

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

April 1, 2021

WARNING LETTER

VIA EMAIL TO admin@southwellness.com
Dr. Tyler Southwell, MD
Southwellness Medical LLC dba Southwellness COVID Solutions
10585 N Tatum Blvd. D130
Paradise Valley, AZ 85253

Re: Unsubstantiated claims for Coronavirus prevention and treatment

To Whom It May Concern:

This is to advise you that FTC staff has reviewed your websites at

https://www.southwellnesscovidsolutions.com/ and https://www.southwellness.com/ in March 2021. We also reviewed your social media websites at

https://www.facebook.com/southwellnesscovidsolutions/,

https://www.facebook.com/SouthwellnessAZ/,

https://www.instagram.com/southwellnesscovidsolutions/,

https://www.instagram.com/southwellnessaz/, and https://twitter.com/SCSCovid, where you direct consumers to your websites https://www.southwellnesscovidsolutions.com/ and https://www.southwellness.com/ to purchase supplements and make appointments for your services. We have determined that you are unlawfully advertising that certain products and services treat or prevent Coronavirus Disease 2019 (COVID-19).

Some examples of Coronavirus prevention or cure claims on your websites include:

• On the homepage of your website https://www.southwellnesscovidsolutions.com/ you state:

"COVID-19 Prevention | Testing | Therapy...

A Holistic Approach to COVID-19 Prevention, Testing & Therapy

Keep your family, employees, and yourself healthy and safe with Southwellness COVID Solutions (SCS), the industry-leading expert for COVID-19 prevention, testing & therapy....

Prevention

- o Private label immune boosting regimen
- o Immunity Boost Infusions...

Therapy...

- o Intensive IV, oral and inhalation therapies
- Custom blend mushroom extracts
- o Lab-developed vitamin formulas...

State-of-the-Art Immunity Booster

[Depiction of a bottle of Dr. Southwell's Immunity Formula Dietary Supplement]

Our private label immune-boosting regimen is custom-formulated based on extensive experience treating a wide range of COVID-19 patients.

Order Now [hyperlink to https://southwellness.getvitaminlab.com/cart"

• On the homepage of your website https://www.southwellness.com/, you have a prominent graphic at the top of the page labeled "IMPORTANT COVID-19 UPDATE." Consumers who click on this button (or who select "COVID-19" and then "Covid-19 Education" from your website navigation menu) are taken to https://www.southwellness.com/covid-update/, which states:

"Covid-19 Education

Dr. Southwell's Immunity Formula!...

While we have been reading every study on COVID we can find to base our strategy here, none of it is properly FDA approved and so you can't say what follows is 'treatment or prevention.' That being said, I think you can say this is 'support,' and we have seen it work time and again....

Therapies we recommend based on currently available research and our clinical experience supporting people infected with COVID-19. Much to our great relief, an evidence-based, low-risk approach using supplements has been working great[.]

General Adult Immune Support:

o Glutathione 500mg per day with food.

- O Vitamin C 1,000mg three times per day with food.
- o Vitamin A 5,000 IU per day with food. Should get blood levels in 6 months.
- o Vitamin D 5,000IU per day with food, should also check this level if you continue after 6 months
- o Zinc 20 mg per day
- o Selenium 100mcg per day
- o NAC 600mg per day
- O Click Here [hyperlink to https://southwellness.getvitaminlab.com/cart] to an easy solution Dr. Southwell' [sic] Immune Boost Formula.

Newly diagnosed asymptomatic or mildly symptomatic, or exposed and awaiting results from testing:...

Click Here [hyperlink to https://southwellness.getvitaminlab.com/cart] to an easy solution, Dr. Southwell' [sic] Immune Boost Formula. In this scenario we recommend doubling the capsules per day from the standard and dividing them through the day with meals. For more serious symptoms even more vitamin C should be added as below.

Moderate or more severe symptoms:...

- Other things we've been using with success:
 - IV THERAPY: we have seen amazing improvement in symptoms using the above vitamin C regimen complimented by IV therapy with simple high doses of vitamin C, glutathione, B vitamins, Engystol (homeopathic antiviral), Zinc, L-Arginine. We tailor this to your needs and can also provide IV medications in severe cases like dexamethasone, etc.
 - Inhalation Therapy: Nebulized N-Acetylcysteine 20% mixed with normal saline 3-4 times per day depending on the severity.
- Mushroom Extracts: these have innumerable research studies showing benefit
 in prevention and treatment of viruses of all different kinds. I recommend for
 everyone except those allergic to the ingredients throughout the course of the
 pandemic.
 - At Southwellness we made a blend when there was a shortage of the following which we still have at a very affordable price...."
- On the webpage https://southwellness.getvitaminlab.com/cart where consumers may purchase Dr. Southwell's Immunity Formula Dietary Supplement, you state:

"DR. TYLER SOUTHWELL'S IMMUNITY BOOST PROGRAM

Dr. Southwell's Immunity Formula

Dr. Southwell's Immunity Formula is a private label immune-boosting regimen of 6 daily capsules. Created by Dr. Tyler Southwell, this formula is based on extensive research, made with premium medical-grade ingredients, and can be shipped directly to you.

