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May 27, 2025

VIA EMAIL: electronicfilings@ftc.gov
Federal Trade Commission
Office of the Secretary
Suite CC-5610
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: Petition for Issuance of Orders Limiting FTC Enforcement Discretion under Sections 5 and 12 of the FTCA in the Context of Health Product Claims

Dear Chairman Ferguson and members of the Commission:

Alliance for Natural Health USA; Xlear, Inc.; and Better Way Health hereby petition pursuant to 16 CFR 1.31 et seq. and 15 USC 57a(1)(B) to reform FTC procedures and practices affecting the issuance of civil investigative demands; FTC burdens of proof and pleading requirements in hearings; and FTC procedures and practices affecting appeals from Initial Decisions of Administrative Law Judges in health benefit advertising cases under Sections 5 and 12 of the Federal Trade Commission Act.

Consistent with the First Amendment to the United States Constitution; Due Process under the Fifth Amendment to the United States Constitution; the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024); the Presidential Memorandum, "Directing the Repeal of Unlawful Regulations" (April 9, 2025); the Executive Order on "Ending the Weaponization of the Federal Government" (January 20, 2025); and the Federal Trade Commission Act, this petition seeks issuance of an order from the Commission rescinding FTC's prior insistence on more than one clinical trial as a condition precedent to the making of health benefit claims and requiring the agency in post-publication review to evaluate the totality of scientific evidence concerning a health benefit claim.

This petition seeks issuance of an order from the Commission clarifying that the FTC lacks any statutory authority to demand, and is barred by the First Amendment from demanding, that any advertiser, to avoid deceptive advertising, must possess a specific kind or quantity of evidence on hand before commencing advertising.

This petition seeks issuance of an order from the Commission directing the Staff to meet a threshold burden of proof under Sections 5 and 12 of the Federal Trade Commission Act before issuing a civil investigative demand and commencing litigation against an accused or respondent party. That threshold evidentiary requirement is required of FTC by the Administrative Procedure Act, the Due Process Clause of the Fifth Amendment, and the First Amendment when

it is engaged in review of health product advertising. In that regard, Petitioners ask the Commission to rule that no investigation and no litigation may commence against an accused or a respondent in the context of health product advertising unless the Staff: (1) possesses competent and reliable scientific evidence that the advertising claims in issue are false; (2) establishes that consumers have suffered actual injury, economic or physical, in reliance on the advertising claims in issue; (3) maintains throughout the proceedings its obligation to satisfy the burdens of proof and production on claim falsity; and (4) formally rejects the idea that any specific number or kind of evidence is required to establish support for a health benefit claim and, instead, examines the totality of the scientific evidence extant that is germane to a claim.

This petition seeks issuance of an order from the Commission (a) prohibiting the Commission and its agents from having any substantive communication whatsoever with agency staff or involvement in any hearing proceeding brought by agency staff against an accused or respondent until after an independent decision on the merits has been issued by the Administrative Law Judge and assigning penalties and bar referrals as sanctions available to the ALJ; (b) prohibiting the agency or its staff from interfering with production of documents responsive to subpoenas issued by Administrative Law Judges to the accused and assigning penalties and bar referrals as sanctions available to the ALJ; (c) prohibiting the agency or its staff from entering into any agreement with the accused or respondent whereby the accused or respondent agrees to waive his or her rights to object during the course of any agency proceeding or appeal therefrom; (d) prohibiting the agency from withholding from the accused or respondent any document possessed by the government or its witnesses germane to hearing issues and of benefit to the accused, save those protected by privilege; (d) prohibiting agency staff from drafting any part of an expert opinion in support of the agency's case against the accused or respondent in any FTC proceeding and assigning penalties and bar referrals as sanctions available to the ALJ; (e) requiring the agency to disclose by a date certain in all administrative hearings all correspondence it has had with any individual or entity outside of the agency germane to the proceedings; (f) prohibiting agency staff from demanding withdrawal of pleadings or arguments in an agency administrative proceeding as a condition precedent to settlement negotiations or entry of a settlement agreement in a case; (g) prohibiting agency settlement demands for monetary sums greater than the actual profits earned from the specific advertising campaigns that are the subject of agency proof of deceptive advertising or deceptive advertising practices in violation of Sections 5 and 12 of the Federal Trade Commission Act; (h) prohibiting agency staff from changing its theory of the case or causes of action against the accused in any administrative hearing except by an amendment to its complaint on proof of no prejudice and by a date certain set by the Administrative Law Judge no later than 90 days before the start of a hearing on the merits; (i) allowing Administrative Law Judge's to include among permissible findings and conclusions that the Federal Trade Commission action against the accused violates the Constitution or laws of the United States, including the Federal Trade Commission Act, and is therefore invalid: (j) allowing the accused or respondent at the start of and during the course of any case brought against the accused or respondent by the agency the right to demand production of all proof of prima facie evidence supporting each claim or cause of action; (k) allowing Administrative Law Judge's authority to dismiss any or all causes of action brought by the agency against the accused or respondent with prejudice for want of required evidence to prove causes of action in the agency Complaint; (l) requiring the Commission to consider every part of an initial decision by an Administrative Law Judge to be final and binding unless the Commission, based on detailed findings of fact from within the administrative record

and on conclusions of law within the scope of legal theories argued against the accused at hearing, concludes otherwise in its written decision on review.

This petition seeks issuance of an order from the Commission prohibiting the drawing of any conclusions related to consumer perception of the meaning of advertising or consumer reliance on advertising without well designed survey evidence establishing that perception to be commonly held (and not the perception of a "significant minority") and to have been actually relied upon by consumers in making purchasing decisions.

Background of the Petitioners

Alliance for Natural Health-US is a non-profit public advocacy organization that represents health care providers, manufacturers and distributors of health products, and 650,000 health product consumers across the United States. The agency policies and procedures here in issue adversely affect ANH-US's corporate members who manufacture and sell health care products by denying them protection against the arbitrary and capricious application of regulations affecting health benefit advertising and by denying them full protection for their rights to freedom of speech and press and due process of the laws. The agency policies and procedures here in issue also adversely affect the 650,000 health product consumers ANH-US represents by denying them access at the point of sale to health information protected by the First Amendment, which information is not conveyed by ANH-US corporate members to avoid running afoul of FTC regulations affecting speech. Alliance for Natural Health USA ("ANH") has offices at 211 N. Union Street, Suite 100, Alexandria, VA 22314. Its phone number is (703) 884-0823. Its email address is office@anh-usa.org. It is represented in this proceeding by Jonathan W. Emord, Emord & Associates, P.C., 11808 Wolf Run Lane, Clifton, VA 20124 with a phone number of 703-239-8968 and an email address of jemord@emord.com.

Xlear, Inc. is the manufacturer and distributor of a nasal cleanse product that was the subject of FTC litigation in federal court. The agency dropped its suit against Xlear with prejudice. The constitutional and statutory issues that arose in that case are central to this petition. Xlear, Inc. has offices at 723 South Auto Mall Drive, American Fork, UT 84003. Its phone number is 801-492-2100. Its email address is joel.melton@xlear.com. It is represented in this proceeding by Jonathan W. Emord, Emord & Associates, P.C., 11808 Wolf Run Lane, Clifton, VA 20124 with a phone number of 703-239-8968 and an email address of jemord@emord.com.

