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OZONETHERAPY AND LEGISLATION Analysis for its regularization.

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Abstract

Ozonotherapy is on the agenda and figures attest to its growing importance. The ozonotherapy is increasingly practiced in different parts of the world. The existence of more than 30 associations of ozonotherapy and more than 26 000 ozonotherapists confirm it. However, while ozone was discovered in 1785 by Dutch physicist Martinus Van Marum (1750-1837) and had been synthesized in May 1840 by the German chemist Friedrich Schonbein Christian (1799-1868), history has shown that it has been difficult to have a significant presence in the world's medical agendas. Only Russia, Cuba, Spain and Italy have provisions from the authorities that specify the criteria to be met so that they can practice. These provisions are analyzed in this study, to rule in favor of working for the regularization of ozonotherapy, 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 ozonotherapy in countries where it is still widely practiced

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I. INTRODUCTION.

Although ozone has been discovered in 1785 by Dutch physicist Martinus Van Marum (1750-1837) and had been synthesized in May 1840 by the German chemist Friedrich Schonbein Christian (1799-1868), history has indicated that it has been difficult to have a significant presence in the world's medical agendas.

But their gradual, steady and rising use primarily in Germany and the former Soviet Union from the sixties of last century has prompted renewed interest in its use in a scientific manner and in accordance with protocols previously adopted. In the ensuing decades has been emerging in different countries of Europe, mainly in Italy, followed by Spain, and then with a widespread use in Cuba, supported by the foundation of the world's only research center in the medical therapy of ozone.

Today we can certainly say that this therapy is increasingly used in many different countries. The number of existing ozone therapists so testify it. Their number already exceeds the 26 000, placing Germany as the first country in number of health professionals who practice it. They are 11 000. China is next in number to 5 000. Russia reaching 3 500 in third place, followed by Italy with 3 000 professionals.¹ The investigation conducted has determined that at least ozonotherapy is practiced in 42 countries worldwide, with around 30 national associations, as well as some international federations and the International Scientific Committee ISCO3 Ozone (www.isco3.org).

Authorities and ozonotherapy

Examples of the widespread use of ozonotherapy abound, to the extent that health authorities in various countries have had to comment on it. In a report by the autonomous community of Andalusia in 2006 indicated that in Spain

"Ozonotherapy raises interest among citizens, confirming the increasing diffusion of this technology in recent years. A not despicable percentage of requests (12/171, 7%) realized by persons through the telephone of direct attention to the citizen, that the Health Technology Assessment Agency of Andalusia (AETSA) offers from May 2005 on have been on ozonotherapy."²

At the express request of the Medical College of Santa Fe province in Argentina, AEPROMO (Spanish Association of Medical Professionals in Ozonotherapy) presented a legal brief on ozonotherapy on September 5, 2011.

The City Council of the City of Cajamar, in the Brazilian state of Sao Paulo, approved a decision asking the Prefecture to offer ozonotherapy in the city health facilities. The Prefecture of Nova

1 Roberto Quintero Mariño. Anexo, 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>

2 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

Lima in the State of Belo Horizonte has also developed projects for the application of ozonotherapy.³

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

"People must understand that [ozonotherapy] is not a cure all, however it does have its benefits as any therapy." It noted that "the increased risk may have the patient is to fall into the hands of inexperienced people who do not know this type of treatment and may actually cause more problems than benefits."⁴

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 ozonotherapy.

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

In Spain, the Canary Islands, asked AEPROMO in February 2012, to enumerate the basic requirements that medical facilities should have to practice ozonotherapy.⁵

Elite sport and ozonotherapy

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

The professional basketball team Cajasol Civic Banking in Seville, Spain, has used ozonotherapy to treat medically Joan Sastre, one of its most important players, to treat a bulging disc, since "the success of this technique is based in same properties of ozone, which is analgesic, antiseptic and water-repellent".⁷ After successful recovery the medical team decided not to operate Sastre, because "with 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."⁸ 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 ozonotherapy that has been done in recent weeks, to solve the problems experienced since the preseason because of a bulging disc in his back."⁹

The national football team of Venezuela has used medical ozone with their players, so they could play in very high places like the capital of Bolivia which is over 3650 meters above sea

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

4 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>

5 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

6 21 de Octubre de 2011, <http://www.aquiespuebla.com/salud/avances/8391-salud>

6 23-9-2011. <http://www.diariodesevilla.es/article/deportes/1071622/calloway/nuevo/refuerzo/para/plaza.html>

7 23-9-2011. <http://www.diariodesevilla.es/article/deportes/1071622/calloway/nuevo/refuerzo/para/plaza.html>

8 13-10-2011 <http://www.diariodesevilla.es/article/deportes/1087565/sastre/no/sera/finalmente/operado.html>

9 17-11-2011 <http://www.europapress.es/deportes/baloncesto-00163/noticia-baloncesto-joan-sastre-cajasol-banca-civica-experimenta-importante->

level or in Quito at 2850 meters. The ozonotherapy

"will help us, we will strengthen the resilience to recover faster. Height is a different choking, breathing is different (...) It seeks to introduce ozonotherapy into the blood stream of players to improve the circulation of each and increase the capacity of the blood in transferring oxygen through the body."¹⁰

Courts and ozone

Physicians who practice ozonotherapy have also been brought to the courts and the information has had an impact on the media. A private hospital with an insurer company had to compensate with 180 000 euros in 2009 to a patient from infection acquired in hospital operating room during an operation of "four spaces at the lumbar spine by resorption and ozone."

It must be stated however, that the complaint filed by the patient and the payment of compensation were not due to ozonotherapy because "the civil liability lawsuit filed by the patient was based on the '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 operation of ozonotherapy, but only informed consent for anesthesia."¹¹

An Argentine newspaper in 2009 titled: "A woman died during ozonotherapy".¹² But then the autopsy determined that the person had died of a subdural hematoma that according to the medical-legal considerations

"cranial hematoma is vital, recent and consistent with falling and banging against a hard surface and resilient, leaving established that the medical ozone gas use does not translate into the autopsy."¹³

Research and ozone

There is a widely accepted view that ozonotherapy, as in the vast majority of the fields of medicine and in the general deepening of human knowledge, research should be a matter of priority.

