



PEOPLE'S Parity Project

July 21, 2020

VIA ELECTRONIC MAIL

The Honorable Stephen Hahn, Commissioner and
Steven Tave, Director
Office of Dietary Supplement Programs and
Janet Woodcock, Director
Center for Drug Evaluation and Research and
Patrizia Cavazzoni, Deputy Director for Operations
Center for Drug Evaluation and Research

Food and Drug Administration 10001 New Hampshire Avenue Hillandale Bldg., 4th Floor Silver Spring, MD 20993 and 10903 New Hampshire Avenue Silver Spring, MD 20993

Re: Request for Enforcement Regarding Unlawful COVID-19 Disease Claims by

Mercola Group

Dear Commissioner Hahn, Directors Tave and Woodcock, and Deputy Director Cavazzoni:

Justice Catalyst Law ("JCL"), ¹ the Center for Science in the Public Interest ("CSPI"), ² and People's Parity Project ("PPP") write to urge the U.S. Food and Drug Administration ("FDA") to bring enforcement proceedings against Joseph Mercola, D.O. ("Dr. Mercola") and his companies (collectively, "Mercola Group") for the Mercola Group's unlawful disease claims that falsely and misleadingly claim to treat, cure, or prevent COVID-19 infections. We are also sending a similar letter to the Federal Trade Commission ("FTC") today.

As we set forth in detail below, Mercola Group has been capitalizing on the coronavirus pandemic by advising consumers to purchase vitamins, supplements, and other products sold on its website to prevent or treat the virus. Mercola Group's website contains many misleading articles, such as "Nutrition and Natural Strategies Offer Hope Against COVID-19," and a "Coronavirus Resource Guide" compiling various unsubstantiated claims about the COVID-fighting properties of various supplements. It also offers "medical" advice, including the extraordinarily dangerous recommendation that individuals actually try to contract COVID-19 after using the supplements it sells to ameliorate the symptoms.

Mercola Group and Dr. Mercola make multiple disease claims in marketing supplements and other products. The products that Mercola Group sells through its online store, and that Dr. Mercola has endorsed in public statements (described below) for the prevention and/or treatment of COVID-19, include: vitamin C (specifically, liposomal vitamin C); vitamin D; zinc and selenium (which Mercola Group sells together); melatonin; licorice; molecular hydrogen; astaxanthin; n-acetyl cysteine; prebiotics, probiotics, and sporebiotics; saunas; ozone therapy; elderberry extract; spirulina; beta-glucan; lipoic acid; and sulforaphane.

Mercola Group's unlawful marketing claims pose a clear danger to the public. Consumers who purchase and use Mercola Group's products based on its claims may be endangered by a false sense of security, both about their own health and the health of those around them. Feeling empowered to return to normal life because they are using one of Mercola Group's putative remedies, consumers may forgo clinically proven prevention measures, such as social distancing or personal protective equipment, prolonging the crisis and endangering many more people.

The acts or practices by Mercola Group described in this letter constitute the sale of unapproved drugs and devices in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"). JCL, CSPI, and PPP urge the FDA to take the following actions: (1) issue a warning letter demanding that Mercola Group immediately cease the sale of such unapproved and unauthorized products for the treatment, cure, or prevention of COVID-19; (2) monitor compliance with the warning letter; and (3) if there is non-compliance, bring an enforcement action in district court seeking permanent injunctive relief and civil penalties and authorizing inspectors to seize the misbranded products that are the subject of this letter.

As detailed in this letter, Mercola Group should be an enforcement priority for the FDA because the marketing claims being made are illegal disease prevention and treatment claims, and are unsubstantiated and false, its audience includes millions of American consumers, and the particular claims being raised present a high risk of substantial harm to the public.

For each of the products covered by this letter, there is a detailed discussion below of the specific disease claims that Mercola Group has made. In addition, because the FDA has made clear that it will prioritize for enforcement unapproved drugs that "lack evidence of effectiveness" and that steer the public toward ineffective products "in lieu of effective treatments," ¹⁰ we also analyzed the evidence to support the Mercola Group's claims and have demonstrated that they are false and misleading. Finally, all of these products and the false and misleading disease claims about them are summarized on the chart in the Appendix, Ex. A.

