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THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH

UNITED STATES OF AMERICA

Plaintiff,

v.

XLEAR, INC., a corporation, and

NATHAN JONES, individually and as an officer of XLEAR, INC.,

Defendants.

Case No. 2:21-cv-00640-RJS

COMPLAINT FOR CIVIL PENALTIES, PERMANENT INJUNCTION, AND OTHER RELIEF

Chief Judge Robert J. Shelby

Plaintiff, the United States of America, acting upon notification and authorization to the Attorney General by the Federal Trade Commission ("FTC") pursuant to Section 16(a)(1) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 56(a)(1), for its Complaint alleges:

NATURE OF THE CASE

1. Defendants Xlear Inc. and Nathan Jones sell a variety of products that contain xylitol, a sugar alcohol, including a line of over-the-counter saline nasal spray products sold under the Xlear Sinus Care brand. These nasal spray products are widely available at national retailers and online, and are labelled as a "Drug-Free" product that can be used to "clean[] sinus and nasal passages," and "wash[] away pollutants."

1. Defendants admit the allegations of Paragraph 1. Defendants further aver that the Government concedes that Xlear is a "saline nasal spray."

2. In response to the Coronavirus Disease 2019 ("COVID-19") pandemic, Defendants began widely advertising their saline nasal spray as a product that is capable of preventing and treating COVID-19. Among other things, Defendants' COVID-19-related advertisements claimed that Xlear nasal spray offers "up to four hours" of protection, and that "[p]eople should be using Xlear as part of a layered defense to prevent getting COVID-19."

2. Defendants admit that Xlear nasal spray was advertised. Defendants admit they have made limited statements supported by competent and reliable scientific evidence about the use of nasal sprays for the prevention and treatment of COVID-19. Defendants deny the remaining allegations of Paragraph 2.

3. Defendants lacked valid factual or scientific bases for these and other COVID-19 claims, and their use of deceptive advertising and misinformation to sell their product to concerned consumers during a pandemic poses a risk to public health and safety.

3. Defendants deny the allegations of Paragraph 3.

4. Despite repeated warnings from the FTC that Defendants' deceptive advertising and misrepresentations violated the FTC Act and the COVID-19 Consumer Protection Act, Defendants continued to make deceptive and misleading statements about the ability of Xlear nasal spray to prevent and treat COVID-19. The United States therefore brings this suit seeking permanent injunctive relief, civil penalties, and other remedies to prevent the harms caused by Defendants.

4. To the extent that Paragraph 4 alludes to a July 29, 2020 Warning Letter from the FTC to Xlear, Defendants admit that, on or about July 29, 2020, Xlear received a letter from the FTC's Division of Advertising Practices regarding statements that it has made about Xlear nasal spray. The letter speaks for itself, and Defendants deny the remaining allegations of Paragraph 4.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because it arises under the laws of the United States. It also has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1337(a) because it arises under an Act of Congress regulating interstate commerce, under 28 U.S.C. § 1345 because the United States is the Plaintiff, and under 28 U.S.C. § 1355 because the United States seeks a civil penalty. At all times relevant to this Complaint, Defendants have maintained a substantial course of trade in or

affecting interstate commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

5. Paragraph 5 contains a statement of jurisdiction to which no response is required. Defendants, however, admit that this Court has jurisdiction over the subject matter at issue.

6. The Court has personal jurisdiction over Defendants because all Defendants reside in this district and because alleged acts giving rise to the claims occurred in this District.

6. Paragraph 6 contains a statement of jurisdiction to which no response is required. Defendants, however, admit that this Court has jurisdiction over the parties.

7. Venue is proper in this District under 28 U.S.C. § 1391(b)(1), (b)(2), and (c)(1), and 15 U.S.C. § 53(b) because Defendants reside in this District and because a substantial part of the events or omissions giving rise to the claims occurred in this District.

7. Paragraph 7 contains a statement of venue to which no response is required.

PARTIES

8. Plaintiff is the United States of America.

8. Paragraph 8 contains the Government's description of its title, to which no response is required. To the extent a response is required, Defendants admit the allegations of Paragraph 8.

9. Defendant Nathan Jones is the founder and CEO of Defendant Xlear, Inc. ("Xlear"). Jones transacts or has transacted business in this District and throughout the United States. At all times relevant to this Complaint, acting alone or in concert with others, he has

formulated, directed, controlled, had the authority to control, or participated in the acts and practices set forth in this Complaint. Jones actively participates in promotions for Xlear through, among other things, videos posted on the company's website and appearances on television and podcasts. He also responded directly to FTC staff's July 29, 2020 warning letter to the company about false or unsubstantiated advertising claims about its nasal spray products.

9. Defendant Jones admits that he is the founder and president of Xlear and is involved in Xlear's business affairs, the formulation of corporate policy and strategic decisions, press releases about the efficacy of Xlear nasal sprays, and responding to the FTC's Warning Letter to Xlear. Defendant Jones further admits that he resides in this District and that, through his role with Xlear, transacts and has transacted business in this District and throughout the United States. Defendant Jones denies the remaining allegations of Paragraph 9.

10. Defendant Xlear, formed by Jones in June 2000, is a Utah corporation with its principal place of business at 723 South Auto Mall Drive, American Fork, Utah 84003. Xlear transacts or has transacted business in this District and throughout the United States. At all times relevant to this Complaint, acting alone or in concert with others, Xlear has advertised, marketed, distributed, or sold Xlear-brand saline nasal spray products to consumers throughout the United States. Xlear's nasal spray products are available for purchase at national retailers including Rite-Aid, CVS, Walgreens, and Target, and online at Amazon.com.

10. Defendant Xlear admits the allegations of Paragraph 10. Defendants admit that Xlear's nasal spray products are available for purchase at national retailers including Rite-Aid, CVS, Walgreens, and Target, and online at Amazon.com. Defendants aver that Xlear has been

sold in the United States for over twenty years, to vast numbers of individuals and families, without a single complaint reporting an adverse effect and without any prior action by the United States against the company.

THE FTC ACT

11. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits "unfair or deceptive acts or practices in or affecting commerce."

