

Before the 1469 5 JUN -6 P3:28

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

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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 (*Binson 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 *Ibanéz 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.

not place an absolute prohibition on ... potentially misleading information . . . if the information also may be presented in a way that is not deceptive.”¹⁹ *Pearson* at 655 (citing *In re R.M.J.*, 455 U.S. 191, 203 (1982)). The government may not presume that health claims will mislead but must meet its burden of proof with empirical evidence documenting that, in fact, consumers will be misled. *Id.* (citing *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994)).

In *Pearson v. Shalala*, the Court held that FDA may not ban health claims that it deems are potentially misleading and not scientifically proven, where the misleading nature of the claim can be cured with a corrective disclaimer.²⁰ In reaching its decision, the *Pearson* Court quoted at length from *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977). *Bates* involved the State Bar's discipline of several attorneys who advertised their fees for certain legal services in violation of the Bar's rule. In that case, the Arizona Bar justified its decision on the ground that such advertising was inherently misleading. Ruling for the attorneys, the Court refused to credit the notion that “the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information.” *Id.* at 374-75. Accordingly, the Court held that the “incomplete” attorney advertising was not inherently

¹⁹ FDA may only restrict claims that are inherently misleading. An inherently misleading claim conveys no scientific information and may be prohibited outright. If the claim is not inherently misleading, it will either be truthful and non-misleading or it will be potentially misleading. As will be explained below, a health claim can be truthful, accurately reflecting the current state of scientific knowledge, but not scientifically proven. Such claims must be allowed without disclaimers if they are not potentially misleading. A potentially misleading claim is one that can be rendered non-misleading through the addition of a disclaimer. Such claims must also be allowed accompanied by mandated disclaimer language that the agency reasonably believes will eliminate the misleading connotation. In every instance of speech restriction, FDA carries the First Amendment burden of proof and must marshal empirical evidence to support the restriction. Moreover, the restriction must be no more extensive than necessary to achieve the goal of eliminating the misleading connotation.

²⁰ *Pearson v. Shalala*, 164 F.3d 650, 659 (1999).

misleading and that “the preferred remedy is more disclosure, rather than less.”²¹ *Id.* at 376. The Court has repeatedly reaffirmed this principle holding that disclaimers are constitutionally preferable to outright suppression. *See Peel*, 496 U.S. at 110; *R.M.J.*, 455 U.S. at 206, n.20; *Shapiro*, 486 U.S. at 478.

Consumers have a constitutional right to receive information and ideas.²² Where consumer confusion exists, the proper remedy is more disclosure, not less. The restriction of health claims, including qualified health claims altered or censored based on consumer survey data, violates the First Amendment when the claim is protected speech. The solution is to disabuse the public of misconceptions through disclosure of more information, not suppression of heretofore “incomplete” information. It is axiomatic that complex speech, if true, may not be lawfully suppressed if few, or any, members of the public comprehend the message. That is because the First Amendment affords protection to the content of the speakers’ communication and does not permit abridgement of that content on the plea that listeners or readers lack an adequate understanding of the message. *See, e.g., Miami Herald Publishing Co. v. Tornillo*, 418 U.S. 241 (1974); *see also New York Times Co. v. Sullivan*, 376 U.S. 254, 279 (1964). The editorial prerogative of the speaker, the speaker’s control over his or her own message, is absolute and cannot be censored on the argument that one or more who receive the message

²¹ The Supreme Court has continuously affirmed that its solution to consumer confusion is more speech, not less.

“[T]he argument assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public. In any event, we view as dubious any justification that is based on the benefits of public ignorance. [citation omitted]... the preferred remedy is more disclosure, rather than less. If the naiveté of the public will cause advertising . . . to be misleading, then it is the [Government’s] role to assure that the populace is sufficiently informed as to enable it to place advertising in its proper perspective.” *Bates v. State Bar of Arizona*, 433 U.S. 350, 374-375 (1977).