Better Way Health is a distributor of immune support supplements, best known for its Beta Glucan product. Founded in 1999, it is a top-rated supplement company based in Kennesaw, Georgia, with a focus on evidence-based, high-quality, all-natural health products. Better Way Health has offices at 1000 Cobb Place Blvd NW, Suite 407, Kennesaw, GA 30144. Its phone number is (800) 746-7640. Its email address is support@betterwayhealth.com. It is represented in this proceeding by Jonathan W. Emord, Emord & Associates, P.C., 11808 Wolf Run Lane, Clifton, VA 20124 with a phone number of 703-239-8968 and an email address of jemord@emord.com.

Background of the Petition

On March 10, 2025, the Department of Justice moved to dismiss with prejudice the FTC's case against Xlear, Inc. in the U.S. District Court for the District of Utah[1], fulfilling the President's Executive Order that demanded an end to lawfare (cases brought by the Department of Justice for partisan political ends during the Biden Administration). See https://www.whitehouse.gov/presidential-actions/2025/01/ending-the-weaponization-of-thefederal-government/.[2] In furtherance of that Executive Order, to ensure that the rule of law replaces biased enforcement at the FTC (in contravention of the Federal Trade Commission Act, the Administrative Procedure Act, and the U.S. Constitution) and in furtherance of the Presidential Memorandum, "Directing the Repeal of Unlawful Regulations" (April 9, 2025), demanding, *inter alia*, implementation of the Supreme Court decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024)[2] and repeal of regulations in violation of that decision, the Petitioner asks the Commission to adopt a series of specific reforms (specified below) by formal rule following notice and comment rule making.

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[1] See FTC v. Xlear, Inc., is cited as 2:21-cv-00640-RJS. In October 2021, the Federal Trade Commission (FTC) filed suit against Xlear, Inc., alleging that the company falsely promoted its saline nasal sprays as an effective way to prevent and treat COVID-19. The DOJ, acting on behalf of the FTC, filed the complaint, alleging that Xlear's advertising statements that its nasal spray could serve as an effective, additional layer of protection against SARS-CoV-2 (COVID19) violated Sections 5 and 12 of the Federal Trade Commission Act and the COVID-19 Consumer Protection Act because Xlear did not possess at the time it advertised more than one well-designed randomized clinical trial corroborating its advertising statements. Xlear countered, arguing that FTC lacked any statutory authority to require more than one clinical trial as support for its claims and that its claims were backed by substantial scientific evidence concerning the efficacy of its product and of the use of nasal sprays containing the same ingredients as those in its product. On March 10, 2025, consistent with the President's Executive Order, "Ending the Weaponization of the Federal Government," issued on January 20, 2025, the Department of Justice moved to dismiss the suit with prejudice, with Xlear's agreement. The dismissal with prejudice permanently bars the FTC from bringing an action against Xlear on the same grounds or on any grounds it could have brought against Xlear based on its advertising.

[2] See https://www.whitehouse.gov/presidential-actions/2025/04/directing-the-repeal-of-unlawful-regulations/. See also President Donald J. Trump, Executive Order, "Ending the Weaponization of the Federal Government," January 20, 2025: "Sec. 3. Ending the Weaponization of the Federal Government. (a) The Attorney General, in consultation with the heads of all departments and agencies of the United States, shall take appropriate action to review the activities of all departments and agencies exercising civil or criminal enforcement authority of the United States, including, but not limited to, the Department of Justice, the Securities and Exchange Commission, and the Federal Trade Commission, over the last 4 years and identify any instances where a department's or agency's conduct appears to have been contrary to the purposes and policies of this order, and prepare a report to be submitted to the President, through the Deputy Chief of Staff for Policy and the Counsel to the President, with recommendations for appropriate remedial actions to be taken to fulfill the purposes and policies of this order."

As explained below, the FTC has for decades commenced non-public investigations and litigation against select companies across the United States in the health product sector not infrequently with little more than a hunch or suspicion that the company has engaged in deceptive acts or practices in violation of Sections 5 and 12 of the Federal Trade Commission Act. It has unlawfully shifted its statutory and constitutional burdens of proof and production to the accused, demanding that the accused prove the claims it has made (and claims FTC presumes implied from claims it has made) are true to a near conclusive degree, thus exempting the Commission from fulfilment of its statutory and constitutional obligation to prove that the actual claims made are false and deceptive by a preponderance of the evidence. The FTCA and the First Amendment place the onus on the government to prove health benefit claims false, not on the accused to prove its claims true to a near certain degree. That is true of commercial and non-commercial speech alike because the First Amendment disarms government of power over speech and press, demanding that government meet a high burden to justify restricting speech.

As evidenced in FTC hearings, including the ECM Biofilms case, FTC staff has often acted in coordination with Commission staff, thus destroying the separation of functions and powers required under the Administrative Procedure Act and essential to impartial decision making on appeal to the Commission. The FTC staff has frequently modified its legal theories and causes of action without amending its complaint and without notice to the accused or respondent. The FTC staff has written substantial parts of expert reports of those it has hired as experts, falsely representing the reports to be the independent professional judgment and product of the experts. The FTC staff has withheld exculpatory information in its possession when demanded by the accused or respondent in FTC hearings. The FTC staff has interfered with the production of documents by those given administrative subpoenas from the accused or respondent. The Administrative Law Judge's Initial Decisions in FTC cases are recommendations, having no legal force or effect, unless and until adopted by the Commission. The Commission has ignored findings and conclusions in ALJ decisions, not addressing each one in its final decisions. The ALJ's have no power to rule decisions of the FTC applied in a case to be unconstitutional, in violation of a statute, arbitrary or capricious, or otherwise contrary to law.

FTC has even modified the claims for which it demands proof and the nature of its causes of action against the accused in FTC administrative hearings without notice to the accused and at every part of the proceeding, even up to the time of recommendation of decision by the Administrative Law Judge. It has denied the accused full discovery against it and against entities with which it has contracted for expert opinion and evidence, communicating with such entities *ex parte* that they are not obligated to respond to subpoenas from the accused. It has tampered with evidence by writing entire portions of expert opinions by individuals it has hired as purportedly independent experts in administrative cases. It has also presumed the accused's advertising content deceptive if the accused did not possess documentation in the form of scientific evidence to prove claims of health benefit before advertising commences, unilaterally relieving itself of its statutory and constitutional burden of proof to establish the falsity and deceptiveness of advertising. It has presumed that its own perception of consumer understanding of the meaning of words conclusive, even in the absence of sound survey evidence to corroborate its perception. It has imposed millions of dollars in defense costs on the accused in cases where it lacks any sound evidence that claims made are deceptive or that even a single real consumer

relied on the advertising content objected to in making a purchasing decision, thus expending tax dollars on prosecutions and imposing enormous financial costs on accused and respondent parties for what are, in fact, academic pursuits with no genuine proof of actual deception, economic injury, or physical injury arising from reliance on false claims. And, it has demanded more than one well-designed randomized clinical trial for a health benefit claim in issue as a condition precedent to advertising, rejecting as insufficient the totality of other generally available scientific evidence.

Each of the foregoing are applications of governing power beyond the agency's statutory authority and in violation of the Due Process and First Amendment rights of the accused or respondent. Each such action also violates the Federal Trade Commission Act and the Administrative Procedure Act. Rectifying these systemic law violations and removing lawfare requires adoption of rules by the Commission designed to achieve needed reforms by rooting action taken in the statutory and constitutional laws affected and in loyalty to and fulfillment of the constitutional oaths of office of each Commissioner.

