

**Before the
FOOD AND DRUG ADMINISTRATION
Rockville, MD**

**In re: Guidance for Industry:)
Qualified Health Claims in the) Docket No. 02D-0515
Labeling of Conventional Foods)
And Dietary Supplements)**

**COMMENTS OF
DURK PEARSON AND SANDY SHAW;
LIFE EXTENSION FOUNDATION, INC.; AND
JULIAN M. WHITAKER, M.D.**

On behalf of Durk Pearson and Sandy Shaw; Life Extension Foundation, Inc.; and Julian M. Whitaker, M.D. (hereinafter collectively, “Commenters”), we hereby submit the following additional comments on FDA’s December 18, 2002 Guidance “Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements” (hereinafter “Qualified Claims Guidance”) in response to those of Public Citizen and the Center for Science in the Public Interest (hereinafter collectively “CSPI”) and to those of the Grocery Manufacturers of America, The Snack Foods Association, The Institute of Shortening & Edible Oils, Inc., and the National Restaurant Association (hereinafter collectively “GMA”).

I. SUMMARY OF COMMENT

In the Qualified Claim Guidance, FDA seeks to implement the constitutional mandate of the U.S. Court of Appeals for the D.C. Circuit found in Pearson v. Shalala, 164 F.3d. 650 (D.C.Cir. 1999) (“Pearson I”). For the reasons that follow, the Commenters find CSPI’s comments to call for action contrary to the constitutional mandate in Pearson v. Shalala and its progeny. The Commenters support the substantive recommendations in the GMA comments, as explained below.

CSPI argues that the Qualified Claims Guidance is contrary to FDA’s statute and regulations. It is wrong on both accounts; indeed, were its position adopted, FDA would be directly at odds with several federal court rulings and would cause the statute to be interpreted to effect unconstitutional outcomes, contrary to the avoidance doctrine.¹ CSPI asks the agency to withdraw the Qualified Claims Guidance, not to sanction health claims unless authorized pursuant to the NLEA health claims approval process, 21 U.S.C. § 343(r)(hereinafter “NLEA health claims approval process”) (of which there are currently six² nutrient disease relationships), and to enforce NLEA’s health claim approval process, including notice and comment rulemaking, before allowing constitutionally protected qualified claims to enter the market. Because CSPI asks FDA to act contrary to controlling precedent and in contravention of the First Amendment, its request for action must be denied.

CSPI would have the agency withdraw the Qualified Claim Guidance and only permit on labels and in labeling health claims that meet the significant scientific agreement (SSA) standard and are the subjects of notice and comment rule making pursuant to the NLEA health claims approval process. 21 U.S.C. § 343(r)(1)(B). Pearson I, 164 F.3d 650, speaks directly to that point and forecloses that alternative. CSPI ignores the plain import and teachings of that decision (and its progeny³) and of the First Amendment. Indeed, CSPI ignores the First Amendment entirely, despite the significant First Amendment issues its requests create. Pearson I teaches that FDA must favor disclaimers over outright speech suppression where speech that is,

¹ Univ. of Great Falls v. NLRB, 278 F.3d 1335, 1340-41 (D.C. Cir. 2002) (“Although we normally defer to an agency’s interpretation of ambiguous statutory language under Chevron, . . . here another even more important principle of judicial restraint weighs upon us, which is that Federal courts traditionally have sought to avoid constitutional questions if at all possible . . . In other words, the constitutional avoidance canon of statutory interpretation trumps Chevron deference.”) (internal quotes omitted).

² Antioxidants and cancer; Folic acid in supplement form and neural tube defects; Folic acid, Vitamin B6, and Vitamin B12 and cardiovascular disease; Omega-3 fatty acids and coronary heart disease; Phosphatidylserine and cognitive dysfunction/dementia; Selenium and cancer/anticarcinogenic effects.

at worst, only potentially misleading can be cured through the addition of a reasonable disclaimer even if the claim in issue is one not authorized under the NLEA health claims provision. Pearson I, 164 F.3d at 654 (“...even if ‘significant scientific agreements’ were given a more concrete meaning, appellants might be entitled to make health claims that do not meet that standard—with proper disclaimers”). Indeed, the four NLEA “unauthorized” claims in Pearson were found by the Court to be speech protected by the First Amendment. Pearson I at 658-59. The Court inverted the normal order of review, addressing the First Amendment claims first, cognizant of the fact that the First Amendment trumps all contrary law. Pearson I at 654. The Court understood that there was no necessary conflict between the higher law of the First Amendment and the NLEA health claims authorization process, reasoning that claims that failed to pass muster under the process (i.e., are not “authorized”) but were, at worst, only potentially misleading could not be suppressed but would have to be permitted with appropriate disclaimers by FDA. The Court recited, among the disclaimers FDA could use as a less speech restrictive alternative, that “The FDA does not approve this claim,” thus plainly contemplating a two-tiered analysis where claims not satisfying the NLEA SSA standard (and thus not achieving FDA “approval” under the NLEA health claim review process) would nevertheless be “permitted” by FDA (to comply with the higher law requirements of the First Amendment). Pearson I at 659. This critical distinction in the law entirely eludes CSPI. Under the First Amendment FDA cannot suppress a claim that is supported by “credible evidence” despite the fact that the claim fails the SSA standard of the NLEA. See, e.g., Whitaker v. Thompson, 248 F. Supp. 2d 1, 27 (D.D.C. 2002).

