



Preliminary Legal Evaluation
LEGAL SITUATION OF OZONE THERAPY IN BRAZIL

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Brazil is the country where the attack against ozone therapy has been the most devastating. It is currently the only country in the world where ozone therapy has been banned if it is not used as an experimental procedure; and the only where its practice may result in sanctions for the physicians who practice it. Aboz (Brazilian Association of Ozone Therapy) and the physicians who practice it deserve and need the support of the international world of ozone therapy. Imeof (International Medical Ozone Federations) is willing to contribute to the challenge. This document is a modest contribution to face the enormous machinery that has been put in place to eliminate ozone therapy from the medical agenda of the country. To the extent of our limited possibilities, we will continue to provide support and solidarity.

We know that the horizon of ozone therapy is not attractive and is full of obstacles. We know from our own experience that the road ahead is tortuous and very long. Despite the obstacles we must move forward and hopefully in a synchronized and joint manner. For this reason we must rely solely on scientific research and using ozone therapy in accordance with the criteria widely accepted by the international scientific community of ozone therapy. Routes of application that have no scientific basis should be definitively banished from our daily practice and from the information provided to patients. No to empiricism.

Currently in Brazil there are three sectors where ozone therapy has been or is being analyzed and / or decisions and / or court decisions taken. Their results are producing impacts with profound repercussions for the daily practice of the therapy. The three sectors are: the National Congress, the National Government and the Federal Council of Medicine (for its acronym in Portuguese CFM).²

OZONE THERAPY IN THE INSTITUTIONS OF THE STATE

Brazilian National Congress

¹ Imeof (International Medical Ozone Federation) is integrated by 22 ozone therapy associations from different countries of the world and its headquarters is in Madrid (Spain). info@imeof.org. www.imeof.org

² The originals of the citations of this document that were in Portuguese and Spanish were translated into English by the authors.



Senator Valdir Raupp of the Brazilian Democratic Movement presented a bill in 2017 authorizing the use of ozone therapy as a complementary medical procedure. The physician, says the proposal, must inform "the patient that ozone therapy shall be prescribed as a complementary treatment" which does not exclude "the access to other therapeutic modalities".³

The bill was approved by the Senate Social Affairs Commission and sent to the Chamber of Deputies where the Social Security and Family Commission is evaluating it. On December 7, 2017 it took place a public debate on the project involving, among others, the then president of Aboz (Brazilian Association of Ozone Therapy) Dr. Emília Gadelha Serra and Dr. Aníbal Lopes on behalf of the Technical Chamber of New Procedures of the Federal Council of Medicine (CFM).

Aníbal Lopes defended that ozone therapy treatment should be considered as an alternative therapy, as have been reiki, music therapy and osteopathy, which are already included in the SUS (for its acronym in Portuguese, Unified Health System) public service. He proposed that instead of passing a law at the national congress on ozone therapy, it would be necessary to request the Ministry of Health to include it in the SUS. The therapy, he added, would be prescribed by a "responsible health professional who does not have to approve a specific course recognized by the Federal Council of Medicine (CFM)."

He affirmed that ozone therapy "is not a medical act" but rather an "integrative and complementary practice in health". The person in charge must inform the patient that this treatment is complementary and that "it does not replace or eliminate other treatments".

For its part, Emília Gadelha Serra argued that ozone therapy should be considered a medical procedure by the CFM, in the same way that, for example, it has been acupuncture. The approval of the CFM would help to prevent the technique "from being managed by unlicensed professionals".⁴ Aboz (Brazilian Association of Ozone Therapy) is of the opinion that the proposal of the CFM, through Lopes "will allow non-medical professionals to practice ozone therapy, which in reality is a 'medical act'".

³ Projeto de Lei do Senado nº 227, de 2017, "Autoriza a prescrição da ozonioterapia em todo o território nacional". <http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=2160126>
Page consulted 18 July 2018.

⁴ <http://www2.camara.leg.br/camaranoticias/radio/materias/RADIOAGENCIA/550532-REGULAMENTACAO-DA-OZONIOTERAPIA-DIVIDE-OPINIOES-EM-COMISSAO.html> Page consulted 18 July 2018



Later on, 38 senators and more than 250 deputies formed the "Joint Parliamentary Front in Defense of the Ozone Therapy" with the aim of obtaining the approval of Senator Valdir Raupp's bill. ⁵

The law project is still in the Social Security and Family Commission of the Chamber of Deputies. No decision has been taken yet. As there will be general elections the upcoming October 2018 ⁶ to elect president, vice president, senators and deputies of the national congress, governors, state vice-governors and state legislative assemblies, it is very likely that no decision will be taken either for or against the project of law on ozone therapy in the current legislature.