Action Requested

ANH, Xlear, and Better Way Health respectfully request that the Commission through rulemaking adopt formal rules that:

(1) Order the Staff not to seek issuance of a civil investigative demand or commencement of a non-public investigation under Sections 5 and 12 of the Federal Trade Commission Act unless the Staff has: (a) adduced competent and reliable scientific evidence that health benefit advertisements in issue are demonstrably false; (b) adduced evidence that consumers have relied upon the alleged deceptive advertising content in making purchasing decisions; and (c) has adduced specific evidence that consumers have suffered actual physical or financial injury in reliance on the demonstrably false advertisements.[3]

(2) Order the Staff to ensure that all expert opinions offered on its behalf in hearings or in Court are independent professional statements and not content authored or recommended by agency staff. Penalties for violation of this requirement should include, at a minimum, in removal of the Staff implicated from a case, and, where appropriate, referrals to FTC internal ethics review and bar counsel for sanctions where appropriate and may include, at a maximum, in addition to the foregoing dismissal of the case brought by the FTC against the accused or respondent with prejudice.

(3) Order the Staff not to interfere with a duly ALJ-issued subpoena obtained by the accused or respondent in agency proceedings, including avoidance of any statement that might dissuade a subpoena recipient from fully responding, notwithstanding preserving the authority of FTC, like

[3] Ordinarily, when falsehood results in no provable injury, it is not material. False speech that yields no provable injury may safely be countered through idea and information contest in the market. That freedom inherent in such a market is, in fact, the hallmark of a free society. It is a truism that even the most well intentioned will from time to time err by communicating less than fully verifiable information. When doing so results in no actual injury, the solution is best left to correction through private contests of ideas and information, for the risk to freedom and free enterprise of government intervention is that an orthodoxy over speech will arise which poses far greater threat to exchange of information indispensable to consumer choice than the loss for a time of an academic correction.

the accused, to file a motion to quash a subpoena with the ALJ if warranted under applicable precedent. Penalties for violation of this requirement should result, at a minimum, in removal of the Staff implicated from a case, and, where appropriate, in referrals to FTC internal ethics review and bar counsel for sanctions where appropriate and may include, at a maximum, dismissal of the case brought by the FTC against the accused or respondent with prejudice.

(4) Order the Staff no later than thirty days after the start of any administrative proceeding to serve a statement on the accused or respondent of the precise theories of liability, elements the government intends to prove, and causes of action and to avoid thereafter any change in the theories or causes of action brought except by motion for leave to amend at least ninety days before the start of a hearing on the merits.

(5) Rule that neither the Commission nor its staff nor agents acting on the behalf of either shall engage in any substantive communication, including *ex parte* substantive communication, with FTC complaint counsel relating to any proceeding brought within the agency after Commission authorization to sue has been given the Staff and until after an Initial Decision has been issued or a settlement agreement has been negotiated pending Commission approval.

(6) Order the Staff not to enter into any accord with the accused or respondent whereby the accused or respondent agrees to waive his or her rights to object during the course of any agency proceeding or appeal therefrom.

(7) Rule that neither the Commission nor the Staff shall withhold from the accused or respondent any document possessed by the government or its witnesses germane to hearing issues and of benefit to the accused, save those protected by privilege. Penalties for violation of this requirement should result, at a minimum, in removal of the Staff implicated from a case, and, where appropriate, referrals to FTC internal ethics review and bar counsel for sanctions where appropriate and may include, at a maximum, dismissal of the case brought by the FTC against the accused or respondent with prejudice.

(8) Rule that the agency under the First Amendment and the Federal Trade Commission Act may not demand as a condition precedent to advertising that a party possess any evidence in support of an advertising claim but must establish itself that advertising content is deceptive within the meaning of Sections 5 and 12 of the Federal Trade Commission Act based on a preponderance of all publicly available evidence germane to the claim and public perception of the advertising before it may conclude a claim deceptive.

(9) Revoke the Health Products Compliance Guidance (December 2022) in light of the absence of authority under the Federal Trade Commission Act and in light of the burdens of proof and production requirements for government to act against speech underlying the FTCA's Sections 5 and 12 and the First Amendment to the United States Constitution.

(10) Admit that absent extrinsic evidence, the FTC cannot comprehend adequately the public's perceived meaning of words in advertising and rule that FTC shall not presume itself capable of comprehending consumer perception of the meaning of words in advertising without first obtaining proof in the form of well designed, reliable and reproducible survey evidence

confirming that overwhelming majority of consumers share a perception of the meaning of words in advertising.

(11) Rule that the Staff may not without grant of a motion to quash withhold information responsive to discovery requests propounded by the accused or respondent to gain strategic advantage, such as to use evidence without prior notice to the accused or respondent in the conduct of a deposition of the accused or the respondent. Penalties for violation of this requirement should result, at a minimum, in removal of the Staff implicated from a case, and, where appropriate, referrals to FTC internal ethics review and bar counsel for sanctions where appropriate and may include, at a maximum, dismissal of the case brought by the FTC against the accused or respondent with prejudice.

(12) Rule that the Staff has no authority to condition settlement negotiations on agreement of the accused or respondent to withdraw argument or seek rescission of any decision.

(13) Rule that FTC shall take no action adverse to the accused in a deceptive advertising case unless it possesses not only well-designed survey evidence corroborating the overwhelming majority of consumers hold the same perception of the meaning of words in advertising at issue but also evidence that a majority of consumers relied on the advertising in issue in making a purchasing decision, incurring either an actual economic loss or a physical injury, or both.

(14) Rule that FTC may not deem health product advertising deceptive on the basis that a set quantum or kind of scientific evidence is lacking (such as on the basis that there is not more than one randomized clinical trial involving the product that supports the claim made) but shall instead evaluate the totality of scientific evidence from all sources and shall itself carry the burden of proving health benefit claims false by a preponderance of the evidence, rather than demanding that the accused or respondent prove health benefit claims true to a near conclusive degree.

(15) Clarify that ALJ's have the authority in their Initial Decisions to declare FTC rules unconstitutional, in violation of statute, arbitrary, capricious, or otherwise contrary to law.

(16) Rule that the accused or respondent shall have full discovery against the FTC, its agents, and those with whom it contracts to obtain access to all communications, documents, and things that are germane to the respondent's case or that may lead to the adduction of relevant evidence.

Legal and Factual Bases for the Action Requested

Legal Standards

Procedural Due Process.

Procedural Due Process guaranteed by the Fifth Amendment applies to strike down federal government proceedings when life, liberty, or property is deprived without fair legal procedures. When an agency proceeds based on corrupt motivations, or violates its own rules of procedure to attain an end (i.e., wherein it lacks impartiality), denies respondent full and fair discovery, withholds evidence from a respondent, interferes with acquisition of evidence from a non-party subpoena recipient, or drafts an expert report but presents it as the independent opinion of the expert, fundamental fairness is denied and Due Process rights are violated. In his seminal "Some Kind of Hearing," Judge Henry Friendly specified the elements required to satisfy procedural Due Process in the civil hearing context. See https://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=5317&context=penn_law_review. Judge Friendly explained that the absence of any one of the following elements would deprive the accused or respondent of rights guaranteed by the Due Process Clause of the Fifth Amendment:

1. A neutral and unbiased tribunal.
2. A notice of the government's intended action and the asserted grounds for it.
3. The opportunity for the individual to present the reasons why the government should not move forward with the intended action.
4. The right for the individual to present evidence, including the right to call witnesses.
5. The right for the individual to see the opposing side's evidence.
6. The right to cross-examine the opponent's witnesses.
7. A decision based exclusively on the evidence presented.
8. The opportunity to representation by counsel.
9. The requirement that the tribunal prepare a record of the evidence presented.
10. Requirement that the tribunal prepare written findings of fact and reasons for its decision.

