

**Before the
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

**In re: Agency Information Collection)
Activities; Proposed Collection;)
Comment Request; Experimental Study)
of Qualified Health Claims; Consumer) Docket No. 2005N-0097
Inferences About Omega-3 Fatty Acids)
and Monounsaturated Fatty Acids from)
Olive Oil.)**

**JOINT COMMENTS OF
LIFE ENHANCEMENT PRODUCTS, INC.;
LIFE EXTENSION FOUNDATION BUYERS CLUB, INC.;
DURK PEARSON and SANDY SHAW;
and
LIFE PRIORITY, INC.**

Life Enhancement Products, Inc.; Life Extension Foundation Buyers Club; Durk Pearson and Sandy Shaw; and Life Priority, Inc. (collectively, “Joint Commenters”), by counsel and in response to the FDA’s solicitation of comments in the Federal Register, 70 Fed. Reg. 16291 (March 30, 2005) (hereinafter “Notice”), hereby submit the following.

I. BACKGROUND OF THE JOINT COMMENTERS

The Joint Commenters participate in this proceeding fearing that it may presage a new round of speech suppression by FDA, one consistent with a pattern of censorship by the agency that has continued, post-*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999 *reh’g denied*, 172 F.3d 72 (D.C. Cir. 1999), despite repeated Court decisions condemning it as a violation of the First Amendment. *See Pearson v. Shalala* (“*Pearson II*”), 130 F.Supp.2d 105 (D.D.C. 2001); *Pearson v. Thompson* (“*Pearson III*”), 141 F.Supp.2d 105 (2001); *Whitaker v. Thompson*, 248 F.Supp.2d 1 (2002). The Joint Commenters are deeply concerned that the FDA will erroneously endeavor to manipulate this proceeding to arrive at a new basis for censoring truthful qualified claims in whole or

in part in violation of the First Amendment rights of the regulated class. Their concern arises from a pattern of speech suppression pursued by this agency even in the advent of seven First Amendment decisions by the federal courts condemning those acts and commanding the agency to favor disclosure of health information over its suppression as the operative rule.¹ In the hope that the agency will recognize that it has no greater duty than to abide by the strictures of the Constitution of the United States and in the hope that its officers will faithfully adhere to the oaths of office each has taken to abide by the Constitution and the laws of the United States, the Joint Commenters offer these comments. If this agency and those officers shirk their constitutional duties, the Joint Commenters stand ready to pursue legal action against the agency in an effort to arrest the abuse and to ensure that their First Amendment rights (and those of all other regulatees) are respected and defended by this government.

Life Enhancement Products, Inc. Life Enhancement Products Inc. (hereafter “LEP”) is a company that is devoted to promoting longevity through supplementation with nutrients known to promote health and wellness. Along with its advancements in the field of life extension supplementation, LEP is an information provider to consumers who are interested in learning about the effects of nutrients on health and well-being. LEP makes use of the qualified health claims permitted by the FDA in labeling for its products and has a keen interest in how this agency will use the information it proposes to collect.

¹ *Washington Legal Foundation v. Shalala*, 13 F. Supp. 2d 51 (D.D.C. July 30, 1998); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999 *reh’g denied*, 172 F.3d 72 (D.C. Cir. 1999)); *Pearson v. Shalala* (“*Pearson II*”), 130 F.Supp.2d 105 (D.D.C. 2001); *Pearson v. Thompson* (“*Pearson III*”), 141 F.Supp.2d 105 (2001); *Thompson v. Western States Medical*, 535 U.S. 357(2002); *Whitaker v. Thompson*, 248 F.Supp.2d 1 (2002) and *Wallach v. Crawford*, No. 04CV216 BTM (S.D.Ca. March 29, 2005).

Life Extension Foundation Buyers Club, Inc. Plaintiff Life Extension Foundation Buyers Club, Inc. (hereinafter “LEFBC”) is a Florida corporation that, through its subsidiaries, makes and sells dietary supplements. LEFBC sells over 500 different dietary supplement products to consumers around the world via catalog and internet sales. LEFBC educates consumers on health, longevity, and nutrition. LEFBC makes use of qualified health claims permitted by the FDA in labeling for its products and has a keen interest in how this agency will use the information it proposes to collect.

