Health Protection. www.aepromo.org. Members area, legislation, other countries.

facilities for outpatient services provided they do not violate the norms, regulations or priorities provisions of the Health Authority, (...)

"To summarize, we can state that the authorization issued to outpatient services, whether medical or surgical, does not prevent, in the field of activity they develop, the practice of oxygen- ozone therapy since there is no policy or regulatory impediment whatsoever, nor is there any mandatory provision issued by the Health Authority."

III.3.3 Court Rulings

The Italian courts have also ruled on the practice of ozone therapy in private centers. A group of physicians, through solicitors, petitioned the courts the "stay of execution" of the Directive 14/3/96 900-2/72/191 issued by the General Hospital Directorate. The court rejected "the suspension incidental claim" and did not enter into the merits of the application on the grounds that

"(...) for lack of the requirement of the serious and irreparable harm, as stated by the State Legal Advisers, shared by the defense of the appellants, in which the content of the circular contested does not inhibit, and in any case does not interfere in the therapeutic practice activity performed in private outpatient centers."⁵¹

The important point of this ruling is that both the defendant - the Italian government through the State Legal Advisers, and the plaintiff - the physicians through their solicitors - were in agreement that the circular did not inhibit or interfere with the practice of ozone therapy in outpatient private clinics.

Later on, another group of physicians called for the nullification, prior to the adoption of precautionary measures

"(...) of the Circular. No. 0000988 - P, 31.12.2002 of the Ministry of Health - General Directorate of Information and Statistical and Structural Investment and Technology - Office IX - Medical Devices."

As in 1996, the Court rejected the request of physicians, to consider

"(...) the prejudice against the appellant's complaint does not present serious and irreparable character as that according to the statement of the State Legal Advisers, the experimental activity (...) can also be performed in outpatient private clinics (...) that fall within the scope of the DM of April 27, 1982."⁵²

Although the ruling did not enter into the substance of the discussion, its importance is that the Court favors the activity of ozone therapy on an experimental basis in outpatient

⁵¹ Tribunale Amministrativo Regionale per il Lazio, Sezione Prima, Ricorso N.° 10309/96, Roma, 26/9/96. www.aepromo.org. Members area, legislation, other countries.

⁵² Tribunale Amministrativo Regionale per il Lazio, Sezione III Ter, Ricorso Ord. N. 1298/03, Roma, 13/5/03. www.aepromo.org. Members area, legislation, other countries.

private clinics.

III.3.4 Conclusions on the regularization in Italy

Italy is a country where ozone therapy has a growing acceptance by both the administration and the judiciary; both nationally and in some regions. Nationally the Ministry of Health - through the Superior Health Council - has accepted that ozone therapy can be practiced in the treatment of sciatica for herniated disc non eject if "the patient, due to the clinical condition (severe comorbidity, serious deficiencies that contraindicate organ surgery) or by personal choice does not wish to undergo surgical therapy, in cases of non-response to medical therapy it may be used for pain control oxygen- ozone therapy intradiscal or intraforaminal or by intramuscular paravertebral injection."

It advises "to obtain the written informed consent of the patient (...)"

It states that the physician should act according to his/her own responsibility, knowledge and belief, performing the medical practice of ozone therapy fulfilling basic requirements regarding training, the equipment and conditions of the facility, and acting in accordance with therapeutic protocols.⁵³

Moreover, ozone therapy is widely tolerated in private outpatient clinics.

At the regional level, three administrations have spoken in favor of the private practice of ozone therapy. The Emilia-Romagna Region has determined that the practice of ozone therapy is the sole responsibility of the physician. In Lombardy it can be practiced in private outpatient clinics under condition of the patient's informed consent, that the equipment used is certified by the European Union. It prohibits its practice in beauty and fitness centers; and recommends the organization of appropriate training courses for physicians who practice oxygen- ozone therapy. In the Marche Region it can be performed "in private outpatient center clinics provided they do not violate the rules, regulations or priorities of the Health Authority" and clarifies that there are no rules preventing the practice of ozone therapy.

The rulings of the Administrative Tribunal of Lazio are accurate in stating that the guidelines of the Ministry of Health do not inhibit, and do not interfere in the therapeutic practice activity performed in private outpatient centers, as long as there is no serious and irreparable damage done.

⁵³ Recommendations. Consensus conference. Lumbar paravertebral intramuscular injection of oxygen-ozone in radicular pain caused by herniated lumbar disc. Istituto Superiore di Sanità. Rome, November 20, 2006. Informes ISTISAN 08/9, ISSN 1123-3117. pp. 30 y 31
<http://www.iss.it/publ/rapp/cont.php?id=2173&lang=1&tipo=5&anno=2008>

III.4 CHINA (2005)

Its practice was introduced in 2000 by Professor Dr. He Xiaofeng from the Nanfang Southern Medical University Hospital in Guangzhou; and in 2005 it was organized the 1st. National Conference of the China Federation of Ozone Therapy. The approximate number of ozone therapists might be 5 000, according to the number of medical generators bought. So China ranks second in the world after Germany, by number of professionals who practice ozone therapy.

Ozone Therapy is applied in different medical areas such as surgery, pain intervention, internal medicine, gynecology, dentistry; and in a wide area of diseases which include disc herniation, joint disease, viral hepatitis, drug-induced hepatitis, diabetic foot, burns, acne, non-Hodgkin's lymphoma, hyperlipidemia, gout, mouth ulcers, psoriasis, bronchial asthma, vaginitis, etc. Basal studies and clinical trials revolving ozone therapy have been conducted.⁵⁴

Ozone therapy is written in Chinese as "blood therapy". This

“may only be applied if the basic clinical research phase at national or international level has been successfully completed and the safety and effectiveness of its clinical use has been confirmed.”

It “may be used for the treatment of bacterial infection, fungal infection, viral infection, immunity dysfunction and intoxication, etc. In the treatment process the instructions of the Clinical Operation Rules, chapter on Physiotherapy and Rehabilitation Medicine, published by the Chinese Medical Association must be followed.”

“ ‘Blood therapies’ which have passed the basic research phase but the safety and effectiveness of which in clinical application has not been confirmed or is still open to doubt, these must be approved by the health authorities at provincial level.”⁵⁵

III.5 RUSSIA (2005 and 2007)

Russia has adopted legal decisions authorizing the use of ozone therapy in all its territory. In this country, it is widely used in public health facilities and is taught in some universities. For several years, the Nizhny Novgorod Department of the Experimental Medical Research Institute of Traumatology and Orthopedics has devoted staff and resources to research on medical ozone issues. Nizhny Novgorod is the capital of the Federal Volga District.

⁵⁴ Professor He Xiaofeng, e-mails addressed to Roberto Quintero on April 21 and 29, 2014

⁵⁵ Notification of the Chinese Ministry of Health on Ozone Therapy (Blood Therapy) issued on March 16, 2005. Non official translation made by AEPROMO (Spanish Association of Medical Professionals in Ozone Therapy) from Chinese into English. www.aepromo.org, members area, legislation, other countries.

The Russian Federal Service Control of Health and Social Development has adopted regularizations on dermatology and cosmetology; obstetrics, gynecology and neonatology; and on traumatology.

Dermatology and cosmetology (2005)

The Russian Federal Service Control of Health and Social Development has dealt with the application of ozone therapy in dermatology and cosmetology and indicated that

“Oxygen and ozone therapy is one of the new methods applied for treatment of dermatological diseases, for the correction of cosmetic defects, as well as adjuvant anti-inflammatory and cicatrizing treatment in postoperative periods. The essence of the method is the parenteral injection and dermal application of medical ozone applied as mono therapies as well in combination therapies. Recommended methods of systemic and localized ozone therapy allow the prescription of the specific physical factor with curative and prophylactic purposes depending on the nature and duration of the disease, the intensity of the inflammatory process, the existence of additional pathologies.”⁵⁶

It may be used for:

- Cutaneous angiitis ulcerative forms;
- Chronic pigmented purpuric syndrome;
- Hives, and other urticaria dermatosis;
- Pyoderma and comedo;
- Alopecia areata.

Although multiple clinical experiences have demonstrated that side effects for the oxygen-ozone mixture are rare, the following contraindications have been indicated by the Russian federal service:

- Innate insufficiency of Glucose-6-phosphate dehydrogenase deficiency (favism);
- First stage post hemorrhagic;
- Alterations in blood coagulation;
- Thrombocytopenia;
- Hyperthyroidism;
- Acute myocardial infarction;
- Cerebral hemorrhage;
- Acute intoxication by alcohol;
- Convulsions in anamnesis;

⁵⁶ Federal Service Control of Health and Social Development, Certificate of Registration FS-2005/058 of October 4, 2005. Non official translation made by AEPROMO (Spanish Association of Medical Professionals in Ozone Therapy) from Russian into English. www.aepromo.org, members area, legislation, other countries.

- Chronic pancreatitis with frequent recurrences;
- Allergic reaction to ozone.⁵⁷

Obstetrics, gynecology and neonatology (2007)

The Russian Federal Service Control of Health and Social Development has authorized the use of medical ozone in obstetrics, gynecology and neonatology. This Federal Service has recognized

"The extensive use of ozone in the system of rehabilitation and treatment of genital and extra-genital chronic diseases, post surgery intervention in women, gynecological operations, cesarean deliveries or spontaneous abortions and in infants with transplacental infection pneumonia or catarrhal omfalitis."

It has established that ozone

"can reduce the drug load by 30%, to reduce the periods of intra-hospital stay of patients by 2-3 days and the frequency of septic complications twice as much."

It has finally pointed out

"The effectiveness of the technology is determined by the rheological improvement of the blood, by the properties of the immunological correction and by the bactericidal and virucidal action."⁵⁸

The same document authorizes the use of three ozone devices to be used in birth houses (hospitals, birth and maternity section), perinatal centers, centers for family planning and reproduction, specialized hospitals and outpatient clinics for women. The technology is aimed at doctors, midwives, gynecologists and neonatologists.

The Russian Federal Service Control of Health and Social Development clarified that ozone may be used in:

- Pregnancy complications (hyperemesis gravidarum, etc.).
- Placental insufficiency.
- Chronic viral infection (citomagalovirus, genital herpes).
- Gestosis.
- Anemia in pregnancy.
- Prevention of transplacental infection.
- Prevention of exacerbation of chronic pyelonephritis.

⁵⁷ Federal Service Control of Health and Social Development, Annex, Certificate of Registration FS-2005/058 of October 4, 2005 [in Russian]. Non official translation made by AEPRIMO (Spanish Association of Medical Professionals in Ozone Therapy) from Russian into English. www.aepromo.org, members area, legislation, other countries.

⁵⁸ Federal Service Control of Health and Social Development, Certificate of Registration FC-2007/014-y of February 15, 2007 [in Russian], addressed to the Scientific Center of Maternity, Gynecology and Perinatology (117997, Moscow, UI Oparin Academy, No 4) and to the following collaborators: Nizhni Novgorod Medical State Academy, I.M. Sechenov Moscow State Academy, and Company OOO "Medozon". Non official translation made by AEPRIMO (Spanish Association of Medical Professionals in Ozone Therapy) from Russian into English. www.aepromo.org, members area, legislation, other countries.