³ Pearson v. Shalala, 130 F. Supp. 2d 105 (D.D.C. 2001)(“Pearson II”); Pearson v. Thompson, 141 F. Supp. 2d 105 (D.D.C. 2001) (“Pearson III”); Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002).

CSPI's interpretation of the NLEA, that any claim appearing on a food or supplement label must be a claim authorized under the NLEA health claims approval provision and promulgated pursuant to a notice and comment rulemaking is not the law in the advent of Pearson and is an unconstitutional interpretation of the statute in light of that decision. That approach was precisely the law articulated by FDA pre-Pearson I. Under the avoidance doctrine, laws must be interpreted not to conflict with the Constitution, if at all possible. Edward J. DeBartolo Corp. v. FL Gulf Coast Bldg. & Const. Trade Council, 485 U.S. 568, 575 (1988); Univ. of Great Falls v. NLRB, 278 F.3d 1335, 1340-41 (D.C. Cir. 2002). Contrary to CSPI's argument, there is no constitutional obligation for a notice and comment rulemaking for claims not authorized or approved by FDA under the NLEA health claims provision. That is, there is no such requirement for qualified health claims. Because the agency lacks constitutional power to restrict protected speech in the form of qualified claims, it also lacks constitutional power to open a comment period for that very purpose. Once the agency determines that the speech in issue is protected by the First Amendment, i.e., that it lacks a constitutional power under Pearson I and Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002), to suppress it, then FDA must take no action to block entry of the constitutionally-protected speech into the market. Any delay, burden, restriction, or limit to the contrary is intolerable under the First Amendment. See Elrod v. Burns, 427 U.S. 347, 373 (1976) (plurality opinion) ("the loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury") (citing New York Times Co. v. U.S., 403 U.S. 713 (1971)); see also Lakewood v. Plain Dealer Publ'g Co., 486, U.S. 750, 758 (1988) (noting that "opportunities for speech," if suppressed, "are irretrievably lost"); Pearson v. Shalala, 130 F. Supp. 2d 105, 119 ("the case law makes it very clear that Plaintiffs are harmed by the FDA's suppression of the Folic Acid Claim"). Having a

notice and comment period as contemplated by CSPI before permitting a qualified health claim to enter the market invites others to use FDA's administrative machinery to restrict speech.

Any member of the public may contribute science and comments to any health claim docket at any time. CSPI has that same right. If new science or safety issues should arise after FDA permits a qualified claim, any member of the public can submit that information to the docket. CSPI thus has had no impediment to being heard and has none to being heard in the future. It need only file a comment in the docket to acquire FDA's attention. CSPI also relies on a false factual predicate. The four Pearson I claims (four of the six) were fully vetted in notice and comment rulemaking proceedings not once but twice. See 58 Fed. Reg. 53,296 (Oct. 14, 1993); 64 Fed. Reg. 48,841 (Sept. 8, 1999); see also Pearson II, 130 F. Supp. 2d at 110. That point eludes CSPI. The remaining two claims, one concerning selenium and cancer/anticarcinogenic effects, and the other concerning phosphatidylserine and cognitive dysfunction/dementia, were assigned public docket numbers, and all correspondence concerning them was posted on FDA's web site and in the FDA public reference room. See <http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091302/091302.htm#02P-0413%20Health%20Claim:%20Phosphatidylserine%20>; http://www.fda.gov/ohrms/dockets/dailys/02/Oct02/101802/101802.htm#_Toc22944690. Any member of the public could file comments in these proceedings as well.

Of the six current qualified health claims for which there are no corresponding regulations, four are direct responses to court orders. Apparently, CSPI ignores the fact that the federal court orders in those cases are binding on the agency. A long history of post-Pearson I cases dictate otherwise. Pearson v. Shalala, 130 F. Supp. 2d 105 (D.D.C. 2001) ("Pearson II"); Pearson v. Thompson, 141 F. Supp. 2d 105 (D.D.C. 2001) ("Pearson III"); Whitaker v.

Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002). As with every health claim petition, any member of the public, including CSPI, had a right to file comments with FDA concerning those claims (and, indeed, may still do so). CSPI elected not to take that course, but it certainly was not foreclosed from doing so by FDA and is not to this day.

Unlike CSPI's comment, GMA's calls not for a notice and comment rulemaking that limits grants to NLEA approvals, but a public notification process following a submission of a qualified claim petition, permitting any interested person to file information and comments that could help guide FDA in the evaluation of, and promulgation of, the qualified claim. The GMA comment puts a 180-day limit on the entire process (and a 60-day limit on comments) from qualified claim submissions to final qualified claim allowances and, thus, ensures rapid market access for protected speech consistent with the First Amendment. The Commenters endorse GMA's recommended approach.

In summary, CSPI's requests for FDA to withdraw the Qualified Claims Guidance, not to sanction qualified health claims unless authorized pursuant to the NLEA health claims approval process, and to require NLEA's procedural requirement of notice and comment rulemaking for claims that fail SSA are requests for unconstitutional agency action. All CSPI's requests should therefore be denied.