Durk Pearson and Sandy Shaw. Pearson and Shaw are scientists residing in Nevada. They design dietary supplement formulations and license them to manufacturing and retailing companies. They are authors of four books on aging and age-related diseases, including the #1, million plus copy best seller *Life Extension: A Practical Scientific Approach* (1982). They have also published three other health books (two of which were best sellers): *The Life Extension Companion* (1984); *The Life Extension Weight Loss Program* (1986); and *Freedom of Informed Choice—FDA Versus Nutrient Supplements* (1993). Durk Pearson and Sandy Shaw were plaintiffs in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999 *reh’g denied*, 172 F.3d 72 (D.C. Cir. 1999)), and in its progeny, *Pearson v. Shalala* (“*Pearson II*”), 130 F.Supp.2d 105 (D.D.C. 2001) and *Pearson v. Thompson* (“*Pearson III*”), 141 F.Supp.2d 105 (2001): the cases that, together with *Whitaker v. Thompson*, 248 F.Supp.2d 1 (2002), define the First Amendment standard to be used by this agency in allowing qualified claims as a less speech restrictive alternative to its legacy of censorship. Pearson and Shaw license for manufacture, sale, and distribution, several dietary supplements containing antioxidant vitamins, fiber, omega-3 fatty acids, and folic acid. Pearson and Shaw authorize use of

qualified health claims permitted by FDA on the labeling of their licensees' products. They have a keen interest in how this agency will use the information it proposes to collect.

Life Priority, Inc. Life Priority Inc. (hereinafter "LPI") provides a diverse array of nutritional supplements and information to consumers worldwide through direct mail and internet sales. LPI products are formulated with a variety of dietary ingredients including vitamins, minerals, fiber, omega-3 fatty acids, folic acid, amino acids, and protein. LPI makes use of qualified health claims permitted by FDA in labeling for its products. Life Priority, Inc. has a keen interest in how this agency will use the information it proposes to collect.

II. SUMMARY

In its Notice, 70 Fed. Reg. 16291 (March 30, 2005), FDA invites comments on (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. The Joint Commenters respond to the first three of these inquiries as follows.

At the outset, the notice is fundamentally flawed because it provides insufficient information to permit the regulated class to provide meaningful comments to the agency.

The notice does not state the purpose for which the information is to be collected. Will the agency rely on the information to alter or amend any existing qualified health claims? Will the agency rely on the information to establish a new policy for determining how best to qualify health claims? Will the agency rely on the information to guide it in performing public education campaigns in association with the allowance of any particular qualified health claim? None of these essential questions requisite to assessment of the data collection is answered by the agency in the Notice. Moreover, the agency does not explain what level of familiarity the general public must have with the two qualified health claims it lists before FDA may accurately assess public perception. It is a condition precedent to any public perception survey that the statements in issue be ones that have been a part of an identifiable market for goods. No proof exists that the qualified claims in issue are present in the market at all, let alone to a degree that will permit an accurate gauge of consumer preferences. Moreover, there are no survey questions listed in the Notice, so regulatees cannot assess the likelihood that survey questions will yield accurate responses, ones unburdened by bias or notions concerning nutrients and disease arising from information other than from the claims themselves. In short, the regulated class has not been afforded adequate information with which to assess the data collection proposed. Meaningful comment is therefore denied because requisite information is not available to the regulated class. The agency has thus violated the Administrative Procedure Acts notice and comment requirement. *See Administrative Procedure Act* (“APA”), 5 U.S.C. § 553.

