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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-related product advertising cases under Sections 5 and 12 of the Federal Trade Commission Act.

Consistent with the First Amendment to the United States Constitution; the Due Process Clause of 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-related product claims and requiring the agency in post-publication review to evaluate the totality of scientific evidence concerning a health-related product claim.

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

This petition seeks issuance of an order from the Commission directing complaint counsel 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 a respondent. 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-related product advertising. In that regard, Petitioners ask the Commission to rule that no investigation and no litigation may commence against a respondent in the context of health-related product advertising unless the Commission or a Commissioner: (1) possesses competent and reliable scientific evidence that the advertising claims in issue are deceptive; (2) establishes that consumers have suffered actual injury, economic or physical, in reliance on the advertising claims in issue; (3) satisfies throughout FTC proceedings the agency's constitutional and statutory obligation to satisfy the burdens of proof and production on deceptive advertising; and (4) formally rejects the idea that any specific number or kind of evidence is required to support a health-related product claim and, instead, examines the totality of the scientific evidence 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 complaint counsel in any hearing proceeding against a respondent until after a recommended decision has been issued by the Administrative Law Judge with strict penalties for violations of the rule; (b) prohibiting complaint counsel from interfering with production of documents responsive to subpoenas issued by Administrative Law Judges with strict penalties for violations of the rule; (c) prohibiting the Commission, any Commissioner, and complaint counsel 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 hearing or appeal therefrom; (d) prohibiting complaint counsel from withholding from a respondent any document possessed by the government or its witnesses germane to hearing issues and of benefit to the respondent, save those protected by privilege; (d) prohibiting complaint counsel from drafting any part of an expert opinion in support of the agency's case against a respondent in an FTC hearing with strict penalties for violations of the rule; (e) prohibiting the Commission, any Commissioner, or complaint counsel from demanding withdrawal of pleadings or arguments in an agency administrative proceeding as a condition precedent to settlement or entry of a settlement agreement in a case; (f) 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 calculated to avoid surprise; (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 the Administrative Procedure Act, and is therefore invalid.

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

[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, representing 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

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 (see the attached text of rule changes) by formal rule following notice and comment rule making.

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 respondent, 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 deceptive by a preponderance of the evidence. The FTCA and the First Amendment place the onus on the government to prove health-related product claims deceptive, not on the accused to prove its claims true to a near certain degree. That is true of commercial

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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."

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 burdening speech.

As evidenced in FTC hearings, including the ECM Biofilms case, complaint counsel have often acted in coordination with Commission staff, thus destroying the separation of functions and powers required under the Administrative Procedure Act, 5 USC 556(d), and essential to impartial decision making on appeal to the Commission. Complaint counsel have frequently modified their legal theories and causes of action without amending their complaints and without notice to the respondent. Complaint counsel have written substantial parts of expert reports of those they have hired as experts, falsely representing the reports to the Administrative Law Judges and to respondents to be the independent professional judgments and products of the experts. Complaint counsel have withheld information in their possession when demanded by the accused or respondent in FTC hearings, using it without advance notice in the conduct of depositions of respondents' principals. Complaint counsel have interfered with the production of documents by those given administrative subpoenas from the respondent, contacting subpoena recipients *ex parte* and advising them that they need not respond to the subpoena. The Administrative Law Judge's recommended decisions have 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 not been granted expressly the power to rule decisions of the FTC applied in a case unconstitutional, in violation of a statute, arbitrary or capricious, or otherwise contrary to law.

FTC has modified the claims for which it demands proof and the nature of its causes of action against the respondent in FTC administrative hearings without notice to the respondent and at every part of the proceeding, even up to the time of recommended decision by the Administrative Law Judge. It has denied the respondent 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 respondent's advertising content deceptive if the accused did not possess documentation in the form of scientific evidence to prove health-related product claims before advertising commences, unilaterally relieving itself of its statutory and constitutional burden of proof to establish the deceptiveness of the 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 and in the absence of any evidence that a majority of consumers shared the perception. It has imposed millions of dollars in defense costs on respondents 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 respondents 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 health-related product claims 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 respondents. 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[3] that:

(1) Amend 16 CFR Part 2, Subpart A, § 2.7(b) as specified in the attached text of proposed amendments to FTC's Rules of Practice to ensure that no civil investigative demand is issued concerning deceptive health-related advertising claims unless the Commission or a Commissioner possesses independent, peer-reviewed competent and reliable scientific evidence supporting the conclusion that the advertising claims are deceptive; unless the Commission or a Commissioner has obtained direct evidence that a majority of consumers have relied upon the advertising claims in issue in making purchasing decisions; and unless the Commission or a Commissioner has obtained direct evidence that those consumers have suffered actual physical or financial injury in reliance on the advertising claims.