11. Paragraph 11 contains a legal conclusion to which no response is required.

12. Misrepresentations or deceptive omissions of material fact are deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

12. Paragraph 12 contains a legal conclusion to which no response is required.

13. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Xlear nasal spray products are "drugs" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

13. Paragraph 13 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny that Xlear nasal spray products are "drugs" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c). Further, Defendants aver that, for twenty-plus years, pursuant to the Food & Drug Administration, Xlear and its components are not classed as drugs.

THE COVID-19 CONSUMER PROTECTION ACT

14. On January 31, 2020, the Secretary of Health and Human Services declared that COVID-19 had caused a public health emergency. As of the date of this filing, this public health emergency declaration remains in effect.

14. Paragraph 14 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 14. Defendants further aver that Paragraph 14 is based on a misconstruction of the facts and a flawed legal analysis.

15. On December 27, 2020, the President signed the COVID-19 Consumer Protection Act into law. For the duration of the ongoing COVID-19 public health emergency, the COVID-19 Consumer Protection Act makes it unlawful for any person, partnership, or corporation to engage in a deceptive act or practice in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a), that is associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19. *See* COVID-19 Consumer Protection Act of the 2021 Consolidated Appropriations Act ("COVID-19 Consumer Protection Act"), Public Law 116-260, 134 Stat 1182, Title XIV, § 1401(b)(1).

15. Paragraph 15 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 15. Defendants further aver that Paragraph 15 is based on a misconstruction of the facts and a flawed legal analysis.

16. A violation of subsection (b)(1) of the COVID-19 Consumer Protection Act is

treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under Section 18(a)(1)(B) of the FTC Act, 15 U.S.C. § 57a(a)(1)(B). *See* COVID-19 Consumer Protection Act, § 1401(c)(1).

16. Paragraph 16 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 16. Defendants further aver that Paragraph 16 is based on a misconstruction of the facts and a flawed legal analysis.

17. A violation of Section (b)(1) of the COVID-19 Consumer Protection Act made with the knowledge required by Section 5(m)(1)(A) of the FTC Act, 15 U.S.C. § 45(m)(1)(A), is subject to monetary civil penalties of up to $43,792 for each violation of the COVID-19 Consumer Protection Act after January 13, 2021, including penalties whose associated violation predated January 13, 2021. *See* 15 U.S.C. § 45(m)(1)(A), as modified by Section 4 of the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, Public Law 114-74, sec. 701, 129 Stat. 599 (2015); *see also* 16 C.F.R. § 1.98(d).

17. Paragraph 17 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 17. Defendants further aver that Paragraph 17 is based on a misconstruction of the facts and a flawed legal analysis.

DEFENDANTS' UNLAWFUL CONDUCT

I. Defendants Deceptively Advertise Xlear Nasal Spray As a Product That Prevents or Treats COVID-19

18. Defendants manufacture and sell a variety of nasal spray products, including

Xlear Saline Nasal Spray with Xylitol. Sold in 1.5 or .75 ounce spray bottles, the product includes unspecified amounts of "Purified Water, Xylitol, Saline, [and] Grapefruit Seed Extract (as a preservative)." The product label instructs users to "[s]pray 2-4 times in each nostril . . . at least twice daily – morning and night," to alleviate congestion, clean sinuses and nasal passages, wash away airborne contaminates, sooth and moisturize nasal passages due to low humidity and other nasal irritants, and to thin and loosen mucous secretions.

18. Defendant Xlear admits the allegations of Paragraph 18. Defendant Xlear further states that Xlear manufactures and sells a high-volume saline irrigation, toothpaste, and mouthwash.

19. Since at least March 2020, Defendants have advertised and promoted Xlear nasal spray for the prevention and treatment of COVID-19. Defendants have used tools like magazine advertorials, YouTube videos, social media posts, and websites like xlear.com to disseminate their claims to consumers nationwide.

19. Defendants admit that Xlear nasal spray is discussed on xlear.com, YouTube, and other social media posts. Defendants admit they have made limited statements supported by competent and reliable scientific evidence about the use of nasal sprays for the prevention and treatment of SARS-CoV-2 (the virus that causes COVID-19). Defendants deny the remaining allegations of Paragraph 19. Moreover, the so-called "magazine advertorials" are not bought and paid for advertorials but are unpaid media interviews.

20. There is no competent and reliable scientific evidence that Xlear nasal spray treats or prevents COVID-19. At present, no published reports of randomized clinical trials establish the use of Xlear nasal spray as effective in preventing or treating COVID-19.

20. Defendants deny that a randomized clinical trial is required to support the statements Xlear made and further aver that competent and reliable scientific evidence supports the statements made regarding Xlear nasal spray and other nasal sprays with respect to the SARSCoV-2 virus. Defendants deny the remaining allegations of Paragraph 20. Moreover, the Defendants aver that in some circumstances involving a novel deadly pathogen (e.g., SARS-CoV2), the specific sorts of trials claimed as being required by the Government in this case may be precluded under the Government's own regulations; prohibited by medical ethics; logistically unfeasible; and/or may yield less conclusive data than other forms of studies. Numerous medical and scientific experts have opined that random controlled clinical trials ("RCTs") are not the best tools in the face of a global pandemic. See, e.g., Adashek, J.J., Kurzrock, R. Balancing clinical evidence in the context of a pandemic. Nat Biotechnol 39, 270–274 (2021). https://doi.org/10.1038/s41587-021-00834-6 (last viewed Dec. 22, 2021) (content attached hereto as Exhibit A pursuant to DUCivR 7-5). Specifically, to the best of the Defendants' knowledge and belief, in 2020, researchers sought FDA permission to run precisely the sort of RCT the Government seeks to require of the Defendants. In June-July 2020, Dr. Gus Ferrer, an international expert on upper respiratory disease and a frontline doctor treating COVID-19 patients, sought FDA permission to run a human clinical trial using Xlear as a treatment for patients already infected with COVID-19. In

August of 2020, the FDA responded and denied permission for the trial. The FDA's stated reason was the Agency does not allow drug action studies to be done on substances classed as cosmetics.