II. SUMMARY OF QUALIFIED CLAIMS GUIDANCE

The Qualified Claims Guidance, as modified by Whitaker, is an implementation of the U.S. Court of Appeals decision in Pearson I. It describes how FDA plans to exercise its enforcement discretion to permit health claims that do not meet the SSA standard of evidence

and describes the process and standards that FDA intends to use to respond to future health claim petitions for both conventional foods and dietary supplements.⁴

III. CSPI'S REQUEST FOR WITHDRAWAL OF THE THE GUIDANCE ASKS THE AGENCY TO ACT UNCONSTITUTIONALLY AND CONTRARY TO LAW

CSPI states that there are statutory and regulatory violations in the Qualified Claims Guidance, principally: (1) the qualified claim procedure is improperly outside of the notice and comment rulemaking prescribed by Congress; (2) the Guidance creates an incentive to make health claims based on preliminary evidence, undermining consumer protection, and is contrary to the structure and purpose of the NLEA; (3) the Qualified Claims Guidance is an improper use of enforcement discretion; and (4) it is inconsistent with prior agency policy on health claims and interpretation of the NLEA.

As discussed in detail below, each of those arguments fail because allowance of qualified claims is a constitutional imperative imposed on FDA by the federal courts, and the NLEA health claims provision does not compel a contrary result. Indeed, were such a conflict to exist, the statutory provision would be rendered unconstitutional.

A. THE QUALIFIED CLAIMS GUIDANCE IMPLEMENTS THE FIRST AMENDMENT MANDATE OF PEARSON I

⁴ It should be noted that the Guidance was promulgated before the U.S. District Court for D.C. issued Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002). Thus, Whitaker trumps the Guidance to the extent of any conflicting analysis. In particular, Whitaker forbids FDA from suppressing any claim unless the following standard is met: "First, when the FDA has determined that no evidence supports [a health] claim, it may ban the claim completely . . . Second, when the FDA determines that evidence in support of the claim is qualitatively weaker than evidence against the claim – for example, where the claim rests on only one or two old studies, it may impose an outright ban . . . Even in those two situations a complete ban is only appropriate where the government could demonstrate with empirical evidence that disclaimers similar to the ones [the Pearson Court] suggested above ["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." Whitaker, 248 F. Supp. 2d at 27-28, citing Pearson I, 164 F.3d at 659-660 (internal quotations omitted).

In Pearson I, the U.S. Court of Appeals defined constitutional limits on FDA’s power to suppress health claims, holding that FDA may not suppress claims that could be rendered non-misleading through the addition of a disclaimer. Whitaker, 248 F. Supp. 2d at 28. CSPI appears to have missed that point entirely, failing to address the First Amendment protections for health claims in the least.

1. Health Claims Are Commercial Speech Protected By the First Amendment

Pearson I and its progeny establish that health claims are commercial speech protected by the First Amendment. Pearson I, 164 F.3d. at 655; e.g., Whitaker, 248 F. Supp. 2d at 23. Conspicuously absent from CSPI’s analysis is any acknowledgment that health claims on conventional foods and dietary supplements are scientific speech and commercial speech, both protected by the First Amendment.

2. FDA Cannot Limit Health Claims to Those Only Authorized Pursuant to the NLEA Health Claims Provision; It Must Permit Qualified Health Claims that Fail SSA When Required to Do So by the First Amendment

Pearson I affirmed the law that there is a general First Amendment preference for disclosure over suppression and specified those limited instances when FDA may prohibit health claims. See Pearson I, supra, at 658-658. To wit,

The Pearson court established clear guidelines for the FDA in determining whether a particular health claim may be deemed “inherently misleading” and thus entirely banned. The Court implied, though it did not declare explicitly, that when “credible evidence” supports a claim, such as the Folic Acid Claim, that claim may not be absolutely prohibited.

Pearson II, supra at 114 citing Pearson I, 164 F.3d at 659. Pearson I identified only two circumstances in which a complete ban on a health claim would be reasonable:

First, when the “FDA has determined that no evidence supports [a health claim] it may ban the claim completely.” Id., 164, F.3d at 659-660 (emphasis in original. Second, when the FDA determines that “evidence in support of the claim is qualitatively weaker

than evidence against the claim – for example, where the claim rests on only one or two old studies,” it may impose an outright ban. *Id.* 164 F.3d at 659, n.10 (emphasis added).

Whitaker, 248 F. Supp. 2d at 27-28. Even in those two situations a complete ban is only constitutionally permissible where “the government [can] demonstrate with empirical evidence that disclaimers similar to the ones [the Pearson Court] suggested above [‘The evidence in support of this claim is inconclusive’ or ‘The FDA does not approve this claim’] . . . bewilder consumers and fail to correct for deceptiveness.” Whitaker, *supra*, citing Pearson I, 164 F.3d at 659-660 (emphasis added). Since Pearson I, each time the agency has attempted to limit health claims to those that meet the SSA standard, it has been rebuked by the federal courts on First Amendment grounds. See Pearson II, Pearson III, and Whitaker, *supra*. The courts have said repeatedly the agency must permit health claims that do not meet the SSA standard when the claims can be made nonmisleading through addition of a reasonable disclaimer.

According to CSPI, the “Guidance demonstrates that the agency consciously and expressly adopted a general policy that is in effect an abdication of its statutory duty,” citing Adams v. Richardson, 480 F.2d 1159, 1162 (D.C. Cir. 1973)(en banc). Again, CSPI considers the Guidance as if it arose in a vacuum and the First Amendment and the Pearson I mandate did not exist. CSPI’s argument would posit a conflict between the NLEA health claims provision and the First Amendment when one does not exist under the controlling precedent of Pearson I progeny. The Qualified Claims Guidance is an adoption of the court directive to the agency that FDA must consider allowance of constitutionally-protected qualified claims in lieu of outright suppression; the directive of no less than four federal court decisions on the health claim process backs the agency’s approach.

