January 8, 2024

Dear _____

Given your leadership of the (NAME OF COMMITTEE THE MEMBER SERVES ON), I write to introduce you to Xlear and offer our insights with respect to the actions of the Federal Trade Commission (FTC). Additionally, we respectfully request your help in addressing the issues set out below.

Xlear is a Utah-based, family-owned, hygiene products company. We make products such as nasal sprays, toothpaste, and mouthwash. All our products are made from natural ingredients. Our nasal spray (called Xlear) has been sold for over 20 years in the United States. We are available at pharmacies (e.g., CVS), big box stores (e.g., Target and Walmart), and supermarkets across the nation and around the world, as well as online (e.g., Amazon.com). We have been used by millions of Americans—many under doctor's direction, and many for years at-a-time. We have never had an adverse safety report filed—a fact the U.S. Government acknowledges.

The vast majority of our products are all manufactured right here in Utah. I started the company after having served in the National Guard for 10 years and working as a commercial diver. Our product was developed by my father, who was a family physician. He had large numbers of patients—children—who suffered from recurring ear infections. He opposed the "Standard of Care," which was to treat them with quantities of antibiotics—he was ahead of his time. He devised the spray, a simple, low cost, risk-free hygiene tool, which was effective in treating and preventing infections. Based on his invention, I started a company in 2000. We are now sold around the nation, online and around the world. I think it is fair to say, we are the sort of company that embodies the American spirit.

Unfortunately, Xlear is also a victim of the FTC's extreme efforts to censor legitimate speech around health issues, in particular COVID-19. With respect to the FTC's COVID-19 censorship,

we believe the Agency's actions have cost the nation trillions of dollars and hundreds of thousands of lives. Xlear is also a test case of the Agency's ongoing unlawful regulatory scheme—a scheme that will harm American citizens far into the future if it is not arrested quickly.

As set out in detail in the Attachments to this letter, the FTC has established a set of highly-restrictive, de facto rules the Agency now *contends* apply to all manner of health products—literally everything from vitamins, to humidifiers, to probiotics.[1] The most recent version of these mandates is called the 2022 "Health Products Compliance Guidance" ("HPCG"). These standards have no basis in law/statute. In recent depositions in our matter, the FTC's own staff—under oath—admitted that they are only "staff guidance" and not legally binding, yet the FTC is suing companies that do not toe their arbitrary line. This litigation is expensive and time consuming to the companies they sue, and is destroying their ability to grow, do research, and create jobs.

Moreover, as discussed below and in the Attachments, the mandates imposed by the FTC under these guidelines are, in fact, more strict than what the FDA requires of many drugs, specifically the COVID-19 vaccines.

As such, the FTC's mandates are a deliberate and serious end run around Congress' authority. If Congress intended the FTC to impose a substantiation scheme, it would have passed legislation authorizing it. If Congress intended health products be regulated just like the FDA regulates drugs and medical devices, it would have shifted the authority here from the FTC to the FDA (which has real expertise in health matters). Congress has done no such thing.

Notwithstanding that the FTC's HPCG—and the slightly less restrictive mandates that existed before the HPCG—is nonbinding, the Agency uses these requirements as if they are binding, duly-promulgated rules in enforcement actions to compel companies to meet their draconian mandates.

To that end, in October of 2021, the Department of Justice ("DOJ") on behalf of the FTC sued Xlear alleging that Xlear violated these rules by making certain statements about a series of published, scientific studies. These studies all showed that Xlear, and/or our ingredients, were effective antivirals and virucidals against the SARS-CoV-2 virus (the COVID-19 virus). (The facts of this case are set out in greater detail in Attachment A.) In response, Xlear has presented the Government with a host of published, independent studies all showing that Xlear's statements were based on adequate, competent and reliable science.

In cases like this one, the Government bears the burden of proof. However, the Government does not dispute our studies. Likewise, the Government has already told us and the Court it has

[1] In 2022, the FTC issued the latest set of rules, known as the "Health Product Compliance Guidance" or "HPCG ". FTC, Health Products Compliance Guidelines, Dec. 2022, available at https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf.

no studies showing Xlear (or any other nasal hygiene product) is ineffective against COVID-19. Nevertheless, the Government continues to prosecute this case under the specific requirements of the FTC's substantiation scheme. Specifically, the FTC says substantiation requires two randomized clinical trials (RCTs) of the specific product showing efficacy against the specific indication (i.e., COVID-19). The FTC alleges that the plethora of studies Xlear has already provided do not meet that bar.

Xlear disputes the FTC's allegations. First, it is our position that the studies provided meet the FTC's substantiation bar. Second, we agree that the FTC Act does not require RCT evidence. Xlear also avers that our statements based on these studies were and are truthful and not misleading under the terms of the FTC Act. We also agree that the studies we have provided more than satisfy the "competent and reliable scientific evidence" test that courts have applied in cases like this one.