In sum, the proposed collection of information is neither necessary nor useful if it is the agency’s intent to rely on the information retrieved to alter or censor the wording of

any qualified health claim. Indeed, modification or elimination of a qualified health claim based on consumer perception (even if that perception could be accurately gauged) may cause truthful and nonmisleading speech to be censored. The constitutional command of *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999 *reh'g denied*, 172 F.3d 72) (D.C. Cir. 1999), and its progeny, *Pearson v. Shalala* (“*Pearson II*”), 130 F.Supp.2d 105 (D.D.C. 2001); *Pearson v. Thompson* (“*Pearson III*”), 141 F.Supp.2d 105 (2001) and *Whitaker v. Thompson*, 248 F.Supp.2d 1 (2002), is for this agency to favor disclosure of health information over its suppression as the operative rule. Thus, if FDA censors an accurate qualified claim by disallowing it in whole or part, it will be engaged in precisely that kind of speech restriction which the Courts have repeatedly condemned it for choosing. *See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999 *reh'g denied*, 172 F.3d 72) (D.C. Cir. 1999); *Pearson II*; *Pearson III*; and *Whitaker v. Thompson*, 248 F.Supp.2d 1 (2002). If, however, this agency intends to rely on consumer perception surveys to guide it in disseminating more information to the public, to explain further the meaning of the science alluded to in qualified health claims, then the exercise may have some utility (albeit its potential is quite limited because reliance on consumer perception surveys to evaluate claims not first established to have been made extensively in a relevant market is a dubious exercise, at best). One purpose of qualified health claims is to educate consumers, most of whom would not be expected to be at least, at first, familiar with the content of the claims.

The methodology and assumptions underlying the study are flawed; however, full descriptions of all basic errors present cannot be communicated to the agency in the absence of disclosure by FDA of its survey methodology, design, assumptions, and

questions. Thus, the FDA has failed to provide full notice and opportunity for comment, as it is required to do under the APA. *See APA* 5 U.S.C. § 553. FDA cannot be sure that a voluntary system of response to internet queries will provide an accurate reflection of public perception, as explained more fully below. FDA cannot be sure that understanding of a qualified claim is based on the claim itself, on preconceived notions arising from inaccurate reporting, or on preconceived notions based on other biased information. FDA starts with the unproven assumption that the public has sufficient familiarity with the claims, but they were allowed only recently and they have not saturated the market (indeed, few products containing the ingredients have the claims on their labels and no company--to the Joint Commenters' knowledge--has included the claims in any general advertising). A gauge of public perception of the claims is thus premature until such time as the claims become more commonplace and the public idea and information marketplace has had a chance to vet them. Public understanding of science (to be sure, even scientific understanding of science) is always less than perfect. That is because the perception of science and of its relative significance varies from expert to expert as it does from consumer to consumer, depending on the relative weight each person places on variables and values within or underlying the claims themselves. That is also because public perception of complex scientific relationships rarely, if ever, equals the richness or degree of completeness that those with advanced study, education, training, or experience have in the subject. It is, thus, an unremarkable statement of logic and fact that members of the public, or perhaps most of the public, will misapprehend true statements of science when first presented to them. Comprehension of complex subjects, nutrition science included, depends upon a steady flow of freely accessible

scientific information on the nutrients and the diseases, not the dearth of data presently allowed by this agency in its Byzantine health claim approval process. Comprehension of complex nutrient-disease relationships requires study, debate, and the passage of time in the presence of the information. The tendency is for greater understanding to arise over time when the information is freely available. No snapshot of consumer perception in an information scarce environment will yield empirical data reliable enough to gauge accurately public perception of the qualified claim or of the underlying nutrient-disease relationship. Misunderstandings are likely to be numerous and varied. The solution lies in further disclosure of scientific information to the public (including dissemination of scientific articles, abstracts, and accurate summaries to consumers), not in revision or suppression of claim language. The proposed survey will likely waste tax dollars and yield little, if any, information capable of providing reliable guidance to regulators or the regulated class. It is folly.

