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UNITED STATES DISTRICT COURT DISTRICT OF UTAH
CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. XLEAR, INC., a corporation and NATHAN JONES, individually and as an officer of XLEAR, INC., Defendants.	**PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS** Case No. 2:21-cv-00640-RSJ-DBP Chief Judge Robert J. Shelby Chief Magistrate Judge Dustin B. Pead

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INTRODUCTION

This case alleges that Defendants: (1) marketed and sold their product as effective at preventing and treating COVID-19 without having any valid scientific evidence for that proposition, and (2) made numerous deceptive and misleading representations about scientific studies to give consumers the false impression that they do have such evidence. Defendants' Motion for Judgment on the Pleadings (ECF No. 149, the "Motion" or "Mot.") argues that the Complaint nevertheless fails to state a claim under the FTC Act or COVID-19 Consumer Protection Act ("CCPA") because the provisions of those statutes Defendants are alleged to have violated do not contain the word "substantiation." It asks the Court to overturn decades of precedent and find, for the first time, that the FTC Act's prohibition against deceptive practices and misleading advertising does not prohibit marketing a product using unsubstantiated disease claims and does not require Defendants to have *any* proof that their product is actually effective at preventing or treating COVID-19 before representing it as such to consumers. In making this argument, Defendants ask the Court to disregard the allegations in the Complaint, the plain text of the FTC Act, a half-century of federal court precedent to the contrary, and the Supreme Court's clear instruction to afford great weight to the FTC's interpretation of its implementing statute. To justify their extraordinary request, Defendants point to the Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024), overruling *Chevron*.[1] But Defendants' reliance on *Loper Bright* is misplaced, as *Chevron* deference is not required to find, as courts have for decades, that "[w]here the advertisers lack adequate substantiation evidence,

[1] Defendants' reference to "*Chevron*" refers to the Supreme Court's decision in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

they necessarily lack any reasonable basis for their claims. And where the advertisers so lack a reasonable basis, their ads are deceptive as a matter of law." *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 8 (1st Cir. 2010).

Moreover, even if Defendants' novel theory were correct and businesses could use unsubstantiated disease claims to mislead consumers into purchasing products without violating the FTC Act, judgment on the pleadings would still not be warranted. This is because Defendants' Motion completely ignores the fact that the Complaint's allegations are not limited to the lack-of-substantiation theory they take issue with. Indeed, the Complaint also alleges that Defendants made affirmative, false, and misleading representations about scientific research that they deceptively implied supported their COVID-19 claims. These allegations alone suffice to state a claim under the FTC Act even under Defendant's misreading of the law. As such, Defendants' Motion fails to justify the dismissal it seeks.

The Court should reject Defendants' arguments and deny the Motion in full.

RELEVANT FACTUAL ALLEGATIONS

The Complaint (ECF No. 2, "Compl.") alleges that Defendants Xlear, Inc. and Nathan Jones (collectively "Defendants") sell a variety of products containing xylitol, a sugar alcohol. *See* Compl. at ¶ 1. In response to the Coronavirus Disease 2019 ("COVID-19") pandemic, Defendants began widely advertising that their saline nasal spray is capable of preventing and treating COVID-19. *Id.* at ¶¶ 2, 19, 21, 39, 45-46. Defendants' advertisements claimed, among other things, that:

- 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." *Id.* at ¶ 21(a) (citing Exhibit A).
- Xlear nasal spray treats COVID-19: "Nasal sprays, like Xlear help subdue the viral load as a simple treatment." *Id.* at ¶ 21(b) (citing Exhibit B).

- "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." *Id.* at ¶ 21(c) (citing Exhibit C).
- Xlear nasal spray prevents or treats COVID-19: "Xlear can help block infection or lessen the severity of symptoms!" *Id.* at ¶ 21(d) (citing Exhibit D).
- "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." *Id.* at ¶ 21(e) (citing Exhibit E).

Defendants made these COVID-19 marketing claims despite having no valid factual or scientific basis for their claims. *Id.* at ¶¶ 3, 20, 22, 40. To "give the impression that there [was] evidence to support their claims about Xlear nasal spray," Defendants "made numerous deceptive statements regarding the results of scientific studies," including "repeatedly mischaracteriz[ing] existing studies and/or ignor[ing] their conclusions or limitations." *Id.* at ¶¶ 23–30. Defendants made these statements in social media posts, in advertisements and promotional materials, on an "Education" page of their website that purported to describe the "Science Behind Xlear," and on a related website (commonsensemedicine.org) used by Xlear. *Id.* at ¶¶ 24, 28-30. For example, Defendants announced in a press release titled "New Studies Conclude Xlear Kills and/or Deactivates SARS-CoV-2" that a University of Tennessee study showed "Xlear's components are antiviral—they block viral adhesion in the nose." *Id.* at ¶¶ 24–26 (citing Ex. C). Contrary to this claim, however, the cited study concerned only "testing done in a test tube, not on people" and "did not show what effect, if any, Xlear nasal spray has on SARS-CoV-2 inside the human nose." *Id.*

The Complaint further alleges that Defendants' "use of deceptive advertising and misinformation to sell their product to concerned consumers during a pandemic poses a risk to public health and safety." *Id.* at ¶ 3. Indeed, some consumers "appear to have based purchasing and treatment decisions on [Defendants' COVID-19] claims." *Id.* at ¶ 33.

LEGAL STANDARD

"After the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." Fed. R. Civ. P. 12(c). "The court reviews a Rule 12(c) motion seeking dismissal of a claim under the same standard it reviews a Rule 12(b)(6) motion for failure to state a claim upon which relief can be granted." *M.S. v. Premera Blue Cross*, No. 2:19-cv-00199, 2020 WL 1692820, at *2 (D. Utah Apr. 7, 2020).

A complaint should not be dismissed so long as it contains "sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 547 (2007)). A claim is plausible on its face "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. The court "accept[s] all well-pleaded facts [in the complaint] as true and view[s] them in the light most favorable to the plaintiff." *M.S.*, 2020 WL 1692820, at *2 (citation omitted).

The reviewing court is required to "draw on its judicial experience and common sense" to evaluate whether the well-pled facts state a plausible claim for relief. *Ashcroft*, 556 U.S. at 678. To clear the plausibility standard, "a complaint need not provide detailed factual allegations"; it need only give "enough factual detail to provide [defendants] fair notice of what the . . . claim is and the grounds upon which it rests." *M.S.*, 2020 WL 1692820, at *2 (citations omitted). Furthermore, it "is generally unacceptable for the court to look beyond the four corners of the complaint when deciding a Rule 12(b)(6) motion to dismiss." *Fischer v. Allstate Fire & Cas. Ins. Co.*, No. 2:22-cv-02267, 2023 WL 3464404, at *2 (D. Colo. May 15, 2023) (citations omitted).

