THE FEDERAL TRADE COMMISSION'S UNLAWFUL HEALTH PRODUCT SUBSTANTIATION REGIME

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Summary: The Federal Trade Commission's health product claims substantiation scheme, in particular the 2022 Health Products Compliance Guidance, lacks statutory authority and is an unlawful regulatory overreach.

Whether by act of Congress or through judicial review the FTC's scheme should be rejected outright.

Background:

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. [1]

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

Specifically, 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.

[1] 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.

Villafranco, Kristi L. Wolff, Misguided: The FTC Attempts to Redefine the Law with its Health Products Compliance Guidance, Dec. 2022 (hereinafter "Misguided").

Most notably, while the FTC's rules have changed, nothing in the underlying FTC Act has changed—a simple sign that the new rules lack an adequate statutory basis.

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.[2]

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."[3]

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.[4]

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[2] Misguided, supra:

> 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.

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

[4] 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.

According to the FTC's logic, for example, any claim that a humidifier helps a person breath 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 an FDA-approved antidepressant drug. Cf., e.g., Elizabeth Crawford, HBW Insight, FTC Requests Drug Claim Support For Bayer Probiotic Supplement, Sep. 2014.[5]

It must be emphasized that none of the FTC's purported substantiation rules were never the product of an actual rulemaking. [6]

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.[7]

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."

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[5] 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.

[6] 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 (2000). To those points, it is fair to wonder if the Pom decision would be similarly decided if the case were heard today.

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

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.)

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.

At the same time, 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).[8]

As a rule, these cases 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.

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[8] 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.

Id.

To date 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.

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) (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.") (punctuation and authorities as in the original).

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 is 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.[9]

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.[10] 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-

[9] 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/.
[10] 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.

to-day lives, a significant rise from 42 percent in 2020."[11] A 2019 Harris Poll found that 86 percent of Americans take vitamins and/or dietary supplements.[12] More than a third of Americans use a sleep-tracking aid.[13]

Given that the EPA rules which impacted a $100.7 billion 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, most 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's 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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[11] Id.

[12] 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.

[13] 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.[14]

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

If Congress intended the FTC to police non-drug and non-medical-device health products just as the FDA oversees pharmaceuticals and medical devices, 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 in-house expertise. The FTC's staff isn't made up of scientists, it is almost entirely staffed by lawyers.] Congress has not done so. Alternatively, Congress could have authorized the FTC to run a program like the FDA's. The Congress has not done so.

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[14] 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.

Instead, what 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 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.