Further, our evidence shows that Xlear has more safety and efficacy human clinical data than the FDA had when it approved the bivalent vaccines (based on an 8 mice study) and more than the Centers for Disease Control (CDC) had when the CDC ordered mask wearing, social distancing, and handwashing. In these examples no RCTs were required, yet the FTC mandates we have two. Which is to say, the Government is seeking to hold Xlear to a vastly higher standard than it has held both itself and the major pharmaceutical companies/vaccine manufacturers.

Xlear's case tests the legal validity of the FTC's substantiation scheme. Likewise, this case shows the serious adverse effects of the FTC's unlawful regulatory scheme are serious:

1. **The FTC scheme denies Americans factually accurate, evidence-based information that they have a right to know in making their own health decisions**. In Xlear's case, the FTC has censored us from, for example, discussing a randomized, controlled clinical trial ("RCT") that found the use of a saline nasal spray containing xylitol (a plant-based sugar), and a pH modifier (the functional equivalent of Xlear), reduced the risk of COVID-19 infection by 62 percent over placebo—a huge benefit that even the vaccines cannot offer (the "Balmforth Study").[2] Oddly, the FTC calls such RCT's the gold standard in science evidence—yet we can't tell people about this one.
2. **The FTC scheme will stop legitimate companies from being able to sell established health-related products and will drive these companies out of business.** RCT's, which are required by the FTC, are highly expensive. Moreover, in many instances, RCT's may not be possible because of ethical and regulatory constraints. However, even without RCT's, scores of health-related products have been shown to be effective (for example using in vitro tests, animal model tests, and/or through centuries of real-world evidence). However, if companies do not have the specific RCT-data the FTC requires,

[2] Damian Balmforth, et al. "Evaluating the efficacy and safety of a novel prophylactic nasal spray in the prevention of SARS-CoV-2 infection: A multi-centre, double blind, placebo-controlled, randomised trial", Journal of Clinical Virology, 155 (2022), 105248, available at https://www.sciencedirect.com/science/article/pii/S1386653222001809.

these manufacturers can no longer market their products. If they cannot afford RCT testing—or if ethical and regulatory constraints preclude them—these companies will be forced out of business.

3. **The FTC scheme impairs America's ability to rapidly counter novel, deadly pathogens.** As Dr. Thomas Frieden, the former head of the CDC has noted, RCT's are time consuming and there are significant ethical and regulatory impediments to conducting them to test countermeasures to emerging, deadly threats.[3] As a result, requiring RCT's will significantly impair our ability to counter the next threats. At a time when every public health agency was lowering requirements to speed discovery of treatments and prophylaxis, *the FTC raised the bar and censored companies that had data showing their products were effective at treating and preventing respiratory viruses caused by coronaviruses.*

4. **As a result, Americans will get needlessly sick and some will die.** Consider the COVID-19 example. The nasal spray in the Balmforth Study reduced infections by 62 percent above placebo.[4] (That is more protection than the Government-supported vaccines provide.[5]) Imagine if that knowledge was widespread among Americans. Imagine if the effect of Americans acting on that information was to cut COVID-19 cases in half or more. Conservatively speaking, a "mere" 50 percent reduction in COVID-19 would have prevented almost 600,000 American deaths and significantly reduced the pandemic's toll on the nation—in lives, economic harms, and societal harms.
5. **Americans will be denied the ability to obtain health-related products—many of which they have relied on for years with great success.** As the FTC increasingly seeks to enforce these "rules" against all health-related products, Americans will lose access to many of these products, including things like their daily vitamins, joint supplements, wrist and knee braces, and room humidifiers.
6. **We will lose important tools for improving health and protecting against novel threats like pandemics.** For example, we are now years into the COVID-19 pandemic. America alone has spent billions of dollars on over-hyped and over-priced pharmaceutical interventions with little to show for it. Throughout history, pandemics, epidemics, and outbreaks have been controlled and halted primarily through sanitation and hygiene. However, in this pandemic, our public health authorities have adopted a vaccine-primacy strategy, which has not succeeded. At the same time, the FTC has censored companies, like Xlear and many others, from trying to inform Americans about other low-cost, science-backed tools they can use to protect themselves. This example is not

[3] Frieden TR. "Evidence for health decision making - beyond randomized, controlled trials". N Engl J Med. 2017;377:465–475 ("These limitations also affect the use of RCTs for urgent health issues, such as infectious disease outbreaks, for which public health decisions must be made quickly on the basis of limited and often imperfect available data.")

[4] Importantly, the placebo was saline, which other studies have shown is effective in both treating and preventing the transmission of COVID-19. Which is to say, the actual efficacy of the nasal spray was higher than 62 percent, when compared with a "no action" alternative.

[5] Studies show that the vaccines are 31 percent or less in preventing transmission of the omicron and more recent variants. Oordt-Speets, Anouk, Julia Spinardi, Carlos Mendoza, Jingyan Yang, Graciela Morales, John M. McLaughlin, and Moe H. Kyaw. 2023. "Effectiveness of COVID-19 Vaccination on Transmission: A Systematic Review" COVID 3, no. 10: 1516-1527.

unique to COVID-19. There are scores of other nonpharmaceutical products people use to better their health—reduce the effects of aging, improve gut health, and the like—which will no longer be available. Denying Americans access to these products isn't going to help them live healthier lives. Quite the opposite.

