

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051
MINORITY (202) 225-5074
<https://oversight.house.gov>

October 28, 2020

The Honorable Dr. Stephen M. Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The Honorable Joseph Simons
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Dear Commissioner Hahn and Chairman Simons:

The Subcommittee on Economic and Consumer Policy seeks information about the efforts by the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) to limit the sale, distribution, and prescription of the drug thymosin alpha-1 for treating COVID-19.

As you know, thymosin alpha-1 has not been approved by FDA, nor has it been proven safe or effective for treating COVID-19. Though FDA and FTC have warned some companies that their marketing and sale of thymosin alpha-1 is unlawful, recent reports indicate that such piecemeal action may not be enough.

One report identified more than 30 medical practice groups and compounding pharmacies across more than a dozen states that have made false claims about thymosin alpha-1 on their websites and on social media since the pandemic began. The majority of practices promoting thymosin alpha-1 do not specialize in infectious diseases, but rather “focus on plastic surgery or promote ‘wellness,’ ‘anti-aging’ and ‘regenerative’ medicine.”¹

In one case, VitaLifeMD, a practice run by well-known “wellness” doctor Dominique Fradin-Read, advertised to thousands of viewers across social media platforms that thymosin alpha-1 was an “FDA-approved” drug that worked like “magic” and was “one of the best ways to

¹ *Web Of 'Wellness' Doctors Promote Injections Of Unproven Coronavirus Treatment*, National Public Radio (Oct. 1, 2020) (online at www.npr.org/2020/10/01/914433778/web-of-wellness-doctors-promote-injections-of-unproven-coronavirus-treatment).

prevent and fight COVID-19.”² Such false claims appear to be illegal and ought to be subject to strict enforcement by FDA and FTC.

The unauthorized sale of thymosin alpha-1 is lucrative. A month’s supply of thymosin alpha-1 costs consumers up to \$400 out of pocket.³ But the sale of “miracle cures” during a pandemic has obvious public health risks. People who take them and assume they are protected risk infecting others. Beyond that, scam sales of this product present significant economic harm to consumers.

The Subcommittee supports actions taken by your agencies to issue several warning letters to entities promoting the unapproved drug as a coronavirus treatment. Your agencies issued a joint warning letter to the Center for Wellness and Interactive Medicine on June 30, 2020 for promoting the unapproved drug as a coronavirus treatment.⁴ FTC issued similar warning letters to Joy Wellness Partners on June 3, 2020 and to New Leaf Wellness, LLC on April 28, 2020.⁵ And FDA also issued a warning letter to thymosin alpha-1 manufacturer Tailor Made Compounding, LLC on April 1, 2020 for unsafe production processes.⁶

However, such piecemeal enforcement is not working: medical practices and manufacturers are making dangerous and false claims. Because warning letters carry no penalty, they are not an adequate deterrent to bad actors. A wellness clinic can break the law and wait to be caught, knowing the worst they face is being asked to stop.

The Subcommittee calls on FDA and FTC to enforce existing laws to eliminate the sale, distribution, and prescription of the drug thymosin alpha-1 for treating COVID-19. I ask you to open an investigation into VitaLifeMD, and to take all appropriate action against VitaLifeMD and its principals. I call on you to leverage the full extent of your enforcement options to bring this problem under control.

² *Id.*

³ *Web Of 'Wellness' Doctors Promote Injections Of Unproven Coronavirus Treatment*, National Public Radio (Oct. 1, 2020) (online at www.npr.org/2020/10/01/914433778/web-of-wellness-doctors-promote-injections-of-unproven-coronavirus-treatment).

⁴ Letter from Donald D. Ashley, Director, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, and Serena Viswanathan, Acting Associate Director, Division of Advertising Practices, Federal Trade Commission, to Tom Yarema, Medical Director, Center for Wellness and Integrative Medicine (June 30, 2020) (online at www.ftc.gov/system/files/warning-letters/fda-covid-19-letter_center_for_wellness_and_integrative_medicine.pdf).

⁵ Letter from Dama J. Brown, Regional Director, Southwest Region, Federal Trade Commission, to Joy Wellness Partners (June 3, 2020) (online at www.ftc.gov/system/files/warning-letters/covid-19-letter_to_joy_wellness_partners.pdf); Letter from Richard A. Quaresima, Acting Associate Director, Division of Advertising Practices, Federal Trade Commission, to Robert Sieman, Medical Director, New Leaf Wellness, LLC (Apr. 28, 2020) (online at www.ftc.gov/system/files/warning-letters/covid-19-letter_to_dap_new_leaf.pdf).

⁶ Letter from Art O. Czabaniuk, Program Division Director, Division of Pharmaceutical Quality Operations Division III, Food and Drug Administration, to Jeremy S. Delk, Chief Executive Officer and Owner, Tailor Made Compounding LLC (Apr. 1, 2020) (online at www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/tailor-made-compounding-llc-594743-04012020).

Amid an unprecedented public health and economic crisis, we cannot allow unscrupulous manufacturers and providers to deceive consumers into purchasing expensive, ineffective, and potentially dangerous “miracle cures.”

The Subcommittee requests that FDA and FTC provide a briefing to our staff to occur by November 13, 2020, on enforcement of false claims about thymosin alpha-1, including:

1. Whether FDA and FTC will commit to opening an investigation into VitaLifeMD and Dominique Fradin-Read, and taking appropriate action against them, if warranted;
2. What FDA and FTC are doing to monitor for false or misleading claims about thymosin alpha-1 as a COVID-19 treatment;
3. FDA and FTC’s enforcement plans for false claims regarding thymosin alpha-1 as a COVID-19 treatment, including options for progressing to more substantial enforcement actions than warning letters;
4. What FDA and FTC are doing to monitor for unsafe conditions at thymosin alpha-1 manufacturing facilities;
5. FDA and FTC’s enforcement plans for unsafe conditions at thymosin alpha-1 manufacturing facilities; and
6. Initiatives to communicate to consumers the risks of non-FDA-approved COVID-19 treatments such as thymosin alpha-1.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate “any matter” at “any time” under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi
Chairman

Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member