I. MERCOLA GROUP IS A DANGER TO PUBLIC HEALTH

Dr. Joseph Mercola is the owner, president, and director of a number of active companies, foundations, and nonprofits. ¹¹ Through its website and other marketing, Mercola Group sells hundreds of supplements, foods, food additives, oils, creams, spices, herbs, books, electronic devices, clothing, and other "alternative" health products promoted as cures or treatments. ¹²

According to Mercola Group, its website, Mercola.com, is the world's "#1 most visited natural health website" and is viewed by "millions of people daily." Mercola Group sells millions of dollars in products annually, including, for example, as much as \$5.3 million worth of tanning beds between 2012 and 2016. Through his businesses, Dr. Mercola has amassed a personal fortune, reported to be in excess of \$100 million. To

Mercola Group also frequently disseminates false and misleading claims via its website, such as a 2011 article asserting that vaccines can cause breast cancer. ¹⁶ Of late, Dr. Mercola has focused his misleading and dangerous advice on COVID-19. He is, for example, preemptively downplaying the effectiveness of potential COVID-19 vaccines, and even warning the public that any potential vaccine would likely be deadly. On a podcast posted April 5, 2020, Dr. Mercola told listeners complete falsehoods about the risks of vaccines, saying: "For every life being saved by a vaccine, you may have another 10, 20, 100 people who are either killed or permanently injured as a result of that vaccine." ¹⁷ Dr. Mercola also endorsed his guest's view that people would probably be dragged from their homes and vaccinated against their will. ¹⁸

Mercola Group's false and misleading disease claims about COVID-19 are really just a thinly-veiled and self-serving attempt to sell its products. But they pose a unique threat at this moment, given the Group's reach and audience size. Consumers that use Mercola Group's products based on its illegal disease claims, and false and unsubstantiated claims, that the supplements will help protect them, may engage in activities that increase risk of illness for themselves, and spread the coronavirus to other people.

II. MERCOLA GROUP'S CURRENT DISEASE CLAIMS WARRANT FDA ACTION

Mercola Group's prior activities have been an area of enforcement activity for both the FDA and FTC, as well as local medical licensing boards, as described below in Section III. Mercola Group's current actions and statements should be a renewed focus of enforcement attention for the FDA because it is capitalizing on the COVID-19 pandemic by advising consumers to purchase the vitamins, supplements, and other products sold on its website to prevent or treat the virus.

Recent articles with Dr. Mercola's personal byline that appear on Mercola Group's website include "Nutrition and Natural Strategies Offer Hope Against COVID-19" and "Essential Nutrition to Protect Yourself from Coronavirus." In addition, Mercola Group's website offers a "Coronavirus Resource Guide" (labeled as a "HOT" searched-for item), compiling its various disease and unsubstantiated claims about the COVID-fighting properties of the supplements being sold therein. ²¹

Dr. Mercola also makes disease claims during his podcast, "*Take Control of Your Health*." On a recent episode of this podcast, posted March 29, 2020, and in an accompanying article published the same day on Mercola Group's website, Dr. Mercola tells the audience that their best option in the face of the global COVID pandemic is to take immunity-boosting supplements, which

Mercola Group sells on its website, and then advises the audience to actually attempt to contract the COVID-19 virus.

He reasons that contracting COVID-19, with an immune system that would be allegedly bolstered by supplements he recommends, is safer and more effective than a potential vaccine could be:

When you get a vaccine, you only simulate your humoral immunity, the B-cells. The T-cells are not stimulated. So, scary as it may sound, the best thing is to get the infection, and have a strong immune system to defend against it so you won't even display any symptoms.²²

Similarly, on his podcast, Dr. Mercola also made the misleading and false assertion that contracting the virus and recovering will confer a "natural immunity" that will be more effective than the immunity provided by a vaccine. ²³ If an individual is infected, Dr. Mercola also promotes vitamins and supplements to treat the severity of illness. ²⁴We turn now to a discussion of the specific disease claims that Mercola Group makes for the following products that Mercola Group sells through its online store ²⁵ and Dr. Mercola endorses for the prevention and/or treatment of COVID-19: vitamin C (specifically, liposomal vitamin C); vitamin D; zinc and selenium (which Mercola Group sells together); melatonin; licorice; molecular hydrogen; astaxanthin; n-acetyl cysteine; prebiotics, probiotics, and sporebiotics; saunas; ozone therapy; elderberry extract; spirulina; beta-glucan; lipoic acid; and sulforaphane. This is also summarized in Exhibit A.

Under Sections 201(g), (p) of the FDCA, 21 U.S.C. § 321(g), (p), dietary supplements marketed to diagnose, mitigate, treat, cure, or prevent a disease—such as COVID-19—are considered "new drugs" and may not be sold without FDA-approval. In addition, the FDA has made clear specifically that any claim that a dietary supplement has antiviral properties, fights infections, or helps the body resist viruses or infections is also an impermissible disease claim. ²⁶ None of the products discussed in this letter are FDA-approved medical treatments for COVID-19 or, to our knowledge, for any disease. ²⁷ Thus, the dietary supplements discussed is this letter are unapproved new drugs sold in violation of Section 505(a) of the FDCA, 21 U.S.C. § 355(a).