- Prophylaxis of post cesarean sepsis, septic deliveries, abortions complications in the first trimester.
- Chronic endometritis, appendicitis.
- Bacterial and fungal vulvovaginitis.
- Benign cervical post radiosurgical treatment.
- Prophylaxis of postoperative sepsis and post surgical suture infection in women with tubal obstruction.
- Myomectomy post operative rehabilitation.

The same Russian federal service has identified the following contraindications:

Absolute contraindications: Hyperthyroidism, bleeding, eclampsia, acute myocardial infarction, acute alcohol intoxication, allergy to ozone and psychiatric illnesses.

Relative contraindications: Hypotension and arterial hypertension, difficult venous access.

Newborns contraindications: hemodynamic decompensation, hypocoagulation.⁵⁹

Traumatology and burn treatment (2007)

The Russian Federal Service Control of Health and Social Development also adopted decisions on ozone and traumatology and burn treatment. It states the application of medical ozone and ozonized solutions

“in patients who have suffered traumatic injury, burns, traumatic complications, burn disease, who have festering and lasting wounds or osteomyelitis. The treatment according to the recommended methods can extend the range of conservative remedies for severe thermal injuries and complications after mechanical trauma and increases the chances of curing patients.”

This “medical technology is intended for specialists: Orthopedic-orthopedists, surgeons, anesthetists-resuscitators who have completed the specialization of ozone therapy.”⁶⁰

The annex of the Certificate of Registration indicates its use for

“superficial and deep burns of grades II-IV-IIIAB of dimension; infected and prolonged wounds; post traumatic and post operative osteomyelitis, as a result of a bullet; illness burn; traumatic disease.”

The Russian federal service has spelled out the following contraindications:

⁵⁹ Federal Service Control of Health and Social Development, Annex to the Certificate of Registration FC-2007/014-y of February 15, 2007 [in Russian]. Non official translation made by AEPROMO (Spanish Association of Medical Professionals in Ozone Therapy) from Russian into English. www.aepromo.org, members area, legislation, other countries.

⁶⁰ Federal Service Control of Health and Social Development, Certificate of Registration FS-2007/029-U of February 28, 2007 [in Russian]. Non official translation made by AEPROMO (Spanish Association of Medical Professionals in Ozone Therapy) from Russian into English. www.aepromo.org, members area, legislation, other countries.

“For localized ozone therapy: Individual intolerance to the components of ozone therapy; for systemic ozone therapy: external and internal bleeding, hypo-coagulative syndrome, hemophilia, thrombocytopenia, vasculitis hemorrhoid, acute myocardial infarction, cerebral hemorrhage, pancreatitis, thyrotoxicosis, individual intolerance to the components of ozone therapy.”⁶¹

III.6 SPAIN (between 2007 and 2012)

Through the semi-federal system of Spain, the Autonomous Communities have the power to autonomously develop matters in health, provided they conform to national legislation. In practice, each community adopts measures that may be different from the others. So Aepromo designed its strategy towards the recognition of the ozone therapy of going first to the bottom level (the autonomous communities) and later on to the national level. So at the bottom level and at the Aepromo request 15 autonomous communities out of 17 that has Spain, have issued "guidelines" where the regional ministries of health, through letters addressed to Aepromo, have enumerated the requirements to practice ozone therapy within their jurisdictions.

The guidelines are manifestations of judgment whereby authorities inform people of the criteria they have about an issue at a given time, indicating the requirements that people must be met to develop a particular activity.

Manifestations of judgment are, for example, expressed in the reports provided by the Administration at the request of the interested parties or the replies to consultations submitted by them; they are informative and constitute advisory elements.

In the case of ozone therapy the guidelines listed in the letters sent to Aepromo by regional ministries of health have a guiding nature in order to specify that ozone therapy can be practiced under the condition that the requisites detailed by the administration are applied by ozone therapists.

The guidelines do not have the rank of mandatory or compulsory norms because they cannot be cataloged as a manifestation of will, whereby the administration through a legal act creates a situation of subjective right.

Although the directives do not have the obligatory status due to their informative status, they are important steps forward in the future adoption of mandatory provisions. The directives indicate what is the opinion that the administration has about the ozonotherapy. The Ozone therapy had been in a legal limbo before the directives. Currently they do indicate who can practice it, under what conditions, according to what regulations, etc.

⁶¹ Federal Service Control of Health and Social Development, Annex, Certificate of Registration FS-2007/029-U of February 28, 2007 [in Russian]. Non official translation made by AEPRIMO (Spanish Association of Medical Professionals in Ozone Therapy) from Russian into English. www.aepromo.org, members area, legislation, other countries.

On the other hand we understand that regional ministries of health should be subject to the criteria listed in its guidelines to maintain continuity and unity of judgment and therefore not create defenselessness.

There are no provisions at the national level specifically dealing with ozone therapy. And due to the semi-federal system of Spain, as indicated before, each community adopts measures that may be different from the others. These differences oblige us to analyze each community separately, as the health directives may be different from one another.

Following the request of AEPRIMO (Spanish Association of Medical Professionals in ozone therapy), autonomous communities have issued written guidelines for the practice of ozone therapy in outpatient private clinics. The first community to do it was Canary Islands on October 2007. Since then the majority of the communities have adopted “guidelines” to practice the therapy of ozone.

III.6. 1 ANDALUCÍA (October 3, 2012)⁶²

This autonomous community has indicated that ozone therapy has not been banned in Andalucía. Those who request authorization for its practice will receive a generic authorization as health center or service, provided that they comply with "the different requirements of the various autonomous communities" listed by AEPRIMO in its letter sent to the Community of Andalucía and are as follows:

- Comply with the national and autonomous communities legislation for the authorization and operation of outpatient private health centers.
- Have a trained and experienced professional in the therapy.
- Include ozone therapy in the health care offerings.
- Have medical oxygen supplied by authorized companies.
- Have appropriate protocols according to the routes of application.
- Have the informed consent signed by patient and physician.
- Take into account the regulations issued by scientific associations of ozone therapy in the absence of legal regulations.
- Perform ozone therapy with full technical and scientific autonomy, without other limitations than those established by principles and legal and ethical values.

In addition, the community has said that the intradiscal application of ozone must be performed in a hospital operating room or an ambulatory surgery unit.

⁶² Andalucía. Junta de Andalucía. Consejería de Salud y Bienestar Social. Dirección General de Calidad, Investigación, Desarrollo e Innovación. Jefe de Servicio de Autorización y Acreditación de Centros, Rufino Domínguez Morales. Carta de 3 de octubre de 2012 dirigida a AEPRIMO. www.ae promo.org. members area, legislation, Spain.

III.6.2 ARAGÓN (November 18, 2010)⁶³

"In particular for the practice of ozone therapy in Aragon, health centers must meet the following requirements:

"To have a medical practitioner trained and experienced in the application of ozone therapy. If there are several physicians who meet these conditions, one of them must be the health officer of the unit, with a written acceptance of appointment. They will present a health service descriptive memory, functional organization, activities and health care offerings including the different forms of administration intended to be used.

"The equipment for the application will have the CE mark, and it will use medical oxygen supplied by an authorized company.

"They shall have appropriate protocols according to different routes of application, agreed among physicians.

"They shall have a convenient system of ventilation and aeration.

"The patient's medical history shall include a signed informed consent.

"They must have a CPR (cardiopulmonary resuscitation) kit and emergency medication.

"The intradiscal administration of ozone will be performed in a hospital operating room or a major ambulatory surgery.

"In case of performing the conscious sedation technique, it shall comply with the requirements set forth in the above Resolution" (Resolution of November 30, 2007, General Directorate of Planning and Assurance, laying down the technical requirements for the authorization centers and health services that perform conscious sedation techniques).

III.6.3 ASTURIAS (April 5, 2011)⁶⁴

Ozone therapy - says Asturias - could be placed within the "non-conventional therapies".

For practice, ozone therapy centers must comply with the legislation governing the authorization of centers and health services to get

"in the first place, the mandatory operating license of the health center, and to carry out the practice within its offering of assistance of the said technique."

If the procedure requires "specific facilities and application, for example, anesthesia or sedation," the Decree 53/2006 of June 8 must be applied concerning facilities and

⁶³ Aragón. Gobierno de Aragón, Departamento de Salud y Consumo, dirección General de Planificación y Aseguramiento, Director, Manuel García Encabo. Carta de 18 de noviembre de 2010 dirigida a AEPRIMO. www.aepromo.org. members area, legislation, Spain.

⁶⁴ Asturias. Gobierno del Principado de Asturias, Consejería de Salud y Servicios Sanitarios, Dirección General de Planificación y Evaluación, Servicio de Autorización de Centros y Servicios Sanitarios. Director General de Planificación y Evaluación, Arcadio Fernández Martínez. Letter of April 5, 2011 addressed to AEPRIMO. www.aepromo.org. members area, legislation, Spain.

equipment.

The center shall have "trained health professionals for its performance", in order that the health work "is done by professionals who have the knowledge, skills, abilities and attitudes of the related activities performed."

III.6.4 BALEARIC (October 30, 2007)⁶⁵

In the Balearic Islands

"(...) it is tolerated in the practice of private medicine in approved outpatient or non- outpatient facilities, (depending on whether outpatient treatment or hospitalization is required)."

The requirements are:

"The health center must have authorization to operate; treatment should be applied by a medical practitioner; the ozone equipment must be qualified as a sanitary product and have the CE mark; oxygen and medical oxygen should be used; the patient has to be informed about the treatment and has to sign the informed consent."

III.6.5 BASQUE COUNTRY (February 7, 2011)⁶⁶

The Basque Government indicates in its guidelines that outpatient health centers wishing

"to include in their health care offerings the therapies with ozone, in which it is not necessary to apply local or general anesthesia and / or sedation (...)

"1. Must have authorization to operate: The offering of ozone therapy practice shall be authorized within the non-conventional therapies, defined in the Royal Decree 1277/2003, as a health care unit in which a physician is responsible for performing the treatments of diseases through naturopathic medicine, or with homeopathic medicines, or by peripheral stimulation techniques with needles, or other means, which demonstrate their efficacy and safety (U.101).

"2. Must submit a descriptive report indicating the type of technique and the route of administration of the treatments provided and the scientific support referring to the evidence on the effectiveness and safety of the same.

"3. Treatment should be applied by a professional medical practitioner with training and experience in the application of ozone therapy and with civil liability insurance.

⁶⁵ Baleares. Govern de les Illes Balear, Margalida García Ordinas, Cap de Secció d' Inspecció de Centres, Est. i Serveis Sanitaris, Direcció General d'Avaluació i Acreditació. E-mail dated October 30, 2007 addressed to Roberto Quintero. www.aepromo.org, members area, legislation, Spain.