BOOST YOUR IMMUNE SYSTEM

\$69 for 1 bottle 45 Day Immunity-Boost Program

OR

\$130 for 2 bottles
90 Day Immunity-Boost Program (save \$8!)..."

• On the webpage titled "COVID-19 Testing, Prevention & Therapy," located at https://www.southwellnesscovidsolutions.com/covid-19-testing-therapy/ and accessible by selecting "Testing & Therapy" from your website navigation menu, you state:

"Prevention & Therapy

SCS specializes in preventive and therapeutic solutions to help keep your immune system strong against COVID-19.

Utilizing the latest research and our own proven clinical experience testing/treating 10,000+ patients, we have developed therapies that specifically address the COVID-19 disease process: from pre-infection immune support through all phases of active infection.

SCS's Supplement Regimens

[Table with specific dosages of supplements – including Glutathione, Vitamin C, Vitamin A, Vitamin D, Zinc, Selenium, NAC, and Dr. Southwell's Immune Boost Formula – for three different regimens: "General Adult Immune Support"; "Newly Diagnosed Non/Mildly Symptomatic, or Exposed & Awaiting Results"; and "Moderate or More Severe Symptoms."]

Oral Therapies

Dr. Southwell's Immunity Formula: \$69/bottle

Taken orally, this specially compounded blend concentrates the high dose antioxidants and vitamins that research has indicated may help fight COVID-19 with very low downside risks. Each bottle contains a 3-month supply for one person or family of three for 1 month. Buy 2 or more: \$59/bottle.

Mushroom Extract: \$25/bottle until February 28th

This extract is formulated from several edible mushroom varieties that have demonstrated wide ranging antiviral properties in several years of innumerable research trials. Although not yet studied in COVID-19, these mushrooms have demonstrated antiviral effect across the majority of virus types, supporting prevention of infection and/or infection spread between cells. Normally \$35/bottle

IV Infusions & Therapies

Immunity Boost Infusion: \$175

Much more than a myers cocktail, this high-dose antioxidant, anti-inflammatory, vitamin-packed infusion is specifically formulated based on clinical trials demonstrating positive results in fighting infection. It helps maximize your immune system for those concerned with the risk of infections, supports you through infections, and can help with energy, detoxification, and also hangovers. Note — this is a very potent IV, but differs in intensity from our recommended COVID options....

COVID SUPPORT: High-Risk Populations and Severe Cases

People 60 years and over or those with underlying medical conditions such as high blood pressure, heart and lung problems, diabetes, asthma, obesity, immune suppression, or cancer are at higher risk of developing serious illness from COVID-19.

Our research and patient recovery experiences have demonstrated the efficacy of our specific COVID-19 infusion therapy protocols. Each patient's individual needs and conditions are individually designed and overseen by Dr. Southwell personally in coordination, if needed, with your other doctors.

The severity of your condition, preexisting health conditions, and the phase of the COVID disease process determines your specific oral/IV protocol and if maximum intensity/Phase 2 or Phase 1 immune support is needed. The infusion recommendations usually include 3 days of IV therapy for those infected. We also offer preventive infusions. Medications like IV or oral dexamethasone are employed if indicated.

SCS COVID Day 1 Immunity Jump Start 1 Infusion......\$299/IV

SCS COVID Day 1 Maximum Intensity Infusion When Warranted	.\$350/IV
SCS COVID Days 2 & 3 Infusion Continued Immunity Support	\$249/IV
SCS COVID Triple Punch Infusion Package Full 3-day Protocol	\$695 (You save

Inhalation Respiratory Therapy

When warranted, this COVID-19 specific breathing treatment is custom-prescribed to restore lung function and self-administered in the comfort of your home.

3-day Treatment Program	\$90
Nebulizer Machine Purchase	\$50
Extra Tubing	.\$10"

• In Facebook and Instagram posts to

https://www.facebook.com/southwellnesscovidsolutions/ and https://www.instagram.com/southwellnesscovidsolutions/ on March 16, 2021, you share a video featuring the medical manager of Southwellness COVID Solutions in which he states: "I'm just touching on IV therapy and the benefits that it can help you and your loved ones. During the COVID pandemic, IV therapy is a huge benefit given what we've been put in. It allows us to directly hydrate you into your vein without you having to down a ton of fluids. It also gives you 100% of the vitamins versus an oral regimen that you're going to lose half of the vitamins in your digestive system. That's just one of the ways that we can keep you healthy and safe here at Southwell."