Under Section 201(h) of the FDCA, 21 U.S.C. § 321(h), an "instrument, apparatus, . . . or other related article" marketed to diagnose, mitigate, treat, cure, or prevent a disease—such as COVID-19—is considered a "device." Devices may not be sold without FDA-approval. To our knowledge, none of the devices discussed in this letter has received FDA approval. Thus, the devices discussed in this letter are unapproved and sold in violation of Section 501(f)(1)(B) of the FDCA, 21 U.S.C. § 351(f)(1)(B).

We demonstrate below that Mercola Group's claims are disease claims that are *per se* violations of the FDCA. No more need be demonstrated to warrant the cessation of the sale of such unapproved and unauthorized products for the mitigation, prevention, treatment, diagnosis, or cure of COVID-19. However, because FDA has made clear that it will prioritize for enforcement unapproved drugs that "lack evidence of effectiveness" and that steer the public toward

ineffective products, ²⁸ we also analyzed the lack of evidence to support Mercola Groups' claims. Thus, the products covered by this letter are both illegal unapproved drugs and devices and ineffective products making false and misleading claims. To assess the adequacy of evidence, we entered the names of each of the purportedly active ingredients listed below into a leading COVID-19 evidence database, L*OVE (Living Overview of the Evidence) Coronavirus - COVID-19, ²⁹ and identified all completed studies with the ingredient. ³⁰ We then entered each ingredient into a separate COVID-19 evidence database, Live Map of COVID-19 Evidence, ³¹ this time restricted to completed randomized, controlled trials (RCTs), but identified no additional studies. We describe the studies (RCTs and others) identified under each ingredient below and found that there are no properly randomized and controlled clinical trials that substantiate any of the COVID-19 claims made about the Mercola Group products that are the subject of this letter.

A. Disease Claim: Vitamin C Prevents and Treats COVID-19 Infection

Between February and April 2020, Dr. Mercola wrote articles and spoke extensively about the effectiveness of vitamin C to prevent and treat a COVID-19 infection. In a February 24, 2020, article published on Mercola.com, without providing any factual basis, Dr. Mercola alleged that an upcoming study from China is likely to show that vitamin C administered by injection will successfully treat COVID-19-induced pneumonia.³² However, as of July 8, 2020, the study is still in the recruiting phase.³³

Dr. Mercola also claims that "the deaths from COVID-19... typically are related to sepsis." Dr. Mercola then frequently cites a small, non-randomized study with a non-concurrent control on the treatment of sepsis that claimed to show that vitamin C, corticosteroids, and thiamine, when administered together, dramatically reduced mortality from sepsis. However, the study's results were subsequently debunked in the *Journal of the American Medical Association* by researchers who conducted a larger RCT that found that the three compounds did not reduce mortality from sepsis. Currently, there is no credible scientific evidence that vitamin C treats sepsis.³⁵

Despite this lack of evidence, Dr. Mercola and guests on his podcast continue to claim that "when we have even a small amount of vitamin C, our risk of dying [from COVID-19], even in the most severe cases, goes down." Dr. Mercola explains that to achieve a "pharmacologic dose [of vitamin C], which you would use when you have an infection," consumers would either need a physician to administer the vitamin intravenously or would need to purchase "oral liposomal," as opposed to regular, vitamin C tablets. The Liposomal vitamin C tablets, in both adult and child formulations, are featured prominently in Mercola Group's online store and on Amazon.com, among other locations. Dr. Mercola joked with a podcast guest, who remarked that vitamin C tablets were selling out in stores rapidly, that he could tell him "privately of a company that has just purchased a two year raw supply" of vitamin C and "is making five million capsules a week," a clear example of the link between Dr. Mercola's "advice" and the sale of the Mercola Group's products.

On a recent episode of his podcast, Dr. Mercola and his guest, Dr. Andrew Saul, repeatedly advised their audience to take vitamin C in "pharmacologic" doses to treat a disease (an illegal disease treatment claim) and in as high doses as their bodies could tolerate in order to bolster their bodies' abilities to fight off COVID-19:

(25:53)

Dr. Saul

"When people go to their doctor and they say, 'well I have this virus' and then the doctor says, 'there's nothing I can do,' well, actually there *is* something you can do. You can take a lot more vitamin C to bowel tolerance orally, the way Dr. Robert Cathcart recommended it. Take enough C, to be symptom free, whatever the amount might be, which is how I've been putting it for 44 years. Dr. Cathcart would say 'take vitamin C to bowel tolerance,' and that's exactly what you think it means: the sicker you are, the more you'll hold. So, if you are really facing an influenza outbreak, you'll hold a lot of C before you get to bowel tolerance and this is something that everyone can do at home. My grandchildren can do this. When they get sick, they manage their own case by taking vitamin C until they get to bowel tolerance and they're in 1st grade and 3rd grade."