To this end, many of the Government's own actions to combat the pandemic—actions that have altered the lives of an entire nation—have been taken without any RCT data. See Peeples, L., Face Masks What the Data Say, Nature, Oct. 6, 2020, available at https://www.nature.com/articles/d41586-020-02801-8 (last viewed Dec. 22, 2021) (content attached hereto as Exhibit B pursuant to DUCivR 7-5) (Reporting that the CDC mask mandate was not backed by a single RCT study at the time) ("'You can't do randomized trials for everything — and you shouldn't." As clinical researchers are sometimes fond of saying, parachutes have never been tested in a randomized controlled trial, either."); Xiao J, Shiu E, Gao H, Wong JY, Fong MW, Ryu S, et al. Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures. Emerg Infect Dis. 2020;26(5):967975, available at https://doi.org/10.3201/eid2605.190994 (last viewed Dec. 22, 2021) (content attached hereto as Exhibit C pursuant to DUCivR 7-5) ("In our systematic review, we identified 10 RCTs that reported estimates of the effectiveness of face masks in reducing laboratoryconfirmed influenza virus infections in the community . . . In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks.") (As published by the Centers for Disease Control); Hassad, R.,

No RCT for Masks? No Problem; Other forms of evidence are available to judge effectiveness of this and other interventions, MedPageToday, Aug. 3, 2020, available at https://www.medpagetoday.com/infectiousdisease/covid19/87870 (last viewed Dec. 22, 2021) (content attached hereto as Exhibit D pursuant to DUCivR 7-5) ("There has been an almost exclusive focus on evidence from experimental studies, specifically the randomized controlled trial (RCT) . . . as it allows for the determination of causality. However, the reason such evidence is still lacking should be obvious—the RCT is neither feasible nor appropriate for determining the effectiveness of mask-wearing in the community in protecting against COVID-19, and moreover, its use will be considered unethical in the context of a deadly pandemic.").

In fact, experts, including those who have run pandemic response for the U.S. Government, believe that RCT's are no longer the single best source of scientific proof. See e.g., Frieden, T., Why the 'gold standard' of medical research is no longer enough, Aug. 2, 2017, available at https://www.statnews.com/2017/08/02/randomized-controlled-trials-medical-research/ (last viewed Dec. 22, 2021) (content attached hereto as Exhibit E pursuant to DUCivR 7-5) (Dr. Frieden served as Director of the Centers for Disease Control and Prevention (CDC), the Government's lead agency in pandemic prevention and response, from 2009 to 2017). Dr. Frieden's expert view on RCT's:

Despite their strengths, RCTs have substantial limitations. They can be very expensive to run. They can take many years to complete, and even then may not last long enough to assess the long-term effect of an intervention such as vaccine immunity, or to detect rare or long-term adverse effects. Findings from RCTs may not be valid beyond

the study population — a trial that included a high-risk population in order to maximize the possibility of detecting an effect, for example, may not be relevant to a low-risk population. RCTs may not be practical for population-wide interventions and often aren't relevant for urgent health issues such as infectious disease outbreaks, for which public health decisions must be made quickly.

. . . .

Glorifying RCTs above other approaches, even when these other approaches may be either superior or the only practical way to get an answer, relegates patients to receiving treatments that aren't based on the best available evidence.

An approach that uses all appropriate evidence types and builds on the existing evidence base using proven best practices is the one most likely to result in clinical and public health action that will save lives.

Id. (emphasis added); see also Frieden T.R. Evidence for health decision making — beyond

randomized, controlled trials. N Engl J Med. 2017;377(5):465–75. https://doi.org/10.1056/NEJMra1614394.

Further, inter alia, the Defendants aver that the available, relevant RCTs support the statements made by Xlear. The Government's complaint states that Xlear is "a saline

nasal spray." Multiple clinical trials, including at least two that the Government specifically knows of, have shown that saline nasal cleansing shows benefits in reducing the duration and severity of the illness in individuals with moderate to high risk, who are already sick with COVID-19.

- A peer-reviewed, published Randomized Clinical Trial (RCT) conducted at Vanderbilt University in 2020, found that the use of nasal sprays significantly reduced the severity and duration of symptoms among non-hospitalized COVID-19 patients (the Vanderbilt University Study): "The effect of nasal irrigation on symptom resolution was substantial, with nasal congestion and headache resolving a median of 7 to 9 days earlier in the intervention groups. Our analysis suggests that nasal irrigations may shorten symptom duration and may have potential as a widely available and inexpensive intervention to reduce disease burden among those affected.

In the interim, we would advocate the use of hypertonic nasal saline irrigations in nonhospitalized COVID-19 patients as a safe and inexpensive intervention to reduce symptom burden." Kimura, K., et al., Interim analysis of an open-label randomized controlled trial evaluating nasal irrigations in nonhospitalized patients with coronavirus disease 2019. Int Forum Allergy Rhinol. 2020; 10: 1325– 1328, available at https://pubmed.ncbi.nlm.nih.gov/32914928/ (last viewed Dec. 22, 2021) (content attached hereto as Exhibit F pursuant to DUCivR 7-5). The Vanderbilt University RCT was funded by the Government's own National Institutes of Health (NIH) and is republished as authority on the NIH's own website. Defendants have specifically made the FTC aware of the findings of this RCT.

- A more recent RCT study, conducted at Augusta University in Georgia, found that nasal irrigation significantly reduces the risk of hospitalization among COVID-19 infected people: "The total risk of hospitalization or death (10.6%) was 8.4 times that of enrolled patients (SE=2.74; P=.006) . . . . There were no significant differences by additive." Amy Baxter, et al., Rapid initiation of nasal saline irrigation to reduce morbidity and mortality in COVID+ outpatients: a randomized clinical trial compared

to a national dataset, medRxiv 2021.08.16.21262044, doi:https://doi.org/10.1101/2021.08.16.21262044 available at

https://www.medrxiv.org/content/10.1101/2021.08.16.21262044v2 (last viewed Dec. 22, 2021) (content attached hereto as Exhibit G pursuant to DUCivR 7-5). It should be stressed that a reduction of 8.4 times (not percent) is a vastly greater impact than a host of other measures now being used to combat the pandemic with the Government's full approval.

