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

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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 recognize and enforce 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 the FTC: (1) 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) 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 of equating the absence of prior FDA health claim approval with deceptive advertising 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 the requirement of two well-designed clinical trials 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] ("NLEA") 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). It is thus the case that claims not approved by FDA under the NLEA are nevertheless constitutionally required to be allowed by the agency under *Pearson I* and its progeny.

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 is *ultra vires* action in violation of 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 from 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 I* and its progeny 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 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 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 reasons provided in detail below the Petitioners respectfully request that the FTC remove from all current Orders and refrain from including in all future Orders, including Consent Orders, the FDA Prior Restraint Compliance Requirement and the Two Clinical Trial Requirement. The Petitioners also respectfully request that the FTC implement the constitutional mandate of *Pearson v. Shalala I* and its progeny 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, present empirical evidence to prove the claim incapable of being rendered non-misleading through qualification. That is FTC's minimum constitutional burden under *Pearson v. Shalala I* 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 I*, certain of its progeny, and in *ANH USA v. Sebelius*) ("ANH USA")) is a Virginia nonprofit corporation, founded in 1992. ANH USA is a membership-based organization with more than 400 members consisting of consumers; healthcare practitioners; food, and dietary supplement

company members; and 150,000 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 ANH USA's dietary supplement company members are companies that would sell dietary supplements with qualified advertising claims of immune system enhancement; 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 eleven 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. In connection with the promotion and sale of the product they would like to include the advertisement text cited herein.[1] 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

[1] Petioners Pearson and Shaw intend to market their prune juice product with the following claims in advertisements:

Durk Pearson & Sandy Shaw's FLUSH

> The prune juice that flushes your regulation problems down the toilet.
>
> Don't put up with a poorly functioning regulatory system—Get regular with a morning constitutional with FLUSH.
>
> FLUSH prune juice helps relieve chronic constipation. See your doctor first to ensure your regulation problem is not more serious than a need to increase your dietary fiber. Use one to four 8 ounce glasses per day as needed to help FLUSH your regulation problem.

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 place them 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")[2]; *see also FTC v. National Urological Group, Inc.*, 645 F.Supp. 2d 1167, 1186 (N.D. Ga. 2008) ("Obviously, this definition is context specific 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.*

[2] *Available at*, http://www.ftc.gov/bcp/policystmt/ad-food.shtm.

FTC, 741 F.2d 1146, 1156 (9th Cir. 1984). However, the FTC never before set a minimum threshold of two studies as requisite to the making of future 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. [3]

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 taking enforcement action against those making 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).[4] 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 "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.

[3] *Available at*, http://www.foodpolitics.com/wp-content/uploads/NAD-Vladeck-Speech-10-5-09.pdf.

[4] *Available at*, http://www.ftc.gov/speeches/vladeck/091022vladeckcrnspeech.pdf.

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 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

A. 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 of"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 on labels and in labeling, barring claims that a dietary supplement treats, cures, prevents, or mitigates disease unless 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 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 NLEA. *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. Seatrain 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 (Bkrtcy. 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 FDCA 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 executive branch administrative agencies are limited to the jurisdiction conveyed in their enabling 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 FDCA. *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 NLEA precisely because Congress has given that jurisdiction exclusively to the FDA.

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 labeling claims contained in the NLEA, 21 USC 343(r)(5)(d) or in 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 NLEA 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 in this instance 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 the FTC.

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 NLEA standard for health claim approval, 21 U.S.C. § 343(r)(5)(d) as implemented by 21 CFR 101.14. By imposing the FDA Prior Restraint Requirement on future advertising claims via its consent orders, the FTC necessarily subjects itself to the constitutional limits on prior restraint 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 NLEA "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 NLEA 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 in *Pearson I*. That mandate *requires* that claims not approved under the NLEA statutory prior restraint regime be evaluated to determine whether claim qualifications would suffice to eliminate misleadingness. The federal government is obliged to allow claims backed by credible but inconclusive evidence to enter the marketplace and 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 *Pearson I* analysis to determine whether there exists any qualified claim that would suffice to eliminate misleadingness or, if not, proving that to be so 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 must not be imposed in any future ones.

Under the NLEA health claim schema, the FDA has no discretion to approve or deny a claim that is, at worst, only potentially misleading and 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 I* and its progeny because they are not approvable under the NLEA schema (but can be rendered nonmisleading through the addition of a claim qualification).

The *Pearson I* decision and its progeny are First Amendment commercial speech 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 violates the *Pearson I* doctrine by imposing an unconstitutional prior restraint on constitutionally protected commercial speech.

