

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

November 5, 2020

WARNING LETTER

VIA EMAIL TO <u>KLMD@rmrm.com</u>; <u>VEMD@rmrm.com</u>

Dr. Vassily Eliopoulos, MD Dr. Khoshal Latifzai, MD Rocky Mountain Regenerative Medicine 2260 Baseline Road, Suite 102 Boulder, CO 80302

Re: Unsubstantiated claims for Coronavirus prevention and treatment

To Whom It May Concern:

This is to advise you that FTC staff reviewed your website <u>https://rmrm.com</u> in October 2020. We also reviewed your social media websites at <u>https://www.youtube.com/channel/UCpqQBAwb_CmuMPPHSzEI-pw</u>, <u>https://www.facebook.com/RMRMBoulder/</u>, and <u>https://www.instagram.com/rmrmboulder/</u>, where you direct consumers to your website <u>https://rmrm.com</u> to purchase supplements and make appointments for treatments including peptide therapy, ozone therapy, and stem cell therapy. We have determined that you are unlawfully advertising that certain products or services treat or prevent Coronavirus Disease 2019 (COVID-19).

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

• On your website at https://rmrm.com/covid-19-natural-treatments/, a page that is accessible by selecting "COVID-19" from the website navigation menu, you state:

"COVID-19 NATURAL IMMUNE SYSTEM SUPPORT

RMRM IS OPEN DURING THE QUARANTINE PERIOD. WE CAN HELP WITH PREVENTION AND COVID-19 NATURAL MANAGEMENT.

COVID-19 NATURAL PREVENTION:

CAN I DO ANYTHING TO PREVENT SEVERE COVID-19 REACTIONS?

<u>There are no current cures or approved COVID-19 natural treatments</u>, although there are many natural interventions you can make. These strengthen your body's immune system improving its reaction to an encounter with any virus, including coronavirus.

Click on the below videos to find out more about each action or treatment:...

- Supplementation
- Peptide Therapy

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SUPPLEMENTATION:

[Embedded YouTube Video, "Vitamin Supplements for Coronavirus," also available at <u>https://www.youtube.com/watch?v=7Ggyy2o4_pE</u>]

Taking the right supplements can help your immune system function and there are specific supplements that have been shown to prevent or minimize the possible complications of COVID-19.

Check out Dr. Vass' video on what to supplement and why.

PEPTIDE THERAPY:

[Embedded YouTube video, "Why Thymosin alpha 1 may be the best peptide for Coronavirus," also available at https://www.youtube.com/watch?v=ADLoWZUvMsg]

Peptides are small proteins that are made by your body. Some peptides have antiviral properties and one in particular has been shown to help prevent cytokine storm which is the way COVID-19 leads to severe disease and death.

Here Dr. Vass talks about peptides for COVID-19.

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Peptide therapy has already been approved for other viral illnesses and has been used against the SARS coronavirus. Peptides may help your body deal with an active COVID-19 infection.

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OXIDATIVE THERAPY:

[Embedded YouTube video, "Shorter version of new COVID Therapy," also available at <u>https://www.youtube.com/watch?v=-GTRIUY2Fns</u>]

Oxidative Therapy – Oxidative therapy is being used in Italy to help people with active CVOID-19 [sic] infection. The Italians have not published their data yet but the verbal reports from the physicians there using it give hope.

Watch Dr. Vass talking about oxidative therapy for COVID-19.

STEM CELL THERAPY:

[Embedded video hosted on rmrm.com, file name Stem-Cell-Therapy-COVID-19.mov]

Stem Cells have been demonstrated in a Chinese study (http://www.aginganddisease.org/EN/10.14336/AD.2020.0228) to be successful in reversing severe and critical COVID-19 infection. This, in our opinion, is the most powerful study to date that demonstrates a solution for severe and critical COVID-19 infection.

Dr. Vass explains the important aspects & how it could be done in the USA.

[From the video:

"This Chinese study for COVID-19 which shows that IV stem cells appear to be an effective therapy for COVID-19 infection. I think this is really important because I don't hear anybody talking about this, but this is the most powerful study I've seen that demonstrates a cure for COVID-19.... This type of therapy could be done here in the United States, but you need to bank your cells now while you're healthy.... I think the time for skepticism is frankly not right now, particularly when you have the kind of results that they're demonstrating in this study.... So the way to do this would be to harvest those cells and bank them while you're healthy...does that cost money, is that expensive, yeah, it's fairly expensive, that being said, if you ended up with a severe COVID infection, and then you had the ability to give yourself your own stem cells? That's priceless.... To me this is a totally viable treatment option.... You need to know this is an option, and that this has been proven to be effective – or, I shouldn't say proven – you need to know this is an option, and this has been shown to be effective in a small study"]

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DURING THE COVID-19 QUARANTINE PERIOD WE ARE OFFERING SPECIAL DISCOUNTS:...

RMRM COVID-19 Vitamin Supplementation regimens run in the \$100-200 range.

RMRM Peptide Therapy regimens usually cost around \$300 but can vary depending on individual recommendations.

Ketamine starts at \$500.00 per infusion and goes up based upon the dosages required.

Oxidative Therapy costs \$200-\$500 depending on the modality.

Stem Cell Therapies are in the thousands of dollars.

WE ARE AVAILBLE FOR TELEMEDICINE CONSULTATIONS AND CAN SEE YOU NO MATTER WHERE IN THE WORLD YOU ARE LOCATED. WE CAN HELP YOU COME UP WITH AN ACTION PLAN FOR PREVENTION AND MANAGEMENT OF COVID-19."