- A third clinical trial case study, peer-reviewed, and published, that studied the efficacy of Xlear nasal spray specifically found (a clinical trial in humans already infected with

COVID-19) that Xlear spray significantly reduced the severity and duration of the illness in COVID-19 patients—all with co-morbidities (the Larkin Hospital Study). The Larkin Hospital Study found Xlear nasal spray showed "remarkable results" in helping treat COVID-19 patients. The Larkin Hospital Study "noted improvement of symptoms as early as day 4. Furthermore, on day 7, patients tested negative on repeat RT-PCR

nasopharyngeal swab instead of the average 14-day period of negativization of COVID-19. By using xylitol plus GSE in the form of an intranasal spray (Xlear nasal spray), as an adjunct to the ongoing treatment, the time to negativization was reduced by 50%." The Larkin Hospital Study noted no complications or adverse effects. Go et al., Intranasal Therapy and COVID-19: A Comprehensive Literature

Review, J Allergy Infect Dis, 2021; 2(1):9-16, citing Go et al., Potential Role of Xylitol Plus Grapefruit Seed Extract Nasal Spray Solution in COVID-19: Case Series, Cureus, 2020 Nov; 12(11): e11315, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7645297/ (last viewed Dec. 22, 2021) (content attached hereto as Exhibit H pursuant to DUCivR 7-5). The Larkin Hospital Study is republished as authority on the Government's (NIH's) website. In order to comply with ethics and Food & Drug Administration rules, the Larkin Hospital Trial Study presents a series of case studies, not a larger-scale trial. As such, the reported results discuss only three of the patients in the Study. Nevertheless, the Larkin Study is a peer-reviewed, published RCT.

- A fourth clinical trial found nasal washing is effective in reducing viral load in the nose. (Multiple experts, including the Government's own Dr. Fauci, have linked viral load in the nose with COVID-19 infection and transmission). Hendley JO, Gwaltney JM, Viral titers in nasal lining fluid compared to viral titers in nasal washes during experimental rhinovirus infection, J Clin Virol. 2004;30(4):326–328, available at https://pubmed.ncbi.nlm.nih.gov/15163422/. This trial looked at viral load of rhinovirus.

Rhinovirus, like SARS-CoV-2, is an upper respiratory viral illness that most commonly starts in the nose. These two diseases are so closely associated that another clinical trial has found that the prevalence of rhinovirus in the nose is a strong indicator that an intervention is effective against COVID-19. Kitanovski, S., Horemheb-Rubio, G., Adams, O. et al. Rhinovirus prevalence as indicator for efficacy of measures against SARS-CoV-2. BMC Public Health 21, 1178 (2021). https://doi.org/10.1186/s12889-021-11178-w, available at https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-11178-w (last viewed Dec. 22, 2021) (content attached hereto as Exhibit I pursuant to DUCivR 7-5).

21. Despite this lack of evidence, Defendants have made numerous claims that explicitly or implicitly state that daily use of Xlear nasal spray is effective in treating or preventing COVID-19. For example, Defendants have claimed that:

a. Xlear nasal spray prevents COVID-19: "Social distancing and wearing masks offers *some* help, but Xlear nasal spray provides additional tested protection for up to four hours, helping keep you and others around you safe." (Exhibit "A" at 0:49-0:58).

b. Xlear nasal spray treats COVID-19: "Nasal sprays, like Xlear help subdue the viral load as a simple treatment." (Exhibit "B").

c. "With the pandemic raging worldwide, we must use every tool we can to fight it ..... Weighing our 20-year safety record, against the risks of this deadly virus, it's clear Xlear needs to be in widespread use." (Exhibit "C").

d. Xlear nasal spray prevents or treats COVID-19: "Great post talking about how Xlear can help block infection or lessen the severity of symptoms!" (Exhibit "D").

e. "People should be using Xlear as part of a layered defense to prevent getting COVID-19. If everyone used Xlear, in addition to taking other steps recommended by public health officials, we believe we could help the nation defeat COVID-19 faster." (Exhibit "E").

21. Defendants admit that Xlear made certain statements, including those set forth in Paragraph 20. Defendants further aver that the statements are supported by competent and reliable scientific evidence. Specifically, a number of independent, published in vitro studies have found that Xlear specifically is virucidal against SARS-CoV2 (it kills and/or deactivates the COVID-19 virus), and antiviral against SARS-CoV-2 (it blocks the COVID-19 virus from adhering to and infecting tissue). These studies include the following:

- Ferrer, Gustavo, et al, A Nasal Spray Solution of Grapefruit Seed Extract plus Xylitol Displays Virucidal Activity Against SARS-Cov-2 In Vitro, BioRxiv (Nov. 25, 2020), available at https://www.biorxiv.org/content/10.1101/2020.11.23.394114v1.full (last viewed Dec. 22, 2021) (content attached hereto as Exhibit J pursuant to DUCivR 7-5);
- Cannon, Mark, et al, In Vitro Analysis of the Anti-viral Potential of nasal spray constituents against SARS-CoV-2, bioRxiv 2020.12.02.408575, available at https://www.biorxiv.org/content/10.1101/2020.12.02.408575v2.full.pdf+html (last viewed Dec. 22, 2021) (content attached hereto as Exhibit K pursuant to DUCivR 7-5);
- Institute for Antiviral Research, Utah State University, Study Report; Antiviral Efficacy

Against Virus Infections in Human-Derived Tracheal/Bronchial Epithelial Cells, Dec. 1, 2021. This new in vitro study tested the antiviral efficacy of each of the compounds in Xlear (namely grapefruit seed extract (GSE) and xylitol) against three viruses, most importantly the Delta strain of SARS-CoV-2 (B.1.617.2). Most notably this study found both xylitol and GSE had significant antiviral efficacy against the Delta strain. In fact, both of these compounds, which are Xlear ingredients, had greater antiviral efficacy than did Remdesivir, which the FDA has approved as a treatment for COVID-19—to great fanfare. See FDA, FDA News Release; FDA Approves First Treatment for COVID-19, Oct. 22, 2020, available at https://www.fda.gov/news-events/pressannouncements/fda-approves-first-treatment-covid-19 (last viewed Dec. 22, 2021) (content attached hereto as Exhibit L pursuant to DUCivR 7-5). Further, this study used the human tissue found in the nasal passages, where the vast majority of COVID-19 infections begin.

Further numerous other studies and published expert medical reviews have called for the use of nasal cleansing and nasal hygiene, generally, to combat COVID-19 infections. Collectively, these studies, a non-exhaustive list included below, are compelling and reliable scientific evidence substantiating Xlear's statements:

- Lipworth B, Chan R, RuiWen Kuo C. COVID-19: Start with the nose. J Allergy Clin Immunol. 2020;146(5):1214. doi:10.1016/j.jaci.2020.06.038;
- Spinelli, M. et al., Importance of non-pharmaceutical interventions in lowering the viral inoculum to reduce susceptibility to infection by SARS-CoV-2 and potentially disease severity, The Lancet, Feb. 22, 2020, available at https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30982-8/fulltext (last viewed

Dec. 22, 2021) (content attached hereto as Exhibit M pursuant to DUCivR 7-5).

