UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALLIANCE FOR NATURAL HEALTH US, et al.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 09-01470 (ESH)**
KATHLEEN SEBELIUS, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiffs Alliance for Natural Health US, Durk Pearson, Sandy Shaw, and Coalition to End FDA and FTC Censorship have sued the Food and Drug Administration ("FDA" or "Agency") and other defendants,[1] seeking review of the Agency's decision to deny plaintiffs' petition for authorization of qualified health claims regarding selenium-containing dietary supplements. Invoking both circuit and district court opinions that have addressed similar claims, plaintiffs seek a declaratory judgment that the FDA's final order denying plaintiffs' petition is invalid and a permanent injunction enjoining the Agency from "taking any action that would preclude [plaintiffs] from placing [their proposed selenium] health claims on [dietary supplement] labels." (Compl. at 29.) Before the Court are 1) plaintiffs' motion for summary judgment and 2) defendants' cross-motion for summary judgment. For the reasons set forth herein, the Court will grant plaintiffs' motion in part and deny defendants' motion.

[1] The other defendants named in the complaint are Kathleen Sebelius, Secretary, United States Department of Health and Human Services ("DHHS"); DHHS; Margaret A. Hamburg, M.D., Commissioner, FDA; and the United States.

BACKGROUND

I. STATUTORY AND REGULATORY FRAMEWORK

A "dietary supplement" is a "product (other than tobacco) intended to supplement the diet that bears or contains" one or more of certain dietary ingredients, including vitamins, minerals, herbs or botanicals, amino acids, concentrates, metabolites, constituents, or extracts. 21 U.S.C. § 321(ff)(1)(A)-(F). A dietary supplement is deemed to be "food," *id.* § 321(ff), which is defined in part as "articles used for food or drink for man or other animals," *id.* § 321(f)(1), except when it meets the definition of a "drug," which is defined in part as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." *Id.* § 321(g)(1)(B). (*See also* Defs.' Cross-Mot. for Summ. J. & Opp'n to Pls.' Mot. for Summ. J. ["Defs.' Mot."] at 3 n.2). A "health claim" is "any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition." 21 C.F.R. § 101.14(a)(1); *see also* 21 U.S.C. § 343(r)(1)(A)-(B).

Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), manufacturers wishing to market a new drug must undergo a "strict and demanding" process designed to ensure consumer safety and product efficacy in order to obtain FDA approval before introducing the product into interstate commerce. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 618-19 (1973); *see also* 21 U.S.C. § 355(a); *Pearson v. Shalala*, 164 F.3d 650, 652 (D.C. Cir. 1999) ("*Pearson I*"). "Prior to 1984, the FDA took the position that a statement that consumption of a *food* could prevent a particular disease was 'tantamount to a claim that the food was a drug . . . and therefore that its sale was prohibited until a new drug application had been approved.'" *Pearson I*, 164 F.3d at 653 (quoting H.R. Rep. No. 101-538, at 9 (1990), *reprinted in* 1990

U.S.C.C.A.N. 3336, 3338). But in the mid-1980s, companies began making health claims on foods without seeking new drug approval, a practice the FDA supported. *Id.* Congress subsequently enacted the Nutrition Labeling and Education Act of 1990 ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified as amended at 21 USC §§ 301, 321, 337, 343, 343-1, 345, 371), amending the FFDCA to provide the FDA with authority to regulate health claims on food. *Pearson I*, 164 F.3d at 653.

The NLEA created a "safe harbor" from the "drug" designation for foods and dietary supplements labeled with health claims. *Pearson v. Shalala*, 130 F. Supp. 2d 105, 107 (D.D.C. 2001) ("*Pearson II*"); *see also* 21 U.S.C. § 343(r)(1). Under the Act, a manufacturer may make a health claim on a *food* without FDA new drug approval if the FDA determines that "significant scientific agreement," based on the "totality of publicly available scientific evidence," supports the claim. 21 U.S.C. § 343(r)(3)(B)(i). For dietary supplement health claims, however, Congress declined to establish an authorization process and instead left the creation of an approval "procedure and standard" to the FDA. *Id.* § 343(r)(5)(D). The FDA subsequently promulgated a regulation adopting the NLEA's standard for food health claims (*i.e.*, "significant scientific agreement") for dietary supplement health claims. 21 C.F.R. § 101.14(c) ("FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence . . . that there is significant scientific agreement . . . that the claim is supported by such evidence."). The FDA may consider a dietary supplement labeled with an unauthorized health claim to be a misbranded food, 21 U.S.C. § 343(r)(1)(B); a misbranded drug, *id.* § 352(f); and/or an unapproved new drug. *Id.* § 355(a). A dietary supplement labeled with such a claim, or a claim that is false or misleading, is subject to seizure,

and the Agency may enjoin the product's distribution or seek criminal penalties against its manufacturer. *Id.* §§ 331(a), 332, 334, 352(a); *see also* Def.'s Mot. at 3.

II. *PEARSON V. SHALALA* AND SUBSEQUENT CASE LAW

A. Introduction

Plaintiffs' lawsuit is the latest in a series of disputes between dietary supplement designers and the FDA regarding the Agency's regulation of health claims regarding dietary supplements after the passage of the NLEA. Pearson, Shaw, and other individuals and groups affiliated with the production, sale, and use of dietary supplements have, since 1995, sought judicial review of FDA decisions denying a variety of proposed health claims. The first of these lawsuits, challenging the FDA's rejection of the plaintiffs' proposed claims on First Amendment grounds, resulted in an invalidation of the Agency's regulations regarding health claim review by the D.C. Circuit. *Pearson I*, 164 F.3d at 661. Since then, the FDA has struggled to balance its concerns for consumer protection and dietary supplement manufacturers' First Amendment commercial speech rights as defined by *Pearson I*. An abbreviated summary of these cases follows.

B. *Pearson I*

In 1995, a group of dietary supplement manufacturers[2] filed suit against the FDA and other defendants under the First Amendment, challenging the FDA's rejection of four health claims[3] that the manufacturers sought to include on certain dietary supplements. *Pearson v.*

[2] Two of these plaintiffs, Pearson and Shaw, are plaintiffs in the instant case.