• In a video dated March 21, 2020 on your YouTube Channel at https://www.youtube.com/watch?v=7Ggyy2o4_pE and titled, "Vitamin Supplements for Coronavirus," you state:

"Ok so here I'm talking about evidence-based supplementation for coronavirus.... A lot of these supplements have become difficult to get locally... We have a formulary... it's invite only. They have most of this available currently so it's not too late if you're having trouble getting a supplement you're going to have to email us, let me know, and we'll figure out a way if we can fold you into the formulary... This is not a complete list. If you want the complete list, you'll have to email us.... The first vitamin that I think is a no-brainer is vitamin C. Vitamin C has been studied for the SARS coronavirus.... The second one is zinc. Zinc has been shown directly in vitro to suppress the replication of coronavirus. Now this is not the COVID-19 or the novel coronavirus, these are other common cold causing coronaviruses, but these are all relatives in the same family.... [Zinc] is something I'm personally taking on a daily basis, and so should you.... The third one I'm going to mention is vitamin D...."

[This video was also shared in a March 21, 2020 Facebook post at <u>https://www.facebook.com/RMRMBoulder</u>, in which you also state, "Supplements in the time of Corona. Dr. Vass discusses evidence based vitamin supplementation. #covid #coronavirus... #prevention..."]

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• In a video dated April 3, 2020 on your YouTube Channel at https://www.youtube.com/watch?v=ADLoWZUvMsg and titled "Why Thymosin alpha 1 may be the best peptide for Coronavirus," you state:

"There's a peptide that's been approved for use for both hepatitis B and C, so there's a lot of safety data behind it. It was used in 2003 as a preventative for the SARS coronavirus. So it's not a big leap to be used as an off-label medication for COVID-19. It has multiple different mechanisms of action: one is that it's directly antiviral, and two, perhaps most importantly, it can prevent cytokine storm.... I'm going to get more in depth into the scientific evidence for thymosin alpha-1.... It's the same mechanism by which it defends you from COVID is the same mechanism by which it helps prevent cancer formation.... [T]here's multiple different ways that thymosin alpha-1 can be efficacious in COVID-19.... Although there's no direct evidence that I can give you for COVID-19, we're extrapolating from its success with the SARS coronavirus, which again is a different virus but from the same family as COVID-19. And the fact that this can help prevent the cytokine storm, which is the thing that directly leads to mortality in COVID-19 infection.... And one of the beauties of this is it's relatively cheap, you're looking at two to three hundred dollars for a month's worth of therapy. It can be used as a preventative, and potentially as a treatment.... If you're interested, send us an email. We can set up a telemedicine evaluation no matter where you are in the country, and we can get this compounded and sent to vou."

[This video is also embedded on your website at <u>https://rmrm.com/covid-19-natural-treatments/</u>, and an excerpt of this video is shared in April 5, 2020 Facebook and Instagram posts at <u>https://www.facebook.com/RMRMBoulder/</u> and <u>https://www.instagram.com/rmrmboulder.</u>]

 In a video dated April 15, 2020 on your YouTube channel at <u>https://www.youtube.com/watch?v=-GTRIUY2Fns</u> and titled, "Shorter version of new COVID Therapy," you state:

"Today I want to talk to you about oxidative therapy, also known as ozone therapy. Ozone is the antimicrobial par excellence. It not only directly kills viruses, but is antibacterial, antifungal, and antiparasitic. It's a very safe therapy, and now there's evidence coming out of Italy where it's being used in 17 hospitals that it has direct efficacy against the progression of COVID-19. It's a no brainer, people.... Oxidative therapy is a totally viable, safe option for COVID-19. And the earlier you start using it, the better."

• In Facebook and Instagram posts dated April 15, 2020, you state:

"WE CAN HELP WITH PREVENTION AND COVID-19 NATURAL TREATMENTS!

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ARE THERE ANY NATURAL COVID-19 TREATMENTS AVAILABLE? There are many natural COVID-19 treatments and options you can take to vastly improve your body's recovery with a coronavirus encounter.

Visit our website to get more information. https://rmrm.com/covid-19-natural-treatments/"

[April 15, 2020 posts at <u>https://www.facebook.com/RMRMBoulder/</u> and <u>https://www.instagram.com/rmrmboulder/</u>]

• In March 21, 2020 posts on Facebook and Instagram, you state: "The four things you should be doing to prepare your body for corona virus! #coronavirus..." These posts include a video in which you state: "There are four things you should do if you're healthy and you're worried about the coronavirus. Number one is proper supplementation. Number two is oxidative therapy... Number four is peptide therapy. All of these have scientific backing..."

[March 21, 2020 posts at <u>https://www.facebook.com/RMRMBoulder</u> https://www.instagram.com/rmrmboulder/]

• In a March 23, 2020 Instagram post, you state: "Stem cells for COVID-19? Yes! Dr. Vass talks about the study and potential implications. #stemcells #coronavirus #covid_19..." This post includes an excerpt of the video embedded on your webpage https://rmrm.com/covid-19-natural-treatments/ relating to stem cell therapy that is described above.

[March 23, 2020 Instagram post at https://www.instagram.com/rmrmboulder/]

• In a March 24, 2020 Facebook post, you state: "Dr. Vass explains the pros and cons of the stem cell study for COVID-19. Watch for critique and comments. #stemcells #covid #rmrmboulder #coronavirus." This post includes the entire video embedded on your webpage https://rmrm.com/covid-19-natural-treatments/ relating to stem cell therapy that is described above.

[March 24, 2020 Facebook post at https://www.facebook.com/RMRMBoulder]

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 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 and services are not supported by competent and reliable scientific evidence. You must immediately cease making all such claims. Rocky Mountain Regenerative Medicine November 5, 2020 Page 7

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 Richard Cleland Assistant Director, via electronic mail at <u>rcleland@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 Mr. Cleland at 202-326-3088.

Very truly yours,

Serena Viswanathan Acting Associate Director Division of Advertising Practices