Researchers that have devoted to the issue of ozone are unanimous in indicating that still needs much more research, knowing that it will never have an end. The meager financial support provided to the investigation of ozonotherapy is quite small compared to the work that needs to be done, what constitutes a serious challenge for randomized and controlled research.

mejoria-lesion-espalda-20111117184402.html

10 21-9- 2011 <http://www.el-nacional.com/noticia/1838/2/Vinotinto-en-la-altura.html>

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

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

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

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

However research in ozonotherapy is carried out in different parts of the world.

In 2010 appeared the first meta-analysis 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.¹⁴ A second meta-analysis was released in 2012, which analyzed the results of eight studies.¹⁵ The meta-analysis investigations have great value of scientific evidence, because they are not the result of a single research but put together mixed results.

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

"(...) To test the effectiveness of treatments for a herniated disc with ozone compared to traditional surgery, once it is tested the effectiveness of ozonotherapy to deal with other diseases. Bernardino Clavo, oncologist of the Dr. Negrín University Hospital, told Efe that is already proven the effectiveness of ozonotherapy to treat sicknesses such as arthritis, cancer, or necrosis, so now it comes to certify its validity for the treatment of disc hernia."¹⁶

The number of clinical studies on ozonotherapy has increased dramatically. While in 1997 were recorded in the database only 2 trials, by 2007 the number had risen to 243.¹⁷

At present the new regulations of clinical trials establish that they are present in public databases. At this time the public database of clinical studies from the National Institutes of Health U.S. records the following seven studies in progress:

1. Efficacy of Medical Ozonotherapy in Patients With Chronic Hepatitis B (China)
2. The Effect of Epiduroscopy and Ozonotherapy in Patients With Failed Back Surgery Syndrome (Brazil)
3. The Effect of Ozonotherapy for Lumbar Herniated Disc (Spain)
4. Intraarticular Ozonotherapy for Pain Control in Osteoarthritis of the Knee (Israel)
5. Safety and Effectiveness Study of the AO-1000 Device to Treat Contained Herniated Discs (Canada)
6. Ozonotherapy in Endodontic Practice, in Vivo Study (Brazil)
7. Healozone Study to Evaluate the Safety and Efficacy of the Use of Ozone for Management of Dental Caries (United States).¹⁸

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

"Working in this field of medicine is 'very difficult' because there is no industry support, and

14 Jim Steppan, 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

15 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

16 19-1-2011. <http://www.abc.es/agencias/noticia.asp?noticia=658763>

<http://www.youtube.com/watch?v=AV7C2Nbkqgk>

<http://www.youtube.com/watch?v=iM8ZUnmEKxo>

17 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.

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

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."¹⁹

Prohibition and persecution of the ozonotherapy

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

The Autonomous Community of Madrid in Spain from 2006 until March 9, 2009 banned the practice of ozonotherapy in outpatient private clinics. Initially by a purely verbal decision and then was forced to put it in writing on May 20, 2008. During the term of the ban ozonotherapists had been inspected and were prohibited to practice ozonotherapy; follow-up inspections were made to verify that they were complying with the ban. They were warned that in case of non-compliance of the order 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 ozonotherapy by invasive methods have been described many accidents, which prevents authorization in such centers (...) The available evidence on treatment with ozonotherapy is insufficient to recommend its widespread use."²⁰

The ban remained into effect until March 9, 2009 when not only lifted the ban but authorized and regularized its practice in private outpatient clinics.²¹

Dr. Heinz Konrad who introduced ozonotherapy in Brazil in 1975, was indicted five years later by the Regional Council of Medicine of the State of Sao Paulo to be 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 it had not violated the ethical code.²²

Then a group of doctors reported him to the same Regional Council of Medicine of the State of Sao Paulo arguing that the ozonotherapy only served to make an economic profit, and that the medical treatment did not appear in the "respectable medical literature" and that his procedure was not ethical or legal. After two years of facing disciplinary proceedings the council closed the case.²³

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

20 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.

21 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.aepromo.org, members area, legislation, Spain.

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

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

In a pioneering way the Egyptian Ministry of Health in December 1999 regularized the practice of ozonotherapy. Despite the progress achieved it reached its end in February 2008 when it banned the practice in private centers, due to the significant economic slowdown that pharmaceutical companies were experiencing, as some of its products were less purchased due to the effectiveness of ozonotherapy.²⁴

In California, United States, the FDA (Food and Drug Administration) seized 79 ozone generators from the Applied Ozone Systems Company on January 30, 2010.²⁵

Legal delay and ozonotherapy

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

However, the increasing use of ozonotherapy and medical advances are not on par with regulatory developments. Despite the legislative intent that countries may do, 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 pose. The spectrum policy is overdue on what should legislate, to the extent that 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 a historical fact easily verifiable that public responses to the challenge at all times has brought attention to the health problems of the community have always been behind the changing needs without ever reaching them, so that it has become a constant among us the inadequacy of health structures to the needs of each succeeding period of time."²⁶

The "easily verifiable historical fact" referred to by the Spanish legislators, can be "touched" in many countries around the world to observe the gap between the advancement of ozonotherapy, and the policies developed by the health authorities. In fact a very few countries have been interested in providing the ozonotherapy with a legal minimum coverage.

II.FOR THE REGULARIZATION OF OZONETHERAPY

Regulate or not regulate

In general terms can be established two lines of thought on how to address the issue of ozonotherapy within the legal framework, to be recognized as a valid therapy and therefore

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

25 <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

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

accepted by the authorities, judges, insurance companies , patients and society in general.