(29:01)

Dr. Mercola

"That's brilliant advice on the dose [of vitamin C: as much as one's body will tolerate], what about the frequency of the dosing?"

Dr. Saul

"The more frequently you can take the C, the better off."

(31:35)

Dr. Mercola

"I guess we're transitioning from the nutrient dose of vitamin C to the pharmacologic dose, which you would use when you have an infection. So, along that line, one of the next steps along is to increase it beyond the bowel tolerance dose. To increase your blood levels even higher. And the way you can do that, is there's two routes. One is you could go the oral route, where it have to be a liposomal approach where you can bypass the GI track and it just goes in directly, and you don't have the bowel tolerance complications, or you can do it intravenously. I think, obviously, the oral is going to be less expensive and easier to do, and you don't have to get out of your house and go see a physician. So, that would be a strategy. But, we know that the higher doses work, this is what they're using in China that you described earlier, and what they're using in New York, some of the New York hospitals now to treat the COVID-19 infections. So, that's the

intermediary step if you can't go beyond the bowel tolerance, is do liposomal, or find a physician to do intravenous vitamin C."

(33:58)

Dr. Mercola

"The key is getting that vitamin C into the cells. . . . It doesn't work magically in the blood. So that's where the liposomal vitamin C tends to be beneficial, because it transports right through the cell membrane into the cell. So I think you get higher levels than a regular oral vitamin C."

We identified one RCT⁴¹ involving vitamin C in which a regimen with vitamin C (along with traditional Chinese medicine, fumigation, and absorption) was compared with two control groups not receiving vitamin C in the treatment of COVID-19. There were 10 patients in each group, but details are sparse (including on blinding status) as we could only identify an abstract. The authors report an improvement in an unusual outcome called "fatigue, cough, dry throat, shortness of breath," but not on chest computerized tomography (CT) findings or viral detection. Therefore, we are not aware of any RCTs that adequately substantiate that vitamin C prevents or treats COVID-19 infection. Accordingly, although vitamin C is being tested as a treatment for COVID-19, there is currently no credible scientific evidence that vitamin C administration helps prevent or treat COVID-19 infection. ⁴²

B. Disease Claim: Vitamin D Prevents and Treats COVID-19 Infection

Mercola Group also advises consumers to use oral vitamin D₃ supplements to combat and prevent COVID-19. Mercola Group's "Coronavirus Resource Page" lists a number of "Top Tips to Help Combat Coronavirus," with "TIP #4" being "INCREASE VITAMIN D INTAKE" and linking to an article written by Dr. Mercola for more information.⁴³

Mercola Group claims that "high-dose[s of] vitamin D" will reduce the risk of respiratory infections such as COVID-19.⁴⁴ On the March 29, 2020 episode of his podcast, Dr. Mercola informs his listeners that they should use a test kit to determine what their current levels of vitamin D are and therefore what their proper supplement dosage should be.⁴⁵ Mercola Group's online store sells a vitamin D test kit for \$65, ⁴⁶ and a combination vitamin D, magnesium, and omega-3 test kit for \$165.⁴⁷

In addition, on the April 19, 2020 episode of his podcast, Dr. Mercola and his guest Dr. Saul inform listeners that vitamin D will help prevent severe cases of COVID-19 when used in combination with vitamin C and other dietary supplements. Drs. Saul and Mercola blame the media for hiding this information from consumers.⁴⁸

Mercola Group's claims regarding vitamin D are illegal, unsubstantiated, and dangerous—especially the suggestion that consumers should take "high" doses of vitamin D to prevent a coronavirus infection. Mercola Group fails to warn consumers that excessive intake of vitamin D

supplements are "associated with increases in all-cause mortality, greater risk of cancer at some sites like the pancreas, greater risk of cardiovascular events, and more falls and fractures among the elderly," according to the National Institutes of Health.⁴⁹

Our review identified four studies examining vitamin D and COVID-19.⁵⁰ One of these conducted a literature review that identified nine additional studies.⁵¹ Together, these studies were either ecological studies (looking at population levels of vitamin D or latitude and COVID-19 outcomes), observational studies (looking at the correlation between vitamin D levels in COVID-19 patients and various outcomes), or, in one case, a small, non-randomized study examining the impact of the administration of vitamin D (along with vitamin B₁₂ and magnesium) on COVID-19 outcomes.⁵² Therefore, we are not aware of any RCTs that substantiate that vitamin D prevents or treats COVID-19 infection.