(2) Amend 16 CFR Part 3, Subpart A, § 3.2 as specified in the attached text of proposed amendments to FTC's Rules of Practice to give express authorization to Administrative Law Judges to rule in their recommended decisions that any statutory or regulatory provision facially or as applied violates the Constitution, the Federal Trade Commission Act, the Administrative Procedure Act, or any other federal law.

(3) Amend 16 CFR Part 3, Subpart A, § 3.3 as specified in the attached text of proposed amendments to FTC's Rules of Practice to prohibit *ex parte* substantive communications between complaint counsel and the Commission, any Commissioner, or any counsel, aide, or staff to the Commission or any Commissioner during the course of any case until after the Administrative Law Judge's recommended decision issues or after a settlement has been reached. The amendment also disallows Commissioners and their counsel, aides, and staff from attending any hearing before an Administrative Law Judge or to direct, advise or suggest how complaint counsel should proceed during the course of any hearing.

(4) Amend 16 CFR Part 2, Subpart B, § 3.11(2) as specified in the attached text of proposed amendments to FTC's Rules of Practice to require complaint counsel to provide the Administrative Law Judge and respondent a more definitive statement of the nature of the case brought. Specifically, it requires complaint counsel to specify the law alleged to be violated, each element complaint counsel intends to prove, and each theory of liability and relief

[3] While this listing explains why the changes are required to protect respondent's rights and interests; the text of the proposed amendments is worded to ensure mutually reciprocal requirements on complaint counsel and respondent as well as penalties for non-compliance that apply to both.

complaint counsel will assert. Greater specificity is required to constrict the causes of action and avoid amendment of them without leave of the presiding officer. It is also required to ensure that the respondent has adequate notice and an opportunity to be heard consistent with the demands of procedural due process.

(5) Amend 16 CFR Part 2, Subpart B, § 3.15(a)(1) as specified in the attached text of proposed amendments to FTC's Rules of Practice to clarify that no change in complaint counsel's complaint, whether to the law alleged to be violated, to an element of the law complaint counsel intends to prove, or to a theory of liability or relief may be made except by formal amendment and notice to respondent. It also specifies times within which such changes may occur as of right and may not occur without leave of the Administrative Law Judge on a showing of a lack of prejudice to respondent. Basic procedural due process demands this to ensure fairness in the proceedings.

(6) Amend 16 CFR Part 3, Subpart C, § 3.21 as specified in the attached text of proposed amendments to FTC's Rules of Practice to prohibit agreements between complaint counsel and respondents that restrict respondent objections or evidence at hearings. Any suggestion, request, demand, or exercise of influence by complaint counsel to induce respondent or its counsel to abandon rights to object or provide evidence at hearings is unethical, violates the basic principles of due process, and corrupts and distorts the truth-seeking process. It must therefore be expressly prohibited in the rules of practice.

(7) Amend 16 CFR Part 3, Subpart C, § 3.25 as specified in the attached text of proposed amendments to FTCs Rules of Practice to prohibit representations by the Commission, any Commissioner, complaint counsel or an agent of any of them that settlement in any case is contingent on respondent's withdrawal of argument, motion to rescind facts pled that underly a decision or order, or motion to rescind any decision or order by the Administrative Law Judge. Such demands are unethical, violate basic principles of due process, and corrupt and distort the truth-seeking process. They must therefore be expressly prohibited in the rules of practice.

(8) Amend 16 CFR Part 3, Subpart D, § 3.31(c)(2) as specified in the attached text of proposed amendments to FTC's Rules of Practice to ensure that respondents have full discovery of all relevant information, documents, and things that may be relevant, that may be exculpatory, or that may lead to the adduction of relevant evidence without regard to where in the agency or government that information, those documents, or things are held and when that information, those documents, or things were generated.

(9) Amend 16 CFR Part 3, Subpart D, § 3.31A (c) as specified in the attached text of proposed amendments to FTC's Rules of Practice to require that each expert report be accompanied by a written declaration from the expert swearing under penalty of perjury that no content in the report has been authored by anyone other than the expert except where specifically attributed to that other source in the report. Moreover, the amendments prohibit complaint counsel or its agents from drafting content in expert reports or otherwise altering the independent professional opinion of experts and assigns appropriately strict penalties for instances wherein these requirements are violated. Such actions to alter

expert opinions are unethical, violate basic principles of due process, and corrupt and distort the truth-seeking process.

