

## United States of America FEDERAL TRADE COMMISSION Southwest Region

1999 Bryan St., Ste. 2150 Dallas, Texas 75201

June 5, 2020

## WARNING LETTER

VIA EMAIL TO <a href="mailto:info@sfstemcellcenter.com">info@sfstemcellcenter.com</a>

Anatara Medicine – San Francisco Stem Cell Treatment Center 1700 California Street, Suite 520 San Francisco, California 94109

Re: Unsubstantiated Claims for Coronavirus Prevention or Treatment

To Whom It May Concern,

This is to advise you that FTC staff has reviewed your website at <a href="https://www.anataramedicine.com/">https://www.anataramedicine.com/</a> on May 25, 2020. We have determined that you are unlawfully advertising that treatments you offer, including stem cell, exosome, and intravenous therapies, treat or prevent Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus treatment or prevention claims on your website include:

- In marketing materials available from your homepage by clicking on a rotating banner titled, "Coronavirus (COVID-19)[.] We want to continually provide you with what we consider to be useful and specific information about how to limit your risk to COVID-19. Get expert advice on Coronavirus by Immunologist, Dr. Ahvie Herskowitz. Click here for information and updates":
  - o In materials titled "Protection Protocol for COVID-19," you claim to "present protection strategies that include specific anti-viral approaches, as well as approaches to help one's immune system to stay in a modulated and anti-inflammatory state during this pandemic," stating that:
    - "In addition to natural supplements more advanced therapies such as stem cell therapy and exosome therapy may be beneficial for prevention COVID-19. Two trials have already demonstrated promising results and a number of other trials are currently underway";

- "PROTECTION AGAINST COVID-19 WITH STEM CELLS AND EXOSOMES . . . [stem cells] have been identified as a potentially effective treatment option for COVID-19 due to their anti-inflammatory, immune modulatory and tissue repair properties. In fact, two clinical trials (1, 2) from China have already demonstrated promising results of intravenous stem cells in moderate and severe COVID-19 cases";
- "Stem cells along with exosomes may also be useful for COVID-19 prevention. Stem cells have been shown to support the immune system by improving the function of specific anti-viral immune cells as well as reducing an overactive immune response";
- "Stem cell therapy is also beneficial for many of the underlying health conditions such as heart, lung and kidney disease and may reduce the risk of severe COVID-19 cases and death";
- "Exosomes, which share many of the therapeutic properties of stem cells, may also be beneficial. In animal studies, exosomes have been shown to inhibit viral replication of the influenza virus, significantly reduce viral shedding and reduce lung damage";
- "Considering SARS-CoV-2 has a number of mechanisms to evade the immune system priming it with natural agents and advanced therapies may be a promising strategy for prevention of COVID-19"; and
- "[S]tem cells and exosomes may exert added benefit for the prevention of COVID-19."
- O In materials titled "Stem Cell Therapy Improves Outcomes of Patients with COVID19 Pneumonia," you claim that stem cell therapy is a "possible treatment" for COVID-19, supporting the claim by citing a researcher who purports to have treated ten patients and found that "'[t]he intravenous transplantation of MSC [mesenchymal stem cells] was safe and effective for the treatment in patients with COVID-19 pneumonia, especially for the patients in critically severe condition' and that 'the improved outcome of COVID-19 patients may be due to regulating inflammatory response and promoting tissue repair and regeneration."
- o In materials titled "The Basics of Coronavirus (COVID-19)," you claim to "help limit infection risk (**PREVENTION**)" and that "[w]hile NOT approved by the FDA as an anti-viral therapy, I use IV (intravenous) Ozone for its anti-microbial and immune modulatory effects using a cocktail of ozone with UV light, Glutathione and Vit C IV to prevent and/or combat infections including viruses.... **There are many natural options available for combating COVID-19**. Please call the office at by phone at (415) 345-0099 or by email at info@anataramedicine.com if you are interested in any of the above IV options.

Please note that the IV suite will book up quickly as the vaccines are not going to come in time to help during this years' epidemic."

It is unlawful under the FTC Act, 15 U.S.C. § 41 *et seq.*, to advertise that a product or service 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 prevention or 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 products and services and immediately cease making claims that are not supported by competent and reliable scientific evidence.

Within 48 hours, please send a message to James E. Elliott via electronic mail at <u>jelliott@ftc.gov</u> 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 Zachary A. Keller at zkeller@ftc.gov.

Very truly yours,

Dama J. Brown Regional Director Southwest Region