C. Disease Claim: Zinc, Zinc Ionophores, and Selenium Prevent COVID-19 Infection

Dr. Mercola has repeatedly urged consumers to use zinc products to "ward off" coronavirus infections.⁵³ Mercola Group's online store sells zinc in supplement form.⁵⁴

Dr. Mercola also advises consumers that they will need additional supplements to ensure proper absorption and effectiveness. He writes: "[z]inc alone is incapable of fully stopping viral replication as it cannot easily enter through the fatty wall of a cell. Getting all the way into a cell is crucial, as this is where the viral replication occurs." He further explains that hydroxychloroquine, the much-discussed antimalarial drug, which has been shown to be ineffective at treating COVID-19, 55 "appears to work against COVID-19 by improving zinc uptake into cells."

Except for "the most serious cases," Dr. Mercola recommends instead taking "[n]atural zinc ionophores that improve zinc absorption includ[ing] quercetin and epigallocatechin-gallate (EGCG)." Mercola Group's online store sells quercetin supplements 7 as well as products containing EGCG. TIP #6" on Mercola Group's "Coronavirus Resources Page" is "USE OUERCETIN." OUERCETIN."

Dr. Mercola has continued to seize on the speculation about hydroxychloroquine to market zinc and other related products. For instance, during the April 19, 2020 episode of his podcast, Dr. Mercola endorsed his guest's assertion that zinc can prevent COVID-19:

(16:36)

Dr. Mercola

"[After a discussion of hydroxychloroquine:] The challenge is [hydroxychloroquine is] not going to be available in your local pharmacy . . ." **Dr. Saul**

"Therefore, we should be taking zinc preventively-"

Dr. Mercola

"Right, yes!"

Mercola Group's zinc supplement includes selenium, another substance Dr. Mercola touts as a COVID-19 treatment. Dr. Mercola stated on the March 29, 2020 episode of his podcast: "a little bit of selenium seems to be very, very helpful and you don't need a lot of this, one or 200 micrograms can be useful. There is evidence that some parts of the world where the selenium in the soils is lower, they have more susceptibility to viruses." ⁶⁰

We are not aware of any scientific evidence, let alone properly conducted RCTs, that zinc or selenium prevent or treat COVID-19 infection.

D. Disease Claim: Melatonin Prevents COVID-19 Infection

Dr. Mercola has been touting yet another substance that is sold on Mercola Group's online store as a COVID-19 treatment: melatonin. Dr. Mercola has claimed that "[m]elatonin has been proven to decrease the risks of COVID-19 infection," and on his podcast Dr. Mercola and Dr. Saul endorsed melatonin as a COVID-19 treatment:

(47:08)

Dr. Mercola

"Another strategy [for treating COVID-19] that's been recommended, it's not really a nutrient, it's actually a hormone, I'm wondering if you have any comments on it because it seems to have some benefit for viral infections, specifically SARS, would be melatonin."

Dr. Saul

"Melatonin's a wonderful thing because the safety studies are very encouraging. If you want to hurt yourself, Melatonin will not do the job."

Dr. Mercola

[Chuckles]

Dr. Saul

"A little bit of melatonin can go a long way and the older you get, the less you make. . . . Melatonin is inexpensive, it's non-prescription, and, obviously, something that's that safe deserves a try."

Dr. Mercola

"Yes, I'm glad you're in favor of that too, especially with the perceived benefits of treating these viral infections." 62

Mercola Group offers melatonin supplements, ⁶³ as well as other products that do not contain melatonin but are touted as increasing the production of melatonin in the body, for sale through its online store. ⁶⁴ We are not aware of any scientific evidence, let alone properly conducted RCTs, that melatonin prevents or treats COVID-19 infection.

E. Disease Claims: Various Other Ways to Prevent COVID-19 Infection

1. Licorice

In early April, Dr. Mercola published a blog post titled "Licorice Inhibits Replication of Coronavirus." In the post, Dr. Mercola explains how glycyrrhizin, the active ingredient in licorice root, has a known history of antiviral effects and, therefore, could be a treatment for COVID-19 (as well as herpes, HIV, hepatitis, influenza, encephalitis, pneumonia, syncytial virus, arboviruses, vaccinia virus, and vesicular stomatitis virus). Dr. Mercola backs up this claim by citing glycyrrhizin's effectiveness in combating SARS, a "COVID-19-like virus." Mercola Group sells a Biodynamic Organic Fermented Licorice Powder in its online shop. We are not aware of any scientific evidence, let alone properly conducted RCTs, that licorice prevents or treats COVID-19 infection.

2. Molecular Hydrogen

Similarly, in late April, Dr. Mercola published a blog post, "How Molecular Hydrogen Can Help Your Immune System." The post claims that molecular hydrogen (H₂ gas) "has powerful antioxidant and anti-inflammatory effects, making it potentially useful for COVID-19." The post goes on to explain that prominent doctors and organizations are investigating the usefulness of H₂ in treating COVID-19 and that the "preliminary results are encouraging." At the end of the post, Dr. Mercola discusses the availability and dosing of H₂ products. He argues that, at this time, the most effective way to consume H₂ is via tablets that are dissolved in water—the exact same form of H₂ that is sold on Mercola Group's online shop. We are not aware of any scientific evidence, let alone properly conducted RCTs, that molecular hydrogen prevents or treats COVID-19 infection.