(10) Amend 16 CFR Part 3, Subpart D, § 3.34 as specified in the attached text of proposed amendments to FTC's Rules of Practice to prohibit complaint counsel from contacting subpoena recipients *ex parte* and informing them that respondent's subpoena need not be given a response. Strict penalties are prescribed for violations of the rule. Any interference of that kind with subpoena responses is unethical, violates basic principles of due process, and corrupts and distorts the truth-seeking process.

(11) Amend 16 CFR Part 3, Subpart D, § 3.38A as specified in the attached text of proposed amendments to require use of privilege logs that gives reasonable detail and identifies the document withheld in production on grounds of privilege and requires full articulation of the basis for privilege, requires production of documents with privileged content redacted wherever possible, and prohibits use of previously withheld documents during deposition or hearing to avoid surprise and unfairness. The amendment also gives the Administrative Law Judge expanded power to engage in *in camera* review of documents alleged to be privileged and witness evaluation in instances where testimony is refused on grounds of privilege as the Administrative Law Judge deems necessary prior to issuance of a decision on an issue of privilege.

(12) Amend 16 CFR, Part 3, Subpart E, § 3.43 as specified in the attached text of proposed amendments to disallow argument concerning the net impression derived from advertising content or understood by consumers about the meaning of advertising content without well-designed, representative, statistically significant survey evidence conducted by a professional statistician documenting that over 50 percent of consumers have that net impression or understanding of the meaning of advertising content. Advertising is only appropriately the subject of government action if it is demonstrably deceptive to most consumers and, thus, unlikely to be cured through the exercise of market forces and the free flow of commercial debate among competing sellers and interested others.

(13) Amend 16 CFR, Part 3, Subpart F, § 3.43 as specified in the attached text of proposed Amendments to ensure that Commission decisions to adopt, modify, or reject the recommended decision are, by rule, limited to the four corners of the Administrative Law Judge's recommended decision and the hearing record and do not draw upon matters that were not the subject of argument below. Moreover, this amendment ensures that the Commission avoids adopting any conclusion of law in its decision that deviates from the plain and intended meaning of the Constitution, the Federal Trade Commission Act, and any other applicable federal law.

In addition to changes in the Rules of Practice, the petition calls on FTC to:

(14) Withdraw its "Health Product Compliance Guidance," https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf, to fulfil the Commissioners' constitutional oaths of office and to conform FTC policy with the requirements of the First Amendment; the Federal Trade Commission Act, Sections 5 and 12; and the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). The petition calls on the Commission to declare in a policy statement or guidance accompanying withdrawal of the Health Product Compliance Guidance that it is not

necessary for a health-related product advertiser to possess a clinical trial before engaging in health-related product advertising or to otherwise possess any specific level, degree, quantity, or quality of scientific evidence; that the burden of proof to establish deceptiveness of any advertising act or practice under Sections 5 and 12 of the Federal Trade Commission Act is on the Federal Trade Commission; and that so long as advertising content communicated is truthful and non-deceptive it is protected from government burden under the First Amendment and the Federal Trade Commission Act. The Commission is asked to further declare that it will not deem health-related product advertising deceptive on the basis that a net quantum or kind of scientific evidence is lacking but shall instead evaluate the totality of scientific evidence from all sources and shall itself carry the burden of proving health-related product claims deceptive by a preponderance of the evidence, rather than demanding that the respondent prove health-related product claims true to a near conclusive degree.

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 subpoena recipient, drafts an expert report but presents it as the independent opinion of an expert, or drafts a final decision that is not based on the findings and conclusions of the Administrative Law Judge and restricted to the plain and intended meaning of the governing law, 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). The agencies of the federal government are further constrained by the requirement that they avoid any interpretation of the governing law at odds with its plain meaning. See *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

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 order issues. Those structure and process challenges include challenges based on the First Amendment, Due Process, and the Federal Trade Commission Act, Sections 5 and 12, 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 and *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024) by this agency, Presidential Memorandum, "Directing the Repeal of Unlawful Regulations" (April 9, 2025), the FTC must act immediately to eliminate the long standing biases and unfair practices and procedures endemic in its hearing processes to bring them into compliance with constitutional requirements, its own enabling statute, 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[4], are forbidden violations of the Administrative Procedure Act and Fifth Amendment Due Process.