[3] *Pearson I* concerned the FDA's rejection of the following health claims: (1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers"; (2) "Consumption of fiber may reduce the risk of colorectal cancer"; (3) "Consumption of omega-3 fatty acids may reduce

Shalala, 14 F. Supp. 2d 10, 14 (D.D.C. 1998). The claims characterized a relationship between dietary supplements and the risk of particular diseases. *Id.* The Agency, applying the "significant scientific agreement" standard set forth in 21 C.F.R. § 101.14, determined that the evidence concerning the supplements "was inconclusive . . . and thus failed to give rise to 'significant scientific agreement.'" *Pearson I*, 164 F.3d at 653. The Agency therefore declined to authorize the claims, finding them to be "*inherently* misleading and thus entirely outside the protection of the First Amendment" as commercial speech. *Id.* at 655 (emphasis in original). The FDA also declined to consider the proposed alternative of "permitting the claim[s] while requiring . . . corrective disclaimer[s]," arguing that even if the proposed claims were only "potentially misleading," it had no obligation under the First Amendment to consider a "disclaimer approach," as opposed to suppression, where the claims at issue lacked significant scientific agreement. *Id.* at 654, 655, 657. The manufacturers sued, arguing that the FDA's "significant scientific agreement" standard was unconstitutionally vague and was tantamount to a blanket ban on commercial speech in violation of the manufacturers' First Amendment rights.[4] *Pearson*, 14 F. Supp. 2d at 14.

After the district court denied the manufacturers' motion for summary judgment, the D.C. Circuit reversed. The Court, applying the commercial speech test set forth in *Central Hudson*

---

the risk of coronary heart disease"; and (4) ".8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form." *Pearson I*, 164 F.3d at 652.

[4] The manufacturers also argued that the "significant scientific agreement" standard for dietary supplement health claims generally and as applied to the four claims proposed by plaintiffs violated the NLEA and the Administrative Procedure Act ("APA"). *Pearson*, 14 F. Supp. 2d at 14.

Gas & Electric Corporation v. Public Service Commission of New York, 447 U.S. 557 (1980),[5] held that there was not a "reasonable fit between the government's goals" of protecting public health and preventing consumer fraud and "the means chosen to advance those goals," namely, the rejection of plaintiffs' proposed health claims without consideration of disclaimers. *Pearson I*, 164 F.3d at 656-58. Specifically, the Court held that under the First Amendment commercial speech doctrine, there is a "preference for disclosure over outright suppression" and for "less restrictive and more precise means" of regulating commercial speech. *Id.* at 657-58. The Agency's rejection of disclaimers without a showing that they were insufficient to meet the government's goal of avoiding consumer confusion demonstrated a disregard for "less restrictive" means of speech regulation that violated the First Amendment. The Court remanded the case to the district court with instructions to remand it to the Agency to consider whether disclaimers could sufficiently prevent consumer confusion and, if so, the content of those disclaimers. *Id.* at 659. The Court also held that the APA requires the FDA to "giv[e] some definitional content to the phrase 'significant scientific agreement,'" because to "declare-without explanation-that a proposed course of private action is not approved" is arbitrary and capricious. *Id.* at 660-61.

In requiring the Agency to consider the adequacy of possible disclaimers accompanying the manufacturers' proposed health claims, the Court recognized that "where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a

[5] The *Central Hudson* analysis, as clarified by the Supreme Court in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002), consists of four parts: 1) "whether 'the speech concerns lawful activity and is not misleading;'" 2) if the speech is protected, "whether the asserted government interest [in regulation] is substantial;" 3) "whether the regulation *directly* advances the governmental interest asserted;" and 4) "whether [the regulation] is not more extensive than is necessary to serve that interest." *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 8-9 (D.D.C. 2002) (quoting *Western States*, 535 U.S. at 367; *Pearson I*, 164 F.3d at 657).

disclaimer and ban it outright." *Id.* at 659. Similarly, the Court "s[aw] no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is *qualitatively* weaker than evidence against the claim." *Id.* at 659 n.10. However, the Court stated that the Agency "must still meet its burden of justifying a restriction on speech," and a "conclusory assertion" as to misleadingness is inadequate. *Id.* (citing *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146 (1994) ("If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.") (citations and internal quotation marks omitted)).

C. *Pearson II*

In late 2000, several of the plaintiffs from *Pearson I* and other dietary supplement designers, sellers, and manufacturers[6] filed a second lawsuit to challenge the Agency's decision prohibiting plaintiffs from including on their dietary supplements' labels a health claim concerning folic acid.[7] *Pearson v. Shalala*, 130 F. Supp. 2d 105, 107 (D.D.C. 2001) ("*Pearson*

[6] The plaintiffs in *Pearson II* were Durk Pearson; Sandy Shaw; American Preventive Medical Association; Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; and XCEL Medical Pharmacy, Ltd. *Pearson II*, 130 F. Supp. 2d at 107 n.1.

[7] The folic acid health claim at issue in *Pearson II* was the same folic acid claim at issue in *Pearson I*, which stated that ".8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form." *Pearson I*, 164 F.3d at 652. With respect to this claim, the Court of Appeals in *Pearson I* "strongly suggested, without declaring so explicitly" that the claim "was only 'potentially misleading,' not 'inherently misleading,' and therefore the FDA's refusal to authorize [the claim] (or to propose a disclaimer to accompany the [c]laim) violated the First Amendment." *Pearson II*, 130 F. Supp. 2d at 110; *see also Pearson I*, 164 F.3d at 659 ("[I]t appears that credible evidence did support [the folic acid claim], and we suspect that a clarifying disclaimer could be added to the effect that 'The evidence in support of this claim is inconclusive.'" (citation omitted)).

II"). After the decision in *Pearson I*, the FDA published a notice requesting submission of scientific data concerning the four health claims at issue in that case, including the folic acid claim. *Id.* at 110. The Agency also issued "Guidance for the Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements."[8] *Id.* at 111. After reviewing the newly submitted scientific data and applying the "significant scientific agreement standard" described in its guidance document and modified by an October 6, 2000 rule,[9] the Agency issued a decision stating that it would not authorize the manufacturers' folic acid claim, even with clarifying disclaimers, because it found the claim to be inherently misleading. *Id.* The plaintiffs argued that the Agency's decision "fundamentally misread and misapplied the legal standard articulated" in *Pearson I* and violated the First Amendment, the FFDCA, and the APA. *Id.* at 107, 112. They sought a preliminary injunction "enjoining the FDA from taking any action which would prevent Plaintiffs from using their desired folic acid health claim." *Id.* at 107.

The district court agreed with the plaintiffs, finding that the FDA "failed to comply with the constitutional guidelines outlined in *Pearson [I]*" when it concluded, without explanation,

[8] The current FDA guidance regarding evaluation of health claims, issued in 2009, is entitled "Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims" [hereinafter "Guidance Document"]. (Administrative Record ["AR"] 003508.)