- Cegolon L, Javanbakht M, Mastrangelo G. Nasal disinfection for the prevention and control of COVID-19: A scoping review on potential chemo-preventive agents [published online ahead of print, 2020 Aug 18]. Int J Hyg Environ Health. 2020;230:113605. doi:10.1016/j.ijheh.2020.113605.

- Ferrer, G, Sanchez-Gonzalez, M., Effective Nasal Disinfection as an Overlooked Strategy in Our Fight against COVID-19, Ear Nose Throat J., 2021 Mar 26;1455613211002929, doi: 10.1177/01455613211002929, available at https://pubmed.ncbi.nlm.nih.gov/33765853/ (last viewed Dec. 22, 2021) (content attached hereto as Exhibit N pursuant to DUCivR 7-5).

Defendants aver that the entire body of scientific evidence here meets and exceeds the competent and reliable scientific evidence standard. See Fed. Trade Comm'n v. QT, Inc., 512 F.3d 858, 861 (7th Cir. 2008) ("Nothing in the Federal Trade Commission Act…requires placebocontrolled, double-blind studies…. The burden is on the Commission to prove that the statements are false…. Placebo-controlled, double-blind testing is not a legal requirement for consumer products."); United States v. Bayer Corp., No. CV 07-01(JLL), 2015 WL 5822595, at *3–4 (D.N.J. Sept. 24, 2015) (citing FTC Guidance) ("The court should look to 'the totality of the evidence' because 'the surrounding body of evidence will have a significant impact both on what type, amount and quality of evidence is required to substantiate a claim and on how that claim is presented.'").

Moreover, Defendants contend that Exhibit D to the Government's Complaint has been selectively edited as to mislead the Court. The full version of this post, attached hereto as Exhibit B, includes a prominent disclaimer that Xlear is not intended to treat anything. And, Defendants aver that this post has long since been removed.

22. Defendants lack any competent and reliable scientific evidence to support the foregoing claims and other similar statements they have disseminated or caused to be disseminated regarding Xlear nasal spray's use in treating or preventing COVID-19.

22. Defendants deny that there is no competent and reliable scientific evidence to support Xlear's claims, and further aver that competent and reliable scientific evidence supports the statements made regarding Xlear nasal spray and other nasal sprays with respect to the SARS-CoV-2 virus. Defendants deny the remaining allegations of Paragraph 22.

II. Defendants Deceptively Imply That Scientific Research Supports Their Claims

23. Defendants have made or caused to be made numerous deceptive statements regarding the results of scientific studies to claim that Xlear nasal spray is effective in treating or preventing COVID-19.

23. Defendants deny the allegations of Paragraph 23.

24. To give the impression that there is evidence to support their claims about Xlear nasal spray when no such competent, reliable scientific evidence exists, Defendants created an "Education" page on their website to promote the "Science Behind Xlear." There, as well as on social media and in other advertisements, Defendants repeatedly mischaracterize existing studies and/or ignore their conclusions or limitations. For example, Defendants stated that:

a. "New Studies Conclude Xlear Kills and/or Deactivates SARS-CoV-2. . . . Xlear's components are antiviral—they block viral adhesion in the nose. See, for example , . . . [t]his Univ. of Tennessee study[.]" Ex. C.

b. "[M]any researchers are looking for a good vaccine or treatment to use

> for COVID-19. . . . [T]here are options that are inexpensive and also effective against Sars-CoV-2. This article reviews three studies that support the idea of using a simple nasal spray like Xlear with xylitol to combat illness..... This [UNC Chapel Hill] study shows that administering treatment through the nose is the best way to treat COVID-19, especially in its early stages." (Exhibit "F").

24. Defendants admit that an "Education" page on Xlear's website discusses various studies. Defendants admit they have made limited statements supported by competent and reliable scientific evidence about the use of nasal sprays for the prevention and treatment of COVID-19. Defendants deny the remaining allegations of Paragraph 24. Defendants admit that the study conducted at the University of Tennessee and referenced by Xlear says that "New Studies Conclude Xlear Kills and/or Deactivates SARS-CoV-2. . . .. Xlear's components are antiviral—they block viral adhesion in the nose. See, for example, . . . [t]his Univ. of Tennessee study[.]" Defendants admit that the study conducted at the University of North Carolina at Chapel Hill and referenced by Xlear says that "[M]any researchers are looking for a good vaccine or treatment to use for COVID-19. [T]here are options that are inexpensive and also effective against Sars-CoV2. This article reviews three studies that support the idea of using a simple nasal spray like Xlear with xylitol to combat illness…This [UNC Chapel Hill] study shows that administering treatment through the nose is the best way to treat COVID-19, especially in its early stages." Moreover, the magazine statements are not bought and paid for advertorials but are unpaid media interviews.

25. In reality, the cited studies do not support Defendants' claims about Xlear nasal spray.

25. Defendants deny that its cited studies do not support Xlear's claims and further aver, as set out above, that competent and reliable scientific evidence supports the statements made regarding Xlear nasal spray and other nasal sprays with respect to the SARS-CoV-2 virus.

26. The study conducted at the University of Tennessee and referenced in Defendants' advertising did not conclude that Xlear's components are antiviral because they block viral adhesion in the nose. That study involved *in vitro* testing—*i.e.,* testing done in a test tube, not on people—and it examined the effects of iota-carrageenan and xylitol on monkey kidney cell cultures infected with SARS-CoV-2. Xlear's nasal spray products, however, do not contain iota-carrageenan, and the Xlear formulation was not used in the study. Additionally, because the experiment was not a human clinical trial, it did not show what effect, if any, Xlear nasal spray has on SARS-CoV-2 inside the human nose. As the study notes, "clinical trials would be needed to fully confirm these hypotheses" regarding the potential use of iota-carrageenan and xylitol.[1]

26. Defendants admit that the in vitro study conducted at the University of Tennessee and referenced by Xlear tested the combined effects of two ingredients, iota-carrageenan and xylitol, on monkey kidney cell cultures infected with SARS-CoV-2. Defendants admit that Xlear nasal spray does not contain iota-carrageenan and further aver that the omission of iotacarrageenan is immaterial to the relevance of this study. Specifically, the Government conveniently fails to inform this Court that the trial specifically addressed the

efficacy of xylitol independent of any other compound: The other remarkably interesting result is that xylitol exhibits antiviral activity on SARS-CoV-2 based on the results obtained with sample P3. Xylitol has been demonstrated to reduce titers of Human Respiratory Syncytial Virus in Hep-2 cells culture and in infected mice [references omitted].

