

Before the
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

**In Re: Petition for Rulemaking to
Adopt Statutory and First
Amendment Limits on FTC
Orders Concerning Health
Benefit Claims and Enact
Regulations to Implement
Pearson v. Shalala, 164 F.3d 650
(D.C. Cir. 1999)**

Docket No. _____

**PETITION FOR RULEMAKING
BY
THE ALLIANCE FOR NATURAL HEALTH USA
AND
DURK PEARSON AND SANDY SHAW**

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TABLE OF CONTENTS

SUMMARY OF ARGUMENT 1

BACKGROUND 8

 A. Interests of the Petitioners 8

 Alliance for Natural Health USA 8

 Durk Pearson and Sandy Shaw 9

 B. The FTC’s New Policies Concerning Claim Substantiation 10

LEGAL ARGUMENT 14

 A. FTC Lacks Jurisdiction to Enforce the Federal Food Drug and
 Cosmetic Act 14

 B. The FTC’s Two Clinical Trial Requirement Violates the First
 Amendment Standard in *Pearson v. Shalala* 21

 C. The FTC Cannot Violate the Constitution in Consent Orders 25

 D. The FTC’s New Policies Chill Protected Speech 27

 1. The FTC’s New Policies Apply to the Industry As a Whole 27

 2. The Fear Of Enforcement Under FTC’s New Policies Chills
 Protected Speech 30

CONCLUSION 33

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PETITION FOR RULEMAKING

The Alliance for Natural Health-USA and Durk Pearson and Sandy Shaw (“Petitioners”), by counsel and pursuant to 16 C.F.R. §§ 1.9, 1.21, and 1.25 and Section 18 of the Federal Trade Commission Act (“FTCA”), 15 U.S.C. § 57(a)(1)(B), hereby petition the Federal Trade Commission (“FTC” or “Commission”) to adopt statutory and First Amendment limits on FTC Orders concerning health benefit claims and to enact regulations implementing *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) and its progeny.

SUMMARY OF ARGUMENT

Recently the FTC altered the content of language used in its Consent Orders to specify two new requirements applicable to the advertisers in question and (by dint of the chilling effect stemming from those Orders) to all advertisers similarly situated, selling essentially equivalent products with essentially the same claims. Thus far, the Orders

imposing the two new requirements have applied to advertising concerning the effects of dietary supplements: (1) on enhancing immune system function with claims FTC views as expressing or implying reduction in the risk of colds and flu (*FTC v. Iovate Health Sciences*, No. 10-CV-587 (W.D.N.Y. 2010)); *In re Nestle Healthcare Nutrition, Inc.*, FTC Docket No. C-4312 (Jan. 18, 2011); *In re The Dannon Company, Inc.*, FTC Docket No. C-4313 (Feb. 4, 2011)); (2) on weight loss (*Iovate Health Sciences*, No. 10-CV-587 (W.D.N.Y. 2010)); and (3) on temporary relief of irregularity and improved digestive transit time (*In re The Dannon Company, Inc.*, FTC Docket No. C-4313 (Feb. 4, 2011)). Based on those Orders, it appears that FTC intends to rely on the same two requirements in future consent orders affecting the aforementioned speech categories as well as other, as yet specified, speech categories.

The alterations in question involve: (1) the FTC using as a proxy for determining the sufficiency of advertising substantiation reference to FDA's prohibition on health claims, barring claims that a dietary supplement treats, cures, prevents, or mitigates disease until approved by FDA under its Nutrition Labeling and Education Act "significant scientific agreement" health claim review standard, 21 U.S.C. § 343(r)(5)(d) and (2) the FTC requiring two well-designed clinical trials substantiating the claim at the time of first advertising to avoid a charge of deceptive advertising or a finding of Order violation.

In particular, the consent order language compelling compliance with FDA's prior restraint on nutrient-disease risk reduction claims and on disease treatment claims reads as follows:

It is ordered that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in

connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product, in or affecting commerce, *shall not represent*, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, *that such product prevents or reduces the risk [or likelihood] of [upper respiratory tract, getting a cold or the flu] unless the representation is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.*

See In Re Nestle, FTC Docket No. C-4312, Order at Part I (emphasis added); *In re Dannon Company*, FTC Docket No. C-4313, Order at Part I; *see also FTC v. Iovate Health Sciences*, Case No. 10-CV-587 (W.D.N.Y), Stipulated Final Judgment and Order for Permanent Injunction at Part I (prohibiting immunity claims unless “such product is subject to a final OTC drug monograph promulgated by the [FDA] for such use, and conforms to the conditions of such use; remains covered by a tentative final OTC drug monograph for such use, and adopts the conditions of such use; or is the subject of a new drug application for such use approved by FDA, and conforms to the conditions of such use”). Throughout this petition we will refer to this requirement as the “FDA Prior Restraint Requirement.”

The consent order language requiring two well-designed clinical trials in substantiation for immunity claims that FTC regards as expressing or implying prevention or treatment of colds and flu; for weight loss claims; for temporary relief of irregularity and improved digestive transit time claims; and for attentiveness claims reads as follows:

It is ... ordered that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of [product] in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or

illustration, that [product] [has a particular health benefit], unless the representation is non-misleading ... *providing, however*, that nothing in this Part II shall prohibit respondent from representing that such benefit can be achieved ... if such claim is non-misleading and respondent possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. *For purposes of this Part II, competent and reliable scientific evidence shall consist of at least two adequate and well-controlled human clinical studies of [product], or of an essentially equivalent product, conducted by different researchers, independently of each other, that conform to acceptable designs and protocols and whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true.* Respondent shall have the burden of proving that a product satisfies the definition of essentially equivalent product.

See In Re Nestle, FTC Docket No. C-4312, Order at Part II (emphasis added); *In re Dannon Company*, FTC Docket No. C-4313, Order at Part II; *see also FTC v. Iovate Health Sciences*, Case No. 10-CV-587 (W.D.N.Y), Stipulated Final Judgment and Order for Permanent Injunction at Part II. Throughout this petition we will refer to this requirement as the “Two Clinical Trial Requirement.”

As explained in detail below, the FDA Prior Restraint Requirement is being imposed by FTC without requisite statutory authority. There is no authority under the FTCA for the Commission to impose a prior restraint on advertising representations; rather, the Act limits FTC authority to post-publication review of advertising. *See* 15 U.S.C. §§ 52, 55. The FDA Prior Restraint Compliance Requirement is also being imposed in violation of controlling precedent holding that the FDA may not encumber the right of a party to communicate potentially, but not inherently, misleading nutrient-disease risk reduction claims *even if* FDA does not authorize the claims under the Nutrition Labeling and Education Act [Pub. L. No. 101-535, 104 Stat 2353] and, more particularly, under its statutory “significant scientific agreement” schema. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (“*Pearson I*”); *Whitaker v. Thompson*, 248

F.Supp. 2d 1 (D.D.C. 2002) (“*Whitaker I*”); *Pearson v. Shalala*, 130 F.Supp. 2d 105, 112-13, 118-19 (D.D.C. 2001) (“*Pearson II*”); *Pearson v. Thompson*, 141 F.Supp. 2d 105, 112 (D.D.C. 2001) (“*Pearson III*”); *Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp. 2d 48 (D.D.C. 2010).