Federal Council of Medicine (for its acronym in Portuguese CFM)

The CFM is an organization with constitutional powers of inspection and standardization of medical practice, to have and maintain the professional registration of physicians and to apply sanctions prescribed in the Code of Medical Ethics. The CMF defends "the corporate interests of physicians, strives to uphold good medical practice, ethical professional practice and good technical and humanistic training, believing that the best defense of medicine is to guarantee quality medical services for the population." ⁷

Since the Brazilian national congress began to debate the ozone therapy bill the CFM in a very unusual movement and at a cruising speed, launched its bureaucratic organization to block with the means at its disposal the project. Just seven days after the public debate in the Chamber of Deputies, the CFM with the objective that congress did not approve the law project made public its open opposition. ⁸ It mobilized and formed an opposition front set up

⁵ This is stated by the deputy Wolney Queiroz (PDT Democratic Labour Party from Pernambuco). 13 December 2018. <http://www2.camara.leg.br/camaranoticias/radio/materias/A-VOZ-DO-BRASIL/550899-GOVERNO-E-AUDITORES-DIVERGEM-SOBRE-NUMEROS-DA-PREVIDENCIA-SOCIAL.html>. Page consulted 19 July 2018

⁶ 1st. round 7 October; 2nd. round 28 October 2018.

⁷ http://portal.cfm.org.br/index.php?option=com_content&view=article&id=20671&Itemid=23
Page consulted 23 July 2018

⁸ CMF "Nota de repúdio ao PL [Proyecto de Ley] que autoriza a ozonioterapia", 14 diciembre 2017
<http://portal.cfm.org.br/images/stories/pdf/nota%20ozonioterapia%20%2015-12-21.pdf>
Page consulted 21 July 2018.



of 29 medical scientific and health professionals associations.⁹ It draws powerfully attention to the fact that among the signatories it appeared the Instituto Cochrane do Brasil, which is neither a medical scientific society nor a health professional association. Its objective is to "contribute to the improvement of health decision making, based on the best scientific information available. Its mission is to develop, maintain and disseminate systematic reviews of randomized clinical trials, the best level of evidence for health decision making."¹⁰ Therefore, its official positions should be totally independent of the medical and professional scientific community.

The Cochrane do Brasil Institute published a systematic review of new integrative medicine practices, in which ozone therapy was included.¹¹ This being not the place to analyze its content, it is enough for now, to point out that it would seem that the Instituto Cochrane do Brasil was in a hurry for the systematic review to be made and published, because the government had included ozone therapy and other integrative and complementary practices on March 12, 2018. In order for the investigation to be carried out in such an accelerated manner, Cochrane had a team of 24 people. That is, it was a job with many hands and therefore the drafting and internal acceptance process necessarily had to be complex. The result was that the following month after the ozone therapy had been authorized to integrate the Brazilian public health system, the SUS, the systematic review was ready. It was sent for publication to the "Sao Paulo Medical Journal" on April 17, 2018. And in a non-strict form for a journal that is supposed to carefully review the articles that are proposed for publication, it was accepted on the same day as the journal had received it on April 17, 2018. The speed to make it public at least indirectly indicates that there was an interest in attacking ozone therapy. Why did the

⁹ Subsequently, the CFM noted that the document had been endorsed by 55 organizations and some paragraphs below indicated that they were 25.

http://portal.cfm.org.br/index.php?option=com_content&view=article&id=27338%3A2017-12-15-18-29-39&catid=3%3Aportal&Itemid=23

Anyway, in the Note of Repudiation posted on the same website the CFM appear a total of 29 associations. Mathematical error or deliberate interest to confuse with the number of signatories?

http://portal.cfm.org.br/index.php?option=com_content&view=article&id=27338%3A2017-12-15-18-29-39&catid=3%3Aportal&Itemid=23

¹⁰ <https://brazil.cochrane.org/o-centro-cochrane-do-brasil>. Page consulted 22 July 2018

¹¹ What do Cochrane systematic reviews say about new practices on integrative medicine? Sao Paulo Medical Journal, vol.136 no.3 São Paulo May/June 2018. Epub June 25, 2018.

http://www.scielo.br/scielo.php?script=sci_arttext&pid=S1516-31802018000300251&lng=en&nrm=iso&tlng=en Page consulted 15 July 2018



Instituto Cochrane do Brasil not previously analyze the decisions of 2006 and 2017 regarding other inclusion of therapies in the SUS?

The front created by the CFM against ozone therapy expressed "its repudiation and concern about the possible approval [by the national congress] of this proposal [of legalization of ozone therapy], which does not have technical and scientific verification." Its authorization "exposes to patients at risk, such as delaying the start of effective treatments, advancing diseases and compromising health." It remembers that the CFM had already analyzed the ozone therapy procedure, having recommended its practice "experimentally". Although it recognizes that it is carrying out a new evaluation on ozone therapy, the CFM starts to discredit it without even having the results of it. It should at least have waited for its conclusions before launching the public manifesto of repudiation of the ozone therapy.

Later on the CFM published the result of the new research, stating that ozone therapy is "a procedure that can be carried out only experimentally. This implies that medical treatments based on this approach must be carried out only within the scope of studies that meet criteria defined by the National Commission of Ethics in Research (Conep)."

The rapporteur appointed by the CFM Leonardo Sérgio Luz concluded "that the strength of evidence supporting the synthesis of efficacy and harm is very low (high risk of bias), which means that there is uncertainty in effect estimates. Thus, the degree of uncertainty involved in the effectiveness of the practice [of ozone therapy] remains high; in addition, there is no benefit in the probable effects of its clinical use when compared to the treatments already consecrated in use. There is also evidence of an estimate of harm to patients submitted to ozone therapy, and may even endanger the health of these individuals."¹²

The CFM specifies that in these experimental cases, "the secrecy and anonymity for those who undergo the practice, the offer of medical-hospital support in case of adverse effects and the non-payment of treatment in any of its stages must be guaranteed."

