Dear Chairwoman Khan and Commissioners,

We write to raise serious concerns about the actions of the Federal Trade Commission (FTC) impairing the freedom of Americans to have access to science-based, health-related information upon which to make decisions for themselves and their families.

As you are aware, the FTC is now imposing substantial burdens on any entity that makes any—direct or implied—health claim in relation to any product. Specifically, based on the 2022 Health Products Guidance, it is the FTC's position that any health-related claims must be backed by randomized, placebo-controlled, double-blind, human, clinical studies (known as RCTs).

We have serious concerns about this regulatory scheme.

I. THIS FTC SCHEME IS A SERIOUS THREAT TO AMERICAN HEALTH

First, the FTC's scheme denies Americans access to important science-based health data. We are informed that in recent depositions in US v. Xlear, witnesses from the FTC testified that RCTs are not feasible when confronting a novel, rapidly emerging, deadly pandemic like COVID-19. In such circumstances—like the Xlear case—a company can have important, truthful scientific information people should be aware of, but because the data is not RCT data, the FTC rules preclude the company from educating the public. This Catch-22 prevents people from having vital health information.

Consider the situation during the COVID-19 pandemic. Federal authorities viewed any alternatives to vaccines with open hostility. Federal officials censored healthcare professionals from discussing non-pharmaceutical countermeasures and/or vaccine alternatives. We are informed that in his deposition in the Xlear matter, a senior FTC official testified that the Agency's actions in censoring this science were intended to prevent people from "acting irresponsibly." The FTC simply has no such authority to dictate the health choices of Americans.

Second, the FTC scheme will stop legitimate companies from being able to sell established health-related products and will drive these companies out of business. RCTs, which the FTC seeks to require, are highly expensive. Moreover, as FTC officials have acknowledged, in many instances, RCTs may not be possible because of ethical and regulatory constraints. Further, as the FTC's prior guidance and FDA rules reflect, even without RCTs, products can have adequate data showing them to be effective (e.g., in vitro tests, animal model tests, and/or through centuries of real-world evidence). However, if companies do not have—and/or cannot obtain—the specific RCT data the FTC seeks to require, these manufacturers can no longer market their products. Given the size of the health-related market in the United States, this could have a serious negative impact on health and a major economic impact on the nation.

Third, 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, potentially including things like their daily vitamins, cholesterol reducers, joint supplements, wrist and knee braces, and room humidifiers.

Fourth, the FTC scheme imposes more stringent regulatory burdens on health-related products—things like humidifiers, probiotics and saline nasal sprays—than the Food and Drug Administration (FDA) requires of many pharmaceutical drugs. An analysis of pivotal trials of 188 novel therapeutic agents for 206 indications, which were relied on by the FDA in granting drug approvals (2005-2012) concluded that 89.3 percent were randomized, 79 percent were double-blind, and 55.1 percent were placebo-controlled—and over a third of the drugs were approved based on just one trial. Downing NS, Aminawung JA, Shah ND, Krumholz HM, Ross JS. Clinical trial evidence supporting FDA approval of novel therapeutic agents, 2005-2012. JAMA. 2014 Jan 22-29;311(4):368-77. doi: 10.1001/jama.2013.282034. PMID: 24449315; PMCID: PMC4144867; see also Benton Bramwell, ND, Matt Warnock, The Randomized, Double-Blind, Placebo-Controlled Trial: Gold Standard or Golden Idol?, Townsend Letter, Nov. 4, 2023. Which is to say, a significant portion of FDA-approved drugs never met the requirements the FTC now imposes on nonpharmaceutical products. For example, the FDA approved the bivalent COVID-19 vaccines based on a study of eight mice, with no human clinical data. This is the definition of an upside-down world. It is nonsensical that a cancer drug or COVID vaccine has less proof than a saline nasal spray or probiotic.

Fifth, as a result of the above dynamics, "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 RCTs and buy clout with the FTC and other regulators.

II. IN ADDITION TO RISKING THE HEALTH OF AMERICANS, THE FTC'S SUBSTANTIATION SCHEMES RAISE A HOST OF SERIOUS LEGAL ISSUES

First, the FTC's substantiation scheme lacks any statutory basis. FTC v. QT, Inc., 448 F. Supp. 2d 908 (N.D. Ill. 2006) ("Nothing in the Federal Trade Commission Act . . . requires placebo-controlled, double-blind studies."); 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, noting that substantiation factors arise from FTC policy statements).

Second, the FTC's scheme is an unlawful restraint on free speech. The FTC Act, rightly, only prohibits false and misleading speech. Under the specific terms of the statute, factual speech is not regulated. Moreover, under law, factual speech is protected under the First Amendment. Efforts by companies to inform members of the public about things people can do to safeguard their health are not commercial speech and are otherwise protected under the First

Amendment.[1] The FTC's scheme censors companies from making factually accurate statements that might help Americans protect their health. An outright ban on such information, as the FTC Guidelines impose, most certainly violates the First Amendment.

Sixth, the FTC scheme is a deliberate—and unlawful—effort to circumvent Congressional authority. As noted above, the FTC Act, which your Agency says is the basis for this substantiation scheme, never mentions RCTs, clinical data, nor even substantiation. If Congress had intended all health-related claims be subject to the same (or greater) standards of proof as the FDA now requires of pharmaceuticals and medical devices, the Congress could have enacted that exact mandate. Alternatively, Congress could have placed health-related claims under the purview of the FDA, which has vastly more expertise than the FTC does in such matters. Alternatively, Congress could have authorized the FTC to develop a health-related claims substantiation regime. Congress—despite numerous opportunities, to include the COVID-19 legislation—has not enacted any such law(s).

As the US Supreme Court held in West Virginia v EPA, "[a]gencies 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 omitted). When an agency, like the FTC here, asserts a highly consequential power, beyond what Congress could reasonably be understood to have granted, the agency must point to "clear congressional authorization" for that power. Id. citing Utility Air Reg. Grp v. EPA, 573 U.S., at 302, 324 (2014); King v. Burwell, 576 U.S. 473, 486 (2015).

The FTC's health-related products substantiation scheme asserts a consequential power without any clear Congressional authorization—it violates the Supreme Court's ruling in West Virginia v EPA.

III. THE ROAD AHEAD

As a result of these policy and legal problems, we strongly suggest that the FTC eliminate the Health Products Guidance. We urge the Agency to take a step back and develop duly promulgated rules, using the notice and comment rulemaking process—rules that implement the specific requirement of the FTC Act (prohibit false and misleading advertising). Such rules should not seek to impose an entirely new regulatory substantiation scheme.

Alternatively, if the FTC considers such a substantiation scheme necessary—and the Agency believes the FTC should oversee such a program—the FTC should come to Congress with a well-considered, reasonable legislative proposal that would provide your Agency the necessary statutory basis to develop such a regulatory framework.

[1] See, e.g., Bigelow v. Virginia, 421 U.S. 809, 821-822 (1975)("The advertisement published in appellant's newspaper did more than simply propose a commercial transaction. It contained factual material of clear "public interest.")

We would welcome the opportunity for you to work with our staff to address the issues raised in this letter.

Thank you in advance for your efforts to address these matters.