UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALLIANCE FOR NATURAL HEALTH US,
1350 Connecticut Avenue, N.W.,
5th Floor
Washington, D.C. 200036;

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

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

Plaintiffs,

v. **Case No. _____**

KATHLEEN SEBELIUS, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
Sixth Floor,
200 Independence Avenue, S.W.,
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., COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION,
5600 Fishers Lane, Room 1471,
Rockville, MD 20857;

FOOD AND DRUG ADMINISTRATION,
5600 Fishers Lane,
Rockville, MD 20857;

	)
and the UNITED STATES OF AMERICA,	)
	)
Defendants.	)

COMPLAINT
SEEKING REVIEW OF ADMINISTRATIVE AGENCY ACTION,
DECLARATORY JUDGMENT,
AND
INJUNCTIVE RELIEF

1. Plaintiffs Alliance for Natural Health US ("ANH"); Durk Pearson and Sandy Shaw ("Pearson and Shaw"); and the Coalition to End FDA and FTC Censorship ("CEC"), hereby submit this complaint against Defendants Kathleen Sebelius, Secretary, United States Department of Health and Human Services (in her official capacity only); the United States Department of Health and Human Services; Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, Food and Drug Administration (in her official capacity only); the Food and Drug Administration ("FDA"); and the United States of America. The Plaintiffs seek declaratory and injunctive relief against a June 19, 2009 Food and Drug Administration final order, FDA Docket No. FDA-2008-Q-0323-0015[1] (hereinafter "Order"), that violates the Plaintiffs' First Amendment free speech 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), *appeal dismissed*, 2003 U.S. App. LEXIS 18288 (D.C. Cir. 2003) (*Whitaker I*).

[1] Available at, http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-Q-0323, (last visited, July 29, 2009).

INTRODUCTION

2. This complaint arises from FDA's suppression of five qualified health claims for selenium-containing dietary supplements. In its Order, the FDA violated Plaintiff's First Amendment rights by banning outright four of Plaintiff's requested qualified health claims associating selenium with reduction in the risk of certain cancers, with anticarcinogenic effects, and with reduction in the risk of certain site specific cancers, and severely restricting a fifth claim of site specific cancer risk reduction with an inaccurate and negatively value laden disclaimer. *See* Order at 7, 32-34, and 37.

3. Each of the five requested selenium health claims at issue in this complaint is supported by credible scientific evidence, is not contradicted by scientific evidence against them, and is not inherently misleading. In its Order, FDA effectively demanded near conclusive scientific proof as a condition precedent for allowing any of the requested claims to be communicated to consumers. That action directly violates the First Amendment mandates from this Court in *Whitaker I* and the Court of Appeals in *Pearson I*. By censoring the claims in issue, FDA has denied consumers accurate representations of nutrition science on the role of selenium in cancer risk reduction. Instead, it has created a rigid construct that categorically rejects review of peer-reviewed science that the scientific community considers persuasive, including animal studies, in vitro studies, and clinical trials (if the trials involve treatment of diseased populations or are deemed by FDA as methodologically deficient for one unreasonably weighted reason or another). FDA thus does not in fact review the totality of scientific evidence but only a small fraction of it, thus either denying claims or saddling them with misleadingly negative disclaimers.

4. Plaintiffs ask this Court to declare FDA's censorship of the selenium health claims invalid under the First Amendment to the United States Constitution and a direct violation of the applicable court mandates in *Pearson I* and *Whitaker I* that FDA has consistently refused to recite, let alone apply, in its health claims decisions. The Plaintiffs further ask this Court to enjoin FDA from taking any action that would prevent Pearson and Shaw's licensees, the ANH corporate members, and the CEC corporate members from placing the selenium health claims on the labels and in labeling of their dietary supplement products that contain recommended daily doses of 200-300µg of selenium, in the form of selenium-enriched yeast or sodium selenite. Finally, the Plaintiffs ask this Court to hold the FDA mandated qualifications required for use in association with the Plaintiff's fifth selenium claim ("Selenium may reduce the risk of colon and digestive tract cancers. Scientific evidence supporting this claim is convincing but not yet conclusive") unconstitutional because they compel plaintiffs to propound a negatively value-laden and inaccurate message to the public ("Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer"), one that denies the right to communicate the credible scientific evidence and censors Plaintiffs' accurate representation of that evidence.