In civil hearing contexts, the courts balance private interests, the government's interest, and the possibility of the government procedure's erroneous deprivation of private interest. See *Matthews v. Eldridge*, 424 U.S. 319 (1976).

In *Axon Enterprises, Inc. v. FTC*, the Supreme Court held that federal district courts have authority to hear constitutional challenges to the FTC's structure and processes before any final agency orders issue. Those structure and process challenges include challenges to Procedural Due Process, such as the challenges brought here. In the advent of *Axon Enterprises, Inc.*, and in light of President Trump's Memorandum requiring implementation of that decision by this agency, Presidential Memorandum, "Directing the Repeal of Unlawful Regulations" (April 9, 2025), the FTC must act to eliminate the long standing biases endemic in its hearing processes to bring them into compliance with Fifth Amendment Due Process requirements, its own statute in light of *Loper Bright Enterprises, Inc*., and the President's Memorandum.

Moreover, corrupt government practices, such as those which have occurred at the agency, most notably in the ECM BioFilms case, as documented by the Initial Decision of the presiding administrative law judge and the transcripts of the hearing, are forbidden violations of the Administrative Procedure Act and of Procedural Due Process under the Fifth Amendment.

Those include: Complaint Counsel writing part or all of the expert report represented to be the independent professional opinion of Complaint Counsel's expert; staff advising recipients of subpoenas from Respondents that the recipients are under no obligation to respond to the subpoenas; Complaint Counsel changing causes of action or theories of liability up to the time of Initial Decision without notice to Respondents and without leave from the Administrative Law Judge; Complaint Counsel communicating with members of the Commission or with their agents concerning theories of active cases, prosecution of active cases, evidence in active cases, and strategies in pursuit of active cases against Respondents, disavowing the separation of functions required under the Administrative Procedure Act; Complaint Counsel withholding evidence from the Respondent to gain strategic advantage; Complaint Counsel conditioning settlement on Respondent's withdrawal of argument or filing of a motion to rescind facts underlying an ALJ decision.

The requested actions in (1) through (15) above will eliminate systemic violations of respondent rights in FTC administrative hearings by altering practices and procedures to comport with fundamental fairness required by the Due Process Clause. Those actions will also fulfill objectives stated in the President's Executive Orders and Action: Executive Order on "Ensuring Accountability for All Agencies" (February 18, 2025), Executive Order on "Ending the Weaponization of the Federal Government" (January 20, 2025), and Presidential Memorandum, "Directing the Repeal of Unlawful Regulations" (April 9, 2025).

First Amendment.

Under the First Amendment and the Federal Trade Commission Act, there is no power delegable, or delegated, to the FTC that allows the agency directly or indirectly to coerce or cajole the regulated class to possess any quantum, degree, nature, or kind of evidence as a condition precedent to advertise. The FTC's regime is not one of prior restraint. The First Amendment and the FTCA squarely place the burden of proof on the government to prove advertisements false, not on the advertiser to prove the advertisement true to a near certain degree. Consequently, if by chance (with no resort to evidence at all), an advertiser happens to communicate a truthful, non-misleading statement of material fact within the context of an advertisement, the mere fact that he, she, or it did so without evidentiary support is not sufficient under the First Amendment or the FTCA to presume or conclude the advertiser to have engaged in false or deceptive advertising.

The Federal Trade Commission Act does not grant FTC authority to require that a prospective health product advertiser possess documentary evidence in proof of claims *before* advertising commences. Moreover, the FTCA does not grant FTC authority to require a certain level, degree, quantity, or quality of scientific evidence as a condition precedent to advertising, the absence of which is de jure deceptive under Section 5 and 12 of the Federal Trade Commission Act. Rather, both the Act and the First Amendment to the U.S. Constitution require that FTC shoulder the burden of establishing a credible basis in relevant scientific evidence that a health product claim is deceptive before it commences a non-public investigation through issuance of a civil investigative demand and, thereafter, commencement of litigation. And FTC has no constitutional or statutory authority to shift that burden of proof or production to the

accused or respondent by demanding that it, she, or he establish claims to be true to a near certain degree or to be backed by randomized clinical trials in support of a health benefit claim. Rather, the irreducible burden the FTC must shoulder under the Act and Constitution throughout proceedings against advertisers is to prove advertising false or deceptive, requiring it to adduce not that there is insufficient evidence to support truth but that there is affirmative evidence to establish falsity.

In its Health Products Compliance Guidance (December 2022), https://www.ftc.gov/business-guidance/resources/health-products-compliance-guidance, FTC asks the regulated class to accept its view that "randomized, controlled human clinical trials (RCTs) are the most reliable form of evidence and are generally the type of substantiation that experts would require for health benefit claims." The Federal Trade Commission Act does not authorize the FTC to require health benefit advertisers to possess RCTs in support of a claim, or any quantum or kind of supportive evidence. Rather, the FTC must prove from the totality of scientific evidence, that any single health benefit claim in context is false (not that it is simply insufficiently supported in the view of the agency). If the claim is false and misleading, the FTC has the additional First Amendment burden of establishing that no disclaimer or claim qualification would suffice as a less speech restrictive alternative to any greater burden. See *Pearson v. Shalala,* 334 U.S. App. D.C. 71, 164 F.3d 650 (1999). The general principles concerning less speech restrictive alternatives arising from the commercial speech standard and articulated in Pearson are of equal force and effect in the context of FTC regulation, even when it proceeds in the post-publication context.

Moreover, neither the First Amendment nor the Federal Trade Commission Act enables FTC to impose (or through guidance pressure, coercion or cajolery) upon the regulated class the de facto requirement that it possess any set quantity of evidence, let alone that which FTC deems sufficient, in support of any advertising claim. Thus, under the FTCA and the First Amendment, the FTC does not have delegated authority to promulgate its Health Products Compliance Guideline, https://www.ftc.gov/business-guidance/resources/health-products-complianceguidance, which operates on the assumption that it has authority to guide the regulated class as to the nature and kind of evidence it must possess to avoid a charge of deceptive advertising. It does not have statutory of constitutional authority to assume that role. That exercise, i.e., of prescribing examples of evidence desired by the agency to avoid prosecution for deceptive advertising, is nowhere authorized in FTC's enabling act. In short, under the First Amendment and the FTCA, if an advertisement lacks evidentiary support, it is nevertheless protected against prior restraint and must be presumed lawful by the FTC unless and until the FTC proves the advertisement false predicated on scientific evidence it adduces (not on a presumption of liability arising from an absence of evidence held by the advertiser). Only then may the First Amendment and the Federal Trade Commission Act be reconciled.

There is a distinct difference between an advertisement lacking the support FTC believes adequate and an advertisement that the FTC can prove is demonstrably false. Only the latter is actionable under the Act and the First Amendment because under both the agency has an irreducible burden of proof and production. Moreover, the FTC has no authority under the Act or the Constitution to address the regulated class and prescribe through examples what evidence it expects to render a claim non-deceptive. That is because the claim is lawful against any prior

restraint and it is beyond the statutory and constitutional authority of the agency to prescribe orthodoxies in speech or in evidence supporting speech.