The FTC lacks jurisdiction to enforce the provisions of the Food Drug and Cosmetic Act. Only the FDA has that jurisdiction. FTC may not lawfully compel parties to remove from their labels, labeling, and advertising nutrient-disease claims by enforcing the FDA Prior Restraint Requirement through its Orders. The FTC is limited in its jurisdiction to determining whether such claims constitute false and deceptive advertising, apart from whether they comply with the FDA Prior Restraint Requirement or the FDCA generally. FTC’s extension of its jurisdiction beyond the bounds of its enabling statute violates the FTCA and the jurisdictional limits on agency authority. *See, e.g., FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125-26 (2000).

The Petitioners ask FTC to eliminate the FDA Prior Restraint Requirement in all present orders and discontinue use of the FDA Prior Restraint Requirement in all future Orders, including Consent Orders. If FTC does not, then FTC, when defining the prior restraint as a proxy for a finding of violation of the FTCA and FTC’s implementing regulations, must simultaneously implement the constitutional mandate in *Pearson v. Shalala* by specifying claim qualifications that will cure misleadingness or, if there are none, by presenting empirical evidence establishing the absence of such qualifications. *See Whitaker v. Thompson*, 248 F.Supp. 2d at 9-10. Under that mandate, the burden of proof lies on the government agency responsible for limiting future speech to establish with empirical evidence that there is no less speech restrictive alternative such as a claim

qualification that would avoid misleadingness. *Alliance for Natural Health U.S.*, 714 F.Supp. 2d at 61-62.

As explained in detail below, the Two Clinical Trial Requirement causes qualified claims of an association between a nutrient and a health benefit effect that can be communicated truthfully with claim qualifications to be disallowed until two well-designed clinical trials on the product are obtained. It thus categorically excludes qualified claims based on evidence other than two clinical trials when such claims qualified to reveal the inconclusiveness of scientific support are an accepted less speech restrictive alternative to outright suppression and to onerous imposition of restrictions that burden speech. *Pearson I*, 164 F.3d at 655-58; *Alliance for Natural Health U.S.*, 714 F.Supp. 2d at 60-62. Thus in the immediate case it has the effect of censoring prospective speech that may be true from the party so restrained but it also has a chilling effect on all similarly situated who sell essentially equivalent products with essentially the same claims. *See Multimedia Holdings Corp. v. Circuit Court of Florida, St. Johns County*, 544 U.S. 1301, 1304 (2005); *Virginia v. Am. Booksellers Ass'n, Inc.*, 484 U.S. 383, 393 (1988); *Laird v. Tatum*, 408 U.S. 1, 12-13 (1972) (stating that “constitutional violations may arise from the deterrent, or ‘chilling’ effect of governmental regulations that fall short of a direct prohibition against the exercise of First Amendment rights”).

For the foregoing reasons, the Petitioners respectfully request that the FTC remove from all current and future Orders, including Consent Orders, the FDA Prior Restraint Compliance Requirement and remove from all current and future Orders, including Consent Orders, the Two Clinical Trial Requirement. The Petitioners also respectfully request that the FTC implement the constitutional mandate of *Pearson v.*

Shalala in all future Orders, including Consent Orders, by refraining from imposing any limit on future speech of an accused party if the agency can identify a qualification for a claim that avoids misleadingness or, if not, presents empirical evidence to prove the claim incapable of being rendered non-misleading. That is its minimum constitutional burden under *Pearson v. Shalala* and its progeny. *Pearson*, 164 F.3d at 659-60 (“we are skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones we suggested above would bewilder consumers and fail to correct for deceptiveness”); *Whitaker v. Thompson*, 248 F.supp. 2d 1, 4-5 (D.D.C. 2002) (“*Whitaker I*”) (“the FDA must demonstrate with empirical evidence that disclaimers similar to those suggested would bewilder consumers and fail to correct for deceptiveness”); *Pearson v. Shalala*, 130 F.Supp. 2d 105, 115 (D.D.C. 2001) (“*Pearson II*”) (same); *Pearson v. Thompson*, 141 F.Supp. 2d 105, 111-12 (D.D.C. 2001) (“*Pearson III*”) (same); *Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp. 2d 48, 60 (D.D.C. 2010) (same).

The FTC’s reliance on Consent Orders rather than formal rulemaking to establish these new criteria does not eliminate the need for constitutional compliance because the agency’s enabling statute and the First Amendment, unlike the Administrative Procedure Act, apply to whether, in the first instance, the FTC has a power to act. Moreover, the FTC may not constitutionally “fence-in” violators in a manner that imposes a prior restraint on future constitutionally protected speech. As explained more fully below, FTC lacks the power to act in the ways it has chosen because its enabling statute includes no jurisdiction to enforce the Food Drug and Cosmetic Act and its actions are prohibited by the First Amendment.

BACKGROUND

A. Interests of the Petitioners:

The **Alliance for Natural Health USA** (formerly the American Association for Health Freedom and, before that, the American Preventative Medical Association, a plaintiff in *Pearson*, certain of its progeny, and in *ANH USA v. Sebelius*) (“ANH USA”) is a Virginia nonprofit corporation, founded in 2002. ANH USA is a membership-based organization with more than 400 members consisting of consumers; healthcare practitioners; food, and dietary supplement company members; and 40,000 advocate members. A key focus for ANH USA is the protection and promotion of access to information in the market on the actual and potential benefits of health foods and dietary supplements. By educating the general public and ANH USA members about the actual and potential benefits of a healthy diet and lifestyle that includes supplements, ANH USA strives to arm consumers with the information necessary for them to make informed market selections and to take personal responsibility for their health, thereby promoting disease prevention, reducing the extent of medical intervention required, and reducing the public cost of healthcare in the United States. Among its dietary supplement company members are companies that would sell dietary supplements with qualified advertising claims of immune system enhancement for purchase during cold and flu seasons; qualified advertising claims of weight loss; and qualified advertising claims of relief from irregularity but engage in self-censorship because they neither have FDA health claims approval for the claims nor possess two well-designed clinical trials in support of them.

In particular, ANH USA board members, comprised of eight representatives of the natural health (consumer, industry, and professional) community, are deprived of the

ability to satisfy the ANH USA mandate: to facilitate the free flow of credible scientific information to educate consumers about the actual and potential benefits of supplements so that they may take more personal responsibility for their health and well-being. The result is that all ANH USA members suffer from the loss of truthful health claims that ANH USA supplement company members would make but for the chilling effect stemming from the FTC Prior Restraint Requirement and the Two Clinical Trial Requirement.