JURISDICTION VENUE

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 for all causes of action because all causes arise under the laws of the United States.

6. This Court may grant relief in this action under 28 U.S.C. § 2201 (declaratory judgment), 28 U.S.C. § 2202 (relief based on declaratory judgment), and 5 U.S.C. § 706(2)(B) (the APA).

7. This court is the proper venue for this action under 28 U.S.C. § 1391(e).

PARTIES

8. ***Alliance for Natural Health US.*** The American Association for Health Freedom (formerly the American Preventive Medical Association, a plaintiff in *Pearson* I) , doing business as Alliance for Natural Health US ("ANH US"), a Virginia nonprofit corporation, was founded in 2002. 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 consumer, healthcare practitioner, and food, dietary supplement, and drug 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 U.S. 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 nutrient selenium. FDA's reversal of previously approved qualified health claims for selenium reduction in the risk of certain cancers and for selenium and anticarcinogenic effects in the body deprive ANH US and ANH US members of vital nutrient information. The American Cancer Society estimates 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 and anticarcinogenic effects of selenium 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 the loss of truthful selenium nutrient information, the possession of which could benefit their personal health and increase interest in professional products and services containing selenium. The result is also that ANH US professional members who sell selenium-containing dietary supplements suffer the loss of their right to communicate truthful selenium 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 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). Pearson and Shaw were plaintiffs in *Pearson I*, *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.* Pearson and Shaw license, and receive royalties from, dietary supplements containing Selenium. Pearson and Shaw wish to authorize their licensees to place the Selenium Qualified Health Claims on the labels and in the labeling of their selenium-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 five 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 selenium and others of whom consume dietary supplements including those containing selenium, 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 selenium, in treating and preventing disease. The Coalition was among the petitioners that petitioned FDA for allowance of the five selenium claims here in issue.

11. ***Kathleen Sebelius, Secretary, United States Department of Health and Human Services; United States Department of Health and Human Services; Margaret***

A. Hamburg, M.D., Commissioner of Food and Drugs, Food and Drug Administration; 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 FDA. The FDA is that 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.

PROCEDURAL HISTORY

12. On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act ("NLEA"). 21 U.S.C. 301, *et seq*. The Act provided a "safe harbor" for health claims (nutrient-disease relationship claims) for dietary supplements and foods. *See* 21 U.S.C. § 343(r)(5)(D). The Act required FDA to create rules for approval of health claims for dietary supplements. 21 U.S.C. § 343(r)(3)(B)(i). The FDA promulgated 21 C.F.R. § 101.14 (adopting for dietary supplements the Significant Scientific Agreement standard used for approving health claims on food) and 21 C.F.R. § 101.70 (a procedure for evaluating the validity of health claims on dietary supplements, identical to that for foods).

13. FDA's Significant Scientific Agreement standard required near conclusive proof before any claim would be authorized by the agency for use on the label and in the labeling of dietary supplements. In rulemaking comments to the FDA filed in 1993,

Pearson and Shaw, along with other co-petitioners including the American Preventive Medical Association ("APMA") (predecessor to ANH) contended that FDA could not constitutionally suppress any claims that the agency would not approve under 21 U.S.C. § 343(r)(3)(B)(i) (even if those claims failed to satisfy FDA's Significant Scientific Agreement standard) so long as the claims were not inherently misleading. Moreover, Pearson, Shaw, APMA and the other co-petitioners argued if the claims were potentially but not inherently misleading FDA was constitutionally forbidden from censoring them unless it could prove with empirical evidence that no disclaimer was capable of eliminating misleadingness. FDA rejected the petitioners' comments and insisted on censoring all claims not approved by the agency under its Significant Scientific Agreement standard, 21 U.S.C. § 343(r)(3)(B)(i). Pearson, Shaw, APMA and the other co-petitioners sued FDA on First Amendment grounds, among others.

