의소 New Civil Liberties Alliance

December 13, 2022

Ms. Abdiel T. Lewis Mr. Evan Rose Federal Trade Commission Western Region San Francisco 90 Seventh St., Suite 14-300 San Francisco, California 94103 (415) 848-5118 alewis4@ftc.gov_erose@ftc.gov

VIA EMAIL

Re: Rule 11 Notice in FTC v. PPO, Case No. 4:22-cv-7307

Dear Ms. Lewis:

I have had an opportunity to review the Complaint in the above-captioned matter. And frankly, I'm taken aback at the filed Complaint. Every attorney has an obligation of candor with the Court. There are allegations in this Complaint that cannot be made after reasonable inquiry and investigation yet have been made in this instance. After a months-long investigation by the Federal Trade Commission ("FTC"), which included my clients providing appropriate sales records, and meetings with FTC staff and each of the FTC Commissioners individually, there are clear misstatements or falsehoods in the as-filed Complaint.

Pursuant to Fed. R. Civ. P. 11(c)(2) I am informing you of the paragraphs of the Complaint that violate the Rule 11 (b)(1) and (3) that require that every attorney signing a pleading "certifies that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances" that:

(1) it is not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation;

and ...

(2) the factual contentions have evidentiary support or, if specifically so identified, will likely have evidentiary support after a reasonable opportunity for further investigation or discovery.

My clients never sold COVID Resist. Not a bottle. Not a capsule. The Commission has acknowledged this fact since at least May 10, 2022, if not before then. Given that fact the following paragraphs of the current Complaint must be struck under sanction of Rule 11:

- Paragraphs 2, 8, 9, 11, 27, 29, 34, 39, 53, and 58 directly state COVID Resist was sold and must be struck as you know that not to be the case.
- As COVID Resist does not exist paragraph 26 is also unsupported.
- Paragraphs 37, 39, and 45 leave the impression that COVID Resist was for sale and it was not.

But there is more. In keeping with the FTC's policy of trying cases out of court with press releases meant to destroy a business whether the FTC is correct or not in its allegations, the FTC has published false and misleading claims to the public. Attached to this letter are three communications written and disseminated by the FTC, each with the false and misleading statement that my clients sold COVID Resist. The first is the press release dated November 22, 2022 and issued with the Complaint with the media contact being one Mitchell J. Katz and the staff contact being you. Attachment 2 is a blog post by one Lesley Fair parroting the false statement that COVID Resist was sold. Attachment 3 is a "Consumer Alert" also with these false claims by Colleen Tressler. All of these claims are false. But I will go further. Virus Resist is no longer sold. The FTC's independent investigation bears this out since at least July 23, 2022. None of these three false pieces of literature or the Complaint mention that. That is also misleading. These were all published with the knowing intent to injure my clients in their trade or business. All of this is far more provably false and misleading than anything you wrongly accuse my clients of doing.

Pursuant to Rule 11(C)(2) I urge you to remove all of the offending paragraphs of the Complaint before Defendants need to respond and to remove the tissue of falsehoods that have been published under the FTC name on its website. As you know appropriate sanctions under Rule 11 include dismissal with prejudice of the Complaint. If these are not removed we will be seeking that sanction.

ery tryly yours,

9s/ John J. Vecchione

Senior Litigation Counsel

cc: Kara Rollins Fred Hagan

Attachment 1



For Release

FTC Acts to Stop Deceptive COVID-19 Advertising Claims by California's Precision Patient Outcomes, Inc.

Case is part of the Commission's ongoing efforts to combat COVID-related fraud

November 22, 2022

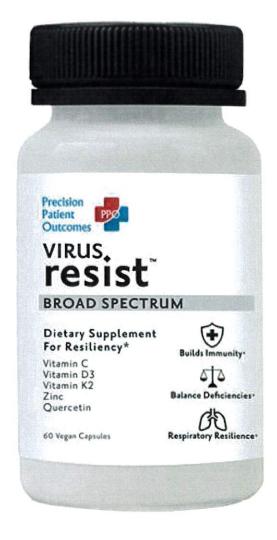
Tags: Consumer Protection | Bureau of Consumer Protection | Western Region San Francisco | Health Coronavirus (COVID-19) | Advertising and Marketing

The Federal Trade Commission is taking action against California-based Precision Patient Outcomes, Inc. and the company's CEO Margrett Priest Lewis for marketing an over-the-counter dietary supplement containing nothing more than vitamins, zinc, and a flavonoid as an effective treatment to mitigate the effects of COVID-19.