Bansal S, Jonsson CB, Taylor SL, Figueroa JM, Dugour AV, Palacios C, Vega JC. Iotacarrageenan and xylitol inhibit SARS-CoV-2 in Vero cell culture. PLoS One. 2021 Nov 19;16(11):e0259943. doi: 10.1371/journal.pone.0259943, available at: https://pubmed.ncbi.nlm.nih.gov/34797868/ (last viewed Dec. 22, 2021) (content attached hereto as Exhibit O pursuant to DUCivR 7-5). (Xlear contains xylitol above the concentration used in this Study.). Defendants further aver that the use of in vitro kidney cells is industry standard. As a result, the Utah study and several other studies use these kidney cells. Defendants deny the remaining allegations of Paragraph 26.

27. The study conducted at the University of North Carolina at Chapel Hill and referenced in Defendants' advertising did not find that "administering treatment through the nose is the best way to treat COVID-19." Ex. F. Rather, the authors "speculate that nasal surfaces *might* be the dominant initial site for SARS-CoV-2 respiratory tract infection," and, therefore, further speculate that widespread use of masks and "complimentary therapeutic strategies that reduce viral titer [concentration] in the nose early in the disease, e.g., nasal lavages, topical antivirals, or immune modulation, *might* be beneficial."[2] This preclinical study "should provide

[1] Bansal et al., *Iota-carrageenan and Xylitol Inhibit SARS-CoV-2 in Cell Culture* (pre-print) (Aug. 21, 2020).
[2] Hou, et al., *SARS-CoV-2 Reverse Genetics Reveals a Variable Infection Gradient in the Respiratory Tract*, 182 Cell 429, 442 (July 23, 2020) (emphasis added).

valuable reference data for future animal model development," but does not and cannot identify the best way to treat COVID-19 in humans. *Id.*

27. Defendants admit that the study conducted at the University of North Carolina at Chapel Hill and referenced by Xlear says that nasal surfaces might be the dominant initial site for SARS-CoV-2 respiratory tract infection and, therefore, "complementary therapeutic strategies that reduce viral titer in the nose early in the disease, e.g., nasal lavages, topical antivirals, or immune modulation, might be beneficial." Defendants deny the remaining allegations of Paragraph 27.

28. Additionally, Defendants have posted a video directing consumers who want to learn more about the science of Xlear to the website dontgetsickclub.com, which then links directly to commonsensemedicine.org/information-you-should-know-about-covid-19/. The commonsensemedicine.org website is purportedly run by Dr. Lon Jones, Defendant Jones's father who invented and patented Xlear and serves on Xlear's advisory board.

28. Defendants admit that Xlear nasal spray is discussed on the websites xlear.com, dontgetsickclub.com, and commonsensemedicine.org. Dontgetsickclub.com was created by Xlear, has no marketing information, and is not a sales website. Rather, this website provides links to scientific studies, which was done in response to discussions with the FTC. Defendants deny the remaining allegations of Paragraph 28.

29. Commonsensemedicine.org promotes the use of Xlear to prevent and treat COVID-19, stating that "[w]ith 90% of viral load in the nose, *people should treat the illness in its early stages with a nasal spray like Xlear to help defend against the virus and regain their*

health faster. Treatment through the nose isn't a novel or unproven method. Here are a few studies, articles, and links that will help you understand the most common-sense way to treat COVID-19." (Exhibit "G").

29. Defendants deny that Xlear made certain statements on Commonsensemedicine.org. Commonsensemedicine.org is owned by a nonprofit run by Dr. Lon Jones, a physician who invented the Xlear formula and is an occasional advisor to Xlear. Defendants have no ownership or control over Commonsensemedicine.org. As such, statements on Commonsensemedicine.org are not made by Defendants nor attributable to Defendants. Defendants deny that Dr. Lon Jones is an owner or director of Xlear.

30. None of the studies cited thereafter by Dr. Jones supports the claim that Xlear is a proven method to defend against and treat COVID-19 in humans. Among other deceptive statements, Dr. Jones repeats Defendants' mischaracterization of the University of North Carolina Chapel Hill verbatim, claiming that the "study shows that administering treatment through the nose is the best way to treat COVID-19, especially in its early stages." *Id.*

30. Defendants deny that its cited studies do not support Xlear's claims. Defendants further aver that competent and reliable scientific evidence supports the statements made regarding Xlear nasal spray and other nasal sprays with respect to the SARS-CoV-2 virus. Defendants admit that Xlear has made statements based on competent and reliable scientific evidence that: "study shows that administering treatment through the nose is the best way to treat COVID-19, especially in its early stages." Defendants deny the remaining allegations of Paragraph 30.

III. Defendants' Deceptive Marketing Has Misled Reasonable Consumers

31. As of the time of filing, a single 1.5 ounce bottle of Xlear's saline nasal spray costs $13.79 at CVS.com. In 2016, Xlear's nasal spray products alone generated $1.5 million in sales. Upon information and belief, Defendants have earned a substantial amount of money from sales of its nasal spray products during the pandemic.

31. Defendants deny the allegations of Paragraph 31. Contrary to the Government's unsupported assertion that Xlear and Mr. Jones have made money from the statements cited as problematic by the Government, domestic sales of Xlear's nasal spray dropped, not increased, since the onset of COVID-19, during the period of time during which the Government alleges Xlear's violations.