The *Pearson I* Court differentiated between "potentially" misleading claims (which cannot be subject to prior restraint) and "inherently" misleading claims (which 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; *Shapero v. Kentucky Bar Association*, 486 U.S. 466, 478 (1988)).

In *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 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.

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

The FTC's Two Clinical Trial Requirement similarly fails under the First Amendment and, in particular, the *Pearson I* 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 that no qualification of the claim will suffice to eliminate misleadingness. *Pearson I*, 164 F.3d at 660, n.10. The District Court of the District of Columbia, applying the original *Pearson I* 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 those similarly situated who are 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 I*, 164 F.3d at 659-60. In *Pearson I* and its progeny, the courts have repeatedly held that when there is "credible evidence" but inconclusive scientific evidence to support a claim, a claim may not be banned but must be allowed with qualifications unless proof exists that no qualification 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 but inconclusive science, including science short of two human clinical trials.

The FTC 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).[5] 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 I*, 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

[5] *Available at*, http://www.ftc.gov/os/caselist/0823158/101215dannonanal.pdf.

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

Finally, the FTC's Two Clinical Trial Requirement conflicts with principles of evidence-based nutrition. FTC's new policy reflects an evidentiary threshold commonly reserved for drug products or evidence-based medicine (EBM). *See* Andrew Shao, PhD and Douglas Mackay, ND, *A Commentary on the Nutrient-Chronic Disease Relationship and the New Paradigm of Evidence-Based Nutrition*, Natural Medicine Journal 2010; 2(12):10-18 (Exhibit 1). The use of human clinical trials to demonstrate nutrient-disease reduction relationships is often impractical or impossible. *Id.* at 10-11; Jeffrey Blumberg, et al., *Evidence-based criteria in the nutritional context*, Nutrition Reviews 2010; 68(8):478-484 (Exhibit 2); Robert P. Heaney, MD, Connie M. Weaver, PhD, and Jeffrey Blumberg, PhD, *EBN (Evidence-Based Nutrition) Ver. 2.0*, Nutrition Today 2011; 46(1):22-26 (Exhibit 3). "Several nutrition researchers have, in recent years, raised concerns over what is perceived to be the misapplication of drug-based trials to assess nutrition questions, without taking into account the totality of the evidence or the complexities and nuances of nutrition." Shao, *supra*, at 11. The difficulties applying clinical intervention studies to the nutrition context lead experts to conclude that "[r]ecommendations, whether they be public health-based or practitioner-patient-based, should be developed from the totality of the available evidence, not on a single study or study design." *Id.* at 12.

Substantial differences between drugs and nutrients limit the effectiveness of clinical trials in the nutrition context. Dr. Shao, Senior Vice President of Scientific & Regulatory Affairs at the Council for Responsible Nutrition, explains:

> Drugs tend generally to have single, targeted effects; drugs are not homeostatically controlled by the body and can easily be contrasted with a true "placebo" group; drugs can act within a relatively short therapeutic window of time, often with large effect sizes. In contrast, nutrients tend to work in complex systems in concert with other nutrients and affect multiple cells and organs; nutrients are homeostatically controlled, and thus the body's baseline nutrient "status" affects the response to a nutrient intervention; a nutrient intervention group cannot be contrasted with a true placebo group (i.e., "zero" exposure group); and with respect to chronic disease prevention, nutrient effect sizes tend to be small and may take decades to manifest. Finally the very absence (or inadequacy) of a given nutrient produces disease, which is a fundamental difference compared to drugs.

Shao, *supra*, at 11.

Dr. Blumberg, head of the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University, Boston, Massachusetts, concurs and explains:

> [C]ertain features of [Evidence-Based Medicine] seem ill-suited to the nutrition context. Some of the differences between the evaluation of drugs and nutrients cited previously are as follows: (i) medical interventions are designed to cure a disease *not* produced by their absence, while nutrients prevent dysfunction that would result from inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large and with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake ranges; (v) drug effects can be tested against a nonexposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate—a difference with significant implications for the feasibility of conducting pertinent [randomized clinical trials].

Blumberg, *supra*, at 480 (concluding "it is unlikely that [randomized clinical trial] evidence could feasibly or appropriately be produced with respect to the role of a nutrient for many

nonindex-disease endpoints"). For example, where low intake is the hypothesis for causation, clinical trials would present "nearly insuperable ethical barriers because the investigative team has to be prepared to put subjects in harm's way" by, for instance, lowering or maintaining low levels of nutrient intake. *See* Heaney, et al, *supra*, at 23.[6]

Accordingly, scientists question "whether we need as much proof of efficacy for a nutrient policy decision as we do for approval of powerful, expensive, and potentially dangerous pharmaceutical agents." *Id.* at 24. Nutrients, by contrast, can often be consumed with low risk of toxicity and are available at low cost. The standards that govern scientific data should be relative to the risks presented by the nutrient, but also reflect the limitations of clinical trials in the nutrient context. *Id.* at 22, 24 (noting that the field of nutrition has "seemingly swallowed [evidence-based medicine] whole without either asking how well it might fit, or adapting it to the unique features of the nutrition context").