14. In 1999, the D.C. Circuit's three judge panel unanimously struck down FDA's policy of censoring all claims it did not approve under its Significant Scientific Agreement standard, 21 U.S.C. § 343(r)(3)(B)(i). *See Pearson I*, 164 F.3d 650 (D.C. Cir. 1999). 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. After analyzing the FDA's censorship, 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 655-660. The court stated, "[i]t 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. Approximately two years later the FDA had failed to draft an appropriate disclaimer for the claims at issue in *Pearson I* finding them inherently misleading because, FDA argued, the "weight" of the scientific evidence was "against" the proposed claim despite the Court's reasoning to the contrary and ruling in *Pearson I*. *Pearson II*, 130 F. Supp. 2d 105, 115 (D.C. Cir 2001). On November 13, 2000 the original petitioners filed suit again seeking declaratory and injunctive relief from the FDA's contumacious maintenance of the unconstitutional censorship. *See Pearson II*, 130 F. Supp. 2d 105 (D.C. Cir 2001). In *Pearson II,* this Court held in favor of the plaintiffs issuing a preliminary injunction and stating, "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 teaching 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*. In the conclusion of its analysis this Court stated, "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.

15. Instead of accepting the D.C. Circuit and this Court's decisions in *Pearson I and II* and drafting the required disclaimers, the FDA filed a motion for reconsideration and clarification 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 the rare circumstance in which FDA could ban a health claim under *Pearson I*. *See id.* at 112. The Court stated,

> 'the 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 in 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.

Id. 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.

16. Several months after the *Pearson III* decision, on July 17, 2001, Plaintiffs were again forced to seek judicial redress for a decision by FDA to disallow another of the claims the D.C. Circuit found unconstitutionally suppressed in *Pearson I*. *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 claim at issue in *Pearson I*. The *Whitaker I* Court restated the essential principle that the FDA must favor disclosure over suppression. *Id*. at 9. 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 circumstance 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 apply, 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. *Id*., 164 F.3d at 659-660 (emphasis in original). Second, when the FDA determines that 'evidence in support of the claim is qualitatively weaker than evidence against the claim--for example, where the claim rests on *only one or two old studies*,' it may impose an outright ban. Id., 164 F.3d at 659 n.10 (emphasis added). 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 659-660) (emphasis in original). After review of the evidence supporting the claim, the Court found evidence supportive and not supportive of the claim but none directly against, concluding that "the rare circumstances identified in Pearson I authorizing the complete ban on a claim's 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, "[o]nce again in its 2001 decision, the FDA has failed to recognize 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).

17. On February 21 2003, the FDA exercised its "enforcement discretion" for two qualified health claims regarding the relationship between selenium and the reduced risk of cancer and selenium's anticarcinogenic effects. *See* Docket No. FDA-2002-P-0457; *see also* FDA Selenium and Certain Cancers (Qualified Health Claim: final decision letter) available at, http://www.foodsafety.gov/~dms/ds-ltr35.html, (last visited July 13, 2009). The FDA found credible evidence supporting the relationship and allowed use of the following two claims:

a. 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.

b. Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive.

18. On December 21, 2007, the FDA published a notice in the Federal Register stating FDA's intention to reevaluate the scientific data available for those two previously approved health claims (and of three additional health claims not in issue here). *See* 72 FR 72738. On February 19, 2008, Plaintiffs Pearson, Shaw, and CEC filed comments in opposition to FDA's proposed re-evaluation.