⁶⁶ País Vasco. Gobierno Vasco, Departamento de Sanidad y Consumo, Viceconsejería de Calidad, Investigación e Innovación Sanitaria. Dirección de Gestión del Conocimiento y Evaluación. Director, Gestión del Conocimiento y Evaluación, José Asua Batarrita. Letter of February 7, 2011 addressed to AEPRIMO. www.aepromo.org. Members area, legislation, Spain.

"4. The ozone equipment shall be classified as a medical device and have the CE mark.

"5. Oxygen used must be medical oxygen, which shall be proved with a supply document signed by an authorized company.

"6. It shall fill out the informed consent document, which contains: general information, indications, alternative treatments and risks of proposed procedure or treatment. This document shall be signed by the patient and the physician responsible for the practice of ozone therapy, which shall be placed in the patient's medical history.

"7. Must have appropriate protocols, depending on the route of administration, with the aim of ensuring the quality of the treatment, which will be validated and certified, which will be based on scientific evidence and means available and supported in guidelines and protocols for clinical practice and care.

"8. Must have cardiopulmonary resuscitation and sterilization / disinfection and emergency medication protocols.

"9. If the process requires the administration of general anesthesia, local/regional, with or without sedation, as in the case of the intradiscal application of ozone, the process shall be performed in a hospital operating room or major ambulatory surgery."

III.6.6 CANARY ISLANDS (October 3, 2007)⁶⁷

In the absence of legal regulations, the regulations issued by scientific associations of ozone therapy shall be taken into account.

This autonomous community has provided specific support to the research of ozone therapy and is publicly in favor of it.⁶⁸

III.6.7 CASTILLA-LA MANCHA (May 13, 2010)⁶⁹

The center to apply ozone therapy must do so in order to "promote, restore or improve the physical and / or psychological condition of people." It lists the requirements that facilities and services shall comply with:

"4. a. Meeting the legal requirements" applicable for healthcare facilities.

"b. "The report on activities shall contain the routes of administration and diseases treated.

"c. It must have a graduate in medicine and general surgery with training

⁶⁷ Canarias. Gobierno de Canarias, Salvador Raúl Ramos de la Plaza, Servicio Canario de la Salud, Dirección. Letter of October 3, 2007 addressed to. www.aepromo.org. members area, legislation, Spain.

⁶⁸ Comunicación, "El Hospital Universitario de Gran Canaria Dr Negrín pone en marcha el primer ensayo mundial con ozonoterapia para tratar hernia discal", 2 de junio de 2008

⁶⁹ Castilla-La Mancha. Consejería de Salud y Bienestar Social, Dirección General de Ordenación y Evaluación. Jefa Servicio de Inspección Sanitaria, Soledad López Sánchez-Élez. Letter of May 13, 2010 addressed to AEPROMO. www.aepromo.org. members area, legislation, Spain.

and proven experience in the application of oxygen- ozone therapy.

“d. It must have the proper equipment to meet current regulations governing it.

"e. It must have updated Standard Operating Procedures, for each of the interventions.

“f. It must have the patient’s informed consent in accordance with current regulations.

“5. In case of the application of intradiscal oxygen-ozone or another technique that requires anesthesia or sedation, it has to be performed in facilities that meet the conditions and requirements" for conscious sedation "and with the minimum equipment for fluoroscopy.

" 6. The center can not engage in misleading advertising which hints at benefits over other techniques or the cure of diseases.”

III.6.8. CASTILLA AND LEÓN (May 12, 2010) ⁷⁰

This autonomous community places ozone therapy within the framework of non-conventional health activities and it requires:

That the center meets the requirements of the law.

“it shall provide in the nature and purpose of the center explanatory reports, appropriate information on the types of techniques and the routes of the administration planned for ozone therapy, as well as the scientific support referring to the evidence on the efficacy and safety of the same.

"The training and professional experience of the responsible physician and other intervening medical staff shall be documented."

III.6.9 CATALONIA (July 8, 2010)⁷¹

It indicates that although there "is not clear scientific evidence" supporting ozone therapy treatment and "in the current classifying typology centers norms according to their authorization" there is "no one referring to ozone therapy (...)".

However

"In any case it would have only a generic approval as a health center or service that meets the current authorization rules in these cases (...) appearing [ozone therapy] specified within the health care offered by the center, and with professionals with experience in the application of the therapy."

⁷⁰ Castilla y León. Junta de Castilla y León, Consejería de Sanidad, Dirección General de Salud Pública e Investigación, Desarrollo e Innovación. Jefe de Servicio de Control Evaluación de Centros y Actividades Sanitarias, José María Fernández Fernández. Letter of May 12, 2010 addressed to AEPROMO.

⁷¹ Cataluña. Generalitat de Catalunya, Departament de Salut, Direcció General de Recursos Sanitaris. Director General, David Elvira i Martínez. Letter of July 8, 2010 addressed to AEPROMO. www.aepromo.org, members area, legislation, Spain.

III.6.10 EXTREMADURA (September 17, 2010)⁷²

It states that "health centers seeking to apply that technique [ozone therapy], must conform to the provisions of the laws" to obtain the required authorization to operate.

It adds that ozone therapy "would be considered as non-conventional therapies (...), in which a physician is responsible for carrying out such treatments."

In addition it also requires that centers have

Professionals with "specific training, licensing and liability insurance.

" Ozone therapy equipment, CE marked.

"Medical Oxygen.

"Copies of Protocols of 'Informed Consent' for the techniques offered, stating: General information, alternative treatments and the risks of the proposed procedure or treatment.

"Protocols of cardio pulmonary resuscitation (CPR) and sterilization / disinfection, and emergency drug unit."

III.6.11 GALICA (March 2, 2010)⁷³

It determines that ozone therapy is not included in the legally "defined care offerings" as a specific service offered; also it is not a specific activity requiring a health license regularization with its own regularization. So to the health center or service will be given only a generic authorization.

Ozone therapy "as with other techniques used in practice clinics" will apply the general principles "of the organization of health professions."

The practice of ozone therapy

"will be performed with full technical and scientific autonomy, without limitations other than those established in the principles and values contained in the legal and ethical code. They tend to unify the criteria for action, which will be based on scientific evidence and the means available and supported in guidelines and protocols for clinical practice and care. The protocols will be used for guidance, to guide decisions for all professionals in a team, and will be regularly updated with the participation of those who must apply them."

⁷² Extremadura. Junta de Extremadura, Consejería de Sanidad y Dependencia, Dirección General de Planificación, Formación y Calidad. Director General de Planificación, Formación y Calidad, José María Vergeles Blanca. Letter of September 17, 2010 addressed to AEPRIMO. www.aepromo.org. Members area, legislation, Spain.

⁷³ Galicia. Xunta de Galicia, Consellería de Sanidade, Secretaría Xeral. Secretario General, Roberto Pérez López. Letter of March 2, 2010 addressed to AEPRIMO. www.aepromo.org. Members area, legislation, Spain.

III.6.12 LA RIOJA (16 November 2010)⁷⁴

"The practice of ozone therapy is allowed by including it within the health care offerings of 'non-conventional therapies', defined by Royal Decree 1277/2003, as the health care unit in which a physician is responsible for performing treatments of diseases through naturopathic medicine, or with homeopathic medicines, or by peripheral stimulation techniques with needles, or other means, which demonstrate their efficacy and safety."

"La Rioja has authorized the practice of ozone therapy [underlined in the letter] in private health facilities. They must fulfill the minimum health technical requirements set out in the Annex to Decree 80/2009. If the procedure requires an operating room and the administration of general anesthesia, loco-regional or local, with or without sedation, such as the intradiscal application of ozone, these centers must be licensed in ambulatory surgery."

III.6.13 MADRID (March 9, 2009)⁷⁵

As indicated above the practice of ozone therapy in outpatient private clinics had been banned in Madrid since at least 2006. But after the substantiated and reasoned request of AEPRIMO (Spanish Association of Medical Professionals in Ozone Therapy), the Community of Madrid not only lifted the ban but regularized and authorized ozone therapy in private outpatient clinics.

The Community of Madrid states that

"the applications of therapies using ozone (ozone therapy) are therapeutic techniques practiced by medical personnel" and that "the techniques and routes of administration of ozone therapy in general, do not require complex structures and facilities or the administration of general or local anesthetics and / or sedation."

It adds that

"the outpatient health center wishing to include in its health care offerings the services with ozone, in which it is not necessary to administer local or general anesthesia and / or sedation, must be in possession of the required sanitary operating authorization (...) and in addition must also meet the following requirements:

"It will include in its health care offerings the practice of ozone therapy, indicating the different routes of administration intended to be used to treat

⁷⁴ La Rioja. Gobierno de la Rioja, Consejería de Salud, Aseguramiento, Acreditación y Prestaciones. Directora General de Aseguramiento, Acreditación y Prestaciones, Carmen Sáenz Pastor. Letter of November 16, 2010 addressed to AEPRIMO. www.ae promo.org. Members area, legislation, Spain.

⁷⁵ Madrid. Comunidad de Madrid, Consejería de Sanidad, Dirección General de Ordenación e Inspección. Director General de Ordenación e Inspección, Manuel Molina Muñoz. Letter of March 9, 2009 addressed to AEPRIMO. www.ae promo.org. Members area, legislation, Spain.

pathologies.

"It will have a licensed physician with training and proven experience in ozone therapy who shall be responsible for the administration of treatment.

"It will have the proper equipment to generate and apply ozone therapy that must have CE marking.

"It will use medical oxygen that must be proven by a supply document signed by an authorized company.

"It shall implement the necessary various protocols, depending on the route of administration of ozone therapy, to ensure the quality of treatment, which should be properly validated and accredited.

"It shall establish a written informed consent to be signed by the patient and the physician responsible for the practice of ozone therapy, which shall be placed in the patient's medical history.

"It will have a ventilation system and proper ventilation."

It determines that the "ozone intradiscal application (...) must be performed in a hospital operating room or Ambulatory Surgery Unit."

III.6.14 NAVARRE (November 29, 2010)⁷⁶

It notes

"the obligation to obtain prior authorization to operate as a health center to all centers that include ozone therapy in their health care offerings."

It states that

"ozone therapy health care offerings are considered as non-conventional therapies and therefore require that the health professional responsible for performing such treatments be a physician with training and experience."

III.6.15 VALENCIA (February 9, 2011)⁷⁷

Including the practice of ozone therapy within the "non-conventional therapies" which are defined in the Royal Decree 1277/2003, the Valencia Community has said that the following requirements must be previously met by the health center:

"Presentation of documentation to support the existence of rigorous scientific studies on the activity of ozone therapy, which ensure the precise internal validity and are endowed with enough external validity to warrant its application in specific pathologies, following pre-defined protocols for each of them.

"The use of appropriate equipment (CE marking) for implementation.

"The existence of prior patient informed consent model, explicitly stating all information relating to the practice of ozone therapy.