The Facebook post also states: "Watch our Medical Manager, Colton, explain how to keep your immune system strong & vigilant with a custom IV infusion..."

The Instagram post also states: "Swipe to see how to protect the ultimate essential worker – your immune system! Watch our Medical Manager, Colton, show you how to keep yourself healthy..." and includes an image with the text: "WE BELIEVE IV'S ARE ESSENTIAL. YOUR IMMUNE SYSTEM WILL THANK YOU FOR IT!"

• In Facebook and Twitter posts to https://www.facebook.com/southwellnesscovidsolutions/ and https://twitter.com/SCSCovid on March 3, 2021, you state: "Even if others are being less cautious, remember — it's not over yet. Find out how to stay healthy and

vigilant! https://conta.cc/3kDuzdI." Consumers who click on the hyperlink in the post arrive at a webpage that states:

"Southwellness COVID Solutions

... you can still dedicate EVERY day to your health and wellness! Keep your immune system ready to fight off COVID-19, even before an exposure!...

Whether you are sick, were exposed, or want to stay vigilant with a customized immune-boosting regimen, our staff is your personal COVID-19 dream team. We are ready to serve you in our office (no appointment necessary), or even in your home, business, or event!

Here [hyperlink to https://www.flipsnack.com/nunuventures/scs-pricing-menu.html] is the wide range of tests and therapies we offer...."

- In Facebook and Instagram posts to https://www.facebook.com/southwellnesscovidsolutions/ and https://www.instagram.com/southwellnesscovidsolutions/ on March 1, 2021, you share a video of a local news story about Southwellness COVID Solutions in which Dr. Tyler Southwell states: "We have a strategy based off clinical experience and peer-reviewed articles to help immune systems be strong to prevent severe disease..."
- In a Facebook post to https://www.facebook.com/SouthwellnessAZ on November 16, you share a link labeled "COVID Update New Immunity Vitamin Regimen." Consumers who click on the link are taken to a webpage that states:

"COVID UPDATE: NEW IMPROVED IMMUNITY VITAMIN

[depiction of a bottle of Dr. Southwell's Immunity Formula Dietary Supplement]

Dear patients!

Things are heating up again! The next 6 months will be rough I think, so I am bringing you a more convenient version of the complex immune support regimen I've developed while treating hundreds of sick patients affected by the pandemic. My hope is that you will consider this to protect you and yours while we weather this storm together.

Every ingredient is evidence-based and specific to the threat facing us.

Please note: this regimen can not be properly claimed to prevent or treat COVID19 because the FDA has not approved it. There's no time for that, and no money in it for a vitamin combination company to afford that anyway....

PREORDER NOW PLEASE...

CLICK HERE [hyperlink to https://southwellness.getvitaminlab.com/cart]"

• In a Facebook post to https://www.facebook.com/SouthwellnessAZ/ on November 4, 2020, and an Instagram post to https://www.instagram.com/southwellnessaz/ on October 23, 2020, you state:

"With the fall season upon us, it's an even more important time to keep boost our immune system. Why you may ask? With a surge coming this fall season, it's possible to come in contact with influenza at the same time you may have coronavirus.... That's why here at Southwellness we've developed an immunity formula based on the latest evidence based research. Even better, we can drop ship it right to your home.

If you'd like to find out more, please call or visit us today © **\$\CLE\$** 480 991 9271

southwellness.com"

In both of these posts you share a video in which Dr. Tyler Southwell states: "As you may know, we've been treating coronavirus here throughout the pandemic... What we've learned about coronavirus from research published since the outbreak is that vitamins can play a really important role.... So we've put together an immune boost formula that's meant to support you before getting infected... and should you get sick you can simply take more of these a day.... This product is amazing..."

• In a Facebook and Instagram posts to https://www.instagram.com/southwellnessaz/ on July 15, 2020, you share a video in which Dr. Tyler Southwell responds to the question "How has the clinic evolved during COVID?" in part by stating: "For treatment, I'm seeing results that are working great with high doses of IV vitamins and inhaled N-Acetyl Cysteine, which are evidence based off of studies that come out of hospitals that we can do here in the clinic and I'm seeing patients respond really well to that and get better faster."

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 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 and services

identified above. Thus, any coronavirus-related prevention or treatment claims regarding such products and 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.

Violations of the FTC Act may result in legal action seeking a Federal District Court injunction and an order may require that you pay back money to consumers. 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.

Within 48 hours, please send a message to Richard Cleland 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 Mr. Cleland at 202-326-3088.

Very truly yours,

Serena Viswanathan Associate Director

cc: Facebook and Instagram *via email to* <u>consumerpolicy@fb.com</u> Twitter *via email to* <u>dc-help@twitter.com</u>