The decision of the CFM is of paramount negative importance for the physician who practices ozone therapy because the CFM has the legal prerogative to apply sanctions against him using

¹² Article 1. To consider ozone therapy as an experimental procedure for medical practice, in accordance with the grounds contained in the annex to this resolution, and can only be performed under clinical protocols in accordance with the rules of the CEP / Conep system, in duly accredited institutions. [CEP: Comitês de Ética em Pesquisa; Conep: Comissão Nacional de Ética em Pesquisa] Resolution CFM No.2.181/2018 (Published in the Official Gazette of the Union, 10 July 2018, section I, p. 106).

<https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2018/2181> Page consulted 18 July 2018.



the Medical Ethical Code. The decision prohibits physicians from practicing it for "outside the standards established by the CFM." That is, the professional can only use it as "experimental". The CFM emphasizes that its non-compliance will lead to investigations and ethical-professional processes against offenders. It insists that "the prescription and use of alternative procedures and therapies, without scientific recognition, are prohibited to Brazilian doctors, in accordance with the provisions of the Medical Ethical Code." ¹³

National Government

The central government in Brasilia since 2001, under the presidency of Fernando Henrique Cardoso, began to study the "establishment of policies to guarantee integrality in health care". Under the presidency of Luiz Inácio Lula da Silva, the government formalized the "National Policy of Integrative and Complementary Practices (PNPIC) in the SUS" [Unified Health System]. ¹⁴

Taking into account the growing legitimacy of integrative and complementary practices by the society on the basis of existing experiences, and "the guidelines and recommendations of several national health conferences and the recommendations of the World Health Organization (WHO), ¹⁵ the new policy was implemented with the intention of preventing, promoting, maintaining and recovering health "based on the model of humanized care and focused on the integrality of the individual". In this way, the government expanded health offers so that the population had access to services that were previously restricted to the private sector.

¹³ http://portal.cfm.org.br/index.php?option=com_content&view=article&id=27716%3A2018-07-09-15-34-31&catid=3%3Aportal&Itemid=23 Page consulted 21 July 2018.

¹⁴ "Health is the right of everyone and the duty of the State", art. 196, Constituição da República Federativa do Brasil de 1988. http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm Page consulted 22 July 2018. Based on this constitutional provision, the Unified Health System was created, "one of the largest public health systems in the world, ranging from simple attention to the evaluation of blood pressure to organ transplantation, guaranteeing comprehensive, universal and free access for the entire population of the country." <http://portalms.saude.gov.br/index.php/sistema-unico-de-saude/sistema-unico-de-saude> Page consulted 22 July 2018.

¹⁵ Ministério da Saúde, Secretaria de Atenção à Saúde, Departamento de Atenção Básica Secretaria de Atenção à Saúde, Departamento de Atenção Básica, "Política Nacional de Práticas Integrativas e Complementares no SUS - Atitude de Ampliação de Acesso", 2ª edição, Brasília-DF, 2015, http://bvsmis.saude.gov.br/bvsmis/publicacoes/politica_nacional_praticas_integrativas_complementares_2ed.pdf Page consulted 22 July 2018



Since 2006, the Ministry of Health has published several ordinances on integrative and complementary practices, which have been offered in the SUS (for its acronym in Portuguese, Unified Health System). Among them are acupuncture, homeopathy, phytotherapy, anthroposophic medicine, art therapy, and ayurveda. Very recently (March 21, 2018) included other practices such as aromatherapy, chromotherapy and also ozone therapy.¹⁶

The Ministry of Health states that "ozone therapy is an inexpensive, complementary and integrative practice", and in a totally opposite position to the CFM it states that the therapy has a "proven and recognized safety". It adds that "the therapeutic potential of ozone" has gained much attention administered with "precise therapeutic doses." It indicates that this therapy "contributes to the improvement of various diseases, since it can help to recover naturally the functional capacity of the human and animal organism."

The CFM, again at an unusual speed, took only one month (April 20, 2018) to manifest, along with other medical entities, against "the allocation of resources for practices that do not present technical and scientific evidence of their effectiveness." He argued that "the integrative practices made in the SUS [for its acronym in Portuguese, Unified Health System] have no basis in the evidence-based medicine (MBS) [for its acronym in Portuguese] - that is, they ignore the integration of the clinical skill with the best available scientific evidence." Consequently, the CFM along with other medical entities, qualify as a "waste" that public money be dedicated to these practices.¹⁷

It was the first time that the CFM pronounced itself in such a categorical way against the Integrative and Complementary Practices in the Unified Health System (SUS) of the Brazilian national government. The Ministry of Health had been analyzing it since 2001 and it began to be implemented since 2006. Why had not been the CFM so strongly against it in the previous years? The answer could perhaps be found in the following: only until 2018 ozone therapy was incorporated into the SUS. It would seem that the CFM is not against other integrative and complementary practices but specifically against ozone therapy, although the CMF itself recognizes that only two practices (homeopathy and acupuncture) have been recognized by

¹⁶ Portaria n° 702, de 21 de março de 2018.

http://bvsmis.saude.gov.br/bvsmis/saudelegis/gm/2018/prt0702_22_03_2018.html Page consulted 18 July 2018.