The requested actions in (1) through (14) above will help 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 and by minimizing the risk of decision based on ultra vires grounds or unconstitutional grounds. 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).

[4] Many abuses that occurred during the ECM Biofilms proceeding are captured in the hearing transcript and in an order sanctioning complaint counsel in that proceeding before an Administrative Law Judge. Those abuses include the following: complaint counsel, pre-hearing, repeatedly requesting that respondent's counsel waive all of respondent's rights to object to testimony and evidence offered by complaint counsel at hearing; complaint counsel wrote penultimate sections of its lead expert's report as discovered during cross-examination at hearing; complaint counsel advised respondent that settlement would not be possible unless the argumentative bases pled to the Administrative Law Judge that resulted in adverse findings against complaint counsel in the presiding judge's order were withdrawn by respondent; complaint counsel contacted respondent's subpoena recipient and advised the recipient that it need not comply with the subpoena; complaint counsel withheld a document responsive to respondent's discovery without assertion of privilege and presented it first during the deposition of respondent's principal, resulting in an adverse ruling by the Administrative Law Judge; and complaint counsel changed its basis for its primary cause of action during the pendency of the case without notice to respondent's counsel and without amending the complaint).

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; it is limited to enforcement post-publication and only upon satisfaction of the burden of proof and production establishing material advertising content to be deceptive. The First Amendment and the FTCA squarely place the burden of proof and production on the government to establish advertising content deception, not on the advertiser to prove advertising content 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 deceptive advertising.

The Federal Trade Commission Act does not grant FTC authority to require that a prospective health-related 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 would be deemed deceptive under Section 5 and 12 of the Federal Trade Commission Act. Rather, both the Act and the First Amendment require that FTC shoulder the burden of establishing based upon relevant scientific evidence that a health-related product claim is deceptive before it commences any non-public investigation through issuance of a civil investigative demand and, thereafter, of litigation. And FTC has no constitutional or statutory authority to shift that burden of proof or production to the respondent by demanding that he, she, or it establish claims to be true to a near certain degree or to be backed by more than one randomized clinical trial. Rather, the irreducible burden the FTC must shoulder under the Act and Constitution throughout proceedings against advertisers is to prove advertising deceptive, requiring it to adduce not that there is insufficient evidence to support truth but that there is affirmative evidence to establish deception.

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-related product 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-related product claim in context is deceptive (not that it is simply insufficiently supported in the view of the agency). If the claim is deceptive, 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 imposition of any burden on the speaker or the speech. 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. The principle articulated in *Pearson* is predicated on general First Amendment commercial speech jurisprudence and is at the core of that jurisprudence.

Moreover, neither the First Amendment nor the Federal Trade Commission Act enables FTC to impose pre-publication upon (or through guidance pressure, coercion or cajolery) the regulated class adherence to any requirement that it possess a set quantity of evidence, let alone that which FTC deems sufficient, in support of any health-related 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 deceptive 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 deceptive. 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 wind and makes a health-related product 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 of claim deceptiveness 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 deceptive. Even then, it must be provably consequential (material) 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 non-misleading through the addition of a claim qualification or disclaimer, it is the constitutional duty of this agency, a duty it cannot lawfully 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 above on First Amendment grounds.

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 even if possessed by other government agencies or even if dated years prior. 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 respondent's subpoena recipients and dissuading them from response. 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 complaint counsel 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-related product claim advertising without first obtaining scientific proof that the content of the advertisements in issue is deceptive and without first establishing that consumers have relied on the alleged deceptive advertising in making purchasing decisions to their economic or physical detriment. In short, the Commission has historically proceeded principally based on little more than 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 respondents by burdening protected speech and by forcing respondents 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 the actions requested above in fulfilment of the Federal Trade Commission Act, Sections 5 and 12.

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 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 without an express 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 avoid investigation and litigation unless possessed of competent and reliable scientific evidence that advertising claims are deceptive and, additionally, 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 on the preposterous notion that Commissioners are *clairvoyant* and able to intuit what consumers think is material in 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 a deceptive 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-related 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 deception 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 is now forbidden. 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-related Product Advertising

The FTC, acting *ultra vires*, has litigated against respondents for alleged deceptive health-related advertising claims when they did not possess in advance of advertising more than one well-designed 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 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-related product claims can be made. 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-related product claims 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-related product claims 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 those amendments, the material language of the Act, prohibiting "unfair or deceptive acts and practices" and "false advertisement," has remained 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-related Product Advertising Claims 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 deception. 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 deceptive—let alone in a way that would cause the less speech restrictive alternative of disclaimers or qualifications to be unavailing.