If FDA insists on its proposed survey, its design and methodology should be published in the Federal Register providing the public the opportunity to comment. Moreover, its best use would be to test the extent to which the public has any knowledge of the underlying nutrient-disease relationship, not to determine whether any language in the two claims, or the claims themselves, should be amended or deleted. For example, whether the public understands that evidence exists associating EPA and DHA omega-3 fatty acids with a reduction in the risk of coronary heart disease, especially sudden death heart attack, is a critical question. If the answer is generally negative, then this agency should ensure that the public acquires that information. In the balance lies an estimated 300,000 lives per year that could be saved from sudden death heart attack if the fatty

acids are ingested daily. See Leaf A, Kang JX, Billman GE. *Clinical Prevention of Sudden Cardiac Death by n-3 Polyunsaturated Fatty Acids and Mechanism of Prevention of Arrhythmias by n-3 Fish Oils. Circulation.* 107:2646-2652, 2003. If few comprehend the existence of the association, the solution lies not in modifying or suppressing existing qualified claim language, but in releasing for distribution as much accurate scientific information on the relationship as possible. Public debate leads to true edification. Government information restriction leads inevitably to misperception. Disclosure over suppression is this agency's constitutional duty. See *Bates v. State Bar of Arizona*, 433 U.S. 350, 376 (1977); *Peel v. Atty Regis. & Disciplinary Comm. Of Illinois*, 496 U.S. 91, 109 (1990); *Pearson*, 164 F.3d at 655.

III. COMMENTS

A. REGULATORY HISTORY OF QUALIFIED HEALTH CLAIMS

In the Nutrition Labeling and Education Act ("NLEA"), Congress created a health claim approval process for substance/disease relationship labeling claims.² Initially, FDA disallowed health claims that failed to meet the significant scientific agreement standard. In *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999 *reh'g denied*, 172 F.3d 72 (D.C. Cir. 1999)) the Court held that the First Amendment does not permit FDA to reject health claims it deems "potentially misleading" if using a disclaimer eliminates the potential to mislead. The Court went further and relied on a plain English meaning assessment of the claim language, deciding the content of the claims was speech protected by the First Amendment that could not be suppressed in light of the less speech restrictive alternative of disclaimers. It went further still in conducting a plain English meaning assessment of

² *Nutrition Labeling and Education Act of 1990 (NLEA)*, Pub. L. No. 101-535, 21 U.S.C. § 343(r)(3)(B)(i). See also *Pearson v. Shalala*, 164 F.3d 650, 653 (D.C. Cir. 1999).

potential disclaimer language, thereby establishing this mode of proceeding as the method for FDA claim evaluation and qualification in accordance with our First Amendment. *See Pearson* 164 at 658-660. In denying the claims in issue in *Pearson*, FDA argued that the claims are “inherently misleading” and would confuse consumers at the point-of-sale. The Court rejected those notions.³

Despite the Court’s directives, FDA failed to allow Plaintiff’s proposed health claims. Plaintiffs sued again to enjoin FDA’s inaction. In what has become known as “*Pearson II*” (*Pearson v. Shalala*, 130 F.Supp.2d 105 (D.D.C. 2001)), the Court again rebuffed the agency’s treatment of plaintiffs’ health claims. The Court held that the agency ignored the Court’s directives in *Pearson I* by failing to permit plaintiffs’ folic acid health claim with the addition of a reasonable disclaimer.⁴ The *Pearson* Court clearly established that when “credible evidence” exists in support of a claim, the agency may not restrict the publication of the claim.⁵ The Court held that in not allowing the proposed folic acid health claim, even with the addition of a disclaimer, the agency “acted unconstitutionally, and particularly in violation of the Court of Appeals decision in *Pearson v. Shalala*, in suppressing Plaintiffs’ Claim rather than proposing a clarifying disclaimer to accompany the Claim.”⁶ This principle was reaffirmed in both *Pearson v.*

³ FDA was basically asking the Court to believe that “consumers were being asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous.” *Pearson* at 655.

⁴ “The case law makes it very clear that Plaintiff is harmed by FDA’s suppression of the Folic Acid Claim. ‘The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.’ *Pearson v. Shalala*, 130 F.Supp.2d 105, 119 (D.D.C. 2001)

⁵ *Pearson v. Shalala*, 130 F.Supp.2d 105, 114 (D.D.C. 2001).

⁶ *Pearson v. Shalala*, 130 F.Supp.2d 105, 120 (D.D.C. 2001).

