

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALLIANCE FOR NATURAL HEALTH US,
1350 Connecticut Avenue, N.W.,
5th Floor,
Washington, D.C. 20036;

DURK PEARSON and SANDY SHAW,
P.O. Box 552,
Tonopah, NV 89049;

and

COALITION TO END FDA AND
FTC CENSORSHIP,
1050 17th St., N.W.,
Suite 600,
Washington, D.C. 20036,

Plaintiffs,

v.

KATHLEEN SEBELIUS,
in her official capacity as Secretary,
United States Department of Health
and Human Services,
200 Independence Avenue, S.W.,
Sixth Floor,
Washington, D.C. 20201;

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, D.C. 20201;

MARGARET A. HAMBURG, M.D.,
in her official capacity as Commissioner,
United States Food and Drug
Administration,
5600 Fishers Lane,
Room 1471,
Rockville, MD 20857;

Case No.

**COMPLAINT FOR
DECLARATORY AND
INJUNCTIVE RELIEF**

FOOD AND DRUG ADMINISTRATION,)
 5600 Fishers Lane,)
 Rockville, MD 20857;)
)
and the UNITED STATES OF AMERICA,)
)
Defendants.)
 _____)

COMPLAINT SEEKING DECLARATORY AND INJUNCTIVE RELIEF

1. Plaintiffs Alliance for Natural Health US (“ANH US”); Durk Pearson and Sandy Shaw (“Pearson and Shaw”); and the Coalition to End FDA and FTC Censorship (“CEC”), by counsel, hereby submit this complaint against Defendants Kathleen Sebelius, Secretary, United States Department of Health and Human Services (in her official capacity); the United States Department of Health and Human Services; Margaret A. Hamburg, M.D., Commissioner of the United States Food and Drug Administration (in her official capacity); the United States Food and Drug Administration (“FDA”); and the United States of America. The Plaintiffs seek a declaratory judgment that FDA’s June 19, 2009 Final Order, FDA Docket No. FDA-2008-Q-0299 (hereinafter “Order”), violates the Plaintiffs’ First Amendment rights and the constitutional mandate of the United States Court of Appeals in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) (“*Pearson I*”), and of this Court in *Whitaker v. Thompson*, 248 F.Supp. 2d 1 (D.D.C. 2002) (“*Whitaker I*”). They also seek an injunction against enforcement of the Order.

2. This complaint arises from FDA’s Order, which bans in perpetuity use of seventeen qualified health claims concerning the effect of antioxidant vitamins C and E on reduction in the risk certain site specific cancers, including the six qualified health claims challenged here:

Vitamin C may reduce the risk of lung cancer. The scientific evidence supporting this claim is convincing, but not conclusive (hereinafter “Claim I”);

Vitamin C may reduce the risk of colon cancer. The scientific evidence supporting this claim is persuasive, but not conclusive (hereinafter “Claim II”);

Vitamin C may reduce the risk of gastric cancer. The scientific evidence supporting this claim is persuasive, but not conclusive (hereinafter “Claim III”);

Vitamin E may reduce the risk of bladder cancer. The scientific evidence for this claim is convincing, but not conclusive (hereinafter “Claim IV”);

Vitamin E may reduce the risk of gastric cancer. The scientific evidence for this claim is persuasive, but not conclusive (hereinafter “Claim V”);

Vitamin E may reduce the risk of lung cancer. The scientific evidence for this claim is convincing, but not conclusive (hereinafter “Claim VI”).

See Order at 3, 38-41.

3. Each of the antioxidant vitamin qualified health claims at issue in this complaint is supported by credible scientific evidence. The scientific evidence for the claims is not outweighed by scientific evidence against them, and the claims are not inherently misleading. In its Order, FDA effectively demanded near conclusive scientific proof as a condition precedent for allowing the requested claims to be communicated to consumers. That action directly violates the First Amendment mandates from this court in *Whitaker I* and from the Court of Appeals in *Pearson I*, two cases in which the courts previously held FDA censorship of the antioxidant vitamin/cancer risk reduction claims unconstitutional. By censoring the claims in issue, FDA has denied consumers access in the market, including at the point of sale, to accurate information concerning the potential of antioxidant vitamins to reduce cancer risk. FDA has created a rigid construct that categorically rejects a large quantum of peer-reviewed

science considered persuasive by the scientific community, including animal studies, in vitro studies, and clinical trials (if the trials involve treatment of diseased populations or if otherwise deemed methodologically deficient by FDA for one unreasonably weighted reason or another). FDA does not in fact substantively review the totality of the scientific evidence but only a small fraction of it, thus creating a false construct of evidence selectively culled, creating the misimpression that evidence is in fact less supportive than it actually is. On that false basis, FDA denies claims or saddles them with misleadingly negative disclaimers.

4. Plaintiffs ask this Court to declare invalid—under the First Amendment and under the applicable court mandates in *Pearson I* and *Whitaker I* (mandates FDA has consistently refused to recite, let alone apply, in its health claims decisions)—FDA’s censorship of the antioxidant vitamins C and E claims here in issue. The Plaintiffs further request that this Court enjoin FDA from taking action that would prevent Pearson and Shaw’s licensees, the ANH US corporate members, and the CEC corporate members from placing the antioxidant Vitamin C and E health claims here in issue on the labels and in the labeling of their dietary supplement products that contain Vitamins C and E. Finally, the Plaintiffs ask this Court to hold the FDA-mandated qualifications required for use in association with Claims III and IV unconstitutional because FDA therein compels Plaintiffs to propound negatively value-laden and inaccurate messages to the public. *See* Order at 2-3 (listing petitioned claims); *see also* Order at 39 (providing burdensome qualifications). Those qualifications deny Plaintiffs the right to communicate accurate representations of the scientific evidence to consumers.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction), and 28 U.S.C. § 1346 (jurisdiction where the United States is a defendant).

6. The Plaintiffs' requested relief is authorized under 28 U.S.C. § 2201 (declaratory relief) and 28 U.S.C. § 2202 (further relief).

7. Venue is properly vested in this Court under 28 U.S.C. § 1391(e) because the Defendants reside in this district and a substantial part of the events giving rise to this action occurred in this district.

PARTIES

8. **Alliance for Natural Health US.** The Alliance for Natural Health US (formerly the American Association for Health Freedom and, before that, the American Preventative Medical Association, a plaintiff in *Pearson I*) ("ANH US") is a Virginia nonprofit corporation, founded in 2002. The ANH US protects the right of integrative medical practitioners to practice complementary and alternative medicine and protects the right of consumers to choose the healthcare options they deem best based on fully informed consent. ANH US is a membership-based organization with more than 400 members consisting of consumers; healthcare practitioners; food, and dietary supplement company members; and 40,000 advocate members. A key focus for ANH US is the protection and promotion of access to information in the market on the benefits of health foods and dietary supplements. By educating the general public and ANH US members about the benefits of a healthy diet and lifestyle that includes supplements, ANH US strives to arm consumers with the information

necessary for them to make informed market selections and to take personal responsibility for their health, thereby promoting disease prevention, reducing the extent of medical intervention required, and reducing the public cost of healthcare in the United States. Likewise, ANH US professional and industry members have a particular interest in the dissemination of truthful nutrient information about dietary supplements they recommend and sell, including dietary supplements containing the essential Vitamins C and E. FDA's rejection of new and previously allowed qualified health claims for Vitamins C and E in the risk of certain cancers and for Vitamins C and E deprives ANH US and ANH US members of vital nutrient information. The American Cancer Society estimates that more than 1.2 million new cases of cancer will be diagnosed this year alone, in addition to the 16 million people who already have cancer. Depriving ANH US professionals and industry members of the right to communicate cancer risk reduction effects of vitamins C and E and of the right of ANH US consumer members to receive that information eliminates freedom of informed choice and contravenes key ANH US goals and principles. In particular, ANH US board members, comprised of eight representatives of the natural health (consumer, industry, and professional) community, are deprived of the ability to satisfy the ANH US mandate: to facilitate the free flow of credible scientific information to educate consumers about the benefits of supplements so that they may take more personal responsibility for their health and well-being. The result is that all ANH US members suffer from the loss of truthful antioxidant vitamin nutrient information, the possession of which could benefit their personal health and increase interest in professional products containing vitamins C and E. The result is also that ANH US professional members who sell vitamins C and E-containing dietary supplements suffer from the loss of their right to

communicate truthful vitamin C and E nutrient information to those who purchase those supplements.