ARGUMENT

I. DEFENDANTS' MOTION IGNORES AND MISCHARACTERIZES THE COMPLAINT'S ALLEGATIONS.

Defendants' Motion disregards the pleading standard applicable to a motion for judgment on the pleadings. Far from "accept[ing] all well-pleaded facts [in the complaint] as true" and drawing all reasonable inferences in favor of the United States, *see M.S.*, 2020 WL 1692820, at *2 (citation omitted), Defendants' motion ignores and mischaracterizes the Complaint's allegations, instead creating and then attacking a strawman version of the United States' claims.

Defendants argue that Plaintiff's claims fail because they rest exclusively on allegations that Defendants made unsubstantiated representations and "[n]owhere do any allegations set forth facts demonstrating that Defendants actually made any false, misleading, or deceptive statements." *See* Mot. at 4. This is not true. The Complaint alleges that Defendants deceptively marketed their product as effective for preventing or treating COVID-19 despite having no valid factual or scientific basis for those claims, *see, e.g.*, Compl. at ¶¶ 3–4, 23, *and* that to further convey the false impression that there was such evidence, Defendants made numerous deceptive statements regarding the results of scientific studies. *Id.* at ¶¶ 23–30. For example, the Complaint alleges that Defendants cited a University of North Carolina Chapel Hill study, asserting that the "study shows that administering treatment through the nose is the best way to treat COVID-19, especially in its early stages." *Id.* at ¶ 24. As detailed in the Complaint, however, the study showed no such thing. *Id.* at ¶ 27.

The Motion expends significant time posing theoretical arguments about whether "all claims that lack substantiation are false or deceptive," Mot. at 10, but whatever academic interest Defendants may have in such questions, their arguments are irrelevant to the issue before this

Court: whether this Complaint contains allegations that, when taken as a whole and considered in the light most favorable to Plaintiff, plausibly state a claim that Defendants have violated the FTC Act and CCPA. It does.

Defendants' arguments about whether "randomized clinical trials are the *only* means by which a party can substantiate a claim," Mot. at 27 (emphasis in original), are likewise irrelevant because the Complaint makes no such allegation.[2] Defendants seize upon a sentence in Paragraph 20 of the Complaint that alleges "no published reports of randomized clinical trials establish the use of Xlear nasal spray as effective in preventing or treating COVID-19," but they ignore that the Complaint is also replete with allegations that Defendants have no competent and reliable scientific evidence of *any other kind* that would support their claims. *See, e.g.*, Compl. at ¶ 20 ("There is no competent and reliable scientific evidence that Xlear nasal spray treats or prevents COVID-19"); *id.* at ¶ 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"). The requirement of competent and reliable scientific evidence is well-established. *See, e.g.*, *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 504 (D.C. Cir. 2015); *FTC v. Pharmtech Rsch., Inc.*, 576 F. Supp. 294, 302 (D.D.C. 1983) ("When an advertiser invokes scientific sources or data in support of health claims for its products, a 'reasonable basis' requires that the claims be supported by competent scientific evidence."); *FTC v. COORGA Nutraceuticals Corp.*, 201 F. Supp. 3d 1300, 1309 (D. Wyo. 2016)

[2] Moreover, the evidence that Defendants offer in support of these arguments (Mot. at 27-30 nn. 59, 64-66) appears nowhere in the Complaint and should not be considered on a motion for judgment on the pleadings. *See supra* 4.

("The FTC typically requires claims about the efficacy or safety of dietary supplements to be supported with competent and reliable scientific evidence") (internal quotation omitted).

Contrary to Defendants' false assertion that no federal circuit court to address the issue found that randomized clinical trials ("RCTs") were necessary, *see* Mot. at 28, the D.C. Circuit Court found that, in the context of the disease claims at issue, one or more RCTs were required. *See, e.g., POM Wonderful*, 777 F.3d at 505 (holding that substantial evidence supported finding that one or more "properly randomized and controlled human clinical trials" "were required to adequately substantiate [defendant's] efficacy claims" as to heart disease and prostate cancer), *cert. denied*, 578 U.S. 965 (2016). But the Court does not need to weigh in on that question to resolve Defendants' Motion. The Complaint alleges that Defendants *lack any competent and reliable evidence at all — in the form of an RCT or otherwise —* to support their COVID-19 claims, and they nonetheless deceptively implied that scientific research supports their claims. Compl. at ¶¶ 23–33. This more than suffices to state a claim under the FTC Act.[3]

[3] In rendering its decision, the Court should decline to consider the proposed memorandum of *amici curiae* filed by the National Health Federation ("NHF") and Citizens for Health ("CFH") on October 15, 2024. *See* ECF No. 150. That submission fails to comply with Local Rules' disclosure requirements regarding the parties' participation in the creation of that brief. *See* L.R. 7-6(d)(1)(C), inexplicably disclosing only that "[t]he legal counsel representing the NHF and CFH authored this Memorandum in part." ECF No. 150 at 3. To the extent that the Court considers the merits of that brief, the arguments raised by the NHF and CFH are irrelevant as they amount to purported public policy arguments against the requirement that "health-related claim[s]" be supported by multiple RCTs, *see* ECF No. 150-1 at 4, an issue which the Court need not decide now. Moreover, to the extent that these arguments had any relevance to the instant Motion (they do not), they are based on evidence which is outside the four corners of the Complaint and therefore should not be considered by the Court. *See supra* at 4.

II. THE COMPLAINT ADEQUATELY ALLEGES CONDUCT THAT VIOLATES THE FTC ACT AND CCPA.

Defendants' Motion is predicated on a false premise: that unsubstantiated marketing claims cannot constitute "Deceptive Acts or Practices" under the FTC Act. This misunderstands the plain text of the FTC Act (and the CCPA by extension), the relevant case law regarding substantiation, and the FTC's appropriate role in interpreting the FTC Act.

A. The Plain Text of the FTC Act and CCPA Make Clear that Xlear's Alleged Representations are Violations.

Section 5 of the FTC Act declares unlawful "unfair or deceptive acts or practices in or affecting commerce," and "empower[s] and direct[s]" the FTC to prevent persons from using such acts or practices. 15 U.S.C. § 45(a)(1)-(2). Section 12 of the FTC Act states that it is an unfair or deceptive act or practice "to disseminate, or cause to be disseminated, any false advertisement . . . for the purpose of inducing, or which is likely to induce . . . the purchase of foods, drugs, devices, or cosmetics." 15 U.S.C. § 52. The FTC Act further defines a "false advertisement" as "an advertisement, other than labeling, which is misleading in a material respect," and instructs that "in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested . . . , but also the extent to which the advertisement fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use of the [advertised] commodity[.]" *Id.* § 55.