¹⁷ http://portal.cfm.org.br/index.php?option=com_content&view=article&id=27716%3A2018-07-09-15-34-31&catid=3%3Aportal&Itemid=23 Page consulted 22 July 2018. Although the resolution was approved on April 20, 2018 it was only made public on July 10.



the council. Why was not the CFM pronounced against for example of the ayurveda or the reiki that were incorporated into the SUS in 2017? ¹⁸

LEGAL ANALYSIS ON THE PRACTICE OF OZONE THERAPY IN BRAZIL

Two opposite regulations

Physicians who practice ozone therapy currently in Brazil face two regulations that *prima facie* would be openly contrary to each other. On the one hand, in accordance with the ordinance No. 702 of March 21, 2018 of the Ministry of Health, ¹⁹ ozone therapy can be used in the public health system of the country and consequently, those who practice it may rely on this ordinance. And on the other hand the CFM (Federal Council of Medicine) has regulated that its practice is prohibited, unless it is used as "experimental"; and that a physician could face sanctions in accordance with the Medical Ethical Code. ²⁰ Which of the two provisions have the highest legal hierarchy and which one prevails over the other? Ordinance No. 702 of March 21, 2018 from the government or Resolution CFM No. 2.181 / 2018?

The Ministry of Health dictates the ordinance based on the single paragraph of Article 87 of the Brazilian Constitution. ²¹ The CFM dictates the resolution based on art. 7 of the law 12.842 / 2013. ²²

¹⁸ Ministério da Saúde, Portaria N° 849, 27 março 2017.

https://www.lex.com.br/legis_27357131_PORTARIA_N_849_DE_27_DE_MARCO_DE_2017.aspx

Page consulted 1 July 2018.

¹⁹ Portaria n° 702, de 21 de março de 2018. http://portal.imprensanacional.gov.br/web/guest/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/7526450/do1-2018-03-22-portaria-n-702-de-21-de-marco-de-2018-7526446 Page consulted 18 July 2018.

²⁰ http://portal.cfm.org.br/index.php?option=com_content&view=article&id=27716%3A2018-07-09-15-34-31&catid=3%3Aportal&Itemid=23

Page consulted 21 July 2018

²¹ Art. 87, Constituição da República Federativa do Brasil de 1988: "The Ministers of State shall be chosen from among Brazilians over twenty-one years of age and in the exercise of political rights.

Single paragraph. It is incumbent upon the Minister of State, in addition to other duties established in this Constitution and in the law:

I - to exercise the orientation, coordination and supervision of the organs and entities of the federal administration in the area of its competence and to comply with the acts and decrees signed by the President of the Republic;

II – To issue instructions for the execution of laws, decrees and regulations".

http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm Page consulted 22 July 2018



The two regulations (that of the Ministry of Health and that of the CMF) have legal basis and will be in force as long as they are not repealed, modified or declared unconstitutional by a competent court. Hence, the importance that justice determines whether or not the CMF has legal authority to sanction physicians who practice ozone therapy.

Federal justice and ozone therapy

In order to decide on this complex legal issue, the judicial machinery is already underway. "Currently, the Federal Court of Ceará is bringing forward, at the initiative of Aboz, a judicial action that questions the competence of the Federal Council of Medicine - CFM, to punish any professional who makes use of ozone therapy." The plaintiffs' lawyers²³ argue that it is "exclusive competence of the Federal Union, States and Municipalities to legislate on procedures applied to health." For this, they are based on the constitutional article 24.²⁴ They add that art. 7 of Law 12.842 / 2013 on the exercise of medicine cannot be above the constitution. According to them the constitution has determined that it is exclusively for the Union to "legislate on the conditions for the exercise of the professions."²⁵

In the preliminary decision adopted, federal judge João Luis Nogueira Matias said that Aboz has requested that an "anticipatory jurisdictional provision be issued that determines the defendant [CFM] to refrain from establishing administrative proceedings against his associates for using ozone therapy as technique for the treatment of diseases." Aboz alleges

²² Art. 7, law 12.842/2013 about the practice of medicine: "It is understood among the competencies of the Federal Council of Medicine to define the experimental character of procedures in Medicine, authorizing or prohibiting their practice by doctors.

"Single paragraph. The supervisory powers of the Regional Councils of Medicine covers the supervision and control of the procedures specified in the *caput* [at the beginning], as well as the sanctions in case of non-compliance with the relevant sanctions in case of non-compliance with the rules laid down by the Federal Council."

<http://www2.camara.leg.br/legin/fed/lei/2013/lei-12842-10-julho-2013-776473-norma-actualizada-pl.pdf>

page consulted 22 July 2018

²³ Paulo Roberto Uchoa Do Amaral and Roberto Wagner Vitorino Do Amaral, attorneys at law from the Ceará State Bar Association.

²⁴ Art. 24. "It is the responsibility of the Union, the States and the Federal District to legislate concurrently on: XII - social security, protection and health protection". Constituição da República Federativa do Brasil de 1988 http://www.planalto.gov.br/ccivil_03/constituicao/constituicao.htm Page consulted 22 July 2018

²⁵ Nota de Esclarecimento Jurídico, 10 julio 2018 <http://www.aboz.org.br/noticias/nota-de-esclarecimento-juridico/83/> Page consulted 23 July 2018



that Law No. 12,842 / 2013 that "attributes to the CFM the competence to define which procedures can be incorporated into medical practice" is unconstitutional.