"That this activity is performed by health professionals, in this case physicians

⁷⁶ Navarra. Gobierno de Navarra, Departamento de Salud, Sección de Régimen Interior, Jefa Sección de Ordenación e Inspección de Centros, Actividades y Prestaciones Sanitarias, María Fe Idoate Cervantes. Letter of November 29, 2010 addressed to AEPRIMO. www.aepromo.org. Members area, legislation, Spain.

⁷⁷ Generalitat Valenciana. Conselleria de Sanitat, Direcció General de Ordenació, Evaluació e Investigació Sanitaria. Letter of February 9, 2011 addressed to AEPRIMO. www.aepromo.org. Members area, legislation, Spain.

(...) with experience and appropriate training.

"That this activity takes place in health facilities duly authorized" according to the current legislation.

III.6.16 Comparison of requirements among the different Spanish autonomous communities

While the guidelines issued by the autonomous communities are not equal, it is possible, however, to highlight the following common points that all outpatient private centers that practice ozone therapy have to meet.

To comply with the national and autonomous communities legislation for the authorization and operation of outpatient private health centers

This requirement is prescribed by all 15 autonomous communities that have issued guidelines to practice ozone therapy.

To have a trained and experienced professional in the therapy

Twelve communities: Andalucía, Aragón, Asturias, Balearic Islands, Castilla-La Mancha, Castilla-León, Catalonia, Extremadura, Madrid, Navarra, Basque Country, Valencia.

To include ozone therapy in the health care offerings

Seven autonomous communities: Andalucía, Aragón, Castilla-La Mancha, Castilla-León, Catalonia, Madrid, Basque Country.

To use medical ozone equipment having the marketing authorization of the European Union, called the CE mark

Eight autonomous communities: Andalucía, Aragón, Balearic Islands, Castilla-La Mancha, Extremadura, Madrid, Basque Country, Valencia.

To have appropriate protocols according to the route of application

Eight autonomous communities: Andalucía, Aragón, Castilla-La Mancha, Extremadura, Galicia, Madrid, Basque Country, Valencia.

To have the informed consent signed by patient and physician.

Seven communities: Andalucía, Aragón, Balearic Islands, Castilla-La Mancha, Madrid, Basque Country, Valencia.

To order that the intradiscal application of ozone must be performed in a hospital operating room or an ambulatory surgery unit

Six autonomous communities: Andalucía, Aragón, Castilla-La Mancha, La Rioja, Madrid, Basque Country.

To consider the practice of ozone therapy within the "non-conventional therapies".

They are defined in the Royal Decree 1277/2003, as health care units in which a

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physician is responsible for performing treatments of diseases through naturopathic medicine, or with homeopathic medicines, or by peripheral stimulation techniques with needles, or other means, which demonstrate their efficacy and safety.

Five autonomous communities: Extremadura, La Rioja, Navarra, Basque Country, Valencia.

To have medical oxygen supplied by authorized companies.

Three communities: Andalucía, Aragón, Madrid.

To take into account the regulations issued by scientific associations of ozone therapy in the absence of legal regulations.

One autonomous community: Canaries.

To perform ozone therapy with full technical and scientific autonomy, without other limitations than those established by principles and legal and ethical values.

Two autonomous communities: Andalucía, Galicia.

Major autohemotherapy in two autonomous communities (Madrid and Catalonia)

Major autohemotherapy became a subject of scrutiny by the Catalonia (July 2012)⁷⁸ and Madrid (January 2016).⁷⁹ Separately both decided that major autohemotherapy had to be performed according to the procedures applied for the hemodialysis. The legal interpretation made by these two communities has not been shared by Aepromo (Spanish Association of Medical Professionals in Ozone Therapy). In a 37 pages long medical and legal document this association challenged the decisions of Catalonia (July 23, 2012)⁸⁰ and Madrid (March 7, 2016)⁸¹. Catalonia did not answer it. Madrid in its written answer dated March 29, 2016⁸² confirmed that Royal Decree 1088/2005 must be applied when using major autohemotherapy.

Major autohemotherapy continues receiving authorization to be practiced, it has not been forbidden by the authorities, but its practice has to be done according to Royal Decree 1088/2005. This interpretation has taken place only in two communities of Spain out of 17; no other community has follow fortunately on this issue to Catalonia and Madrid so far.

Aepromo proposed to apply as a substitute of the "major autohemotherapy" the "ozonized saline solution" which is a route of application with similar results and equally safe to major autohemotherapy. Ozonized saline solution has been

⁷⁸ Note of Request sent by the Catalogne Regional Ministry of Health to different physicians, July 2012. www.aepromo.org, members area.

⁷⁹ Answer to a Madrid medical center no authorizing it the practice of major autohemotherapy, January 2016. www.aepromo.org, members area.

⁸⁰ Letter of Aepromo addressed to the Catalogne Regional Minister of Health Boi Ruiz i Garcia. July 23, 2012. www.aepromo.org, members area.

⁸¹ Letter of Aepromo addressed to the Madrid Regional Ministry of Health, Inspection General Director and Ordination Luis Fernández Hermida. March 7, 2016. www.aepromo.org, members area.

⁸² Letter of the Madrid Regional Ministry of Health addressed to Aepromo, March 29, 2016. www.aepromo.org, members area.

recommended in the 2nd. ed. of the Madrid Declaration on Ozone Therapy (item 3.1.22).

III.7 CUBA (2009 and 2015)

Ozone therapy was introduced in Cuba in 1986 and because of its medical benefits, under the scientific supervision of the National Center for Scientific Research, the government founded the Ozone Research Center, with scientific personnel coming from various professional sectors.⁸³ This center has since become an international reference for ozone therapists from different parts of the world due to the important research and contributions that was doing. Unfortunately, according to the information available to us today, the Ozone Research Center has been reduced to treating patients in an international clinic and producing ozone-based products. Medical research has been removed.

In any case ozone therapy, integrated in the programs of Traditional and Natural Medicine ((MTN for its acronym in Spanish) since 2002,⁸⁴ has being consolidated as a therapy of national application.

In 2012, more than 30% of patients attending primary care consultations received MTN treatments (including ozone therapy), and this percentage rose to 40% in stomatologic care.⁸⁵ By 2015 two million patients had benefited from ozone therapy in Cuba.⁸⁶

Cuban regulations on ozone therapy

The Ministry of Public Health in 2009⁸⁷ “approved for medical care, teaching and scientific research in health services throughout the national territory” ten modalities of Natural and Traditional Medicine "among them ozone therapy (art. 1).

The Council of Ministers resolves in 2014⁸⁸ to place the Natural and Traditional Medicine under the Ministry of Public Health (article 1); making it responsible for setting up "a general and specific system of professional and teaching training in the field of Natural and Traditional Medicine" (art. 2); and with the aim that its "main promoters be health professionals" (art. 3). It also indicates the impetus that has to be given to the "development of different natural products" and "special attention" to "ozone derivatives" (art. 9).

The 2009 Ministerial Resolution was repealed six years later.⁸⁹ In its replacement it

⁸³ https://www.ecured.cu/Centro_de_Investigaciones_del_Ozono

⁸⁴ Acuerdo No. 4282, Comité Ejecutivo, Consejo de Ministros. Crea el Centro Nacional para el Desarrollo de la MTN (Medicina Tradicional y Natural) como organismo rector en la materia.

⁸⁵ Dra. Martha Pérez Viñas, jefa del Departamento de Medicina Natural y Tradicional del Ministerio de Salud Pública. 13-2-2012. <http://www.granma.cubaweb.cu/2012/02/13/nacional/artic05.html>

⁸⁶ <http://www.ain.cu/salud/10465-beneficiados-dos-millones-de-pacientes-en-cuba-con-ozonoterapia>

⁸⁷ Resolución Ministerial 261, 24 agosto 2009, Ministerio de Salud Pública, República de Cuba.

⁸⁸ Acuerdo No. 7551, 9 abril 2014, Consejo de Ministros, República de Cuba, Actualización del Programa Nacional de Médica Natural y Tradicional.

⁸⁹ Resolución No. 381, Ministerio de Salud Pública, Gaceta Oficial No. 17 Extraordinaria 20 mayo 2015. Ministerio

recognized

"Natural and Traditional Medicine as a medical specialty, integrative and holistic of health problems, employs methods to health promotion, diseases prevention, their diagnosis, treatment and rehabilitation from the traditional medical systems and other therapeutic modalities approaches that integrate with one another, and with the conventional treatments of Modern Western Medicine. "(art. 1).

It included in the Natural and Traditional Medicine a total of 11 "modalities and therapeutic ranges" among them to ozone therapy, which it defines as follows:

"It is the therapeutic use of ozone and ozonized substances in regulated doses, produced for medical use, by equipment that generates this gas "(article 2, e).

It stated in its article 4 who can apply it and the obligation to have a degree:

"professionals and technicians of health and related professions, according to occupational profiles and in all cases its practitioners hold a prior degree in correspondence with the program. academic training that supports it for the exercise of the therapeutic modality that it applies."

It explicitly stated that

"instructors of sports practices, masseurs and collectors sellers of medicinal herbs that exert as self-employed, are not recognized the therapeutic character in the exercise of their activities." (art 6)

III.8 SULTANATE OF OMAN (2010) ⁹⁰

At least from 2010 the Ministry of Health is issuing Licenses for the Exercise of the Medical Profession to ozone therapists as Advisors of the Medicine of Ozone. The same ministry authorizes private medical centers to practice ozone therapy.

III.9 DUBAI - UNITED ARAB EMIRATES (UAE) (2011) ⁹¹

The UAE is a federation of seven emirates. One of the Constituent Emirates is Dubai, to whom it has been delegated power on health matters through The Dubai Health Authority (DHA).

Dubai has officially recognized the practice of ozone therapy and physicians are allowed to legally work under the condition of sticking to the regulations stipulated by both the "Complementary and Alternative Medicine (CAM) - Facility Guideline" and the "Healthcare Facility Licensing Guidelines". It clearly states that the Dubai Health Authority (DHA) health regulation approves the following CAM facilities categories: (...) 7. Ozone Therapy Center".

This guideline enumerates the procedure to follow to obtain a license to operate a CAM facility in the Emirate of Dubai.

The Dubai Health Authority (DHA) Rashid Hospital has an ozone therapy center.

III.10 PORTUGAL (2013 and 2014)

In 2003 Portugal passed the Law 45/2003 of August 22 on Non Conventional Therapies.⁹² Its objective was to place a framework for the activities and practice of professionals of non conventional therapies (art. 2). It enumerated only six therapies that fall within the scope of the law. Ozone therapy was not included.

Ten years later the Portuguese Government decided to authorize the use of ozone therapy in the health public sector and the health private sector working for the government. The way of doing was through the Ordinance No 163 of 2013 of April 24⁹³ that specified the prices that medical centers were obliged to applied.

The importance for the ozone therapy lies in that this Ordinance includes for the first time in Portugal this therapy and it specifies the prices for the following interventions:

- Intraarticular large and small joints ozone therapy.
- Intra-dismal ozone therapy.
- Other applications of ozone therapy.