[9] On October 6, 2000, the FDA published a notice stating that "[r]ather than denying all petitions that do not meet the significant scientific agreement standard pending completion of the general rulemaking," it would instead "exercise enforcement discretion in appropriate circumstances," such as when "the scientific evidence in support of [a] claim outweighs the scientific evidence against the claim, the claim is appropriately qualified, and all statements in the claim are consistent with the weight of the evidence . . . ." 65 Fed. Reg. 59855, 59856 (Oct. 6, 2000).

that the "weight of the evidence is *against* both aspects[10] of the proposed [folic acid] claim" and that the claim was therefore "inherently misleading" and not susceptible to correction by disclaimer. *Id.* at 112, 114. Although the court deferred to the Agency's "method of dissecting" and reading the folic acid claim per the APA, *id.* at 114 n.24, it disagreed with the FDA's weighing of the scientific data and found "as a matter of law that [the folic acid claim] is not 'inherently misleading.'" *Id.* In coming to this conclusion, the court analyzed the scientific data regarding folic acid and concluded that "[t]he mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence 'against' it." *Id.* at 115. Moreover, the court held that the "question which must be answered under *Pearson* [*I*] is whether there is any 'credible evidence'" in support of the claim. *Id.* at 114, 118 (quoting *Pearson I*, 164 F.3d at 658). If so, unless that evidence is "outweighed by evidence against the claim" or is "qualitatively weaker" than evidence against the claim, the claim "may not be absolutely prohibited." *Id.* at 114-15.

Because the court found that there was credible evidence to support the folic acid claim, it held that the FDA's determination that the folic acid claim was "inherently misleading" and could not be cured by disclaimers was "arbitrary and capricious" under the APA and that the FDA had not "undertake[n] the necessary analysis required by *Pearson* [*I*]." *Id.* at 119. The court granted the plaintiffs' motion for a preliminary injunction and remanded the case to the FDA to "draft one or more appropriately short, succinct, and accurate disclaimers." *Id.* at 120.

[10] The court considered whether .8 mg of folic acid is superior to .4 mg and whether folic acid is superior to folate found in foods in common form in preventing neural tube defects. *Pearson II*, 130 F. Supp. 2d at 115, 117.

D. *Pearson III*

After the preliminary injunction was entered in *Pearson II*, the FDA filed a motion for reconsideration, arguing that the district court had "assign[ed] undue weight to a particular clinical study and fail[ed] to consider the relevant scientific evidence in totality" and "creat[ed] a legal standard which is inconsistent with [*Pearson I*]." *Pearson v. Thompson*, 141 F. Supp. 2d 105, 108 (D.D.C. 2001) ("*Pearson III*"). The district denied the motion, pointing to the FDA's "fail[ure] to fully and accurately describe the record evidence" and "speculative" arguments. *Id.* at 109. The district court also restated the holdings in *Pearson I*, which included 1) the obligation of the Agency to "demonstrate with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness," *id.* at 112 (quoting *Pearson I*, 164 F.3d at 659-60, and 2) the establishment of "a very heavy burden which Defendants must satisfy if they wish to totally suppress a particular health claim." *Id.*

E. *Whitaker v. Thompson*

In June 2001, the plaintiffs [11] filed another lawsuit to challenge the Agency's decision not to authorize the antioxidant claim at issue in *Pearson I*.[12] *Whitaker*, 248 F. Supp. 2d at 2, 7. The Agency, after reviewing the antioxidant-cancer relationship studies submitted at its request subsequent to *Pearson I*, "found a lack of significant scientific agreement as to the relationship between antioxidant vitamin intake and reduction in the risk of developing cancer." *Id.* at 7. The FDA concluded "that the weight of the scientific evidence against the relationship [between cancer and antioxidant vitamins] was greater than the weight of evidence in favor of the

[11] The plaintiffs in *Whitaker* were Julian M. Whitaker, M.D.; Durk Pearson; Sandy Shaw; American Association for Health Freedom; Wellness Lifestyles, Inc.; and Pure Encapsulations, Inc. *Whitaker v. Thompson*, 248 F. Supp. 2d 1, 2 n.1 (D.D.C. 2002).

[12] The claim at issue was that "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers." *Whitaker*, 248 F. Supp. 2d at 2; *see also Pearson I*, 164 F.3d at 652.

relationship" and, similar to its analysis of the folic acid claim in *Pearson I* and *II*, it determined that the plaintiffs' antioxidant claim was therefore "inherently misleading and c[ould not] be made non-misleading with a disclaimer or other qualifying language." *Id.*; *see also Pearson II*, 130 F. Supp. 2d at 111-12. Plaintiffs argued that the Agency had again misapplied the standard articulated in *Pearson I* in violation of the First Amendment, and the district court agreed. *Id.* at 7-8.

Citing the Supreme Court's then-recent decision in *Western States*, the court held that the Agency had not met its "burden . . . to prove that its method of regulating speech [wa]s the least restrictive means of achieving its goals." *Id.* at 9 (citing *Western States*, 535 U.S. at 371-73). Specifically, the court held that the FDA had failed to present evidence that the proposed antioxidant claim, "if accompanied by a disclaimer, would be deceptive or unlawful." *Id.* In coming to its conclusion, the court reviewed the Agency's analysis of the claim in light of *Pearson I*, noting that "[t]he deference due to an agency's expert evaluation of scientific data does not negate 'the duty of the court to ensure that an agency . . . conduct a process of *reasoned* decision-making." *Id.* at 11 (quoting *K N Energy, Inc. v. F.E.R.C.*, 968 F.2d 1295, 1303 (D.C. Cir. 1992)). As such, the court reviewed over 150 intervention and observational studies regarding the relationship between antioxidant vitamins and cancer relied upon by the FDA in reaching its conclusions and found that nearly one-third of the studies "supported" the antioxidant/cancer relationship. *Id.* The court determined that the FDA had "failed to follow its own [Guidance] Report and give appropriate weight" to these studies. *Id.* at 12. Furthermore, the court held that the FDA had improperly emphasized and de-emphasized the import of certain studies, directly contrary to the protocol it established in the Guidance Report. *Id.* In short, the court concluded that the "basic finding" on which the FDA rested its denial of the proposed

claim was "unreasonable because it [wa]s not supported by an overall review of the available evidence or the FDA's own Guidance Report." *Id.* at 13. The court then found that the circumstances under which the Agency might ban a claim as misleading, described in *Pearson I*, were not present because 1) one-third of the evidence examined supported the claim; and 2) the FDA failed to provide "empirical evidence that an appropriate disclaimer would confuse customers and fail to correct for deceptiveness." *Id.* As a result, the court granted a preliminary injunction after concluding that the Agency's decision to suppress the claim did not "comport with the First Amendment's clear preference for disclosure over suppression of commercial speech." *Id.* at 15, 17 (remanding case to FDA to draft "short, succinct, and accurate alternative disclaimers").