7. **Big Pharma will dominate American lives even more than it does now—and will reap even more outlandish profits and wield even greater political clout.** As all these other health tools become unavailable, people will be left with big pharma drugs and devices. Big pharma has the deep pockets to both fund RCT's and buy clout with the FTC and other regulators.

There are no checks upon the FTC's actions. The FTC has a virtually unlimited budget and no incentive to mitigate costs. (In fact, the FTC seeks still more money from Congress.) The FTC bureaucrats are insulated from liability. The FTC uses the investigatory and legal processes not to seek truth, but to punish companies that do not readily submit. (We are aware that in one case the FTC's lawyers said, "The process is the punishment.") In our case, the FTC (and their DOJ lawyers) have taken a series of steps obviously designed to compel us to spend more money—things our legal team does not see in the normal practice. Even if Xlear, or any other company, prevails against the FTC, it has no way to recoup its legal costs, which are in the millions of dollars. The monies Xlear has spent defending itself should have gone to productive uses, such as: funding a larger manufacturing facility; establishing wider distribution hubs in other regions/states; and hiring more staff.[6]

It is imperative that the Congress act to counter the FTC's unlawful health regulatory scheme. Congress has several tools readily available to curtail the Agency's power grab:

- Congress could pass legislation eliminating the HPCG and prohibiting the FTC from enforcing the substantiation scheme;
- Congress could prohibit the FTC from spending funds to enforce the HPCG in the upcoming appropriations;
- Congress could pass legislation directing the FTC to enforce the literal prohibitions of the Federal Trade Commission Act and prohibit the creation of an extra-statutory substantiation scheme;
- Congress could pass legislation allowing companies that prevail in enforcement actions to recoup reasonable legal fees from the FTC (specifically via the off-budget fines paid into the FTC); and/or,
- Congress could simply cut the FTC's budget and send a message to stop these actions.

Xlear would welcome the opportunity to brief you and/or your staff. Additionally, we would welcome the opportunity to testify before the Subcommittee (or Committee) about our

[6] The FTC's actions not only have caused Xlear to spend monies that would have funded more research—research the FTC requires; The Agency's actions are also a disincentive to companies doing more research. Xlear has presented the FTC with scores of studies; The FTC staff's recent depositions showed that the Agency's decisionmakers seemed to have never read our data.

experiences. We would gladly do whatever we can to help bring an end to the FTC's harmful & unlawful regulatory scheme.

If you should have any questions or wish to follow up, I can be reached via email (nate.jones@xlear.com) or by phone (385-455-3982).

Thank you in advance for your consideration.

Sincerely,

Nathan Jones
CEO

Attachments

Attachment A: Summary of US v. Xlear

For over two decades, doctors have been telling patients to use Xlear to help ameliorate and prevent upper respiratory infections caused by both bacteria and viruses. In fact, the Centers for Disease Control (CDC) has long advised Americans to use drug-free nasal sprays (like Xlear) to help alleviate colds and flu. This is nothing new, people have used nasal hygiene to fight and treat respiratory diseases for thousands of years.

Early in the pandemic, Xlear was advised by medical experts that our Xlear nasal spray could help prevent COVID-19 infections and, if used by those already infected, could help lessen the duration and severity of the illness. These medical experts based these conclusions on their experiences treating COVID-19 patients—as well as other respiratory infections. These expert conclusions were also based on published, peer reviewed studies including in vitro studies using our product and its ingredients; a clinical case study using our product; extensive human clinical trials using highly similar (functionally equivalent) products; and medical expert articles.

Relying on these expert views and the studies, Xlear took steps to inform Americans of this data. We felt compelled to do so not to sell product,[7] but to help save lives. At no time did Xlear say our nasal spray was a silver bullet, or cure, for COVID-19. We took great pains to emphasize that Xlear can be additional layer of protection, along with vaccinations, masking, and other public health guidance.

Xlear felt the need to inform people about these studies because our government's experts essentially refused to discuss anything that wasn't an expensive pharmaceutical product, in particular vaccines.[8] We tried to work with health professionals to petition the CDC to promulgate guidance on the use of nasal hygiene generally to combat COVID-19; the CDC rejected that request out-of-hand.

In late July 2020, as the pandemic raged and the death toll mounted, the FTC sent us a warning letter demanding we stop telling Americans about published science (many of these studies were posted on the government's own National Institutes of Health's (NIH) website). The FTC also told us we could not repost social media messages from independent COVID-expert doctors telling people to use nasal hygiene to combat the disease.

At first, we sought to work with the FTC to address the Agency's concerns. We removed posts and/or added disclaimers. We established a compliance review process. However, during this

[7] Throughout the pandemic: Xlear never changed the price of our product (although we could have); and, Xlear's sales remained relatively stable, apart from a wave of panic buying set off by the Government's actions.