It is worth saying that the Ordinance does not include any of the non conventional therapies enumerated in the law 45/2003. So it is possible to say that ozone therapy is not considered by the authorities as a non conventional therapy.

The Ordinance No. 163 of 2013 was derogated the following year and it was replaced by Ordinance No. 20/2014 of January 29⁹⁴, which also determines the prices to be paid for ozone therapy treatments:

- Intraarticular large and small joints ozone therapy.
- Intra-dismal ozone therapy.
- Other applications of ozone therapy

The inclusion of ozone therapy in both ordinances implies the official acceptance of the practice of ozone therapy in both the public health services and the private services with contracts with the state.

⁹² Lei 45/2003, Diário da Republica – I série A, No. 193, 22 agosto de 2003, page 53910

⁹³ Ordinance No 163/2013 of April 24, Diário da Republica – 1ª. Série, No. 80, 24 abril de 2013, Item 2.5, Table Pain Medicine, Annex III, page 2556. www.aepromo.org, members area, legislation, other countries. http://www.acss.min-saude.pt/Portals/0/Portaria%20163_2013-24Abril2013.pdf

⁹⁴ Ordinance No 20/2014 of January 29., Diário da Republica – 1ª. Série, No. 20, 29 de janeiro de 2014. Item 2.5, Table Pain Medicine, Annex III, p. 654 www.aepromo.org, members area, legislation, other countries.

III.11 TURKEY (2014)

The Ministry of Health in its Strategic Plan for 2013-2017 decided "to strengthen regulations regarding traditional, complementary and alternative medicine practices to ensure the effectiveness and safety of them."

With this purpose it organized the 2014 Conference "International approach to traditional alternative and complementary medicine" with the objective to "provide grounds to discuss CAM [Complementary and Alternative Medicine] in every detail (...) to share experiences and good practices on achieving the benefits for public health and health safety."⁹⁵

Previously to the conference, and after several years of research, the Ministry of Health had identified a total of 31 categories of professional and practical alternative, complementary and traditional medicine. In these categories it was included ozone therapy along with others such as acupuncture.

ISCO3 had to opportunity to present its opinions at the conference (March 7-8, 2014) with a presentation for its President Dr. Velio Bocci. Roberto Quintero in his capacity of Legal Advisor of ISCO3 delivered the presentation "International Comparative Legal Status of CAM (Complementary and Alternative Medicine) and Ozone Therapy – A Preliminary Overview".

After the conference and conforming to the Ministry of Health Strategic Plan for 2013-2017 it was passed the Regulations of the Traditional and Complementary Medicine on October 27, 2014.⁹⁶

The Regulation

"identifies traditional and complementary medicine practice methods for human health, clarify the rules of education and licensing of the health professionals that will be practicing this therapy, to determine the working principles and procedures of the health institutions." (art. 1).

It "covers the health professionals and the health institutions that are owned by government or private enterprises that will be practicing traditional and complementary medicine." (art. 2).

So traditional and complementary medicine may be performed in public and private institutions.

⁹⁵ Istanbul, March 7-8, 2014. Invitation letter to Roberto Quintero sent by Prof. Dr. Irfan Şencan, General Director, General Directorate of Health Services, Ministry of Health, Republic of Turkey. February 20, 2014.

⁹⁶ Regulations, Traditional and Complementary Medicine. Official Gazette No: 29158, October 27, 2014 <http://www.resmigazete.gov.tr/eskiler/2014/10/20141027-3.htm> Non official translation made by ISCO3 from Turkish into English. www.aepromo.org, members area, legislation, other countries.

The Informed Consent is required (art. 8.4 and 11.5). Any adverse effects shall be fully reported (art. 11.4). Only traditional and complementary medicine therapies enumerated in the annex of the Regulation may be practiced in the country (art. 8, 1). Out of the 31 previously identified authorizes its practices to only 15 of them, in which the ozone therapy has been included in item 13.

It defines the ozone therapy as a

“local or systemic application method where a mixture of ozone-oxygen gas is used”.

The following ozone therapy methods are applicable as per the conditions stipulated in the Regulation: Major autohemotherapy; minor autohemotherapy; bagging method; rectal or vaginal insufflations; intradiscal application, performed only by specialists, under sterile conditions and by the help of imaging techniques (C-arm scope or fluoroscopy); and musculoskeletal.

Ozone therapy shall be done by certified physicians and dentists and applied as a supportive treatment in areas stipulated by the Regulation. The physician must determine that the therapy of ozone will be supportive and never state that it will cure or make the disease disappear.

III.12 BRAZIL (2015 in dentistry)

For several years ABOZ (Brazilian Association of Ozone Therapy) has been interested that ozone therapy is regulated in its country, both medical and dental. In this important initiative it has had the permanent support of Aepromo (Spanish Association of Medical Professionals in Ozone Therapy) and IMEOF (International Medical Ozone Federation) which have provided ABOZ with legal and scientific-medical information and advice to help guide and substantiate its request.

In Brazil the Federal Medical Council is the national body responsible for the recognition of new medical therapy procedures. This council adopted in 2012 the procedure that must be followed to obtain official recognition.⁹⁷

ABOZ submitted its request to this council in December 2013 and has continued contacts through its Technical Chamber. IMEOF in May 2015 sent a letter to the Federal Council of Medicine supporting the petition presented by ABOZ.

In spite of the important effort made the ozone therapy in the medical field still does not have the recognition on the part of the Federal Council of Medicine.

Where it took a step of transcendence was in dentistry. Since the Federal Council of

⁹⁷ Resolução CFM N° 1.982/2012. Conselho Federal de Medicina. D.O.U., 27 de fevereiro de 2012, Seção I, p. 186-7. http://www.portalmedico.org.br/resolucoes/CFM/2012/1982_2012.htm

Dentistry (CFO) did recognize ozone therapy. At the request of the Dental Section of the Brazilian Association of Ozone Therapy (ABOZ), the CFO decided to recognize and regulate the use of ozone therapy for dental practice by Resolution 166 of November 24, 2015.⁹⁸

On the basis of this resolution it was approved the Annex to Resolution CFO-166/2015.⁹⁹ It is indicated that

"ozone, produced from pure oxygen in precise concentrations according to the therapeutic window, can be used for dental purposes". He points out that ozone "is a potent antimicrobial and its action occurs through several biochemical pathways and chains with important action on bacteria, viruses and fungi." It adds that in "dental practice, ozone has been proposed as an antiseptic alternative, thanks to the potent antimicrobial action. The new therapeutic strategies for the treatment of infection and inflammation take into account not only the antimicrobial power of the substances used, but also the influence that this exerts on the immune response of the patient "(art. 1).

It specifies the areas of application of ozone therapy in dentistry (art. 2).

It prescribes that the professional in dentistry and enrolled in the Regional Council of Dentistry must have a minimum of 32 hours of course in ozone therapy promoted by an institution of higher education duly registered in the Ministry of Education and recognized by CFO (art.3).

III.13 OZONE THERAPY IN OTHER COUNTRIES

The extrapolation of applicable legislation for ozone therapy

Based on German judicial rulings and assessments of state laws in the United States, we have set legal extrapolations that allow us to conclude that ozone therapy is widely tolerated in Germany and it can be legally practiced in 15 U.S. states.

III.13.1 GERMANY

Germany was the country where the ozone was synthesized in May 1840 by the chemist Christian Friedrich Schönbein; is the place with the highest number of ozone therapists in the world;¹⁰⁰ and is the headquarters to large worldwide companies with great

⁹⁸ Resolução No 166, 24 novembro 2015. Reconhece e regulamenta o uso pelo cirurgião-dentista da prática da Ozonioterapia. Diário Oficial da União - Seção 1, Nº 234, terça-feira, 8 de dezembro de 2015, p. 95. ISSN 1677-7042 95

<http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=95&data=08/12/2015>

⁹⁹ Regulamento sobre o exercício pelo cirurgião-dentista da prática de ozonioterapia. Anexo Resolução CFO-166/2015 <http://cfo.org.br/wp-content/uploads/2016/01/resolucao-cfo-166-2015.pdf>

¹⁰⁰ 11.000. Roberto Quintero Mariño. Annex, Table 1- Countries where ozone therapy is performed, list of relative National Associations, and estimated number of ozone therapists. Velio Bocci et al. , (2011). Oxygen-ozone therapy is at a cross-road. Revista Española de Ozonioterapia. Vol.1, no 1, pp. 74-86. <http://www.revistaespañoladeozonioterapia.es/index.php/reo/article/view/8/20>

influence in the medical ozone equipment market. However, there are no regulations or laws on ozone therapy at local or national level. Nevertheless it is widely tolerated in all of Germany.

There are judicial decisions that may be applied to ozone therapy. The jurisprudence of the Federal Court of Justice and the Federal Social Court, has not been of use for a legislative or administrative recognition of the ozone therapy. However, this therapy has been widely tolerated by the central government and the states of that country.

Three German authors¹⁰¹ indicate that a ruling in July 1996 of the Federal Court of Justice (Bundesgerichtshof - BGH)¹⁰² and one from the Federal Social Court (Bundessozialgericht - BSG)¹⁰³ of the same month but of the previous year, made
 “possible the acceptance of empirical medicine not only by the classical school but also by the legally recognized health insurance organizations.”

The condition, according to the Federal Court of Justice, is that the
 “treatment method is available and is used that is suited to provide relief for the disease concerned or to act against its aggravation" (BGH 1996). “This presupposes a success of the treatment method applied in a number of treated cases sufficient to establish a certain prognosis”.

According to the three German authors
 “it is thus possible to interpret § 2, Section 1, 3 SGB V in such a manner that such forms of treatment, even though they have not yet obtained recognition by the Federal Commission of Physicians and Health Insurance Organizations (Bundesausschuß der Ärzte und Krankenkassen), are still in agreement with regulations because proof of their efficacy in a guaranteed number of cases speaks in their favour, and because no serious objections exist against them in the context of quality (...)”

To demonstrate the efficacy of medical technology, the Federal Social Court has stated that the potential success must be based on
 "statistics on the number of treated cases and the efficacy of a new method conducted in a scientifically correct manner" (BSG 1995).

Both judicial decisions led to Beck et al. to extrapolate the case for ozone therapy,
 “provided that every case of successful treatment with ozone is documented statistically in the scientifically correct manner (...)”

Bearing in mind that the Social Legal Code (SGB) determines that it is no longer

¹⁰¹ Beck E. G., Wasser G., Viebahn-Hänsler R., “The Current Status of Ozone Therapy - Empirical Developments and Basic Research”, Forsch Komplementärmed. 1989; 5:61-75 engl. Vers. P. 26 y s.

¹⁰² Bundesgerichtshof (BGH) [Federal Court of Justice]: Urteil vom [Judgement pronounced on] 10. Juli 1996, Az. [File Reference]: IV ZR 135/96

¹⁰³ Bundessozialgericht (BSG) [Federal Social Court]: Urteil vom [Judgement pronounced on] 5. Juli 1995, Az. [File Reference]: 1 RK 6/95

possible to base success on each and every individual case, the Medical Society for the Use of Ozone in Prevention and Therapy decided to publish statistical forms, for distribution to physicians upon request, to record the individual successes of the patients' treated with ozone therapy, to be duly registered. This will provide scientific basis for the successes obtained empirically and independently of the scientific research.

