

Serena Viswanathan Associate Director Division of Advertising Practices United States of America FEDERAL TRADE COMMISSION Washington, D.C. 20580

April 30, 2021

WARNING LETTER

VIA EMAIL TO info@krystalanesthesia.com and info@infinityfunctionalperformance.com

Glenn Cochrane Krystal Anesthesia & Pain Specialists 2704 W. Arkansas Ln. Arlington, TX 76016

Infinity Functional Performance LLC 171 Old Barn Ln. Holly Lake Ranch, TX 75765

Re: Unsubstantiated claims for Coronavirus prevention or treatment

Dear Mr. Cochrane:

This is to advise you that FTC staff has reviewed your websites at https://www.krystalanesthesia.com/ and https://www.infinityfunctionalperformance.com/ in April 2021. We also reviewed your social media websites at https://www.facebook.com/Krystalanesthesia/, https://www.facebook.com/Krystalanesthesia/, https://www.facebook.com/texasfunctionalperformance/, and https://www.instagram.com/infinityfunctionalperformance, where you direct consumers to your websites https://www.infinityfunctionalperformance/, and https://www.infinityfunctionalperformance.com/ to schedule services and purchase supplements. We have determined that you are unlawfully advertising that certain products prevent or treat Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus prevention or treatment claims include:

• On a page on your website titled "How am I staying healthy during these times???" you state:

"I am routinely asked at my functional pain management practice, 'What are you doing to stay healthy and protect yourself from Covid-19?' Well...I have always hesitated in my answer... as I am a horrible salesman and never want to come off as one. But health is what I do, and I would like to think I do it well. I will share what I do to take care of myself, my family, and what I recommend for my patients. You will find no silver bullet in this post, no magic pixie dust, or mysterious potions ground from unicorn horn. You will only find suggestions I use based on the best available current evidence...Most important you will not find much from my recommendations that will harm you....

What you're really asking...below is my supplement regimen. These are all available through my practice or you can get them on your own. I don't care either way. In other words, you can buy your products at some giant mega retailer that gave you no meaningful advice whatsoever so the CEOs can afford their caviar, or you can just ask me so my children won't have to fight to the death over the last piece of bread to dip in their cabbage water at dinner next week...no pressure...

My supplement regimen:

- <u>Vitamin C 5000mg PO/Day</u> Multiple theories on why vitamin C works. One is the ability to form free radicals that destroy bacteria and viruses but are safe to humans. Another is the amazing antioxidant properties it has that replenish those that are depleted during infections and other assaults on our immune system. We provide IV infusions of vitamin C in our offices and also have oral formulations available with and without zinc....
- <u>Zinc 75mg PO/Day-</u> Zinc appears to have multiple antiviral and pro immune system functions. It inhibits viral replication and may help to inhibit viral entry into vulnerable cells. Those with zinc deficiency are also found to have reduced antibody production, low natural killer cell activity, reduced cytokine production, thymic atrophy, altered thymic hormone production, and lymphopenia. Zinc deficiency also reduces the number of peripheral and thymic T cells....
- <u>Vitamin D 5,000 u PO/Day-</u> One of the biggest supplements I preach about on the daily. Not only do I check Vitamin D levels in all my pain patients because of the huge role that deficiency plays in pain and hormone function, but it's found to be one of the largest preventative indicators for those most susceptible to having poor outcomes from COVID-19. There has been some controversy on this topic as the government has criticized some of the research (nearly a dozen legitimate studies worldwide showing clearly positive results). The only controversy I see is that the government once again has no evidence to support their position other than the standard 'we are the government and what we say goes'...take your

Vitamin D...levels below 25-30 nmol/L places you at risk...you get an F. If you hit 50 then I give you a B...80 is an A+ student in my book.

- <u>Quercetin 1000-1500 mg PO/Day-</u> Quercetin is a flavonoid with exceptional antioxidant and antiviral activity. Quercetin inhibits viral entry into cells and also facilitates the transport of zinc across lipid membranes. Quercetin also promotes SIRT2 which in turn inhibits the NLRP3 inflammasome assembly involved with COVID-19 infection.
- <u>Thiamin (Vitamin B-1) 200mg PO/Day-</u> Thiamin deficiency is commonly found in critically ill patients. Deficiency can quickly lead to an anaerobic state, elevated lactate levels and subsequent metabolic acidosis. No real downside here.
- <u>Magnesium Glycinate 1000mg PO/Day-</u> Not only is magnesium a great option to relieve stress, decrease anxiety, and improve sleep, but it helps prevent hypomagnesemia which can worsen the cytokine storm seen in COVID. I personally choose the glycinate formulation as it is absorbed well and doesn't cause the laxative effects experiences with the citrate and oxide versions.
- <u>Famotidine 40mg PO/Day-</u> We commonly think of heart burn when we think of this H2 blocker. As a bonus it has been found that Famotidine inhibits viral replication. In COVID we think this works through inhibition of 3C-like main protease which in turn prevents COVID-19 replication.
- <u>Melatonin 5 mg PO/Day-</u> Although it may be effective in helping us to sleep away this entire pandemic, it's not the only reason melatonin is effective. A supplement with an excellent safety profile, melatonin also has excellent antiviral properties that has been effective in treating respiratory disease, viral infections, and arthrosclerosis. It is an antioxidant and an anti-inflammatory.... It has also shown to decrease capillary permeability and improve outcomes in those who have suffered from acute lung injury or respiratory distress syndrome during hospitalization.
- **Immunitea (by regenr8) 1 serving/day-** A preventative tea with targeted herbal ingredients that are well-known and well-studied for immune system support:
 - *Elderberry (Sambucus)* been shown to improve heart and respiratory health and provide a strong immune boost. Elderberry is rich in bioflavonoids and other compounds that have been shown to support immunity during acute stress.
 - *Rose Hips* rich in disease-fighting antioxidants, such as vitamin C, catechins, quercetin, and ellagic acid....

