Kenneth A. Okazaki (USB #3844)
Nathan D. Thomas (USB #11965)
Elizabeth M. Butler (USB #13658)
JONES WALDO HOLBROOK & McDONOUGH PC
170 South Main Street, Suite 1500
Salt Lake City, Utah 84101
Telephone: (801) 521-3200
kokazaki@joneswaldo.com
nthomas@joneswaldo.com
ebutler@joneswaldo.com

Lynn E. Calkins (*pro hac vice*)
Christine Walz (*pro hac vice*)
HOLLAND & KNIGHT LLP
800 17th Street, N.W., Suite 1100
Washington, D.C. 20006
Telephone: (202) 955-3000
lynn.calkins@hklaw.com
christine.walz@hklaw.com

Attorney for Defendants Xlear, Inc. and Nathan Jones

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA Plaintiff,v. XLEAR, INC., a corporation, and NATHAN JONES, individually and as an officerof XLEAR, INC., Defendants.	Case No. 2:21-cv-00640-RJS **DEFENDANTS' ANSWER TO THE GOVERNMENT'S COMPLAINT FOR CIVIL PENALTIES, PERMANENT INJUNCTION, AND OTHER RELIEF** Chief Judge Robert J. Shelby

Defendants Xlear, Inc. ("Xlear") and Nathan Jones (collectively "Defendants"), by and through counsel, respectfully respond to the allegations in Complaint filed by the United States on October 28, 2021 (Dkt. No. 2) as follows:

NATURE OF THE CASE

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

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 deny the allegations of Paragraph 3.

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

PARTIES

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

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

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. 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. 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. 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. 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[1]

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. 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

[1] Defendants deny any factual allegations contained in the headings of the Government's Complaint.

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. 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 SARS-CoV-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-CoV-2), 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):967-975, 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 laboratory-confirmed 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 non-hospitalized 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. 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/press-announcements/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 placebo-controlled, 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 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.

23. Defendants deny the allegations of Paragraph 23.

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-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." Moreover, the magazine statements are not bought and paid for advertorials but are unpaid media interviews.

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. Defendants deny the remaining allegations of Paragraph 25.

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 iota-carrageenan 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. Iota-

carrageenan 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. 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. 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. 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. 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.

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. 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. 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.

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

herein.

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 deny the allegations of Paragraph 40.

41. Defendants deny the allegations of Paragraph 41.

42. Defendants deny the allegations of Paragraph 42.

43. Defendants deny the allegations of Paragraph 43.

COUNT TWO
COVID-19 Consumer Protection Act Violations

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

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. 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 deny the allegations of Paragraph 47.

48. Defendants deny the allegations of Paragraph 48.

49. Defendants deny the allegations of Paragraph 49.

50. Defendants deny the allegations of Paragraph 50.

51. Defendants deny the allegations of Paragraph 51.

52. Defendants deny the allegations of Paragraph 52.

53. Defendants deny the allegations of Paragraph 53.

CONSUMER INJURY

54. Defendants deny the allegations of Paragraph 54.

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.

PRAYER FOR RELIEF

56. The Government's prayer for relief characterizes the relief the Government seeks to which no response is required. To the extent a response is required, Defendants deny that they have engaged in any of the unlawful acts or omissions alleged against them and deny that the Government is entitled to any of the relief prayed for in the prayer for relief or any other relief. The Government's sought after injunction will constitute a significant burden on Defendants' First Amendment Rights.

ADDITIONAL DEFENSES

Pursuant to Fed. R. Civ. P. 8 and 12(b), Defendants assert the following additional defenses. By listing the following defenses, Defendants do not concede, explicitly or implicitly, that any or all of the listed defenses are affirmative defenses under applicable law or that Defendants bear the burden of proof thereon. Defendants also do not by listing their defenses in this Answer limit their ability to present any defense that does not need to be identified by Answer.

FIRST DEFENSE

The Government fails to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6).

Most notably, the crux of this case is the Government's allegation that the Defendants lacked adequate competent and reliable scientific evidence to reasonably satisfy experts in the field. The field here is COVID-19 medicine and nasal hygiene as a disease prevention tool. The Defendants aver a host of studies that support the statements made.

In contrast, the Government fails to offer a single scientific study, RCT or otherwise, that counters or refutes the Defendants' studies. In fact, the Government does not refute the

Defendants' science in anyway. Instead, the Government baldy concludes inadequacy.