²² *Stanley v. Georgia*, 394 U.S. 557, 564 (1969)

misunderstand it or find it incomprehensible. Truth is defended even if it is beyond the comprehension of every listener or reader. It has been said repeatedly by the Court that our First Amendment depends on a free and open idea and information exchange. Edification depends not on a single statement but on the contest of statements in the idea marketplace. Truth arises from the dross of conflicting opinions; the government's duty is to keep itself out of this robust and wide-open exchange except in the most extraordinary circumstances. See *Miami Herald Publishing Co.* at 252-253; *New York Times Co.* at 270. FDA has a history of frequently overstepping its statutory and constitutional bounds, censoring speech that is beyond its lawful authority to suppress (*Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) *reh'g denied*, 172 F.3d 72 (D.C. Cir. 1999); *Washington Legal Foundation v. Shalala*, 13 F. Supp. 2d 51 (D.D.C. July 30, 1998); 880 F. Supp. 26 (D.D.C. 1995); and *Pharmanex, Inc. v. Shalala*, 35 F.Supp. 2d 1341 (C.D.UT. 1998)). The public is in the best position to judge the validity of scientific information and ideas if only the public is well enough informed.²³ Given the opportunity, contest in the market will permit assessment of the credibility of every qualified health claim and will yield a better understanding of the claim's meaning and utility.

**C. ANALYSIS CONSUMER CONFUSION CONCERNING HEALTH CLAIMS
CANNOT BE MEASURED BY AN INTERNET SURVEY**

²³ "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." *VA State Board of Pharmacy v. VA Citizens Consumer Council*, 425 U.S. 748, 770 (1976).

1. Consumers have a constitutional right to receive truthful and nonmisleading scientific health-related information at the point-of-sale.

The First Amendment protects the publication of truthful and nonmisleading speech. Consistent with Congressional intent under NLEA and the decision in *Pearson*, FDA is required to establish and maintain a system that permits truthful and non-misleading claims on a product's label and in product labeling.

Economic literature confirms that the exercise of informed consumer choice hinges on the availability of accurate information at the point of sale in the consumer marketplace. *See generally* John E. Calfee & Janis K. Pappalardo, How Should Health Claims for Foods Be Regulated? 26-27 (Bureau of Economics, Federal Trade Commission 1989) *cited in Pearson*, 164 F.3d at 658, n.7 (explaining that channels other than the label and labeling impose higher search costs on consumers and reach them less effectively than claims directly on the label); *see also* The Hartman Group, "Organic Products—How do consumers choose?" *Natural Sensibility* 1999, 2:1-2; "Branding in the V[itamin]M[ineral and]H[erbal]S[upplement] marketplace," *Natural Sensibility*, 1998, 1:1-2 (presenting data from a survey of 4,000 households revealing that consumers most depend upon the information contained on labels of food and food products for nutrition information). In a 1998 study, Alan Mathios demonstrated that suppression of health claims and health benefit information "stifles the flow of useful information to consumers especially less-educated consumers" and results in consumers changing their purchasing habits to make less healthy food purchases.²⁴

Qualified health claims provide dietary supplement consumers with access to truthful and nonmisleading scientific health information at the point of sale. The

²⁴ Mathios, A., "The Importance of Nutrition Labeling and Health Claim Regulations on Product Choice: An Analysis of the Cooking Oil Market." *Agricultural and Resource Economics Review*, 1998

information allows consumers to make better informed dietary choices. It also serves to counteract fraud while raising public awareness of the importance of nutrition and healthy eating habits.

- a. Rather than assessing consumer confusion, FDA should be fostering the dissemination of more scientific information on the nutrient-disease relationship at the point-of-sale.

Rather than attempting to discern consumer confusion regarding the scientific weight afforded recently allowed qualified health claims, the agency should start with the assumption that the claims are too new, that consumer understanding of the truthful content of them is likely primitive and incomplete, and that FDA ought to permit disclosure of more scientific information to the public by allowing its regulatees to send consumers scientific articles, abstracts, and accurate summaries of the scientific evidence concerning the relationship and by educating the public of the science through its own public service announcements, via its website, and via press releases and consumer information bulletins. That would maximize to the fullest extent possible the opportunity for public appreciation of the science. FDA has a history of denying consumers access to scientific information at the point of sale when it concerns nutrient-disease relationships.²⁵ FDA has repeatedly denied consumers access to health-related scientific literature, even truthful scientific government reports, and products at the point-of-sale.²⁶ There is substantial evidence that denying consumers access to truthful and nonmisleading health information at the point-of-sale contributes to a widespread failure

²⁵ *Washington Legal Foundation v. Friedman*, 13 F.Supp.2d 51 (D.D.C. 1998); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999 *reh'g denied*, 172 F.3d 72 (D.C. Cir. 1999)); *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002). See also *Pearson v. Leavitt*, No. 8:04-cv-3600 (S.D.Md. 2004)(pending).