The federal judge has stated that for prudence is appropriate to maintain "the prohibition of the use of ozone therapy by the medical establishment, because of what it has been disclosed in the media about the matter." And it brings as an element of support the report on July 8, 2018 of the Red Globo Fantastic Program,²⁶ where according to federal judge João Luis Nogueira Matias "cases of physicians who used the technique in their patients and promised the cure of various diseases were reported." He adds that it is of "public knowledge that physicians are using ozone therapy as a 'miraculous' technique for the treatment of diseases that traditional [allopathic] medicine (based on scientific evidence) still does not offer cure."

Finally, the judge decides not to accept the application of "urgent temporary protection"²⁷ that had been requested by Aboz. It is a preliminary decision because the process continues its course until it reaches its end with a ruling that must be appealable to a higher instance.

Can the doctor now practice ozone therapy without being sanctioned?

While the court decides on the legal competence or not of the CMF to sanction physicians for practicing ozone therapy, and the two regulations in force (one from the government and the other from the CFM) are neither repealed nor modified, what can the doctor do?

Ordinance No. 702 of March 21, 2018 of the Ministry of Health²⁸ is in force. Therefore ozone therapy can be used in the public health of the country and whoever practices it, within the public sector, can rely on this ordinance despite what the CMF says.

What happens to doctors who practice ozone therapy in the private sector? In this regard there is a legal vacuum because there is no specific legislation on ozone therapy for the private sector. However, the normative interpretation of equal rights for people who are exercising the

²⁶ <http://g1.globo.com/fantastico/noticia/2018/07/questionada-pela-ciencia-terapia-com-ozonio-ganha-espaco-em-consultorios.html> Page consulted 13 July 2018

²⁷ Federal judge, 5^a vara/CE. 16 July 2018
<http://portal.cfm.org.br/images/PDF/decisao%20denegatoria%20ozonioterapia1.pdf> Page consulted 24 July 2018

²⁸ Portaria n° 702, 21 March 2018. http://portal.imprensa.nacional.gov.br/web/guest/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/7526450/do1-2018-03-22-portaria-n-702-de-21-de-marco-de-2018-7526446 Page consulted 18 July 2018



same activity would be impaired. The same physician who works in the public sector where he is using ozone therapy covered by ordinance 702 of 2018, could not use the same therapy in his private practice? Obviously his equality of rights for professional practice would be diminished. So it could be made the following interpretation of ordinance 702 of 2018: The content of the ordinance might be applied to the private sector, as long as there is no specific disposition for ozone therapy that fills the legal vacuum that currently exists. Why an activity regulated in the public sector cannot be performed in the private sector under the conditions of respecting the requirements laid down in the public? Professionals working in the private sector could be covered under ordinance 702 of 2018, as are professionals in the public sector.

This was suggested by Dr. Aníbal Lopes, member of the Technical Chamber of New Procedures of the Federal Council of Medicine (CFM) in the public debate in the Chamber of Deputies. There he expressed the possibility that the ozone therapy treatment would be considered an alternative therapy, as were reiki, music therapy and osteopathy, among others, that are now offered by the Ministry of Health under the Unified Health System (SUS).

Lopes observes that, in this way, it would not be necessary to approve an ozone therapy law, but rather a petition that would be sent to the Ministry of Health requesting that the therapy be incorporated into SUS. He added that the therapy would be applied by a responsible health professional, who would not need to go through a specific course recognized by the Federal Council of Medicine (CFM).

Lopes affirms that ozone therapy "is not a medical act, it becomes an act of indication of a procedure of integrative and complementary practice in health." The person in charge must inform the patient that the character is complementary, that is, it does not substitute or eliminate other treatments."²⁹

Lopes even in his speech enumerated the requirements that these integrative and complementary practices should have to be included in the SUS:

That they be complementary practices of traditional use.

That scientific verification, although desirable, is not essential.

That is of current use in the country.

That does not present significant risks.

That they are performed by health professionals and therapists.

²⁹ <http://www2.camara.leg.br/camaranoticias/radio/materias/RADIOAGENCIA/550532-REGULAMENTACAO-DA-OZONIOTERAPIA-DIVIDE-OPINIOES-EM-COMISSAO.html> Page consulted 18 July 2018



That they are activities financed by the basic care service. In this point he emphasized that the use of these practices were remunerated and not performed as voluntary work.

He recalled that there were several ordinances of the Ministry of Health where were listed who were the professionals qualified to practice the therapies included in the SUS.³⁰

Who are competent to practice ozone therapy in the SUS?

Several ordinances of the Ministry of Health detail what activities can be performed by doctors, nurses, and other health professionals, specifying even specialties, and the prices that must be charged for the services provided.³¹ It is to be assumed then that since the ozone therapy has already been integrated into the SUS, the Ministry of Health shall specify who can practice it, how much could be charged for each treatment, etc.

FINDINGS

The bill on the authorization of ozone therapy as a complementary medical procedure is in the Social Security and Family Commission of the Chamber of Deputies. It will most likely be left without any decision being taken, for the time being, given the general elections in Brazil next October.