On its face, the text of the FTC Act thus forecloses Defendants' position that an advertisement cannot be false, misleading, and deceptive if it does not affirmatively state facts proven to be false; the statute expressly contemplates that an advertisement may be misleading based upon "representations made or suggested" and for failing to reveal facts that are material in

light of those representations. *See FTC v. Grand Canyon Educ., Inc.*, No. CV-23-02711-PHX-DWL, 2024 WL 3825087, at *13 (D. Ariz. Aug. 15, 2024) (quoting *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1154 (9th Cir. 1984)) ("The failure to disclose material information may cause an advertisement to be deceptive, even if it does not state false facts."); *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1099 (9th Cir. 1994) ("Indeed, a 'false advertisement' need not even be 'false'; it need only be 'misleading in a material respect.'").

An act or practice is deceptive if there is a representation (either express or implied), omission, or practice that is likely to mislead consumers acting reasonably under the circumstances, and the representation, omission, or practice is material. *See FTC v. Gill*, 265 F.3d 944, 950 (9th Cir. 2001); *see also FTC v. Cap. Choice Consumer Credit, Inc.*, No. 02-21050 CIV, 2004 WL 5149998, at *32 (S.D. Fla. Feb. 20, 2004) ("[I]mplied claims as well as express claims may be deceptive."), *aff'd*, 157 F. App'x 248 (11th Cir. 2005). "Deception may be found based on the 'net impression' created by a representation." *Grand Canyon*, 2024 WL 3825087, at *13 (*quoting FTC v. Stefanchik*, 559 F.3d 924, 928 (9th Cir. 2009)). Thus, a "solicitation may be likely to mislead by virtue of the net impression it creates even though the solicitation also contains truthful disclosures." *Grand Canyon*, 2024 WL 3825087, at *13 (internal quotation omitted)*; see also Donaldson v. Read Magazine, Inc.*, 333 U.S. 178, 188, (1948) ("Advertisements as a whole may be completely misleading although every sentence separately considered is literally true.").

The CCPA makes it unlawful under Section 5 of the FTC Act "for any person, partnership, or corporation to engage in a deceptive act or practice in or affecting commerce . . . associated with the . . . treatment, cure, prevention, mitigation, or diagnosis of COVID–19. . . [or] a

government benefit related to COVID–19." COVID-19 Consumer Protection Act, Pub. L. No. 116-260, 134 Stat. 3275, 3276 (December 27, 2020).

Against this backdrop, it is difficult to imagine what conduct could possibly fit the common-sense understanding of the terms "deceptive" and "misleading" if not, as Defendants have done, marketing a product with claims that it is effective for the prevention or treatment for a particular disease without proof to support those claims, Compl. at ¶¶ 2-3, 19-20, 21-22, 39-40, 45-46, in addition to making deceptive and misleading statements about scientific studies to give consumers the false impression that those representations have scientific support, *id.* at ¶¶ 23–30.

Defendants insist that the FTC Act does not prohibit unsubstantiated claims because the words "substantiation" and "unsubstantiated" do not appear in the statute. Mot. at 10. What they overlook is that the term "deceptive" under the FTC Act is sufficiently broad to encompass unsubstantiated claims. As the FTC explained more than fifty years ago, and as federal courts have agreed, unsubstantiated claims are deceptive because they give consumers the false impression that the advertiser has proof of its claims. *See Firestone Tire & Rubber Co. v. FTC*, 481 F.2d 246, 251 (6th Cir. 1973) ("[W]e conclude that the Commission's finding (that Firestone's 'broad stopping claim' was 'unfair and deceptive to consumers' because it was 'without substantial scientific test data to support it') was supported by the evidence in this record . . . ."); *Nat'l Dynamics Corp.*, 82 F.T.C. 488, 549-50 (1973) ("[T]he absence of a reasonable basis to support such claims would not only be a material fact, the knowledge of which might significantly affect consumer purchase decisions, but it would also mislead in light of the implied representation of substantiation."); *accord POM Wonderful*, 777 F.3d at 490 ("If an ad conveys an efficacy claim, the advertiser must possess a 'reasonable basis' for the claim.") (citing *Pfizer Inc.*, 81 F.T.C. 23,

26 (1972)); *Am. Fin. Servs. Ass'n v. FTC.,* 767 F.2d 957, 980 n.27 (D.C. Cir. 1985) ("[U]nsubstantiated claims are deceptive because consumers expect that the advertiser has some basis for making the claim."). Defendants' advertising claims create the "implied representation of substantiation," and because no such adequate substantiation exists, the claims are deceptive under the FTC Act. Thus, it is well-established that the "best reading" of the "unfair or deceptive acts" in the FTC Act encompasses precisely the type of unsubstantiated claims alleged in this case.

Defendants counter that "[n]ot all claims that lack substantiation are false or deceptive," reasoning that some untested claims may be true. Mot. at 10. This argument misses the mark for two reasons. First, the question of whether "all claims" that lack substantiation violate the FTC Act is not before the Court. The relevant inquiry is the far narrower question of whether the Complaint adequately alleges that Defendants' unsubstantiated COVID-19 claims and false and misleading representations about scientific research violated the FTC Act and CCPA. As discussed above, *see supra* 8, that answer to that question is clearly yes. Second, an unsubstantiated claim need not be proven "false" to be "deceptive" or "misleading" for purposes of the FTC Act.

Indeed, it is well-established that literally true statements may still be deceptive under the FTC Act. *See, e.g., FTC v. NCH, Inc.*, 106 F.3d 407, 1997 WL 22246 (9th Cir. 1997) (unpublished) ("A representation is deceptive and violates Section 5 [of the FTC Act] if its net impression is likely to mislead consumers, even if the representation is literally true."); *Kraft, Inc. v. FTC*, 970 F.2d 311, 322 (7th Cir. 1992) ("[E]ven literally true statements can have misleading implications."); *Thompson Med. Co. v. FTC*, 791 F.2d 189, 197 (D.C. Cir. 1986) (quoting favorably the FTC's summation that "literally true statements may nonetheless be found deceptive"). As the D.C. Circuit explained in *Thompson Medical*, "[i]f and when [the defendant]

comes up with evidence that [its product] is effective, it will be free to again make efficacy claims in its advertising. Until that time, it should not say what it cannot prove." 791 F.2d at 197; *id.* at 193 ("We decline to hold that firms may not be prevented from advertising their products as efficacious until they are proved otherwise. Such a conclusion would turn the statutory scheme on its head."). The Court should find, consistent with the text of FTC Act and the CCPA, that the Complaint alleges cognizable claims against Defendants.