III.13.2 UNITED STATES OF AMERICA¹⁰⁴

The FDA and ozone

In 2005, Professor Velio Bocci wrote that the U.S. government agency the FDA (Food and Drug Administration) had forbidden the use of ozone in most states of the United States; "this fact has negatively influenced a correct development of ozone therapy, that, however, is more or less tolerated in other parts of the world."

A serious obstacle to development lies - according to this author - in the fact that the United States has established a ruling dogma that "**ozone is always toxic any way you deal with it**" [bold letters in the text]. This sentence was written to Bocci by one of the best U.S ozone chemists in 1995. However, this professional would not discuss the issue of ozone therapy with him despite his insistence.¹⁰⁵

According to Bocci, the expanded dogma in the U.S that

"**ozone is always toxic and should not be used in medicine** [bold letters in the text]' (...) is an absurd and unscientific idea and today we have a million reasons for saying that it is totally wrong.

"It is disappointing that some influential American scientists still BELIEVE that is correct. The FDA decision has negatively influenced the Health Authorities of other countries and this fact is not surprising because today only a few super-developed countries have a dominant (and not necessarily always positive) influence over the world's medical resources."¹⁰⁶

Roberto Quintero, contacted the FDA (Food and Drug Administration) asking for its position on the statements by Professor Bocci regarding the prohibition of ozone therapy in most of the United States and requested the documentation on which the banned decision has been taken.

The laconic response received was:

"Ozone is not an FDA approved drug, and thus we do not have information to

¹⁰⁴ More detailed information on United States in "La ozonoterapia frente a la legislación: Hacia un análisis global de derecho comparado", Adriana Schwartz y Roberto Quintero Mariño, México, 2008.

http://www.aepromo.org/pdf/ponencia_mexico.pdf

¹⁰⁵ Sentence underlined by Bocci. Velio Bocci. "Ozone a New Medical Drug", Springer, Dordrecht, The Netherlands. 2005, P. 2.

¹⁰⁶ Sentence underlined by Bocci. Velio Bocci. "Ozone a New Medical Drug", Springer, Dordrecht, The Netherlands. 2005, P. 232.

support it or regarding its safety or effectiveness for any therapeutic claim.”¹⁰⁷

The answer unfortunately does not support the reasons why ozone has not been approved as a drug by the FDA in the United States.

The FDA says the following on its web page about ozone:¹⁰⁸

“Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals.

“ b) The predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs to result in pulmonary edema.

“c) A number of devices currently on the market generate ozone by design or as a byproduct. Since exposure to ozone above a certain concentration can be injurious to health, any such device will be considered adulterated and/or misbranded within the meaning of sections 501 and 502 of the act if it is used or intended for use under the following conditions: (...)

“(4) In any medical condition for which there is no proof of safety and effectiveness.”

Health Freedom States

As the FDA has jurisdiction over the entire U.S., then the assertion of Bocci has fallen short. Ozone therapy is forbidden in the U.S. However when the issue is analyzed more closely and comparatively, there are important nuances and limitations about way the health laws are enforced in various states of the United States. As this country has a federal structure, its states have certain powers to legislate on matters that have been authorized.

Our investigation carried out in accordance to the Foundation for the Advancement of Innovative Medicine (FAIM)¹⁰⁹ found 15 states that the FAIM has been called "Health Freedom States" and that are divided into three categories:

States with laws that protect patient access to alternative therapies practiced by licensed physicians:

Alaska,¹¹⁰ Colorado,¹¹¹ Georgia,¹¹² Indiana,¹¹³ Massachusetts,¹¹⁴ New York,¹¹⁵ North

¹⁰⁷ RC, Division of Drug Information Center for Drug Evaluation and Research Food and Drug Administration.

“This communication is consistent with 21CFR10.85(k) and constitutes and informal communication that represents our best judgment at this time but does not constitute and advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.” E-mail dated March 6, 2007 addressed to Roberto Quintero Mariño.

¹⁰⁸ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=801.415>

Page accessed September 28, 2009

¹⁰⁹ The laws of the states of United States were obtained from the FAIM website updated on February 14, 2002. The page was accessed on February and March 2008.

<http://www.faim.org/states.htm>. Sección “Legal Issues”.

¹¹⁰ Alaska Statute, Section 08.64.326 (a) (8) (A), Enacted June 14, 1990.

 info@ae promo.org www.ae promo.org	 info@isco3.org www.isco3.org	Ozone Therapy and Growth Factors Doc: OM 1 Legal framework Version: 1 SPA Date: 9/10/ 2017 Page 48 of 57
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Carolina,¹¹⁶ Ohio,¹¹⁷ Oklahoma,¹¹⁸ Oregon,¹¹⁹ Texas¹²⁰ and Washington.¹²¹

States with laws that protect patient access to alternative therapies practiced by all licensed professionals in health care:
 Florida.¹²²

States with regulations protecting patient access to alternative therapies by licensed physicians:
 Louisiana,¹²³ Nevada,¹²⁴ and Texas.¹²⁵

Health freedom legislation in 15 states

The comparative law analysis for the 15 states conducted by Schwartz et al,¹²⁶ was made on six specific themes: Definitions of non-conventional medicine and / or alternative medicine and / or complementary and / or integral; persons authorized to practice unconventional medicine; sanctions for physicians; patient rights; informed consent; participation in state medical boards; and non-discrimination for alternative medicine.

Conclusion: Ozone therapy can be practiced in 15 U.S. states.

Although ozone is not a drug approved by the FDA, the legal analysis showed that non allopathic medicine can be used in the following 15 U.S. states: Alaska, Colorado, Florida, Georgia, Indiana, Louisiana, Massachusetts, Nevada, New York, North

¹¹¹ Colorado General Statute, Section 12-36-117. Enacted August 1997

¹¹² Official Code of Georgia Annotated, Section 43-34-42.1 Enacted April 22, 1997

¹¹³ IC 25-22.5-1-2-.1. As added by P.L. 44-1998, SEC. 2. Amended by P.L. 49-1999, SEC. 1.

¹¹⁴ Massachusetts General Lay Annotated, Chapter 112, Section 7. Enacted in 1901. Despite of having been approved early in the XX century “the Massachusetts law has been and continues to be upheld as a health freedom law”.

¹¹⁵ The New York Act, Chapter 558 of 1994, amended one section of the education law and two sections of the Public Health Law. Enacted July 26, 1994.

¹¹⁶ North Carolina General Statute, Section 90-14 (a) (6). Enacted June 29, 2003; and Section 90-2 Medical Board. Approved August 1, 2003.

¹¹⁷ Section 47.31 of the Ohio Revised code. Enacted July 10, 2000.

¹¹⁸ The 1994 Medical Practice Statute, Statute Title 59, Section 59. Enacted June 8, 1994.

¹¹⁹ Oregon Revised Statutes, Section 677. 190. Subsection (1) Unprofessional Conduct. Enacted May 30, 1995.

¹²⁰ Texas Administrative Code: 22 TAC 200.1-200.3 [regulation]. Adopted October 24, 1998. Although Article 16 of the Texas State Constitution (adopted in 1846) and Texas Medical Practice Act: TMPA 3.06 (adopted in 1907) established the health freedom, were never implemented.

¹²¹ Washington Revised Code Annotated, Section 18, 130, 180 (4). Enacted May 21, 1991.

¹²² Florida Statutes, 456. 41. Complementary or alternative health care treatments. Enacted May 8, 2001,

FAIM says: The Florida law applies to all health care professions.

¹²³ Title 46, Professional and Occupational Standards. Chapter 41. Integrative and Complementary Medicine. Enacted through publication in the Louisiana Register, November 2001, pages 1951-1954. It is a regulatory norm and not a law.

¹²⁴ Chapter 630 of Nevada Annotated Code [Regulation]. Adopted August 26, 2000 by the Nevada State Board of Medical Examiners.

¹²⁵ Texas Administrative Code: 22 TAC 200.1-200.3 [regulation]. Adopted October 24, 1998. Although Article 16 of the Texas State Constitution (adopted in 1846) and Texas Medical Practice Act: TMPA 3.06 (adopted in 1907) established the health freedom, were never implemented.

¹²⁶ More detailed information on United States in “La ozonoterapia frente a la legislación: Hacia un análisis global de derecho comparado”, Adriana Schwartz y Roberto Quintero Mariño, México, 2008.
http://www.aepromo.org/pdf/ponencia_mexico.pdf

Carolina, Ohio, Oklahoma, Oregon, Texas and Washington.

No regulation in the fifteen states specified ozone therapy, but also did not list any unconventional therapy. However it may be interpreted that ozone therapy may be used in 15 U.S. states, under the health freedom laws - named for the Foundation for the Advancement of Innovative Medicine (FAIM)¹²⁷ - to be used as non-conventional therapy.

The practice of ozone therapy will be subject to the specific regulations of each of the 15 states. Basically these requirements can be summarized in two parts:

- The therapy is to be practiced by a medical professional licensed to practice the profession and with skills in the use of ozone therapy.
- Preparation of an informed consent that varies from state to state, where - among other points - the type of treatment to be done is specified. In two states, informed consent must specify that ozone therapy is still experimental and is not authorized by the FDA.

III.13.3 MÉXICO ¹²⁸

The General Health Law, article 102 provides that

"[T] he Health Secretariat may allow for preventive, therapeutic, rehabilitative research on drugs or materials for human use that are not yet scientifically proven for therapeutic efficacy or of substances intended to modify the therapeutic indications of known products."

And the following article states that

"[I] n the treatment of a sick person, the physician may use new therapeutic resources or diagnostics, when there is potential for saving life, to reestablish health or reduce the suffering of the patient, provided [the physician] has the patient's written consent, or that of his/her legal representative, if any, or of his/her next of kin in bond, and meets the other requirements prescribed in this Law and other applicable provisions without prejudice."

¹²⁷ The laws of the states of United States were obtained from the FAIM website updated on February 14, 2002. The page was accessed on February and March 2008.

<http://www.faim.org/states.htm>. Sección "Legal Issues".

¹²⁸ México, Ley General de Salud, Nueva Ley publicada en el Diario Oficial de la Federación el 7 de febrero de 1984, actualizada el 18 de diciembre de 2007.

<http://www.salud.gob.mx/unidades/cdi/legis/lgs/index-indice.htm>

III.13.4 CHILE ¹²⁹

An evaluation of the Ministry of Health, outlined the minimum requirements that the regularization of ozone therapy should include:

"To avoid exposure of the respiratory tract to toxic concentrations of ozone to patients and to those who operate the equipment, particularly those who are most susceptible, such as patients with asthma or chronic obstructive pulmonary disease." [The Annex of the "Madrid Declaration on Ozone Therapy" has several points that have addressed this issue].