CSPI’s remaining arguments, that consumers are at greater risk of confusion and that qualified claims are an improper use of enforcement discretion also fail to withstand scrutiny.

Even if those arguments were supported in the law they are secondary to the interests, rights, and protections that the First Amendment accords speakers and cannot overcome the supremacy of the First Amendment. See Whitaker, 248 F. Supp. 2d at 45 (“Even if [a health claim] is in some respects ‘potentially’ misleading, the resulting injury that could flow to consumers cannot compare, as a matter of law, with the First Amendment injury Plaintiffs have continually borne in the more than three years since Pearson I was decided”).

Notwithstanding CSPI’s position to the contrary, health claims that do not meet the SSA standard but are supported by credible evidence and made nonmisleading by a disclaimer are protected from government suppression by the First Amendment and must be allowed as a matter of constitutional law. FDA cannot use the NLEA offensively to prohibit qualified claims that the First Amendment requires be allowed. The First Amendment is, after all, the higher law, and FDA—like the courts—must interpret the NLEA health claims provision to be consistent with, not in opposition to, the outcomes directed by the higher law.

B. THE NLEA DOES NOT PRECLUDE QUALIFIED CLAIMS

The NLEA health claims provision defines when FDA authorizes health claims. 21 U.S.C. §§ 343(r)(1)(B), (r)(3); and (r)(5)(D). To be sure, FDA endorses authorized claims, determining that they meet SSA, and publishing them in the Federal Register in rule form following a notice and comment rulemaking. By contrast, FDA does not authorize qualified claims but allows them to be made when accompanied by the agency’s disclaimer, despite the absence of FDA approval. Qualified claims are not created by statute nor do they conflict with it because they do not constitute an act of authorization which is prescribed in 21 U.S.C. § 343(r)(1)(B). “Allowance” of qualified claims is a recognition by the courts and by FDA that it

lacks a constitutional power to suppress certain unauthorized claims that—while failing SSA—nevertheless are protected from suppression by the First Amendment.

As discussed below, if CSPI’s interpretation of the law were correct then the NLEA health claims process would be unconstitutional to the extent that it conflicted with the teachings of Pearson I and its progeny. Those sections of the statute concerning health claims cannot stand if they preclude qualified health claims on conventional foods and dietary supplements.

Applying the traditional tools of statutory construction, and the avoidance doctrine, however, CSPI’s interpretation of the law is necessarily incorrect.

1. The NLEA Defines FDA Authorized Claims But Does Not Preclude Qualified Claims

CSPI interprets the NLEA to limit strictly health claims to authorized claims (and to exclude qualified claims). Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), dictates the rules for judicial review of agency statutory construction to determine whether Congress has expressed a clear intent on the issue at hand. Id. at 843, n.9. The issue at hand is whether Congress intended the authoritative health claim process, that requires notice and comment rulemaking, to be the exclusive basis for health claims to appear on conventional foods and dietary supplement.

The first step in a Chevron analysis involves assessment of the actual words of the statute. E.g., Arkansas AFL-CIO v. FCC, 11 F.3d 1430 (8th Cir. 1993) citing Chevron, 467 U.S. at 843. “If the intent of Congress is clear from the plain language of the statutory provision, that will be the end of the judicial inquiry.” E.g., Arkansas AFL-CIO, 11 F.3d at 1440 citing Chevron, supra.

The plain language of the NLEA is clear. It defines a process that FDA must follow to “authorize” health claims on conventional foods and dietary supplements. It does not limit

claims appearing on conventional foods and dietary supplements to only claims authorized by the FDA. Hence, the mandate of Pearson I that the FDA must permit qualified health claims, claims that are potentially misleading but can be rendered non-misleading by the addition of a disclaimer, is not in conflict with the NLEA but is separate and apart from it (as our Court of Appeals necessarily determined when it rejected FDA’s statutorily based argument that claims failing SSA are by that fact alone suppressible). Pearson I, 164 F.3d at 658.

The NLEA defines a procedure for “authorization” of health claims (21 U.S.C. § 343(r)(1)(B)) for conventional foods (21 U.S.C. § 343(r)(3)) and for dietary supplements (21 U.S.C. § 343(r)(5)(D)). Congress required that regulations be promulgated for “authorizing” food health claims, thus compelling FDA to use rulemaking to adopt final regulations after it had first determined that the totality of publicly available scientific evidence revealed “that there is significant scientific agreement among experts..., that the claim is supported by such evidence.” 21 U.S.C. § 343(r)(3). Congress left the standard for dietary supplements health claims review up to the agency. 21 U.S.C. § 343(r)(5)(D). FDA adopted the statutory food standard as its standard for dietary supplement health claims. 21 C.F.R. § 101.14 (applicable to both foods and dietary supplements); see also Pearson I, 164 F.3d at 654, n.2.