Consequently, if an advertiser throws caution to the winds and makes a health benefit claim without resort to any supporting evidence, the FTC is powerless under the FTCA and the First Amendment to act against it. Rather, the claim will be tested in the idea and information market free of government constraint as the core principals of the First Amendment and the legal limits of the FTCA provide. *Only* if the FTC marshals evidence that proves the claim false may it lawfully proceed under the FTCA and the First Amendment against the claim. FTC preference for evidentiary type and nature are irrelevant unless it also possesses proof that the advertising claim in context is false. Even then, it must be material. Even then, it must be provably consequential to consumers such that it was relied upon by them to make purchasing decisions resulting in economic or physical injury or both. Even then, if the claim made can be rendered nonmisleading through the addition of a claim qualification or disclaimer, it is the constitutional duty of this agency, a duty it cannot constitutionally shirk, to rely on qualification as a less speech restrictive alternative to imposition of greater continuing burdens on the speaker or the speech, such as those arising from fencing in provisions.

For the foregoing reasons, ANH-US, Xlear, and Better Way Health ask the FTC to adopt by rule the Requested Actions in numbers (1), (8), (9), and (14) above.

Administrative Procedure Act.

The Administrative Procedure Act (APA) mandates a separation of functions to ensure the independence and objectivity of administrative decision-making. Specifically, Section 554(d) of the APA prevents individuals involved in investigative or prosecuting functions from later participating in or advising on the decision, recommended decision, or agency review in the same or a factually related case. This is to prevent advocates from judging their own case. In Axon Enterprises, Inc., the FTC respondent sued the agency during the pendency of the agency's action in federal district court in a case the Supreme Court held rightfully brought under the District Court's ordinary federal question authority in 28 USC Section 1331. The respondent sought a ruling declaring the entire system of FTC review unconstitutional based on its violation of the Separation of Powers Doctrine and the agency's combination of prosecutorial and adjudicative functions in the Commission itself. See Complaint in No. 2:20-cv-00014 (D. Ariz) (protesting that the FTC acts "as prosecutor, judge, and jury"). While that ultimate basis for suit was not reached before the agency dismissed its action against Axon Enterprises, Inc., the question remains a central one that must be resolved by the current Commission to fulfill both the President's Memorandum and the requirements of Loper Bright Enterprises (to square agency practice with its enabling statutory authority and to square agency practice with the Due Process Clause of the Constitution).

In that regard, ANH-US, Xlear, and Better Way Health have asked the agency to adopt by formal rule Requested Actions (5), (9), (13), and (15) above to ensure to the maximum extent possible procedural fairness and lack of bias in FTC administrative hearings and in FTC review of Initial Decisions by Administrative Law Judges.

Federal Trade Commission Act.

The Federal Trade Commission Act does not authorize the FTC to disallow the accused in agency administrative proceedings full discovery, including of all documents germane to the accused's or respondent's defense. The Federal Trade Commission Act does not authorize the FTC to presume itself expert in consumer perception without any reliance on well-designed survey evidence establishing that an overwhelming majority of consumers have that perception of the advertising content in issue. The Federal Trade Commission Act does not authorize the FTC to interfere by contacting subpoena recipients and dissuading them from production in response to subpoenas issued to non-parties on behalf of the accused. The Federal Trade Commission Act does not authorize the FTC to interfere with the content of experts hired by the agency in litigation by enabling the agency to draft material content in expert reports in place of the independent expert opinion and content of the expert him or herself. The Federal Trade Commission Act does not authorize the FTC to change the content of causes of action or legal theories brought against the accused or respondent in administrative proceedings with no advance notice to the accused or the Administrative Law Judge and without regard to the prejudice suffered by the accused.

For decades, the Federal Trade Commission has depended on a reversal of the statutory and constitutional burdens of proof, from itself to the accused. It has investigated parties and has brought action against them for alleged deceptive health product advertising without first obtaining scientific proof that the content of the advertisements in issue is false and without first establishing that consumers have relied on the alleged false advertising in making purchasing decisions to their economic or physical detriment. In short, it has proceeded principally based on a hunch, a suspicion, but not on probable cause of a statutory violation or of injury sufficient to warrant the extraordinary action of prosecution in matters of speech.

The result of this burden shifting has been a chronic denial of the rights of the accused by burdening protected speech and by forcing the accused to expend resources in defense of claims for which science provides support and for which no proof exists of economic or physical harm resulting from reliance on the allegedly deceptive claims. See, e.g., *ECM Biofilms, Inc. v. FTC, 851 F.3d 599 (6th Cir. 2017), USA v. Xlear, No. 2:21-cv-640 RJS DBP, 121424 (D. Utah July 8, 2022).*

In that regard, ANH-US, Xlear, and Better Way Health have asked the agency to adopt by formal rule Requested Actions (2), (3), (4), (6), (7), (10), (11), (12), (15), and (16) above.

Loper Bright Enterprises Compels the Reforms Sought by Petitioners

Under *Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984), the Courts have long deferred to FTC's shifts of the burdens of proof and production from itself to the parties it accuses. That regime has ended, however, with the Supreme Court's decision in *Loper Bright Enters. v. Raimondo,* 603 U.S. 369, 144 S. Ct. 2244 (2024). Now, FTC may not proceed absent a statutory grant of authority. Having no statutory basis for shifting the burdens of proof and production and, indeed, having an express statutory obligation to proceed against a party if and only if it has established a credible basis for asserting an advertisement is deceptive

and injurious to consumers, the FTC, post Loper Bright, must now abandon burden shifting and compel its Staff to avoid investigation and litigation unless it possesses credible scientific evidence that claims asserted are false and that consumers have relied on the claims in making purchasing decisions to their economic or physical detriment.

FTC has long taken advantage of decisions allowing it to avoid use of consumer survey evidence in determining whether the public has been misled by advertising. See, e.g., *Kraft, Inc. v. FTC,* 970 F.2d 311, 320 (7th Cir. 1992). The Commission has taken the position that it may impose liability if "at least a significant minority of reasonable consumers would likely interpret the ad to assert the claim." *ECM Biofilms, Inc. v. FTC*, 851 F.3d 599, 610-11 (6th Cir. 2017); see also, *FTC v. Am. Future Sys.,* No. 20-2266, 2024 57396, at *1 (E.D. Pa. Mar. 29, 2024); *FTC v. Am. Future Sys.,* No. 20-2266, 2024 57396, at *54 (E.D. Pa. Mar. 29, 2024);

FTC has taken the position, and the pre-Loper Bright Courts have deferred, that when an advertisement is amenable to more than one interpretation, it is deceptive if "at least a significant minority of reasonable consumers" would "likely" interpret the advertisement as making the misleading claim. *United States v. Nepute,* No. 4:21-CV-437 RLW, 2023 124168, at *39 (E.D. Mo. July 19, 2023).

In addition, the FTC has taken the position that an advertiser is, as a matter of law, engaged in deceptive advertising if it lacked at the time it commenced advertising, documentary evidence sufficient to prove the validity of its health product advertising. "Where advertisers lack adequate substantiation evidence, 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." See *FTC v. Quincy Bioscience Holding Co.,* 646 F. Supp. 3d 518, 523 (S.D.N.Y. 2022).

The FTC contends that all claims about the effectiveness of over-the-counter hair loss products must be supported by "valid scientific evidence, including well-controlled, double-blind clinical tests." See, *FTC v. Sabal,* 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998). The Federal Trade Commission usually requires two well-controlled clinical tests before a non-specific establishment claim may be made. See *Thompson Med. Co. v. FTC,* 253 U.S. App. D.C. 18, 791 F.2d 189, 190 (1986).