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 health-related product claim in context is deceptive, the claim 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 deceptive 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 commercial speech. 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 deceptive under its enabling Act, not to demand that an advertiser prove a claim true. The government may not presume to burden or regulate speech unless it first establishes that the speech is deceptive. That 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 deception 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 deceptive. *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 those harms 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-related product claim is deceptive solely because the advertiser lacks supporting evidence is nothing more than speculation or conjecture as to the verifiability of the claim. The Supreme Court has made clear that reliance on such speculation does not satisfy the government's First Amendment burden of proof and production, which demands that the government marshal actual proof of deception. The only meaningful proof, which the government must marshal before prosecuting speakers, speech or imposing restrictions, is affirmative evidence that the claim itself 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 on the FTC to possess competent and reliable scientific evidence that a health-related product claim is deceptive 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 adducing a competent foundation for presuming the speech deceptive. 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 deception 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 deceptive 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 explained the major questions doctrine most recently 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-related product 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 efficacy to-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 requested actions, as articulated definitively in the attached text of proposed amendments to the FTC's rules of practice, to help end the unconstitutional and unlawful agency actions explained hereinabove.

Sincerely,

/s/ Jonathan W. Emord

Jonathan W. Emord,
Counsel to Alliance for Natural Health USA;
Xlear, Inc.; Better Way Health

TEXT OF PROPOSED AMENDMENTS TO FTC'S RULES OF PRACTICE

(1) Amendment to 16 CFR Part 2, Subpart A, § 2.7(b) to include the addition or deletions of the text marked in red:

§ 2.7(b) ***Civil Investigative Demands.*** Civil Investigative Demands ("CIDs") shall be the only form of compulsory process issued in investigations with respect to unfair or deceptive acts or practices under section 5(a)(1) of the Federal Trade Commission Act (hereinafter referred to as "unfair or deceptive acts or practices"). **No CID shall issue concerning deceptive health-related advertising claims unless the Commission or a Commissioner (a) has obtained independent, peer-reviewed competent and reliable scientific evidence supporting the conclusion that the advertising claims are deceptive; (b) has obtained direct evidence that a majority of consumers have relied upon those advertising claims in making purchasing decisions; and (c) has obtained direct evidence that those consumers have suffered actual physical or financial injury in reliance on those advertising claims.**

(2) Amendment to 16 CFR Part 3, Subpart A, § 3.2, to include the revisions in red:

§ 3.2 Adjudicative proceedings are those formal proceedings conducted under one or more of the statutes administered by the Commission which are required by statute to be determined on the record after opportunity for an agency hearing. The term includes hearings upon objections to orders relating to the promulgation, amendment, or repeal of rules under sections 4, 5 and 6 of the Fair Packaging and Labeling Act, but does not include rulemaking proceedings up to the time when the Commission determines under § 1.26(g) of this chapter that objections sufficient to warrant the holding of a public hearing have been filed. The term also includes proceedings for the assessment of civil penalties pursuant to § 1.94 of this chapter. The term does not include other proceedings such as negotiations for and Commission consideration of the entry of consent orders; investigational hearings as distinguished from proceedings after the issuance of a complaint; requests for extensions of time to comply with final orders or other proceedings involving compliance with final orders; proceedings for the promulgation of industry guides or trade regulation rules; or the promulgation of substantive rules and regulations. In adjudicative proceedings before Administrative Law Judges, those judges have authority to rule in their recommended decisions that any statutory or regulatory provision facially or as applied violates the Constitution of the United States; that any action or rule of the Federal Trade Commission facially or as applied violates the Constitution of the United States; that any regulatory provision facially or as applied violates the Federal Trade Commission Act, the Administrative Procedure Act, or any other federal law.

(3) Amendment to 16 CFR Part 3, Subpart A, the addition of a new subsection at the end identified in red as, 3.3:

§ 3.3 No *ex parte* substantive communication between complaint counsel and the Commission, any Commissioner, or any counsel, aide, or staff to the Commission or any Commissioner.

Neither the Commission nor any Commissioner nor any counsel, aide, or staff to the Commission or any Commissioner shall engage in any *ex parte* substantive communication concerning any matter in hearing and during the course of any case brought by complaint counsel against a respondent until after the Administrative Law Judge has issued a recommended decision or after a settlement has been approved by the Commission. Neither the Commission nor any Commissioner nor any counsel, aide, or staff to the Commission or any Commissioner shall appear before or attend any hearing before an Administrative Law Judge. Neither the Commission nor any Commissioner nor any counsel, aide, or staff to the Commission shall direct, advise, or suggest how complaint counsel shall proceed during the course of any hearing before an Administrative Law Judge.