B. Congress Intended to Prohibit Unsubstantiated Disease Claims as Deceptive.

In drafting the FTC Act, Congress adopted a broad reading of the terms "unfair or deceptive acts" and "false advertising," and has charged the FTC with interpreting and applying those broad terms in practice. As such, the FTC's interpretation that an advertiser's unsubstantiated claims are deceptive acts prohibited by the statute is entitled to deference. Defendants attempt to rebut this position by arguing that, "to the extent the Commission heretofore would have relied on *Chevron* deference for help here, under [*Loper Bright*], that avenue is blocked." Mot. at 2. But no reliance on *Chevron* is necessary to deny Defendant's Motion. Moreover, *Loper Bright* confirms that the Court should give weight to an agency's past practice and expertise in cases such as this. 144 S. Ct. at 2247 ("Courts exercising independent judgment in determining the meaning of statutory provisions, consistent with the [Administrative Procedures Act ("APA")], may—as they have from the start—seek aid from the interpretations of those responsible for implementing particular statutes") (*citing Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)).

The legislative and judicial history of the FTC Act and the CCPA demonstrate Congress's intent that the Acts' prohibitions were meant to be flexibly interpreted by the FTC. *See, e.g.*, H.R. Rep No. 75-1316, at 5 (1937) ("The definition is broad enough to cover every form of

advertisement deception over which it would be humanly practicable to exercise government control."). Defendants' own authorities support this position. For example, Defendants rely on a single phrase from *FTC v. Colgate-Palmolive Co.*, Mot. at 7 n.12, but conspicuously ignore the two paragraphs preceding this cherry-picked quotation, which state in no uncertain terms that the FTC Act's statutory scheme gives the Commission an influential role in interpreting that statute. *See FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 384–85 (1965). Therein, the Court emphasized that the statutory scheme underlying the FTC Act:

> *necessarily gives the Commission an influential role in interpreting [Section] 5 and in applying it to the facts of particular cases arising out of unprecedented situations*. Moreover, as an administrative agency which deals continually with cases in the area, *the Commission is often in a better position than are courts to determine when a practice is 'deceptive' within the meaning of the Act*. This Court has frequently stated that the Commission's judgment is to be given great weight by reviewing courts. This admonition is especially true with respect to allegedly deceptive advertising since the finding of a [Section] 5 violation in this field rests so heavily on inference and pragmatic judgment.

Id. (emphasis added) (internal citations omitted).

As made clear by decisions following *Loper Bright*, courts should still defer to an agency's interpretation where, as here, a statute expressly delegates interpretive authority to an agency or allows the agency to "fill up the details of a statutory scheme." *Clinkenbeard v. King*, No. 0:23-cv-03151, 2024 WL 4355063, at *4 (D. Minn. Sept. 30, 2024) (citing *Loper Bright*, 144 S. Ct. at 2263). Furthermore, in *Skidmore v. Swift & Co.*, decided decades *before Chevron*, the Supreme Court explained that a federal agency's "rulings, interpretations and opinions" under its implementing statute, "constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance." 323 U.S. at 140. Following *Skidmore*, federal

courts have consistently adopted the FTC's interpretation of deceptive conduct under the FTC Act. As one court explained: The FTC "is often in a better position than are courts to determine when a practice is 'deceptive' within the meaning of the [FTC] Act," and that "admonition is especially true with respect to allegedly deceptive advertising since the finding of a [Section] 5 violation in this field rests so heavily on inference and pragmatic judgment." *POM Wonderful* 777 F.3d at 490 (quoting *Colgate–Palmolive Co.*, 380 U.S. at 385); *see also FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 454 (1986) ("The legal issues presented . . . [are] for the courts to resolve, although even in considering such issues the courts are to give some deference to the Commission's informed judgment that a particular commercial practice is to be condemned as 'unfair.'"); *ECM BioFilms, Inc. v. FTC*, 851 F.3d 599, 609 (6th Cir. 2017) ("Because the FTC 'deals continually' with deception cases, 'the Commission is often in a better position than are courts to determine when a practice is deceptive") (quoting *Colgate–Palmolive Co.*, 380 U.S. at 385).

Despite Defendants' argument to the contrary, nothing in *Loper Bright*, suggests that the Court should depart from this well-settled practice of deferring to the FTC's interpretation of the FTC Act. To the contrary, *Loper Bright* specifically endorses *Skidmore*. *See* 144 S. Ct. at 2247.

Moreover, *Loper Bright* expressly instructed that the Court's holding did "not call into question prior cases that relied on the *Chevron* framework," and that the holdings of such cases "are still subject to *stare decisis*[.]" 144 S.Ct. at 2273. *Loper Bright* therefore provides no justification for Defendants to ignore the more than five decades of case law recognizing that advertisements making baseless claims are properly condemned as false, deceptive, and misleading violations of the FTC Act.

Defendants nevertheless argue that the absence of any specific reference to "substantiation" in the FTC Act is proof that Congress did not intend to prohibit unsubstantiated claims because it could have included such language "either at the statute's enactment or by subsequent amendment." Mot. at 11. This argument makes no sense. Congress has no reason to amend a statute that is being enforced as it intended. As detailed above, Congress delegated wide latitude to the FTC in determining what constitutes deceptive conduct under the FTC Act, *see supra* 12-14, and the FTC and the federal courts have been consistent in finding that the FTC Act prohibits unsubstantiated claims for more than a half-century. As Defendants note, if this interpretation was inconsistent with Congress's intent in enacting the FTC Act, it could have amended the statute to limit the FTC's latitude or to prohibit such claims. *Id.* The fact that Congress has chosen not to amend the FTC Act to alter the FTC's longstanding practice weighs heavily against Plaintiff's interpretation. *See also NLRB v. Canning*, 573 U.S. 513, 525 (2014) ("[T]he longstanding 'practice of the government' . . . can inform our determination of 'what the law is' . . . ."); *id.* ("this Court has treated practice as an important interpretive factor even when the nature or longevity of that practice is subject to dispute, and even when that practice began after the founding era").

The CCPA provides further evidence of Congress's intent. When Congress enacted the CCPA, it did so against a long and consistent history of the FTC Act being applied to prohibit unsubstantiated claims. Rather than exclude those claims, however, Congress chose specifically to apply the FTC's framework to conduct relating to COVID-19. *See supra* 9-10. Congress' enactment of the CCPA demonstrates that it specifically intended the FTC's interpretation of "deceptive" conduct to apply to COVID-19.