²⁶ In 1995, FDA took substantial measures to ensure the safety of imported fish products. See 60 Fed.Reg. 65096 (December 18, 1995). The Final Rule was applied not only to fish but also to fish oil. 60 Fed.Reg. 65110.

to address and prevent a number of illnesses and diseases responsive to nutrition.²⁷

FDA's aim, consistent with the First Amendment mandate *Pearson* places upon the agency, must be to disclose scientific information, not suppress it.

Consumers have the right to receive truthful information, regardless of their comprehension of it.²⁸ They have no constitutional right to understand truthful speech nor is there any constitutional power in government to suppress truthful speech because listeners or readers fail to comprehend it or comprehend it in a way that the government finds displeasing. See *Western States Medical* at 375; *44 Liquormart* at 503. The Courts have continuously rejected the paternalistic notion that the government has the authority to restrict the publication of truthful and nonmisleading speech when the government bases suppression on the notion that consumers will misunderstand the truth.²⁹

- b. If FDA proceeds with its proposed study, the information collected will be insufficient to prove consumer confusion.

Data obtained from the proposed survey will fail to prove the existence, degree, or character of any consumer confusion. This is especially true in light of the fact that the agency has predicted an estimated response rate of 0.2%.³⁰ This is prima facie evidence of massive response bias, as nonresponders (here 98.8% of the participants) may have

²⁷ See discussion of the folic acid health claim, *supra* at footnote 7. The consequences of the agency's ill-advised rule were both tragic and resulted in thousands of preventable serious birth defects.

²⁸ *Stanley v. Georgia*, 394 U.S. 557, 564 (1969)

²⁹ *Thompson v. Western States Medical Center*, 535 U.S. 357, 375 (2002) ("We have previously rejected 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."); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (The court rejected the "State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely" The court also noted that "bans on truthful and non-deceptive advertising usually rest solely on the offensive assumption 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." (citing *Linmark Assoc.*, 431 U.S. at 96), *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490, 505 (1981) ("A State may not completely suppress the dissemination of truthful information about an entirely lawful activity merely because it is fearful of that information's effect upon its disseminators and its recipients."))

³⁰ 70 Fed.Reg. 16291, 16292 (March 30, 2005)

very different views. The proposed survey is, thus, an unwarranted exercise, a waste of tax dollars.

FDA cannot be sure that perception of the qualified health claim is based on the claim itself or on undisclosed preconceived notions concerning the underlying nutrient-disease relationship arising from inaccurate media reports or other sources. The claims are too new and, thus, not yet vetted through the idea marketplace such that the complexities and nuances of them are largely unfamiliar to the public. Any attempt to interpret data suggesting misunderstanding will be fraught with great risk of error because there are a myriad of reasons why comprehension may be lacking, most of which may arise not from the claim language itself but from inadequate information in the idea marketplace on the nature of the relationship (i.e., from the paucity of science this agency allows to be disseminated concerning the nutrient-disease relationship). Moreover, the claims are by their very wording based on less than conclusive evidence. They, thus, beg differences in comprehension based on relative weight assigned by each reader of the claim. The far better approach is to assume limited public understanding of the science on the nutrient-disease relationship and to use agency resources not to study that limited understanding but to disseminate widely scientific information concerning the relationship so that greater public understanding is achieved. Disclosure over suppression is this agency's First Amendment mandate.

Because the FDA bears the First Amendment burden of proof, it may not deem disclaimers infeasible because it *lacks* conclusive evidence of their perfect comprehension or that few, if any, consumers understand the plain meaning of all qualified claim language.

Consumer confusion does not make a health claim or qualified health claim inherently misleading. Even where confusion is shown, so long as the disclosed information is truthful, the disclosure is protected speech under the First Amendment, regardless of consumer understanding of it. It is only through greater disclosure, not less, that consumer confusion will be reduced over time.

2. FDA's Proposed Survey Is an Inadequate Tool to Measure Consumer Confusion

Focusing on the Omega-3 fatty acids and monounsaturated fatty acids from olive oil health claims, FDA intends to study consumer confusion in the context of the public's understanding of the relative significance of the scientific evidence supporting qualified health claims. Silent as to the methodology or design of the proposed survey, the Notice simply states that "data will be collected using participants of an Internet panel ..." ³¹ No specific information is provided as to the survey's design, format, questions, sampling pool, or how the collected data will be measured, analyzed and used. The agency has only said that the experimental study data will be collected using voluntary participants of an Internet panel of approximately 600,000 people. ³² Considering the importance of the study to consumers and the food and dietary supplement industries, the precise study questions, the precise study design, and the precise study methodology must be revealed to permit meaningful opportunity for comment, as required by the APA, 5 U.S.C. § 553. The agency's failure to explain the proposed study with specificity denies the public, and, here, the "Joint Commenters," the opportunity to comment fully on the subject of the Notice.