19. On April 24, 2008, Plaintiffs submitted a new health claim petition pursuant to 21 U.S.C. § 343(r)(3)(B)(i) seeking FDA approval of ten qualified health claims involving the relationship between selenium and the reduction of risk for cancer, two of which were restatements of the previously allowed selenium claims. *See* Docket No. FDA-2008-Q-0323-0001[2] (hereinafter "Petition"). Plaintiffs' petition included the following five model claims (including qualifications) at issue in this case:

a. Selenium may reduce the risk of certain cancers. Scientific evidence supporting this claim is convincing but not yet conclusive. (Hereinafter "claim I")

b. Selenium may produce anticarcinogenic effects in the body. Scientific evidence supporting this claim is convincing but not yet conclusive. (Hereinafter "claim II")

c. Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive. (Hereinafter "claim III")

d. Selenium may reduce the risk of lung and respiratory tract cancers. Scientific evidence supporting this claim is convincing but not yet conclusive. (Hereinafter "claim IV")

e. Selenium may reduce the risk of colon and digestive tract cancers. Scientific evidence supporting this claim is convincing but not yet conclusive. (Hereinafter "claim V")

20. On June 19, 2009, the FDA issued its Order completely banning the use of the previously approved claims I and II along with claims IV and V and severely restricting claim III through the demand that unreasonably negative value laden qualifications accompany it. *See* Order at 7, 37.

[2] Available at, http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-Q-0323, (last visited, July 29, 2009).

FDA ORDER

21. In its Order, the FDA completely banned Plaintiffs' use of claims I, II, IV and V in violation of Plaintiffs' First Amendment rights. *See* Order at 7, 33. Not only did FDA refuse to allow the scientifically supported qualified health claims for site specific cancers, the FDA reversed its prior allowance for the selenium qualified health claims concerning selenium and reduction of certain cancers and selenium's production of anticarcinogenic effects in the body. *See id*. Since the 2003 allowance of the two selenium qualified health claims, scientific support for the effect of selenium on cancer risk reduction has increased significantly, not decreased. *See* Petition at 12.

22. Although the FDA allowed the use of the site specific prostate cancer claim (claim III) proposed in the Plaintiffs' petition, the FDA saddled the claim with an onerous, value laden, and misleading disclaimer violating the applicable constitutional mandates from this Court and the Court of Appeals for the District of Columbia Circuit. *See* Order at 37.

23. The Petitioned selenium prostate claim reads:

> Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive."

The prostate claim with FDA qualifications inserted reads:

> Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer.

See Order at 37.

24. In addition, the FDA irrationally limited the claim to dietary supplements containing one type of selenium, selenomethionine, *see id.* at 35

25. In its petition, Plaintiffs submitted over 150 peer-reviewed scientific publications supporting the risk reduction relationship between selenium and cancer. *See* generally Docket No. FDA-2008-Q-0323[3]. In addition to the 150 submitted with the petition, the FDA reviewed an additional 77 publications during the year plus long pendency of its assessment for a total of 233 publications in support of the qualified health claims. *See* Order at 12. The FDA dismissed all but a very small number of the studies as irrelevant, unreliable, unsupported, or inapplicable for a myriad of reasons that are not generally accepted by peer-review scientists who rely on the studies in question in their own evaluations of the strength of the evidence. *See* Order at 52-56. As a result of its rigid requirements for excluding, rather than reviewing, science in support of petitions for health claims, in its final analysis the FDA gave credence to only 20 publications out of 233. *See id*. at 13, 26 (discussing the use of only 1 intervention study out of 30 and of only 19 observational studies out of 105). The FDA did not have any independent scientific peer-review of its decision.

26. The FDA chose to exclude all credible scientific evidence in over twenty animal and in vitro studies. *See* Order at 12. Although not conclusive, the studies provide credible scientific evidence that selenium is protective against cancer. In addition, the FDA excluded from its analysis all credible evidence received from both human intervention and observational studies conducted in populations that were said to be malnourished, selenium deficient, or had a high prevalence of hepatitis or H. pylori. *See* Order at 21-23, 52-56. There was, contrary to FDA's representation, no evidence that participants in the

[3] Available at, http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-Q-0323, (last visited, July 29, 2009).

studies were malnourished. *See* Docket No. FDA-2008-Q-0323-0002[4] at 13 (hereinafter "Schrauzer Rep.") (discussing personal communication with the doctor conducting the research).

27. In its Order, the FDA failed even to cite, let alone apply, the standard for First Amendment in *Pearson I* and *Whitaker I*. In sum, the FDA has once again censored health claims without abiding by this Court's order in *Whitaker I* and of the D.C. Circuit's order in *Pearson I*.