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

The other line of thought is the one which proclaims that it is best not to stir the waters and therefore not coming near 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 ozonotherapy, sooner than later, is widely recognized and accepted by the competent bodies. In our view, it is necessary that the building of ozonotherapy is built on solid foundations in both medical and legal level because any health administrative action against ozone may cause the collapse of what has been built so far.

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

To this end we invite the national associations of ozonotherapy to take the necessary steps to request the competent state body to recognize the practice of ozonotherapy. One of the measures to be taken is to write down 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.

A support value is in "The Declaration of Madrid on Ozonotherapy" which was adopted at the "International Meeting of School of Ozonotherapy", held at the Royal Academy of Medicine in Madrid on June 3 and 4, 2010 under the auspices of the Spanish Association of Medical Professionals in Ozonotherapy (AEPROMO).²⁷ So far twenty-six national associations and international federations of ozonotherapy in Africa, America, Asia and Europe have signed the "Madrid Declaration on Ozonotherapy" and it has been translated into ten languages, with the official versions in Spanish and English.

The "Madrid Declaration on Ozonotherapy" is the first document of consensus in the global history of ozonotherapy, and has become the only document of ozonotherapy truly international and of great acceptance in the world.

27 Madrid Declaración on Ozonotherapy, June 4, 2010. http://www.aepromo.org/declaracion_madrid/Madrid_declaration.pdf

The Declaration is the guiding and working document of ISCO3 - International Scientific Committee of Ozonotherapy - which has the responsibility to introduce amendments where necessary, in order to keep it up in accordance with the scientific research on ozonotherapy conducted in the entire world.

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

“To encourage the different associations to work in their own countries where the 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 the

"Ozone therapy is a 'medical act' and should be practiced by medical personnel and implemented with a scientific rigor, it can produce with a low frequency a minimum of adverse cases."²⁸

III. COUNTRIES THAT HAVE REGULARIZED THE PRACTICE OF OZONETHERAPY

Despite the time elapsed since the discovery of the medical ozone so far, a very few countries have decided to include it into its legal structure. However it is worth emphasizing that in all countries where it is practiced today, if there is not legal backing, it is widely tolerated. The tolerance has greatly facilitated the daily work of health professionals, and the patients have benefited from the use of a good therapy. Although the tolerance which has benefited the ozonotherapy has to be considered highly satisfactory, it is not sufficient. It is necessary to establish minimum rules for the practice of the ozonotherapy, so all actors involved know in advance what to expect.

RUSSIA

Russia has been the first country in the world to adopt legal decisions on ozonotherapy. In this country is widely used in the health facilities of the state and is taught in some universities. The Nizhny Novgorod Department of the Experimental Medical Research Institute of Traumatology and Orthopedics for several years has devoted staff and resources to research on ozone issues.

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

²⁸ Madrid Declaración on Ozonotherapy, June 4, 2010. Anex, paragraph 5. http://www.aepromo.org/declaracion_madrid/Madrid_declaration.pdf

operations, cesarean deliveries or spontaneous abortions, in infants with intrauterine pneumonia or catarrhal omfalitis."

It has established that the ozone

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

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."²⁹

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 of Control in the Public Health and Social Development Area clarified that ozone can be used in:

- Current diseases of the pregnancy (hyperemesis gravidarum, etc.).
- Placental insufficiency.
- Chronic viral infection (citomagalovirus, genital herpes,)
- Toxicosis of pregnancy (gestosis).
- Anemia in pregnancy
- Prophylactic of intrauterine fetal infection
- Prophylactic of chronic deterioration of the pyelonephritis.
- Prophylaxis of complications post cesarean sepsis, septic deliveries, abortions of the first quarter.
- 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.
- Neonatal purulent infection complication.
- Early neonatal Pneumonia.
- Omfalitis in newborns.

The same Russian federal service has identified the following contraindications:

29 Federal Control Service Area of Public Health and Social Development, Registry Identification Certificate FC-2007/014-y of February 15, 2007, addressed to the Scientific Center of Maternity, Gynaecology 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".

Absolute contraindications: hyperthyroidism, bleeding, tendency to myoclonic jerks (eclampsia), acute myocardial infarction, acute alcohol intoxication, allergy to ozone, psychiatric illnesses.
Relative contraindications: Hypotension and arterial hypertension, difficult venous access.
Newborns contraindications: hemodynamic decompensation, hypocoagulation.³⁰

CUBA

Cuba adopted in 1996, the Traditional and Natural Medicine Development Program (MTN for its acronym in Spanish), and in 2002 passed the Agreement no. 4282 of the Executive Committee of the Council of Ministers, which among other decisions, created the MTN National Center Development as the lead agency in this area. The MTN

“(…) covers methods of health promotion, disease prevention, diagnosis, treatment and rehabilitation of patients using, among others, the modalities of Traditional Chinese Medicine (Acupuncture, Digitopuntura, Moxibustion, Suction Pads, Therapeutic Massages), Herbal Medicine, Apitherapy, Homeopathy, Flower Therapy, Suggestion and Hypnosis. It also includes the use of other natural resources such as mineral waters and mud, the ozone, as well as the controlled use of magnetic fields and other natural energy sources.”

So that ozonotherapy might have been integrated into the National Health System, it had to prove its effectiveness, as the other components of the Traditional and Natural Medicine (MTN), through

“Research supported by scientific evidence confirming their safety and their therapeutic effects or actions (…) The MTN is a medical specialty and its entire dimension should be practiced only by health professionals and staff properly trained and accredited.”³¹

Health professionals – physicians, estomatologists, nurses, psychologists – are those in charge in Cuba of the application of therapeutic procedures of the Natural and Traditional Medicine (MNT), previously approved by health authorities.³² In addition

“More than 30% of patients attending primary care consultations received MNT treatments, and that percentage rises to 40% in dental care.”³³

The ozonotherapy is widely applied in family doctors facilities, health institutes, provincial hospitals, and clinics. Given the positive results obtained, it was decided to found in 1994, under the umbrella of the Cuba Scientific Research National Center (CNIC for its acronym in Spanish), the Ozone Research Center. This center has a scientific staff coming from several professional fields. It is responsible for directing the studies and expands the applications of ozone across the country.³⁴

The process of continuous advancement of the practice of ozonotherapy allowed the regularization of ozonotherapy through Ministerial Resolution 261 of August 24, 2009, the

30 Federal Control Service Area of Public Health and Social Development, Annex to the Registry Identification Certificate FC-2007/014-y of February 15, 2007.