Thompson (“*Pearson III*”), 141 F.Supp.2d 105 (2001)⁷ and later in *Whitaker v. Thompson*, 248 F.Supp.2d 1 (2002).

In *Whitaker v. Thompson*, 248 F.Supp.2d 1 (2002), the “credible evidence” standard was explained in detail.⁸ Like in *Pearson*, the *Whitaker* plaintiffs argued that their proposed health claim, accompanied by a reasonable disclaimer, was not misleading, and thus the FDA's prohibition of the claim violated the providers' First Amendment rights. FDA argued that the ban was warranted because there was not significant scientific agreement supporting the claim, and the evidence against the claim outweighed the evidence supporting the claim. The court granted injunctive relief against FDA, declaring the FDA's prohibition unconstitutional.⁹ Disclosure of truthful

⁷ “Defendants again seem to ignore the thrust of *Pearson I*. While the decision might leave certain specific issues to be fleshed out in the course of future litigation, the philosophy underlying *Pearson I* is perfectly clear” that “First Amendment analysis applies in this case, and that if a health claim is not inherently misleading, the balances tilts in favor of disclaimers rather than suppression.” *Pearson v. Thompson*, 141 F.Supp.2d 105, 112 (D.D.C. 2001).

⁸ In 2004 the United States District Court for the District of Columbia reaffirmed their position that the First Amendment prevents FDA from rejecting health claims on the sole basis that they are not supported by significant scientific agreement. In conducting its analysis, FDA must consider whether the use of a disclaimer could cure the potential deception, and, if so, the health claim must be permitted under the existing free speech doctrine. *CSPI v. FDA*, 2004 U.S. Dist. LEXIS 18541 (D.D.C. 2004) (citing *Pearson v. Shalala*, 334 U.S. App. D.C. 71, 164 F.3d 650, 658 (D.C. Cir. 1999)). Citing a July 2003 Guidance, the court concluded that the “FDA can allow qualified health claims ‘as long as some credible evidence supports it, even where the weight of the evidence does not.’” *CSPI* at 6, citing Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data, and Guidance for Industry and FDA: Interim Procedures for Health Claims in the Labeling of Human Dietary Supplements (“July Guidance”).

⁹ In examining restrictions on commercial speech under the First Amendment, the United States Supreme Court has consistently rejected the “highly paternalistic” view that government has complete power to suppress or regulate commercial speech in order to protect the public. Thus, in finding that speech is misleading, the government must consider that people will perceive their own best interests if only they are well enough informed, and the best means to that end is to open the channels of communication rather than to close them. *Thompson v. Western States Medical*, 535 U.S. 357(2002) citing *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), (“It is a matter of public interest that [economic] decisions, in the aggregate, be intelligent and well-informed. To this end, the free flow of commercial information is indispensable.” Indeed, we recognized that a “particular consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate.”)

information is the operative First Amendment rule, with the constitutional presumption in favor of disclosure over suppression.¹⁰ See *Pearson*, 164 F.3d at 657.

After comment and deliberation, FDA announced in a December 18, 2002 notice that it would apply the *Pearson* decision to health claims in both conventional foods and dietary supplement labeling. Its record of application since that date has been inconsistent, making disclosure not the rule but the exception contrary to the fundamental principles of our First Amendment articulated in *Pearson* and its progeny.

In July 2003, FDA issued a Guidance notifying the public of interim procedures for petitioners submitting qualified health claim petitions to the agency. The guidance included procedures that FDA intended to use, on an interim basis, to respond to qualified health claim petitions until a Final Rule could be established. The Guidance stated that FDA intended to review qualified health claims on the basis of the totality of the publicly available evidence associated with the claims.¹¹ The FDA began accepting such petitions on September 1, 2003. Petitions are to include evidence substantiating the wording of the claim and why the wording of the claim is accurate and not misleading. The petition is to include the claim's potential effects on the total intake of the substance (i.e., current

¹⁰ The Court identified only two distinct circumstances in which a complete ban of a health claim would be acceptable and characterized them as remote circumstances, doubtful that FDA could justify suppression of the claims. When the Food and Drug Administration (FDA) has determined that **no** evidence supports a health claim and when FDA determines that evidence in support of the claim is qualitatively weaker than evidence against the claim, it may ban the claim but only where it has also proved with empirical evidence that no disclaimer can correct for deceptiveness. Disclaimers are constitutionally preferable to outright suppression of commercial speech. In other words, more disclosure rather than less is the required approach. See *Whitaker v. Thompson*, 248 F.Supp.2d 1 (2002).