9. **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 number one, million plus copy New York Times best seller, *Life Extension: A Practical Approach* (1982). They have also published three other 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). Pearson and Shaw were plaintiffs in *Pearson I*, 164 F.3d at 650; *Pearson v. Shalala*, 130 F.Supp. 2d 105 (D.C. Cir. 2001) (“*Pearson II*”); *Pearson v. Thompson*, 141 F.Supp. 2d 105 (D.D.C. 2001) (“*Pearson III*”); and *Whitaker I*, 284 F.Supp. 2d at 1, in which the Courts held FDA censorship of health claims unconstitutional. Pearson and Shaw license, and receive royalties from, dietary supplements containing antioxidant Vitamins C and E. Pearson and Shaw wish to authorize their licensees to place the qualified health claims for Vitamins C and E challenged here on the labels and in the labeling of their Vitamins C and E-containing dietary supplements and, but for FDA’s censorship of those claims, would do so. Pearson and Shaw were among those who petitioned FDA for allowance of the 17 claims, including the 6 claims here in issue.

10. **Coalition to End FDA and FTC Censorship.** CEC is an association of 100 persons, companies, and individuals, certain of whom sell dietary supplements including those containing Vitamins C and E and others of whom consume dietary supplements including those containing Vitamins C and E, and have united for the purpose of advocating that federal government agencies not block consumer access to accurate representations concerning the

science on the role of nutrients, including antioxidant Vitamins C and E, in reducing risk of disease and treating disease. The CEC was among the petitioners that petitioned FDA for allowance of the 17 claims, including the 6 claims here in issue.

11. **Kathleen Sebelius; the United States Department of Health and Human Services; Margaret A. Hamburg, M.D.; the United States Food and Drug Administration; and the United States of America.** Kathleen Sebelius (sued in her official capacity only) is the Secretary of the United States Department of Health and Human Services, the executive department having jurisdiction over the FDA. Margaret A. Hamburg, M.D. (sued in her official capacity only) is the Commissioner of the United States Food and Drug Administration. The FDA is the administrative agency granted authority by Congress to regulate the interstate manufacture, sale, and distribution of foods, drugs, cosmetics, biologics, medical devices, and dietary supplements in the United States. The Department of Health and Human Services and the FDA are part of the executive branch of the United States government.

STATEMENT OF FACTS

PROCEDURAL HISTORY

12. The FDA has an historic bias against dietary supplement products and dietary supplement health claims. According to Senator Orrin Hatch:

For more than three decades, FDA has tried to restrict severely the ability of the dietary supplement industry to sell and market its products and, consequently, the ability of consumers to buy them. The agency has repeatedly attempted to impose unnecessary and stringent standards that would leave many if not most supplement companies with no practical choice but to close their doors. The institutional animosity never made sense, but it is even less logical today in light of the growing body of scientific evidence regarding the disease prevention powers of nutrients. Unfortunately, the effect of the FDA's heavyhanded policy

is that consumers are left uninformed and the Nation pays millions of dollars for health care that could have been saved through disease prevention. ... In sum, over the last 30 years, FDA has tried to prevent consumer education regarding the disease prevention properties of vitamin A, vitamin C, vitamin E, and other dietary supplements and, at times, has attempted to assert that many of these products were unsafe.

See Statement of Orrin Hatch, Proceedings and Debates of the 103rd Congress, 139 Cong. Rec. S4561-02, at S4577 (Apr. 7, 1993), *available at*, 1993 WL 102951.

13. The statutory framework for dietary supplement health claims became a part of the law on November 8, 1990, when President Bush signed the Nutrition Labeling and Education Act (“NLEA”). 21 U.S.C. § 301, *et seq.* The NLEA created a “safe harbor” for dietary supplement and food health claims (nutrient-disease relationship claims). See 21 U.S.C. § 343(r)(5)(D). The NLEA required FDA to create rules for approval of health claims for dietary supplements. 21 U.S.C. § 343(r)(3)(B)(i). In 1993, the FDA promulgated 21 CFR 101.14 (adopting for dietary supplements the statutory Significant Scientific Agreement standard for food) and 21 CFR 101.70 (a procedure for evaluating the validity of health claims). See *Food Labeling; General Requirements for Health Claims for Food*, 58 Fed. Reg. 2478-01 (Jan. 6, 1993); *Food Labeling; General Requirements for Health Claims for Dietary Supplements*, 59 Fed. Reg. 395-01 (Jan. 4, 1994).

14. An antioxidant vitamin/cancer risk reduction health claim was one of four claims the United States Court of Appeals for the D.C. Circuit held unconstitutionally suppressed by FDA in violation of the First Amendment in *Pearson I*. See *Pearson I*, 164 F.3d at 656.

15. Following Congress’s mandate to issue regulations implementing Section 343(r)(5)(D) and, specifically, to determine whether to allow a claim associating antioxidant vitamins with a reduction in the risk of cancer, the FDA published a proposed rule in the Federal Register on June 18, 1993, inviting comments on that association among others. See

Pearson v. Shalala, 14 F.Supp. 2d 10, 14 (D.D.C. 1998). Plaintiffs Pearson and Shaw, along with other co-petitioners including the American Preventative Medical Association (“APMA”) (predecessor to ANH US), submitted comments demanding that FDA permit with disclaimers claims associating nutrients with disease risk reduction, including the antioxidant vitamin/cancer risk reduction, upon the basis of credible, but not conclusive, scientific evidence, with the addition of disclaimers designed to inform consumers that the science was inconclusive. *Id.* In the FDA Final Rule, the agency rejected the Plaintiffs’ comments and prohibited use of Plaintiffs’ antioxidant health claims with or without disclaimers. *Id.*

16. FDA’s Significant Scientific Agreement standard requires near conclusive proof before any claim is authorized by the agency for use on the label and in the labeling of dietary supplements. Pearson, Shaw, APMA (now ANH US), and the other co-petitioners argued that if their claims were at worst only potentially, but not inherently, misleading FDA was constitutionally forbidden from censoring them unless it could prove through empirical evidence that no disclaimer was capable of eliminating misleadingness. Upon FDA’s first disallowance of the antioxidant vitamin/cancer risk reduction claim, Pearson, Shaw, APMA (now ANH US), and other co-petitioners sued FDA on First Amendment grounds, among others.

17. In 1999, the D.C. Circuit’s three-judge panel unanimously struck down FDA’s censorship of the antioxidant vitamin/cancer risk reduction claim, among others. *See Pearson I*, 164 F.3d at 659-61. In *Pearson I*, Plaintiffs appealed the FDA’s denial of four health claims supported by evidence the FDA concluded was “inconclusive for one reason or another and thus failed to give rise to ‘significant scientific agreement’ but the Court found backed by credible evidence.” *Id.* at 653. Because the claims were at worst only potentially misleading,

the Court required FDA to use claim qualification in lieu of outright suppression as a less speech-restrictive means to eliminate potential misleadingness. *Id.* at 655-60. The court stated, “It is clear ... that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a ‘far less restrictive means.’” *Pearson I*, 164 F.3d at 658.