The Ordinance No. 702 of March 21, 2018 of the Ministry of Health that incorporated ozone therapy within the SUS (Unified Health System) is fully in force and can be practiced legally by doctors in the public health sector of the country.

The CFM [Federal Council of Medicine] Resolution No.2.181 / 2018 that authorizes the practice of ozone therapy only as an experimental procedure is legally valid and therefore can be applied against any doctor who practices ozone therapy in a non-experimental manner. The judicial process underway filed by Aboz to request the unconstitutionality of the CFM's ruling

³⁰ <http://www2.camara.leg.br/atividade-legislativa/webcamara/videoArquivo?codSessao=71781#videoTitulo>
Page consulted 18 July 2018

³¹ Among them are the Portaria No. 853, 17 de novembro 2005.

http://189.28.128.100/dab/docs/legislacao/portaria853_17_11_06.pdf Page consulted 23 July 2018

Portaria No. 154 de 18 de março de 2008

http://189.28.128.100/dab/docs/legislacao/portaria154sas_18_03_08.pdf Page consulted 23 July 2018

Portaria No. 633, de 28 março de 2017

http://189.28.128.100/dab/docs/portaldab/documentos/prt_633_28_3_2017.pdf Page consulted 23 July 2018



is ongoing and the provisional measure of not implementing it requested by Aboz, while the application is decided in substance, was rejected by the federal judge.

The CFM with an unusual speed, from the moment he learned that a bill had been presented to authorize the use of ozone therapy as a complementary medical procedure, mobilized all its bureaucratic machine and other medical organizations, to strongly oppose ozone therapy. Equally quickly has been the Instituto Cochrane do Brasil; actually in less than a month it had written a document to position itself against ozone therapy and against other therapies included by the government in the SUS (Unified Health Service). The speed is astounding considering that neither the CFM nor the Cochrane Institute of Brazil had pronounced so forcefully against therapies included in the SUS even though the first ones had been accepted in 2006.

SUGGESTIONS FOR ABOZ (BRAZILIAN ASSOCIATION OF OZONOTERAPIA)

Legal strategy

1. We suggest that Aboz develop a legal strategy to eliminate the current contradictory dichotomy generated between the legal application of ozone therapy in the public sector (SUS) and its non-authorization in the private sector. There must not be legal norms with force of law that while they authorize the practice of ozone therapy in the public sector, they prohibit it in the private sector. It should be suggested and hopefully convince the Ministry of Health about the profile, knowledge and experience of the professionals who can be qualified to practice the different ozone therapy therapies, and the ways of using it, both in the public sector and in the private.
2. The strategy may take into account the suggestion defended by Dr. Aníbal Lopes, member of the Technical Chamber of New Procedures of the Federal Council of Medicine (CFM) in the public debate at the Chamber of Deputies. It is worth remembering that his intervention took place a few months before the government included ozone therapy in the SUS. Aníbal Lopes expressed the possibility that the ozone therapy treatment would be considered as an alternative therapy, as were reiki, homeopathy, music therapy and osteopathy, among others, which today, said Lopes, are offered by the Sistema Único of Health (SUS). Lopes noted that, in this way, it would not be necessary to approve an ozone therapy law, but rather a petition sent to the Ministry of Health requesting its incorporation in the SUS. The therapy would be applied by a responsible health professional, who would not need to go through a specific course recognized by the Federal Council of Medicine (CFM). Ozone therapy would then be an act of indicating an integrative and complementary practice



procedure in health that does not replace or eliminate other treatments.³² A similar approach, *mutatis mutandi*, could help strengthen the proposal for the government to authorize its practice in the private service.

3. An analysis of international comparative law lead us to find justifications for this strategy. For example, in the Cuban and Turkish legislation.
4. The Caribbean island regulated the practice of ozone therapy within the Natural and Traditional Medicine framework, defined as a "medical specialty, integrating and holistic of health problems, employing methods for health promotion, disease prevention, diagnosis, treatment and rehabilitation from traditional medical systems and other therapeutic modalities that are integrated with each other and with the conventional treatments of Modern Western Medicine." (art. 1). It defined ozone therapy (art. 2, e), it specified in article 4 who can apply it and the obligation to have a degree. It stated explicitly that "the instructors of sports practices, masseurs and collectors selling medicinal herbs who exercise as self-employed workers, are not recognized as therapeutic in the exercise of the activities they develop." (art. 6).³³
5. Turkey in the Regulation of Traditional and Complementary Medicine (October 27, 2014) included ozone therapy.³⁴ The regulation "identifies the methods of practice of traditional and complementary medicine for human health, clarifies the standards of

³² <http://www2.camara.leg.br/camaranoticias/radio/materias/RADIOAGENCIA/550532-REGULAMENTACAO-DA-OZONIOTERAPIA-DIVIDE-OPINIOES-EM-COMISSAO.html> Page consulted 18 July 2018.

³³ Resolución No. 381, Ministerio de Salud Pública, Gaceta Oficial No. 17 Extraordinaria 20 mayo 2015. Ministerio de Justicia, República de Cuba. In Roberto Quintero et al., *Ozonoterapia y Legislación – Análisis para su Regularización*, 3ª edición actualizada y ampliada, Madrid, 9 octubre 2017. Written for the exclusive use of the 3rd. Distance Diploma Course of "Ozone Therapy and Ozonized Growth Factors" organized by AEPROMO with the endorsement of ISCO3.