[8] Further, it should be stressed that this took place in the timeframe where it became obvious that Government officials had oversold the vaccines. Vaccines were no longer capable of preventing infections/transmission. (Data shows some nasal sprays like Xlear greatly reduce transmission.). Additionally, studies were being published showing that the Government approved antiviral was ineffective. (One study done for Xlear, which showed our nasal spray was highly effective, also determined Remdesivir was all but totally ineffective.). To halt this pandemic new tools and approaches were (and still are) necessary.

period of negotiations, the FTC also sought to impose a forward-looking burden on Xlear that we would make no statements about COVID-19 at all (no matter the data); and, we would make no statements of any kind about any other disease or health threat unless we possessed two randomized, clinical trials ("RCTs") proving our specific product was effective. Moreover, it was the FTC's position that if Xlear merely posted a link to published, independent, peer-reviewed scientific study, we were making a claim that violated the Agency's terms.

Xlear regarded these demands as untenable. First, we viewed this as a serious—prior restraint—violation of the company's First Amendment rights. Second, our legal team could find no support for the FTC's two RCT legal requirement under the Federal Trade Commission Act ("FTC Act"), which the Agency claimed as its basis. We took this as a serious regulatory overreach. Xlear sought to negotiate these issues; the FTC refused.

As a result, the FTC referred the matter to the Department of Justice (DOJ), which filed suit against Xlear in the US District Court, District of Utah. Ironically, the DoJ-FTC have public stated that Xlear has made false claims about the efficacy of our nasal spray against COVID-19. This is, in fact, false itself. The DOJ-FTC has offered no evidence to date to show our nasal spray doesn't work to combat COVID-19 (DOJ-FTC bears the burden of proof in the case). And, they have made no actual claim that what Xlear said was untrue.

Rather, what they have alleged is that Xlear's statements (e.g., posting scientific studies and reposting statements by independent medical experts) are not adequately substantiated. Specifically, DOJ-FTC allege that our claims are misleading because we do not have two RCT studies of the form they require to support the statements.

In response, Xlear has provided the DOJ-FTC with an abundance of peer-reviewed, published scientific studies all of which support our statements. Several of these studies are RCTs (clinical trials), several are in vitro trials, one is a case study (using Xlear to treat COVID-19 patients). Some of these studies are specific to Xlear and its ingredients. Some use functionally equivalent products, including one we are told was engineered to mimic Xlear. Some use simple saline—which has been found effective against COVID-19 (and the DOJ-FTC admit Xlear is a saline nasal spray). They all support our claims. It is Xlear's position that the totality of all this and other evidence more than meets the FTC Act's requirements.

In recent depositions of the FTC staff who investigated Xlear it was apparent that the FTC staff never really read the studies that Xlear provided. Not one of the three FTC staffers questioned had any knowledge of the studies, let alone an in-depth understanding.

Moreover, in the depositions we learned that the only person with any science background who participated in the FTC's investigation of Xlear prior to the lawsuit was a nutritionist. No one at the FTC who judged Xlear had any expertise in virology, upper respiratory diseases, nasal hygiene, or COVID-19. No one at the FTC who judged Xlear had ever treated a patient of any kind. (In contrast, the many doctors who support the use of Xlear against COVID-19 are experts

in COVID-19, upper respiratory diseases and virology and had treated hundreds of covid patients.)

Nevertheless, the FTC refuses to accept Xlear's data. In addition, to date, the Agency has refused to say how all this data is inadequate. The FTC's posture is to simply categorically deny the weight of evidence.

Further, during the recent depositions of FTC staff, the Agency's motive behind this censorship seems to have been revealed in testimony. The testimony suggests that the FTC had a knee jerk reaction with respect to any COVID marketing claims. Two FTC witnesses testified that the FTC was acting to protect Americans. The Agency feared that if consumers knew there were ways other than vaccination to protect against COVID, then Americans might act "irresponsibly." The FTC, in essence, viewed its efforts as part of wider government efforts to drive Americans into being vaccinated. As if the average American wants the government making their health decisions.

To date Xlear has already spent over $2.5 million dollars to defend itself from the FTC's efforts to censor science. The DOJ-FTC has done virtually everything possible to draw the case out and compel Xlear to spend more money in defense. For example:

- The DOJ-FTC has denied our efforts to obtain all but a select few documents from the Food & Drug Administration (FDA). (The FDA worked with the FTC to investigate Xlear.[9]) As a result we were forced to ask the Court to compel the Government to meet basic discovery requests—requiring Xlear to spend money and time.
- The Government has failed to turn over clearly responsive documents—such as exculpatory studies in the FTC's possession. Here again, we are being forced to ask the Court to compel the Government to meet basic discovery requests—requiring Xlear to spend money and time.
- The Government has refused to make officials from the FDA (which were part of the initial investigation) available for depositions. Here again, we were forced to ask the Court to compel the Government to meet basic discovery requests—requiring Xlear to spend money and time.
- The Government has refused to answer basic questions, such as: what triggered the FTC investigation; and what does the FTC consider the substantiation standard that is applicable in this case.
- Early on, the DOJ-FTC denied a routine request from Xlear to amend our answer to the complaint. Such requests early on are routine courtesies and typically granted. Here again, we were forced to ask the Court to allow our amendment—requiring Xlear to spend money and time.

Most tellingly, in a recent email, a DOJ attorney implied that if Xlear didn't hire more attorneys (and spend still more money faster) the DOJ would seek sanctions from the court.