Defendants point out that an amendment to the Food, Drug, and Cosmetic Act ("FDCA")—which they mistakenly refer to as "the FDA Act"—contains the word "substantiation," but this is irrelevant. *See* Mot. at 11-12. Plaintiff's claims are brought pursuant to the FTC Act and the CCPA, not the FDCA. The fact that a different statute, implemented by a different agency, and regulating one specific class of products contains different language says nothing about the FTC Act. *See Bristol-Myers Co. v. FTC*, 738 F.2d 554, 559 (2d Cir. 1984) ("Insofar as FDA requirements and regulations are concerned, they simply do not govern this case.").

C. This Action is Consistent with Prior FTC Act and CCPA Enforcement.

For decades, the FTC and federal courts have consistently applied the FTC Act, and now also the CCPA, against conduct like what is alleged here. Defendants argue that, prior to the FTC's decision in *Pfizer, Inc.*, "the Commission did not purport to require or even discuss substantiation." Mot. at 18. This is simply not true. The Commission recognized the FTC Act's substantiation requirements long before *Pfizer*. For example, in *Heinz W. Kirchner*, the FTC affirmed a general duty for advertisers to ensure claims were substantiated. In dictum, the Commission stated:

> [W]e are inclined to think that an advertiser is under a duty, *before* he makes any representation which, if false, could cause injury to the health or personal safety of the user of the advertised product, to make reasonable inquiry into the truth or falsity of the representation. He should have in his possession such information as would satisfy a reasonable and prudent businessman, acting in good faith, that such representation was true. To make a representation of this sort, without such minimum substantiation, is to demonstrate a reckless disregard for human health and safety, and is clearly an unfair and deceptive practice.

63 F.T.C. 1282 (1963) (emphasis in original).

Defendants nevertheless insist that *Pfizer* was a deviation from the FTC's prior practice by claiming that "[t]he origin of the Commission's position that a marketer must have a 'reasonable basis' for its claims can be traced—not to any statutory analysis by a court—but directly to the

Commission itself." Mot. at 19. In so doing, Defendants attempt to distinguish the D.C. Circuit's decision in *Tashof v. FTC,* 437 F.2d 707, 715 (D.C. Cir. 1970), which the FTC relied on in *Pfizer*. But, contrary to Defendant's arguments, *Tashof* is directly on point. There, the D.C. Circuit upheld an FTC order compelling the defendant "to cease and desist from representing that it sells 'any article of merchandise' at a discount price . . . unless it first takes a 'statistically significant survey' which shows that the prevailing price" is higher. *See id*. In other words, the D.C. Circuit found the defendant could not legally claim that its goods were sold at a discount without substantiation. Defendants' argument that *Tashof* "merely affirmed a remedial order" (Mot. at 19) is inapposite. In upholding the Commission's order requiring a survey, the Court made clear that such a survey was necessary to "preclude the revival of the illegal practices" and was a "reasonable business procedure" to "prevent repetition of that wrong." *Tashof,* 437 F.2d at 715. Thus, in affirming the FTC's order, the Court made clear that a business making discount price claims without basis would be an "illegal practice[]." *See id.*

Defendants further assert that "[c]ases decided since *Pfizer,* even those that impose a substantiation requirement, do not support imposition of any requirement to show substantiation absent an initial finding of false or deceptive marketing," reasoning that a substantiation requirement can only be imposed as "part of a remedial order after the respondent had been found to have engaged in false or misleading advertising." Mot. at 22-25. Once again, Defendants' assertion is simply false. Numerous courts have recognized that the FTC Act requires advertisers of health and disease claims to have adequate substantiation for those claims, and that dissemination of unsubstantiated claims violates the Act regardless of whether the violator was subject to a prior remedial order. In *Pharmtech*, 576 F. Supp. at 294, for example, the court granted

a preliminary injunction where the FTC established a likelihood of success "on its claims that the defendant lacks a reasonable basis for its claims that the use of Daily Greens reduces the risk of cancer." *See also id.* at 302 ("Section 5 requires a manufacturer to have a 'reasonable basis' for any affirmative performance claims for a product. . . . Absent such a reasonable basis, the advertisement is unfair . . . and deceptive." (citations omitted) (collecting cases)). And in *Thompson Med. Co.*, while the D.C. Circuit affirmed an FTC order preventing a violator from making future unsubstantiated claims, that provision was justified by a finding that the defendant had *already* violated the FTC Act in the first instance by making representations about Aspercreme's efficacy when "there was no reasonable basis shown" for such claims. 791 F.2d 189 at 197; *see also id.* at 193 ("[I]n general an advertisement is considered deceptive if the advertiser lacks a 'reasonable basis' to support the claims made in it.").

Indeed, the very cases cited by Defendants confirm that advertisers who make unsubstantiated claims may be liable under the FTC Act. *See, e.g., Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1249 (2d Cir. 1979) ("[I]f a representation is true, the argument runs, no one is deceived or treated unfairly by the mere lack of prior substantiation. But *cases both without and within this circuit have held otherwise in situations where a seller or manufacturer has misrepresented safety or performance*.") (emphasis added). This is consistent with other cases finding that liability attached for unsubstantiated claims under the FTC Act. *See supra* 8-12, 16-17. Defendants' apparent reading of these cases (that a prior finding of wrongdoing was necessary for liability to attach for unsubstantiated claims) compels a ridiculous result, as it would permanently insulate advertisers' unsubstantiated claims provided they were not found liable for some other reason. This is not the law. Nor is it logical to infer, as Defendants apparently do, that because some FTC

orders contain substantiation requirements that have been justified in part by the violator's prior unlawful acts, the FTC Act does not prohibit unsubstantiated marketing claims.

The issue of "fencing in," as discussed in the cases Defendants cite, refers to a provision of remedial orders issued by the FTC prohibiting (among other things) dissemination of false or deceptive advertisements about a product and/or representations about the efficacy of a product unless they are adequately supported. For example, Defendants argue that the Supreme Court had only "blessed" the imposition of a substantiation requirement in limited circumstances. *See* Mot. at 22. Contrary to Defendants' description, however, the actual language of these cases makes clear that the Supreme Court afforded the FTC broad leeway in enforcing the FTC Act. As the Court explained: "(t)he Commission has wide discretion in its choice of a remedy deemed adequate to cope with the unlawful practices' disclosed." *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952) (quoting *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611 (1946)); *see also FTC v. Nat'l Lead Co*., 352 U.S. 419, 428 (1957) ("[T]he Court named the Commission 'the expert body to determine what remedy is necessary to eliminate the unfair or deceptive trade practices which have been disclosed. It has wide latitude for judgment and the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist.'"). Indeed, each of the cases that Defendants cite *upheld* the fencing in requirement. Thus, to the extent that Defendants suggest that these cases limit Plaintiff's ability to enforce substantiation claims under the FTC Act, that misunderstands the case law. At most, these cases demonstrate that—should Defendants be found liable—inclusion of a prior substantiation requirement would likely be appropriate.