³⁴ Regulations, Traditional and Complementary Medicine. Official Gazette No: 29158, October 27, 2014. In Roberto Quintero et al., *Ozonoterapia y Legislación – Análisis para su Regularización*, 3ª edición actualizada y ampliada, Madrid, 9 octubre 2017. Written for the exclusive use of the 3rd. Distance Diploma Course of "Ozone Therapy and Ozonized Growth Factors" organized by AEPROMO with the endorsement of ISCO3.



education and diplomas of health professionals who will be practicing this therapy, determines the working principles and procedures of health institutions." (art. 1).

6. "It covers health professionals and public and private health institutions that will practice traditional and complementary medicine" (art. 2). Informed consent is required (art. 8.4 and 11.5). Any adverse effect must be duly informed (art. 11.4). Only the traditional and complementary medicine therapies listed in the annex of the Regulation can be practiced in the country (art. 8, 1). It defines ozone therapy, lists the routes of administration, specifies that ozone therapy should be performed by certified doctors and dentists and applied as supportive treatment in the areas stipulated by the Regulation. The physician must inform that the ozone therapy will be supportive and never declare that it will cure or make the disease disappear.

Strategy on routes of administration of ozone therapy

7. We suggest that Aboz include in the table of routes of administration of ozone therapy only those that have a scientific basis and are widely accepted by the international scientific community. The use of non-recommended routes allows the discrediting of ozone therapy and may be used to justify the prohibition of it. For example, the CFM lists among the main administration routes the intravenous.³⁵ It does not specify whether it is referring to the major and minor autohemotherapy, or to the direct intravenous therapy. The latter is not recommended because it is not safe and it does not have any scientific endorsement, nor is it accepted by a large sector of the world ozone therapeutic community, as attested by the "Madrid Declaration on Ozone Therapy",³⁶ which is available in 12 languages, including the Portuguese; and the scientific document published by Isco3 "Non-recommended routes of application in ozone therapy" that lists the routes that should not be applied by the physicians.³⁷
8. In the report of July 8, 2018 of the Red Globo Fantastic Program, clearly one of the physicians, to the question of how ozone is administered, illustrates the journalist about the application of direct intravenous. All the physicians interviewed affirmed that ozone cures cancer and AIDS, even one of them claims that chemotherapy is "an

³⁵Statement of Motives. <https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2018/2181>
Page consulted 18 July 2018

³⁶ Madrid Declaration on Ozone Therapy, Isco3, 2^a. ed., 2015.
<https://isco3.org/madrid-declaration-on-ozone-therapy-2nd-edition-2/> Page consulted 25 July 2018

³⁷ <https://isco3.org/wp-content/uploads/2015/09/Non-recommended-routes.pdf> Page consulted 25 July 2018



idiocy".³⁸ These types of practices and affirmations obviously discredit therapy and its therapists.

Training strategy inside of Aboz

9. We suggest that Aboz develops internal rules of training and application of therapy in a strict and professional manner that obliges all its members to strictly respect and apply them and not to support those who apply them. The example is found in the American Academy of Ozone Therapy (AAO), which saw the need in 2015 to issue a position paper on "DIV (Direct I.V. injection of ozone/oxygen)". It states "that all members of the AAO avoid using DIV therapy in human subjects" for several reasons listed in the document. "All AAO members will be required to acknowledge either by mail or email that they will not engage in the use of DIV ozone therapy unless it is done to animals or to humans under the auspices of an IRB [Institutional Review Board] approved research study." It adds "if any of our members have problems as a result of the practice of DIV, this academy will not support such practice."³⁹

Information strategy

10. We suggest that Aboz develops an information strategy for the general public through its web page, training to the health sector, and approaching the media to eliminate, as far as possible, the mistaken idea that ozone therapy is a "miraculous technique" that heals everything and serves for everything, which even cures AIDS and cancer, to which the federal judge rightly referred to.
11. We understand it is a huge, difficult and complex challenge, because going against the interests of the powerful pharmaceutical companies carried through the different ways of communication means confronting the ant against the elephant, but it must be done.

Review of the contents of the Aboz documents

12. We suggest that Aboz reviews more carefully the content of its documents to transmit, as much as possible, the information closest to reality and objectivity, contrasting the information. Before the federal judge Aboz referred to the Havana (Cuba) Ozone Research Center as if it still existed. The center was closed in 2010. He claimed that approximately 15,000 doctors used ozone therapy in the world. Figure far below

³⁸ <http://g1.globo.com/fantastico/noticia/2018/07/questionada-pela-ciencia-terapia-com-ozonio-ganha-espaco-em-consultorios.html> Page consulted 13 July 2018

³⁹ <https://aaot.site-ym.com/page/PostitionPapers> Page consulted 24 March 2015



according to the statistics published in the Spanish Journal of Ozone Therapy in 2011.⁴⁰ On the website of Aboz, it is stated that ozone therapy in Spain is being "strongly used as a complementary in cancer treatments".⁴¹ It is a completely false statement. It reports that among the pathologies that may be treated with ozone therapy are "several types of cancer, helping to fight tumors and reducing the side effects of Radiotherapy and Chemotherapy."⁴² The informative imprecision of the message could contribute to the erroneous thinking that ozone therapy is used to treat and cure several types of cancer. What is not true. The language used must be clear and precise, not misleading.

