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VACCINES, RESEARCH CONTRACTS AND OZONE THERAPY

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Throughout 2020 we witness the desperate race of pharmaceutical companies in search of the "Holy Grail" of the vaccine that would eliminate the pandemic unleashed by COVID-19. Scientific career in which pharmaceutical companies sought both to continue climbing the ladder of scientific prestige, and to obtain exorbitant profits with the discovery of the appropriate vaccine to defeat COVID-19.

The result of the economic, investigative, obtaining legal authorizations race, and intriguing geopolitical games, has already yielded concrete results.

At least 73 research projects to discover vaccines against COVID-19 have been launched in a very few countries in the world with research capacity in health. Out of the 73 projects, so far, only nine have received authorization to be commercialized, in at least one country. These nine are: ¹

- BioNTech-Pfizer (2 doses. Storage: -80 to -60°C. Efficiency: 95% *) from German biotechnology BioNTech and American pharmaceutical company Pfizer.
- Covaxin (2 doses. Storage: 2 to 8°C. Efficacy *: 78%) from Bharat Biotech International of India.
- Johnson & Johnson. (1 dose. Storage: 2 to 8°C. Efficacy *: 72%) from the American Janssen.
- Modern (2 doses. Storage: -25 to 15°C. Efficiency *: 94%) of the American Modern Biotechnology.

https://www.dw.com/en/the-covid-19-vaccines-where-do-they-come-from-where-will-they-go/a-56134178 https://es.statista.com/grafico/23569/eficacia-estimada-de-los-candidatos-a-vacuna-en-la-prevencion-de-la-covid-19/#:~:text=Vacuna%20contra%20la%20COVID%2D19&text=El%20primer%20ant%C3%ADdoto%20aprobado%20por,prevenci%C3%B3n%20de%20la%20COVID%2D19. (consultado 16 mayo 2021)

¹ https://www.bbc.com/news/world-asia-china-56967973

- Novavax (2 doses. Storage: 2 to 8°C. Efficiency *: 96%). Novavax, Inc. From the American company Novavax.
- Oxford-AstraZeneca (2 doses. Storage: 2 to 8°C. Efficacy *: 76%) from the Swedish-British pharmaceutical company AstraZeneca in association with the University of Oxford.
- Sinopharm (2 doses. Storage: 2-8°C. Efficacy *: 79%) from Sinopharm or China National Pharmaceutical Group, backed by the state.
- CoronaVac (2 doses. Storage: 2 to 8°C. Efficiency *: 67%). 2 to 8°C from the Chinese company Sinovac Biotech Ltd.
- Sputnik V (2 doses. Storage: -18°C liquid form; 2 to 8°C dry form. Efficiency *: 79%). With this product, Russia became the first country in the world to approve a vaccine in August 2020, months before other countries. It is developed by the Gamaleya State Research Institute and the Ministry of Health of the Russian Federation, and funded by the Sovereign Wealth Fund of Russia (RDIF).
- * The true efficacy of vaccines has not yet been fully established. It can even vary with the different variants of the virus.

Good intentions against the reality of the market

Throughout the desperate race, the United Nations launched the message of solidarity with all human beings: "No one is safe, until everyone is". ² It was repeated by 23 heads of state from different continents of the world on March 30, 2021, and they added: "No single government or multilateral agency can address this threat alone." ³

To make this praiseworthy humanitarian message a reality, the WHO precisely identified the price of vaccines as a priority issue. "Unaffordable prices for medicines have become one of the most pressing concerns" for everyone. ⁴

The WHO pointed out the following about prices:

- Pricing must be done within a transparent and consistent process. Prices must be obtained and validated from verifiable data sources.
- Price transparency should be essential in the design and implementation of the pricing policy.
- Lack of transparency in medicine prices can conflict with the principles of good governance. Confidential agreements (pharmaceutical-states) can compromise clear lines of responsibility.
- The contributions received by pharmaceutical companies for R&D must be publicly known.
- Low prices are obtained by promoting the use of quality-assured generic drugs.

However, WHO confirms that reality is the opposite of the published directives. It points out the lack of price transparency, and the proliferation of confidential agreements.

Although it has been repeated ad nauseam that "immunization is a global public good", the exorbitant price of vaccines and the immense profits that the pharmaceutical companies that own the vaccines are making are major obstacles to achieving the required immunization.

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² https://www.un.org/sw/desa/%E2%80%9Cno-one-safe-until-everyone-%E2%80%9D

³ https://www.who.int/es/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture

⁴ https://www.who.int/publications/i/item/9789240011878

Pharmaceutical company profits

Analysis carried out indicates the probability that the five main western pharmaceutical companies involved in the manufacture of vaccines share around 38.5 billion dollars in sales. And even if the market might decline in the future it could still be worth more than US\$ 10 billion a year. ⁵ Pfizer hopes to greatly exceed the US \$ 5.8 billion it obtained in 2020 with Prevnar (vaccine vs pneumonia) in 2021. Moderna's shares increased almost 700% in 2020 and it is expected to accumulate US \$ 13.2 billion in 2021 from the sale of its vaccine. ⁶ The pharmaceutical industry, one of the most profitable, is estimated to be worth \$ 1.4 trillion by the end of 2020.