31 Padrón Cáceres Leoncio y Pérez Viñas Martha. “Integración de las prácticas de la medicina tradicional y natural al sistema de salud”. Ideas Cuba, Innovación para el Desarrollo y la Cooperación Sur-Sur. IDEASS is supported by United Nations specialized agencies such as the UNDP, UNOPS and ILO, p. 1 and following.

32 13-2-2012 <http://www.granma.cubaweb.cu/2012/02/13/nacional/artic05.html>

33 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>

34 <http://www.ozono.cubaweb.cu/acerca/historia.htm>

Ministry of Health of the Republic of Cuba.

The development achieved by Cuba in health is widely recognized by the United Nations.³⁵

SPAIN

Through the semi federal system that has Spain, the Autonomous Communities have the power to autonomously develop their powers in health, provided they conform to national legislation. In practice each community adopts measures which may be different from the others. These differences oblige us to analyze each community separately, as the norms and / or health policies may be different from one another.

There are no laws or norms at the national level specifically dealing with ozonotherapy.

Following the request of the Spanish Association of Medical Professionals in Ozonotherapy (AEPRIMO), autonomous communities have established written criteria for the practice of ozonotherapy in outpatient private clinics.

ARAGÓN (November 18, 2010)³⁶

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

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

"The equipment for the application will have the CE mark, and it will use medical oxygen supplied by 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 the signed informed consent.

"They must have CPR kit and medication urgency.

"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, 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).

35 Of the Latin American and Caribbean countries, and according to the Human Development Index (HDI) prepared by the United Nations Development Programme (UNDP), Cuba is located among the "high human development countries."
<http://www.eclac.org/publicaciones/xml/1/21541/lcg2331e.pdf>

36 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.

ASTURIAS (April 5, 2011)³⁷

Ozonotherapy - says Asturias - could be placed within the "non conventional therapies". For the practice of ozonotherapy 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 offer 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 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."

BALEARIC (October 30, 2007)³⁸

In the Balearic Islands

"(...) it is tolerated in the practice of private medicine in approved outpatient or not 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 sanitary product and have the CE mark, oxygen medical oxygen should be used, the patient has to be informed about the treatment and he has to sign the informed consent."

CANARY ISLANDS (October 3, 2007)³⁹

In the absence of legal regulations, the regulations issued by scientific associations of ozonotherapy shall be taking into account.

This autonomous community has provided specific support to research of ozonotherapy and has stated publicly in favor of it.⁴⁰

CASTILLA-LA MANCHA (May 13, 2010)⁴¹

The center to apply ozonotherapy 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:

37 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.

38 Balears. 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.

39 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.

40 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

41 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 AEPRIMO. www.aepromo.org. members area, legislation, Spain.

"Meeting the legal requirements" applicable to healthcare facilities.

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

"It must have a graduate in medicine and general surgery with training and proven experience in the application of oxygen-ozonotherapy.

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

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

"It must have the patient informed consent in accordance with current regulations.

"In case of application of intradiscal oxygen-ozone or other 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.

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

CASTILLA AND LEÓN (May 12, 2010)⁴²

This autonomous community places the ozonotherapy within the framework of the non conventional health activity and it requires to practice it the following: That the center meets the requirements of the law.

That "it shall provide in the nature and purpose of the center explaining report, appropriate information on the types of techniques and routes of administration planned of ozonotherapy, as well as the scientific support referred to the evidence on efficacy and safety of the same."

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

CATALONIA (July 8, 2010)⁴³

It indicates that although there "is not clear scientific evidence" of the ozonotherapy treatment and "in the current classifying typology centers norm according to their authorization" there is "no one referring to the ozonotherapy (...)". However

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

EXTREMADURA (September 17, 2010)⁴⁴

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

It adds that ozonotherapy "would be framed in the non conventional therapies (...), in which a physician is responsible for carrying out such treatments."

42 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 AEPRIMO.

43 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 AEPRIMO. www.aepromo.org, members area, legislation, Spain.

44 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.

In addition it also requires that centers have professionals with

"specific training, licensing and liability insurance.

"Ozonotherapy equipment CE marked.

"Medical Oxygen.

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

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

GALICA (March 2, 2010)⁴⁵

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

The ozonotherapy "as with other techniques used in practice clinic" will apply the general principles "of organization of health professions."

The practice of ozonotherapy

"will be performed with full technical and scientific autonomy, without other limitations 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."

LA RIOJA (16 November 2010)⁴⁶

"The practice of ozonotherapy is allowed by including it within the health care offers of 'non conventional therapies', defined by Royal Decree 1277/2003, as 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 ozonotherapy [emphasis 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 operating room and the administration of general anesthesia, loco-regional or local, with or no sedation, such as intradiscal application of ozone, these centers must be licensed in ambulatory surgery."

MADRID (March 9, 2009)⁴⁷

As stated above the practice of ozonotherapy in outpatient private clinics had been banned

45 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.

46 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.aepromo.org. Members area, legislation, Spain.

47 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.aepromo.org. Members area, legislation, Spain.

since at least 2006. But after the substantiated and reasoned request of AEPRIMO, Spanish Association of Medical Professionals in Ozone, the Community of Madrid not only lifted the ban but regularized, authorized the ozonotherapy in outpatient private clinics.