³¹ *Id.*

³² 70 Fed. Reg. 16292 (March 30, 2005).

1. Methodology

Well designed web-based surveys offer researchers many advantages over traditional methods of data collection including, but not limited to, more design options, the use of graphics, greater control over respondents' behavior, reduced costs and faster response times.³³ However, for each of those advantages, there are technical challenges and potential limitations that must be considered by the researcher including presentation, hardware (different browser settings and user preferences), diversity of the sample pool, and distribution and data measurement. A poorly designed web-based survey encourages web-users to break off the survey process early, making it less effective than more traditional methods of surveying, such as mail, telephone or email.³⁴ The agency has provided no information regarding the structure or format of the proposed survey, denying commenters their APA right to a meaningful opportunity for comment. *See* 5 U.S.C. § 553.

2. Questions

The Notice does not say what type of questions will be asked.³⁵ No examples of sample questions have been provided. How the questions are written and the language used will directly affect the quality of the scientific data obtained. The questions must be designed to avoid bias. Consumer confusion cannot possibly be determined based on quantifiable data alone.

³³ Andrews, D., Nonnecke, B., Preece, J. (2003) Conducting Research on the Internet: Online Survey Design, Development and Implementation Guidelines. *International Journal of Human-Computer Interaction*, page 4.

³⁴ Andrews, D., Nonnecke, B., Preece, J., Conducting Research on the Internet: Online Survey Design, Development and Implementation Guidelines. *International Journal of Human-Computer Interaction*. Page 5 (2003).

³⁵ Will the questions be "adaptive" (questions are individualized according to a respondent's answer to an earlier question) or in "batch form" (consumers complete a series of predetermined questions).

3. Sampling

Sampling is the process by which a survey pool is selected. The Notice only states that participation will be voluntary. No other information is provided about how the participants will be selected. Meaningful opportunity for comment has thus been denied in violation of the APA. *See* 5 U.S.C. § 553.

Generally, there are two main methods for selecting a sample pool: probability and non-probability based approaches (frequently referred to as “random” and “nonrandom” approaches to surveys).³⁶ Because FDA is silent as to the approach it will use, the “Joint Commenters” are unable to comment on the actual survey to be used, and the Notice violates the APA as a consequence. *See* 5 U.S.C. § 553.

FDA has not stated how it intends to create the sample pool. The public is not told whether the agency intends to use a probability or non-probability-based approach. Additionally, the agency has not said who will be included in the sample pool, and

³⁶ Probability-based approaches (“nonrandom”) involve having prior knowledge of a sample frame, most often through pre-recruitment or prior demographic identification of the sample pool. Prior knowledge affords the researcher greater control over recruiting while providing them with greater understanding of data collected and the nonresponse rate. *See* Couper, Mick P., *Web Surveys: A Review of Issues and Approaches*. Public Opinion Quarterly, Vol. 64: 464-494, 484 (2000). Some of the most commonly used probability based approaches include intercept (targeting web users on a particular website and inviting every nth person to participate in the survey), list-based coverage (invitations are sent out to potential respondents from pre-selected weblists asking them to participate in the survey), mixed-mode surveying (data is collected from a sample group using different methods such as mail, email, telephone and web-based surveys), pre-recruitment (respondents selected by researcher prior to the survey) and probability samples of full populations (subjects are provided with the equipment and tools needed to participate). Using a probability based approach, a risk of bias exists considering that participants are pre-selected from a predetermined website or based on a specific characteristic. However, one advantage to such an approach is that the nonresponse rate is measurable.

With non-probability based approaches (“random” sampling), researchers are unfamiliar with the background of the survey group beforehand. The two most popular approaches are self-selection and volunteer response. With self-selection, web postings are located on a number of different websites inviting respondents to participate in the survey by going to the survey. This approach involves no attempt to statistically sample the online population and depends exclusively on online traffic. *See* Andrews, D., Nonnecke, B., Preece, J., *Conducting Research on the Internet: Online Survey Design, Development and Implementation Guidelines*. International Journal of Human-Computer Interaction. Page 8 (2003). The second approach relies on demographic information to randomly select participants.

whether that demographic pool will include dietary supplement buyers and consumers. Again, the APA has been violated. 5 U.S.C. § 553.