[9] The FDA refused to join the FTC's case, which makes its documents all the more important.

Based on the evidence, we strongly believe we will prevail in this litigation.

However, even assuming we win, the company will still have spent millions of dollars on a completely unproductive expenditure.

Our spending just to this midpoint in discovery is already $2.5 million. (By way of comparison, we have spent more on this single defense than the company has spent on legal bills in the last twenty-plus years.) As noted above, these monies should have gone to productive uses, such as: funding a larger manufacturing facility; establishing wider distribution hubs in other regions/states; and hiring more staff.

If Xlear wins, we have little to no chance of recouping this wasted money. The FTC and its officials are largely immune from lawsuit. The Federal law doesn't provide for a prevailing party in a FTC enforcement case to seek and obtain costs and fees.

There simply is no check upon the FTC's actions. We would like to propose legislation that could help curb this obvious overreach.

Attachment B: Background on the Lack of Statutory Basis for the FTC's Actions

The FTC regulates marketing and advertising claims made by health-related products under sections 5 and 12 of the FTC Act. At base, the FTC Act prohibits false and misleading claims. See FTC, Health Products Compliance Guidance, Dec. 2022, at 2, endnote 1. [10]

Based on those modest statutory provisions, the FTC has built a stringent, rigid compliance regulatory regime that has no basis in the law.

As the FTC itself recognizes, the highly specific substantiation regulatory scheme currently enforced by the agency arises not from any provision of the FTC Act, but from the policy statements of the FTC interpreting the FTC Act and case law deferring to those interpretations. Id. at 2; see also Federal Trade Commission v. Natural Solution, Inc., Case No. CV 06-6112-JFW (JTLx) (C.D. Cal. Aug. 7, 2007) (citing Federal Trade Commission v. QT, supra, noting that substantiation factors arise from FTC policy statements).

During our recent depositions, the FTC officials testified that the FTC Act never mentions substantiation, or RCTs, or in vivo or in vitro testifying.

Rather, the substantiation scheme has evolved through a series of FTC guidance documents purportedly issued to assist companies in complying with the modest prohibitions against false and misleading claims found in the FTC Act. See FTC, Health Products Compliance Guidance, Dec. 2022; FTC, Dietary Supplements; An Advertising Guide for Industry, Apr. 2001; FTC, FTC Policy Statement Regarding Advertising Substantiation, Nov. 23, 1984.

The FTC has used these guidance documents to consistently increase the regulatory burdens of substantiation on industry. Compare FTC, Health Products Compliance Guidance, Dec. 2022; with FTC, Dietary Supplements; An Advertising Guide for Industry, Apr. 2001; see also John E. Villafranco, Kristi L. Wolff, Misguided: The FTC Attempts to Redefine the Law with its Health Products Compliance Guidance, Dec. 2022 (hereinafter "Misguided").

The latest guidance, the 2022 Health Products Compliance Guidance, marks the FTC's most heavy-handed and draconian effort to raise the substantiation bar on any party making any health-related claim.

Under the 2022 Health Products Compliance Guidance, any party making any health-related claim must have double-blinded, placebo-controlled, randomized, human clinical studies (so called RCTs) to support that claim. Misguided, supra.[11]

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[10] See FTC, Health Products Compliance Guidance, Dec. 2022, at 2, endnote 1. The 2022 Guidance summarizes the statutory framework: "Section 5 of the FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce," and Section 12 prohibits the dissemination of false advertisements for foods, drugs, devices, services, or cosmetics. 15 U.S.C. §§ 45, 52. Section 15 of the FTC Act defines "false advertisement" as "advertising that is misleading in a material respect[.]" 15 U.S.C. § 55(a)(1)." Id. at endnote 1.

[11] Misguided, supra:

This is not a simple restatement of long-existing FTC substantiation rules. This marks a new and fundamental change to substantiation law, and a fundamental change to the structure of the entire health and wellness industry sector. Simply put, all sorts of health-related claims, must now, in effect, meet the very high bar required by the FDA's statutory new drug approval program.

The FTC's guidance does not specifically delineate what sorts of products and services (and associated claims) are covered by the FTC's claim substantiation scheme. However, the 2022 Health Products Compliance Guidance notes that the agency has settled or adjudicated over 200 cases involving "dietary supplements or other health- related products, including foods, over the counter (OTC) drugs, homeopathic products, health equipment, diagnostic tests, and health-related apps."[12]

Which is to say, if one follows the FTC's line of thinking, any product or service that may claim any sort of health or wellness benefit to the user is subject to the FTC's scheme.[13]

According to the FTC's logic, for example, any claim that a humidifier helps a person breathe better must now have as much RCT human clinical evidence as FDA-approved heart medication. Any claim that a probiotic helps digestion must now have as much RCT human clinical evidence as a FDA-approved antidepressant drug. Cf., e.g., Elizabeth Crawford, HBW Insight, FTC Requests Drug Claim Support For Bayer Probiotic Supplement, Sep. 2014.[14]

It must be emphasized that none of the FTC's purported substantiation rules were ever the product of an actual rulemaking.[15] During our recent depositions, the FTC officials testified that

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> Instead of simply recognizing that RCTs may be the "most reliable" form of evidence, as set forth in the 1998 Guidance, the new Guidance provides that RCTs are the only form of evidence that will suffice, regardless of whether the claim would be considered a health claim, a structure-function claim, or a drug claim under FDA law: "[a]s a general matter, substantiation of health-related benefits will need to be in the form of randomized, controlled human clinical testing to meet the competent and reliable scientific evidence standard."