The FDCA states that a food is misbranded if it is one

for which a claim is made in the label or labeling of the food which expressly or by implication—

* * *

(B) characterizes the relationship of any nutrient ... to a disease or a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

21 U.S.C. § 343(r)(1). The health claim statutory provision for conventional foods is, in pertinent part, Section 343(r)(3):

(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made—

- (i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and

(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The FDCA section for health claims on dietary supplements states:

A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

21 U.S.C. § 343(r)(5)(D). Moreover, conventional foods and dietary supplements,

for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) of this title or sections 403(r)(1)(B) and 403(r)(5)(D) of this title, is made in accordance with the requirements of section 403(r) of this title is not a drug solely because the label or the labeling contains such a claim.

The statutory section plainly prescribes a process for FDA “authorization” of health claims. It makes no reference to nutrient disease claims that FDA does not authorize. Thus, applying Chevron step one examining the plain language of the statute, qualified claims do not conflict with the NLEA procedures for authorized claims because they are not approved or authorized by FDA. There is no statutory obligation that FDA act against qualified claims failing the SSA test, only that it not “authorize” them. The question thus becomes whether FDA in the exercise of administrative discretion may elect to suppress unauthorized qualified claims. The answer given to the agency by the Courts is a decidedly negative one with rare exceptions. The First Amendment forbids suppression unless FDA shows (1) no scientific evidence supports the claim or (2) the weight of the scientific evidence against the claim outweighs the weight of the evidence for it and, in both cases, (3) that no disclaimer exists that can eliminate potential

misleadingness. Whitaker, 248 F. Supp. 2d at 27. Thus, separate and apart from the NLEA health claims provision stands a First Amendment bar to the exercise of FDA enforcement against qualified claims. Compliance with that bar is a constitutional order imposed on FDA by not one, but four, federal court decisions. Not a one found the bar incongruous with the NLEA health claims provision because each, in line with Pearson I, is based on the understanding that the statute deals with health claims “authorization,” whereas the First Amendment dictates not the terms for placing FDA’s imprimatur on a claim but, rather, the limits of the exercise of FDA power to take enforcement action against unauthorized, qualified claims.

2. The Avoidance Doctrine Requires that the NLEA Be Interpreted To Permit Unauthorized, Qualified Health Claims

In neither Pearson I; Pearson II; Pearson III; nor Whitaker did any of the federal courts assessing FDA health claim denials under the NLEA health claims provision find any statutory conflict with the constitutional ban on suppression of unauthorized, qualified health claims. 164 F.3d at 659(“The government’s general concern that, given the extensiveness of government’s regulation of the sale of drugs, consumers might assume that a claim on a supplement’s label is approved by the government, suggests an obvious answer: the agency could require the label to state that “The FDA does not approve this claim”).

CSPI (citing a 1993 Federal Register) states that FDA’s pre-Pearson interpretation of the statute “remains accurate: In the absence of a regulation, either final or interim (pending completion of a public comment period), the statute does not authorize the FDA to countenance health claims.” Were that interpretation correct, then the statute would conflict with the First Amendment as explained in Pearson I, Pearson II, Pearson III, and Whitaker. Under the avoidance doctrine, however, if the statute reasonably can be interpreted to avoid conflict with the Constitution, it must be. U.S. ex rel. Atty. Gen. v. Del. & Hudson Co., 213 U.S. 366, 408

(1909); Edward J. DeBartolo Corp. v. FL. Gulf Coast Bldg. & Const. Trades Council, 485 U.S. 568, 575 (1988) (It is beyond debate that a court will construe a statute to avoid constitutional problems unless such construction is plainly contrary to the intent of Congress); Univ. of Great Falls v. NLRB, 278 F.3d 1335, 1340-41 (D.C. Cir. 2002). Following that doctrine, and in light of Pearson I and its progeny, section 343(r) must be read as requiring notice and comment rulemaking only for those health claims authorized by FDA. To interpret the NLEA otherwise, as CSPI has done, unnecessarily causes the NLEA health claims provision to violate the First Amendment. FDA has thus protected the constitutional validity of the NLEA health claims provision by avoiding the statutory interpretation urged upon it by CSPI and must continue to do so—not only because Pearson I and its progeny require that approach but also because it is the agency’s duty to defend the validity of its enabling statute. Cf. Johnson v. Robinson, 415 U.S. 361, 368 (1974) (“[A]djudication of the constitutionality of congressional enactments has generally been thought beyond the jurisdiction of administrative agencies”).

C. QUALIFIED HEALTH CLAIMS ARE IN THE PUBLIC INTEREST

1. Health Information in the Marketplace Furthers Consumers Ability to Make Informed Choices at the Point of Sale

It is more than a little strange for a public interest organization that purports to advance the interests of consumers to advocate government suppression of constitutionally protected health information.⁵ Yet that is what CSPI aims to do. Such an approach redounds to consumers’ great detriment because it denies them at the point of sale useful information that may guide them in making informed choices. The FDA Commissioner has recognized officially the indispensable need for access to accurate health information and has committed the agency to

⁵ That information can prove indispensable to the exercise of informed choice in the market and can save lives by diminishing the incidence of disease. For example, the qualified Omega-3 fatty acid and cardiovascular disease claim has the potential to help prevent 150,000 sudden death heart attacks per year in America. See Exhibit A.

that end with his Consumer Health Information for Better Nutrition initiative. See <http://www.fda.gov/oc/mccllellan/chbn.html>.