4. Demographic Data

The American Herbal Products Association reports that in 2003, consumers spent approximately \$12.5 billion on vitamins and other dietary supplements.³⁷ Of that amount, \$6.2 billion was spent on dietary supplements alone, the fastest growing subsector in the health foods market.³⁸ 2003 sales (in dollars) increased 2.6% from 2002.³⁹

According to data from the 1999-2000 National Health and Nutrition Examination Survey, a total of 52% of adults reported taking a dietary supplement in the past month.⁴⁰ Of the adults surveyed, 35% took a multivitamin or multimineral supplement. Prevalent characteristics among dietary supplement users include: female gender, older age, more education, non-Hispanic White race/ethnicity.

In the United States, 59% of males and 54% of females use the Internet. Teenagers and young adults use the Internet more than any other age group.⁴¹ Seventy-six percent of people ages 18 to 24 and 72% of people ages 25 to 34 use the Internet, while only 66% of people ages 35 to 44, 61% of people ages 45 to 54, 46% of people

³⁷ Euromonitor, *Vitamins And Dietary Supplements in the USA*, page 72 (July 2004)

³⁸ *Id.* at 83.

³⁹ *Id.*

⁴⁰ The information is from a nationally representative, cross-sectional survey of U.S. health and nutrition conducted to assess prevalence of dietary supplement use overall and in relation to lifestyle and demographic characteristics.

⁴¹ Pew Internet & American Life Foundation, *Internet Use by Region in the United States*, 2 (2003) at http://www.pewinternet.org/pdfs/PIP_Regional_Report_Aug_2003.pdf. See also U.S. Department of Commerce, *A Nation Online: How Americans are Expanding Their Use of the Internet*, Executive Summary (February 2003) at <http://www.ntia.doc.gov/ntiahome/dn/html/toc.htm> ("Children and teenagers use computers and the Internet more than any other age group. Ninety percent of children between the ages of 5 and 17 (or 48 million) now use the Internet.")

ages 55 to 64 and 15% of people ages 65 and over use the Internet.⁴² Lower income homes are less likely to have Internet access. Only 38% of households making \$30,000 or less have access to the Internet while 61% of households that make \$30,000 to \$50,000, 77% of households making \$50,000 to \$75,000, and 86% of households making over \$75,000 have Internet Access.⁴³ 59% of non-Hispanic Whites, 42% of non-Hispanic Blacks, 54% of Hispanics, and 60% of people listing themselves as "Other" use the Internet.⁴⁴ Only 22% of people with less than a high school degree use the Internet, while 45% of people with a high school degree, 70% of people with some college education, and 82% of college graduates or people with further education use the Internet.⁴⁵

Based on the above demographics, the following conclusions can be drawn: mostly older Americans, and particularly women, use dietary supplements.⁴⁶ That group is underrepresented among those who use the Internet most and are to be subjects of the proposed survey. A recent study reported that only 15% of American adults over the age of 65 use the Internet, and when the federal government last studied American Internet use in 2003, it reported that that "[c]hildren and teenagers use computers and the Internet more than any other age group."⁴⁷

⁴² Pew Internet & American Life Foundation, *Internet Use by Region in the United States*, 2 (2003) at http://www.pewinternet.org/pdfs/PIP_Regional_Report_Aug_2003.pdf.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ R. Bethene Ervin, et al, *Prevalence of Leading Types of Dietary Supplements Used in the Third National Health and Nutrition Examination Survey*, 1988-94, Advance Data/Centers for Disease Control and Prevention, Nov. 9, 2004, at 3 at <http://www.cdc.gov/nchs/data/ad/ad349.pdf> (reporting that roughly 57% of women use supplements compared with 47% of men; reporting approximately 63% of adults over the age of 60 take supplements, only 43% of adults between the ages of 20 and 39 take supplements); Kathy Radimer, et al., *Dietary Supplement Use by US Adults: Data from the National Health and Nutrition Examination Survey, 1999-2000*, *American Journal of Epidemiology*, Feb. 27, 2004, at 341.

⁴⁷ Pew Internet & American Life Foundation, *Internet Use by Region in the United States*, 2 (2003) at http://www.pewinternet.org/pdfs/PIP_Regional_Report_Aug_2003.pdf; U.S. Department of Commerce, *A Nation Online: How Americans are Expanding Their Use of the Internet*, Executive Summary (February 2003) at <http://www.ntia.doc.gov/ntiahome/dn/html/toc.htm>.