Before the pandemic, did pharmaceutical companies do research in the area of vaccines? Until the end of 2019, when the pandemic had not yet spread, pharmaceutical companies were very reluctant to invest in vaccine research, despite the fact that "A vaccine prototype to protect against the SARS coronavirus strain had been developed in 2016 at the University of Texas". No drug company wanted to fund the completion of the full set of clinical trials. ⁷

What made pharmaceutical companies change their minds in 2020? The enormous size of the pandemic, and therefore of the potential market that was opening up to them; the unprecedented levels of public funding that they would receive without harming their own resources; and the type of contracts signed imposing their corporate interests to the states.

Government subsidies given by rich countries in the Western world to private pharmaceutical companies to carry out research and discover vaccines against COVID-19 are estimated at 93 billion €. ⁷

What was signed between the states and the pharmaceutical companies

Despite the enormous amount of public money, that is, of the citizens, given to the pharmaceutical companies, the states did not require from the pharmaceutical companies, clauses of price transparency, accessibility and affordability. The signed contracts were confidential. Although the vaccines may be supplied, within the established contractual terms, the reality is that the criterion of "good government" is almost hidden, and the parliaments "seat of popular sovereignty" do not know the contracts.

In addition to keeping patents fully in force, contracts establish additional exclusive rights, such as trade secrets (know-how) and data protection, and prevent third parties from making or using the invention. Pharmaceutical companies decide the scale of production. They determine the totality of the investigation, including the design, the methodology and its participants. They have been exonerated from potential lawsuits due to lack of safety or efficacy of the vaccine (collateral effects), thus the potential payers of the lawsuits won must be paid by the defendant state, that is, its citizens through taxes. ⁷

The subsidies were awarded free of charge, squandering the historic opportunity to force the pharmaceutical industry to openly share its intellectual property and know-how. The powerful are the pharmaceutical companies and the states the weak.

Citing the confidentiality of the signed contracts, the European Commission refused to publish them. After months of constant social pressure, with the prior agreement of the pharmaceutical companies, the signed contracts began to be published. What has been published, in addition to being incomplete, is redacted (to obscure or remove [text] from a document prior to publication or release. https://www.merriam-webster.com/dictionary/redact) 7 y 8

⁵https://www.publiceye.ch/fileadmin/doc/Medikamente/2021_PublicEye_BigPharmaTakesItAll_Report.pdf

⁶ https://edition.cnn.com/2020/12/11/business/pfizer-vaccine-covid-moderna-revenue/index.html

⁷ https://www.publiceye.ch/fileadmin/doc/Medikamente/2021 PublicEye_BigPharmaTakesItAll_Report.pdf

⁸ https://www.politico.eu/article/mep-pascal-canfin-european-commission-we-details-curevac-coronavirus-vaccine-contract/

WHAT ROLE SHOULD OZONE THERAPY PLAY IN THE MASS VACCINATION PIRIO OF THE POPULATION?

As we affirmed in these pages, a year ago, ⁹ ozone therapy and in particular the Ozonized Saline Solution (O₃SS), a route of application of ozone therapy, used in a complementary way, plays an important role to face COVID-19. O₃SS, both as a preventive treatment and applied to patients affected by the virus, helps in a complementary, safe, effective and much more economical way for the states coffers, and the pockets of the patients, without having side effects.

The research carried out in a Madrid hospital with moderate to severe COVID-19 patients, ¹⁰showed that "results obtained indicate that O₃SS improves oxygen metabolism; decreases oxidative stress, inducing the synthesis of endogenous antioxidants; it acts as a powerful anti-inflammatory and anti-platelet 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 found that the Ozonized Saline Solution acted as a prophylaxis for health personnel. None of the professionals who worked in the hospital on the front line and who received the treatment, became ill.

According to the results obtained, published in a scientific journal, ¹¹ "Patients with COVID-19 with mild to severe symptoms who received intravenous O₃SS as an adjunct treatment experienced no side effects. The main results of O₃SS treatment were a tendency to improve clinical symptoms without side effects. None of the patients treated died."

In the conclusions of the study it is stated: "Early evidence of efficacy shown improvements in symptoms such as dyspnea, weakness, and reduction in body temperature were observed and corresponded to improvements in laboratory results including D-dimer, fibrinogen, lactate dehydrogenase, and C-reactive protein."

Research conducted and published

In the midst of enormous efforts, because no subsidies have been received from either state or pharmaceutical companies, 22 investigations have been conducted and published on COVID-19 and ozone therapy, of which 13 (59%) are on MedLine (PubMed),

The main results of the studies indicate that ozone decreases the inflammation indices and the time of assisted breathing, improves oxygen saturation and makes CRP negative in shorter periods. Increases oxygen saturation. And it could reduce mortality.