(4) Amendment to 16 CFR Part 2, Subpart B, § 3.11(2) to be replaced with the new content in red:

§ 3.11 Commencement of proceedings.

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(2) A clear and concise factual statement of each provision of the law alleged to be violated, of each element of the law complaint counsel intends to prove, and of each theory of liability and relief the complaint counsel will assert sufficient to inform each respondent definitively of the nature of the case against the respondent;

(5) Amendment to 16 CFR Part 2, Subpart B, § 3.15(a)(1) to be replaced with the new content in red:

3.15 Amendments and supplemental pleadings.

(a) *Amendments* —

(1) *By leave.* No change in the law alleged to be violated, to an element of the law complaint counsel intends to prove, or to a theory of liability and relief may be made to the complaint except by amendment and notice to the respondent. Amendments to the complaint or to the answer may be made as of right by the parties if filed no later than three months prior to the scheduled hearing upon notice to the opposing party of the amended complaint or amended answer. Thereafter, any amendment to the answer may only be made if filed at least one month preceding the scheduled hearing and only then if by grant of leave of the Administrative Law Judge upon proof that the amendment will not cause prejudice. A motion for amendment of the complaint or notice may be filed no later than two months prior to the scheduled hearing and shall only be allowed by the Administrative Law Judge if it does not cause prejudice to the respondent and if it does not cause a change in the law alleged to be violated; each element of the law complaint counsel intends to prove; and each theory of liability and relief from the original complaint or from any amendment made to the complaint during the period when the complaint could be amended as of right.

(6) Amendment to 16 CFR Part 3, Subpart C, § 3.21, the addition of a new subsection at the end, identified here in red as, 3.21(h):

§ 3.21(h) *Prohibition on Agreements between complaint counsel and respondents to restrict respondent objections or evidence at hearing.* Complaint Counsel shall neither seek to enter into nor enter into any agreement with Respondent or its counsel whereby Respondent would agree to waive, restrict, or avoid objections or restrict or avoid motions to introduce evidence during the course of any hearing before an Administrative Law Judge.

(7) Amendment to 16 CFR Part 3, Subpart C, § 3.25, the addition of a new subsection at the end, identified here in red as, 3.25(h):

§ 3.21(h) Neither complaint counsel nor the Commission nor any Commissioner nor anyone acting on behalf of complaint counsel or the Commission or a Commissioner shall directly or indirectly inform respondent or its counsel that settlement in any case is contingent on respondent's withdrawal of argument or motion to rescind facts pled that underly a decision or order or motion to rescind any decision or order by the Administrative Law Judge or the Commission.

(8) Amendment to 16 CFR Part 3, Subpart D, § 3.31(c)(2) to include the addition of the text in red:

> ***(2)Limitations.*** **Complaint counsel need only search for materials that were collected or reviewed in the course of the investigation of the matter or prosecution of the case and that are in the possession, custody or control of the Bureaus or Offices of the Commission that investigated the matter, including the Bureau of Economics. The Administrative Law Judge may authorize for good cause additional discovery of materials in the possession, custody, or control of those Bureaus or Offices, or authorize other discovery pursuant to § 3.36. Neither complaint counsel, respondent, nor a third party receiving a discovery request under these rules is required to search for materials generated and transmitted between an entity's counsel (including counsel's legal staff or in-house counsel) and not shared with anyone else, or between complaint counsel and non-testifying Commission employees, unless the Administrative Law Judge determines there is good cause to provide such materials. Notwithstanding the foregoing, respondent shall have full discovery of all relevant information, documents, and things that may be relevant, that may be exculpatory, or that may lead to the adduction of relevant evidence. The frequency or extent of use of the discovery methods otherwise permitted under these rules shall be limited by the Administrative Law Judge if he or she determines that:**
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> ****

(9) Amendment to 16 CFR Part 3, Subpart D, § 3.31A(c) to include the addition of the text in red:

> **§3.31A, Expert discovery.**

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(c) Each report shall be signed by the expert and contain a complete statement of all opinions to be expressed and the basis and reasons therefor; the data, materials, or other information considered by the witness in forming the opinions; any exhibits to be used as a summary of or support for the opinions; the qualifications of the witness, including a list of all publication authored by the witness within the preceding 10 years; the compensation to be paid for the study and testimony; and a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding 4 years. Each report shall include a written declaration from the expert, sworn under penalty of perjury, that no content in the report has been authored by anyone other than the expert except where specifically attributed to that other source in the report. A rebuttal or surrebuttal report need not include any information already included in the initial report of the witness.