Id.

[12] See FTC, Health Products Compliance Guidance, Dec. 2022, at 1.

[13] Conceivably this even includes pharmaceuticals and medical devices. While medical devices and drugs are principally regulated by the FDA, and the FTC largely defers to the FDA in these areas, the 2022 Guidance stresses that the FTC shares oversight in these areas. Id. at 3-4.

[14] These new standards fly in the face of the FDA's recent approval of the bivalent COVID-19 vaccines on the basis of data from eight mice and no human clinical data of any kind.

[15] The DC Circuit Court in Pom Wonderful noted that the FTC may announce new standards in an adjudication without going through notice and comment rulemaking. POM Wonderful, supra at 497. That, however, is a different issue than the legal deficiencies raised here. However the FTC elects to impose substantiation standards—via rulemaking or an adjudication—that rule must be founded upon some clear statutory grant of authority. See West Virginia v EPA, 597 U.S. ___ (2022). Likewise, if that rule is imposed via mere guidance, as is the case with the FTC's Health Products Compliance Guidance, then that rule is afforded substantially less deference than a properly promulgated rule. Christen v. Harris County, 529 U.S. 576, 120 S.Ct. 1655, 1662-1663

the FTC has never promulgated this guidance as a rule. They also testified that the "staff guidance" is not legally binding.

Moreover, the FTC's purported substantiation rules have no actual, clear statutory basis. As Judge Easterbrook writing for the Seventh Circuit Court of Appeals Court in FTC v. QT, Inc., 448 F. Supp. 2d 908 (N.D. Ill. 2006), stressed:

> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand. The burden is on the Commission to prove that the statements are false. (This is one way in which the Federal Trade Commission Act differs from the Food and Drug Act.) Think about the seller of an adhesive bandage treated with a disinfectant such as iodine. The seller does not need to conduct tests before asserting that this product reduces the risk of infection from cuts. The bandage keeps foreign materials out of the cuts and kills some bacteria. It may be debatable how much the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false. Placebo-controlled, double-blind testing is not a legal requirement for consumer products.[16]

This finding of the Seventh Circuit Court of Appeals Court was buttressed by the deposition testimony of the FTC witnesses that the FTC Act makes no mention of any substantiation scheme.

Nevertheless, and in parallel, the FTC has sought to bootstrap these unlawful substantiation requirements through the use of enforcement actions, relying on judicial deference to the agency's scheme. In effect, the Agency has worked hard to create law out of "non-law."

Beginning years ago, the FTC brought a series of enforcement cases which the FTC settled with the defendants. In these judicially entered settlements (consent orders), the FTC imposed RCT requirements upon the defendants. See, e.g., US v. Bayer Corp., Civil Action No. 07-01(JLL) (D.N.J. Sep. 24, 2015) (discussing terms of Bayer's consent order); see also Randal Shaheen, Amy Mudge, Has the FTC Changed the Game On Advertising Substantiation?, 25 ABA Antitrust 65 (2010)(discussing the evolution of FTC substantiation rules via consent orders). (Presumably the defendants were happy to have their cases over without major penalties, so they accepted the FTC's other terms.)

(2000). To those points, it is fair to wonder if the Pom decision would be similarly decided if the case were heard today.

[16] FTC v. QT, Inc., 448 F. Supp. 2d 908 (N.D. Ill. 2006).

Then, in future actions the FTC argued the presence of the RCT substantiation requirement in these consent orders was evidence that the RCT standard was, in effect, already the law.

In making this argument, the FTC was misstating the law. Enforcement settlements are binding only on the parties to the agreement and order. They have no precedential value. They are hybrids between contracts and judgments and are not law per se.

Nevertheless, in many of the same series of cases, the FTC had success in convincing a string of courts that RCT evidence is required under the FTC Act's statutory language given the specific facts of the case. See, e.g., POM Wonderful, LLC v. FTC, 777 F.3d 478, 490 (D.C. Cir. 2015); ECM Biofilms, Inc. v. FTC, 851 F.3d 599 (6th Cir. 2017).[17]

To date it seems no court has been presented with a fact pattern in which reasonable experts in the field would not require a RCT. This is precisely the fact pattern that is set to be heard in the case US v. Xlear, which is pending before the United States District Court, District of Utah.

As a rule, the cases finding RCTs are required do not point to clear statutory support for requiring RCT data in substantiation. Rather, the FTC has been able to establish RCT requirements through the agency's interpretations and relying on the deference courts provide to federal agency rules and interpretations under the Chevron Doctrine.