III. FACTUAL AND PROCEDURAL HISTORY

In July 2002, Wellness Lifestyles, Inc., one of the plaintiffs in *Whitaker*, submitted to the FDA two proposed health claims regarding the relationship between selenium and cancer risk. On February 21, 2003, the FDA exercised enforcement discretion with respect to two "qualified" [13] versions of the health claims.[14] (Pls.' Statement of Uncontested Material Facts

[13] "Qualified health claims" are health claims that include one or more disclaimers designed to eliminate potentially misleading assertions. They were created in response to the D.C. Circuit's holding in *Pearson I*. (*See* FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims ["2009 Guidance Document"], at FDA 003510.)

[14] The original proposed health claims were 1) "Selenium may reduce the risk of certain cancers;" and 2) "Selenium may produce anticarcinogenic effects in the body." (Petition for Health Claims: Selenium and Reduction in the Risk of Certain Cancers; Selenium and Anticarcinogenic Effects (July 10, 2002), *available at* http://www.fda.gov/ohrms/dockets/dailys/02/Oct02/101802/800330ab.pdf (last visited May 25, 2010). The FDA concluded that the petition "d[id] not meet the 'significant scientific agreement standard'" but ultimately exercised enforcement discretion with respect to qualified versions of the claims that stated as follows: 1) "Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive;" and

["Pls.' SMF"] ¶ 10.) In December 2007, the FDA, in response to an Agency for Healthcare Research and Quality ("AHRQ") study, announced its intention to "reevaluate the scientific evidence on these two qualified health claims and determine if the scientific evidence continues to support the qualified health claim, and if so, whether the qualified health claim language should be modified to reflect a stronger or weaker relationship." 72 Fed. Reg. 72738, 72739 (Dec. 21, 2007). The Agency commenced a public comment period on this issue, and plaintiffs filed extensive comments in opposition to the FDA's proposed re-evaluation of the two selenium claims. (Pls.' SMF ¶ 14.)[15]

In addition to opposing the FDA's planned re-evaluation of the qualified selenium health claims, plaintiffs submitted a health claim petition seeking authorization of ten new qualified health claims (collectively, "qualified selenium health claims")[16] concerning the purported

---

2) "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." (Pls.' SMF ¶ 10; Selenium and Certain Cancers (Qualified Health Claim: Final Decision Letter) (Docket No. 02P-0457) (Apr. 28, 2003), *available at* http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm072780.htm (last visited May 25, 2010)).

[15] Plaintiffs' opposition was not addressed by the Agency in its response to plaintiffs' petition (Letter from Barbara O. Schneeman, Director, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA to Jonathan W. Emord (June 19, 2009) ["FDA Resp."] at AR 001959), nor is it a subject of plaintiffs' complaint.

[16] Plaintiffs proposed the following claims:

1. Selenium may reduce the risk of certain cancers. Scientific evidence supporting this claim is convincing but not yet conclusive.

2. Selenium may produce anticarcinogenic effects in the body. Scientific evidence supporting this claim is convincing but not yet conclusive.

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

relationship between selenium and cancer. (Petition for Qualified Health Claims: Selenium and the Reduction in the Risk of Site-Specific Cancers ["Petition"] at AR 000001, 000022.) Plaintiffs' submission included over 150 scientific articles purporting to examine one or more aspects of the relationship between selenium and cancer, which supplemented the 17 articles previously submitted to the FDA during the public comment period.[17] (*See* FDA Resp. at AR 001967-001968.)

After conducting a comprehensive review of the petition and posting it on the FDA website for a 60-day comment period, the Agency responded in June 2009. (FDA Resp. at AR 001957-002012.) The FDA concluded that while scientific evidence supports qualified health claims concerning the relationship between selenium intake and a reduced risk of bladder,

---

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

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

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

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

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

9. Selenium may reduce the risk of liver cancer. Scientific evidence supporting this claim is limited and applies only to hepatitis B virus-induced forms of the disease.

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

(Petition at AR 000045.)

[17] Plaintiffs also submitted three supplements to their petition including "recent publications on selenium and cancer chemoprevention" and "an analysis and opinion of a recent publication of the National Cancer Institute (NCI) Selenium and Vitamin E Prevention Trial." (FDA Resp. at AR 001958.)

prostate, and thyroid cancer, no such evidence exists to support a relationship between selenium intake and a reduced risk of urinary tract (other than bladder), lung and other respiratory tract, colon and other digestive tract, brain, liver, and breast cancers. (*Id.* at AR 001959.) The Agency also concluded that proposed Claims 1 and 2, regarding selenium intake and certain cancers and anticarcinogenic effects, "are misleading because they are overbroad, fail to disclose material information, and are not supported by the scientific evidence the agency reviewed . . . ."[18] (*Id.*) Accordingly, the FDA denied Claims 1, 2, 5, 6, 8, 9, and 10 and stated that it would exercise enforcement discretion with respect to modified versions of Claims 3, 4, and 7.[19] (*Id.* at AR 001992-001993.)

Plaintiffs filed the instant lawsuit on August 4, 2009, claiming a violation of the First Amendment as a result of the FDA's denial of Claims 1 ("certain cancers claim"); 2 ("anticarcinogenic effects claim"); 5 ("lung/respiratory tract claim"); and 6 ("colon/digestive

[18] In its response letter, the Agency also summarized the process by which it reviewed plaintiffs' petition (*id.* at AR 001959-001960); the weight it accords certain types of scientific studies (*id.* at AR 001960-001962); its definition of the term "cancer" and its application to Claims 1 and 2 (*id.* at AR 001962-001965); its safety review of selenium (*id.* at AR 001965-001976); its assessment of the various studies submitted in support of the various claims in the petition (*id.* at AR 001968-001987); the strength of the scientific evidence (*id.* at AR 001987-001990); other enforcement discretion factors (*id.* at AR 001990-001992); its consideration of disclaimers or qualifying language (*id.* at AR 001992); and its conclusions (*id.* at AR 001992-001994).