(d) Neither complaint counsel nor any other employee or agent of the federal government nor respondent's counsel nor an agent of respondent shall author content contained in any expert report or otherwise alter the independent professional opinion expressed by the expert therein. Penalties for violation of this subpart by complaint counsel shall include, at a minimum, the striking of the expert report and the testimony of the expert, the removal of complaint counsel in violation of this subpart (d) from the case and, where in the Administrative Law Judge's judgment the facts and circumstances warrant, referral of those facts and circumstances and the Administrative Law Judge's related findings to the FTC Associate General Counsel for Ethics and to bar counsel in the states wherein complaint counsel are licensed to practice law for appropriate disciplinary action, and, in instances where egregious or repeat violations are found, dismissal of the case brought by the Commission against the Respondent with prejudice. Penalties for violation of this subpart (d) shall include, at a minimum, for violations by respondent's counsel: the striking of the expert report and the testimony of the expert, and, where in the Administrative Law Judge's judgment the facts and circumstances warrant, referral of those facts and circumstances to bar counsel in the states wherein respondent's counsel is licensed to practice law for appropriate discipline.

[The remaining subsections of this subpart should be relettered consecutively after the above insert]

(10) Amendment to 16 CFR Part 3, Subpart D, § 3.34, to add a new subpart (d) in red:

§ 3.34 Subpoenas.

(d) At the time a subpoena is issued by a party to a subpoena recipient, a copy of the subpoena shall be served upon the opposing party. Following receipt of the subpoena copy, the opposing party may not contact the subpoena recipient directly or indirectly to cause a delay in or discourage response to the subpoena. Penalties for violation of this subpart (d) shall include, at a minimum, for violations by complaint counsel: a presumption in favor of the truth of the matters asserted in the discovery sought (if not obtained) or obtained from the subpoena, removal of complaint counsel from the case or, where in the Administrative Law Judge's judgment the facts and circumstances warrant, referral of those facts and

circumstances and the Administrative Law Judge's related findings to the FTC Associate General Counsel for Ethics and to bar counsel in the states wherein complaint counsel are licensed to practice law for appropriate discipline, and, at a maximum, where egregious or repeat violations are found by complaint counsel, dismissal of the case brought by the Commission against the respondent with prejudice. Penalties for violation of this subpart (d) shall include, at a minimum, for violations by respondent's counsel: a presumption in favor of the truth of the matters asserted in the discovery sought (if not obtained) or obtained from the subpoena or, where in the Administrative Law Judge's judgment the facts and circumstances warrant, referral of those facts and circumstances to bar counsel in the states wherein respondent's counsel is licensed to practice law for appropriate discipline.

(11) Amendment to 16 CFR Part 3, Subpart D, § 3.38A, to include the revisions in red:

§ 3.38A Withholding requested material.

(a) Any person withholding material responsive to a subpoena issued pursuant to § 3.34 or § 3.36, written interrogatories requested pursuant to § 3.35, a request for production or access pursuant to § 3.37, or any other request for the production of materials under this part, shall assert a claim of privilege ~~or any similar claim~~ not later than the date set for production of the material. Such person shall~~, if so directed in the subpoena or other request for production,~~ submit, together with such claim, a ~~schedule~~ privilege log which describes the nature of the documents, communications, or tangible things not produced or disclosed - and does so in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim. The ~~schedule~~ privilege log need not describe any material outside the scope of the duty to search set forth in § 3.31(c)(2) except to the extent that the Administrative Law Judge has authorized additional discovery as provided in that paragraph.

(b) A person withholding material for reasons described in § 3.38A(a) shall comply with the requirements of that subsection in lieu of filing a motion to limit or quash compulsory process.

(c) No withheld document may be used in examining opposing witnesses during deposition or at hearing. If a document can be produced with the precise privileged content redacted without waiver of the privilege, then it must be so produced.

(d) If a contest arises concerning the applicability of a privilege, the Administrative Law Judge may require that an unredacted complete copy of the document be supplied for *in camera* review before ruling. Likewise, if a witness refuses to answer on grounds of privilege, the Administrative Law Judge may before ruling demand that the witness testify *in camera* represented by the witness's counsel and excluding the presence of complaint counsel.