Durk Pearson and Sandy Shaw design dietary supplement formulations, including products that affect the immune system, contribute to satiety and weight maintenance, and improve digestive function. They license those products to companies that, in turn, sell them, depending on the ability to make truthful claims in the market based on qualifications of the evidence to avoid misleadingness. FTC's requirements have a chilling effect on Pearson and Shaw who have ordered their licensees not to communicate to the public on labels, in labeling, or in advertising any claim of association between the products they sell and immune system enhancement, weight loss, and relief of temporary irregularity for fear that the FTC will deem the claims deceptive advertising in light of the FDA Prior Restraint Requirement and the Two Clinical Trial Requirement. In particular, they do not possess two well-designed clinical trials to support the qualified claims and they do not possess FDA approval for any of the truthful qualified claims concerning immune system enhancement, weight loss, and relief of temporary irregularity that they would like to make.

For example, Pearson and Shaw have a prune juice product. The label for the product is attached as Exhibit 1. In connection with the promotion and sale of the

product they would like to include the advertisement that is Exhibit 2. Although they possess scientific evidence concerning the benefit of fiber to reduce the symptoms of chronic constipation and the claim is one accepted generally as true, they do not possess two well designed clinical trials substantiating the claim nor do they have FDA approval for the claim. Consequently, they fear that if the content is communicated in advertising, it will incur the wrath of this agency, causing them to be at risk of adverse FTC action.

B. The FTC’s New Policies Concerning Claim Substantiation:

The FTC and FDA have collaborated in regulating products since 1954. Under a Memorandum of Understanding between the two agencies, Working Agreement between FTC and Food and Drug Administration, 4 Trade Reg. Rep. (CCH) ¶ 9,850.01 (1971) (“Memorandum of Understanding”), FTC “has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics” and the FDA “has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce.” The FTC’s standard for substantiating advertisements has long been whether an advertiser possesses “competent and reliable scientific evidence;” heretofore the FTC has consistently rejected a “fixed formula” to define “competent and reliable scientific evidence.” See FTC Enforcement Policy Statement (May 1994) (“[t]here is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration”)¹; see also *FTC v. National Urological Group, Inc.*, 645 F.Supp. 2d 1167, 1186 (N.D. Ga. 2008) (“Obviously, this definition is context specific

¹ Available at, <http://www.ftc.gov/bcp/policystmt/ad-food.shtm>.

and permits different variations on ‘competent and reliable scientific evidence’ depending on what pertinent professionals would require for the particular claim made”).

FTC has, on some occasions, stipulated that two clinical trials would suffice as “competent and reliable scientific evidence.” *See FTC v. California Pacific Research, Inc.*, No. CV-N-88-602BRT (D.Nev. 1991) (unpublished), 1991 WL 208470, *1; *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1156 (9th Cir. 1984). However, the FTC never before set a minimum threshold of two studies as requisite to health benefit claims. FTC has explained that:

The benefits of a flexible approach are especially significant when the information relates to consumer health. Advertising and labeling can be extremely effective tools to educate consumers about diet-disease relationships, to increase their awareness of diseases, to inform them of different treatment options, and to empower them to manage better their own health. The ability to present information in advertising and labeling can also provide a strong incentive to competitors to develop new products and to improve existing products, giving consumers more and better choices.

See Comment of the Staff of Bureau of Economics, the Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission in the Matter of Request for Comment on First Amendment Issues, FDA Docket No. 02N-0209 (Sept. 13, 2002), at 22.

In August 2009, the FTC sued Lane Labs-USA, a supplier of dietary supplements alleged to have violated a 2000 FTC Consent Order. *See FTC v. Lane Labs-USA, Inc.*, No. 00-cv-3174 (D.N.J. 2009) (unpublished), 2009 WL 2496532, *overruled by*, 624 F.3d 575 (3d Cir. 2010). Asked to interpret whether Lane Labs violated the consent decree, the Federal District Court for the District of New Jersey determined that FTC did not meet its heavy burden to prove that Lane Labs lacked “competent and reliable” scientific

evidence to support its advertisements. *Id.* at *9-10. The FTC publicly stated that the Court’s decision in *Lane Labs* stemmed from an overbroad definition of “competent and reliable scientific evidence” included in the Consent Decree. The Commission publicly stated that it would narrow consent orders in response to *Lane Labs*.

Director of FTC’s Bureau of Consumer Protection, David Vladeck, speaking before the National Advertising Division in New York on October 5, 2009, stated:

[S]ome federal courts seem to have had difficulty, in certain situations, applying the standard injunction that prohibits particular kinds of claims unless the defendant “possesses and relies upon competent and reliable scientific evidence that substantiations the representation.” As a result, we will be crafting more precise language in future orders. In addition to achieving greater precision, we will also seek orders that harmonize with laws and regulations administered by sister agencies. A third goal will be to address those situations where a given piece of research, though it may have been conducted according to established protocols, achieved results inconsistent with the weight of scientific evidence in the relevant field.

See Remarks of David Vladeck, National Advertising Division Annual Conference, New York, NY (Oct. 5, 2009) at 3.²

Speaking before the Council for Responsible Nutrition, on October 22, 2009, Mr. Vladeck reiterated that FTC will heighten scrutiny of dietary supplement and health products and collaborate with FDA in enforcing health benefit claims. *See* Remarks by David C. Vladeck, Council for Responsible Nutrition Annual Symposium for the Dietary Supplement Industry, Rancho Palos Verdes, CA (Oct. 22, 2009).³ Discussing the *Lane Labs* decision, Mr. Vladeck explained:

Our experience in bringing enforcement and contempt actions in federal courts suggests that we need to take steps to make our standard injunctive language that prohibits particular kinds of claims unless the defendant

² Available at, <http://www.foodpolitics.com/wp-content/uploads/NAD-Vladeck-Speech-10-5-09.pdf>.

³ Available at, <http://www.ftc.gov/speeches/vladeck/091022vladeckcrnspeech.pdf>.

“possesses and relies upon competent and reliable scientific evidence that substantiates the representation” more exact. For instance, you may be aware of the recent decision in the *Lane Labs* case, where a district court judge denied the FTC’s motion to find the defendants in contempt of a prior FTC order requiring them to have “competent and reliable scientific evidence” substantiating the health claims. The Commission is disappointed with the results and intends to appeal.

We will be looking for more precise injunctive language in future orders that will provide clearer guidance to defendants and courts alike as to the amount and type of scientific evidence that will be required in future advertising.

Id. at 11-12.