"The FTC will halt baseless claims about COVID-19 treatments that harm consumers' pocketbooks and health," said Samuel Levine, Director of the Commission's Bureau of Consumer Protection. "We don't simply seek to stop this kind of fraud, but to permanently prohibit companies and company owners engaging in misconduct from endangering the health and well-being of American consumers."

In its complaint , the FTC is seeking to permanently stop the company and its CEO from using deceptive treatment or prevention claims with no supporting scientific evidence to sell their dietary supplement. The FTC alleges that these practices violate the FTC Act and the COVID-19 Consumer Protection Act. The latter allows the Commission to seek civil penalties in cases of COVID-related consumer fraud.





Images of COVID Resist (left) and Virus Resist bottles

Precision Patient Outcomes, based in Berkeley, California, developed, labeled, advertised, marketed, distributed, and sold a supplement under the names COVID Resist and VIRUS Resist, to consumers nationwide during the COVID pandemic. According to the FTC's complaint, in May 2021 the defendants began advertising and marketing COVID Resist on the company's website and social media pages with deceptive claims that the product can treat, prevent, or mitigate COVID-19.

Lewis, the company's co-founder and CEO, formulated the product and is in direct control of Precision Patient Outcomes' business operations. Among other things, she has been actively involved in promoting COVID Resist and VIRUS Resist using the company's website; through posts on Facebook, Instagram, and TikTok; and on her personal social media accounts.

Despite knowing about the Commission's enforcement action under the COVID-19 Consumer Protection Act against a company making similar claims about the science and efficacy of its products, the defendants only changed the name of the product from COVID Resist to VIRUS Resist and continued to deceptively advertise it as an effective treatment for COVID-19.

The Commission vote authorizing the staff to file the complaint was 4-1, with Commissioner Christine S. Wilson dissenting. The complaint was filed in the U.S. District Court for the Northern District of California.

The Federal Trade Commission works to promote competition and protect and educate consumers. Learn more about consumer topics at consumer.ftc.gov, or report fraud, scams, and bad business practices at ReportFraud.ftc.gov. Follow the FTC on social media, read consumer alerts and the business blog, and sign up to get the latest FTC news and alerts.

Press Release Reference

In First Action Under COVID-19 Consumer Protection Act, FTC Seeks Monetary Penalties for Deceptive Marketing of Purported Coronavirus Treatments

Contact Information

Media Contact

Mitchell J. Katz Office of Public Affairs 202-326-2161

Staff Contact

Abdiel T. Lewis FTC's Western Region San Francisco 415-848-5118

Attachment 2



Business Blog

FTC challenges supplement claims under COVID-19 Consumer Protection Act

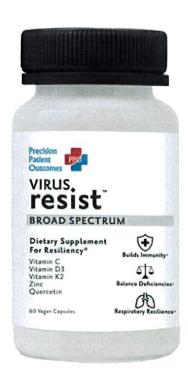
By: Lesley Fair | November 22, 2022

"A dose of this formula a day keeps viruses away and their variants." That's just one example of a representation California-based Precision Patient Outcomes, Inc., and CEO Margrett Priest Lewis made for a dietary supplement sold under the names COVID Resist and VIRUS Resist. The FTC has gone to court, alleging that the defendants' claims that the product can treat, prevent, or mitigate COVID violate the COVID-19 Consumer Protection Act and the FTC Act.

Beginning in May 2021, the defendants advertised COVID Resist on their website for \$34.95 per bottle. According to the label, the product contained Vitamin C, Vitamin D3, Vitamin K2, zinc, and quercetin dihydrate. The website included a page titled "Our Research" with quotes and references that the defendants said supported their claims. They also took to social media – Facebook, Instagram, TikTok, etc. – to promote the product as effective both before exposure to COVID and after.