(e) Penalties for violation of this subpart by complaint counsel shall include, at a minimum, the adoption of an adverse inference against the argument or position asserted by complaint counsel based on the matter contained in the wrongfully withheld document or testimony, exclusion of the wrongfully withheld document or testimony from evidence if adverse to respondent denied timely access to the document or testimony, the removal of complaint counsel in violation of this subpart § 3.38A from the case and, where in the Administrative Law Judge's judgment the facts and circumstances warrant, referral of the

facts and circumstances and the Administrative Law Judge's related findings to the FTC Associate General Counsel for Ethics and to bar counsel in the states wherein complaint counsel are licensed to practice law for appropriate disciplinary action, and, in instances where egregious or repeat violations are found, dismissal of the case brought by the Commission against the respondent with prejudice. Penalties for violation of this subpart § 3.38A by respondent shall include, at a minimum, the adoption of an adverse inference against the argument or position asserted based on the matter contained in the wrongfully withheld document or exclusion of the wrongfully withheld document or testimony from evidence if adverse to complaint counsel denied timely access to the document or testimony, and, in instances where egregious or repeat violations are found, referral of the facts and circumstances to bar counsel in the states wherein respondent's counsel is licensed to practice law for appropriate disciplinary action.

(12) Amendment to 16 CFR, Part 3, Subpart E, § 3.43, the addition of a new subsection at the end, identified here in red as, 3.43(j):

(j) *Essential evidence of consumer deception.* No argument that advertising, or the net impression derived from advertising content, is understood by consumers to convey a specific deceptive impression, shall be admissible into evidence or shall be the basis for any finding or conclusion in a recommended decision by an Administrative Law Judge, or the basis for any final decision by the Commission unless supported by a well-designed, representative, statistically significant consumer survey conducted by a professional statistician and of a design and methodology generally accepted among professional statisticians to yield accurate, reliable and reproducible results ("competent survey evidence"). Only competent survey evidence may be the subject of any recommended decision or final decision of the Commission involving the meaning of terms in advertising and the overall or net impression of advertising to consumers. No finding of deceptive acts or practices dependent in whole or part on competent survey evidence shall be made by an Administrative Law Judge in a recommended decision or by the Commission in a final decision unless more than half of all consumers are shown to have understand the advertising in issue to have a meaning or a net impression that is deceptive.

(13) Amendment to 16 CFR, Part 3, Subpart F, § 3.54, the insertion of a new subsection (c) and a relettering of existing (c) to be a new subsection (d) with new subsection (c) identified here in red as, 3.54(c):

(c) The decision of the Commission is confined to the four corners of the recommended decision of the Administrative Law Judge and the hearing record. In its decision, the Commission will evaluate every finding, and every conclusion reached by the Administrative Law Judge and will provide a complete explanation as to whether under the law it supports, modifies, or rejects each finding and conclusion, along with the reasons therefore. The Commission shall not base its decision on any argument not raised before the Administrative Law Judge and preserved on appeal. The Commission shall not adopt any conclusions of law in its decision that deviate from the plain and intended meaning of the Constitution, the Federal Trade Commission Act, or any other applicable federal law.

RECOMMENDED WITHDRAWAL OF GUIDANCE

(14) Withdraw the FTC "Health Products Compliance Guidance," https://www.ftc.gov/system/files/ftc_gov/pdf/Health-Products-Compliance-Guidance.pdf

The Commission should formally withdraw and rescind the Health Products Compliance Guidance and in doing so advise that its action is taken to fulfill the Commissioners' constitutional oaths of office and to conform agency policy with the requirements of the First Amendment to the United States Constitution; the Federal Trade Commission Act, Sections 5 and 12; and the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). The Commission should declare in a policy statement or guidance accompanying the withdrawal of the Health Product Compliance Guidance that it is not necessary for a health-related product advertiser to possess a clinical trial before engaging in health-related advertising or to otherwise possess any specific level, degree, quantity, or quality of scientific evidence; that the burden of proof to establish deceptiveness of any advertising act or practice under Sections 5 and 12 of the Federal Trade Commission Act is on the Federal Trade Commission; and that so long as advertising content communicated is truthful and non-deceptive it is protected from government burden under the First Amendment and the Federal Trade Commission Act. The Commission should further declare that it will not deem health-related 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-related product claims deceptive by a preponderance of the evidence, rather than demanding that the respondent prove health-related product claims true to a near conclusive degree.