The Supreme Court held in *Ashcroft v Iqbal*, a complaint is inadequate if "it tenders 'naked assertion[s]' devoid of 'further factual enhancement' . . . . Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing and quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)) (internal quotations omitted).

The Government offers no facts to support its allegations that reasonable experts in the field of COVID-19 medicine would find the Defendants' substantiation inadequate. The Government presents not a single expert's opinion in the field of COVID-19 medicine and/or nasal hygiene disease prevention that Defendants' substantiation is inadequate. All the Government pleads is a series conclusory statements that the substantiation requirement is not met. This is precisely the sort of threadbare element supported only by conclusory statements that the Supreme Court rejected in *Iqbal*.

SECOND DEFENSE

The statements identified are not false or misleading but are truthful and accurate. Each statement is supported by competent and reliable scientific evidence, including various studies. The Government's contention that RCTs are required by law is wholly without merit; RCTs are not always necessary to substantiate claims about the health benefits of foods and nutrients. Moreover, under certain circumstances with respect to a novel, deadly pathogen (e.g., SARS-CoV-2 (COVID-19)) the specific types of RCTs the Government seeks to mandate from whole cloth here can be: precluded under the Government's own regulations; prohibited by medical ethics; logistically unfeasible; and/or yield less conclusive data than other forms of studies. The

statements at issue in this litigation are substantiated by medical evidence, include effective disclaimers disclosing the limitations of the supporting research, and are based on the type of scientific evidence that could have been regulatorily and ethically obtained.

As discussed above, Defendants aver that there is substantial competent and reliable scientific evidence to substantiate their statements.

THIRD DEFENSE

Defendants' conduct is not "egregious," does not constitute significant consumer harm, provides a benefit to consumers, and there has not been any justifiable reliance on the part of consumers.

FOURTH DEFENSE

The statements at issue in the Complaint did not result from any misconduct or deceitfulness on the part of the Defendants, and the Government will be unable to demonstrate that Defendants had knowledge that any such statement was conveying a "misleading claim."

FIFTH DEFENSE

At all relevant times, Defendants acted in good faith and in a lawful manner toward consumers and in conformity with all applicable laws and regulations.

SIXTH DEFENSE

Defendants allege that any and all damages and injury alleged in the Complaint, if any, were caused, if at all, in whole or in part, by the conduct, fault and/or negligence of persons or entities other than Defendants.

SEVENTH DEFENSE

Xlear is not violating or imminently about to violate laws enforced by the FTC.

EIGHTH DEFENSE

Xlear has remedied any concerns the FTC may have regarding its statements and business practices, and there will be no proof of any purported ongoing consumer harm such that this action is moot.

NINTH DEFENSE

The Government's actions here constitute a violation of the Defendants' First Amendment Rights, and the injunctive relief sought is barred by the First Amendment because it would have the effect of prohibiting speech that is neither false nor misleading.

Throughout this matter, the Government has routinely sought to restrain Defendants from raising public awareness—in a time of a deadly global pandemic. Government's efforts here with regard to Defendants' commercial speech fail the test set out by the Court in *Central Hudson. See Pom Wonderful v. Fed'l Trade Comm'n.*, 777 F.3d 478 (D.C. Cir. 2015), *citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566, 100 S.Ct. 2343, 65 L.Ed.2d 341 (1980); *see also Edenfield v. Fane*, 507 U.S. 761,766 (1993) ("The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish. Some of the ideas and information are vital, some of slight worth. But the general rule is that the speaker and the audience, not the government, assess the value of the information presented. Thus, even a communication that does no more than propose a commercial transaction is entitled to the coverage of the First Amendment . . . .").

The Government's systemic restraint on Defendants' speech goes well beyond the four-

corners of the Government's complaint. For example, the Defendants have sought to promote a petition initially signed by healthcare researchers and front-line healthcare workers (doctors and others) to the Centers for Disease Control (CDC). The petition calls for the CDC to issue guidance, much like other CDC Guidance on masking and social distancing, on the use of nasal cleansing to combat COVID-19. That petition now has over 5,000 individual signatories. During the course of Defendants' interactions with the Government, the Government demanded that the Defendants cease efforts to promote the petition of the CDC.