If you've been following the FTC's ongoing action plan for combating false or deceptive claims that products can prevent, treat, or cure COVID, you'll want to read the complaint for details about an interesting interaction between the defendants and FTC staff at about the time the product was introduced. On May 5, 2021, Precision Patient Outcomes CEO Lewis wrote to the FTC that the company would be launching COVID Resist and invited staff to review the website. The letter continued, "[O]ur statements are supported by competent and





reliable scientific evidence," the products "are clearly in compliance with FTC, DSHEA, and FDA's regulations," and they "have not made any false or misleading claims."

FTC staff responded that the agency "does not prereview advertising materials to opine on their compliance with the FTC Act or any other applicable laws," but referred CEO Lewis to multiple resources on ftc.gov with guidance about substantiating health claims. In addition, staff cited the roughly 400 warning letters sent to marketers that had made COVID prevention, treatment, or cure claims and the law enforcement actions filed to date. Furthermore, staff told CEO Lewis, "We have sent numerous warning letters to marketers of supplements that include one of more of the same ingredients as your proposed COVIDresist supplement." A few months later, the FTC alleges the defendants stopped selling COVID Resist on their website, but began marketing VIRUS Resist, also promoted with COVID-related health claims.

Filed in federal court in California, the <u>complaint</u> alleges that the defendants made false or unsubstantiated efficacy claims for COVID Resist and VIRUS Resist. What's more, the FTC has charged that the defendants falsely represented that their products were scientifically proven to treat, prevent, or mitigate COVID-19. As the lawsuit alleges, "[N]o well-controlled human clinical study has been conducted on the efficacy of COVID Resist/VIRUS Resist, or its individual ingredients, to treat, prevent, or mitigate COVID-19." Among other things, the FTC has asked the Court to impose civil penalties under the <u>COVID-19 Consumer Protection Act</u>.

Even at this early stage, the case is a reminder of the additional remedies Congress has authorized to help combat deceptive COVID claims. Looking for more information about how the FTC has responded to the COVID crisis with education, outreach, and law enforcement? Visit <u>Coronavirus Pandemic: The FTC in Action</u>.

Tags: Consumer Protection | Bureau of Consumer Protection | Coronavirus (COVID-19) | Advertising and Marketing Health Claims

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Samuel Levine, Director, FTC Bureau of Consumer Protection | November 18, 2022

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<u>\$2.6 million settlement addresses earnings claims for business opportunities</u> and crypto bot, Consumer Review Fairness Act – and more

Lesley Fair November 16, 2022

Business Blog

Compliance deadline for certain revised FTC Safeguards Rule provisions extended to June 2023

Lesley Fair November 15, 2022



Attachment 3



Consumer Alert

FTC squashes company claims that dietary supplements treat or prevent COVID-19

By: Colleen Tressler, Division of Consumer and Business Education, FTC | November 22, 2022









There are no supplements proven to treat or prevent COVID-19.

Before you try any supplement, talk with your doctor or healthcare professional.

Learn more:

ftc.gov/coronavirus/scams



In the FTC's latest case targeting fake COVID-19 claims, the agency took action against Margrett Priest Lewis and the company she founded and manages, Precision Patient Outcomes, Inc. (PPO). Lewis and PPO claimed their dietary supplements, branded as COVID Resist and VIRUS Resist, could treat, prevent, or mitigate COVID-19, and that scientific evidence supported their claims. But the complaint says Lewis and PPO don't have scientific evidence to back up their treatment, prevention, or mitigation claims.

There are no supplements proven to treat or prevent COVID-19.

When it comes to fighting COVID-19 and spotting unsupported treatment claims:

Always talk with your doctor or healthcare professional before you try any product claiming to

treat, prevent, or cure COVID-19.

- When there's a medical breakthrough to treat, prevent, or cure a disease, you're not going to hear about it for the first time through an ad or sales pitch on social media.
- Visit <u>CDC.gov</u> and the <u>FDA.gov</u> for the most up-to-date information about COVID-19 and available vaccines.

Now, please share what you know, and ask others to do the same.

- Learn more about COVID-related scams at ftc.gov/coronavirus
- Sign up for consumer alerts at ftc.gov/consumeralerts
- Tell us about scams you're seeing at ReportFraud.ftc.gov

Topics: Shopping and Donating, Health

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