



editorial

The challenge that COVID-19 represents for ozone therapy as complementary medicine

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COVID-19 forced us to change plans, projects, routines and even ways of making medicine; including how to approve drugs that did not meet the conditions of safety and efficacy, which are supposedly required of all products intended to treat diseases of human beings.

According to the different WHO (World Health Organization) communiqués issued since the start of the pandemic, we should all be very clear about two points that are the indelible marks of the challenge posed by the pandemic to health science: (1) The COVID-19 virus has characteristics quite unknown, and with a speed of mutability frankly different from other viruses. (2) There is still no "magic potion" from previous centuries, called today a "vaccine" that can effectively deal with the virus.

The desperate career of pharmaceutical companies began in February 2020, in search of the "Holy Grail" that eliminates the pandemic, in order to continue climbing the ladder of scientific prestige, in addition to obtaining exorbitant profits from the supposed panacea of what they discover.

Remdesivir

The first concrete example is already found in the US pharmaceutical company Gilead. The US FDA (Food and Drug Administration), considering that since February 4, 2020 the United States was in a public health emergency that could potentially affect the national security or the health of its inhabitants, decided on March 27 the emergency authorization to use medications and biological products during the COVID-19 pandemic. On this basis, it decided on May 1, by means of a letter to Gilead, to authorize the use of remdesivir for the treatment of COVID-19. This despite the fact that the same FDA, in the same letter of May 1, recognizes that remdesivir "is an investigational drug and is not currently approved for any indication."

However, it considers that based on the available scientific evidence “it is reasonable to believe that remdesivir may be effective in treating COVID-19” and that it overcomes the known and potential risks of this product. It further adds that “there is no suitable, approved and available alternative for emergency use” other than remdesivir.

<https://www.fda.gov/media/137564/download> (accessed July 8, 2020)

Gilead itself has also explicitly said: “remdesivir is an investigational drug that has not been approved by the FDA for any use.” <https://www.gilead.com/remdesivir> (accessed July 8, 2020)

Regarding side effects, the FDA says that “remdesivir is still being studied so it is possible that all of the risks are not known at this time”. And it adds: “Serious and unexpected side effects may happen.”

<https://www.fda.gov/media/137565/download> (accessed July 8, 2020)

After the authorization given on May 1 by the United States, in the European Union, the Committee for Medical Products for Human Use, made up of experts from the competent authorities of the different Member States of the EU, including the AEMPS (Spanish Agency for Medicines and Health Products), on June 25, 2020, “has recommended granting a [conditional marketing authorisation](#) to Veklury (remdesivir) for the treatment of COVID-19” because “it fulfil an unmet medical need” to the extent that the public health benefit of its “immediate availability to patients outweighs the risk inherent to the fact that not all the data are yet available.”

<https://www.aemps.gob.es/informa/notasinformativas/medicamentosusohumano-3/2020-medicamentosusohumano-3/la-ema-emite-recomendacion-posit-para-autorizacion-de-comercializacion-conditional-del-primer-treatment-for-the-covid-19/>

(accessed July 9, 2020)

<https://www.ema.europa.eu/en/news/first-covid-19-treatment-recommended-eu-authorisation>

(accessed July 9, 2020)

In the race to find the “Holy Grail” of medicine to defeat COVID-19, the pitfall of **security** was overlooked despite the FDA saying remdesivir is still under study, so it is possible that all risks are not known now and that “serious unexpected side effects may occur.” Likewise, the pitfall of **efficacy** has disappeared despite the fact that the FDA has said that remdesivir is an investigational drug that has not been approved for any use; and that the Committee for Medical Products for Human Use European Medicines Agency of the European Union has affirmed that Remdesivir has “less complete data than normally expected”.

<https://www.ema.europa.eu/en/news/first-covid-19-treatment-recommended-eu-authorisation>

(accessed July 9, 2020)

Economic benefits for the pharmaceutical company Gilead

But in the frantic race the money talks. The pharmaceutical company Gilead announced that the price of remdesivir, for developed countries, would be the lowest, at 2,082.00 € per patient and that of the longest therapies at 3,818.00 €.

https://www.abc.es/sociedad/abci-tratamientos-contra-coronavirus-remdesivir-costaran-2082-euros-o-mas-paciente-202006291703_noticia.html#vca=230990&vso=nw&vmc=20200629200002-0100-100-coronavirus_0425&vli=re_pa-not-18-txt&vus=dd5ff699a32545a392388aa8a11c444a

(accessed June 29, 2020)

According to the data collected in the United States, Great Britain, France, Sweden, South Africa, India, Bangladesh, Malaysia, Brazil, Turkey, Pakistan, Egypt and China, "the 10-day course of treatment would therefore cost \$ 4.80 per person. After adjustment for the cost of formulation (and 20% losses projected during formulation), cost of vials, profit margin and tax, the estimated cost per treatment would be approximately \$ 9 [7,99 €] per person (...) daily cost is estimated to be \$0.93 [0,83 €]." In this price, additional non-medical components, such as "syringe, sterile water for reconstitution and IV lines, as well as staff-time cost associated with the healthcare professional administering the infusion" and would likely increase the price of treatment. Andrew Hill et al. "Minimum costs to manufacture new treatments for COVID-19" Journal of Virus Eradication, April 2020.

http://viruseradication.com/journal-details/Minimum_costs_to_manufacture_new_treatments_for_COVID-19/
(accessed July 3, 2020)

However, the sale price of the remdesivir set by Gilead does not include these additional non-medical costs. For each treatment, the lowest, Gilead will charge 2,082.00 €. Compared to the cost price (7.99 €) then the pharmaceutical company would be pocketing a profit of more than 99% for each remdesivir treatment that it sold in developed countries.