FTC initiated enforcement proceedings against four major companies marketing health benefit claims in the summer of 2010. See *In re Nestlé HealthCare Nutrition, Inc.*, FTC File No. 092-3087 (filed July 2010); *In re The Dannon Company, Inc.*, FTC File No. 0823158 (filed December 2010); *In re POM Wonderful LLC and Roll International Corp.*, FTC Docket No. 9344 (filed September 2010); *Federal Trade Commission v. Iovate Health Sciences USA, Inc.*, FTC File No. 072 3187 (filed July 2010). The FTC’s orders included the FDA Prior Restraint Requirement and the Two Clinical Trial Requirement. See *In re Nestlé HealthCare Nutrition, Inc.*, FTC File No. 092-3087 (Jan. 18, 2011); *In re The Dannon Company, Inc.*, FTC File No. 0823158 (Feb. 4, 2011); *Iovate Health Sciences*, No. 10-CV-587 (W.D.N.Y 2010).

FTC’s new Consent Order language and the public pronouncements of its agents to the industry send engender a chilling effect on commercial speech. Advertisers similarly situated with the defendants in the above-referenced Consent Orders, who sell essentially equivalent products with essentially the same claims, perceive that they may not continue to do so without risk of adverse FTC enforcement unless they first satisfy the FDA Prior Restraint Requirement and the Two Clinical Trial Requirement..

LEGAL ARGUMENT

E. FTC Lacks Jurisdiction to Enforce the Federal Food Drug and Cosmetic Act

The FTC regulates food advertising in accordance with its statutory authority under Section 5 of the Federal Trade Commission Act (“FTCA”), 15 U.S.C. §45, to prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce, and under Sections 12 and 15 of the FTCA, 15 U.S.C. §§ 52, 55, which prohibit the dissemination “any false advertisement” that is likely to induce the purchase of food. Moreover, the FTC is authorized to prescribe “interpretive rules and general statements of policy with respect to unfair or deceptive acts or practices in or affecting commerce” and “rules which define with specificity acts or practices which are unfair or deceptive acts or practices affecting commerce.” *Id.* at § 57a(a)(1). Although FTC may regulate advertising claims, it has no authority to compel compliance with the FDCA, enforce the FDCA, or use as a proxy for determining the sufficiency of advertising substantiation reference to FDA’s prohibition on health claims, barring claims that a dietary supplement treats, cures, prevents, or mitigates disease until approved by FDA under its Nutrition Labeling and Education Act “significant scientific agreement” health claim review standard, 21 U.S.C. § 343(r)(5)(d).. The FTC’s FDA Prior Restraint Compliance Requirement exceeds the authority vested in FTC by the Federal Trade Commission Act. The FTC may not act without specific Congressional authorization and it has no authorization from Congress to enforce the Nutrition Labeling and Education Act. *See, e.g., La. Pub. Serv. Commn. v. FCC*, 476 U.S. 355, 374 (1986) (“an agency literally has no power to act . . . unless and until Congress confers power upon it.”); *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 650 (1990) (stating that “[a]lthough agency determinations within the scope of delegated authority are entitled to deference, it

is fundamental ‘that an agency may not bootstrap itself into an area in which it has no jurisdiction’”) (quoting *Fed. Mar. Commn. v. Seatrains Lines, Inc.*, 411 U.S. 726, 745 (1973)); *Am. Library Assn. v. FCC*, 406 F. 3d 689, 702 (D.C. Cir. 2005) (an agency does not possess plenary authority to act within a given area simply because Congress has endowed it with some authority to act in that area); *In re Keim*, 212 B.R. 493, 499 (Bkrcty. D. Md. 1997) (“[a]n act of a governmental agency is *ultra vires* if it is beyond the express or implied powers conferred by statute”). Accordingly, “[a]gency action taken without statutory authorization, or which frustrates the congressional policy which underlies a statute, is invalid.” *Yankton Sioux Tribe v. Kempthorne*, 442 F. Supp. 2d 774, 784 (D.S.D. 2006).

The FTC simply has no authority to enforce the Federal Food Drug and Cosmetic Act through FTC consent orders (an *ultra vires* activity). The FTCA does not provide authority to compel compliance with the FDCA, or institute enforcement proceedings for failure to comply with FDA regulations. See *Food and Drug Administration v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125-26 (2000). The Supreme Court has held that administrative agencies of the executive branch are limited to the jurisdiction conveyed in their organic statutes. *Id.* In *Brown & Williamson*, the Supreme Court addressed the FDA’s attempt to regulate tobacco products, a category of goods excluded from FDA’s jurisdiction in the Federal Food Drug and Cosmetic Act. *Id.* at 134-43. “Regardless of how serious the problem an administrative agency seeks to address ... it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law.” *Id.* at 125-126 (holding that “we believe that Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco

products. Such authority is inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme..."). FDA could not regulate tobacco products, which were already regulated by the Bureau of Alcohol, Tobacco, Firearms and Explosives. As in *Brown & Williamson*, so too here, the FTC cannot unilaterally extend its jurisdiction beyond the express language of the FTCA to enforce provisions of the Nutrition Labeling and Education Act because the FDA is given that jurisdiction exclusively.

Under Section 5 of the FTCA the FTC is only authorized to regulate and prevent deceptive acts or practices in food advertising. See *Peters v. Hobby*, 349 U.S. 331, 345 (1955) ("[a]gencies, whether created by statute or executive order, must of course be free to give reasonable scope to the terms conferring their authority. But are not free to ignore plain limitations on that authority"); *Marquette Cement Mfg. Co. v. FTC*, 147 F.2d 589, 594 (7th Cir. 1945) (the jurisdiction and authority of administrative agencies is confined solely to that which Congress bestows, and there are no limitations upon this congressional power other than the Constitution). That authority under the FTCA permits FTC to regulate false and deceptive claims once published and does not incorporate FDA's prior restraint on nutrient-disease relationship claims contained in the Nutrition Labeling and Education Act, 21 USC 343(r)(5)(d) or FDA's implementing regulations in 21 C.F.R. § 101.14. *Pediamed Pharm., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 727 (D. Md. 2006) (explaining that only the FDA is entitled to enforce the FDCA, including adulteration, mislabeling, and new drug applications); *Eli Lilly and Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 476 (D.N.J. 1998) ("[o]nly the federal

government, by way of either the FDA or the Department of Justice, has exclusive jurisdiction to enforce violation of the FDCA”).

By requiring advertisers to comply with the Nutrition Labeling and Education Act prior restraint on nutrient-disease claims, 21 USC 343(r)(5)(d), as a condition precedent to deeming the claims when in advertising not deceptive, the FTC has exceeded its statutory grant of authority and has invaded a province vested in a sister agency, the FDA. If the *sine qua non* for FTC claim substantiation is compliance with FDA laws, then FTC can enforce its Order only by interpreting and applying the FDCA in an FTC proceeding. Those actions are *ultra vires* for this agency.