SUMMARY OF EVIDENCE SUPPORTING SELENIUM ANTICARCINGENIC EFFECTS

28. Selenium is an essential trace element in human nutrition. *See* Petition at 2 and 5. Selenium is present in many foods consumed in the daily diet, most prevalent in organ meats and seafood; muscle meats; cereals and grains; and dairy products. *See id.*. Selenium is a metalloid element with the atomic number 34 and an atomic weight of 78.96 daltons. *See id*. at 5. Studies show that when consumed at twice the quantity found in a normal diet, selenium has antioxidant and anticarcinogenic effects in the body. *See id*. at 2. Selenium comes in many forms, including selenium-enriched yeast which contains natural forms of L-selenomethionine and L-selenocysteine. High-selenium yeast, selenomethionine, sodium selenate, and sodium selenite are the forms sold and used by Plaintiffs and the most common forms in dietary supplements. *See id*. at 9.

29. Ecological studies demonstrate the safe and most effective selenium dose for cancer risk reduction is 250-300 µg per day; however, according to government data less than 50% of Americans ingest selenium at the recommended 250-300 µg level, i.e., most

[4] Available at, http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-Q-0323, (last visited, July 29, 2009).

Americans fail to ingest an amount sufficient to produce anticarcinogenic effects in the body. *See id*. at 10.

30. Cancer is the second leading cause of death in the United States. *See* Petition at 19. Cancer is a constellation of diseases characterized by proliferation of abnormal mutated cells. *See id*. Cancer is caused by both external and internal factors. *See 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* Docket No. FDA-2008-Q-0323-0003[5] at 3 (hereinafter "Passwater Rep."). As such, risk reduction for various cancers can be addressed through a common anticarcinogenic mechanism. *See id*.

31. Evidence of selenium's anticarcinogenic effects dates back to the 1960s. *See* Passwater Rep. at 11. In a 1969 observational study an inverse relationship between cancer mortality and forage crop selenium was recognized by Shamberger and Frost. *See id.* Since that time there have been numerous studies providing convincing support for the early observations regarding selenium's anticarcinogenic characteristics. *See id*. (citing Combs et al., 1998, Combs et al., 2001, Whagner, et al., 2004, and Ip, et al., 1998).

32. In a 1977 ecological study that compared the blood selenium levels in healthy individuals with cancer mortality (*See* Schrauzer Rep. at 6 (citing Schrauzer et al., 1977)), the results revealed a "statistically highly significant" inverse relationship for total cancer mortalities "as well as for cancers of the colon, rectum, prostate, breast, ovary leukemia, pancreas, bladder, skin, buccal cavity and pharynx." *Id*. The study

[5] Available at, http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-Q-0323, (last visited, July 29, 2009).

concluded that "optimal daily intake of an adult for cancer prevention is in the order of 200-300 micrograms per day." *Id*.

33. In a 1983 five year "nested" case-control study involving 10,000 American men and women, researchers found an increased risk of cancer among those with the lowest quintile of baseline selenium blood serum levels (cancer risk was twice as high as the rate in the highest quintile). *See* Passwater Rep. at 12. (citing Willet et al., 1983).

34. A 1989 case-control study revealed serum selenium levels from 43 persons who developed thyroid cancer (when tested against a control group) demonstrated that low selenium levels were a prediagnostic indicator of thyroid cancer risk. *See* Passwater Rep. at 50 (citing Glattre et al., 1989); Schrauzer Rep. at 12 .

35. Another 1989 observational study examined the association between selenium levels and the development of bladder cancer finding that selenium levels were significantly lower in those who later developed bladder cancer than those who did not. *See* Passwater Rep. at 31 (citing Helzlsouer et al., 1989).

36. In a 1993 cohort study involving 120,852 Dutch men and women aged 55-69, scientists found an inverse association between the level of selenium in the blood and lung cancer. *See* Schrauzer Rep. at 11 (citing Van Den Brandt et al., 1993).

37. In a 1994 exploratory observational study conducted in Japan, scientists found that those with lower levels of serum selenium were at an increased risk of lung cancer. *See* Passwater Rep. at 32 (citing Kabuto et al., 1994).