32. Numerous posts on Defendants' own Facebook page and online product reviews show that consumers have been purchasing Defendants' nasal spray products with the belief that it prevents or treats COVID-19. For example:

a. V.C.: "I believe in your product and the extra protection it provides me against covid".

b. M.W.S.: "I personally had a bad case of COVID ..... I was going to treat with Ivermectin and HCQ, but then saw the studies and results on the Xlear. Knowing it was affordable, accessible and safe, I bought some. I can tell you this, with in [sic] 24 hours I started to feel so much better[.]"

c. Sept. 18, 2021 Amazon review: "Fraud claims of killing Covid - I bought after reading this nasal spray would kill 'noticeable' amounts of covid 19. All a scam. Fraud item."

d. Sept. 14, 2021 Amazon review: "Not for me - I ordered this spray when I had covid. They didn't help, made my nose more runny."

32. Defendants deny the allegations of Paragraph 32. To the extent a response is required, Defendants state that the alleged quotes speak for themselves. Defendants note that Xlear's Facebook page has a disclaimer on the front page. Defendants state that Xlear has no control over third-party reviews posted on the website of an independent, third-party retailer's website. Moreover, contrary to the Government's contention, none of the third-party reviews discuss or describe any statements made by Xlear. For example, example "32.b" clearly recounts the reviewer's own personal experience: "I personally had a bad case of COVID . . . then saw the studies and results on Xlear. Knowing it was affordable, accessible and safe, I bought some. I can tell you this, with in [sic] 24 hours I started to feel so much better." The scientific studies regarding Xlear and COVID-19 are independently done and published in journals. It is counter-intuitive for the Government to use this person's experience—using Xlear to feel better while sick with COVID-19—to allege consumer injury.

33. Defendants' misrepresentations and deceptive statements about Xlear nasal spray's ability to prevent or treat COVID-19 are material because, as indicated by the sample comments above, consumers believe Defendants' unsubstantiated claims and appear to have based purchasing and treatment decisions on those claims.

33. Paragraph 33 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 33. Defendants admit that Xlear has made statements based on competent and reliable

scientific evidence.

IV. Defendants Refuse to Cease Deceptive Advertising Despite Notice from FTC

34. On July 29, 2020, staff of the FTC's Division of Advertising Practices advised Defendant Xlear that its xlear.com website, Facebook page, and YouTube channel were unlawfully advertising that Xlear nasal spray products treat or prevent COVID-19, including by claiming without competent and reliable scientific evidence that Xlear nasal spray products are, "a simple, safe, and cheap option that could be an effective solution to the pandemic." (Exhibit "H").

34. Defendants admit that, on or about July 29, 2020, Xlear received a letter from the FTC's Division of Advertising Practices regarding statements that it has made about Xlear nasal spray. The letter speaks for itself, but Defendants admit that the letter contains the language excerpted in Paragraph 34. Defendants deny the remaining allegations in Paragraph 34.

35. Defendants and their counsel responded to the July 29, 2020 warning letter and subsequent FTC staff communications and promised to revise or remove the unlawful claims. Xlear's website and social media pages and Defendant Jones, however, continued to make false or unsubstantiated claims about Xlear nasal spray's purported ability to prevent or treat COVID-19. Over the course of several months and in response to numerous warnings from FTC staff, Defendants engaged in a pattern of modifying or removing the unlawful claims, only to reinstate them or add additional deceptive statements later. Defendants have since removed some but not all of their unsubstantiated and deceptive statements, and have added disclaimers to

the bottom of their website.

35. Defendants admit that Xlear responded to the July 29, 2020 FTC letter and subsequent FTC staff communications and admit Xlear removed statements that the FTC alleged were unsupported. Defendants' efforts to appease the Government were based solely on Defendants' desire to avoid costly and protracted litigation. Defendants deny the remaining allegations of Paragraph 35.

36. In early March 2021, FTC staff advised Defendants' counsel during a teleconference that the COVID-19 Consumer Protection Act imposes civil liability for making false or unsubstantiated claims about products preventing or treating COVID-19.

36. Defendants admit that counsel spoke with the FTC staff in early March 2021. Paragraph 36 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the remaining allegations of Paragraph 36.

37. Based on the facts and violations of law alleged in this Complaint, the United States has reason to believe that Defendants are violating or are about to violate the FTC Act and the COVID-19 Consumer Protection Act.

37. Paragraph 37 contains a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 37. Defendants further aver that these allegations are stale and relate to conduct more than a year and a half ago.

COUNT ONE

FTC Act Section 5(a) and Section 12 Violations

38. Paragraphs 1 through 37 are incorporated as if set forth herein.

38. Defendants incorporate their responses to paragraphs 1-37 as if fully set forth herein.

39. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Xlear nasal spray products, including through the means described in Paragraphs 18-30 of this Complaint, Defendants have represented, directly or indirectly, expressly or by implication, that Xlear nasal spray products are effective in treating or preventing COVID-19, and that the results of scientific studies show that Xlear is effective in treating or preventing COVID-19 in humans.

39. Defendants admit that Xlear has made statements based on competent and reliable scientific evidence that the use of Xlear nasal spray products are effective in treating or preventing COVID-19, and that the results of scientific studies show that Xlear is effective in treating or preventing COVID-19 in humans. Defendants deny the remaining allegations of Paragraph 39.

40. Defendants' representations are false or misleading, or were not substantiated at the time the representations were made.

40. Defendants deny the allegations of Paragraph 40.

41. Defendants' representations are material to consumers' decisions.

41. Defendants deny the allegations of Paragraph 41

42. Upon information and belief, Defendants continue to make similar misrepresentations regarding the efficacy of Xlear nasal spray and/or its ingredients for treating or preventing COVID-19.

42. Defendants deny the allegations of Paragraph 42.

43. Defendants' false, misleading, or unsubstantiated representations are deceptive acts or practices and false advertisements that violate Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

43. Defendants deny the allegations of Paragraph 43.

COUNT TWO

COVID-19 Consumer Protection Act Violations

44. Paragraphs 1 through 43 are incorporated as if set forth herein.

44. Defendants incorporate their responses to paragraphs 1-43 as if fully set forth herein.

45. In numerous instances since December 27, 2020, Defendants have made false, misleading, or unsubstantiated representations that Xlear nasal spray products are effective for the treatment or prevention of COVID-19.

45. Defendants admit that Xlear has made statements based on competent and reliable scientific evidence that the use of Xlear nasal spray products are effective in treating or preventing COVID-19, and that the results of scientific studies show that Xlear is effective in treating or preventing COVID-19 in humans. Defendants deny the remaining allegations of Paragraph 45.