CSPI argues that “the new policy” of qualified claims undermines the consumer protection arising from limiting health claims to those meeting the SSA standard.⁶ There is, however, no proof that consumers are in any way harmed by the qualified claims FDA has permitted. CSPI argues that there is a consumer protection interest in denying consumers access to emerging science, even when communicated in a nonmisleading manner. That kind of paternalism is antithetical to the core values protected by our First Amendment precedent and has been rejected, repeatedly, by the federal courts.⁷ It is a canon of First Amendment law that courts will reject the paternalistic argument that government must deny the public access to information on the supposition that people cannot be trusted to act responsibly with it. The U.S. Supreme Court recently reiterated its condemnation of “the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.” Western States, 535 U.S. at 374.

There is, of course, an alternative to this highly paternalistic approach. That alternative is to assume that this information is not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them...But the choice among these alternative approaches is not ours to make or the [legislature’s]. It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us. [The government] is free to require whatever professional standards it wishes of its [speakers]...But it may not do so by keeping the public in ignorance of the entirely lawful [speech at issue].

⁶ CSPI believes the “new policy” a product of the Guidance but it is not. The “new policy” follows directly from the First Amendment mandates in Pearson I and its progeny. CSPI’s persistence in ignoring the First Amendment belies its apparent effort to undermine it. It is unlikely to achieve such a momentous goal and cannot do so sub silentio.

⁷ E.g., Pearson I, 164 F.3d at 655 citing Peel v. Attorney Registration and Disciplinary Comm’n of Illinois, 496 U.S. 91, 105 (1990).

Western States, citing Virginia State Board, *supra*, at 770 (citation omitted); see also 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503(1996)(“Bans against truthful nonmisleading commercial speech...usually rest solely on the offensive assumption that the public will respond ‘irrationally’ to the truth. The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good”(citations omitted)).

Moreover, any tenuous interest in consumer protection from qualified health claims does not outweigh the interest in protecting the free speech rights of speakers. In Pearson II the court stated,

It is especially important to recognize that, in the present case, the potential harm to consumers from deception is severely limited ... At worst, any deception resulting from Plaintiffs’ health claim will result simply in consumers spending money on a product that they might not otherwise have purchased, or perhaps spending more money on a product with a higher folic acid content. This type of injury, while not insignificant, cannot compare to the harm resulting from the unlawful suppression of speech.

Id. at 119. Pearson II also noted, in response to Plaintiffs’ application for a preliminary injunction preventing FDA from suppressing their claim about the effect of folic acid supplementation on neural tube defects:

The public interest would be served in two ways by the issuance of an injunction. First, it is clearly within the public interest to ensure that governmental agencies, such as the FDA, fully comply with the law, especially when that law concerns the parameters of a party’s First Amendment rights to effectively communicate its health message to consumers.

Second the public health risk from neural tube defects is undeniably substantial...Given that the scientific consensus, even as acknowledged by the FDA, confirms that taking folic acid substantially reduces a woman’s risk of giving birth to an infant with a neural tube defect, the public interest is well served by permitting information about the folic acid/NTD connection to reach as wide a public audience as possible.

Id. at 119-120. Thus, qualified claims are in the public interest, CSPI’s preference for state paternalism notwithstanding.

2. Qualified Claims Do Not Eliminate the Incentive for Authorized Claims

CSPI states there is a “perverse incentive created by the Guidance” to make qualified claims as opposed to authorized claims. To the contrary, there is a significant incentive to seek authorized claims. The Commenters find qualified claims generally disadvantageous from an advertising perspective because their length and inconclusiveness often not only make it difficult to place them on product labels but also do not likely increase consumer purchases to any degree comparable to that experienced when FDA authorizes a claim. While to be sure the Commenters value qualified claims because their informational content aids consumers and may improve marketing of products, they value authorized claims much more and will always prefer an authorized claim to an unauthorized one and only thereafter an unauthorized one to none at all. Indeed, the two-tiered claim approach has the effect of encouraging research because rather than an all-or-nothing SSA option, the fact that a qualified claim exists affords enough security to justify risking capital in the process. Thus there is a significant incentive to seek authorized claims over qualified claims whenever feasible and, in any event, the duality of authorized and qualified claims maximizes financial incentives for nutrition science research to support claim submissions.

3. The Petitions for Qualified Claims Are, and Shall Be, Publicly Available.

In another public interest argument (stated in its first footnote) CSPI argues that petitions for qualified claims may not be made publicly available because “the statute does not permit the FDA to make available to the public petitions that have been denied” and cites 21 C.F.R. § 101.70(j)(2) for that proposition.⁸ Again CSPI shows its misunderstanding of the law. Under 21

⁸ CSPI notably makes no mention of the six qualified health claims currently permitted, for which all six petitions are publicly available in FDA’s Docket. See FDA Dockets Management Branch Dockets No. 91N0101 (Antioxidants); 91 N 0103 (Omega-3 Fatty Acids); 91N100H (Folic Acid in Supplement Form); 99P3029 (B Vitamins); 02P0413 (Phosphatidylserine); and 02P0457 (Selenium).