Although the court affirmed the FTC's remedial order requiring defendant to gain the support of at least one randomized, controlled, human clinical trial study before claiming a causal relationship between consumption of the products and the treatment or prevention of any disease, there was inadequate justification for the FTC's blanket requirement of at least two such studies as a precondition to any disease-related claim, warranting a modification of the FTC's remedial order. See *POM Wonderful, LLC v. FTC,* 414 U.S. App. D.C. 111, 116, 777 F.3d 478, 483 (2015).

Each of those enforcement actions have violated the First Amendment to the United States Constitution, Sections 5 and 12 of the Federal Trade Commission Act, and the major questions doctrine. Moreover, each effectively shifts the burden of proof to establish falsity from the FTC to the accused in violation of the First Amendment.

In the advent of *Loper Bright* the plain and intended meaning of the FTC's enabling statute, the Federal Trade Commission Act, governs. Deference to FTC interpretation of its statutory authority has been overruled. Under that Act, FTC has not been delegated any authority to commit any of the acts referenced above for which Petitioners seek change. Moreover, the statute and the Constitution require the reforms sought.

A. Neither the Plain Language of the FTCA Nor the Legislative History Supporting Sections 5 and 12 of the FTCA Allow FTC to Demand Possession of Scientific Evidence, including More Than One Well-Designed Clinical Trial, before Health Product Advertising

The FTC, acting ultra vires, has litigated against respondents for alleged deceptive health benefit advertising when they did not possess in advance of advertising more than one welldesigned clinical trial in support of the specific claim. See, e.g., *USA v. Xlear,* No. 2:21-cv-640 RJS DBP, 121424 (D. Utah July 8, 2022). However, neither the plain wording of the FTCA nor the legislative history underlying Section 5 and 12 of the Act authorize such a requirement.

The provisions of Section 5 and 12 of the FTCA are clear. They forbid false and deceptive advertising and declare unlawful all unfair or deceptive trade acts or practices. Nowhere does the FTCA grant the FTC the authority to impose evidentiary standards that prevent truthful statements from being made on the assumption that a particular kind or quantum of evidence must be present before health benefit claims can be advertised. The language in Section 5, 15 USC 45(a)(1), did not in any way state or suggest that "unfair or deceptive acts or practices" included all health benefit ads for which the advertiser lacked "competent and reliable scientific evidence" in the form of two well-designed prospective randomized double-blind placebo controlled clinical trials (RCTs). There is also no legislative history revealing an intent to construe "unfair or deceptive acts or practices" within the meaning of Section 5, 15 USC 45(a)(1), to include all health benefit advertising for which the advertiser lacks such evidence.

Furthermore, Sections 5 was originally enacted on September 26, 1914, and amended in 1938, to expand the Act beyond antitrust to include "unfair or deceptive acts or practices." Section 12 was also amended in 1975 to change the phrase "in commerce" to "in or affecting commerce," broadening the jurisdictional reach of the statute. Despite these amendments, the material language of the Act, prohibiting "unfair or deceptive acts and practices" and "false advertisement," remains unchanged since 1938. Thus, the language of Section 5 must be interpreted as it was understood in 1938, while Section 12 must be construed according to its 1914 meaning.

Under the Fixed-Meaning Canon, these statutory provisions must retain their original meaning at the time of enactment. See *United States v. Rabinowitz,* 339 U.S. 56, 70 (1950 (Frankfurter, J., dissenting) ("Words must be read with the gloss of the experience of those who framed them"). Furthermore, under the Omitted-Case Canon, courts are not at liberty to presume the existence of content that is non-existent. Or, as articulated in *Ebert v. Poston,* 266 U.D. 548, 554 (1935) (per Brandeis, J.), "A casus omissus does not justify judicial legislation."

Despite this, the FTC takes the position that any advertiser making claims about a product's beneficial health effects must possess "competent and reliable scientific evidence" in the form of more than one well-designed RCT before lawfully making such claims. See FTC, Health Products Compliance Guidance (December 2022) ("Before disseminating an ad, advertisers must have adequate substantiation for all objective product claims conveyed, expressly or by implication, to consumers acting reasonably").

B. FTC Evidentiary Demands as Conditions Precedent to Health Product Advertising Violate Loper-Bright Enterprises and the First Amendment

Consumers have a well-recognized right to receive information, which is equally protected under the First Amendment alongside the right of the speaker to convey it, including in the context of commercial speech. See, e.g., *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.,* 425 U.S. 738, 756 (1978) ("Freedom of speech presupposes a willing speaker. But where a speaker exists … the protection afforded is to the communication, to its source and to its recipients both"). As the Supreme Court explained in *Zauderer v. Office of Disc. Counsel,* 471 U.S. 626, 642 (1985), "the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides . . ."

Despite this constitutional protection, the FTC in several cases against manufacturers relied solely on a presumption (the absence of two supportive RCTs at the time of health benefit advertising) rather than presenting affirmative proof of falsehood or misleadingness. The FTC assumes that an advertiser who claims a health benefit for a product is necessarily acting deceptively if, at that time of advertising, the advertiser does not possess documentary evidence corroborating the claims. That agency requirement is nowhere imposed by statute or allowed under the First Amendment. The mere fact that an advertiser lacks evidence does not inherently render an advertisement misleading—let alone potentially misleading in a way that would justify requiring disclaimers or qualifications.

The FTC's demand for more than one RCT as a precondition for advertising health benefits enables the suppression of speech that may, in fact, be true, solely because the advertiser lacks documentary proof in a government-approved form. This is precisely the kind of official discretion over speech that the First Amendment was designed to prevent. As the Supreme Court stated in *Riley v. Nat'l Fed'n of the Blind,* 487 U.S. 781, 791 (1988), "The very purpose of the First Amendment is to foreclose public authority from assuming a guardianship of the public mind through regulating the press, speech, and religion." *Thomas v. Collins,* 323 U.S. 516, 545 (1945) (Jackson, J., concurring).

Unless and until the government marshals affirmative proof that a claim in context is false, it remains protected speech under the First Amendment and beyond the reach of enforcement powers delegated pursuant to the FTCA.

The FTC's evidentiary demand is therefore not only unconstitutional, but also fails the "best" interpretation test of *Loper Bright* (it is not a power conveyed by the statute and it is an assumption of power prohibited by the First Amendment). In *Loper Bright*, courts are now required --without deference to FTC -- to determine the "best" statutory meaning, guided by the

language of the statute, the legislative history, and the canons of statutory construction. *Loper Bright Enterprises v. Raimondo,* 603 U.S. 369, 144 S.Ct. 2244, 2266 (2024) (citing *Wisconsin Central Ltd. v. United States,* 585 U.S. 274, 284 (2018)).

C. FTC Violates the First Amendment by Shifting the Burden of Proof from the Agency to Respondents

The First Amendment has long placed the burden of proof on the government to establish by a preponderance of the evidence that the statement in issue is false before it can regulate, restrict, or censor such speech. The government "carries a heavy burden of showing justification for the imposition of . . . a restraint" on speech. *Org. for a Better Austin v. Keefe,* 402 U.S. 415, 419 (1971). This standard applied to protect political speech but also extends to a commercial speech context. In *Edenfield v. Fane,* 507 U.S. 761, 770-771 (1993), the Supreme Court held that "[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it." It is therefore the duty of the FTC to prove an ad false under its enabling Act, not to demand that an advertiser prove a health benefit ad true based solely on two clinical trials it finds satisfactory. The government may not presume to burden or regulate speech unless it first establishes that the speech is false. This provability is not presumed from the mere absence of substantiation in the hands of the advertiser. Courts, in both the commercial and political speech contexts, require the government to marshal evidence proving falsity before acting to regulate, restrict, or ban speech. The government may not presume speech false simply because the advertiser lacks evidence of its truthfulness. The burden of proof is fixed on the government; it may not proceed against a respondent without establishing that the material representations made in commerce were false. *See FTC v. DIRECTV, Inc.,* No. 15-cv-01129-HSG, 139192, at 5 (N.D. Cal. Aug. 16, 2018) "… the FTC bears the burden of proof and must prove each element of its case by a preponderance of the evidence". See also, *United States v. F/V Repulse,* 688 F.2d 1283, 1284 (9th Cir. 1982).