The Community of Madrid states that

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

It adds that

"the outpatient health center wishing to include in its health care offer 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 operating sanitary authorization (...) and addition also meet the following requirements:

"It will include in its health care offer the practice of ozonotherapy, indicating the different routes of administration that intends to use according to according to treat pathologies.

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

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

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

"It shall implement the necessary various protocols, depending on the route of administration of ozonotherapy, 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 ozonotherapy, which shall be placed on 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."

NAVARRA (November 29, 2010)⁴⁸

It notes

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

It states that the

"Ozonotherapy health care offer is framed among non conventional therapies and therefore

48 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.

it requires from the health professional responsible for performing such treatments to be a physician with training and experience."

BASQUE COUNTRY (February 7, 2011) ⁴⁹

The Basque Government indicates in its letter that outpatient health centers wishing "include in their health care offers the therapies with ozone, in which does not be necessary to apply local or general anesthesia and / or sedation (...)

"1. Must have authorization to operate: The offer of ozonotherapy practice shall be authorized within the non-conventional therapies, defined in the Royal Decree 1277/2003, as 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 (U.101).

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

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

"4. The ozone equipment shall be classified as 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 ozonotherapy, which shall be placed on 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 intradiscal application of ozone, the process shall be performed in a hospital operating room or major ambulatory surgery."

Comparison of requirements among the different Spanish autonomous communities

While measures taken by the Autonomous Communities are not equal, it is possible, however highlight the following common points that all outpatient private centers that practice the ozonotherapy have to meet:

49 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.

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

This requirement is prescribed in all autonomous communities.

To have a trained and experienced professional in the therapy.

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

To include in the health care offer ozonotherapy.

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

To use medical ozone equipment that have the marketing authorization of the European Union, called the CE mark.

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

To have appropriate protocols according to the route of application.

Six autonomous communities: Aragón, Castilla-La Mancha, Extremadura, Galicia, Madrid, Basque Country.

Informed consent signed by patient and physician.

Five communities: Aragón, Balearic Islands, Castilla-La Mancha, Madrid, Basque Country.

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

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

To locate the practice of ozonotherapy within the "non conventional therapies" which are defined in the Royal Decree 1277/2003, as 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.

Four autonomous communities: Extremadura, La Rioja, Navarra, Basque Country.

To have medical oxygen supplied by authorized companies.

Two communities: Aragón, Madrid.

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

One autonomous community: Canaries.

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

One autonomous community: Galicia.

ITALY

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.

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 been 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."⁵⁰

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 Societa Scientifica di Ossigeno ozonoterapia (SIOOT), and the Rome Province College of Physicians to explore the possibility that ozone could play in the treatment of disc herniation lumbociatalgias by paravertebral intramuscular injection within a properly regulated and precise specifications.⁵¹

In its recommendations the "Consensus Conference" specified when ozonotherapy 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 is indicated sending to the surgeon when the severe and disabling sciatica, continues without improvement or with deterioration. Before a month of conservative therapy is recommended sending 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, in cases of non-response to medical therapy it may be used for pain control oxygen-ozonotherapy intradiscal or intraforaminal or by intramuscular paravertebral injection."

It advises to obtain written informed consent of the patient:

"In the consent form must be stated that the practice of oxygen-ozonotherapy via intramuscular paravertebral still has no sure evidence of efficacy according to the criteria

50 Ministry of Health, Session President Curucullo Franco, Superior Council of Health, letter to the Minister of Health, May 20, 2004, on the letter (May 5, 2004) sent by the President of the Italian Federation of Oxygen-Ozone, Prof. Leonardi, on the "Use of ozone in medicine as oxygen-ozone mixture."

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

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 ozonoterapia] [it perfectly could be extended to any other scientific organization of ozonotherapy]"

It states that the physician should act on his own responsibility, knowledge and belief, performing the medical practice of ozonotherapy fulfilling basic requirements regarding training, equipment and conditions of the facility, and acting in accordance with therapeutic protocols.⁵²

Italian Regions

Lombardy Region (2003)⁵³

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 ozonotherapy, indicates the following concerning use of private medical services:

"[The circular] does inhibited and therefore does not interfere with the activity of therapeutic practice with the use of oxygen-ozonotherapy 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 procedures of oxygen-ozonotherapy;

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

"That the practice of oxygen-ozonotherapy must not be performed in beauty and fitness centers or similar.

"It is further recommended the organization of appropriate training courses for physicians who practice the oxygen-ozonotherapy."

Regarding the use of ozonotherapy in public centers said:

"Regarding the use of oxygen-ozonotherapy 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-Ozonotherapy. It shall be understood as including, therefore, the operational procedures relating to ozone intramuscular injections, paravertebral, intraforaminales,

52 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>

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

periganglionares and episacarales."

Emilia-Romagna Region (2007)⁵⁴

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

Marche Region (2009)

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

"1. The practice of O.O.T. [Oxygen-ozonotherapy] can be performed in private facilities for outpatient services provided 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 from, in the field of activity they develop, the practice of oxygen-ozonotherapy since there is not policy or regulatory impediment whatsoever, nor is there any mandatory provision issued by the Health Authority."

Court Rulings

The Italian courts have also ruled on the practice of ozonotherapy 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 ground 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 outpatients centers."⁵⁶

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

Later on, another group of physicians called for the nullification, prior 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

54 Regione Emilio-Romagna. Sciarrone Franca, Departamento 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.

55 Regione Marche. Ruta Carmine, Servicio 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.

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

"(...) the prejudice to 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."⁵⁷

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

Conclusions on the regularization in Italy

Italy is a country where ozonotherapy has been taking 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 ozonotherapy 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-ozonotherapy intradiscal or intraforaminal or by intramuscular paravertebral injection."

It advises

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

It states that the physician should act on his own responsibility, knowledge and belief, performing the medical practice of ozonotherapy fulfilling basic requirements regarding training, equipment and conditions of the facility, and acting in accordance with therapeutic protocols.⁵⁸

Moreover ozonotherapy is widely tolerated in the outpatient private clinics.