Ultimately we will be the patients, who through our taxes (in public medicine) or by paying directly in private medicine, who will provide the great benefits to Gilead.

THE OZONIZED SALINE SOLUTION (O₃SS) AND THE COVID-19

United States through the FDA says that "there is no suitable, approved and available alternative for emergency use" other than Remdesivir. And the European Union through the Committee for Medical Products for Human Use Medicines Agency pins down that Remdesivir "fulfil an unmet medical need" and its "immediate availability to patients outweighs the risk inherent to the fact that not all data are yet available."

We say loud and clear that there is another path and that the medical necessity can be covered in a safe, efficient and much more economical way for state coffers and patient pockets, and without side effects for patients. It is the Ozonized Saline Solution (O₃SS), an application route of ozone therapy, used in a complementary way in patients affected by COVID-19.

Results of the application of the Ozone Saline Solution (O₃SS)

The results obtained from the work carried out directly with hospitalized patients, whose condition ranged from moderate to severe, at the height of the pandemic in Madrid, clearly show the enormous benefits of the Ozonized Saline Solution since it "improves oxygen metabolism; decreases oxidative stress, inducing the synthesis of endogenous antioxidants; it acts as a powerful anti-inflammatory and as an antiplatelet agent, thus preventing thrombus formation."

In just "24 hours, the PCR (parameter that measures inflammation) curves plummeted. The same occurred with other biochemical parameters and clinical symptoms. Fever rapidly normalized, while dyspnea and fatigue subsided significantly. **At 72 hours** the oxygen saturation in all of them had improved remarkably (towards 96-98%). **On the fifth day** of treatment, the basic medication was reduced in most of them and discharges began. **On the tenth day**, the entire COVID-19 floor of the hospital had been discharged. The medical team observed no side effects and no deaths were recorded."

Additionally, it was verified that the Ozonized Saline Solution acted as prophylaxis for health personnel. None of the professionals who worked in the hospital and who received the treatment became ill. <https://aepromo.org/en/ozonized-saline-solution-o3ss-could-be-an-effective-supplement-in-the-management-of-patients-with-covid-19/> (accessed July 10, 2020)

It is no longer about “believing” as the FDA says: “it is reasonable to believe that remdesivir may be effective in treating COVID-19”, but with facts and figures in hand, “demonstrate” as we have done in the Madrid hospital, that Ozonized Saline Solution, as complementary therapy, can indeed be a medical tool to confront the pandemic.

We are not sending a negative message against pharmaceutical companies. Their research is necessary within the market economy in which we have had to live. But governments should prioritize the health needs of their populations and limit the exorbitant profits of pharmaceutical companies in a reasonable but demanding way. Two Nobel Prize in Chemistry could help us understand our request.

Laureate Ada Yonath with the Nobel Prize in Chemistry (2009):

“Pharmaceutical companies provide these patients with very expensive drugs that keep them alive (...) the laboratories hate me. I tell them that they are making bad decisions by not designing new antibiotics, I understand that they need profits for their investors, but if more and more people die again at 50 or 60, they will no longer have consumers for expensive treatments.”

https://elpais.com/sociedad/2019/05/23/actualidad/1558635795_212524.html

(accessed May 30, 2019)

The Nobel Prize in Chemistry (2006) Roger Kornberg, son of the Nobel Prize in Medicine (1959) Arthur Kronoberg:

“It is a mistake to think that pharmaceutical companies can substitute research with public funds (...) a company cannot invest money to do something that may never have a benefit. It is impossible (...) pharmaceutical companies are allergic to risk by nature. Businesses avoid risks.”

https://elpais.com/elpais/2019/07/08/ciencia/1562590067_810342.html

(accessed July 16, 2019)

Challenge for ozone therapists

Ozonized Saline Solution (O₃SS) is not of interest to pharmaceutical companies because, as ozone is extremely volatile, it cannot be encapsulated and sold, and therefore cannot be patented. Consequently no economic gain is obtained.

The scientific works published on the validity of the Ozone Saline Solution give support, to what “*in vivo*” could be verified in the Madrid hospital.

Through our effort, knowledge, direct experience with patients, and dissemination through courses and scientific works, we seek to ensure that ozone therapy, and now specifically Ozonized Saline Solution (O₃SS), is taken into account by health authorities and allow their massive use, both prophylactically and with patients already affected with COVID-19.

That is our hope and our message. We trust that you dear colleague and reader friend, accept this challenge, and contribute to this team effort starting today. How?

We invite you to read the publications on Ozonized Saline Solution, at least the most recent ones; to train yourself, if you have not already done so, in the correct and professional use of the Ozonized Saline Solution. <https://formacionmedizeus.com/>
And that from your workplace anywhere in the world, spread this complementary therapy so that hopefully, governments begin to look at this "ant" that is the Ozonized Saline Solution, a route of application of ozone therapy as stated in the 3rd ed. of the Madrid Declaration on Ozone Therapy (point 3.1.3), and not so much to the "elephant" such as Gilead, who seek more economic benefits. We repeat: That is our hope and our message!

Recent published scientific work on Ozonized Saline Solution

"Potential cytoprotective activity of ozone therapy in SARS-CoV-2 / COVID-19", Gregorio Martínez, Adriana Schwartz and Vincenzo Di Donna. Antioxidants (impact factor 4,520). <https://www.mdpi.com/2076-3921/9/5/389/pdf>

"Potential Use of Ozone in SARS-CoV-2 / COVID-19", ISCO3, 2020. It is available in eight languages. <https://isco3.org/wp-content/uploads/2020/04/Castellano-Covid-19-2.pdf>