Defendants nevertheless attempt to undermine *Pfizer's* application to this case by touting that "the Commission in *Pfizer* grounded its decision in the 'unfairness' prong of the FTC Act,

rather than the' "deceptive' prong" because of the differing standards between "unfair" and "deceptive" claims. *See* Mot. at 21-22. However, substantiation claims may appropriately fall under *both* the unfair and deceptive prongs. *See, e.g., Pharmtech*, 576 F. Supp. at 302 ("The Commission has also employed a reasonable basis test as a means of determining whether an advertisement is unfair or deceptive. . . . Absent such a reasonable basis, the advertisement is unfair, and deceptive.") (internal quotation omitted). Indeed, in *Nat'l Dynamics Corp.*, decided less than a year after *Pfizer*, the FTC made clear that: "performance claims lacking a reasonable basis in fact *may be found deceptive* within the meaning of Section 5 of the Federal Trade Commission Act." 82 F.T.C. 488 (1973) (emphasis added). Here, the Complaint alleges that Defendants' unsubstantiated claims are a deceptive practice. *See* Compl. ¶¶ 51–52. As such, Defendants' arguments regarding the "unfair" prong are irrelevant. *See* Mot. at 22.

Defendants further argue, without citation to any case law, that interpreting the FTC Act as prohibiting unsubstantiated disease claims is a "self-determined, extra-statutory standard [the FTC] has created by agency fiat." Mot. at 4. This dramatic proclamation ignores that *federal courts* interpreting the FTC Act have consistently found that "deceptive" practices under the FTC Act include unsubstantiated claims. *See, e.g., Direct Mktg. Concepts, Inc.*, 624 F.3d at 8 ("[W]here the advertisers . . . lack a reasonable basis, their ads are deceptive as a matter of law."); *see also Thompson Med. Co., Inc*. 791 F.2d at 193 ("[I]n general an advertisement is considered deceptive if the advertiser lacks a reasonable basis to support the claims made in it.") (internal quotations omitted); *FTC v. OMICS Grp. Inc.*, 302 F. Supp. 3d 1184, 1190 (D. Nev. 2017) ("Where the maker

lacks adequate substantiation evidence, they necessarily lack any reasonable basis for the claims."). The case law on this point is voluminous and consistent.[4]

Nowhere in the Motion do Defendants cite a single case which reaches the opposite conclusion. Instead, Defendants inexplicably cite the Seventh Circuit's opinion in *FTC v. QT, Inc.*, 512 F.3d 858 (7th Cir. 2008) for the proposition that the FTC Act does not require substantiation. *See* Mot. at 8. But *QT* does not support Defendant's claim. Far from it, the *QT* court made clear that "[p]roof is what separates an effect new to science from a swindle." *QT, Inc.*, 512 F.3d at 862. Accordingly, the Seventh Circuit upheld the lower court's ruling that the defendant's statements that a bracelet's efficacy in treating pain had been "test-proven" were deceptive under the FTC Act. *Id.* As the Seventh Circuit explained, the statement "test-proven" was "misleading unless a reliable test had been used and statistically significant results achieved." *Id.*[5] This conclusion is entirely consistent with Plaintiff's allegations in this case, where Plaintiff alleges that Defendants' proffered tests are inadequate to substantiate their claims that, *inter alia*, Xlear provides "additional tested protection for up to four hours, helping keep you and others around you safe." Compl. at ¶ 21(a). Defendant's cherry-picked quotation, which addresses only whether the FTC Act specifically requires "placebo-controlled, double-blind studies" in *all* cases, *see* Mot. at 8, says

[4] *See also, e.g., COORGA Nutraceuticals*, 201 F. Supp. 3d at 1312 ("Defendants' efficacy claim . . . is unsubstantiated and, therefore, Defendants lack a reasonable basis for the claim"); *FTC v. Alcoholism Cure Corp.*, No. 3:10-CV-266-J-34JBT, 2011 WL 13137951, at *26 (M.D. Fla. Sept. 16, 2011) ("Where advertisers lack a reasonable basis for their advertisements, their advertisements are deceptive as a matter of law.").

[5] In reaching this conclusion, the Court emphasized that it was not enough that the defendants relied on some form of testing to support their claims, where "[t]he 'tests' on which they relied were bunk." *QT*, 512 F.3d at 862.

nothing about whether Defendants are permitted to make unsubstantiated claims that their product effectively treats or prevents COVID-19. They are not.

The brief history of the CCPA further supports this interpretation. In *United States v. Nepute*, for example, the government alleged that the defendant violated the FTC Act and the CCPA by making unsubstantiated claims that supplements containing Vitamin D and/or zinc are effective for the treatment, cure, prevention, or mitigation of COVID-19, and that they provide equal or better protection against COVID-19 than available vaccines. No. 4:21-cv-00437, 2023 WL 4623089, at *1 (E.D. Mo. July 19, 2023). The *Nepute* Court granted partial summary judgment to the government on the issue of whether the defendant had a reasonable basis to make these claims—finding that he did not. *Id.* at *19 Thus, while the posture is different, the *Nepute* case demonstrates that the FTC Act's "reasonable basis" requirement properly applies to COVID-19-related claims under the CCPA.

Thus, contrary to Defendants' arguments, this case is part of a consistent pattern of FTC Act enforcement actions targeting unsubstantiated claims.

III. THE COURT NEED NOT REACH XLEAR'S MERITLESS CONSTITUTIONAL AND MAJOR QUESTIONS DOCTRINE ARGUMENTS.

Defendants' arguments that this enforcement action is unconstitutional—like the other arguments in their Motion—mischaracterize the Complaint and ignore its actual allegations. Defendants argue that "prohibit[ing] every unsubstantiated claim on every product, regardless of whether the claim is true, and irrespective of the type of product at issue or the circumstances presented," would violate the First Amendment. Mot. at 13–15. But that abstract argument is irrelevant to *this case*, which alleges that Defendants misleadingly marketed and sold a product as effective for preventing or treating a particular disease without having valid evidence that it

actually does, and misrepresented scientific studies to give consumers the false impression that their marketing claims had scientific support. This case does not, as Defendants posit, depend on "only" an allegation "that a claim was made and a bald contention that it was not substantiated" or upon a supposed "substantiation fiat." *Id.* at 16 and 25. Because Defendants' constitutional arguments do not address the Complaint's actual allegations, the Court need not, and should not, decide them. "In the interest of judicial restraint, a court should not decide a constitutional question unless it is absolutely necessary to the court's decision." *Overstreet ex rel. NLRB v. SFTC, LLC*, 943 F. Supp. 2d 1296, 1304 (D.N.M. 2013).