At the regional level, four administrations have spoken in favor of the private practice of ozonotherapy. In the Emilia-Romagna Region has been determined that the practice of ozonotherapy is the sole responsibility of the physician. In Lombardy it can practice in outpatient private clinics under condition of the patient's informed consent, that the equipment used are 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 the oxygen-ozonotherapy. In the Marche it can be performed "in outpatient private centers clinics provided do not violate the rules, regulations or priorities of the Health Authority" and clarifies that there are no rules preventing the practice of ozonotherapy.

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 outpatient private centers, as there is not serious and irreparable damage.

⁵⁷ 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.

⁵⁸ 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>

GERMANY

Is the country that discovered ozone, is the world's highest number of ozone therapists,⁵⁹ and is headquarters to large worldwide companies with great influence in the medical ozone equipment market. However there are no regulations or laws on ozonotherapy whether at state or national level. Nevertheless it is widely tolerated in all of Germany.

There are judicial decisions that may be applied to the ozonotherapy.

The jurisprudence of the Federal Court of Justice and the Federal Social Court, has not being of use for a legislative or administrative recognition of the ozonotherapy. However, it has been useful to be widely tolerated by the central government and the states of that country.

Three German authors⁶⁰ indicate that a ruling in July 1996 of the Federal Court of Justice (Bundesgerichtshof - BGH)⁶¹ and one from the Federal Social Court (Bundessozialgericht - BSG)⁶² 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 to the ozonotherapy,

“provided that every case of successful treatment with ozone is documented statistically in

59 11.000. Roberto Quintero Mariño. Anexo, Cuadro estadístico en artículo de 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>

60 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.

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

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

the scientifically correct manner (...)"

Bearing in mind that the Social Legal Code (SGB) determines that it is no longer 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 ozonotherapy, to be duly registered. This will provide scientific basis to the successes obtained empirically and independently of the scientific research.

UNITED STATES OF AMERICA⁶³

The FDA and ozone

In 2005 Professor Velio Bocci wrote that the U.S. government agency Food and Drug Administration (FDA) had forbidden the use of ozone in most states of the United States; "this fact has negatively influenced a correct development of ozonotherapy, that, however, is more or less tolerated in other parts of the world." A serious obstacle to development lies - according to this author - that the United States has established itself as the ruling dogma that "**ozone is always toxic any way you deal with it**", sentence written to Bocci by one of the best U.S. ozone chemists in 1995. However, this professional would not discuss the issue of ozonotherapy with him despite his insistence.⁶⁴

According to Bocci, the U.S. the expanded dogma in the U.S that " '**ozone is always toxic and should not be used in medicine**' (...) is an absurd and unscientific idea and today we have a million reason for saying that it is totally wrong. It is disappointing that some influent 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." ⁶⁵

An investigator contacted the Food and Drug Administration asking for its position on the statements by Professor Bocci regarding the prohibition of ozonotherapy in most 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 support regarding its safety or effectiveness for any therapeutic claim."⁶⁶

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

63 Información más detallada sobre Estados Unidos en "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

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

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

66 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

The FDA says on ozone the following on its web page:⁶⁷

“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.”

States with laws of health freedom

As the FDA has jurisdiction over the entire U.S. territory, then the assertion of Bocci has fallen short. Ozonotherapy is not only not allowed in some states but all over the U.S. territory. However this strong finding, has nuances and limitations of major impact, when analyzed more closely and in comparative way the health laws in force in the various states comprising the United States. As it known this country has federal structure and its states have certain powers to legislate on matters that have been authorized.

Investigation carried out in accordance to the Foundation for the Advancement of Innovative Medicine (FAIM)⁶⁸ found 15 states that the FAIM has been called "Health Freedom States" and divided into three categories:

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

Alaska,⁶⁹ North Carolina,⁷⁰ Colorado,⁷¹ Georgia,⁷² Indiana,⁷³ Massachusetts,⁷⁴ New York,⁷⁵ Ohio,⁷⁶ Oklahoma,⁷⁷ Oregon,⁷⁸ Texas⁷⁹ and Washington⁸⁰.

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

Page accessed September 28, 2009

68 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".

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

70 North Carolina General Statute, Section 90-14 (a) (6). Enacted June 29, 2993; and Section 90-2 Medical Board. Approved August 1, 2003.

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

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

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

74 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".

75 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.

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

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

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

79 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.

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

State with a law that protects patient access to alternative therapies practiced by all licensed professionals in health care:

Florida.⁸¹

States with regulations protecting patient access to alternative therapies by licensed physicians:

Louisiana,⁸² Nevada,⁸³ and Texas.⁸⁴

Health freedom legislation in 15 states

The analysis of comparative law on the 15 states conducted by Schwartz et al,⁸⁵ 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; sanction to physician; patient rights; informed consent; participation in state medical boards; and non-discrimination of alternative medicine.⁸⁶

Conclusion: The ozonotherapy can be practiced in 15 U.S. states

Although ozone is not a drug approved by the Food and Drug Administration (FDA), the legal analysis carried out states that non allopathic medicine can be used in the following 15 U.S. states: Alaska, North Carolina, Colorado, Florida, Georgia, Indiana, Louisiana, Massachusetts, Nevada, New York, Ohio, Oklahoma, Oregon, Texas and Washington.

No regulation of the fifteen states specified ozonotherapy, but also no list any unconventional therapy. However reasonably may be interpreted as the ozonotherapy may be used in 15 states of the country, under the laws of health freedom - named for the Foundation for the Advancement of Innovative Medicine (FAIM)⁸⁷ - to be located as a non conventional therapy.

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

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

OTHER COUNTRIES

Extrapolation of applicable legislation to ozonotherapy

With the exception of Russia, Cuba, Spain and Italy no other countries have administrative regulations, laws, decrees, or judicial decisions specific to ozonotherapy. In Germany (judicial

81 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.