38. In an extensive 1997 epidemiological study, scientists found an inverse association between selenium serum levels and regional cancer incidence in various regions of China. *See* Schrauzer Rep. at 12-13. An intervention trial involving members

of the general population demonstrated selenium reduced incidence of primary liver cancer by thirty-five percent. *Id*. (citing Yu et al., 1997).

39. In a 1998 peer-reviewed cohort study involving 34, 000 male health professionals, participants with the lowest serum selenium levels were three times more likely to develop prostate cancer as those with the highest serum selenium levels. *See* Passwater Rep. at 11-12 (citing Yoshizawa et al., 1998). The peer-reviewed study was funded by the Public Health Service, the National Cancer Institute, the National Heart, Lung and Blood Institute, and the National Institutes of Health.

40. In another 1998 "nested" case-control study of 9,000 Finns, researchers found a significantly higher risk of lung cancer in participants with low serum selenium levels. *See id*. at 12 (citing Knekt et al., 1998).

41. In a 1999 "nested" case-control study a significant inverse relationship was found between selenium levels in stored plasma and the development of liver cancer in 7,000 Taiwanese men. *See id*. (citing Yu et al., 1999).

42. In a 2001 observational study conducted on residents of four Canadian provinces, scientists found a statistically significant inverse relationship between selenium serum levels and cancers of the colon and lung. *See* Schrauzer Rep. at 13 (citing Morris et al., 2001).

43. In a 2002 case-cohort study, scientists reported an inverse association between toenail selenium levels and bladder cancer risk in a case-cohort analysis from the Netherlands Cohort Study. *See* Passwater Rep. at 31 (citing Zeegers et al., 2002).

44. Since the FDA approval of the selenium qualified health claims in 2003 (Docket No. FDA-2002-P-0457), there have been no scientific publications refuting

studies that previously revealed selenium's anticarcinogenic effects or the inverse association between selenium serum levels and cancer risk at specific sites in the body. *See id*. at 5.

45. Since 2003, new intervention, prospective, and mechanistic studies have been published which provide additional support for the original qualified health claims approved in 2003 and credible evidence for the additional site specific claims proposed in Plaintiffs' 2008 petition. *See id.* at 13, 23-39 (discussing studies).

46. The 2003 Nutrition Prevention of Cancer Trial (NPC), an intervention study, was among those FDA used in approving the selenium qualified health claims. *See id*. at 13-14. At that time the study found that daily supplementation of diets with 200 micrograms of selenium-enriched yeast reduced cancer mortality 50 percent. *See id*. (discussing FDA final decision letter approving 2003 qualified health claims). The NPC trial has been updated since the FDA's review. *See id*. at 13. Overall participants in the NPC trial demonstrated reductions in the incidence of lung cancer by forty-six percent, prostate cancer by sixty-three percent, and colon cancer by fifty-eight percent. *Id*. at 13-14. The cancer protective effects were not apparent for women in the trial; however, that is likely due to the lower percentage of female participants in the trial. *See id*. at 14 (indicating that 75% of the participants were men).

47. In a 2004 French intervention study, scientists found that supplementation of an individual's diet with 100 micrograms of selenium, in addition to several other vitamins and nutrients, reduced the total incidence of cancer in men by thirty-one percent. *See id*. at 16. The reductions in cancer incidence were widespread by type of cancer, including "thyroid, urinary tract, skin, respiratory tract, digestive tract and oral cavity

cancers." *Id*. These results were reached with only half of the amount of selenium supplementation used in the NPC trials. *See id.* at 15.

48. In a 2004 meta analysis, reviewing 16 studies, scientists found a significantly reduced risk of lung cancer with increased intake and serum levels of selenium. *See* id. at 33 (citing Zhuo et al., 2004).

49. In a 2006 case-control study of 178 bladder cancer cases, scientists linked the increase of 10 μg/L in serum selenium concentration with significant reductions in the risk of bladder cancer. *See* Passwater Rep. at 31-32 (citing Kellen et al., 2006); Schrauzer Rep. at 10.