Even if the Court were to reach Defendants' arguments that the case violates the First Amendment, the Equal Protection Clause, and the Major Questions Doctrine ("MQD"), it should reject those arguments as meritless, just as other courts have.

A. This Action Does Not Violate the First Amendment.

Defendants argue that barring "all claims that are not substantiated, whether or not those claims are true, plainly implicates serious First Amendment concerns." Mot. at 13; *id.* at 15 ("A reading of the FTC Act that prohibits every unsubstantiated claim on every product, regardless of whether the claim is true, and irrespective of the type of product at issue or the circumstances presented, is overbroad and cannot survive constitutional scrutiny"). As an initial matter, the Complaint nowhere alleges that the FTC Act bars "*all* claims that are not substantiated." Nor does it depend on a reading of the FTC Act that *every* unsubstantiated claim on *every* product, "irrespective of the type of product at issue or circumstances presented" is prohibited. The constitutionality of those broad propositions are not before the Court. Rather, this case concerns

whether Defendants' lack of substantiation rendered their statements deceptive. Case law makes clear that deceptive commercial speech is not protected by the First Amendment.

The Supreme Court has afforded varying degrees of First Amendment protection to different categories of speech. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 64 (1983). Although not wholly unprotected, commercial speech is afforded less protection than other forms of expression. *Id* Furthermore, "[f]or commercial speech to come within the First Amendment, it at least must concern lawful activity and not be misleading." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'r of N.Y.*, 447 U.S. 557, 566 (1980); *see also POM Wonderful*, 777 F.3d at 499 (declining to find deceptive commercial speech to be protected by the First Amendment). In other words, there is no First Amendment protection for misleading advertisements. *See Daniel Chapter One v. FTC*, 405 F. App'x 505, 506 (D.C. Cir. 2010) ("Deceptive commercial speech is entitled to no protection under the First Amendment."). Consequently, "[m]isleading advertising may be prohibited entirely." *In re R.M.J.*, 455 U.S. 191, 203 (1982).

On a motion for judgment on the pleadings, Defendants cannot dispute that the representations at issue in the Complaint are deceptive commercial speech. Speech is commercial if: (i) it is contained in an advertisement; (ii) it is made with an economic motive; or (iii) it refers to a specific product. *See Proctor & Gamble Co. v. Haugen*, 222 F.3d 1262, 1273 (10th Cir. 2000). All three factors are met. The challenged representations are contained in advertisements posted on Xlear's website (Compl. Ex. A, G); social media pages (Compl Ex. B, D); magazine advertorials (Compl. Ex. F); or in press releases issued by Xlear (Compl. Ex. C, E). Each of these advertisements refers to Xlear's nasal spray product by name and touts its effectiveness in the treatment or prevention of COVID-19. As noted in the Complaint, however, these representations

are deceptive because they lack any valid factual or scientific basis, *id.* at ¶¶ 3, 20, 22, 40, and because they mischaracterize scientific studies to give the false impression that "there is evidence to support their claims about Xlear nasal spray," *id.* at ¶¶ 23–30. Thus, the representations referred to in the Complaint are unprotected as deceptive commercial speech.

A finding that Defendants' statements constitute unprotected, deceptive commercial speech is in line with similar cases. For example, the court in *Pharmtech*, 576 F. Supp. at 294, granted a preliminary injunction enjoining the defendant from representing that the use of its dietary supplement "is associated with a reduction in the incidence of cancer in human beings or with building human biological defenses unless, at least 30 days prior to the dissemination of any such representation or claim, defendant possesses and furnishes to [FTC] competent and reliable scientific evidence that substantiates any such representation or claim." *Id.* at 304. The court properly rejected the defendant's argument that the prohibition on such false or misleading advertising "would raise a serious First Amendment Question." *Id.* at 303. Other federal courts consistently reached this same conclusion. *See, e.g.*, *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 399 (9th Cir. 1982) ("[T]he Commission may require prior reasonable substantiation of product performance claims after finding violations of the [FTC] Act, without offending the [F]irst [A]mendment."); *Bristol-Myers Co. v. FTC*, 738 F.2d 554, 562 (2d Cir. 1984) ("Nor is the prior substantiation doctrine as applied here in violation of the First Amendment."); *Jay Norris, Inc.*, 598 F.2d at 1251–52 ("The use of the requirement of substantiation as regulation is clearly permissible."); *accord FTC v. Affiliate Strategies, Inc*., No. 5:09-cv-04104, 2010 WL 11470103, at *9 (D. Kan. June 8, 2010) ("The FTC's advertising substantiation requirements have withstood repeated First Amendment challenges").

Defendants' assertion that "[t]hey sought to educate the public about ways to fight a global pandemic" does not alter this conclusion. Mot. at 13. First, it inappropriately departs from the four corners of the Complaint, which contain no such allegations regarding Defendants' purported educational goals. Second, speech can be categorized as commercial "notwithstanding the fact that [it] contain discussions of important public issues." *Bolger*, 463 U.S. at 67–68; *see also Porous Media Corp. v. Pall Corp.*, 173 F.3d 1109, 1121 (8th Cir. 1999) (explaining that "'commercial speech' need not originate *solely* from economic motives" and that a defendant's speech was commercial in nature despite his purported "nobler concerns") (emphasis in original). "Advertisers should not be permitted to immunize false or misleading product information from government regulation simply by including references to public issues." *Bolger*, 463 U.S. at 68. The Supreme Court has made clear that "advertising which 'links a product to a current public debate' is not thereby entitled to the constitutional protection afforded noncommercial speech." *Id.* (quoting *Cent. Hudson*, 447 U.S. at 563).

As such, because Plaintiff's alleged unsubstantiated and misleading representations are deceptive commercial speech, they are not afforded protection under the First Amendment.

B. This Action Does Not Violate the Equal Protection Clause.

Defendants next argue that the Government's "attempt to create a substantiation requirement improperly shifts its burden of persuasion onto Defendants in violation of the Equal Protection Clause." Mot. at 15. This claim appears to flow from Defendants' unfounded contention that allegations that they engaged in false, deceptive, or misleading advertising by making unsubstantiated claims do not show "a violation of the statutory provision (that is, that the

claim is false or deceptive)," and are therefore insufficient to require defendants to bear the burden of proving they did not violate the FTC Act. *Id.* at 16-17.