¹¹ The Guidance Statement provides for a "Evidenced-based Rating System." Based on this system of review, the agency categorizes qualified health claims into one of three levels (i.e., a "B", "C", or "D" level). Different levels of scientific evidence result in different required levels of qualifying language to ensure that the claim is truthful and not misleading. This guidance does not apply to unqualified health claims, which must meet the "Significant Scientific Agreement" (SSA) standard. In reviewing each claim and determining appropriate qualifying language, FDA intends to review and evaluate the third party report, the totality of the publicly available evidence, and all of the public comments submitted within the comment period, as well as consider how the proposed qualified claim will affect consumers' dietary choices. *Id.*

intakes plus increases due to the claim) and any positive or negative dietary changes that result from the intake of the substance.

The evidentiary standard for qualified health claims is credible evidence.¹² In addition to evaluating actual health claim language, FDA must assess whether any qualifying language can render the claim non-misleading and permit the claim with qualification. Only if there is no qualification capable of avoiding misleadingness can FDA choose censorship.¹³

The inclusion of qualified health claims on the label and labeling of food and dietary supplements allow consumers to make more informed decisions about their health

¹² *Whitaker v. Thompson*, 248 F.Supp.2d 1, 25-27 (2002)

¹³ Currently, there are eight qualified health claims approved for use by food and dietary supplement companies. These include qualified health claims discussing a nutrient/disease relationship between 1) Antioxidant Vitamins and Cancer Approved for Dietary Supplements (*e.g.*, Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer. Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.); 2) Omega-3 Fatty Acid and Coronary Heart Disease Approved for Dietary Supplements (*e.g.*, Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive.); 3) Omega-3 Fatty Acid and Coronary Heart Disease Approved for Dietary Supplements and Conventional Foods (*e.g.*, Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [] gram of EPA and DHA omega-3 fatty acids.); 4) Folic Acid and Neural Tube Defects Approved for Dietary Supplements (*e.g.*, 0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form. FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic acid daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects.); 5) Folic Acid and Neural Tube Defects Approved for Dietary Supplements and Conventional Foods (*e.g.*, Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect, or adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.); 6) Vitamin B6/B12/Folic Acid and Vascular Disease Approved for Dietary Supplements (*e.g.*, As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6, and Vitamin B12 may reduce the risk of vascular disease. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.); 7) Phosphatidylserine and Cognitive Dysfunction Approved for Dietary Supplements (*e.g.*, Consumption of phosphatidylserine may reduce the risk of dementia in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of dementia in the elderly. FDA concludes that there is little scientific evidence supporting this claim.); and 8) Selenium and Cancer for Approved for Dietary Supplements (*e.g.*, Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.).

and dietary intake at the point-of-sale. The two qualified health claims in question, omega-3 fatty acids and monounsaturated fatty acids from olive oil, provide consumers with beneficial information about the nutrient/disease relationship of these two nutrients. The qualified health claims system is an extension of the court decision in *Pearson* and only retains legitimacy to the extent that it protects and advances the First Amendment principles that underlie *Pearson* and its progeny.