3. Astaxanthin

In early May, Dr. Mercola published a blog post claiming astaxanthin helps calm the immune system's response to COVID-19, reducing the risk of sepsis, organ failure, and death. According to Dr. Mercola, astaxanthin, a derivative of microalgae, protects DNA from damage and mitigates cytokine storms (severe overreactions of the immune system), a condition that can afflict individuals with COVID-19. To Dr. Mercola provides a lengthy list of ways that astaxanthin may help with COVID/SARS symptoms, including reducing the risk of lung injury and inflammation. Mercola Group's online shop sells a number of different astaxanthin products. We are not aware of any scientific evidence, let alone properly conducted RCTs, that astaxanthin prevents or treats COVID-19 infection.

4. N-acetyl Cysteine

In late May, Dr. Mercola published a blog post about how one of his products, N-acetyl Cysteine (NAC), and glutathione can assist in COVID-19 treatment. According to the post, NAC, the product sold by Mercola Group's shop, may be effective at fighting the blood clotting and strokes occurring in many COVID-19 cases as well as reducing the risk of acute respiratory

distress syndrome. Dr. Mercola tries to bolster his argument by citing a number of studies and case reports that echo his endorsement of NAC.

At the end of the post, Dr. Mercola notes that there are no trials currently underway testing the efficacy of NAC with COVID-19 patients, but, quoting his podcast guest, Dr. Roger Seheult, Dr. Mercola says "if we connect the dots, it looks promising." A search of NAC on Mercola Group's website links directly to its branded liver support supplement with 500mg of NAC per serving. We are not aware of any scientific evidence, let alone properly conducted RCTs, that N-acetyl cysteine prevents or treats COVID-19 infection.

5. <u>Prebiotics, Probiotics, and Sporebiotics</u>

"TIP #11" of Mercola Group's "Top Tips to Help Combat Coronavirus" is "TRY PRE-, PRO-AND SPOREBIOTICS." The tip is based on a theory advanced by Dr. Mercola that COVID-19 infections may enable Prevotella bacteria to colonize the lungs causing some of the severe symptoms associated with the virus. As Dr. Mercola writes: "should the inclusion of Prevotella bacteria in COVID-19 turn out to be accurate, prebiotics, probiotics and sporebiotics may be of significant use. A number of studies have shown Bifidobacterium bifidum strain probiotics can help reduce Prevotella." Dr. Mercola has high praise as well for "sporebiotic" Bacillus spores, suggesting they would be *even more effective than antibiotics* at fighting the Prevotella bacteria:

Bacillus spores also create 24 different substances that have strong antimicrobial properties. However, they do not kill indiscriminately like antibiotics do. They specifically suppress pathogens that do make a valuable contribution to the whole.

As COVID-19 continues to take its toll, taking measures to strengthen your immune system would be a wise strategy as a strong immune system is your No. 1 defense against all types of infections, both viral and bacterial, and the nutraceuticals discussed in this article can all aid you in that effort.⁷⁸

Mercola Group's online store offers probiotic and "Spore Restore" cocktails containing Bifidobacterium and Bacillus spores. ⁷⁹ We are not aware of any scientific evidence, let alone properly conducted RCTs, that prebiotics, probiotics, or sporebiotics prevent or treat COVID-19 infection.

6. Saunas

Similarly, Dr. Mercola claims that Mercola Group's signature line of saunas (currently not available for sale due to a "redesign") 80 are also a great way to prevent or treat COVID-19. On the March 29, 2020 episode of his podcast, Dr. Mercola told his listeners: "When you [raise your core body temperature] with a sauna, you're going to preventively treat any lingering infection that's just starting to go around." Dr. Mercola relatedly claims that "COVID-19 is 'highly sensitive' to high temperatures . . . and coronaviruses (as a general group) . . . appear[] to be destroyed by temperatures around 133 degrees F (56 degrees Celsius), which is easily achieved

in a sauna."⁸² We are not aware of any scientific evidence, let alone properly conducted RCTs, that saunas prevent or treat COVID-19 infection.

7. Ozone

In early April, Dr. Mercola devoted an entire episode of his podcast to exploring ozone's effectiveness against COVID-19. 83 On a subsequent episode of his podcast, Dr. Mercola again advanced the claim that ozone can be an effective COVID-19 treatment, stating: "[There are] some even more effective interventions than intravenous vitamin C . . . ozone therapy appears to be more effective than intravenous vitamin C and to me it's tragic that no one's touching that with a 10-foot pole to treat this." Mercola Group's online store sells air purifiers touted as generating ozone. 85 We are not aware of any scientific evidence, let alone properly conducted RCTs, that ozone prevents or treats COVID-19 infection.