As discussed above, however, allegations that a defendant advertised its product as effective in preventing or treating disease without support for those claims is a core violation of the FTC Act. *See supra* 8-12. As the Complaint makes clear, Defendants have widely advertised their saline nasal spray as a product that is capable of preventing and treating COVID-19. *Id.* at ¶¶ 2, 19, 21, 39, 45-46. These advertisements included statements such as: "[s]ocial 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." *Id.* at ¶ 21(a) (citing Exhibit A). Statements like this give the reasonable consumer the impression that they are substantiated by competent and reliable scientific evidence, when in reality they are not. *Id.* at ¶¶ 3, 20, 22, 40. The Complaint thus clearly does allege cognizable violations of the FTC Act's prohibition on false or deceptive advertising.

Tellingly, Defendants cannot point to a single case in which a Court has found that the FTC Act's prohibition on unsubstantiated claims violated the Equal Protection Clause by impermissibly shifting the burden of proof to Defendants. This is unsurprising, as it does not.[6] In an effort to fill

[6] In a footnote, Defendants make the bald assertion that that the FTC is "seek[ing] to circumvent the APA by issuing mere guidance and not a rule." Mot. at 16 n.37. It is not clear what "guidance" Defendants refer to but, in any event, nothing in the Complaint invokes APA concerns and Defendants have asserted no APA claims. As such, Defendants' argument is unintelligible and the Court should reject it based on this scant briefing. To the extent that Defendants are arguing that the FTC's substantiation standard should have been promulgated through traditional rulemaking, that argument lacks merit. *See, e.g., POM Wonderful*, 777 F.3d at 497 (explaining that it "is well settled that an agency is not precluded from announcing new principles in an adjudicative proceeding, and that the choice between rulemaking and adjudication lies in the first instance within the agency's discretion.") (internal quotations omitted).

the void, Defendants cite *Basic Rsch., LLC v. FTC*, No. 2:09-cv-00779, 2014 WL 12596497, at *8 (D. Utah Nov. 25, 2014) for the proposition that "FTC must make a *prima facie* case before shifting the burden on to the defendant to show substantiation." Mot. at 16 n.38. But Defendants' reliance on *Basic Research* is misplaced at best, and misleading at worst. The court there was discussing not the pleading requirements to state an FTC Act violation, but the burden of *proof* carried by the FTC to establish that the defendant violated an agreement with the Commission. *Basic Rsch.*, 2014 WL 12596497, at *8. And critically, the court identified no Equal Protection concerns when finding that the FTC would carry its burden if it showed that the defendant "(1) made claims or representations that fell within the terms of the [Agreement], and (2) that [defendant] did not have a reasonable basis to make the claims or representations because it lacked competent and reliable scientific evidence." *Id.* (explaining that at that point "the burden then shifts to [defendant] to show that it did have competent and reliable scientific evidence to support its claims or representations").

Defendants next invoke the Supreme Court's decision in *Director, Office of Workers' Compensation Programs, Department of Labor v. Greenwich Collieries*, 512 U.S. 267, 269 (1994), but that case is inapposite. In *Greenwich Collieries*, the Supreme Court found that the Department of Labor's application of a "true doubt" rule for benefits claims would "shift[] the burden of persuasion to the party opposing the benefits claim" because "when the evidence is evenly balanced, the benefits claimant wins." *Id.* The Supreme Court held that this scheme was inconsistent with Section 7(c) of the APA, which states that "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d); s*ee also Greenwich Collieries*, 512 U.S. at 269. That case bears no relationship to the one at hand. As a preliminary matter, the issue before the Court is not a rulemaking under the APA, but the proper

interpretation of the FTC Act. Moreover, nothing in the Complaint or the FTC Act dictates that "when the evidence is evenly balanced," the FTC wins. As explained above, Plaintiff has alleged facts sufficient to carry its pleading burden. Accordingly, the Court should reject Defendants' unsupported Equal Protection Clause argument.

C. This Action Does Not Violate the Major Questions Doctrine.

Defendants argue that the Court should dismiss this lawsuit because the FTC's enforcement of the substantiation requirement is "a major federal action lacking specific statutory authority."[7] Mot. at 26. Not so. Because this lawsuit is entirely consistent with more than 50 years of past practice, and in light of the broad authority conferred on the FTC by Congress to enforce the FTC Act, the MQD does not apply. The MQD requires federal agencies, under certain circumstances, to "point to clear congressional authorization to regulate" in a certain manner. *See West Virginia v. EPA*, 597 U.S. 697, 732 (2022) (internal quotation omitted). The doctrine is reserved for "extraordinary" cases, "in which the history and the breadth of the authority that [the agency] has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority." *Id.* at 721 (internal quotations omitted). The MQD applies where "an agency claims to discover in a long-extant statute an unheralded power to regulate 'a significant portion of the American economy'" or make "decisions of vast 'economic and political significance.'" *Bradford v. U.S. Dep't of Lab.*, 101 F.4th 707, 725 (10th Cir. 2024) (internal quotation omitted).

[7] Plaintiff assumes from context that Defendants' "major federal action" argument, Mot. at 25-26, is intended to refer to the Major Question Doctrine.

The MQD does not apply in this case. Here, Plaintiff is attempting to enforce the FTC Act entirely consistent with the past practices of the FTC as well as Congress's broad delegation of authority to that agency. *See supra* 12-22. In *ATS Tree Services, LLC v. FTC*, the court found that the MQD did not apply to the FTC's promulgation of substantive rules to prevent unfair methods of competition that had significant economic impact. No. 2:24-cv-01743, 2024 WL 3511630, at *18 (E.D. Pa. July 23, 2024). As the *ATS* court explained, "[i]n *West Virginia*, the Supreme Court noted that the EPA had only issued one prior rule under the relevant section of the statute." *Id.* In contrast, the court explained that the FTC's rule was "consistent with its past use of Section 6(g) to promulgate substantive rules to prevent unfair methods of competition." *Id.*; *see also United States v. Stratics Networks Inc.*, No. 3:23-cv00313, 2024 WL 966380, at *18 (S.D. Cal. Mar. 6, 2024) ("[T]he Telemarketing Act and the TSR contemplated ringless voicemail in its definition of a 'telephone call.' And as discussed above, the regulatory history of the TSR shows ringless voicemail was included in its scope. Therefore, the FTC is not finding "new-found powers in old statutes."). This case is even more straightforward than *ATS Tree Services.* Here, the Government is not seeking to promulgate a new rule, but rather enforce existing, well-settled statutory requirements. In *FTC v. Kochava Inc.*, the court explained that the MQD does not apply where "the FTC is not flexing its regulatory muscles—it is merely asking a court to interpret and apply a statute enacted by Congress." 671 F. Supp. 3d 1161, 1180 (D. Idaho 2023). So too here. The Court should reject Defendant's misplaced reliance on the MQD.

CONCLUSION

For the reasons set forth above, the Motion should be denied.

DATED this 12th day of November 2024.

Respectfully submitted,

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