The Act of petitioning the Government for a change in Government policy with the intent of saving American lives is pure protected speech. *See Cent. Hudson Gas & Elec. v. Public Svc. Comm'n*, 447 U.S. 557, 562 (1980) ("commercial speech is 'speech that proposes a commercial transaction.'") A petition for a change in Government policy does not propose a transaction—it proposes the Government actually take action to safeguard American lives. As the Supreme Court held in *United Mineworkers*, "the rights to assemble peaceably and to petition for a redress of grievances are among the most precious of the liberties safeguarded by the Bill of Rights." *United Mineworkers of America v Illinois State Bar Assoc.*, 389 U.S. 217, 222 (1967). However, here the Government has deliberately and unlawfully sought to preclude Defendants from exercising that right.

The Government does not raise its longstanding efforts to restrain Defendants' First Amendment Rights in its complaint for obvious reasons. However, that does not negate the fact of the Government's actions. These actions provide vital context and motive to all the Government's actions and allegations.

Moreover, the Government's actions here have already had a chilling effect on Defendants'

First Amendment Rights. For example, when the Augusta University, Georgia, RCT Study noted above first came to Defendants' attention, Defendants wanted to inform the public about the study. (That study found that nasal cleansing with a saline irrigant can reduce the rate of COVID-19 hospitalization among people already sick with COVID-19 and at moderate to high risk by 8.4 times.) People facing a deadly pandemic have a vital interest in that information. However, the Defendants did not do so because they feared Government reprisals.

When the Defendants received the results of the Institute for Antiviral Research, Utah State University, Study (attached hereto at Exhibit A), finding the components of Xlear have greater antiviral efficacy (in vitro) than the FDA-approved COVID-19 treatment Remdesivir, the Defendants thought the public had a right to know this information. However, the Defendants have not publicized these study results out of fear of Government reprisals. The Delta strain remains, at the time of this writing, the strain causing the vast majority of new COVID cases in the U.S. with the Omicron variant rapidly spreading as well. The Defendants have yet to run testing against the Omicron strain. However, lab tests have already found efficacy against no less than three strains and there is no data to suggest it would not have similar effect on Omicron. The public would have been well, and better, served to know this information.

TENTH DEFENSE

Defendants hereby give notice that they intend to rely upon any other defense that may become available or appear during the course of discovery proceedings in this case.

PRAYER FOR RELIEF ON THE GOVERNMENT'S COMPLAINT

WHEREFORE, Defendants pray that judgment be entered against the Government to include that:

A. The Government takes nothing from the Complaint;

B. The Government's Complaint be dismissed with prejudice;

C. Defendants be awarded their costs and attorneys' fees; and

D. For such other and further relief as the Court deems just and proper.

Respectfully submitted,

By: */s/ Nathan D. Thomas*
Kenneth A. Okazaki (USB 3844)
Nathan D. Thomas (USB 11965)
Elizabeth M. Butler (USB 13658)
JONES WALDO HOLBROOK & McDONOUGH PC
170 South Main Street, Suite 1500
Salt Lake City, Utah 84101
Telephone: (801) 521-3200
kokazaki@joneswaldo.com
nthomas@joneswaldo.com
ebutler@joneswaldo.com
Attorney for Defendants Xlear, Inc. and Nathan Jones

By: */s/ Lynn E. Calkins*
Lynn E. Calkins (*pro hac vice)*
Christine Walz (*pro hac vice*)
HOLLAND & KNIGHT LLP
800 17th Street, N.W., Suite 1100
Washington, D.C. 20006
Telephone: (202) 955-3000
lynn.calkins@hklaw.com
christine.walz@hklaw.com
Attorney for Defendants Xlear, Inc. and Nathan Jones

CERTIFICATE OF SERVICE

I hereby certify that, on this 22nd day of December, 2021, that a true and correct copy of the foregoing **DEFENDANTS' ANSWER TO THE GOVERNMENT'S COMPLAINT FOR CIVIL PENALTIES, PERMANENT INJUNCTION, AND OTHER RELIEF** has been filed with the Clerk of Court, by using the CM/ECF system to deliver a true and correct copy of the foregoing to the following:

Andrea T. Martinez, Acting Assistant Attorney General
Joel A. Ferre, Assistant United States Attorney
Office of the United States Attorney
111 S. Main St., Suite 1800
Salt Lake City, UT 84111
joel.ferre@usdog.gov

Noah T. Katzen, Trial Attorney
Alisha M. Crovetto, Trial Attorney
Consumer Protection Branch
Civil Division
United States Department of Justice
Office of Consumer Litigation
Civil Division
United States Department of Justice
450 5th Street, NW
6th Floor, South
Washington, DC 20001
noah.t.katzen@usdoj.gov
alisha.m.crovetto@usdoj.gov

/s/ Nathan D. Thomas