50. On May 5, 2006 the United States Agency for Healthcare Research and Quality (AHRQ) published a report evaluating the evidence in support of the anticarcinogenic effects of selenium. *See* Huang HY, et. al., *Multivitamin/Mineral Supplements and prevention of Chronic Disease*, Evidence Report/Technology assessment No. 139 at 46, Agency for Healthcare Research and Quality. May 2006, also available at, http://www.ahrq.gov/downloads/pub/evidence/pdf/multivit/multivit.pdf, (last visited, July 14, 2009) (hereinafter "AHRQ Rep.").

51. The purpose of the AHRQ report was to review and synthesize published literature on the efficacy of multivitamin/mineral supplements and certain single nutrient supplements in the primary prevention of chronic disease in the general adult population, and on the safety of multivitamin/mineral supplements and certain single nutrient supplements, likely to be included in multivitamin/mineral supplements, in the general population of adults and children. *See* Passwater Rep. at 17.

52. After review of the available publications, the AHRQ scientists concluded: "Taking into consideration the quantity, quality, and consistency of evidence on the efficacy of selenium in preventing chronic disease, . . . the overall strength of evidence is 'moderate.'" *See* AHRQ Rep. at 46.

53. In a 2007 in-vitro study, biopsy-derived glioma cells were treated with selenium. The study scientists concluded "that selenium not only induces tumor cell-specific apoptosis but also has anti-invasive potential." *See* Passwater Rep. at 50-51 (citing Rooprai et al., 2007).

54. In another 2007 observational study, scientists reported that dietary selenium intake was inversely related with risk of lung cancer in men. *See id*. at 33 (citing Mahabir et al., 2007).

55. Over 100 additional publications supportive of the petitioned claims were also submitted to the FDA. *See* generally Docket No. FDA-2008-Q-0323.[6]

CLAIMS FOR RELIEF

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

Plaintiffs reallege and restate paragraphs 1 through 55 and incorporate them herein.

56. The Plaintiffs' selenium health claims are commercial speech that conveys scientific information vital to those who seek to reduce their risks of certain kinds of cancers through dietary means and is protected from government censorship by the First Amendment to the United States Constitution. *See Pearson I*, 164 F.3d at 655; *WhitakerI,* 248 F. Supp. 2d at 8.

[6] Available at, http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-Q-0323, (last visited, July 29, 2009).

57. 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.

58. 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. 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 analyze appropriate value-neutral disclaimers as recommended in *Pearson I* and *Whitaker I*. *See Pearson I,* 164 F.3d at 655-659; *see also Whitaker I,* 248 F. Supp. 2d at 14-15.

59. 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 14-5 (quoting *Western States*, 122 S. Ct. at 1507) (emphasis in original).

60. 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 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 [*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 in original).

HEALTH CLAIMS I AND II

61. The FDA's censorship of claims I and II violates the First Amendment and the rulings in *Pearson I* and *Whitaker I* because:

a. there is credible scientific evidence in support of selenium's anticarcinogenic effects in the body and of its effect of reducing the risk of certain cancers in the body, *see supra* paragraphs 28-55;

b. there is no specific evidence against the claims and over 150 studies in support of them; 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*, at 10 (quoting Pearson I, 164 F.3d at 659-660).

HEALTH CLAIM IV

62. The FDA's censorship of claim IV 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 selenium supplementation to reduce the risk of bladder and urinary tract cancers, *see supra* paragraphs 32, 35, 43, 47 and 49;

b. there is no specific evidence against the claim and at least 5 recent studies in support of it; 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*, at 10 (quoting Pearson I, 164 F.3d at 659-660).

HEALTH CLAIM V

63. The FDA's censorship of claim V 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 selenium supplementation to reduce the risk of lung and respiratory tract cancers., *see supra* paragraphs 36, 37, 40, 42, 46, 47, 48, and 54;

b. there is no specific evidence against the claim and at least 25 recent studies in support of the claim; 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*, at 10 (quoting Pearson I, 164 F.3d at 659-660).