18. On September 8, 1999, nine months after the *Pearson I* decision (during which time FDA maintained its unconstitutional censorship of the antioxidant vitamin/cancer risk reduction claim, among others), the FDA published notice in the Federal Register that it wished to review new scientific data, research study results, and other related information concerning, among others, the antioxidant vitamin/cancer risk reduction claim. *See* 64 Fed. Reg. 48841-42 (Sep. 8, 1999). In April of 2000, the APMA (now ANH US), Durk Pearson, and Sandy Shaw, and others filed responsive comments with FDA in support of the antioxidant qualified health claim. *See, e.g.*, Supplemental Comments of Julian M. Whitaker, et al., FDA Docket No. 91N-0101 (April 3, 2000). The Plaintiffs’ comments cited 28 articles from peer-reviewed journals and respected scientific sources, 10 of which described clinical intervention and controlled population studies that supported the antioxidant health claims. *Id.* at 13.

19. On October 3, 2000, FDA published in the Federal Register its decision to deny yet again the antioxidant vitamin/cancer risk reduction claims. *See* 65 Fed. Reg. 58917, 58918 (Oct. 3, 2000) (revoking regulation but still prohibiting use: “such claims still may not be used in labeling pending reconsideration of these claims by FDA”). In a separate claims action (concerning FDA’s censorship of a folic acid/neural tube defect risk reduction claim), on November 13, 2000, the original petitioners filed suit once again seeking declaratory and injunctive relief in response to FDA’s contumacious refusal to abide by *Pearson I*. *See*

Pearson II, 130 F.Supp. 2d 105, 115 (D.C. Cir. 2001). In *Pearson II*, this Court held in favor of the plaintiffs issuing a preliminary injunction and stated, “it is clear that the FDA simply failed to comply with the constitutional guidelines outlined in *Pearson I*.” *Id.* at 112. This Court restated the teachings from *Pearson I* that “disclaimers are constitutionally preferable to outright suppression; in other words more disclosure rather than less is the preferred approach so long as the advertising is not inherently misleading.” *Id.* This Court concluded, “The FDA has simply failed to adequately consider the teachings of *Pearson I*: that the agency must shoulder a very heavy burden if it seeks to totally ban a particular health claim.” *Id.* at 119. Instead of accepting the D.C. Circuit and this Court’s decisions in *Pearson I* and *Pearson II* and drafting the required disclaimers, the FDA filed a motion for reconsideration of the *Pearson II* decision. *See Pearson III*, 141 F.Supp. 2d 105 (D.D.C. 2001). In addressing the FDA’s motion, this Court explained that FDA could not constitutionally ban a health claim under *Pearson I* except in the rarest of circumstances. *See id.* at 112. The court stated,

[T]he FDA [may] impose an outright ban on a claim where evidence in support of the claim is *qualitatively* weaker than evidence against the claim—for example, where the claim rests on only one or two old studies’ or ‘where evidence in support of a claim is outweighed by evidence against the claim.’ [*Pearson I*], 164 F.3d at 660 n.10 (emphasis original). *Pearson II* fleshes out the term “against”: The mere absence of significant affirmative evidence in support of a particular claim ... does not translate into negative evidence ‘against’ it. [*Pearson II*], 130 F.Supp. 2d at 115.

Pearson III, 141 F.Supp. 2d at 105. The Court then denied the motion for reconsideration stating,

In moving for reconsideration, Defendants again seem to ignore the thrust of *Pearson I* ... the philosophy underlying *Pearson I* is perfectly clear: that the First Amendment analysis in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n of N.Y.*, 447 U.S. 557 (1980), applies in this case, and that if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression. In its motion for reconsideration, the FDA has again refused to accept the reality and finality of that conclusion by the Court of Appeals.

Id.

Despite the courts' decisions in *Pearson I* and *II*, the FDA still refused to permit the antioxidant vitamin/cancer risk reduction claim. *See, e.g.*, May 4, 2001, FDA Letter to Jonathan Emord, FDA Docket No. 91N-0101 (responding to Plaintiffs three months after the *Pearson II* decision and stating that "FDA is not exercising enforcement discretion for a qualified claim for a relationship between vitamin C or vitamin E, alone or in combination, and the risk of certain kinds of individual cancers ...").

20. Although subject to the courts' decisions in *Pearson I*, *II*, and *III*, the FDA continued to suppress the Plaintiffs' antioxidant vitamins C and E health claim. Therefore, several months after the *Pearson III* decision, on July 17, 2001, Plaintiffs once again filed suit against the agency, seeking to compel its compliance. *See Whitaker I*, 248 F.Supp. 2d 1 (D.D.C. 2002), *appeal dismissed*, 2003 U.S. App. LEXIS 18288 (D.C. Cir. 2003). In *Whitaker I*, the Plaintiffs sought declaratory and injunctive relief against FDA's post-*Pearson I* maintenance of the same antioxidant vitamin/cancer risk reduction claim censorship at issue in *Pearson I*. Plaintiffs challenged the FDA's "contumacious disobedience of three constitutional orders of the Courts" in *Pearson I*, *II*, and *III*. *See* Complaint, *Whitaker I*, No. 01-1539(GK) (July 16, 2001).

21. The *Whitaker I* Court restated that the constitutional conclusion that FDA must favor disclosure over suppression. *Id.* at 9. In *Whitaker I*, this Court held that "Plaintiff's antioxidant vitamin claim [was] not inherently misleading." *Id.* The Court explained that the "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." *Id.*

at 9 (quoting *Central Hudson*, 447 U.S. at 566), and has placed the burden of proof squarely on FDA to choose the least restrictive means to avoid misleadingness:

The First Amendment places the burden on the government to prove that its method of regulating speech is the least restrictive means of achieving its goals. The First Amendment does not allow the FDA to simply assert that Plaintiff's Claim is misleading in order to supplant [its] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.

Id. at 9 (internal citations omitted). This Court next found that claims must be permitted “so long as information can be presented in a way that is not deceptive,” *id.* at 9, and held the circumstances rare when FDA may constitutionally ban a health claim, providing FDA this unequivocal standard for future claim review, a standard FDA has never recited, let alone applied, in any health claim review since:

Specifically, *Pearson I* identified two situations in which a complete ban would be reasonable. First, when the FDA has determined that no evidence supports a health claim, it may ban the claim completely. Second, when the FDA determines that evidence in support of the claim is qualitatively weaker than evidence against the claim—for example, where the claim rests on *only one or two old studies*, it may impose an outright ban. Even in these two situations, a complete ban would only be appropriate when the government could demonstrate with empirical evidence that disclaimers similar to the ones [the Court] suggested above [“The evidence in support of this claim is inconclusive” or “The FDA does not approve this claim”] would bewilder consumers and fail to correct for deceptiveness.

Id. at 10 (quoting *Pearson I*, 164 F.3d at 659-60) (emphasis original; internal citations omitted).

The Court found some credible evidence supportive and some not supportive but none directly against the claim, concluding that “the rare circumstances identified in *Pearson I* authorizing the complete ban on a claims inherent misleadingness [were] not present.” *Id.* at 14. The Court then documented the fact that FDA’s refusal to abandon censorship was a repeat occurrence, writing, “Once again in its 2001 decision, the FDA has failed to recognized that its decision to suppress the plaintiff’s [claim] does not comport with the First Amendment’s clear preference for

disclosure over suppression of commercial speech.” *Id.* at 15. The Court then granted the relief sought and ordered the FDA to draft “one or more *short, succinct, and accurate* alternative disclaimers, which can be chosen by the Plaintiffs to accompany their [claim].” *Id.* at 17 (emphasis added).