C.F.R. § 101.70(j)(2) FDA does not make publicly available petitions that have been denied and not filed (i.e., not accepted for comprehensive review). Those petitions are denied because they fail to meet the “preliminary requirements” of Part A explaining “how the substance conforms to the requirements of § 101.14(b).” 21 C.F.R. § 101.70(j)(2). However, meeting the requirements of Section 101.14(b) and being accepted for comprehensive review under 21 C.F.R. § 101.70(j)(2) is the very first requirement for a qualified claim under the Qualified Claims Guidance. See id. at 3. Thus, there is no conflict between the qualified claims process and 21 C.F.R. §101.70(j)(2) because qualified claims have historically and continue to be accepted for comprehensive review. CSPI’s argument is thus based on a false factual predicate and is, therefore, erroneous.

D. EXERCISE OF ENFORCEMENT DISCRETION TO AVOID ACTION AGAINST QUALIFIED CLAIMS IS AN APPROPRIATE RESPONSE TO FIRST AMENDMENT REQUIREMENTS

CSPI cites Heckler v. Chaney, 470 U.S. 821, 831 (1985) for the proposition that “the decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency’s absolute discretion.” CSPI’s implied argument is that it fears FDA will take the position in the future that its allowance of a qualified health claim is unreviewable (part of FDA’s absolute discretion).

CSPI offers Cutler v. Kennedy, 475 F. Supp. 838 (D.D.C. 1979) for the analogy that “just as FDA lacked authority to approve drugs that were safe but of questionable efficacy, FDA lacks authority to waive requirements for qualified health claims.” Cutler is inapposite. Unlike in Cutler, here federal courts have specifically stated that on First Amendment grounds FDA cannot suppress health claims even if they do not meet the SSA standard so long as they can be made nonmisleading. See e.g., Pearson I, 164 F.3d 650.

For lack of a better phrase FDA has described in the Qualified Claims Guidance its process for permitting qualified health claims as an “exercise of enforcement discretion.” In the qualified claims context, however, once FDA finds under Pearson I that the First Amendment prohibits suppression of a claim, the FDA at that point lacks any power whatsoever to deny the claim market entry. It in fact exercises no enforcement discretion except to prohibit its personnel from taking any action against use of the claim.

2. Announcing in a Guidance an Intent to Use Enforcement Discretion When Evaluating Qualified Claims Is Entirely Appropriate

FDA regularly uses Guidance Documents to announce its intent to use enforcement discretion in future agency actions of a particular type. See 65 Fed. Reg. 59,855 (Oct. 6, 2000); 66 Fed. Reg. 36,794 (July 13, 2001). CSPI objects to the Guidance stating that it goes well beyond a decision not to pursue enforcement action in a particular case. A policy statement concerning the law determined by a federal court, the Guidance is not required to be the subject of notice and comment rulemaking. 5 U.S.C. § 553(b)(3)(A); see also Syncor Int’l Corp v. Shalala, 127 F.3d 90, 94-95 (D.C.Cir. 1997). The December 18, 2002 Guidance does not impose any new rights or obligations. See American Bus Assoc. v. U.S.A., 627 F.2d 525, 529 (D.C.Cir. 1980) citing Texaco v. FPC, 412 F.2d 740, 744 (3d Cir. 1969). It recognizes First Amendment rights defined by the federal courts and it properly prevents use of agency power to violate those rights. The Guidance explains the agency’s position, updates the industry on its implementation of Pearson I, and describes a process that the agency will follow to ensure that FDA does not violate the First Amendment by suppressing a claim that is, at worse, only potentially misleading. The Guidance is not a binding norm, nor does it finally determine the issues or rights of future petitioners. See American Bus Assoc. v. U.S.A., 627 F.2d 525, 529 (D.C.Cir. 1980) citing Pacific Gas & Electric Co. v. FPC, 506 F.2d 33, 38 (D.C.Cir. 1974).

In this circumstance, FDA is under no legal obligation whatsoever to rely on rulemaking. Indeed, to do so in the face of a finding that the speech in issue was – at worst – only potentially misleading is to deny the speakers’ rights pending the resolution of a long and drawn out solicitation of comment. When initiated after FDA has evaluated the health claimant’s submission and has determined that it is backed by credible evidence (and assuming the food or supplement is otherwise lawfully saleable), the exercise is unjustifiably burdensome and ultimately futile because regardless of others’ sentiments about the claim, it may not constitutionally be suppressed or restricted. Thus, use of that method, would maintain suppression of protected speech longer than necessary when the First Amendment precedent defines such delays as intolerable. See Elrod v. Burns, 427 U.S. 347, 373 (1976)(plurality opinion)(“the loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury”) (citing New York Times Co. v. U.S., 403 U.S. 713 (1971)); see also Lakewood v. Plain Dealer Publ’g Co., 486, U.S. 750, 758 (1988)(noting that “opportunities for speech,” if suppressed, “are irretrievably lost”); Pearson v. Shalala, 130 F. Supp.2d 105, 119(“the case law makes it very clear that Plaintiffs are harmed by the FDA’s suppression of the Folic Acid Claim”).