- *Echinacea* stimulates the production of T-cells and increases the white blood cells ability to fend off pathogenic invaders.
- *Green Tea* rich in antioxidants. Several studies have shown that green tea has antimicrobial properties that inhibit the growth of bacteria and viruses. Two particular polyphenol catechins, epigallocatechingallate (EGCG) and epicatechingallate(ECG) have the ability to suppress the activities of bacterial and viral factors and can even reverse the resistance of tough pathogens.
- *Blackberry leaves* among the richest sources of chlorogenic acid. Though more research needs to be conducted using human subjects, the study indicated that they are rich sources of bioactive natural products with antioxidant, anti-inflammatory and antimicrobial properties.
- <u>Thymosin Alpha-1 450mcg SQ/Day-</u> Thymosin Alpha 1 is a peptide originally taken from thymic tissue. It has shown promise in the treatment of a number of diseases associated in immune deficiency and reduced T cell activity. A number of studies have shown significant reduction in mortality in COVID patients treated with Thymosin Alpha-1. After a brief consultation we can prescribe this peptide that can be self-administered in your home.

So...you asked! This is how I stay healthy...Or how I stay COVID healthy that is...What if caught the COVID?? More of the same...with a few extra bonus features...until next time when I share what we do then...

Want to learn more about how to build an immune plan for yourself? Contact us today!!!"

[https://www.krystalanesthesia.com/blog/stayhealthy-covid-krystalfunctionalpainmanagement]

• In Facebook and Instagram posts on November 12, 2020, you state:

"Thymosin Alpha 1 inhibits viral replication, stimulates stem cells, and aids in the production of new immune cells. Once it helps activate the immune system, it then helps kill bacteria, fungal, viral infections, and tumor cells. The immune system function is very critical to prevent disease and infection, especially during viral pandemics, such as COVID-19.

Thymosin Alpha 1 Benefits:

- * Boosts the Immune System
- * Prevents Infections
- * Reduces Inflammation

- * Suppresses Tumors
- * Has Antibacterial, Antiviral, and Antifungal Properties
- * Eradicates Unhealthy Cells
- * Potent Antioxidant

For more information, click the link... or contact us!"

[November 12, 2020 Facebook post at <u>https://www.facebook.com/texasfunctionalperformance/</u> and Instagram post at <u>https://www.instagram.com/infinityfunctionalperformance/</u>]

• In a Facebook post on September 2, 2020, you state:

"Promising treatment options with Thymosin alpha-1... Thymosin alpha-1 Protected T Cells from Excessive Activation in Severe COVID-19"

The post shares a link to an article titled "Thymosin alpha-1 Protected T Cells from Excessive Activation in Severe COVID-19." The linked article states: "Two typical features of uncontrolled inflammation, cytokine storm and lymphopenia, are associated with the severity of coronavirus disease 2019 (COVID-19), demonstrating that both innate and adaptive immune responses are involved in the development of this disease. Recent studies have explored the contribution of innate immune cells to the pathogenesis of the infection. . . Our data suggest that protection of T cells from excessive activation might be critical for the prevention of severe COVID-19."

[September 2, 2020 Facebook post at <u>https://www.facebook.com/Krystalanesthesia/</u>, sharing link to <u>https://www.researchsquare.com/article/rs-25869/v2</u>]

• In a second Facebook post on September 2, 2020, you state: "Thymosin Alpha 1 Reduces the Mortality of Severe Coronavirus 2019 by Restoration of Lymphocytopenia and Reversion of Exhausted T Cells" and share a link to a *Clinical Infectious Diseases* article with that title.

[September 2, 2020 Facebook post at <u>https://www.facebook.com/Krystalanesthesia/</u>, sharing link to <u>https://academic.oup.com/cid/article/71/16/2150/5842185</u>]

• In a Facebook post on August 25, 2020, you share a link to a News Medical Life Sciences article titled "Vitamin D could improve outcomes in Covid-19" The article further states: "A new study published on the preprint server medRxiv* in May 2020 shows that vitamin D could have a beneficial effect on the course of illness for COVID-19 patients."

[August 25, 2020 Facebook post at <u>https://www.facebook.com/Krystalanesthesia/</u>, sharing link to <u>https://www.news-medical.net/news/20200507/Vitamin-D-could-improve-outcomes-in-COVID-19.aspx</u>]

It is unlawful under the FTC Act, 15 U.S.C. § 41 *et seq.*, to advertise that a 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 identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products 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.

Violations of the FTC Act may result in legal action seeking a Federal District Court injunction. In addition, pursuant to the COVID-19 Consumer Protection Act, Section 1401, Division FF, of the Consolidated Appropriations Act, 2021, P.L. 116-260, marketers who make deceptive claims about the treatment, cure, prevention, or mitigation of COVID-19 are subject to a civil penalty of up to \$43,792 per violation and may be required to pay back money to consumers.

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,

Serena Viswanathan Associate Director Division of Advertising Practices

cc: Facebook and Instagram via email to <u>consumerpolicy@fb.com</u>