B. HEALTH CLAIMS AND THE FIRST AMENDMENT

Health claims are commercial speech¹⁴ and are evaluated under the commercial speech standard.¹⁵ The First Amendment protects the dissemination of truthful and non-misleading commercial messages about lawful products and services.¹⁶ Commercial speech is speech that “propose[s] an economic transaction” or pertains “solely to the economic interests of the speaker and audience.” *Board of Trustees v. Fox*, 492 U.S. 469, 473 (1989). *Virginia Pharmacy Board v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976); *Central Hudson Gas & Electric Co. v. Public Service Commission*, at 561 (1980). Restrictions on commercial speech are reviewed under intermediate scrutiny (*Central Hudson Gas & Electric Corp. v. Public Service Comm’n*, 447 U.S. 557 (1980); *Pearson*, 164 F.3d 650 at 655; *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 482 (1995)). Under intermediate scrutiny, before FDA may impose any restriction on

¹⁴ Health claims, including qualified health claims, on labels and in labeling are scientific speech. Health claims are drafted to reflect the current state of scientific evidence on a particular nutrient-disease relationship. Scientific speech rests at the core of the First Amendment and is entitled to the highest degree of constitutional protection. *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 62 (D.D.C. 1998); see also *Keyishian v. Bd. of Regents*, 385 U.S. 589, 603 (1967); *Board of Trustees of Leland Stanford Junior University v. Sullivan*, 773 F. Supp 472, 474 (D.D.C 1991). Any restriction of scientific speech is evaluated under strict scrutiny (*Burson v. Freeman*, 504 U.S. 191 (1992)). For a ban on scientific speech to survive, the government must show that the ban furthers a compelling state interest and is narrowly tailored to achieve that interest. *Turner Broad Sys. V. FCC*, 512 U.S. 622, 662 (1994); *Boos v. Barry*, 485 U.S. 312, 321 (1988). See, e.g., *Riley v. Nat’l Fed. Of the Blind of NC*, 487 U.S. 781 (1988).

¹⁵ *Pearson v. Shalala*, 164 F.3d 650, 655 (1999); see also, *Central Hudson Gas & Electric Co. v. Public Service Commission*, 447 U.S. 557, 564-565 (1980).

¹⁶ *44 Liquormart v. Rhode Island*, 517 U.S. 484, 496 (1996).

commercial speech, it must first determine whether its restriction satisfies the *Central Hudson* test.¹⁷ Speech that is neither inherently misleading nor related to an unlawful activity can be restricted only if FDA proves that (1) the Government interest is substantial; (2) the regulation directly advances the Government interest; and (3) the regulation is no more extensive than necessary to serve the interest. *Central Hudson*, 447 U.S. at 564. See *Pearson v. Shalala*, 164 F.3d at 655-656; *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 482 (1995). FDA bears the burden of proof under the commercial speech standard. It must prove with empirical evidence that the harms it recites are real and that its regulatory means will alleviate those harms to a material degree. *Pearson*, 164 F.3d at 659; *Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (“This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree”). The Government’s burden is a “heavy” one. *Peel v. Atty Regis. & Disciplinary Comm. Of Illinois*, 496 U.S. 91, 109 (1990).

The FDA may not deny and suppress potentially misleading health claims but must authorize them with such disclaimer as is, or such disclaimers as are, reasonably necessary to avoid a misleading connotation. *Pearson* at 659.¹⁸ The government “may

¹⁷ *Central Hudson Gas & Electric Co. v. Public Service Commission*, 447 U.S. 557, 564-565 (1980).

¹⁸ Commercial speech, including a health claim, may only be denied and suppressed outright if it is inherently misleading, *Pearson*, 164 F.3d at 655, and cannot be rendered non-misleading with the addition of a disclaimer. *Pearson*, 164 F.3d at 657-58. The burden is upon government to prove based on empirical evidence that the speech in issue is inherently misleading and cannot be corrected through disclaimer. *Pearson* at 659, citing *Ibanez v. Florida Dep’t of Business and Prof’l Regulation*, 512 U.S. 136, 146 (1994). Health claims that are scientifically *inconclusive* are not inherently misleading by that fact alone and must therefore be authorized with corrective disclaimers. *Pearson*, 164 F.3d at 658-59. Health claims that are not backed by “significant scientific agreement” are not inherently misleading by that fact alone and must therefore be authorized with corrective disclaimers to cure any potential for the consumer to be misled. *Pearson*, 164 F.3d at 658.