In addition, even if FTC possessed requisite authority to enforce the FDCA, the FTC’s Prior Restraint Compliance Requirement violates controlling constitutional precedent limiting FDA’s ability to prevent a party from communicating potentially, but not inherently, misleading nutrient-disease risk reduction claims even if the FDA disallows the claims under the Nutrition Labeling and Education Act standard for health claim approval, 21 U.S.C. § 343(r)(5)(d) as implemented by 21 CFR 101.14. By including the FDA Prior Restraint Requirement for future advertising claims in its consent orders, the FTC necessarily subjects itself to the constitutional mandate in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (“*Pearson I*”); *Whitaker v. Thompson*, 248 F.Supp. 2d 1 (D.D.C. 2002) (“*Whitaker I*”); *Pearson v. Shalala*, 130 F.Supp. 2d 105, 112-13, 118-19 (D.D.C. 2001) (“*Pearson II*”); *Pearson v. Thompson*, 141 F.Supp. 2d 105, 112 (D.D.C. 2001) (“*Pearson III*”); *Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp. 2d 48 (D.D.C. 2010). In *Pearson I* our Court of Appeals held that FDA could deem a claim unapproved under the Nutrition Labeling and Education Act

“significant scientific agreement” standard but would still be required to permit the unapproved claim to enter the market unless the agency could prove with empirical evidence that no qualification of the claim would suffice to eliminate misleadingness. *See Pearson I*, 164 F.3d at 657-58.

The FDA Prior Restraint Requirement expressly requires that the defendants obtain FDA approval for claims under the Nutrition Labeling and Education Act schema (which is the health claims approval process in 21 USC 343(r)(5)(d)). The pertinent language reads that the defendant “*shall not represent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, that such product prevents or reduces the risk [or likelihood] of [upper respiratory tract infection, getting a cold or the flu] unless the representation is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.*” The requirement imposed by FTC does not mention, let alone apply, the constitutional mandate that is superimposed over this statutory regime. That mandate from *Pearson v. Shalala* *requires* that claims not approved under the statutory regime be evaluated to determine whether claim qualifications would suffice to eliminate misleadingness. The federal government is obliged to rely on claim qualification as a less speech restrictive alternative to prohibition unless the government can prove with empirical evidence that no claim qualification will suffice to eliminate misleadingness. *Pearson I*, 164 F.3d at 658-60; *Whitaker I*, 248 F.Supp. 2d at 4-5; *ANH USA*, 714 F.Supp. 2d at 58-60. Thus, FTC violates that constitutional stricture because its FDA Prior Restraint Requirement is imposed to prohibit future speech concerning a nutrient-disease

relationship without undertaking the required analysis to determine whether there exists any qualified claim that would suffice to eliminate misleadingness or, if not, proving that to be so with empirical evidence before demanding that the party comply with the prior restraint. The burden of proof is on the government, i.e., the government must prove that no claim qualification will suffice; the speaker is not required to offer claim qualifications in anticipation of a potential act of suppression by the state. *ANH USA*, 714 F.Supp. 2d at 61-62. Thus, the FDA Prior Restraint Requirement imposed by FTC in its Consent Orders violates the First Amendment and must immediately be removed from all existing consent orders and not used in any future ones.

Under the NLEA health claim schema, the FDA has no discretion to approve or deny a *truthful* claim that falls short of FDA's "significant scientific agreement" standard. See *Whitaker v. Thompson*, 248 F.Supp. 2d at 9-10. Thus, under the FDA Prior Restraint Requirement, the FTC is condemning prospectively a whole class of claims constitutionally required to be permitted under *Pearson* because they are not approvable under the NLEA schema but can be rendered nonmisleading through the addition of a claim qualification.

The *Pearson* decision and its progeny are First Amendment commercial speech decisions, not FDA administrative cases. The FTC is bound by constitutional doctrine when it implements a claim-approval schema of its own, including when using the NLEA prior restraint on health claims as a proxy for advertising substantiation.. Because the FTC's FDA Prior Restraint Compliance Requirement requires FDA pre-approval under Section 343(r)(5)(D) without providing room for approval of claims expressly not approved under the NLEA, the FTC's approach circumvents the *Pearson* doctrine and

imposes an unconstitutional prior restraint on constitutionally protected commercial speech.

The *Pearson* Court differentiated between “potentially” misleading claims which cannot be subject to prior restraint from “inherently” misleading claims that can be, thus applying the four-part test as established in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of New York*, 447 U.S. 557 (1980) in the context of health claims. *Id.* at 655 (citing *In Re R.M.J.*, 455 U.S. 191 (1982)) (states may not place an absolute prohibition on potentially misleading information if the information also may be presented in a way that is not deceptive). The Court also held that the preferred remedy for potentially misleading advertising information is “more disclosure, rather than less,” *Id.* at 657 (citing *Bates v. State Bar of Arizona*, 433 U.S. 350, 376 (1977)) and that the Supreme Court has repeatedly pointed to “disclaimers as constitutionally preferable to outright suppression.” *Id.* (citing *Peel v. Attorney Registration and Disciplinary Comm’n of Illinois*, 496 U.S. 91 at 110 (1990); *In Re R.M.J.*, 455 U.S. at 206, n.20; *Shapiro v. Kentucky Bar Association*, 486 U.S. 466, 478 (1988)).

In its most recent decision, the *Alliance for Natural Health U.S.* the United States District Court for the District of Columbia reaffirmed that:

The government has the burden of showing that the regulations on speech that it seeks to impose are not more extensive than is necessary to serve the interests it attempts to advance. If the Government can achieve its interests in a manner that does not restrict commercial speech, or that restricts less speech, the Government must do so... For this reason, the Court in *Pearson I* concluded that when government chooses a policy of suppression over disclosure—at least here there is no showing that disclosure would not suffice to cure misleadingness—the government disregards a far less restrictive means.

ANH USA, 714 F.Supp. 2d at 61-62. As held in *Pearson I* and *Whitaker I*, and reaffirmed in *ANH USA*, the *government* bears the burden to show with empirical evidence that “disclaimers would bewilder consumers and fail to correct for deceptiveness.” See *ANH USA*, 714 F.Supp. 2d at 62; *Pearson I*, 164 F.3d at 659-60; *Whitaker I*, 248 F.Supp. 2d at 11.

