



United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Richard A. Quaresima
Acting Associate Director
Division of Advertising Practices

June 5, 2020

WARNING LETTER

VIA EMAIL TO info@bioxcellerator.com
BioXcellerator
2122 East Highland Ave Suite 265
Phoenix, AZ 85016

Re: Unsubstantiated claims for Coronavirus treatment

To Whom It May Concern:

This is to advise you that FTC staff reviewed your website at www.bioxcellerator.com on June 1, 2020. We also reviewed your social media website at www.facebook.com/bioXcellerator/, where you direct consumers to your website www.bioxcellerator.com, where they can schedule consultations for stem cell treatments. We have determined that you are unlawfully advertising that certain products or services treat Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus prevention or treatment claims include:

- “WJ-MSCs and COVID-19, what to expect?”

Image reads: “What are stem cell treatments, and how can they help you?”

[Facebook post dated April 3, 2020 at 6:35 p.m. at www.facebook.com/bioXcellerator/]

This Facebook post links to an article titled, “WJ-MSCS AND COVID-19, WHAT TO EXPECT?,” at <https://www.bioxcellerator.com/blog/wj-mscs-and-covid-19-what-to-expect-1>, which states:

This year, humankind and science have been pushed and tested with the rise of COVID-19.... BioXcellerator is innovating in the world of Wharton jelly mesenchymal stem cells (WJ-MSC) and its applications, in this case, IMMUNOMODULATION.

The human immune system is quite complex, and so is its response to external “attacks” such as COVID-19. The COVID-19 pathogen binds to specific cellular receptors on the cellular membrane and thereby entering the cell and causing disease, and this causes the immune system to create an inflammatory response, which is responsible for the release of cytokines. They kill the virus and infected cells, but in the process of doing so can harm its host. (You) ...

Here is when science comes in with the stems, especially WJ-MSC, to do what is called immunomodulation. Tissue regeneration for the acute scar tissue, studies have shown that MSCs improved functional outcomes, demonstrating that IV infusions of MSCs is a safe and effective approach for treating patients with COVID-19 pneumonia, including elderly patients with severe cases of pneumonia. This treatment is particularly challenging as there is no vaccine or medication for this strain of the virus....

We have all the confidence that WJ-MSCs treatment for acute phases of the disease and the scarring tissue generated by the condition can be avoided with our procedures. Science by humans for humans.”

- “COVID-19 and an observation of MSC’s Interaction on ARDS”

Image reads: “What are stem cell treatments, and how can they help you?”

[Facebook post dated March 31, 2020 at 2:42 p.m. at www.facebook.com/bioXcellerator/]

This Facebook post links to an article titled, “ACUTE RESPIRATORY DISTRESS SYNDROME AND HOW TO TREAT WITH STEM CELLS,” at <https://www.bioxcellerator.com/blog/covid-19-and-an-observation-of-mscs-interaction-on-ards>, which states:

“The COVID-19 was first reported on December 31st, 2019, by Chinese authorities to the WHO. (World Health Organization)... In the beginning, international officials didn’t realize the ability of the virus to spread so quickly; frankly, no one knew much about it. The way it spread and the implications to the human body and its response to the virus, and realizing there were no medications or vaccines available for COVID-19....

International efforts now are combined in researching effective methods to avoid the spread and manage the infection....

Because of this, researchers in the field of advanced stem cell therapy have come forward to help. They have started trials to assess the efficacy, safety, and outcomes of stem cell therapy in patients with the infection and with Acute Respiratory

Distress Syndrome or multi-organ failure due to the immunological body response to the novel infection....

What has been observed in vitro and in vivo studies so far, MSCs [Mesenchymal Stem Cells] could be a treatment for patients with COVID-19. Both the infection and its complications post-infection because of the MSC's ability to regenerate damaged tissue. Research must and will continue towards finding a cure and solving a problem that involves the whole world, being MSCs a plausible solution and already at the reach of humanity. What remains now is to start doing treatments and evaluate the responses of the studied individuals with the help of governments all around the world—allowing the therapy to be available to whoever needs it and at a proper time frame.”

- “Why IV Stem Cell Therapy Works Against the COVID-19 Virus (The Science)”

Image reads: “New BioXblog

Why IV Stem Cell Therapy Works Against the COVID-19 Virus (The Science)”

[Facebook post dated April 13, 2020 at 7:43 p.m. at www.facebook.com/bioXcellerator/]

This Facebook post links to a bioXcellerator blog post titled, “WHY IV STEM CELL THERAPY WORKS AGAINST THE COVID19 VIRUS (THE SCIENCE),” at <https://www.bioxcellerator.com/blog/why-iv-stem-cell-therapy-works-against-the-covid-19-virus-the-science>, which states:

“...MSCs [Mesenchymal Stem Cells] are understood as cells that can recognize the microenvironment to they are exposed, modify their phenotype and secretome and, finally, modulate the behavior of other cells. The MSC can induce direct and indirect tissue regeneration, through their anti-inflammatory and immunomodulatory effects on damaged and diseased tissues. ...

Due to the recent COVID-19 outbreak and as there is a lack of medications or vaccines against it, other possibilities are being researched and proven to decrease the intensity of the symptoms and the damage the infection causes to pulmonary tissue. In the more complicated cases, patients suffer from a condition called Acute Respiratory Distress Syndrome or ARDS; this condition is a common cause of respiratory failure, it is characterized by hypoxemia, pulmonary edema, damage to the alveoli and pulmonary “stiffness”. There are multiple medical approaches to the treatment of this condition, but usually, the pulmonary damage is irreversible and causes long term morbidity to the patient. So, what’s one of the new approaches to this therapy? Mesenchymal stem cells.

Stem cells have shown excellent anti-inflammatory effects by doing immunomodulation, this is done by applying the cells thru an IV...

So, in conclusion, MSCs have shown anti-inflammatory properties, anti-apoptotic effects, enhanced tissue recovery from the blood vessels and the lungs, alveolar clearance of fluid and microbes, improvements in pulmonary injury, and distal organs injury thereby improving the survival of the patient.

Here at bioXcellerator, we are hoping to improve the quality of life of our patients and those who surround them, that's why the whole team is working around the clock to get this kind of treatment cleared and at reach for the population—science by humans for humans.”

[See also article titled, “Phenomenal results of IV Stem Cell Therapy on Chronic Lung Disease,” available at <https://www.bioxcellerator.com/blog/phenomenal-results-of-iv-stem-cell-therapy-on-chronic-lung-disease> and posted on www.facebook.com/bioXcellerator/ on April 24, 2020 at 1:50 p.m.]

It is unlawful under the FTC Act, 15 U.S.C. § 41 *et seq.*, to advertise that a service or product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. For COVID-19, no such study is currently known to exist for the products or services identified above. Thus, any coronavirus-related treatment claims regarding such products or services are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims.

You are also advised to review all other claims for your services and immediately cease making claims that are not supported by competent and reliable scientific evidence.

Within 48 hours, please send a message to Richard Cleland, Assistant Director via electronic mail at rcleland@ftc.gov describing the specific actions you have taken to address the FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Richard Cleland at 202-326-3088.

Very truly yours,

Richard A. Quaresima
Acting Associate Director
Division of Advertising Practices