22. Following the *Whitaker I* decision, on February 21, 2003, the FDA exercised its “enforcement discretion” to permit two qualified health claims regarding the relationship between antioxidant Vitamins C and E and the reduced risk of cancer, and Vitamin C and E’s anti-carcinogenic effects. *See* FDA Docket No. FDA-2002-P-0457; *see also* Letter Regarding Dietary Supplement Health Claim for Antioxidant Vitamins and Risk of Certain Cancers, FDA Docket No. 91N-0101 (Apr. 1, 2003), *available at*, <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072789.htm> (last visited Aug. 13, 2009). The FDA found credible evidence supporting the relationships and allowed use of these three claims:

- a. 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.
- b. Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA does not endorse this claim because this evidence is limited and not conclusive.
- c. FDA has determined that although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive.

23. On April 16, 2003, the FDA filed a Consent Motion to Dismiss with this Court in *Whitaker I* requesting that the Court “dismiss [FDA’s appeal] following the Food and Drug Administration’s agreement to allow Plaintiffs’ use of their antioxidant vitamin/cancer risk reduction claim with anyone of [the] three

disclaimers.” *See Whitaker I*, Joint Motion for Dismissal, No. 01-1539(GK) (D.D.C. Apr. 16, 2003).

24. Thus, one decade after Plaintiffs first sought approval of the antioxidant health claims, FDA finally withdrew its suppressive policy and permitted the antioxidant qualified health claims to enter the market but did so for less than four years.

25. From April 2003 through December 2007, FDA allowed the Plaintiffs’ antioxidant vitamins C and E health claims. Then, on December 21, 2007, the FDA published a notice *sua sponte* in the Federal Register stating FDA’s intention to reevaluate the scientific data available for the three previously approved health claims (and of two additional health claims not in issue here). *See* 72 Fed. Reg. 72738. On February 19, 2008, Plaintiffs Pearson, Shaw, and the CEC filed comments in opposition to FDA’s proposed re-evaluation. In its 2007 Notice, true to form FDA declared that “new scientific evidence may have the effect of weakening the substance-disease relationship for [the antioxidant vitamin] health claims.” *Id.* at 72738.

26. On April 9, 2008, Plaintiffs submitted a new qualified health claim petition pursuant to 21 U.S.C. § 343(r)(3)(B)(i) seeking FDA approval of ten Vitamin C qualified health claims and 7 Vitamin E qualified health claims involving the relationship between Vitamins C and E and the reduction in the risk for cancer. *See* FDA Docket No. FDA-2008-Q-0299-0001 (hereinafter “Petition”). In support of their new 2008 petition, Plaintiffs submitted over 200 scientific publications demonstrating a nutrient-disease relationship between vitamins C and E and site-specific cancers. *Id.* In total, FDA had before it nearly 300 studies concerning vitamins C and E and site-specific cancer risk-reduction. Plaintiffs concluded that

17 site-specific cancer qualified health claims were supported by credible evidence. *Id.* at 22-

23. Among the 17 petitioned claims, Plaintiffs' petition included the following 6 claims

(including qualifications) at issue in this case:

- I. Vitamin C may reduce the risk of lung cancer. The scientific evidence supporting this claim is convincing, but not conclusive (hereinafter "Claim I");
- II. Vitamin C may reduce the risk of colon cancer. The scientific evidence supporting this claim is persuasive, but not conclusive (hereinafter "Claim II);
- III. Vitamin C may reduce the risk of gastric cancer. The scientific evidence supporting this claim is persuasive, but not conclusive (hereinafter "Claim III);
- IV. Vitamin E may reduce the risk of bladder cancer. The scientific evidence for this claim is convincing, but not conclusive (hereinafter "Claim IV");
- V. Vitamin E may reduce the risk of gastric cancer. The scientific evidence for this claim is persuasive, but not conclusive (hereinafter "Claim V");
- VI. Vitamin E may reduce the risk of lung cancer. The scientific evidence for this claim is convincing, but not conclusive (hereinafter "Claim VI").

27. In January of 2009, the FDA revised its Guidance document for industry concerning "Evidence-Based Review System for the Scientific Evaluation of Health Claims." *See* Guidance for Industry (Jan. 2009).¹ According to FDA, the guidance document represented "the agency's current thinking on (1) the process for evaluating the scientific evidence for a health claim, (2) the meaning of the significant scientific agreement standard in section 403(r)(3) of the [FDCA], and (3) credible scientific evidence to support a qualified

¹ Available at, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm> (last visited August 13, 2009).

health claim.” *Id.* at 2. The FDA mischaracterized its burden under *Pearson I* and, in fact, never mentioned *Whitaker I*. *Id.* at 3-4. Indeed, the FDA guidance reaffirmed FDA’s incorrect conclusion that review of evidentiary material is identical regardless of whether health claims or qualified health claims are sought. *See id.* at 4 (“it became apparent to the agency that the components of the scientific review process for an SSA health claim and qualified health claim are very similar. Because of the similarity between scientific reviews for SSA and qualified health claims, FDA intends to use the approach set out in this guidance for evaluating the scientific evidence in petitions that are submitted for an SSA health claim or qualified health claim”). FDA’s approach under the still undefined SSA standard, however, involves the systematic downgrading or elimination of science that comes in the form of animal studies, in vitro studies, or clinical trials that are not prospective, randomized, large scale, double blind placebo controlled clinical trials deemed subjectively to be free of methodological deficiencies of one kind or another (a review alien to the scientific community at large that finds precious few studies to be persuasive and none to be conclusive). The review does not consider the totality of the scientific evidence, thus violating *Pearson I* and its progeny.

28. On June 19, 2009, the FDA issued its Order completely banning the use of the previously approved claims and severely restricting claims III and IV through the demand that unreasonably negative value-laden qualifications based on a fraction of the totality of the scientific evidence that accompany them. *See Order* at 38-41.

29. In its Order, FDA banned outright all but four of the Plaintiffs’ seventeen requested qualified health claims. *See Order* at 39-41. Thus, not only did FDA fail to allow the scientifically supported qualified health claims concerning antioxidant Vitamins C and E, FDA reversed its prior allowance for qualified health claims concerning cancer risk-reduction

and antioxidant Vitamins C and E. *See id.* at 39-41; *see also* FDA Letter Concerning Antioxidant Qualified Health Claims, Docket No. 91N-0101, *supra*.

30. Concerning the four claims FDA allowed, each was changed fundamentally from the form submitted and was saddled with negative value-laden, and misleading, qualifications violating the applicable constitutional mandates from this Court and the Court of Appeals for the D.C. Circuit.

- a. The petitioned Vitamin C and gastric cancer claim (Claim III) was:

Vitamin C may reduce the risk of gastric cancer. The scientific evidence supporting this claim is persuasive, but not conclusive.

The Vitamin C gastric cancer claim with FDA qualifications that FDA will permit reads:

One weak study and one study with inconsistent results suggest that vitamin C supplements may reduce the risk of gastric cancer. Based on these studies, FDA concludes that it is highly uncertain that vitamin C supplements reduce the risk of gastric cancer.

- b. The petitioned Vitamin E and bladder cancer claim (Claim IV) was:

Vitamin E may reduce the risk of bladder cancer. The scientific evidence supporting this claim is convincing, but not conclusive.

The Vitamin E bladder cancer claim with FDA qualifications that FDA will permit reads:

One small study suggests that Vitamin E supplements may reduce the risk of bladder cancer. However, two small studies showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of bladder cancer.

See Order at 39.