F. The FTC’s Two Clinical Trial Requirement Violates the First Amendment Standard in *Pearson v. Shalala*.

The FTC’s Two Clinical Trial Requirement similarly fails under the First Amendment and, in particular, the *Pearson* doctrine. The Two Clinical Trial Requirement causes future advertising that could be communicated in a non-deceptive way by revealing the limited nature of supportive evidence, i.e., its inconclusiveness, to be prohibited based on an arbitrary two clinical trial requirement. Thus, the universe of truthful advertising is delimited not by proof of deception but by the creation of an arbitrary barrier making the minimum price for the right to advertise about immune system enhancement, weight loss, temporary relief of irregularity and improved digestive transit time, and attentiveness the possession of two well designed clinical trials. FTC thus categorically excludes truthful qualified claims that reveal the existence of the association between a nutrient and one of those physiological effects to be supported by credible but inconclusive evidence. The Two Clinical Trial Requirement has the effect of censoring prospective speech protected under the First Amendment. See *Pearson I*, 164 F.3d at 655-58; *ANH USA*, 714 F.Supp. 2d at 60-62.

The federal courts have explained that a blanket ban on health benefit claims is permissible only under the narrowest of circumstances. The federal government may only impose an outright ban on a health claim when it can prove with empirical evidence

that no qualification of the claim will suffice to eliminate misleadingness. *Pearson*, 164 F.3d at 660, n.10 The District Court of the District of Columbia, applying the original *Pearson* decision in *Pearson II*, held “the mere absence of significant affirmative evidence in support of a particular claim ... does not translate into negative evidence against it.” *Pearson II*, 130 F. Supp. 2d at 115.

FTC’s Two Clinical Trial Requirement, defining the type and number of studies that must be present before commercial speech in the categories thus far defined may lawfully be communicated in advertising, produces a chilling effect that causes all similarly situated selling substantially similar products with substantially similar claims to engage in self-censorship, eliminating from their advertising lexicon all manner of truthful, qualified claims concerning immune system enhancement, weight loss, temporary relief of irregularity and improved digestive transit time, and attentiveness. *See Pearson*, 164 F.3d at 659-60. FTC curiously states that “advertisers should not make qualified claims where the studies they rely on are contrary to a stronger body of evidence. In such instance, even a qualified claim could mislead consumers.” *See Federal Trade Commission, Dietary Supplements: An Advertising Guide For Industry* (April 2001).

Those statements are contrary to case law and inconsistent with constitutionally mandated FDA decision-making. In *Pearson* and its progeny, the courts clearly held that when there is “credible evidence” to support a claim, a claim may not be banned but must be allowed with qualifications unless empirical evidence shows qualifications will not suffice to cure misleadingness. *Pearson*, 164 F.3d at 659. If credible evidence exists, a disclaimer is appropriate and constitutionally mandated. The *Pearson* Court was

skeptical that “the government could demonstrate with empirical evidence that disclaimers similar to the ones [the Court] suggested ... [“The evidence in support of this claim is inconclusive” or “The FDA does not approve this claim”] would bewilder consumers and fail to correct for deceptiveness.” *Id.* at 659-660. The FTC’s Two Clinical Trial Requirement thus increases burdens on protected speech because it eliminates a class of health claims supported by credible science, but short of the two human clinical trials.

FTC also unconstitutionally shifts its burden onto advertisers to prove that disclaimers will cure misleadingness. That burden belongs to the governmental entity imposing the speech limitation. . Summarizing its recent Consent Order in the Dannon Matter, the FTC explained:

Respondent may decide to make an advertising claim characterizing limited scientific evidence supporting the relationship between a covered product and a reduced likelihood of [disease]. However, if the net impression of that advertising is that the covered product reduces the likelihood of getting [the disease], and not merely that there is limited scientific evidence supporting the claim, the advertisement would be covered [by the Consent Order]. The Commission notes that its experience and research show that it is very difficult to adequately qualify a disease risk-reduction claim in advertising to indicate that the science supporting the claimed effect is limited. In other words, reasonable consumers may interpret an advertisement to mean that the product will reduce the likelihood of getting [the disease], even if respondent includes language indicating that the science supporting the effect is limited in some way. **However, if respondent possesses reliable empirical testing demonstrating that the net impression of an advertisement making a qualified claim for a covered product does not convey that it will reduce the likelihood of getting [the disease], then that claim would be covered under [the Consent Order].**

See In re The Dannon Company, Inc., FTC File No. 0823158, Analysis of Proposed Consent Order to Aid Public Comment (Dec. 15, 2010).⁴ The FTC’s conclusion, when applied not to advertising already in the market but as a prior restraint on prospective advertising in one of the categories defined in the Consent Orders above, violates the constitutional requirement of *Pearson I*, *Whitaker I*, and *Alliance for Natural Health*. *See Pearson I*, 164 F.3d at 659-60; *Whitaker I*, 248 F.Supp. 2d at 7; *ANH USA*, 714 F.Supp. 2d at 63. It is not the prospective advertiser that must bear the burden of proof, it is the government. Apposite precedent in the prior restraint context (such as exists when Consent Orders restrict the right to engage in future advertising) places the burden firmly on the government to prove that less speech-restrictive measures, such as claim qualifications, cannot cure misleadingness as a condition precedent to imposition of the commercial speech restriction. *See Pearson*, 164 F.3d at 659 (“[a]lthough the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech”) (emphasis added); *Whitaker I*, 248 F.Supp. 2d at 7 (“both *Pearson I* and *Pearson II* established a very heavy burden which Defendants must satisfy if they wish to totally suppress a particular health claim”); *ANH USA*, 714 F.Supp. at 61 (“[t]he government has the burden of showing that the regulations on speech that it seeks to impose are not more extensive than is necessary to serve the interests it attempts to advance”); *Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) (governments’ obligation to “demonstrate that the harms it recites are real and that

⁴ Available at, <http://www.ftc.gov/os/caselist/0823158/101215dannonanal.pdf>.

its restriction will in fact alleviate them to a material degree” “is not satisfied by mere speculation or conjecture”).

In sum, FTC’s Two Clinical Trial Requirement violates the First Amendment by imposing a prior restraint on the right to engage in commercial speech in the absence of two well designed clinical trials and impermissibly shifts the burden of proof to advertisers..

G. The FTC Cannot Violate the Constitution in Consent Orders

The FTC’s “fencing-in” authority does not permit the agency to expand consent orders beyond the limits of the First Amendment. The FTC has authority to “fence-in” violators, but that authority has generally been limited to product categories and methods of advertising. *Telebrands Corp. v. FTC*, 457 F.3d 354, 357 (4th Cir. 2006) (“[f]encing-in’ relief refers to provisions in a final FTC order that are broader than the conduct that is declared unlawful. Fencing-in remedies are designed to prevent future unlawful conduct”). In *Telebrands*, the Court discussed FTC’s fencing-in authority at length. *Id.* A reasonable relationship must exist between the violation and the FTC’s remedy. But fencing-in authority has never been interpreted to grant FTC authority to expand the substantiation requirements for claims, only the scope of the order. The FTC lacks authority *ab initio* to insert unconstitutional language in its consent orders. *See* 5 U.S.C. § 706(2)(B) (agency action is unauthorized if “contrary to constitutional right, power, privilege, or immunity”).