This burden of proof is not satisfied by mere speculation or conjecture. As the Supreme Court reiterated in *Edenfield,* 507 U.S. at 770-771, the government must demonstrate that the harms it recites are real and that its restrictions will alleviate them to a material degree. See also *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio,* 471 U.S. 626, 648-649 (1985)*; Bolger v. Youngs Drug Products Corp.,* 463 U.S. 60, 73 (1983)*; In re R.M.J.,* 455 U.S. 191, 205-206 (1982)*; Central Hudson Gas & Electric Corp. v. Public Service Commission,* 447 U.S. 557, 569 (1980)*; Friedman v. Rogers,* 440 U.S. 1, 13-15 (1979); *Linmark Associates, Inc. v. Willingboro,* 431 U.S. 85, 95 (1977).

The FTC's presumption that a health benefit claim is false solely because the advertiser lacks supporting evidence at the time of advertisement is nothing more than speculation or conjecture. The Supreme Court has made clear that reliance on such speculation does not satisfy the government's First Amendment burden of proof, which demands that the government marshal actual proof of falsity and deception. The only meaningful proof, which the government must marshal before prosecuting speakers, speech or imposing restrictions, is affirmative evidence that the claim itself is false and that it actually deceives, causing consumer injury. Thus, while there is no constitutional basis to require an advertiser to have two RCTs before advertising, there is an

affirmative constitutional requirement that the FTC prove an advertisement false before acting against it.

In the seminal commercial speech case *Central Hudson Gas & Electric Corp. v. Public Service Commission,* 447 U.S. 557, 566 (1980), the Supreme Court established a four-part test for determining when government may regulate commercial speech. First, the expression must be protected by the First Amendment, meaning it concerns lawful activity and is not misleading. Second, the government must assert a substantial interest. Third, the regulation must directly advance that interest. Fourth, the regulation must not be more extensive than necessary to serve that interest. The FTC's approach fails this test at the outset by treating potentially truthful speech as inherently misleading without first proving its falsity. In this same case above, the Supreme Court imposed on government the requirement that it not proceed with any restriction or burden on commercial speech unless, in the first instance, it established that the speech was either inherently false or misleading, admitting constitutional protection exists for even potentially misleading speech. *Pearson v. Shalala,* 164 F.3d 650 (D.C. Cir. 1999), *reh'g en banc denied,* 172 F.3d 72 (D.C. Cir. 1999). See also re R.M.J., 455 U.S. 191, 203 (1982), where the Court demanded that the government "not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive" such as through government mandated claim qualification or disclaimer- an option the FTC has ruled out in this context and even in its Guidance).

Thus, the FTC's presumption of falsity based on the absence of more than one RCT shifts the burden of proof from the agency to respondents, violating the First Amendment. The government may not presume speech false because the advertiser lacks evidence of its truthfulness. Rather, it must marshal affirmative evidence of falsity before proceeding against a defendant. The FTC's failure to do so renders its actions unconstitutional and beyond the scope of its statutory authority.

D. FTC's Demand for More than One Clinical Trial to Support Specific Health Benefit Claims Violates the Major Questions Doctrine

The FTC asserts that any advertiser making a health benefit claim about a product must possess "competent and reliable scientific evidence" in the form of two well-designed randomized controlled trials (RCTs) before lawfully communicating that claim. See *FTC, Health Products Compliance Guidance* (December 2022) ("Before disseminating an ad, advertisers must have adequate substantiation for all objective product claims conveyed, expressly or by implication, to consumers acting reasonably") (emphasis added). However, this mandatory substantiation requirement, imposed as a condition precedent to even speaking about a product's health benefits, violates the major questions doctrine.

The Supreme Court articulated the major questions doctrine in *West Virginia v. EPA*, 142 S. Ct. 2587 (2022), holding that agencies may not resolve questions of "vast economic and political significance" without clear and specific statutory authorization from Congress. This principle has since been reaffirmed in cases such as *SEC v. Payward, Inc.*, No. 23-cv-06003WHO, 2025 16288, at 1 (N.D. Cal. Jan. 24, 2025); *Nebraska v. Su*, 121 F.4th 1, 4 (9th Cir. 2024); and *Mayfield v. United States DOL*, 117 F.4th 611, 614 (5th Cir. 2024). The doctrine is

grounded in the presumption that Congress does not delegate authority over matters of major political or economic consequence to executive agencies unless it does so explicitly.

Here, the FTC's requirement that advertisers substantiate health benefit claims with more than one RCT is an assertion of regulatory authority that Congress never granted. Nowhere in the Federal Trade Commission Act (FTCA) or any other statute has Congress authorized the FTC to impose such a rigid evidentiary standard. Instead, the agency has assumed this power unilaterally, acting *ultra vires* and exceeding the limits of its statutory mandate. The Supreme Court's ruling in *Loper Bright Enterprises v. Raimondo* further cements this principle, making clear that agencies must interpret their enabling statutes in accordance with their plain and intended meaning, not expand their authority beyond what Congress expressly delegated.

If Congress had intended for the FTC to require multiple RCTs as the exclusive standard of substantiation for health benefit claims, it would have explicitly stated so in the law. The agency's attempt to impose this requirement without clear statutory authorization is precisely the type of regulatory overreach that the major questions doctrine was designed to prevent. By demanding more than one clinical trial before an advertiser may speak, the FTC not only exceeds its statutory authority but also encroaches on constitutional protections for commercial speech.

Supporting Data

The economic impact of FTC actions in violation of the plain and intended meaning of the FTCA and the First Amendment over the last half century is likely in the hundreds of millions of dollars and has resulted in loss of employment and loss of business opportunities, qualifying those statutory and constitutional violations to be major question doctrine violations in the absence of express statutory authority.

"The Supreme Court has adopted a two-prong framework to analyze the major questions doctrine. First, courts ask whether the agency action is unheralded and represents a transformative expansion in the agency's authority in the vague language of a long-extant, but rarely used, statute. Second, courts ask if the regulation is of vast economic and political significance and extraordinary enough to trigger the doctrine. If both prongs are met, the major questions doctrine applies, and courts should greet the agency's assertion of authority with skepticism and require the agency to identify clear congressional authorization for its action." See *Nebraska v. Su,* 121 F.4th 1, 4 (9th Cir. 2024).

"There are three indicators that each independently trigger the major questions doctrine: (1) when the agency claims the power to resolve a matter of great political significance; (2) when the agency seeks to regulate a significant portion of the American economy or require billions of dollars in spending by private persons or entities; and (3) when an agency seeks to intrude into an area that is the particular domain of state law." *Mayfield v. United States DOL,* 117 F.4th 611, 614 (5th Cir. 2024).