These RCT decisions are out of step with today's administrative law. Since Chevron, the Supreme Court has developed a tiered approach to the level of deference an agency's determinations and interpretations are afforded. Things like mere guidance, which are not the product of notice and comment rulemaking, are accorded the lowest level of deference. Christen v. Harris County, 529 U.S. 576, 120 S.Ct. 1655, 1662-1663 (2000) (citing "See, e.g., Reno v. Koray, 515 U.S. 50, 61, 115 S.Ct. 2021, 132 L.Ed.2d 46 (1995) (internal agen-cy guideline, which is not ''subject to the rigors of the Administrative Procedur[e] Act, including public notice and comment,'' entitled only to ''some deference'' (internal quotation marks omitted)); EEOC v. Arabian American Oil Co., 499 U.S. 244, 256– 258, 111 S.Ct. 1227, 113 L.Ed.2d 274 (1991) (interpretative guidelines do not receive Chevron deference); Martin v. Occupational Safety and Health Review Comm'n, 499 U.S. 144, 157, 111 S.Ct. 1171, 113 L.Ed.2d 117 (1991)

[17] These courts have typically reached the conclusion that the facts of the case require RCT substantiation by examining what level of substantiation reasonable experts in the field would require to validate the claims at issue. See, e.g., POM Wonderful, supra at 495 (D.C. Cir. 2015):

> We conclude that the Commission's finding is supported by substantial record evidence. That evidence includes written reports and testimony from medical researchers stating that experts in the fields of cardiology and urology require randomized, double-blinded, placebo-controlled clinical trials to substantiate any claim that a product treats, prevents, or reduces the risk of disease.

(interpretative rules and enforcement guidelines are ‘‘not entitled to the same deference as norms that derive from the exercise of the Secretary’s delegated lawmaking powers’’).”) The FTC’s efforts to impose an entirely new health product substantiation regulatory regimen that has no clear statutory basis runs directly afoul of the law. Christen v. Harris County, 529 U.S. 576, 120 S.Ct. 1655, 1662-1663 (2000) (“To defer to the agency’s position would be to permit the agency, under the guise of interpreting a regulation, to create de facto a new regulation.”)

Today, any court considering what level of substantiation is required to support a claim under the FTC Act should afford the FTC’s RCT-mandate interpretation with the lowest level of deference. Along those lines, because the FTC Act does not mention RCTs and the like, the court should reject the FTC’s interpretation as unfounded and unreasonable. Instead, any such court should look to the statute’s actual language and weigh was the statement at issue false or misleading in the plain sense of those terms. Further, in considering these questions, the FTC must bear the burden of proving that the claim was, in fact, false or misleading.

Likewise, the FTC’s non-statutory health product substantiation regulatory regime also fails the test the Supreme Court set out in West Virginia v EPA, 597 U.S. 2022.

The major question doctrine set out in West Virginia v EPA is properly applicable to the FTC’s efforts to regulate health products.

In 2023, the U.S. coal and natural gas markets, which the EPA rules at issue in West Virginia v EPA targeted, is estimated at $100.7 billion.[18] In comparison, the U.S. nonpharmaceutical, health and wellness industry was valued at $450 billion in 2022 and is growing at 5 percent per year.[19] Products in this sector range from vitamins and probiotics to humidifiers to sleep and stress apps for phones and other electronic devices.

This sector has a disproportionate effect on American lives. As a 2022 McKinsey study noted, “Overall, around 50 percent of US consumers now report wellness as a top priority in their day-to-day lives, a significant rise from 42 percent in 2020.”[20] A 2019 Harris Poll found that 86

[18] IBIS World, Coal & Natural Gas Power in the US - Market Size, Industry Analysis, Trends and Forecasts (2023-2028), available at https://www.ibisworld.com/united-states/market-research-reports/coal-natural-gas-power-industry/.

[19] McKinsey and Company, Still Feeling Good: The US Wellness Market Continues to Boom, Sep. 19, 2022, available at https://www.mckinsey.com/industries/consumer-packaged-goods/our-insights/still-feeling-good-the-us-wellness-market-continues-to-boom.

[20] Id.

percent of Americans take vitamins and/or dietary supplements.[21] More than a third of Americans use a sleep tracking aid.[22]

Given that the EPA rules which impacted a $100.7 billon energy sector constituted a "major question," then surely rules that threaten a market sector 4.5 times larger, which touches the day-to-day health and wellness of millions of Americans, certainly must as well.

Likewise, both the rules at issue in West Virginia v EPA and the FTC's health products compliance rules have little to no direct, clear statutory basis.

As the Supreme Court stressed in West Virginia v EPA:

> "Extraordinary grants of regulatory authority are rarely accomplished through "modest words," "vague terms," or "subtle device[s]." Whitman, 531 U.S., at 468. Nor does Congress typically use oblique or elliptical language to empower an agency to make a "radical or fundamental change" to a statutory scheme. MCI Telecommunications Corp. v. American Telephone & Telegraph Co., 512 U.S. 218, 229 (1994). Agencies have only those powers given to them by Congress, and "enabling legislation" is generally not an "open book to which the agency [may] add pages and change the plot line."