[19] The Agency stated that it would consider the exercise of its enforcement discretion for the following qualified health claims: 1) "One study suggests that selenium intake may reduce the risk of bladder cancer in women. However, one smaller study showed no reduction in risk. Based on these studies, FDA concludes that it highly uncertain that selenium supplements reduce the risk of bladder cancer in women;" 2) "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;" and 3) "One weak, small study suggests that selenium intake may reduce the risk of thyroid cancer. Based on this study, FDA concludes that it is highly uncertain that selenium supplements reduce the risk of thyroid cancer." (FDA Resp. at AR 001993.)

tract claim"). (Compl. ¶¶ 56-63). Plaintiffs also maintain that the FDA's modification of Claim 3 ("prostate claim") violates their First Amendment rights because it "constructively suppress[es] [this] claim 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." (*Id.* ¶ 67.) Plaintiffs also oppose the FDA's proposed qualifications of Claim 3 as being "unreasonably long and burdensome for Plaintiffs and other industry members to include on their dietary supplement labels," thereby violating *Central Hudson*'s requirement that the governments means of accomplishing its goals be reasonable. (*Id.* ¶ 67.) They seek: 1) a declaratory judgment that the FDA's June 19, 2009 final order denying plaintiffs' petition is invalid; 2) an order that the FDA "refrain from taking any action" precluding plaintiffs from placing Claims 1, 2, 3, 4, and 5 on selenium dietary supplement labels; and 3) a permanent injunction, enjoining the FDA from taking any action precluding plaintiffs from placing Claims 1, 2, 3, 4, and 5 on selenium dietary supplement labels. (*Id.* at 28-29.)

ANALYSIS

I. LEGAL STANDARD

A. Scope of Review

Plaintiffs raise their claims under the First Amendment to the United States Constitution.[20] (Compl. ¶¶ 56-67). "[A] Court's review of 'constitutional challenges to agency

[20] The Court "has the authority to examine and rule on any actions of a federal agency that allegedly violate the Constitution," apart from the power of review granted by the Administrative Procedure Act ("APA"). *Rydeen v. Quigg*, 748 F. Supp. 900, 905 (D.D.C. 1990), *aff'd mem.*, 937 F.2d 623 (Fed. Cir. 1991) (citing *Porter v. Califano*, 592 F. 2d 770, 780 (5th Cir. 1979)). However, the APA "also provides for the Courts to make an independent assessment of constitutional issues," and the role of the Court is the same "whether the plaintiff sues directly under the Constitution or under [the APA]." *Id.* at 905 n.8 (citing 5 U.S.C. § 706(2)(b)).

actions . . . is *de novo*.'" *Poett v. United States*, 657 F. Supp. 2d 230, 241 (D.D.C. 2009) (quoting *Cullman Reg'l Med. Ctr. v. Shalala*, 945 F. Supp. 287, 293 (D.D.C. 1996)). The Court shall make "an independent assessment of [the plaintiffs'] claim of constitutional right when reviewing agency decision-making," *Porter*, 592 F.2d at 780, and it need not accord deference to the agency's "pronouncement on a *constitutional* question." *J.J. Cassone Bakery, Inc. v. NLRB*, 554 F.3d 1041, 1044 (D.C. Cir. 2009) (quoting *Lead Indus. Ass'n Inc. v. EPA*, 647 F.2d 1130, 1173-74 (D.C. Cir. 1980) (emphasis added)).

The parties disagree as to which standard the Court should apply in reviewing the Agency's decision to deny the majority of plaintiffs' qualified selenium health claims. Plaintiffs maintain that "[r]eview of an agency action does not default to arbitrary and capricious review when a constitutional issue is raised *even if it is raised under the APA*," (Pls.' Mem. in Reply and Opp'n to Def.'s Opp'n to Pls.' Mot. for Summ. J. and Cross-Mot. for Summ. J. ["Pls.' Reply"] at 13), and therefore a more stringent standard applies, "not the deferential *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984) or [APA] standards." (Pls.' Mem. in Supp. of Mot. for Summ. J. ["Pls.' Mot."] at 18.) The Agency contends that because "this case does not involve a challenge to a regulation broadly prohibiting an entire category of misleading speech" and instead involves "particularized findings concerning the scientific evidence relating to plaintiffs' specific health claims," the "APA's deferential [arbitrary and capricious] standard applies here." (Defs.' Mot. at 22.) This disagreement has been ongoing since *Pearson I* was decided. *See Pearson II*, 130 F. Supp. 2d at 115 n.25. In *Pearson II*, the district court decided it need not reach this issue because it found that the Agency's decision in that case violated both standards. *Id.* In *Whitaker*, the court did not address the disagreement directly. Instead, it acknowledged the "deference due to an agency's expert evaluation of scientific data" but

concluded that such deference did not negate the court's obligation to ensure that the agency engaged in reasoned decision-making and that its reasoning was not "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" 248 F. Supp. 2d at 11 (quoting 5 U.S.C. § 706(2)(A)). The court went on to review the scientific evidence evaluated by the FDA and concluded that the FDA's finding on which it rested its decision to deny plaintiffs' proposed health claim was "unreasonable" because that finding was "not supported by an overall review of the available evidence or the FDA's own Guidance Report." *Id.* at 13.

The Court concludes that it is obligated to conduct an independent review of the record and must do so without reliance on the Agency's determinations as to constitutional questions. *See J.J. Cassone Bakery, Inc.*, 554 F.3d at 1044 (constitutional challenges to agency actions are "entertain[ed] . . . *de novo*"). But it would be inconsistent with binding precedent and wholly inappropriate to evaluate the voluminous scientific studies at issue in this case without some deference to the FDA's assessment of that technical data. *See, e.g.*, *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 377 (1989) ("Because analysis of the relevant documents requires a high level of technical expertise, we must defer to the informed discretion of the responsible federal agencies.") (internal citation and quotations omitted); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998) (agency "evaluations of scientific data within its area of expertise" are "entitled to a high level of deference") (internal quotations omitted); *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1490 (D.C. Cir. 1995) ("[C]ourts give a high level of deference to an agency's evaluations of scientific data within its area of expertise."); *see also J.J. Cassone Bakery, Inc.*, 554 F.3d at 1044 (distinguishing between "other aspects of a[n agency] decision, which we review deferentially" and "a constitutional question," to which "a reviewing court owes no deference"). Moreover, deference to the Agency's interpretation of scientific

information, provided such interpretation is reasoned and not arbitrary or capricious, is consistent with the test set forth in *Pearson I*. By instructing the FDA to employ less restrictive means of regulating speech and to provide greater empirical support for its regulatory decisions, the D.C. Circuit did not purport to tell the Agency how to assess scientific data. Rather, it provided the Agency with guidelines for developing regulations once it had evaluated the evidence before it. *See, e.g., Pearson I*, 164 F.3d at 659 ("[W]here evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright.").