31. In their petition, Plaintiffs submitted to FDA more than 200 peer-reviewed scientific publications supporting the risk-reduction relationship between antioxidant Vitamins C and E and the site-specific cancers. *See generally*, FDA Docket No. FDA-2008-Q-0299. Of

those publications, the Plaintiffs presented 17 human intervention studies and 134 observational studies. *See* Order at 12. Plaintiffs incorporated an additional 74 studies from past FDA dockets, which included 10 cell culture studies and 16 animal studies. *See* Pryor Report, FDA Docket No. 2008-Q-0299-0005 (citing scientific studies available under FDA Docket No. 91N-0101). FDA ignored the science cited from previous dockets. *See generally* FDA Docket No. 91N-0101. FDA identified an additional 17 human intervention studies and 21 observational studies. *See* Order at 12. The FDA dismissed outright all but a very small number of studies as irrelevant, unreliable, unsupported, or inapplicable. *See* Order at 12-31. In its final analysis the FDA gave credence to just 13 publications out of nearly 300 submitted. *See id.* at 12, 13, 24 (discussing the use of only 2 intervention studies out of 34 and only 11 observational studies out of 155). The FDA did not submit its decision to any form of external scientific peer-review.

32. FDA's downgrading or elimination of the science before it violates the constitutional requirement in *Pearson I* and *Whitaker I* that it review the totality of the scientific evidence. For example, the FDA chose to eliminate 14 randomized, placebo-controlled, double-blind intervention studies on the basis that the studies "did not screen" for existing cancers at the beginning of the trials. *See* Order at 14-17. On that basis FDA determined that "scientific conclusions could not be drawn" from the intervention studies. *Id.* According to FDA, without pre-study screening for existing cancers the studies "may have involved subjects who had these site-specific cancers and, therefore the results with respect to these cancers may be biased." *Id.* at 15. The failure to screen test subjects in an intervention trial, however, does not render the scientific data worthless, as FDA concludes. It is very difficult to test for the existence of small nonpalpable cancers. In fact, no specific tests exist

for most types of cancer and in cancers where tests do exist, they are usually expensive and often painful. The usual way scientists cope is to exclude cases in which cancer develops in the first two years or so of a human intervention trial. For example, the Plaintiffs' submitted one paper wherein the researchers stated that "[t]o avoid bias from the influence of preclinical cancer on baseline serum levels or dietary intake, we did separate analyses that excluded case patients diagnosed early during follow-up ..." Woodson, *et al.*, "Serum alpha-tocopherol and subsequent risk of lung cancer among male smokers," *The Journal of the National Cancer Institute* 91:1738-43 (1999). Moreover, FDA entirely ignores the significance of randomization in clinical trials. Randomization of subjects to receive either active treatment or placebo is intended, *inter alia*, to reduce the likelihood of any significant disparity of pre-existing conditions between those receiving treatment and those receiving placebo. Randomization produces groupings that are equally representative of the study population whereby pre-existing conditions would be expected to occur in equal frequency within the control and test groups. FDA thus violated the courts command in *Pearson I* and *Whitaker I* by dismissing outright all intervention trials that did not screen for existing cancers. The FDA statement that no scientific conclusions can be drawn from such studies is false and misleading. It is important to note that independent peer reviewers considered these studies to be reasonable and justified by the evidence when each study was published in a peer-reviewed journal. Because the trials still produced meaningful results, FDA was obligated to consider the merits of each study without resorting to a short-cut approach of categorical elimination. FDA did not consider the totality of the scientific evidence and thus violated the First Amendment.

33. Similarly, FDA chose to eliminate 6 animal and in vitro studies (and never considered an additional 20 such studies) on the basis that “[a]nimal and in vitro studies ... cannot adequately support a relationship between the substance and the disease.” Order at 5. In vitro and animal studies provide important information on mechanisms that help explain observed effects of a substance on a disease in humans. Animal and in vitro studies contribute to an understanding of the mechanisms that help explain observed effects of a substance on a disease in humans. By entirely excluding such science, FDA failed to evaluate the totality of the evidence.

34. FDA refused to consider 10 intervention studies because they “measured endpoints other than validated surrogate endpoints of cancer risk for certain site-specific cancers...” Order at 18. In other words, FDA eliminated ten studies because they evaluated the end result rather than symptoms associated with that end result. In its Order, FDA provides no explanation for why clinical trials measuring endpoints, as opposed to surrogate endpoints, would lack credibility. *Id.* Indeed, that position is at odds with FDA’s own review standards. In its Guidance document, FDA states that “[w]hile surrogate endpoints of disease risk have been validated, they are not as accurate as measuring the actual onset of a disease.” FDA Guidance, *supra*, at 18.

35. The FDA refused to consider 48 studies that measured serum or plasma concentration as a biomarker of vitamin C or vitamin E intake because “serum or plasma C or E are not reliable biomarkers of vitamin C or vitamin E intake.” Order at 26. Regardless of the relationship between intake and blood levels, however, scientific conclusions can be reached about an effect of vitamin E or C on a disease and particular blood level of E or C. Relating the blood level to a specific intake would certainly require additional information

about each individual to identify factors affecting vitamin intake and blood levels, but it is not true, as FDA concludes, that no scientific conclusions can be reached from the studies that show a relationship between blood levels of vitamins E or C and a disease. Without examining the particular studies, therefore, FDA cannot determine whether each study provides significant support for a nutrient-disease relationship. FDA has thus failed to review the totality of the evidence.

36. FDA refused to consider 5 intervention studies because they involved foreign subjects and 1 intervention study because it involved subjects with a genetic predisposition to the disease. Order at 15-18. According to FDA, because qualified health claims are applicable to United States consumers, scientific evidence in support of a nutrient-disease relationship must demonstrate the nutrient's effect on U.S. citizens, not non-citizens (an absurd and irrational distinction bearing no relationship to sound science). *See* Order at 17. The elimination of credible scientific data on the basis of place of birth lacks a credible scientific foundation. Similarly, studies that examine a nutrient's risk-reduction properties within a population predisposed to a disease are not worthless, as FDA concludes, simply because the general U.S. population may not have that predisposition. Studies that show a nutrient is effective in reducing risk of disease within populations predisposed to the disease could event be more persuasive if the nutrient reduced disease risk when the disease was more likely to have occurred. FDA did not assess the gravity of the scientific evidence or whether the biological mechanisms could be extrapolated to the general U.S. population. Rather, the FDA eliminated studies selectively in a biased effort to reach a pre-determined conclusion. FDA's decision is principally the product of politics not of science.

37. Having eliminated all but 13 of the nearly 300 studies, the agency then acted as if the dismissed studies never existed when it reviewed the remaining evidence. Thus, FDA did not review the totality of the evidence but, rather, ignored significant data and reviewed only an unrepresentative sample. In *Pearson I* and its progeny, the courts commanded FDA to review all evidence in support of a claim and prohibit health claims *in toto* only in extremely rare circumstances. See *Whitaker I*, 248 F.Supp. 2d at 10.