8. <u>Elderberry Extract, Spirulina, Beta-glucan, Lipoic Acid, and Sulforaphane</u>

An article on Mercola Group's Coronavirus Resource Guide lists "several nutrients available in supplement form that may be of particular benefit against COVID-19." In addition to the dietary supplements and products already discussed, the article recommends: elderberry extract, present in Mercola Group brand "Organic Fermented Elderberry;" Spirulina, present in several Mercola Group products; beta-glucan, present in Mercola Group brand "Fermented Beta Glucans" and other Mercola Group products; pipoic acid, present in Mercola Group brand "MSM Sulfur Complex;" and sulforaphane, present in Mercola Group brand "Fermented Broccoli Sprouts."

We are not aware of any scientific evidence, let alone properly conducted RCTs, that elderberry extract, spirulina, beta-glucan, or sulforaphane prevent or treat COVID-19 infection. For lipoic acid, we identified one RCT⁹² in which 17 patients were randomized to lipoic acid or placebo. There was no statistically significant difference between lipoic acid and placebo patients with respect to either SOFA Score (an index of organ function) or all-cause mortality. Therefore, we are not aware of any RCTs that substantiate that lipoic acid prevents or treats COVID-19 infection.

III. PRIOR CEASE AND DESISTS HAVE BEEN INSUFFICIENT TO PREVENT THIS FRAUD AND MORE ACTION IS NEEDED

Throughout the years, Dr. Mercola's unsupported and predatory claims repeatedly have subjected Mercola Group to regulatory scrutiny. Federal agencies have brought the following enforcement actions against Mercola Group:

• In February 2005, the FDA issued a warning letter to Dr. Mercola and his company Optimal Wellness Group for marketing and labeling several products, including chlorella and coconut oil, as "intended for use in the cure, mitigation, treatment or prevention of diseases." These statements, according to the FDA, effectively categorized the products as "drugs," in violation of the Federal Food, Drug, and Cosmetic Act; 93

- In September 2006, the FDA issued a warning letter to Dr. Mercola and Optimal Wellness Group for marketing and labeling several products, including different chlorella and coconut oil products, using drug claims in violation of the Federal Food, Drug, and Cosmetic Act;⁹⁴
- In March 2011, the FDA issued a warning letter to Dr. Mercola and Dr. Mercola's Natural Health Center for marketing telethermographic cameras for unapproved medical purposes;⁹⁵
- In April 2016, the FTC filed a complaint against Dr. Mercola, Mercola LLC, and Mercola.com Health Resources, LLC alleging that they had made false and deceptive claims that their indoor tanning systems reduced the risk of skin cancer. ⁹⁶ In a settlement agreement, Mercola Group was banned from selling indoor tanning equipment and forced to issue full refunds to more than 1,300 defrauded customers. ⁹⁷

In addition, in 2005, the Illinois Department of Financial and Professional Regulation opened an investigation into Dr. Mercola under the Medical Practice Act. The investigation was prompted by the Department's belief that articles posted on Mercola Group's website contained false and potentially harmful medical advice. According to the Complaint, Dr. Mercola's posts misled the public and the website offered products with "questionable value." ⁹⁸

Based on these allegations, the Chief of Medical Prosecutions called for an administrative review and for the suspension or revocation of Dr. Mercola's medical licenses. ⁹⁹ It is unclear how the administrative review process was resolved, but it appears that the Department reached a settlement with Dr. Mercola, which included the removal of content from Mercola Group's website and Dr. Mercola's agreement to no longer see patients. ¹⁰⁰ As of June 25, 2020, Dr. Mercola's physician and surgeon licenses are still active in Illinois and Florida. ¹⁰¹

IV. CONCLUSION

Mercola Group's unlawful disease claims that falsely and misleadingly claim to treat, cure, or prevent COVID-19 infections pose a high risk of substantial harm to the public. Accordingly, JCL, CSPI, and PPP urge the FDA to issue a warning letter to the Mercola Group covering all of the products discussed in this letter demanding that Mercola Group immediately cease the sale of such unapproved and unauthorized products for the treatment, cure, or prevention of COVID-19. Because of the agency's numerous prior regulatory enforcement actions against the Mercola Group, we also request that the FDA monitor compliance with such a warning letter, and in the case of non-compliance, bring an enforcement action in district court seeking permanent injunctive relief and civil penalties and authorizing inspectors to seize the misbranded products described in this letter. We also urge the agency to coordinate enforcement activities with other appropriate federal and state law enforcement authorities.

We would be pleased to discuss this or related issues with you at your convenience.