This is not, however, to say that where the FDA's conclusions are contrary to its purported evaluation standards or are otherwise arbitrary, as the court concluded they were in *Pearson II* and *Whitaker*, a reviewing court should not overturn the Agency. *See, e.g., Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (agency's decision may be overturned where it has "failed to respond to specific challenges that are sufficiently central to its decision"); *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976) (court has duty to give "close scrutiny" to technical evidence and to "hold[] agencies to certain minimal standards of rationality."). But "[t]he enforced education into the intricacies of the problem before the agency is not designed to enable the court to become a superagency that can supplant the agency's expert decision-maker. To the contrary, the court must give due deference to the agency's ability to rely on its own developed expertise." *Id.*

B. Regulation of Commercial Speech

Because the qualified selenium health claims are commercial speech, the FDA's refusal to authorize them must be evaluated under the analytical framework established in *Central Hudson*, discussed by the D.C. Circuit in *Pearson I*, and elaborated upon by the Supreme Court

in *Western States*. *Whitaker*, 248 F. Supp. 2d. at 8; *see also Pearson I*, 164 F.3d at 655 ("Under *Central Hudson*, we are obliged to evaluate a government scheme to regulate potentially misleading commercial speech by applying a three-part test."). The Supreme Court has "rejected the 'highly paternalistic' view that government has complete power to suppress or regulate commercial speech." *Central Hudson*, 447 U.S. at 562 (quoting *Virginia Pharmacy Bd. v. Virginia Citizens Consumer Council*, 425 U.S. 748, 770 (1976)). Moreover, it has distinguished between "inherently misleading" speech and "potentially misleading" speech. "[Actually or inherently m]isleading advertising may be prohibited entirely." *In re R.M.J.*, 455 U.S. 191, 203 (1982). "But the States may not place an absolute prohibition on certain types of potentially misleading information . . . if the information also may be presented in a way that is not deceptive." *Id.* Moreover, "[t]he First Amendment does not allow the FDA to simply assert that [a plaintiff's c]laim 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.'" *Whitaker*, 248 F. Supp. at 9 (quoting *Ibanez*, 512 U.S. at 146). Indeed, in *Pearson I*, the D.C. Circuit rejected the FDA's contention that health claims lacking "significant scientific agreement" are inherently misleading as "almost frivolous." *Pearson I*, 164 F.3d at 655. Even when it finds "that speech is misleading, the government must consider that 'people will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication rather than to close them.'" *Whitaker*, 248 F. Supp. 2d at 9 (quoting *Virginia Pharmacy Bd.*, 425 U.S. at 770).

Central Hudson established a multi-step analysis of speech regulation. "As a threshold matter," the Court must determine "whether the commercial speech [being regulated] concerns unlawful activity or is misleading." *Western States*, 535 U.S. at 367. If so, the speech is not

protected. *Id.* But if the speech is lawful and not misleading, or is only potentially misleading, the Court must ask "whether the asserted governmental interest in regulating the speech is substantial." *Id.* (quoting *Central Hudson*, 447 U.S. at 566)). If it is, the Court then ascertains "whether the regulation [at issue] directly advances the governmental interest asserted" and "whether [the regulation] is not more extensive than is necessary to serve that interest." *Id.* (quoting *Central Hudson*, 447 U.S. at 566.) This last step requires the Court to evaluate "whether the fit between the government's ends and the means chosen to accomplish those ends is . . . reasonable." *Pearson I*, 164 F.3d at 656 (citation omitted).

The government has the burden of showing that the regulations on speech that it seeks to impose are "not more extensive than is necessary to serve" the interests it attempts to advance. *Western States*, 535 U.S. at 371 (quoting *Central Hudson*, 447 U.S. at 566). "[I]f the Government c[an] achieve its interests in a manner that does not restrict [commercial] speech, or that restricts less speech, the Government must do so." *Id.* Therefore, the Court in *Pearson I* noted that disclaimers are "constitutionally preferable to outright suppression," *Pearson I*, 164 F.3d at 657, and that generally, "the preferred remedy is more disclosure, rather than less." *Id.* (quoting *Bates v. State Bar of Arizona*, 433 U.S. 350, 376 (1977)); *see also Pearson II*, 130 F. Supp. 2d at 113 ("[M]ore disclosure rather than less is the preferred approach, so long as advertising is not inherently misleading."). For this reason, the Court in *Pearson I* concluded 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-the government disregards a far less restrictive means." *Pearson I*, 164 F.3d at 658 (quotations omitted).

II. FDA'S COMPLETE BAN OF PLAINTIFFS' CLAIMS

In its response to plaintiffs' petition, the Agency denied four of the proffered claims outright. (FDA Resp. at AR 001963, 001965, 001992-001993.) Under *Central Hudson* and *Pearson I*, the FDA may refuse to consider disclaimers for health claims (*i.e.*, prohibit their use completely) only if such health claims are inherently misleading, *Whitaker*, 248 F. Supp. at 9, or are potentially misleading but the Agency has deemed the claim "incurable by disclaimer." *Pearson I*, 164 F.3d at 659. The court in *Whitaker* arguably went even further than *Pearson I*, holding that "any complete ban of a claim would be approved only under narrow circumstances, *i.e.*, when there was almost no qualitative evidence in support of the claim *and* where the government provided empirical evidence proving that the public would still be deceived even if the claim was qualified by a disclaimer."[21] *Whitaker*, 248 F. Supp. 2d at 11 (emphasis added); *see also Pearson I*, 164 F.3d at 659-60 (suggesting that government might completely ban health claim where "evidence in support of a claim is outweighed by evidence against the claim" or where it "demonstrate[d] with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness"). The Court considers each of plaintiffs' claims to

[21] The FDA argues that *Whitaker* "strayed from *Pearson I* by suggesting that [the Agency] is required, under the First Amendment, to present empirical evidence about the misleading nature of a claim even where there is no evidence supporting the claim or the evidence in support of the claim is qualitatively weaker than the evidence against the claim." (Defs.' Reply in Supp. of Its Cross-Mot. for Summ. J. and In Opp'n to Pls.' Mot. for Summ. J. ["Defs.' Reply"] at 7.). Plaintiffs maintain that "no doctrinal or legal difference of any decisional significance between *Pearson I* and *Whitaker*" exists. (Pls.' Surreply to Defs.' Reply in Supp. of Defs.' Cross-Mot. for Summ. J. and In Opp'n to Pls.' Mot. for Summ. J. at 7.) Despite extensive debate, the Court need not decide whether *Whitaker* has improperly increased the government's burden, because it concludes that the FDA has not shown that there is no credible or only qualitatively weaker evidence in support of plaintiffs' claims or that the claims are "incurable by disclaimer." *See Pearson I*, 164 F.3d at 659.