Broad categorical restrictions, like those attempted in the recent agreements, have been struck down by the courts in previous FTC arguments. In *Beneficial Corp. v. FTC*, 542 F.2d 611 (3rd Cir. 1976), *cert. denied*, 430 U.S. 983, 97 S.Ct. 1679, 52 L.Ed.2d 377

(1977), the Third Circuit reviewed an FTC order that forced a company “to abandon entirely its copyrighted and heavily promoted phrase (‘Instant Tax Refund’).” *Id.* at 618. While the court upheld FTC's finding that previous “Instant Tax Refund” advertising campaigns were deceptive, it would not enforce the order as far as it proscribed use of the term or other similar words in future advertising because the order went farther than was necessary to eliminate the deception. *Id.* at 620. Violations of the FTCA do not lift the constitutional limitations on prior restraint affecting future speech in FTC consent orders. *See U. S. v. Reader's Digest Ass'n, Inc.*, 464 F.Supp. 1037, 1051 (D.C. Del. 1978).

Rather, federal courts have consistently held that the doctrine of prior restraint and First Amendment protections are directly applicable to FTC consent orders and limit the expansion of FTC advertising regulation. *See, e.g., Standard Oil C. of California v. F.T.C.*, 577 F.2d 653, 662 (9th Cir. 1978) (“first amendment considerations dictate that the Commission exercise restraint in formulating remedial orders which may amount to a prior restraint on protected commercial speech”); *Sears, Roebuck and Co. v. F.T.C.*, 76 F.2d 385, 399 n.31 (9th Cir. 1982); *Beneficial Corp.*, 542 F.2d at 611; *F.T.C. v. Simeon Management Corp.*, 532 F.2d 708, 713 (1976) (“[a]lthough commercial advertising may be subject to regulation serving an important public interest, it is not beyond the protection of the first amendment... [S]afeguards would be inadequate if courts were required under section 53(a) to enjoin advertising because FTC claimed it was false, without first making an independent determination of the sufficiency of that claim”).

The First Amendment limits explained in cases concerning nutrient-disease relationship claims are applicable to all instances of federal government imposition of prior restraints, not solely to those arising under the FDA’s enabling statute, the NLEA,

but also to the FDA Prior Restraint Requirement and the Two Clinical Trial Requirement imposed in FTC Consent Orders. They are global protections that guard against restrictions on protected commercial speech.

H. The FTC's New Policies Chill Protected Speech

1. The FTC's New Policies Apply to the Industry As a Whole

The FDA Prior Restraint Requirement and the Two Clinical Trial Requirement for health benefit advertising announced in the Iovate, Dannon, and Nestlé consent orders apply to all similarly situated advertisers who sell substantially the same kind of products and make substantially the same kind of claims. The FTC has been vocal in communicating the restrictions to the industry through its agents. Although those agents disclaim that their views are those of the agency, they are the very individuals responsible for creating and enforcing the new requirements. *See* Dan Schiff, *FTC's Pending Claims Substantiation Changes Will Weigh on Small Firms*, *The Tan Sheet* at 9, Mar. 1, 2010. Richard Cleland, Assistant Director of the Division of Advertising Practices, has explained that “FTC plans to promulgate the revised standard initially through consent orders and eventually revise its advertising guide for the supplement industry.” *Id.*

The FTC's use of consent orders to express policy qualifies as an industry-wide rule. The APA defines a “rule” as

the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency.

5 U.S.C. § 551(4). Courts recognize the applicability of FTC consent orders on the entire market. *See Watson v. Philip Morris Companies, Inc.*, 420 F.3d 852, 859 (8th Cir. 2005)

(“[b]ringing a single case against one cigarette company would have the effect of bringing the whole industry into compliance and would do so much more quickly than would a formal rulemaking process”). Interpreting *Watson*, the United States District Court for the District of New Mexico explained that “[t]he FTC’s enforcement mechanisms through consent orders is no less effective and coercive than direct enforcement through a formal regulation.” See *Mulford v. Altria Group, Inc.*, 506 F.Supp.2d 733, 762 (D.N.M. 2007); see also *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 513 & n.7 (1992) (stating that FTC has “long regulated unfair and deceptive advertising practices in the cigarette industry,” and citing a number of FTC opinions in support of this proposition, implicitly recognizing that FTC opinions and orders are a form of FTC regulation). “The legal and regulatory effect of the consent orders is evidenced by the FTC’s own description of its consent orders as ‘regulatory activity.’” *Mulford*, 506 F.Supp. 2d at 762 (stating further that “[t]he history of FTC involvement in cigarette advertising demonstrates that the FTC used consent orders such as these to regulate the cigarette industry, make general rules, and express FTC policies for the industry in lieu of formal rulemaking”).

Although the *Watson* decision, relied upon in *Mulford*, has been overruled by the Supreme Court on the issue of whether an informal industry agreement between the FTC and the cigarette industry constituted a delegation of FTC authority thus making it a federal contractor, the Court’s observation that FTC uses consent orders as binding regulatory policy is still good law. See *Watson v. Philip Morris Companies, Inc.*, 551 U.S. 142, 156, 127 S.Ct. 2301 (2007) (*Watson II*). In fact, the Supreme Court in *Watson II*, cited the FTC’s regulatory activity, including the use of consent orders recognized in

Watson, as binding regulation for the cigarette industry. *See Watson II*, 551 U.S. at 154-155 (accepting as true facts listed in Phillip Morris brief). Thus, the proposition in *Mulford* that interpretations and commentary in FTC consent orders bind advertisers is the law.⁵

The content of consent orders demonstrating the FTC’s thinking or interpretation of substantiation requirements is significant evidence that the consent orders with Nestle, Iovate, and Dannon constitute an agency rule under the APA standard. *See* 5 U.S.C. § 551(4). The FTC and the courts are fully aware of the coercive nature of FTC consent orders on the market and intend those advertisers similarly situated who sell substantially the same products and make substantially the same claims take heed and avoid doing so. FTC relies on the regulatory power of those actions time after time as evidenced in the string consent orders used to regulate the cigarette industry. *See e.g., Mulford*, 506 F.Supp.2d at 762; *Cipollone*, 505 U.S. at 513 & n. 7, 112 S.Ct. 2608; *Watson I*, 420 F.3d at 859-60; *Watson II*, 551 U.S. at 154-155.