There is not a scientific consensus, therefore, that strict reliance on clinical trials is appropriate in evidence-based nutrition. Because clinical trials are rarely, if ever, designed to demonstrate nutrient disease-*reduction* relationships, a two clinical trial requirement forecloses claims that can be supported by the totality of the scientific record without need for well-

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[6] Dr. Blumberg further explains that clinical trials are rarely effective in nutrition because the goals of an intervention trial are inapposite:

> [Evidence-based nutrition] thus departs from the situation of [evidence-based medicine], where, for most interventions, the use of a no-intake control group is usually quite appropriate. In EBM, the hypothesis is that *adding* an intervention ameliorates a disease, whereas in EBN it is that *reducing* the intake of a nutrient causes (or increases the risk of) disease. This distinction is critical. No one proposes in EBM that a disease is caused by the absence of its remedy; wherease for nutrients the hypothesis is precisely that malfunction is caused by deficiency. A hypothesis about disease causation can rarely, if ever, be directly tested in humans using the [randomized clinical trial] design.

Blumberg, *supra*, at 480.

designed clinical trials. The FTC's requirement of two clinical trials conflicts with scientific principles uniquely applicable in the nutrition science context and serves to bar nearly all nutrition claims.[7]

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 unconstitutionally shifts the burden of proof to advertisers.

C. The FTC Cannot Violate the Constitution in Consent Orders

The FTC's "fencing-in" authority does not excuse agency violations 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

[7] The Department of Agriculture's Dietary Guidelines have never been supported by multiple clinical trials. *See* Roger Clemens, *Dietary Guidelines May Produce Unintended Health Consequences*, Food, Medicine & Health (Exhibit 4); Joanne Slavin, *Dissecting the Dietary Guidelines*, Food Technology (2011) (Exhibit 5). The Guidelines are "based on evidence that consuming … foods within the context of an overall healthy eating pattern is associated with a health benefit…" *See* Dietary Guidelines for Americans, 2010 (Jan. 31, 2011), at Ch. 4, *available at*, http://tinyurl.com/6k55bl6. Again, "making strict recommendations for optimal dietary practices is difficult to support with evidence-based nutrition science." Slavin, *supra*, at 40, 46 ("the scientific support for these recommendations is more historical than evidence-based"). "Intervention studies, where diets following the Dietary Guidelines are fed long-term to human volunteers, do not exist." *Id.* at 46 (noting that, "[g]enerally, adherence to the Dietary Guidelines is measured in epidemiological studies by determining a healthy eating index (HEI), a measurement of adherence to the diet recommendations of the Dietary Guidelines"). What is good for the goose must likewise be good for the gander. The federal government has never subjected itself to a two-clinical trial requirement when promulgating dietary guidelines which are intended to impact on consumer purchasing decisions. *See* USDA Press Release, *USDA and HHS Announce New Dietary Guidelines to Help Americans Make Healthier Food Choices and Confront Obesity Epidemic* (Jan. 31, 2011), *at*, http://tinyurl.com/4kpafy5.

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 power to render more onerous the substantiation requirements for prospective claims, only alter 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 cases. 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 prior use of "Instant Tax Refund" in advertising was deceptive, it would not enforce the order to prohibit 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 F2d 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 enforcement of its enabling statute, but also to the FDA Prior Restraint Requirement and the Two Clinical Trial Requirement imposed in FTC Consent Orders. The First Amendment limitations on prior restraint are global protections that guard against restrictions of protected commercial speech, which includes speech not only provable to a conclusive degree but also speech that is backed by credible but inconclusive scientific evidence.

D. 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 another issue, 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 good law. S*ee 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.[8]

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 to 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

[8] 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).

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 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 along with two clinical trials are requisite to avoid a charge of deceptive advertising for the type of health claim addressed above in the cited 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 be their fate 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 the dietary supplement 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 I*, 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 stemming from its consent orders 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 [the] 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 arising from fear of prospective regulatory action against a speaker. *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—those claims that are not FDA approved and are without two human clinical trials substantiating them in the categories thus far identified in the above-referenced FTC consent orders. 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 I*, 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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DATED: April 26, 2011