"To avoid potential indirect damage in patients who may have access to other effective therapies to treat their pathologies, and as consequence delay or suspend access to these therapies induced by the supposed benefits of an ozone-based therapy. For this reason, it is essential to provide proper public education about ozone therapy." [The requirement of a written informed consent indicating the benefits and possible negative consequences of the treatment, would be an effective means of patient education].

"To foresee that any method of ozone administration is not used involving the use of invasive techniques without meeting the minimum operator training and infection control standards (universal precautions)."

III.13.5 COLOMBIA

In 1998 this country regulated the practice of alternative therapies through Resolution 2927 of 1998 of the Ministry of Health.

As per art. 7 of Law 1164 of 2007, a committee was set up for alternative medicine, alternative and complementary therapies. These included traditional Chinese medicine, ayurvedic, naturopathic medicine and homeopathic medicine.

Article 19 of the law states that

"The professionals authorized to practice a profession in the area of health may use alternative medicine and procedures for alternative and complementary therapies within the scope of their profession, which must be authorized by the respective academic certification, issued by an institution of higher education legally recognized by the State."

Another paragraph of that article 19 says

"It should be understood that alternative medicine and therapies use those practices techniques, procedures, approaches or knowledge for the stimulation of natural laws for the self-regulation of the human being in order to prevent

¹²⁹ "Ozonoterapia: efectividad y riesgos - Síntesis de evidencia", Unidad de Evaluación de Tecnologías de Salud del Ministerio de Salud de Chile. 2005, p.18 y s. www.aepromo.org. Members area, legislation, reports.

disease, promote, treat and rehabilitate the health of the population through holistic thinking.

" Traditional Chinese, Adyurveda, Naturopathic and Homeopathic medicines among others are considered alternative medicine.

"Herbology, acupuncture, moxibustion, manual therapy and therapeutic exercise among others are considered within the complementary and alternative therapies."

According to a working paper of the Bogotá District Health Department, alternative medicine and complementary therapies are different from each other. Complementary therapies are used alongside of conventional medicine. Alternative medicine is used instead of conventional medicine.¹³⁰

It is worth recalling the view of the World Health Organization (WHO) who states that "The terms 'complementary' and 'alternative' (and sometimes also 'unconventional' or 'parallel') are used to refer to a wide range of health practices that are not part of the tradition of a country, or are not integrated in its predominant health system."¹³¹

Although the law 1164 of 2007 does not refer to the requirements for authorization of a medical activity, but to the training, monitoring and control of health professionals, it could serve as a positive element for facilitating the regularization of ozone therapy.

III.13.6 OTHER COUNTRIES

It is quite likely that the legal analysis of the laws in other countries would allow us to reach the conclusion that the practice of ozone therapy would be permitted. Nevertheless, as indicated previously, our interest is that the authorization to practice ozone therapy may be included specifically in the legal provisions of each country.

IV. POINTS TO CONSIDER IN DEVELOPING A STRATEGY TO REQUEST THE REGULARIZATION OF OZONE THERAPY

IV.1 The political-administrative structure of the state

Basically states now have two different systems of political-administrative organization:

¹³⁰ Proposed by promoting alternative medicine and complementary therapies on the public network attached to the Bogotá District Health Department. No date. Circa 2010.

¹³¹ Organización Mundial de la Salud, "Estrategia de la OMS sobre medicina tradicional 2002-2005", WHO/EDM/2002 1, p.8

the federal system and the centralized system.

In the federal system some functions are the sole responsibility of the central government such as the currency, national defense, immigration, war, foreign relations, etc. Other functions are delegated to the states (or regions or autonomous communities, or provinces, or departments, etc.) with broad powers to legislate, provided that they comply with the country's constitution and national regulations. These may include education, health, transport, police, etc. The distribution of functions and powers between the central government and the states varies widely from country to country and therefore is not always equal.

In the centralized system all decisions are taken by a system of central government. Regional and local authorities will only implement the decisions taken at the national level.

There are states that, although not defined as either federal or centralized, can have a semi federal organization as, for example, Spain. In this parliamentary kingdom, important functions, among them health, are the responsibility of the autonomous communities.

However, although a country is defined as a federal state in its constitution, it may happen that in everyday reality, that country may act as a centralized state, where the capital of the country has enough influence on regional decision-making.

In designing the strategy to follow in the process of the regularization of ozone therapy, it is crucial to know who has the authority to legislate and manage health issues. If the states (or regions or autonomous communities, or provinces, or departments, etc.) have that authority, it would be better to design the search strategy of the regularization at the regional level instead of seeking it at the national level. This is the strategy used in Spain by AEPRIMO and it has been fruitful because most of its autonomous communities have regularized ozone therapy.

Nevertheless one community - Cantabria (October 6, 2010)¹³² - decided against it, claiming it was a national competence and not for its community.

"No authorization on health techniques is granted by the community, because the preliminary recognition, to our knowledge, is competence of the Inter-Territorial Council within the Ministry of Health and Social Policy."

All the other autonomous communities asked by AEPRIMO to establish requirements to practice ozone therapy, did it.

¹³² Cantabria. Gobierno de Cantabria, Consejería de Sanidad, Dirección General de Ordenación, Inspección y Atención Sanitaria, Director General de Ordenación, Inspección y Atención Sanitaria, Fernando Villoria Díez. Letter of October 6, 2010 addressed to AEPRIMO. www.aepromo.org. Members area, legislation, Spain.

In Russia, despite being a federal state, the regularization was taken at the central level. In Cuba, a centralized state, the decision was made directly by the Ministry of Health. In Italy, although there are already national decisions on ozone therapy, three regions spoke explicitly on issues related to ozone.

It is therefore essential to decide in advance where to go, whether at the regional, or national level. The decision has to be taken by analyzing who has the power to decide in matters of health. The decision of this strategy of "who to turn to" not only requires legal knowledge on the political-administrative organization of the state, but also knowing how that organization works in practice.

IV.2 What legal formalities must the regularization have?

Countries have very different ways of making their decisions: For written means (constitution, laws, decrees, regulations, rules, norms, statutes, regulations, followed by a long etc.); and sometimes by letters or verbally; and sometimes not saying anything (laissez-faire). In the vast majority of countries where ozone therapy is practiced the latter is what usually happens: Laissez-faire, i.e., is the policy of tolerance.

In Brazil (for dentistry) the decision was made by means of a resolution. China stated its decision with a Notification of the Ministry of Health. In Cuba by Ministerial Resolutions signed by the Minister of Health. In Greece by presidential decrees. In Dubai (UAE) by means of Guidelines adopted by the Government. In Italy the format of decisions is very varied. It ranges from a letter addressed to a the scientific association by the Ministry of Health, to a circular sent to various government agencies, to a memorandum etc. Although it seems that in Oman there are not written decisions the government is issuing licenses to health professionals.

In Portugal Ordinances of the Ministry of Health have been employed. In Russia it was by Registry Identification Documents issued by the Federal Service Control of Health and Social Development. In Turkey the regularization process has passed with Ministry of Health Regulations. In Ukraine through written instructions from the Ministry of Health.

In Spain initially the decision to ban the practice of ozone therapy in outpatient private clinics by the Community of Madrid, was taken orally in 2006 and applied orally. Then in 2008 it was stated in writing. Since then all the information issued regarding the requirements to practice ozone therapy has been made through letters addressed to AEPROMO, (Spanish Association of Medical Professionals in Ozone Therapy).

Conclusion: The legal formalities for the authorization are different.

IV.3 What should the ideal regularization format be?

In countries the basic rule is the constitution and below it is the law which is usually

approved by parliament (or congress or courts, etc.). There are different types of laws in accordance with the range of issues decided, and there is even a hierarchy among the different laws.

Is it ideal to have a national law? That is what the FIO (Italian Federation of Oxygen-Ozone Therapy) is trying to get. There is even a bill and members of the parliament have taken part in roundtable discussions organized by the FIO to promote the bill in the Italian parliament. Within the same line would be the Mexican Association of Ozone Therapy (AMOZON) which is looking for a regularization adopted by the national congress.

Certainly if the regularization were obtained through a law or decree, or resolution, or directive, and so on, either at the national or regional level and to be published in the Government Gazette, or in the Official Journal of the region, it would be an excellent result for both ozone therapy legal certainty and publicity. However any other formal way that administration often used for decision making should not be ruled out, such as letters to scientific associations, or circulars to local authorities. What ultimately should matter to ozone therapy scientific associations is to obtain from the authorities or legislators written rules that will allow both ozone therapists and patients to know in advance if there is a medical center to practice ozone therapy legally.

Whatever the form adopted for the regulation of ozone therapy, it is important to bear in mind that it is not enough that a law or government policy exists for ozone therapy to be practiced without hindrance. If the rules do not have an effective implementation the decision will be a dead one.

IV.4 The importance of the comparative international law assessment

It is axiomatic that the human body is the same in all parts of the world. If there were exceptions, they would be anomalies of nature. The legal world instead is quite the opposite. The legal system within a federal country may be very different in each of its states. And the legal system among countries is different, even among those that have their origins in a similar legal system such as the countries using the traditional Roman system, or countries under the influence of common law, or the countries covered by Muslim or Islamic law.

Nevertheless in the current period of globalization, legal systems, more than ever before, tend to mix and influence each other. The most obvious example is the European Union, where despite differences in legal systems that exist within its midst, a legal framework has been in force in all states of the union.

Hence there is a huge interest in knowing how ozone therapy is regularized in different countries that have done it, comparing them and extracting the most beneficial examples for other countries. It is very convenient that public health agencies, and lawmakers know the normative development outside their borders.

IV.5 International law

Increasingly international law that is binding on two or more countries is growing in areas as diverse as communications, transport, movement of capital and people, etc. This is particularly important in Europe where the European Union has a legislative, judicial and regulatory power, which is mandatory in all its member states.

The decisions taken by international bodies such as the United Nations and its specialized agencies have varying degrees of validity depending on the legal formality that the decision has. Likewise, proposals or statements of private international organizations may have an impact on the internal decisions of the countries.

It is necessary to find out what the international norms are and what their legal weight is, which may be useful to use to convince the states going through the process of regularizing ozone therapy.

IV.6 The Declaration of Helsinki

For example let us take the Declaration of Helsinki of the World Medical Association. The provisions of the Declaration may have a profound impact on the world of ozone therapy and should wield some articles in favor of it.

The Declaration was designed to establish medical principles for medical research. However there are parts of the Declaration of Helsinki that can be perfectly assimilated to the context of the application of ozone therapy, as the provision in paragraph 35 of the Declaration:

"35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgment it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available."¹³³

Elsewhere the World Medical Association recommends:

"In the treatment of the sick person, the doctor should have the freedom to use a new diagnostic method and therapy, that in his view offers the hope of saving lives, restoring health or alleviating suffering."¹³⁴

¹³³ WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964. Last amendment on the 59th WMA General Assembly, Seoul, Korea, October 2008.

<http://www.wma.net/en/30publications/10policies/b3/>. Page accessed December, 2011.