Industry members cannot afford to disregard FTC’s FDA Prior Restraint Requirement or its Two Clinical Trial Requirement in relevant consent orders. FTC consistently refrained from specifying precise quantitative requirements for advertising substantiation of health claims, stating instead that the FTC has discretion to determine

⁵ In addition, several state courts have also acknowledged the coercive and rule like nature of consent orders published by the FTC. *See Azar v. Prudential Ins. Co. of America*, 68 P.3d 909, 929 (2003) (suggesting that agency can “expressly permit” action in interpretations where it “specifically addressed” and authorized action); *see also Price v. Philip Morris, Inc.*, 219 Ill.2d 182, 848 N.E.2d 1, 46, 53-54 (2005) (holding that FTC's informal regulatory activity of cigarette advertising, including use of consent orders, fell within Illinois Consumer Fraud Act's exemption provision exempting actions or transactions “specifically authorized by laws administered by” a state or federal regulatory body).

on a case-by-case basis what evidence is required to meet the standard. *See, supra*, FTC, Dietary Supplements: An Advertising Guide for Industry (April 2011) (“[t]here are no fixed formula for the number or type of studies required...”). An affirmative statement in a consent order requiring FDA prior approval under the NLEA or two clinical trials represents to industry that FTC believes FDA prior approval and two clinical trials requisite to avoid a charge of deceptive advertising for the type of health claim addressed in the consent orders. Indeed, when interpreting text, even Courts generally give a word or phrase the same meaning when it is repeated in other sections of that text. *See Sierra Club v. Seaboard Farms Inc.*, 387 F.3d 1167 (10th Cir. 2004); *Sorenson v. Sec’y of the Treasury*, 475 U.S. 851, 860 (1986). It is logical for industry to do the same.

2. The Fear Of Enforcement Under FTC’s New Policies Chills Protected Speech

Because the FTC’s consent orders apply across the industry, the FTC’s FDA Prior Restraint Requirement and Two Clinical Trial Requirement have created an environment of fear for companies promoting the health benefits of products substantially the same as those in the Consent Orders with substantially similar claims. Courts recognize that a history of prosecution can give rise to an actionable belief on the part of the advertisers that similar prosecution could befall them in the future. *See Lopez v. Candaele*, 630 F.3d 775, 786-87 (9th Cir. 2010) (speaker need not be the direct target of government enforcement to have standing; a “history of past enforcement against parties similarly situated to the plaintiffs cuts in favor of a conclusion that a threat is specific and credible”). Therefore, the FTC’s new policies create a real fear within industry that similarly situated advertisers will be required to meet the FTC’s new standards for

advertising substantiation without the constitutionally mandated protections articulated in *Pearson v. Shalala*, 164 F.3d at 655-58.

The FTC polices health benefit claims with unbridled discretion to launch costly, time consuming investigations of companies without being required to produce any evidence that targeted advertising claims cannot be remedied with adequate qualifications. That power to investigate anyone in the market without the requirement to meet any kind of burden before instituting the investigation has a chilling effect on important beneficial speech. The threat of FTC enforcement action constitutes a prior restraint that chills speech. *See Multimedia Holdings Corp. v. Circuit Court of Florida, St. Johns County*, 544 U.S. 1301, 1304 (2005) (“A threat of prosecution or criminal contempt against a specific publication raises special First Amendment concerns, for it may chill protected speech much like an injunction against speech by putting that party at an added risk of liability”); *Virginia v. Am. Booksellers Ass'n, Inc.*, 484 U.S. 383, 393 (1988), (“self-censorship . . . can be realized even without an actual prosecution”); *Rangra v. Brown*, 566 F.3d 515, 519 (5th Cir.2009) (“A credible threat of present or future prosecution is an injury sufficient to confer standing, even if there is no history of past enforcement”).

The Supreme Court does not require formal action from an agency restricting the speech of an individual or company to find a prior restraint, “informal procedures undertaken by officials and designed to chill expression can constitute a prior restraint” of themselves. *Multimedia Holdings*, 544 U.S. at 1306 (citing *Bantam Books, Inc. v. Sullivan*, 372 U.S. 58 (1963)). “Any system of prior restraints of expression comes to [a] Court bearing a heavy presumption against its constitutional validity.” *Bantam Books*,

Inc. v. Sullivan, 372 U.S. 58, 70 (1963). The presumption against prior restraints was designed to prevent self censorship. See *City of Lakewood v. Plain Dealer Publishing Co.*, 486 U.S. 750, 757-58 (1988); see also Blasi, *Toward a Theory of Prior Restraint: The Central Linkage*, 66 Minn.L.Rev. 11 (1981); Emerson, *The Doctrine of Prior Restraint*, 20 Law & Contemp.Probs. 648 (1955).

In *Lakewood*, the Supreme Court explained the danger that exists to First Amendment rights when a prior restraint is created by the threat of prosecution when an agency has unbridled discretion to act against individuals or companies,

Self-censorship is immune to an “as applied” challenge, for it derives from the individual's own actions, not an abuse of government power. It is not difficult to visualize a newspaper that relies to a substantial degree on single issue sales feeling significant pressure to endorse the incumbent mayor in an upcoming election, or to refrain from criticizing him, in order to receive a favorable and speedy disposition on its permit application. Only standards limiting the licensor's discretion will eliminate this danger by adding an element of certainty fatal to self-censorship.

City of Lakewood v. Plain Dealer Publishing Co., 486 U.S. 750, 757-58. Thus, it is unnecessary that an agency actually abuses the power it has, it is enough that the power exists. See *id.* (quoting *Thornhill v. Alabama*, 310 U.S. 88, 97 (1940)) (“Proof of an abuse of power in the particular case has never been deemed a requisite for attack on the constitutionality of a statute purporting to license the dissemination of ideas. . . . It is not merely the sporadic abuse of power by the censor but the pervasive threat inherent in its very existence that constitutes the danger to freedom of discussion”).

The potential for unlawful application of the FTC’s new FDA Prior Restraint and Two Clinical Trial Requirements thus has the effect of chilling protected health benefit claims in advertising that are not FDA approved or are without two human clinical trials substantiating the claims. The new policies limit even traditional, well-recognized health

benefit claims in advertising supported by abundant scientific evidence, but without two human clinical trials, such as Pearson and Shaw’s desired claim for their prune juice product relieving symptoms of chronic constipation.

CONCLUSION

For the foregoing reasons, to bring the FTC’s Consent Orders concerning health benefit claims in advertising within the confines of the First Amendment, the petitioners hereby request that FTC remove from all Consent Orders issued to date and avoid inclusion in all future Consent Orders and other Orders of the FTC the FDA Prior Restraint and the Two Clinical Trial Requirements. The petitioners also request that FTC enact regulations implementing *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) and its progeny by avoiding the imposition of any restriction on the future right to make a claim of health benefit without first establishing with empirical evidence that claim qualifications will not suffice to cure for misleadingness.

Petitioners request that the Commission act expeditiously in its response to this petition. *See Elrod v. Burns*, 427 U.S. 373 (1976) (“[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury”); *Washington Free Community v. Wilson*, 426 F.2d 1213, 1218 (D.C. Cir. 1969) (“Speakers...cannot be made to wait for years before being able to speak with a measure of security”).

Respectfully submitted,

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