"Under the major questions doctrine, courts expect Congress to speak clearly if it wishes to assign to an agency decision of vast economic and political significance. It requires that in the extraordinary case where an agency claims the power to regulate a significant portion of the

American economy that has vast economic and political significance, that agency must show it has clear congressional authorization*." SEC v. Payward, Inc.,* No. 23-cv-06003-WHO, 16288, at *1 (N.D. Cal. Jan. 24, 2025).

"...[T]he judicial role is to determine the extent of the agency's delegated authority and then determine whether the agency has acted within that authority. Similarly, an agency construction of a statute cannot survive judicial review if it reflects an action that exceeds the agency's authority." See *Nat'l Ass'n of Postal Supervisors v. United States Postal Serv.,* 456 U.S. App. D.C. 18, 23, 26 F.4th 960, 965 (2022).

The more than one well-designed RCT rule violates the generally accepted principle of scientific validity which is, instead, predicated on the totality of scientific evidence without specific regard to the number of clinical trials present.

RCTs Have Limited Utility for Evaluating Complex Nutritional Interventions

The FTC guidance has increasingly interpreted "competent and reliable scientific evidence" to mean at least one RCT that proves a causal link between a health product and its claimed benefit. This approach misapplies a narrow evidentiary framework developed for pharmaceutical products to a fundamentally different scientific domain: health maintenance, including by food and nutritional products.

Although RCTs are considered the gold standard for internal validity—because their design minimizes confounding variables—they are poorly suited for nutritional interventions and other multifactorial health influences. As noted by Concato, Shah, and Horwitz in a landmark comparative analysis, "well-designed observational studies do not systematically overestimate the magnitude of the effects of treatment as compared with those in randomized, controlled trials" (*Concato J, Shah N, Horwitz RI. Randomized, controlled trials, observational studies, and the hierarchy of research designs.* N Engl J Med. 2000;342(25):1887-92).

The scientific community has also recognized that RCTs suffer from low external validity when applied to real-world dietary exposures. Glasgow *et al.* highlight that "efficacy trials [RCTs] often fail to translate to real-world settings because of the lack of attention to context, sustainability, and multiple interacting factors" (*Glasgow RE, Lichtenstein E, Marcus AC. Why don't we see more translation of health promotion research to practice? Rethinking the efficacyto-effectiveness transition. Am J Public Health*. 2003;93(8):1261-7).

Further, leading epidemiologist Dr. John P.A. Ioannidis has argued that "a large share of randomized trials are not useful, and many are misinterpreted," concluding that "insistence on randomized trials for every intervention may waste resources and misguide policy" (*Ioannidis JP. Why Most Clinical Research Is Not Useful. PLoS Med.* 2016;13(6):e1002049).

The FTC's Implied Requirement to Prove Causation Is Scientifically and Legally Unsound

By requiring at least one RCT, the FTC effectively mandates proof of causation—a standard that is extraordinarily difficult, if not impossible, to meet in the context of nutrition and dietary products especially. Nutritional health outcomes arise from long-term, complex

interactions among dietary patterns, genetics, variations in the gut microbiome, lifestyle factors, and an almost limitless array of different environmental exposures.

The legal and scientific communities both recognize that **causation cannot be conclusively demonstrated by any one study type**, including RCTs. This principle was articulated sixty years ago by epidemiologist Sir Austin Bradford Hill, who proposed a framework for inferring causation based on the totality of circumstances, including biological plausibility, strength and consistency of the association, and coherence with existing knowledge (*Hill AB. The Environment and Disease: Association or Causation? Proc R Soc Med.* 1965;58(5):295-300). The FTC's own precedent supports a flexible approach to substantiation. In *Pfizer, Inc. v. FTC*, the Commission held that substantiation requires "competent and reliable scientific evidence," not necessarily an RCT, and that "what constitutes a reasonable basis depends greatly on the circumstances of the advertisement and the claims made" (*Pfizer, Inc. v. FTC*, 81 F.T.C. 23, 64 (1972)). Similarly, while the Commission's decision in *Daniel Chapter One v. FTC* was ultimately upheld, the court did not adopt a *per se* rule requiring RCTs as the sole form of competent and reliable scientific evidence (*Daniel Chapter One v. FTC*, No. 9345, 2009 FTC LEXIS 85 (F.T.C. Aug. 5, 2009)).

The Totality of Evidence Approach Is the Scientifically Accepted Framework

Major scientific institutions and regulatory bodies—including the Institute of Medicine (now the National Academy of Medicine), the World Health Organization, and the U.S. Food and Drug Administration—routinely use a "totality of evidence" standard in evaluating nutrition and health claims. A "totality of evidence" approach involves weighing and integrating multiple types of evidence across a spectrum of evidence which will inevitably demonstrate variable levels of quality, rigor, relevance, and conclusivity. This approach acknowledges that no single study type is sufficient on its own and instead seeks convergence across different methodologies. The kinds of evidence commonly considered in such an approach include:

- **Mechanistic studies**, which are typically derived from *in vitro* (cellular/molecular models), *in silico* models (computer-based simulations that help to inform responses or processes in biological systems). These explore biological plausibility and mechanisms of action;
- **Animal studies**, offering controlled insight into efficacy and safety;
- **Observational and epidemiological studies**: these include **cohort studies**, which track large populations over time to compare incidence of outcomes based on exposure status; **case-control studies**, which compare those with a condition (cases) to those without (controls) to identify retrospective exposures, and; **cross-sectional studies**, which evaluate exposure and outcomes at a single point in time. All of these study types evaluate effectiveness under real-world conditions, unlike randomized control trials, which assess efficacy under controlled, experimental conditions only;
- **Human biomarker and physiological studies**, which measure intermediate endpoints (e.g., inflammatory markers, lipid levels) that are known predictors of clinical outcomes
- **Real-World Evidence (RWE),** which can be derived from medical (electronic) health records, registries, insurance claims, adverse reporting systems, and post-marketing surveillance.

- **Case reports and case series**, which include detailed observations of individual and grouped patient experiences and clinical evidence.
- **Historical Epidemiological Evidence**, including long-term public health or demographic studies including long-term history of use of specific interventions.
- **Expert Consensus and Clinical Experience,** that summarize the totality of available evidence with expert interpretation and clinical evidence derived from years or decades of experience.

The FDA represents that it does not require RCTs in its evaluation of qualified health claims, instead applying an evidence-based review system that considers multiple forms of scientific data (*U.S. Food and Drug Administration, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims*, available at https://www.fda.gov/media/71858/download (Jan. 2009)).

Likewise, the Institute of Medicine has emphasized that nutrition policy must be based on an integration of mechanistic, epidemiologic, and clinical evidence (*Institute of Medicine, Dietary Reference Intakes for Calcium and Vitamin D*, 2011, at 19). The World Health Organization, in its fortification guidelines, similarly advises reliance on a range of evidence types in assessing nutrient-related health effects (*World Health Organization, Guidelines on Food Fortification with Micronutrients*, 2006, at 11).

The RCT Requirement Is Anti-Competitive and Stifles Innovation

Insisting on RCTs creates a *de facto* regulatory barrier that disproportionately affects smaller entities and health innovators. The cost of conducting RCTs is prohibitive for most natural health product companies and results in a chilling effect on speech, contrary to the First Amendment protections recognized in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), which established that truthful, non-misleading commercial speech about dietary supplements may not be suppressed without a substantial governmental interest and narrow tailoring.

Conclusion

For the foregoing reasons, the FTC should act promptly to propose by rule the adoption of each of the above 16 requested actions to help end the unconstitutional and unlawful agency actions explained hereinabove.

Sincerely,

/s/ Jonathan W. Emord

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