determine whether the FDA has met its burden with respect to those claims it has banned outright. [22]

A. Plaintiffs' "Certain Cancers" and "Anticarcinogenic Effects" Claims

The FDA asserts that claims that selenium may reduce the risk of certain cancers and may produce anticarcinogenic effects are "misleading on their face," "independent of the proffered scientific evidence." (Defs.' Mot. at 23.) Specifically, the Agency concluded that the certain cancers claim "is incomplete and misleading because it fails to reveal the individual cancer(s) that selenium may have an effect on," thus leading a consumer to purchase selenium in hopes of preventing a cancer for which there is no evidence of risk reduction from selenium intake. (FDA Resp. at AR 001963.) The FDA also argues that by "referring in general terms to 'certain cancers,' the requested claim language . . . suggests that cancers at different sites are essentially the same disease and that it is not important to distinguish between them." (*Id.*) Similarly, the anticarcinogenic effects claim "falsely implies that [selenium] can protect against all cancers," when in fact cancer "is not a single disease" but a "collective term for a large number of individual diseases that differ with respect to risk factors, etiology, methods of

[22] The Court considers only the first sentence of each of plaintiffs' proposed claims, not the suggested disclaimer in the second sentence (*i.e.*, that the "[s]cientific evidence supporting this claim is convincing but not yet conclusive"). (FDA Resp. at AR 001957-001958.) To the extent the FDA denied these claims outright, it did so on the basis of the claimed relationship between selenium dietary supplements and various cancers, not because of the disclaimer. (*See, e.g.*, Defs.' Mot. at 23 (FDA concluded that certain cancers and anticarcinogenic effects claims were misleading "independent of the proffered scientific evidence")). Specifically, where the FDA banned a claim entirely because it found "no credible evidence of a risk reduction relationship" or believed the claim was inherently misleading, it concluded that the proposed disclaimer was "clearly false" without further assessment of its merits. (FDA Resp. at AR 001993.) To the extent the Court overturns the Agency's findings as to the substance of the health claims, it must allow the FDA to consider plaintiffs' proposed disclaimer and/or alternate disclaimers in the first instance. *See, e.g.*, *Pearson I*, 164 F.3d at 659 ("We do not presume to draft precise disclaimers for each of appellants' . . . claims; we leave that task to the agency in the first instance.").

diagnosis and treatment, and mortality risk." (*Id.* at AR 001964; *see also* Defs.' Mot. at 23.) Moreover, the Agency argues that the phrase "anticarcinogenic effects" is ambiguous because "anticarcinogenic" might mean both the "treatment and mitigation of existing cancer as well as the reduction of risk of getting cancer in the first place." (Def.'s Mot. at 24.) Since "[c]laims about treatment or mitigation of disease are classified as drug claims, not health claims," the FDA "believes that no qualified claim based on that phrase would be truthful and non-misleading." (FDA Resp. at AR 001965.)

The Court concludes that the FDA's position fails under *Pearson I*. The Agency has not provided any empirical evidence, such as "studies" or "anecdotal evidence," that consumers would be misled by either of plaintiffs' claims were they accompanied by qualifications. *See Pearson I*, 164 F.3d at 659 (government's "conclusory assertion" of misleadingness insufficient to meet burden); *see also Edenfield v. Fane*, 507 U.S. 761, 771 (1993) (rejecting restriction of commercial speech where government "present[ed] no studies" and "record d[id] not disclose any anecdotal evidence . . . that validates the [government's] suppositions" that unregulated speech would cause "fraud and overreaching"). Moreover, the explanation the FDA offers to demonstrate that plaintiffs' claims are misleading—that the claims leave out pertinent information—is not support for banning the claims entirely, but rather favors the approach of remedying any potential misleadingness by the disclosure of additional information.

The FDA's position is particularly troubling in light of its admission that plaintiffs' certain cancers claim "is literally true . . . in that there is credible evidence that selenium may reduce the risk of at least three cancers" and that the anticarcinogenic effects claim "is true to the extent that it refers to reducing the risk of . . . three cancers[.]" (Defs.' Reply at 10 n.8.) As the Circuit Court in *Pearson I* made clear, "the government's interest in preventing the use of labels

that are true but do not mention [material information] would seem to be satisfied-at least ordinarily-by inclusion of a prominent disclaimer setting forth [that information]." 164 F.3d at 659 (emphasis added). Here, the FDA has not provided any evidence that completing plaintiffs' certain cancers claim by "reveal[ing] the individual cancer(s) that selenium may have an effect on" and explaining that cancers at different sites are different diseases and respond differently to treatments would not eliminate the consumer confusion it fears. And, the FDA's argument that "disclaimer language defining 'anticarcinogenic' as reducing the risk of, rather than treating or mitigating, cancer would not cure the misleading nature" of the claim because it "would still fail to specify the disease at issue" (Defs.' Mot. at 27) begs the question why an additional disclaimer, specifying the disease[s], would not remedy the purported problem. [23]

[23] In its reply, the FDA appears to answer this question by arguing that qualifying language would "merely add more information [to the certain cancers and anticarcinogenic effects claims] without solving the problem created by the inherently misleading language of the claim itself." (Defs.' Reply at 11.) Specifically, it maintains that a disclaimer defining the phrase "anticarcinogenic effects" and specifying the cancers at issue would "undercut the claim and create confusion as to why the broad 'anticarcinogenic effects' statement appears on the product if the evidence only supports risk reduction for three cancers." (*Id.* at 11-12.) It then contends that

> appending qualifying language such as 'specifically prostate, bladder, and thyroid cancer' to the 'certain cancers' claim to inform consumers of the cancers for which there is credible evidence of possible risk reduction would not be sufficient to prevent deception because the broader 'certain cancers' language would still incorrectly suggest a possible protective effect against other unnamed cancers, and the inconsistency between the broader language of the claim and the narrower language of the disclaimer would create confusion and uncertainty as to the scope of the claimed benefit.

