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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.”

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.”

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.

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.

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.

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.

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.

PARTIES

8. Plaintiff is the United States of America.

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.

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.

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."

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

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).

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.

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).

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).

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).

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 contaminants, sooth and moisturize nasal passages due to low humidity and other nasal irritants, and to thin and loosen mucous secretions.

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.

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.

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”).

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.

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.

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").

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

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

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.*

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.

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”).

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.*

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.

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."

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.

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").

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.

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.

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.

COUNT ONE

FTC Act Section 5(a) and Section 12 Violations

38. Paragraphs 1 through 37 are incorporated as if 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.

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

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

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.

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.

COUNT TWO

COVID-19 Consumer Protection Act Violations

44. Paragraphs 1 through 43 are incorporated as if 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.

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:

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

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

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

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

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

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).

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

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.

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.

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.

Dated: October 28, 2021

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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)