The total number of patients treated in the different investigations, including prevention studies, post-COVID studies and with COVID-19 patients has been 721. The routes of application have been ozonized saline solution, major autohemotherapy, and rectal insufflation.

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⁹ https://ozonetherapyglobaljournal.es/en/the-challenge-that-covid-19-represents-for-ozone-therapy-as-complementary-medicine/

 $[\]frac{10}{\text{https://aepromo.org/en/ozonized-saline-solution-o3ss-could-be-an-effective-supplement-in-the-management-of-patients-with-covid-19/}$

¹¹ https://jppres.com/jppres/pdf/vol9/jppres20.971 9.2.126.pdf

Ozone therapy research, beyond COVID-19, continues to advance. Currently (May / 2021) in the Medline database (PubMed) there are 3329 documents related to ozone therapy of which 251 are clinical trials, 169 randomized controlled trials, 24 of systematic review and 18 meta-analysis studies, which support the use of ozone in medicine. In addition, there are 37 registered studies for ozone therapy on ClinicalTrials.gov (database of clinical trials at the US National Institutes of Health). 12

The WHO (World Health Organization) has published in its virtual library "COVID-19 - Global literature on coronavirus disease" three following investigations on Ozonized Saline Solution and COVID-19.

(1) Complementary application of the ozonized saline solution in mild and severe patients with pneumonia COVID-19: A non-randomized pilot study

Schwartz, Adriana. et al. ¹³

(2) Potential Cytoprotective Activity of Ozone Therapy in SARS-CoV-2 / COVID-19.

Martínez-Sánchez, G. Schwartz A. et al. 14

(3) Potential use of ozone in SARS-CoV-2 / COVID-19

ISCO3. Schwartz A. Martínez – Sánchez G. International Scientific Committee of Ozone Therapy.

The future of ozone therapy

We are aware, at least while economic factors prevail over people's health, that ozone therapy will not be a massive therapy, since it affects the interests of pharmaceutical companies. Despite this, we will continue researching, disseminating, teaching and practicing ozone therapy, as a "medical act" and complementary medicine, which has scientific foundations and is used for a certain list of diseases, but not for all.

The practice of ozone therapy requires that the ozone therapist be properly trained and updated. Due to the constant research advances that therapy is having, it is extremely important that the health professional is constantly updated. Knowledge of ten years ago, even less, will not necessarily be the same today regarding ozone therapy.

After enormous efforts and dedication, today ozone therapy is totally or partially regulated in 14 countries of the world; ¹⁶ there is a free access ozone therapy library; ¹⁷ the Madrid Declaration on Ozone Therapy, in its 3rd. ed. (2020), available in nine languages, ¹⁷ is the ideal reference instrument for practice anywhere in the world. The 8th 300-hour course "Ozone Therapy and Growth Factors Induced with Ozone", fully online and bilingual (starts 15 November 2021 – ends 15 June 2022) is an excellent opportunity to precisely learn and/or deepen about this excellent therapy. ¹⁸

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¹² Data compilation made by Dr. Gregorio Martínez Sánchez.

 $[\]frac{13 \text{ https://search.bvsalud.org/global-literature-on-novel-coronavirus-} 2019-ncov/resource/en/covidwho-984802}{Acces to full paper <math display="block">\frac{\text{https://jppres.com/jppres/pdf/vol9/jppres20.971_9.2.126.pdf}}{\text{https://jppres.com/jppres/pdf/vol9/jppres20.971_9.2.126.pdf}}$

¹⁴ https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/en/covidwho-854062 Acces to full paper https://aepromo.org/la-revista-antioxidants-factor-de-impacto-4-520-publica-articulo-sobre-ozonoterapia-y-covid-19/

https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/?lang=en&q=au:%22International%20Scientific%20Committee%20of%20Ozone%20Therapy%22
Acces to full document in eight languages https://isco3.org/officialdocs/

¹⁶ https://aepromo.org/en/venezuela-the-fourteenth-country-in-the-world-to-regularize-the-practice-of-ozone-therapy/

¹⁷ https://isco3.org/

¹⁸ https://aepromo.org/diplomatura/en/

On behalf of AEPROMO I wish to publicly congratulate the Spanish oncologist and PhD Dr. Bernandino Clavo Varas for the well-deserved "Can de las Ciencias" award from the Spanish Gran Canaria Council (Cabildo) "for his extensive and enriching research work in cutting-edge treatments in chronic and oncological diseases, and in particular for his profitable research work on clinical uses of ozone."

Dr. Clavo is a member of AEPROMO (Spanish Association of Medical Professionals in Ozone Therapy) and ISCO3 (International Scientific Committee of Ozone Therapy). He has also been a professor of all the editions of the diploma course "Ozone Therapy and Growth Factors activated with Ozone", organized by AEPROMO.