13. An official application document for the regularization of ozone therapy must be based on data and information that effectively support the objective pursued. The inclusion of bylaws of foreign ozone associations, or adding a screenshot of an ozone therapy web page, without linking them to the objective sought, does not make a methodological sense and decreases the documentary quality.

Diseases in which ozone therapy may be applied

14. We suggest that Aboz delimits the curative scope of ozone therapy exclusively to those pathologies where there is more scientific evidence, efficacy and safety in its application. The almost innumerable list of diseases that may be treated with ozone therapy must necessarily be reduced. It is one of the ways to banish the concept of "miraculous medicine that heals everything" to which the federal judge referred to.

FINAL WORDS

In recent years ozone therapy has acquired a vital presence in the medical agenda, to the point that there are already more than 50 countries where it is practiced, of which twelve have decided to regulate it. In the other countries, its application is widely tolerated. This important advance is being halted due to the growing attack against ozone therapy that is being

⁴⁰ Roberto Quintero Mariño. Annex, Statistical table, 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://xn--revistaespaoladeozonoterapia-7xc.es/index.php/reo/article/view/8/8> Page consulted 24 July 2018.

⁴¹ <http://www.aboz.org.br/ozonize-se/como-e-a-ozonioterapia-ao-redor-do-mundo-/16/>
Page consulted 25 July 2018

⁴² <http://www.aboz.org.br/ozonize-se/a-ozonioterapia-e-indicada-para-que-/14/>
Page consulted 25 July 2018



orchestrated in different parts of the world. One of those places is Spain. The Spanish Medical College Organization that groups all the official provincial colleges of physicians of the kingdom included ozone therapy among pseudoscientific therapies. This entity states that "there is no credible scientific evidence to support the use of ozone as a type of medical therapy, much less as a cancer treatment. It may even be dangerous. They have been published medical reports and articles about deaths of patients with this method."⁴³

This organization has not been waiting and has already posted the link on its official website with the information of the CFM against ozone therapy.⁴⁴ The editorial of the latest edition of the Spanish Journal of Ozone Therapy entitled "Ozone Therapy and Pseudoscience" refers specifically to the position of the Spanish Medical College Organization.⁴⁵

The position against the medical use of ozone by the government of the United States is still in force.⁴⁶ So far, the Mexican government has been expressed, successfully, against the regulation of ozone therapy by the national congress.

Brazil is the country where the attack against ozone therapy has been the most devastating. It is currently the only country in the world where ozone therapy has been banned if it is not used as an experimental procedure;⁴⁷ and it is the only country in the world where its practice may result in sanctions for the physicians who practice it. Aboz and the Brazilian ozone therapists deserve and need the support of the international world of ozone therapy, provided that these contributions and support are welcomed by Brazilian colleagues. This document is a modest contribution to face the enormous machinery that has been put in place to eliminate

⁴³ <http://www.cgcom.es/pr%C3%A1cticas-biol%C3%B3gicas> Page consulted 25 July 2018

⁴⁴ <http://www.cgcom.es/aggregator/sources/19> Page consulted 25 July 2018

⁴⁵ Vol., 8, No. 1, 2018-07-25 <http://xn--revistaespaoladeozonoterapia-7xc.es/index.php/reo/article/view/122>
Page consulted 25 July 2018

⁴⁶ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=801.415>. Page consulted 26 July 2018

⁴⁷ In the Community of Madrid (Spain) the practice of ozone therapy was banned in outpatient centers from 2006 to 2008. Physicians were fined by the Madrid Regional Ministry of Health and others were threatened with fine if they continued practicing it. Thanks to the actions undertaken by Aepromo (Spanish Association of Medical Professionals in Ozone Therapy) since March 9, 2009, its practice is totally legal. Roberto Quintero et al, Ozone Therapy and Legislation - Analysis for its Regularization. Isco3, 2nd updated and extended edition May 20, 2015, Pág. 11. <https://isco3.org/wp-content/uploads/2015/09/Update-May-2015-for-ISCO3.pdf> Page consulted 15 July 2018



ozone therapy from the medical agenda of the country. To the extent of our limited possibilities, we will continue to provide support and solidarity.

We know that the horizon of ozone therapy is not attractive and is full of obstacles. We know from our own experience that the road ahead is tortuous and very long. Despite the obstacles we must move forward and hopefully in a synchronized and joint manner. For this reason we must rely solely on scientific research and using ozone therapy in accordance with the criteria widely accepted by the international scientific community of ozone therapy. Routes of application that have no scientific basis should be definitively banished from our daily practice and from the information provided to patients.

Now more than ever it is necessary to unify criteria and establish a code of good practices, something that has been embodied since 2010 in the 1st. edition of the Madrid Declaration on Ozone Therapy and then on its 2nd. edition in 2015;⁴⁸ and in the constant and arduous work that the ISCO3 (International Scientific Committee of Ozone Therapy) has been doing through its more than 30 official documents published on its website.⁴⁹ This demonstrates that the experience accumulated in these documents deserves to be taken into account.

⁴⁸ <https://isco3.org/madrid-declaration-on-ozone-therapy-2nd-edition-2/>

⁴⁹ <https://isco3.org/officialdocs/>