IV. NO NOTICE AND COMMENT RULEMAKING PROCEEDING IS NECESSARY PRIOR TO PERMITTING QUALIFIED HEALTH CLAIMS

CSPI objects to the agency permitting qualified claims on conventional foods and dietary supplements without a notice and comment rulemaking. There is, however, no constitutional or legal requirement for notice and comment rulemaking for qualified claims. The point is substantially superfluous because all claims filed to date and all filed under the Guidance are given public dockets and may be commented upon by the public. Any member of the public may file at any time information in those dockets for FDA consideration. CSPI, thus, has no

cognizable injury because it, too, could file comments in any one of the dockets. Extending the NLEA formal notice and comment rulemaking proceeding to qualified claims would effect no added benefit but would infringe the petitioner’s speech rights where FDA has determined prior to the notice and comment that the claim is backed by credible evidence. In fact, once FDA determines that a claim is permissible as a qualified claim, it lacks legal power to suppress the claim or restrict its entry into the market. It thus follows that if FDA lacks legal power to suppress the claim, it also lacks legal power to delay its entry into the market (suppressing it for a time) to conduct a formal notice and comment rulemaking. As explained below, while not legally required, the better approach is the notification recommended by the GMA in its Comments. The Commenters support that alternative.

Moreover, the Administrative Procedure Act (APA) 5 U.S.C. § 553, the section on rulemaking, states,

Except when notice or hearing is required by statute, this subsection does not apply –

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

As explained above, the NLEA health claims provision does not apply to qualified claims, and the First Amendment prohibits unreasonable delay in allowing qualified claims to enter the market. Once FDA finds a qualified claim constitutionally protected, that claim cannot be suppressed or denied entry into the market through unreasonable delay. Thus, the APA does not require a rulemaking.

V. AGENCY POLICY AND REGULATIONS THAT ARE NOT IN ACCORDANCE WITH PEARSON I AND ITS PROGENY ARE UNENFORCEABLE

CSPI argues that the Qualified Claims Guidance conflicts with prior agency policy and with the agency's health claims regulations. To the extent that qualified claims and the teachings of Pearson I and its progeny conflict with 21 C.F.R. § 101.14, those regulations are unenforceable.

For example, 21 C.F.R. § 101.14(e) states, in pertinent part:

Prohibited health claims. No expressed or implied health claim may be made on the label or in labeling for a food, regardless of whether the food is in conventional food form or dietary supplement form, unless: (1) the claim is specifically provided for in subpart E of this part [subpart E is where all the regulations for authorized health claims appear]...

The six currently permitted qualified health claims do not appear in subpart E of Part 101.

However, 101.14(e) cannot be enforced against manufacturer's using those qualified health claims because to do so would be an unconstitutional restriction of the speaker's First Amendment rights and would violate the orders in Pearson I and its progeny.

CSPI cites to FDA's 2000 Guidance on implementing Pearson I for the suggestion that Pearson I does not apply to conventional foods (as if the First Amendment contains a conventional foods exclusion) and for the proposition that the procedural requirements of the NLEA are unaffected by Pearson I. It also cites to a 1993 Federal Register, 58 Fed. Reg. 2478, 2423, for an interpretation of the NLEA health claim provisions. The 1993 discussion by the agency of how it interprets the NLEA health claims provisions is totally irrelevant to the extent that it conflicts with Pearson I. To the extent that the agency's 1993 policy conflicts with the teachings of Pearson I, the agency's policy has no further legal force or effect. Even the post-Pearson 2000 Guidance is unenforceable and inapplicable to the extent that it conflicts with Whitaker, 248 F. Supp. 2d 1.

IV. THE COMMENTERS ENDORSE GMA'S COMMENT

The Commenters endorse GMA's May 29, 2003 Comments. GMA proposes a program whereby applicants for qualified claims would submit information substantively identical to that required for health claim petitions but entitled "premarket notifications." Premarket notifications would not be subject to notice and comment rulemaking. Moreover, the premarket notification process would also be available to health claimants who failed SSA but desired a qualified claim instead. Contrary to CSPI, GMA acknowledges that the First Amendment and Pearson I apply equally to qualified claims and understands the First Amendment requirements apply to conventional foods and dietary supplements alike. Under GMA's proposed rule, within 30 days of receipt of the premarket notification for a qualified health claim, FDA would publish a notice of filing in the Federal Register. This notice of filing would specify that within 60 days, any interested person could submit to FDA any comments, data, or information, including additional proposed claims, expanded claims, and additional categories of food or dietary supplements to which the claim would also apply. In addition, all contents of the premarket notification for a qualified health claim would become public upon FDA's publication of the notice of the filing in the Federal Register. FDA would then take into account all of the additional submitted information as part of its consideration of the premarket notification for a qualified health claim. Throughout the review period, the notifying party or parties could engage in informal discussions in an attempt to reach an agreement on an appropriate qualified claim. Within 180 days of FDA's publication of the notice of filing, FDA would inform the person submitting the premarket notification for a qualified health claim of its decision. Even after a qualified claim is agreed to by FDA, any interested party would be able to submit comments or information on the claim, as is the case with the current qualified claims. GMA's proposed procedure for qualified claims thereby does not impose the strictures and delays of notice and comment rulemaking but

does codify in the regulations a formal opportunity for comment in lieu of the informal opportunity now present.

IV. CONCLUSION

The Qualified Claims Guidance is a lawful method for implementing the mandate of Pearson I. CSPI asks FDA to ignore the First Amendment and Pearson I and to limit health claims to only those that are “authorized” under the NLEA health claims provision, following notice and comment rulemaking. CSPI’s request calls for unconstitutional and unlawful agency action and thus cannot be followed. GMA, by contrast, offers a notification process with a 180-day time limit that is a lawful and reasonable approach endorsed by the Commenters.

Respectfully submitted,

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Exhibit A

Attached File: OMB Press Release on Omega-3.pdf