38. The record scientific evidence supports the Plaintiffs' antioxidant vitamins C and E qualified health claims. Vitamins C and E are essential vitamins in human and animal nutrition. See Petition at 4, FDA Docket No. 2008-Q-0299-0001 (hereinafter "Petition"). Vitamin C, as ascorbic acid, is a water-soluble vitamin that is necessary to form collagen, heal wounds, and repair and maintain cartilage, bones, and teeth. *Id.* All fruits and vegetables contain Vitamin C. *Id.* Green peppers, citrus fruits, and leafy greens tend to be highest in Vitamin C. *Id.* Vitamin E is a fat-soluble vitamin that assists with immune function, DNA repair, and various metabolic processes. *Id.* Vitamin E exists in eight different forms and is contained in vegetable oils, nuts, green leafy vegetables, and fortified cereals. *Id.*

39. No evidence suggests vitamins C or E produce unsafe effects either in food or supplement form. Tocopherals and α -tocopherol acetate are generally recognized as safe when used in accordance with good manufacturing practices. *Id.* at 10. Vitamin E is generally recognized as safe with no-predetermined daily intake limitation. *Id.* In addition, vitamin C as ascorbic acid is generally recognized as safe when used in accordance with good manufacturing practices. *Id.* The maximum (safe) daily intake of vitamin E and C is generally limited to the amount reasonably required to accomplish an intended nutritive effect. *Id.*; see also 21 CFR 172.5. Therefore, vitamins C and E are generally recognized as safe at any daily

intake level justified for a particular nutritive effect. The safe upper limit for vitamin E has not been established but has generally been set at above 1000 IU/day in adults. *See* Petition at 10. The tolerable upper intake level for vitamin C in adults is 2,000 mg per day. *Id.*

40. Cancer is the second leading cause of death in the United States. *See id.* at 6. Cancer is a constellation of diseases characterized by proliferation of abnormal mutated cells. *Id.* Cancer is caused by both external and internal factors. *Id.* A common route to the development of cancer involves free radical pathology which damages cell membranes and DNA. That damage, in turn, causes dysfunctional cells that may become cancer cells and proliferate. *See* FDA Docket No. 2008-Q-0299-0005, at 1 (hereinafter “Pryor Report”). Accordingly, risk reduction for various cancers can be addressed through a common anticarcinogenic mechanism. *Id.*

41. The scientific record demonstrates that antioxidant vitamins C and E possess general cancer risk-reducing effects. Cell culture studies have shown that antioxidants protect against certain cell transformations leading to cancer. *See* Pryor Report at 1. Antioxidants either protect cells from chemically induced transformation or reverse the transforming effects of oxidative stress. *See id.* (citing, *inter alia*, Kuroda, *et al.* (1986) and Block and Schwarz (1994)). Moreover, a number of animal studies have shown that antioxidants protect against numerous carcinogens in several organs. *See id.* (citing, *inter alia*, Block (1991)).

42. The published scientific evidence indicates that the relationship between antioxidant vitamins and cancer risk-reduction has grown over the last several decades. *See, e.g.,* Dr. Michael Glade, *Antioxidant Vitamins Reduce the Risk of Cancer*, FDA Docket No. 2008-Q-0299-0004, at 1 (hereinafter “Glade Report”). A 24-year prospective study demonstrated that the risk of death from cancer was reduced significantly by greater intakes of

vitamin C. *See* Glade Report at 1 (citing Pandey, *et al.* (1995)). Another 17-year prospective study showed that the protective effect of Vitamin C was more pronounced among smokers. *Id.* (citing Eichholzer (1999)). The results of observing a cohort of 11,580 initially cancer-free residents of a retirement community for 8 years indicated that the risk of developing cancer in women was inversely correlated with the daily consumption of vitamin C. *Id.* (citing Shibata (1992)). Moreover, there exists no evidence that increased consumption of vitamin C increases cancer risk. *See id.* at 2.

43. The results of a longitudinal study of 21,172 men aged 15-99 years throughout six geographic regions in Finland indicated that high serum alpha-tocopherol concentration was associated with a reduced risk of cancer. *See id.* at 16-17 (citing Knekt (1988)). The alpha-Tocopherol, Beta-Carotene Cancer Prevention study in Finland demonstrated the risks for death from cancer were inversely correlated with pre-study serum alpha-tocopherol concentrations. *Id.* (citing, *inter alia*, Wright (2006)).

44. Credible scientific evidence demonstrates a correlation between vitamins C and E and risk-reduction for site-specific cancers. Studies demonstrate that vitamin C reduces the risk of lung cancer. *Id.* at 10-13. When a team of analysts re-analyzed the data from eight previously published prospective clinical studies that were conducted in North America and Europe, pooling the data obtained from 430,281 men and women, each of whom had been observed for between 6 and 16 years, they determined that the multivariate-adjusted risk of anyone developing lung cancer was reduced significantly by routine long-term consumption for the largest amounts of vitamin C from foods. *Id.* at 11 (citing Cho, *et al.* (2006)). Moreover, the results of prospective observational studies support the conclusion that increased consumption of vitamin C reduces the risk for lung cancer. *Id.* (citing, *inter alia*, Eichholzer, *et*

al. (1996), Eichholzer, *et al.* (1999), Feskanich, *et al.* (2000), Voorrips, *et al.* (2000)). For example, the results of combining the data obtained from 77,283 female participants in the prospective observational Health Professionals Follow-up Study indicated that increasing the consumption of foods high in vitamin C contents may reduce the risk of developing lung cancer in women. *Id.* (citing Feskanich, *et al.* (2000)). In a 17-year prospective study of 2,974 men in Basel, Switzerland, the combination of serum vitamin C concentration and serum vitamin E concentration significantly increased the risk of developing lung cancer, compared with higher serum vitamin C and E concentrations. *See id.* at 12 (citing Eichholzer, *et al.* (1999)).

45. Credible scientific evidence demonstrates that vitamin C has a risk-reducing effect on colon cancer. In a prospective study that compared patients with adenomatous colonic polyps to subjects without polyps, one month of dietary supplementation with vitamin C produced a significantly greater decrease in cell proliferation within crypts of macroscopically normal-appearing colonic mucosa in subjects with polyps than was produced by placebo consumption, while there was no change in subjects without polyps, suggesting that vitamin C does not interfere with normal cell cycling but does slow abnormally accelerated proliferation in the colon epithelium. *See id.* at 2 (citing Cahill, *et al.* (1993)). In the case-control North Carolina Colon Cancer Study, a group of men and women with “high” vitamin C intakes experienced half the risk for colon cancer than was experienced by another otherwise similar group of men and women with “low” vitamin C intakes. *Id.* at 3 (citing Satia-Abouta, *et al.* (2003)). Similarly, in a case-control study conducted in the Seattle, Washington area, the age and sex-adjusted odds of developing colon cancer were reduced significantly in men and women who supplemented their diets with vitamin C. *Id.* (citing White, *et al.* (1997)). In a

case-control study conducted in Shanghai, China, the odds of men developing colon cancer also were reduced significantly by greater daily intake of vitamin C. *Id.* (citing Chiu, *et al.* (2003)). In a case-control study conducted in Denmark, the odds of adenomatous polyp recurrence were inversely correlated with daily intakes of vitamin C. *Id.* (citing Olsen, *et al.* (1994)).

46. Credible scientific evidence indicates that increased consumption of vitamin C reduces the risk for gastric cancer. *See id.* at 5. The results of a double-blind, randomized placebo-controlled clinical trial conducted in the Andes Mountains of Columbia in which all subjects exhibited confirmed multifocal nonmetaplastic gastric atrophy or intestinal metaplasia at the beginning of the study demonstrate that compared to the lack of effects of placebo consumption, daily dietary supplementation with 1000 mg of vitamin C for 72 months produced significant lesion regression. *Id.* at 5 (citing Correa, *et al.* (2000)). Among 1,045,923 of the men and women in the 16-year prospective observational American Cancer Society Cancer Prevention Study II of men and women in the U.S., compared to no supplementation, the regular consumption of any amount of supplemental vitamin C was associated with a significantly reduced risk of developing gastric cancer. *See id.* at 6 (citing Jacobs, *et al.* (2002)). In a case-control study conducted in the U.S., compared to men and women with daily vitamin C intakes less than the 25th percentile, men and women with daily vitamin C intakes greater than the 75th percentile exhibited significantly reduced odds of developing gastric cardia adenocarcinoma or noncardia gastric cancer. *Id.* (citing Virtamo, *et al.* (2000)). In a case-control study in New York State, the multivariate-adjusted odds of developing “intestinal” gastric adenocarcinoma or diffuse gastric adenocarcinoma both were inversely correlated with vitamin C intake. *Id.* (citing Harrison, *et al.* (1997)). In a case-

control study in Italy, the multivariate-adjusted odds of developing gastric cancer were reduced significantly by vitamin C intakes greater than the RDA. *Id.* at 7 (citing La Vecchia, *et al.* (1994)).