Sincerely,

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¹ JCL is a nonprofit law firm that focuses on combatting social and economic injustice, working nationally to support cases and policy work in the fields of antitrust, consumer law, employment law and civil rights.

² CSPI is an independent, science-based consumer advocacy organization that works to improve the food system and health of consumers. CSPI regularly advocates for greater transparency, disclosure, and safety for food ingredients and dietary supplements, including by pointing out areas ripe for enforcement by federal agencies.

³ PPP organizes law students and new attorneys nationwide to unrig the legal system and build a justice system that values people over profits. We believe that by dismantling the coercive legal tools that enhance corporate power and fighting for a judiciary that is representative of – and thus responsive to – people, not corporations, we can reshape the legal profession.

⁴ Dr. Joseph Mercola, *Nutrition and Natural Strategies Offer Hope Against COVID-19*, Mercola.com (Mar. 29, 2020), https://articles.mercola.com/sites/articles/archive/2020/03/29/andrew-saul-vitamin-c.aspx.

⁵ Mercola.com, *Coronavirus Resource Page* (last visited June 16, 2020), https://www.mercola.com/coronavirus-resources.htm.

⁶ Joseph Mercola and Andrew Saul, *Nutrition and Natural Strategies Offer Hope Against COVID-19 Discussion Between Drs. Andrew Saul and Mercola*, Dr. Joseph Mercola - Take Control of Your Health (Mar. 29, 2020), https://podcasts.apple.com/us/podcast/nutrition-natural-strategies-offer-hope-against-covid/id1286870871?i=1000469858840 [hereinafter "Podcast, Mar. 29, 2020"].

⁷ 21 U.S.C. §§ 351(f)(1)(B), 355(a).

⁸ 21 U.S.C. §§ 331(a), 332(a); 333.

⁹ 21 U.S.C. § 334.

¹⁰ FDA, Small Entity Compliance Guide on Structure/Function Claims (Jan. 9, 2002), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims.

¹¹ Mercola.com, LLC – Registered in Nevada; Mercola Health Resources, LLC – Registered in Nevada; Mercola Consulting Services, LLC – Registered in Illinois; Mercola Health Exports, Inc. – Registered in Florida; Natural Health Management, LLC – Registered in Florida; Natural Health Services, LLC – Registered in Florida; MHR Metals, LLC – Registered in Florida; Mangrove Pines Farm Foundation, Inc. – Registered in Florida; and Natural Health Research Foundation, Inc. – Registered in Florida.

¹² See https://shop.mercola.com/ (last visited June 16, 2020).

¹³ See Health Website Rankings: Mercola.com is World's Most Visited Natural Health Site, Mercola.com, https://www.mercola.com/forms/rankings.htm.

¹⁴ Marketers of Indoor Tanning Systems to Pay Refunds to Consumers, FTC (Apr. 14, 2016), https://www.ftc.gov/news-events/press-releases/2016/04/marketers-indoor-tanning-systems-pay-refunds-consumers.

¹⁵ Neena Satija & Lena H. Sun, *A Major Funder of the Anti-vaccine Movement has Made Millions Selling Natural Health Products*, Wash. Post (Dec. 20, 2019), https://www.washingtonpost.com/investigations/2019/10/15/fdc01078-c29c-11e9-b5e4-54aa56d5b7ce_story.html.

¹⁶ Russell L. Blaylock, MD, CCN, *New Studies Reveal Alarming Hidden Cause of Breast Cancer*, Mercola.com (Mar. 18, 2011), https://articles.mercola.com/sites/articles/archive/2011/03/18/vaccines-increase-cancer-risk.aspx.

¹⁷ Joseph Mercola & Robert Rowan, *Battling COVID-19 With Ozone Therapy: A Special Interview with Dr. Robert Rowen*, Dr. Joseph Mercola - Take Control of Your Health (Apr. 5, 2020), https://podcasts.apple.com/us/podcast/nutrition-natural-strategies-offer-hope-against-covid/id1286870871?i=1000469858840 [hereinafter "Podcast, Apr. 5, 2020"].

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²⁷ Emergency Use Authorization: Emergency Use Authorization (EUA) Information, and List of all Current EUAs, FDA, https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.

²⁸ FDA, Guidance for FDA Staff and Industry: Marketed Unapproved Drugs – Compliance Policy Guide (Sept. 19, 2011), https://www.fda.gov/files/drugs/published/Marketed-Unapproved-Drugs----Compliance-Policy-Guide.pdf.

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³⁴ Paul E. Marik *et al.*, *Hydrocortisone*, *Vitamin C, and Thiamine for the Treatment of Severe Sepsis and Septic Shock: A Retrospective Before – After Study*, 151 CHEST J. 1229 (June 2017), https://journal.chestnet.org/article/S0012-3692(16)62564-3/pdf.

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