82 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.

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

84 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.

85 Adriana Schwartz y Roberto Quintero Mariño. "La ozonoterapia frente a la legislación: Hacia un análisis global de derecho comparado", México, 2008. http://www.aepromo.org/pdf/ponencia_mexico.pdf

86 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

87 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".

rulings) and United States (analysis of state laws) we set extrapolations that allow us to conclude that ozonotherapy is widely tolerated in Germany and can be legally practiced in 15 U.S. states.

It is quite likely that other countries where the legal analysis of their laws would allow us to reach the conclusion that the practice of ozonotherapy would be permitted.

MÉXICO

The General Health Law, article 102 provides that

"[T]he Health Secretariat may allow for preventive, therapeutic, rehabilitative or research the use in human of drugs or materials for which have not yet enough scientific evidence of therapeutic efficacy or it is 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 diagnostic, when there is founded potential saving life, to reestablish health or reduce the suffering of the patient, provided [the physician] has his written consent, or his legal representative, if any, or next of kin in bond, and without prejudice to meet the other requirements prescribed in this Law and other applicable provisions."⁸⁸

CHILE

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

- 1) "To avoid exposure of the respiratory tract to toxic concentrations of ozone among patients and 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 Ozonotherapy" has several points that have addressed this issue].
- 2) "To avoid potential indirect damage in patients who may have access to effective therapies against the disease, see delayed or suspend access to those induced by the supposed benefits of a therapy based on ozone. This is essential to the proper public education about it. "[The requirement of written informed consent indicating where the benefits and possible negative consequences of treatment, would be an effective means of patient education].
- 3) "To foresee that is not used any method of ozone administration involving the use of invasive techniques without meeting the minimum operator training and infection control standards (universal precautions)."⁸⁹

COLOMBIA

This country in 1998 regulated the practice of alternative therapies through Resolution 2927 of 1998 of the Ministry of Health.

⁸⁸ 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>

⁸⁹ "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.

As per art. 7 of Law 1164 of 2007 it was set up a committee to 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 for alternative medicine and therapies those practices techniques, procedures, approaches or knowledge using stimulation of the operation of natural laws for self-regulation of the human being in order to promote, prevent, treat and rehabilitate the health of the population from holistic thinking.

"It is considered alternative medicine, among others, traditional Chinese medicine, medicine Adyurveda, Naturopathic Medicine and Homeopathic medicine.

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

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 with conventional medicine. Alternative medicine is used instead of conventional medicine. (Proposed by promoting alternative medicine and complementary therapies on the public network attached to the Bogotá District Health Department)

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."⁹⁰

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

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

IV. POINTS TO CONSIDER IN DEVELOPING THE STRATEGY TO REQUEST THE REGULARIZATION OF OZONETHERAPY

Political-administrative structure of the state

Basically states now have two different systems of political-administrative organization: Federal system and 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 central government and the states vary widely from country to country and therefore are 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 decision taken at the national level.

There are states that although not defined as either as federal or centralized, they 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 defined as a federal state in its constitution, it may happen that in everyday reality, may act as a centralized state, where the capital has enough influence to regional decision making.

In designing the strategy to follow in the process of regularization of ozonotherapy, it is crucial to know who has the authority to legislate and manage the health issue. If the states (or regions or autonomous communities, or provinces, or departments, etc.) have that authority would be better to design the search strategy of the regularization at the regional level instead of seeking at the national solution. This is the strategy used in Spain and it has been fruitful because most of its autonomous communities have regularized it. Nevertheless a community - Cantabria (October 6, 2010)⁹¹ - decided against it, claiming it was a national competence and not of 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 to whom it was asked to establish requirements to practice ozonotherapy did it.

In Russia, despite being a federal state the regularization was taken at the central level. In

91 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 AEPROMO. www.aepromo.org. Members area, legislation, Spain.

Cuba, centralized state, the decision was made directly by the Ministry of Health. In Italy, although there are already national decisions on ozonotherapy, four regions have spoken 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 "who to turn" requires legal knowledge on the political-administrative organization of the state, but also to know how it works in practice that organization.

What legal formalities must have the regularization?

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 verbally; and sometimes not saying nothing, leaving just to do. In the vast majority of countries where ozonotherapy is practiced the latter is what usually happens: Letting do, i.e., is the policy of tolerance.

In Cuba, the decision was made by means of a Ministerial Resolution signed by the Minister of Health.⁹²

In Russia by a Registry Identification Document issued by the Russian Federal Service for Control in the Public Health Area and Social Development.⁹³

In Spain initially the decision to ban the practice of ozonotherapy 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.⁹⁴ Since then all the information issued regarding the requirements that must be taken to practice ozonotherapy has been made through letters addressed to AEPRIMO, Spanish Association of Medical Professionals in Ozonotherapy.

In Italy the format of decision is very varied. It ranges from the letter addressed to the scientific association by the Ministry of Health,⁹⁵ to the circular sent to various government agencies,⁹⁶ to the memorandum,⁹⁷ etc. The formats are different.

What should be the ideal regularization format?

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

92 Resolución Ministerial 261, Ministerio de Salud Pública, 24 de agosto de 2009. www.aepromo.org. Members area, legislation, other countries.

93 Federal Control Service Area of Public Health and Social Development, Registry Identification Certificate FC-2007/014-y of February 15, 2007, addressed to the Scientific Center of Maternity, Gynaecology 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".

www.aepromo.org. Members area, legislation, other countries.

94 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 Roberto Quintero Mariño. www.aepromo.org. Members area, legislations, Spain.

95 Ministry of Health, Session President Curucullo Franco, Superior Council of Health, letter to the Minister of Health, May 20, 2004, on the letter (May 5, 2004) sent by the President of the Italian Federation of Oxygen-Ozone, Prof. Leonardi, on the "Use of ozone in medicine as oxygen-ozone mixture."