47. Plaintiffs presented credible scientific evidence showing that vitamin E reduces the risk of bladder cancer. *Id.* at 18-19. The results of a 12-year prospective observational Health Professionals Follow-Up Study of 51,529 initially cancer-free men aged 40 to 75 years indicated that the risk for bladder cancer was reduced significantly among those subjects with “high” daily vitamin E intakes. *Id.* at 18 (citing Michaud, *et al.* (2000)). Moreover, among 991, 522 of the men and women in the 16-year prospective observational American Cancer Society Cancer Prevention Study II of men and women in the U.S., compared to no supplementation, the regular consumption of any amount of supplemental vitamin E for more than 10 years was associated with a significantly reduced risk of dying from bladder cancer. *Id.* (citing Jacobs, *et al.* (2002)). In a case-control study of middle-aged men and women conducted in Washington State, individuals consuming the most vitamin E from dietary supplements experienced significantly less risk for bladder cancer. *Id.* (citing Bruemmer, *et al.* (1996)).

48. Credible scientific evidence supports the disease risk-reduction relationship between vitamin E and gastric cancer. *Id.* at 20-21. In a 6.3-year prospective observational study of 120,852 men and women aged 55 to 69 years, the age and sex-adjusted risk of developing gastric carcinoma was reduced significantly in the combined groups of subjects with “high” daily vitamin C intakes plus “high” daily vitamin E intakes, compared to the risk group of subjects with “low” intakes. *Id.* at 20 (citing You, *et al.* (2000)). In a case-control study conducted in the U.S., compared to men and women with daily vitamin E intakes less

than the 25th percentile, men and women with daily vitamin E intakes greater than the 75th percentile exhibited significantly reduced odds of developing noncardia gastric cancer. *Id.* at 21 (citing Virtamo, *et al.* (2000)). In a case-control study conducted in Mexico City, Mexico, the multivariate odds of developing any form of gastric adenocarcinoma were reduced significantly by greater intakes of vitamin E. *Id.* at 21 (citing Lopez-Carillo, *et al.* (1999)).

49. Credible scientific evidence demonstrates that vitamin E reduces the risk of lung cancer. *See id.* at 22-26. Subjects with pre-study serum α -tocopherol concentrations in the highest quintile experienced significantly less risk of developing lung cancer than the subjects with pre-study serum α -tocopherol concentrations in the lowest quintile. *Id.* at 23 (citing Woodson, *et al.* (1999)). Further support for the conclusion that increased consumption of vitamin E reduces the risk for lung cancer was provided when the data obtained during two multi-year double-blind randomized placebo-controlled clinical trials of men and women aged 55 years and older and with either type 2 diabetes or vascular disease were combined; the risk of developing lung cancer was reduced significantly by daily dietary supplementation with 400 IU of vitamin E. *Id.* (citing Lonn, *et al.* (2005)). The results of a 20-year prospective observation of 4,538 initially cancer-free Finnish men aged 20-69 years indicated that the risk of developing lung cancer was inversely correlated with vitamin E intake. *Id.* at 24 (citing Knekt, *et al.* (1991)). In a case-control study nested within an 18-year prospective observational study in Washington County, MD, the mean serum α -tocopherol concentration was significantly lower in men who developed lung cancer than in men who did not. *Id.* (citing Comstock, *et al.* (1997)); *see also id.* at 24 (citing 9 retrospective observational studies evidencing support for vitamin E and lung cancer risk-reduction relationship).

50. The Plaintiffs cited nearly 300 articles supporting anti-carcinogenic effects linked to antioxidant vitamins C and E. The above summary is a representative, non-exhaustive sampling of the scientific support. *See generally*, FDA Docket No. 2008-Q-0299.

COUNT I

FDA'S BAN OF QUALIFIED HEALTH CLAIMS I, II, III, IV, V, AND VI VIOLATES THE FIRST AMENDMENT TO THE UNITED STATES CONSTITUTION

51. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 50, *supra*.

52. The Plaintiffs' antioxidant Vitamins C and E health claims convey information indispensable to the exercise of informed consumer choice in the market and is protected from government censorship by the First Amendment to the United States Constitution. *See Pearson I*, 164 F.3d at 655; *Whitaker I*, 248 F.Supp. 2d at 8.

53. The FDA Order violates the First Amendment because it fails to recite, let alone apply, the First Amendment standard of the D.C. Circuit in *Pearson I*, 164 F.3d at 655, and of this Court in *Whitaker I*, 248 F.Supp. 2d at 8.

54. The FDA based its suppression of Plaintiffs' protected speech on the same analysis and review overturned by the D.C. Circuit and this Court on four prior occasions (in *Pearson I, II, III*, and *Whitaker I*). *See Order* at 12-41. The FDA Order summarily dismissed credible scientific evidence in support of the claims, failed to weigh the totality of the evidence in support of the claims, and refused to rely upon factual, value-neutral disclaimers as recommended in *Pearson I* and *Whitaker I*. *See Pearson I*, 164 F.3d at 655-59; *see also Whitaker I*, 248 F.Supp. 2d at 14-15.

55. In its order, FDA again fails to accept that the “burden in [First Amendment suppression cases] is on the FDA to prove that suppression of the [claims] ‘was a necessary as opposed to merely *convenient* means of achieving its interests.’” *Whitaker I*, 248 F.Supp. 2d at 14-15 (quoting *Western States*, 122 S.Ct. at 1507) (emphasis original).

56. By court mandate, there are only two rare instances when FDA may completely suppress a claim and neither instance exists here:

First, when the FDA has determined that no evidence supports [a health] claim, it may ban the claim completely ... Second, when the FDA determines that evidence in support of the claim rests on *only one or two old studies*, it may impose an outright ban... Even in these two situations, a complete ban would only be appropriate when the government could demonstrate with empirical evidence that disclaimers similar to the ones [*Pearson I*] suggested above [“The evidence in support of this claim is inconclusive” or “the FDA does not approve this claim”] would bewilder consumers and fail to correct for deceptiveness.

Whitaker I, 248 F.Supp. 2d at 10 (internal citations omitted) (emphasis original).

57. In its Order, FDA provided no empirical data and offered no facts suggesting that consumers would be confused or bewildered by use of the disclaimers presented in the Plaintiffs’ petition. Indeed, FDA entirely ignored the courts’ commands in *Pearson I* and *Whitaker I*. Without mention of this Court’s decision in *Whitaker I*, the FDA concludes that it may ban outright claims without reference to empirical data concerning misleadingness. *See* Order at 38.

HEALTH CLAIMS I, II, AND III

58. The FDA’s censorship of Claims I, II, and III violates the First Amendment and the rulings in *Pearson I* and *Whitaker I* because:

- a. there is credible scientific evidence in support of the ability of antioxidant vitamin C supplementation to reduce the risk of certain cancers in the body, including lung, colon, and gastric cancers, *see supra* paragraphs 41-50;

- b. scientific evidence finding “no effect” is not the same as evidence against the claims and does not outweigh the claims and the over 106 scientific studies supporting them, *see Pearson I*, 164 F.3d at 659; Glade Report at 1; Pryor Report at 1-5; and
- c. the FDA produced no empirical evidence that disclaimers similar to the ones suggested by the D.C. Circuit in *Pearson I* (“the evidence in support of this claim is inconclusive” or “the FDA does not approve this claim”) and this Court in *Whitaker I* “would bewilder consumers and fail to correct for deceptiveness.” *Whitaker I*, 248 F.Supp. 2d at 10 (quoting *Pearson I*, 164 F.3d at 659-60).