5. Demographics of the Sample Pool

Data shows that 1) the web population is not reflective of the overall American population⁴⁸ and 2) the web-user population is not reflective of the dietary supplement user population. The demographic data presented above clearly confirms those facts. Dietary supplement buyers and consumers are the proper survey audience but reliance on the web will not likely involve a representative sampling of those buyers and consumers. Surveying people who are unfamiliar with dietary supplements will yield gross and unrepresentative biases and will involve a population far more likely to be unfamiliar with the science supporting any qualified health claims.

6. Nonresponse Rate

In addition to methodology and sampling, the overall response rate is important to a survey's overall success. The Notice in the Federal Register states that of the 600,000 participants, the agency estimates 1,600 individuals will respond. That represents a response rate of 0.2%.⁴⁹ The "Joint Commenters" are concerned that the low response rate will have an adverse impact on the survey's ability to collect statistically significant data. Any evidence contained in a survey with a response rate of 0.2% surely cannot be considered accurate and representative. For this reason, it appears that the proposed survey is unlikely to yield accurate and reliable results and is an entirely unjustified expenditure of tax dollars.

⁴⁸ "The online population is not reflective of the offline population distribution, and it is changing continually. To infer for a general population based on a sample drawn from an online population is not yet possible and will not be possible until the online and offline populations reflect each other." Andrews, D., Nonnecke, B., Preece, J. (2003) Electronic survey methodology: A case study in reaching hard to involve Internet users. *International Journal of Human-Computer Interaction*. 16, 2, 185-210.

⁴⁹ 70 Fed.Reg. 16293 (March 30, 2005).

Research shows that the nonresponse rate may be attributed to a number of factors including 1) absence of motivation tools (e.g., pre-notification letters or follow-up letters) encouraging participants to complete the survey; 2) technical difficulties such as slow modem speed, unreliable connections or low-end browsers; 3) cost concerns; 4) perceived difficulty and technical intimidation may discourage some participants from completing the survey; 5) disinterest; 6) privacy and confidentiality concerns; and 7) lack of adequate instructions.⁵⁰

7. Piloting

The Notice provides that prior to distribution the survey will be piloted or tested on thirty individuals. Considering the magnitude of the survey, 600,000 individuals, and the importance of the information being collected, the test group is not large enough to adequately evaluate the strengths and weaknesses of the draft survey. Piloting is commonly used by researchers to discover deficiencies in surveys.⁵¹ Common mistakes most frequently caught through piloting include bias in question/answer wording, requesting inappropriate demographic data, overlapping questions scales or selection options, inaccurate or missing instructions, technical vocabulary with no definitions, insufficient space for open-ended question answers and lack of motivational techniques encouraging respondent to complete the survey.⁵² The failure of the Notice to reveal in detail the piloting criteria denies commenters a meaningful opportunity for comment in violation of the APA, 5 U.S.C. § 553.

⁵⁰ Couper 473-475.

⁵¹ "Survey piloting is crucial to achieving research goals and ensuring that subjects complete the survey. To quote a leader in survey development, "Survey piloting is the process of conceptualizing and re-conceptualizing the key aims of the study and making preparations for the fieldwork and analysis so that not too much will go wrong and nothing will have been left out." Andrews, D... pg 15.

⁵² Id at 17.

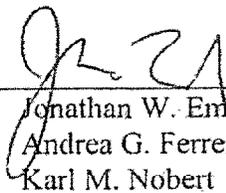
IV. CONCLUSION

For the foregoing reasons, FDA should abandon its proposed internet survey and, instead, fulfill its First Amendment mandate by allowing the dissemination (and causing the dissemination) of more scientific information on the olive oil and omega-3 fatty acid/heart disease relationships. Disclosure of information over its suppression is the constitutional requirement. Any attempt to rely on the proposed survey to alter or censor a qualified health claim will violate the First Amendment. If the agency insists on use of a consumer perception survey, it should rely on it solely for the purpose of pinpointing those areas in which greater FDA public information campaigns could be used to improve public understanding and foster greater public debate on the role of the particular nutrients in reducing heart disease risk.

Respectfully submitted,

LIFE ENHANCEMENT PRODUCTS, INC.;
LIFE EXTENSION FOUNDATION BUYERS
CLUB, INC.; DURK PEARSON AND SANDY
SHAW; and LIFE PRIORITY, INC.,

By


Jonathan W. Emord
Andrea G. Ferrenz
Karl M. Nobert

Emord & Associates, P.C.
1800 Alexander Bell Drive
Suite 200
Reston, VA 20191
P: (202) 466-6937
F: (202) 466-6938
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