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

97 Regione Emilio-Romagna. Sciarrone Franca, Departamento di Sanità Publica, 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.

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

Is it ideal to have a national law? That is what is trying to get the FIO, Italian Federation of Oxygen-Ozonotherapy. Even there is 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 Ozonotherapy (AMOZON) which is looking for a regularization adopted by the national congress. Instead the Brazilian Association of Ozonotherapy (ABOD) is seeking the regularization through a decision taken by the Ministry of Health. The same desire has been expressed by Turkish ozonotherapists.

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 legal certainty and publicity. However it should not be ruled out any other formal way that administration often used for decision making, such as letters to scientific associations, or circulars to local authorities. What ultimately should matter to ozonotherapy scientific associations is to obtain from the authorities or legislators writing rules that will allow both ozonotherapists and patients to know in advance what should have a medical center to practice for legally the ozonotherapy.

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

Importance of the comparative law assessment

It is axiomatic that the human body is the same in all parts of the world, if there are exceptions there would be anomalies of the 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 are different, even among those that have their origins in a similar legal system such as the countries located in the tradition of the 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 is the European Union, where despite differences in legal systems that exist within its midst, has built a legal framework in force in all states of the union.

Hence the huge interest to know how ozonotherapy is regularized in different countries that have done it to compare it and extract the most beneficial to set an example for other countries. It is very convenient that public health agencies, and lawmakers know the normative development outside their borders.

International law

Increasingly there is growing international law binding on two or more countries, 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 international norms and what are their legal weight that may be useful to use to convince the states in their work to regularize the ozonotherapy.

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 ozonotherapy 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 ozonotherapy, 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 judgement 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."⁹⁸

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, whether in his view offers the hope of saving lives, restoring health or alleviate suffering."⁹⁹

Is the Declaration of Helsinki binding on States? If so, could one argue its contents to regulate the practice of ozonotherapy? 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."¹⁰⁰

98 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.

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

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

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

To be approved by an international body representing the states, such as the UN, OAS, European Union, or by two or more states, etc.

The document to be called resolution, treaty, covenant, etc. But it should not be designed "declaration" or "charter" (in the meaning of declaration), because in principle 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 even do not have to pass through congress or parliament.

To be the document 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 legally binding vary substantially when a State decides to incorporate into its domestic law with binding character a declaration of an international public or private organization.

For example: The United Nations Charter (in Spanish Declaración, in French Déclaration), the most important document in the world today, which gave birth to the United Nations, although not binding, has become the guiding instrument of all current international politics. There is no country that has spoken out against the Charter. Even many countries with constitutions or constitutional amendments after the founding of the United Nations (including Spain), explicitly refer to it in its constitution.

Although the United Nations Charter is not binding, for many states have such a moral power that has acquired legal validity 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 on the ethics of human research, has ever written. Also given the representative nature of the World Medical Association, its Declaration has become of 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 to be a global organization representing physicians, has not capacity that 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 to respect 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 (...)"¹⁰¹

101 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 (...)"

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 review and approval by an independent ethics committee (IEC).”¹⁰²

Among the various reasons given, the FDA

“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 to include in the applications for regularization the points of the Helsinki Declaration mentioned above. If the State has not explicitly committed to fulfill 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 fulfill it its inclusion in the application of regularization has no argument.

Madrid Declaration on Ozonotherapy

It is worth making explicit the force that has the "Madrid Declaration on ozonotherapy" 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 ozonotherapy. Twenty-six national and international associations of ozonotherapy have signed it, and there are other firms by other associations in the process of fruition. It is translated into ten languages and in the near future will join others. It is today the reference document and guide for the vast majority of ozonotherapists 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 when necessary.

The "Declaration of Madrid on Ozonotherapy" is not binding on any state. However, given the representation that it has today in the world of ozonotherapy, gives it an enormous moral force before the states due to the authority it has within the ozonotherapy associations and the upgradeability that the Declaration has.

The requirements listed in paragraph 5 of the Annex to the Declaration, are the proposals that the international community of ozonotherapy makes to the states so that they are imposed as

102 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

necessary for all outpatient private clinics that want to include it in their health care offers.

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 (1999).¹⁰³

Lobby

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

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

The second step is to write down 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 is a physician or specialized on health issues, is not necessarily an expert in ozonotherapy. Neither will have enough time, even though it desires, to know in depth and in detail the ozonotherapy. In his office is dealing with multiple issues and as ozonotherapy is not an issue of importance in his daily administrative activities, he may devote little attention to it.

Therefore it is convenient to forget to send in the attachment to the application 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 it is asked, why it is requested, and the reasons for asking. Avoid citations from third parties. Where possible should be citations of first hand. At the end of the application add the formal and educated paragraph, that if it required additional information, the signatory will be able to provide it. The drafters of the document must be able to provide the additional information if requested.

¹⁰³ 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.

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. Should be avoided to the maximum that the request is stored in a drawer and the answer is waiting.

From now on initiatives are varied and depend on the circumstances of each region or country, to make lobbying with the aim of getting 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 very prepared for questions that may arise. All this is a time consuming exercise, leave the practice to attend meetings, etc.. So we talk about apostolate, knowing that the regularization of ozonotherapy will not fall by a miracle from heaven.

V. CONCLUSION

The ozonotherapy is increasingly practiced in different parts of the world. The existence of more than 30 associations of ozone and more than 26 000 ozonetherapists well attest it. The authorities are speaking more frequently about this therapy, the media have echoed its practice, there have been cases that have reached the courts, research is being done despite having limited financial aid. However, for reasons of various kinds, the norms do not go to the rhythm of the wide application that the ozonotherapy is experiencing. Sometimes it becomes an obstacle, such as when it was banned in some place for several years in outpatient private clinics. This paper militates in favor of working for the regularization of ozonotherapy, 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 Ozonotherapy, 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 ozonotherapy in countries where it is being widely practiced.

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