HEALTH CLAIMS IV, V, AND VI

59. The FDA’s censorship of claims IV, V, and VI violates the First Amendment and the rulings in *Pearson I* and *Whitaker I* because:

- a. there is credible scientific evidence in support of the ability of antioxidant vitamin E supplementation to reduce the risk of certain cancers in the body, including gastric, lung, and bladder cancers, *see supra* paragraphs 41-50;
- b. scientific evidence finding “no effect” is not the same as evidence against the claims and does not outweigh the claims and the over 100 scientific studies support them, *see Pearson I*, 164 F.3d at 659; Glade Report at 1; Pryor Report at 1-5; and
- c. the FDA produced no empirical evidence that disclaimers similar to the ones suggested by the D.C. Circuit in *Pearson I* (“the evidence in support of this claim is inconclusive” or “the FDA does not approve this claim”) and this Court

in *Whitaker I* “would bewilder consumers and fail to correct for deceptiveness.”

Whitaker I, 248 F.Supp. 2d at 10 (quoting *Pearson I*, 164 F.3d at 659-60).

COUNT II

FDA’S REQUIRED, NEGATIVELY VALUE-LADEN QUALIFICATIONS FOR HEALTH CLAIMS III AND IV VIOLATE THE FIRST AMENDMENT BY PROPOUNDING A FALSE MESSAGE

60. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 60, *supra*.

61. The petitioned claims were:

a. The petitioned Vitamin C and gastric cancer claim (Claim III) was:

Vitamin C may reduce the risk of gastric cancer. The scientific evidence supporting this claim is persuasive, but not conclusive.

The Vitamin C gastric cancer claim with FDA qualifications reads:

One weak study and one study with inconsistent results suggest that vitamin C supplements may reduce the risk of gastric cancer. Based on these studies, FDA concludes that it is highly uncertain that vitamin C supplements reduce the risk of gastric cancer.

b. The petitioned Vitamin E and bladder cancer claim (Claim IV) was:

Vitamin E may reduce the risk of bladder cancer. The scientific evidence supporting this claim is convincing, but not conclusive.

The Vitamin E bladder cancer claim with FDA qualifications reads:

One small study suggests that Vitamin E supplements may reduce the risk of bladder cancer. However, two small studies showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of bladder cancer.

See Order at 39.

62. The FDA's qualifications for those claims violate the constitutional mandates from this Court and the D.C. Circuit wherein the courts directed the FDA to "draft and submit one or more such appropriate *short, succinct, and accurate* disclaimers." *Whitaker I*, 248 F.Supp. 2d at 10 (emphasis added); *see also Pearson I*, 164 F.3d at 659 (providing examples of disclaimers: "The evidence in support of this claim is inconclusive" or "The FDA does not approve this claim").

63. The FDA qualifications for those claims violate Plaintiffs' First Amendment rights by censoring claims III and IV with the imposition of qualifications that propound false, negatively value-laden, and inaccurate claims to the public. *See Order at 39.* FDA's disclaimers mislead consumers because they inaccurately represent the publicly available scientific evidence and force Plaintiffs' to adopt FDA's inaccurate and negatively value-laden description of the science as Plaintiffs' own or not communicate about the nutrient-disease risk reduction. In addition, the disclaimers are unreasonably long and burdensome for Plaintiffs and other industry members to include on their dietary supplement labels and in their labeling. The disclaimers thus violate *Central Hudson's* requirement that the government's chosen means to accomplish its ends be reasonable and violate binding precedent requiring that disclaimers be "short, succinct, and accurate." *See Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 477 U.S. 557, 564-66 (1980); *Whitaker I*, 248 F.Supp.2d at 10; *Pearson I*, 164 F.3d at 659.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court,

(1) **Declare** in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act) that the FDA's June 19, 2009 Order (Docket No. FDA-2008-Q-0299) denying Plaintiffs' petition for qualified health claims is invalid; in particular, they request that this Court declare:

- a. that the FDA's June 19, 2009 Order (Docket No. FDA-2008-Q-0299) violates the First Amendment to the United States Constitution;
- b. that the FDA's June 19, 2009 Order (Docket No. FDA-2008-Q-0299) violates *Pearson I*, *Pearson II*, *Pearson III*, and *Whitaker I*; and
- c. that the FDA's proposed misleading qualifications for Plaintiffs' claim concerning antioxidant Vitamins C reducing the risk of lung, colon, and gastric cancers and vitamin E reducing the risk of bladder, gastric, and lung cancers violates the First Amendment by imposing unreasonable restrictions on Plaintiffs' truthful and nonmisleading speech;

(2) **Order** FDA to refrain from taking any action that would preclude the Plaintiffs from placing the following health claims on the labels and in the labeling of their dietary supplements with doses of less than 2,000 mg of Vitamin C and less than 1,000 mg of Vitamin E per day:

Vitamin C may reduce the risk of lung cancer. The scientific evidence supporting this claim is convincing, but not conclusive.

Vitamin C may reduce the risk of colon cancer. The scientific evidence supporting this claim is persuasive, but not conclusive.

Vitamin C may reduce the risk of gastric cancer. The scientific evidence supporting this claim is persuasive, but not conclusive.

Vitamin E may reduce the risk of bladder cancer. The scientific evidence for this claim is convincing, but not conclusive.

Vitamin E may reduce the risk of gastric cancer. The scientific evidence for this claim is persuasive, but not conclusive

Vitamin E may reduce the risk of lung cancer. The scientific evidence for this claim is convincing, but not conclusive.

(3) **Enjoin** through a permanent injunction FDA from taking any action that would preclude the Plaintiffs from placing the following health claims on the labels and in the labeling of their dietary supplements with suggested doses of less than 2,000 mg of Vitamin C and less than 1,000 mg of Vitamin E per day:

Vitamin C may reduce the risk of lung cancer. The scientific evidence supporting this claim is convincing, but not conclusive.

Vitamin C may reduce the risk of colon cancer. The scientific evidence supporting this claim is persuasive, but not conclusive.

Vitamin C may reduce the risk of gastric cancer. The scientific evidence supporting this claim is persuasive, but not conclusive.

Vitamin E may reduce the risk of bladder cancer. The scientific evidence for this claim is convincing, but not conclusive.

Vitamin E may reduce the risk of gastric cancer. The scientific evidence for this claim is persuasive, but not conclusive

Vitamin E may reduce the risk of lung cancer. The scientific evidence for this claim is convincing, but not conclusive.

- (4) Retain jurisdiction of this action to ensure compliance with this Court's decree; and
- (5) Grant such other and further relief as the Court deems just and proper.

TRIAL BY THE COURT WITHOUT A JURY

Pursuant to 28 U.S.C. § 2402, this action shall be tried by the court without a jury.

Respectfully submitted,

ALLIANCE FOR NATURAL HEALTH US;
DURK PEARSON and SANDY SHAW;
COALITION TO END FDA AND FTC CENSORSHIP,

By _____/s/_____

Jonathan W. Emord (D.C. Bar # 407414)

Andrea G. Ferrenz

Peter A. Arhangelsky

Christopher K. Niederhauser

EMORD & ASSOCIATES, P.C.

11808 Wolf Run Lane

Clifton, VA 20124

Tel: (202) 466-6937

Fax: (202) 466-6938

Email: jemord@emord.com

Attorneys for Plaintiffs

DATED: August 14, 2009