<u>CAUSE OF ACTION II</u>: FDA'S REQUIRED, NEGATIVELY VALUE-LADEN QUALIFICATIONS FOR HEALTH CLAIM III VIOLATE THE FIRST AMENDMENT BY PROPOUNDING A FALSE AND INACCURATE MESSAGE

Plaintiffs reallege and restate paragraphs 1 through 63 and incorporate them herein.

64. The petitioned claim reads as follows:

> Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive.

65. The claim FDA will allow reads:

> Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer.

See Order at 37.

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

67. The FDA disclaimer violates Plaintiffs' First Amendment rights by constructively suppressing claim III with the imposition of an onerous, value laden set of qualifications that only allow Plaintiffs to propound a false, negatively value-laden, and inaccurate claim to the public. *See* Order at 37. The FDA disclaimer misleads consumers because it fails to provide an accurate representation of the state of all publicly available scientific evidence and forces Plaintiffs' to adopt FDA's inaccurate and negatively value-laden description of the science as their own or not communicate about the nutrient-disease risk reduction at all. In addition, the disclaimer is unreasonably long

and burdensome for Plaintiffs' and other industry members to include on their dietary supplement labels and in their labeling thus violating the final requirement of *Central Hudson* that the government's chosen means to accomplish its ends be reasonable and this Court and the D.C. Circuit's requirement that disclaimers be "short, succinct, and accurate." *See Central Hudson Gas & Elect. Corp v. Public Serv. Comm'n of N.Y.*, 477 U.S. 557, 564-566 (1980); *Whitaker I*, 248 F.Supp.2d at 10; *Pearson I*, 164 F.3d at 659.

RELIEF REQUESTED

The Plaintiffs respectfully request that this Honorable Court:

Declare in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act) that the FDA's June 19, 2009 final order (Docket No. FDA-2008-Q-0323-0015[7]) denying Plaintiff's petition for qualified health claims is invalid; in particular, they request that this Court declare:

(a) that the FDA's June 19, 2009 final order (Docket No. FDA-2008-Q-0323-0015[8]) violates the free speech clause of the First Amendment to the United States Constitution;

(b) that the FDA failed to follow the required court mandated analysis in *Pearson I*, *Pearson II*, *Pearson III* and *Whitaker I*; and

(c) that the FDA's proposed misleading qualifications for Plaintiffs' claim concerning selenium reducing the risk of prostate cancer violates the First Amendment by imposing unreasonable restrictions on Plaintiff's speech.

[7] Available at, http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-Q-0323, (last visited, July 29, 2009).
[8] Available at, http://www.regulations.gov/search/Regs/home.html#docketDetail?R=FDA-2008-Q-0323, (last visited, July 29, 2009).

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 suggested doses of 200-300 μg of selenium per day:

> Selenium may reduce the risk of certain cancers. Scientific evidence supporting this claim is convincing but not yet conclusive.
>
> Selenium may produce anticarcinogenic effects in the body. Scientific evidence supporting this claim is convincing but not yet conclusive.
>
> Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive.
>
> Selenium may reduce the risk of lung and respiratory tract cancers. Scientific evidence supporting this claim is convincing but not yet conclusive.
>
> Selenium may reduce the risk of colon and digestive tract cancers. Scientific evidence supporting this claim is convincing but not yet conclusive.

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 200-300 μg of selenium per day:

> Selenium may reduce the risk of certain cancers. Scientific evidence supporting this claim is convincing but not yet conclusive.
>
> Selenium may produce anticarcinogenic effects in the body. Scientific evidence supporting this claim is convincing but not yet conclusive.
>
> Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive.
>
> Selenium may reduce the risk of lung and respiratory tract cancers. Scientific evidence supporting this claim is convincing but not yet conclusive.

Selenium may reduce the risk of colon and digestive tract cancers. Scientific evidence supporting this claim is convincing but not yet conclusive.

TRIAL BY THE COURT WITHOUT A JURY

Pursuant to 28 USC § 2402 this action shall be tried by the court without a jury.

Respectfully submitted,

_____

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

Counsel for Plaintiffs

Dated: July 30, 2009