West Virginia v EPA, 597 U.S. ___ (2022) (authorities in original).

The Supreme Court went on to explain that the Court was "'reluctant to read into ambiguous statutory text'" the delegation claimed to be lurking there. Utility Air, 573 U.S., at 324.To convince us otherwise, something more than a merely plausible textual basis for the agency action is necessary. The agency instead must point to "clear congressional authorization" for the power it claims. Ibid." Id. (authorities in original).

Similarly, there is no "clear congressional authorization" for the FTC health-related substantiation regimen. As the Seventh Circuit Court of Appeals court in FTC v. QT, Inc., 448 F. Supp. 2d 908 (N.D. Ill. 2006), stressed:

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[21] American Osteopathic Association, Poll Finds 86% of Americans Take Vitamins or Supplements Yet Only 21% Have a Confirmed Nutritional Deficiency, Jan. 16, 2019, available at https://osteopathic.org/2019/01/16/poll-finds-86-of-americans-take-vitamins-or-supplements-yet-only-21-have-a-confirmed-nutritional-deficiency/ -:~:text=CHICAGO—January 16, 2019—,of the American Osteopathic Association.

[22] Amer. Academy Sleep Med., One in three Americans Have Used Electronic Sleep Trackers, Leading to Changed Behavior for Many, Nov. 15, 2023, available at https://aasm.org/one-in-three-americans-have-used-electronic-sleep-trackers-leading-to-changed-behavior-for-many/ - :~:text=Many Americans are interested in,an electronic sleep-tracking device.

> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand."

That is all the FTC Act authorizes. Any regulatory scheme that goes beyond that has no statutory basis. By clearly exceeding those bounds, the FTC health product claims substantiation regulatory scheme runs afoul of the Supreme Court's holding in West Virginia v EPA.[23]

Along those lines, if Congress intended nondrugs to meet FDA new drug approval requirements, the Congress has had ample opportunity to establish this requirement in statute. The Congress has not done so.

If the Congress intended the FTC to police non-drug and non-medical-device health products just as the FDA oversees pharmaceuticals and medical devices, the Congress could simply eliminate the FTC's oversight of these products and transfer that authority to the FDA. [After all, while the FDA has vast scientific and technical knowledge as to health products, the FTC has no significant inhouse expertise.] Congress has not done so. Alternatively, the Congress could have authorized the FTC to run a program like the FDA's. The Congress has not done so.

[In fact, the merger of the FTC's substantiation rules with the FDA's new drug approval requirements highlights a significant flaw in the FTC's approach. The FDA's approval requirements (proven safety and efficacy) are by their nature inherently more stringent than the

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[23] West Virginia v EPA, 597 U.S. ___ (2022). The West Virginia v EPA major question doctrine is correctly applied to the FTC's health related substantiation scheme. The Court in that case held:

> [the doctrine] . . . refers to an identifiable body of law that has developed over a series of significant cases all addressing a particular and recurring problem: agencies asserting highly consequential power beyond what Congress could reasonably be understood to have granted. Scholars and jurists have recognized the common threads between those decisions. So have we. See Utility Air, 573 U.S., at 324 (citing Brown & Williamson and MCI); King v. Burwell, 576 U.S. 473, 486 (2015) (citing Utility Air, Brown & Williamson, and Gonzales).

Id. (authorities in original).

Those same factors apply here. The body of substantiation law is the product of "a series of significant cases all addressing a particular and recurring problem . . . ." Scholars and jurists have recognized in the FTC's actions a common thread of overreaching. See, e.g., Axion Enterprise, Inc. v. FTC, 598 US _ (2023); FTC v. QT, Inc., 448 F. Supp. 2d 908 (N.D. Ill. 2006); Howard Beales, In Defense of the Pfizer Factors, George Mason Law & Economics Research Paper No. 12-49, Jun. 2012, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776; Jennifer Huddleston, Supreme Court Considers Case Against Agencies Run Amok, Regulatory Rev., Nov. 22, 2022, available at https://www.theregreview.org/2022/11/22/huddleston-supreme-court-considers-case-against-agencies-run-amok/; Misguided, supra.

FTC's Act's limits (no false and misleading statements). However, during the COVID-19 pandemic, the FDA approved a series of drugs, such as the bivalent vaccines, without RCT support. It makes no sense that a vaccine given to millions of Americans doesn't require RCT data, but something like a nasal spray or humidifier must have RCT data.]

Instead, what the Congress should do now is legislate away the FTC's health product substantiation rules and compel the FTC to go back to doing what the FTC Act authorizes the agency to do: stop false and misleading claims.

Instead, what the Court's should do now is stop deferring to the FTC's findings about science, especially as the FTC has no scientific expertise. The FTC should be made to prove every element of any such cases per the statutory requirements.

If the FTC believes that a claims substantiation scheme is required—one that imposes drug approval evidentiary standards on products like vitamins and humidifiers—the agency should go to Congress and seek legislation authorizing that program. If the Congress agrees with the FTC, it should pass such a law. (Although, given the FTC's actions of late, I can't see that happening any time soon.)

Until then the FTC should stop trying to impose such a scheme by agency fiat.