¹³⁴ Recomendaciones para orientar a los médicos en la investigación biomédica con seres humanos, II. Investigación

Is the Declaration of Helsinki binding on states? If so, could one argue its contents to regulate the practice of ozone therapy? The Declaration of Helsinki is a document issued by the World Medical Association (WMA), and as indicated by its own website:

“The World Medical Association (WMA) is an international organization representing physicians (...) created to ensure the independence of physicians, and to work for the highest possible standards of ethical behaviour and care by physicians, at all times (...) the WMA has always been an independent confederation of free professional associations.”¹³⁵

For an international document to be considered mandatory for one particular state, that state should meet several requirements, including:

- To be approved by an international body representing the states, such as the UN, OAS Organization of American States), European Union, or by two or more states, etc.
- The document is to be called resolution, treaty, covenant, etc. But it should not be designated as a “declaration” because in principle it is not binding on any state, although it has been approved by them.
- To be signed by the representative of the State in the conference in which it was adopted.
- To be later on ratified by the congress or parliament of that country. This procedure is applied differently in many countries, or does not even have to pass through congress or parliament.
- To be published in the official gazette with the signature of the Head of State.

In principle, then the Declaration of Helsinki (which is a private document) is not binding on any state, because it does not meet the above requirements.

Nevertheless, the status of legal binding varies substantially when a State decides to incorporate into its domestic law a declaration of an international public or private organization that is legally binding. For example: The Universal Declaration of Human Rights, the most important document in the world today on human rights although not binding, has become the guiding instrument on matters related to human rights and fundamental freedoms. There is no country that has spoken out against the Declaration. Even several countries with constitutions or constitutional amendments adopted after the approval of the Universal Declaration of Human Rights by the General Assembly of United Nations in 1948, explicitly refer to it in their constitutions. One of these countries is Spain.¹³⁶

médica combinada con atención profesional (investigación clínica). Punto 5. Adoptadas por la 18a Asamblea Médica Mundial Helsinki, Finlandia, junio de 1964. Last amendment on the 41th WMA General Assembly, Hong Kong, September 1989. Page accessed December, 2011.

¹³⁵ <http://www.wma.net/en/60about/index.html>. Page accessed December 2011.

¹³⁶ “The norms relative to basic rights and liberties which are recognized by the Constitution shall be interpreted in conformity with the Universal Declaration of Human Rights and the international treaties and agreements on those matters ratified by Spain.” Article 10.2 of the 1978 Spanish Constitution.

Although the Universal Declaration of Human Rights is not binding, it has acquired legal validity and moral power for many states and is of paramount significance.

The Declaration of Helsinki states medical principles for medical research related to humans. The Declaration may be considered as one of the most important documents ever written on the ethics of human research. Also, given the representative nature of the World Medical Association, its Declaration has become a national and international reference, though not mandatory. It is certainly a declaration of global significance, due to the degree of representation that it has, and given the fact that countries' medical associations are members of the World Medical Association.

However, the association as a global organization representing physicians, has no capacity to have its texts become legally binding. Furthermore, as the title indicates the document is only a declaration. Nevertheless, given the importance of its content, the Kingdom of Spain, for example, has incorporated it in its legislation, thus giving it a binding character. In several legal norms, Spain undertakes respecting the principles of the Declaration of Helsinki. The Royal Decree 414/1996 specifically confirmed the binding character when it says:

"It is imperative to apply the spirit of the Declaration of Helsinki (...)"¹³⁷

In contrast, other countries are less inclined to adopt the provisions of the Declaration of Helsinki. For example, the United States. The FDA (Food and Drug Administration) said in 2008 that

"The final rule [of the FDA] replaces the requirement that these studies be conducted in accordance with ethical principles stated in the Declaration of Helsinki (Declaration) issued by the World Medical Association (WMA), specifically the 1989 version (1989 Declaration), with a requirement that the studies be conducted in accordance with good clinical practice (GCP), including the review and approval by an independent ethics committee (IEC)."¹³⁸

Among the various reasons given by the FDA are:

¹³⁷ Royal Decree 414/1996 of March 1st, which regulates medical devices. ANNEX X. Paragraph 2.1 "Clinical investigations must be conducted in accordance with the Helsinki Declaration, adopted in 1964 by the Eighteenth World Medical Assembly in Helsinki (Finland) last amended by the Forty-first World Medical Assembly in 1989 in Hong Kong. It is imperative to apply the spirit of the Declaration of Helsinki, to all provisions relating to the protection of people, and this in every stage of the clinical investigation from the very first consideration of the need and justification of the study to the publication of results."

http://noticias.juridicas.com/base_datos/Admin/rd414-1996.html

RESOLUTION of September 2, 2005, of the Carlos III Health Institute, to provide grants from the Program of Promotion of Biomedical Research in Health Sciences, for research studies on evaluation of health technologies in the context the National R + D + I 2004-2007, during year 2005. BOE September 21, 2005. Number 226. Article 5. Principles that must be respected by the projects

5.1 "The research projects must respect the fundamental principles established in the Declaration of Helsinki (...)"

¹³⁸ Department of Health and Human Services, Food and Drug Administration 21 CFR Part 312 [Docket No. 2004N-0018] Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application. 22800 Federal Register / Vol. 73, No. 82 / Monday, April 28, 2008 / Rules and Regulations <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=0900006480537f08>

“noted that the Declaration is a document that is subject to change independent of FDA authority and, therefore, could be modified to contain provisions that are inconsistent with U.S. laws and regulations. We further noted that although revisions to the Declaration could not supersede U.S. laws and regulations, the changes might be confusing for sponsors.”

We recommend including in the applications for regularization the points of the Helsinki Declaration mentioned above. If the State has not explicitly committed to fulfilling it, at least the Declaration does have a moral force that may oblige the state to take it into consideration. If the State has already committed to fulfilling it, its inclusion in the application of regularization has no argument.

IV.7 The Madrid Declaration on Ozone Therapy. Isco3, 2nd. ed., 2015, 50 pp

It is worth making explicit the force that the "Madrid Declaration on Ozone Therapy" has in the context of the regularization process. Mutatis mutandis, it has the same force as the Declaration of Helsinki. It is the first and only truly global document that exists on ozone therapy. It has been translated into 11 languages, with the official version in English.¹³⁹ It is today the reference document and guide for the vast majority of ozone therapists of the world who are implementing it daily. In addition, it also has a specialized international committee, the International Scientific Committee (ISCO3) responsible for updating it each every year. ISCO3 approved the updated and expanded 2nd. ed. of the Declaration on May 20, 2015.

The "Madrid Declaration on Ozone Therapy" is not binding on any state nor on ozone therapists. However, the representation that it has today in the world of ozone therapy, gives it an enormous moral force on states due to the authority it has among ozone therapists and the upgradeability it has.

The requirements listed in paragraph 5 of the Annex to the Declaration, are the proposals that the international community of ozone therapy makes to the states so that they are imposed as necessary for all outpatient private clinics that want to include ozone therapy in their health care offerings.

IV.8 Non-conventional medicines and the Parliamentary Assembly of the Council of Europe

In the European context the decision of the Parliamentary Assembly of the Council of Europe on non-conventional medicines may be an important reference point.

“The Assembly - said the resolution - believes that a common European approach to non-conventional medicine based on the principle of patients’ freedom of choice in health care should not be ruled out. Resolution 1206

¹³⁹ The 2nd. edition of the Declaration was approved by ISCO3 on May 10, 2015. <http://isco3.org/madrid-declaration-on-ozone-therapy-2nd-edition-2/>

(1999).¹⁴⁰

IV.9 Lobby

Everybody must be well aware that the work towards the regularization of ozone therapy requires an enormous effort of conviction, time and energy. In other words it must be taken as an apostolate. There are several steps to take.

The first step is to determine to whom the application for regularization should be sent. To the central authorities? To the regional authorities? To answer these questions it is necessary to have an expert to provide advice on this legal issue. But the legal component is not enough. A political convenience assessment has to be done regarding which authorities the request has to be sent to. In some federal countries, it may be more prudent to go to the central body, since in practice the state operates more like a centralized entity rather than a federal one.

The second step is to write the scientific, medical and legal paper to be submitted to the authorities. It is advisable to consider several points: In most cases, the staff who will decide on the application, even if they are physicians or specialists in health issues, they do not necessarily have to be experts in ozone therapy. Neither group will have enough time, even though it is desirable, to know about ozone therapy in depth and in detail. The office may be dealing with multiple issues and as ozone therapy is not an issue of importance in the physicians or specialists daily administrative activities, little attention may be devoted to it.

Therefore it is not convenient to send an attachment to the application that includes books, papers, research, etc. The staff will not read them. Instead, the drafters of the document must spend time in writing the document in order to include all the key points of the application, with appropriate substantiated footer quotations, so that after reading, the health official may have a fair idea of what is asked, why it is requested, and the reasons for asking. Avoid citations from third parties. Where possible citations should be primary. At the end of the application add a formal and well phrased paragraph that indicates if additional information is needed, the signatory will be able to provide it. The drafters of the document must be able to provide the additional information, if requested.

The third step is to present the document in due form to the competent authority. However, the work does not stop there. Because staff is busy dealing with different issues, the drafters, after a reasonable period of time, should contact the authorities to know what particular staff was assigned the task of reading the petition and possibly to draft a reply. The request should not be put in a drawer and with answer pending.

¹⁴⁰ Resolution 1206 (1999). Council of Europe, Parliamentary Assembly A European approach to non-conventional medicines, Extract from the Official Gazette of the Council of Europe – November 1999. <http://assembly.coe.int/main.asp?Link=/documents/adoptedtext/ta99/eres1206.htm> Resolution 1206 (1999)

From now on initiatives are varied and depend on the circumstances of each region or country, to lobby to get a positive answer. It is convenient to be very well aware that the signatories of the application will have to make many telephone contacts, to frequent government offices, to attend meetings and to be well- prepared for the questions that may arise. All this is a time-consuming exercise, requires practice in attending meetings, etc.. So we talk about apostolate, knowing that the regularization of ozone therapy will not fall like a miracle from heaven.

V. CONCLUSION

Ozone therapy is increasingly practiced in different parts of the world. The existence of more than 40 national and international associations of ozone and more than 30 000 ozone therapists well attest to this. Authorities are speaking more frequently about this therapy. The media has echoed its practice. There have been cases that have reached the courts, and research is being done despite having limited financial aid.

However, for reasons of various kinds, the norms do not match the extent of the wide application that ozone therapy is experiencing. Sometimes such popularity becomes an obstacle, such as when it was banned in some places for several years in outpatient private clinics.

This paper is in favor of working for the regularization of ozone therapy, taking as reference the measures adopted for its practice in some countries. Specific points are proposed in this paper, including the “Declaration of Madrid on Ozone Therapy”, domestic and international law, lobbying, the methodology to adopt, and others, to be taken into account when developing a strategy that can lead to the regularization of ozone therapy in countries where it is being widely practiced.

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