46. In support of their advertising, marketing, promotion, offering for sale, or sale of Xlear nasal spray products, Defendants have represented, directly or indirectly, expressly or by implication, that there is a causal connection between Xlear nasal spray and the treatment or prevention of COVID-19, including claims that:

e. Use of Xlear nasal spray is proven to provide four hours of protection against infection with the SARS-CoV-2 virus. Ex. A.

f. Xlear can prevent deaths from COVID-19: "With the pandemic raging worldwide, we must use every tool we can to fight it. Failing that needlessly risks millions of lives. Weighing our 20-year safety record,

against the risks of this deadly virus, it's clear Xlear needs to be in widespread use." Ex. C.

g. Xlear should be used to prevent COVID-19: "People should be using Xlear as part of a layered defense to prevent getting COVID-19. If everyone used Xlear, in addition to taking other steps recommended by public health officials, we believe we could help the nation defeat COVID-19 faster." Ex. E.

46. Defendants admit that Xlear has made statements based on competent and reliable scientific evidence that:

a. The use of Xlear nasal spray is proven to provide four hours of protection against infection with the SARS-CoV-2 virus.

b. "With the pandemic raging worldwide, we must use every tool we can to fight it. Failing that needlessly risks millions of lives. Weighing our 20-year safety record, against the risks of this deadly virus, it's clear Xlear needs to be in widespread use."

c. "People should be using Xlear as part of a layered defense to prevent getting COVID-19. If everyone used Xlear, in addition to taking other steps recommended by public health officials, we believe we could help the nation defeat COVID-19 faster."

Defendants deny the remaining allegations of Paragraph 46.

47. Defendants' representations are false or misleading, or were not substantiated at the time the representations were made.

47. Defendants deny the allegations of Paragraph 47.

48. Defendants' representations are material to consumers' decisions.

48. Defendants deny the allegations of Paragraph 48.

49. Defendants have been aware of the COVID-19 Consumer Protection Act since March 2021 at the latest.

49. Defendants deny the allegations of Paragraph 49.

50. Upon information and belief, Defendants continue to make similar misrepresentations regarding the efficacy of Xlear nasal spray for treating or preventing COVID-19.

50. Defendants deny the allegations of Paragraph 50.

51. These ongoing false, misleading, or unsubstantiated representations constitute deceptive acts or practices in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

51. Defendants deny the allegations of Paragraph 51.

52. Therefore, these representations also constitute deceptive acts or practices in violation of Section 1401(b)(1) of the COVID-19 Consumer Protection Act.

52. Defendants deny the allegations of Paragraph 52.

53. Each dissemination of an advertisement that makes deceptive COVID-19-related representations is a separate violation of the COVID-19 Consumer Protection Act subject to civil penalties.

53. Defendants deny the allegations of Paragraph 53.

CONSUMER INJURY

54. Consumers are suffering, have suffered, and likely will continue to

suffer substantial injury as a result of Defendants' violations of the FTC Act and the COVID-19 Consumer Protection Act. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers and harm the public interest.

54. Defendants deny the allegations of Paragraph 54.

PRAYER FOR RELIEF

55. Wherefore, Plaintiff, pursuant to Sections 5(a)(1), 5(m)(1)(A), 13(b), and 19 of the FTC Act, 15 U.S.C. §§ 45(a)(1), 45(m)(1)(A), 53(b), and 57b, Section 1401(c)(2)(A) of the COVID-19 Consumer Protection Act, and the Court's own equitable powers, requests that the Court:

A. Enter a permanent injunction to prevent future violations of the FTC Act and the COVID-19 Consumer Protection Act by the Defendants;

B. Award such relief pursuant to Section 19 of the FTC Act as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of Section 5 pursuant to the COVID-19 Consumer Protection Act, including rescission or reformation of contracts, the refund of money or return of property, the payment of damages, and public notification respecting the unfair or deceptive act or practice;

C. Award Plaintiff monetary civil penalties from Defendants for every violation of the COVID-19 Consumer Protection Act alleged in this Complaint; and

D. Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

55. To the extent there are any remaining factual allegations that have not been expressly denied, those allegations are denied. Moreover, as set out more fully below, Defendants aver that the greater harm to consumers—in fact the American public generally—comes from the Government's refusal to adopt scientifically-substantiated countermeasures to COVID-19, and the Government's efforts to silence those who seek to educate the public about these countermeasures, of which this lawsuit is part and parcel.

Dated: October 28, 2021

FOR THE UNITED STATES OF AMERICA:

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INDEX OF EXHIBITS

Exhibit A: Xlear.com video (*Transformational Hygiene with Xlear Nasal Spray*, WWW.XLEAR.COM (captured Feb. 3, 2021))

Exhibit B: Apr. 14, 2020 Xlear Facebook post (Xlear, FACEBOOK (captured Aug. 21, 2020), facebook.com/pg/xylitolexperts/posts/?ref=page_internal))

Exhibit C: Press release posted on Xlear.com/media/ (*New Studies Conclude Xlear Kills and/or Deactivates SARS-CoV-2*, BUSINESS WIRE (last visited Oct. 15, 2021), businesswire.com/news/home/20201130005291/en/New-Studies-Conclude-Xlear-Kills-andor-Deactivates-SARS-CoV-2)

Exhibit D: Xlear Facebook post (Xlear, FACEBOOK (last visited Oct. 15, 2021), facebook.com/xylitol.experts/)

Exhibit E: Xlear press release (*Xlear Submits COVID-19 Pre-Emergency Use Authorization Request with FDA Regarding Use of Xlear Nasal Spray in Help in Combating SARS-CoV-2*, BUSINESS WIRE (March 24, 2021), businesswire.com/news/home/20210324005241/en/Xlear-Submits-COVID-19-Pre-Emergency-Use-Authorization-Request-with-FDA-Regarding-Use-of-Xlear-Nasal-Spray-in-Help-in-Combating-SARS-CoV-2)

Exhibit F: Xlear magazine advertorial (*Studies Show the Importance of Nasal Sprays Like Xlear During This Time*, VITAMIN RETAILER, Nov. 2020, at 59)

Exhibit G: Linked website promoted in video on Xlear.com (*Information You Should Know About COVID-19*, COMMON SENSE MEDICINE (last visited Oct. 15, 2021), https://commonsensemedicine.org/information-you-should-know-about-covid-19/)

Exhibit H: FTC Warning Letter (July 29, 2020)