(Defs.' Reply at 12.) But these conclusory contentions are insufficient to meet the Agency's burden under the commercial speech doctrine. *See Edenfield*, 507 U.S. at 770-71 (government's obligation to "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree" "is not satisfied by mere speculation or conjecture"). The Agency offers no support for its claim that limiting the type of "protective effect" and "risk

Supreme Court precedent and *Pearson I* obligate the FDA to, at a minimum, consider "less restrictive" means of correcting that misleadingness before it turns to suppression. *Pearson I*, 164 F.3d at 657-58; *see also Bates*, 433 U.S. at 374-75 (rejecting notion that "the public is better kept in ignorance than trusted with correct but incomplete information"). Because the Agency has not done so here, the Court will remand the claims relating to certain cancers and anticarcinogenic effects to the FDA for the purpose of drafting one or more disclaimers or, alternatively, setting forth empirical evidence that any disclaimer would fail to correct the claims' purported misleadingness.

---

reduction" claimed would insufficiently prevent consumers from assuming that selenium may also lower the risk of other cancers. It also fails to explain what "confusing contradiction" would result from such disclaimers. On the contrary, it acknowledges that the claims are true because of, not in spite of, evidence that selenium may reduce the risk of particular cancers. (Defs.' Reply at 10 n.8.)

The FDA's reliance on *International Dairy Foods Association v. Boggs*, No. 08-628, 2009 WL 937045, at *5 (S.D. Ohio Apr. 2, 2009), which involved a state regulation that prevented sellers of dairy products made from cows not treated with rbGH from advertising their products as "rbGH free," is unavailing. There, the court held that the phrase "rbGH free" was inherently misleading because it implied that there was a "compositional difference between those products that are produced with rbGH and those that are not," when in fact no such difference exists. *Id.* at *6. The restricted claims in *Boggs* are different from plaintiffs' claims. The "rbGH free" claim, while literally true, sent a message—that rbGH free milk is different from milk produced by cows given rbGH—that was completely false. Here, by contrast, the FDA concedes that plaintiffs' anticarcinogenic and certain cancers claims "contain a kernel of truth," but are overly broad. (Defs.' Reply at 10 n.8.) Yet, the FDA rejects disclaimers explicitly limiting the scope of plaintiffs' proposed claim to those circumstances supported by credible evidence, arguing that such disclaimers would "defeat the purpose of making the claim[s] in the first place." (*Id.* at 12 (quoting *Boggs*, 2009 WL 937045, at *7).) The Court fails to see how limiting a claim so that it accurately reflects the evidence in support of the claim defeats the purpose of making the claim at all. Nor is this situation analogous to *United States v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 542-43 (D.R.I. 1994), where the disclaimers at issue were clearly inconsistent with the message defendants sought to convey and therefore effectively served to undo the original claims. *See Pearson I*, 164 F.3d at 659 (where evidence in support of claim is outweighed by evidence against it, disclaimer that "no evidence supports this claim" would not cure claim's misleadingness). Absent evidence that consumers are unable to read qualified versions of plaintiffs' claims without assuming that selenium prevents diseases not stated by the claims, the FDA has not demonstrated that disclaimers would be ineffective and that suppression of these claims is thus warranted.

B. Plaintiffs' Lung and Respiratory Tract Claim

In contrast to the certain cancers and anticarcinogenic effects claims, the FDA considered the scientific evidence proffered by plaintiffs and concluded that it could draw scientific conclusions from only four of those studies concerning plaintiffs' lung/respiratory tract claim.[24] (FDA Resp. at AR 001985.) Because all of those studies reported "no significant difference in mean serum levels" between control cases and lung cancer cases, the Agency concluded that "there is no credible evidence for a claim about selenium supplements and reduced risk of lung cancer or other respiratory tract cancers." (*Id.* at AR 001985, 001989.) Plaintiffs contend that a number of the studies discounted by the FDA provide sufficient credible evidence of a positive relationship between selenium intake and a lowered risk of lung and respiratory tract cancers. (Pls.' Mot. at 34-36; Pls.' SMF ¶¶ 37-39.)

As an initial matter, the FDA's determination regarding the lung and respiratory tract claim is not inconsistent with *Pearson I*, in which the Court allowed for the possibility that "where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright." 164 F.3d at 659. Here, the Agency claims that there is no evidence in support of the proposed claim and cites studies suggesting that there is no relationship between selenium intake and reduced lung cancer risk. However, the Court in *Pearson I* also suggested that when "'credible evidence' supports a claim, that claim may not be absolutely prohibited." *Whitaker*, 248 F. Supp. 2d at 10; *see also Pearson I*, 164 F.3d at 658-59 (where "credible evidence" supported a proposed claim, "a clarifying disclaimer

[24] The only studies relied upon by the FDA for this claim concerned the relationship between selenium and lung cancer, as opposed to other respiratory tract cancers. (FDA Resp. at AR 001985.)

could be added" to note that the evidence was inconclusive). Therefore, the proper inquiry is what qualifies as "credible evidence" and is there any such evidence to support the lung and respiratory tract claim?

In its latest Guidance Document, the FDA states that it uses an "evidence-based review system" to evaluate the strength of the evidence in support of a statement. The process

> involves a series of steps to assess scientific studies and other data, eliminate those from which no conclusions about the substance/disease relationship can be drawn, rate the remaining studies for methodological quality and evaluate the strength of the totality of scientific evidence by considering study types, methodological quality, quantity of evidence for and against the claim (taking into account the numbers of various types of studies and study sample sizes), relevance to the U.S. population or target subgroup, replication of study results supporting the proposed claim, and overall consistency of the evidence. After assessing the totality of the scientific evidence, FDA determines whether there is [significant scientific agreement] to support an authorized health claim, or *credible evidence to support a qualified health claim.*

(Guidance Document at AR 003512 (emphasis added).) While the document does not define "credible," it does set forth threshold questions and categorizations the Agency uses to prioritize certain types of evidence over others. For example, it states that "[r]andomized, controlled trials offer the best assessment of a causal relationship between a substance and a disease." (*Id.* at AR 003513.) In contrast, "research synthesis studies" and "review articles" "do not provide sufficient information on the individual studies reviewed" to determine critical elements of the studies and/or whether those elements were flawed. (*Id.* at AR 003517.) The FDA also explains the questions it considers in determining whether scientific conclusions can be drawn from an intervention or observational study, such as where the studies were conducted (*i.e.*, on what type of population); what type of information was collected; and what type of biomarker of disease risk was measured. (*Id.* at AR 003518-003522.) If the FDA concludes that the elements of a

study are flawed such that it is impossible to draw scientific conclusions from the study, it eliminates that study from further review. (*Id.* at AR 003518.)

Using the above procedure, the FDA disregarded the studies plaintiffs cite as "credible evidence" in support of their proposed lung/respiratory tract claim: the van den Brandt et al. study; the Knekt et al. study; the Zhuo et al. review article; and the "SU.VI.MAX" study.[25] (Pls.' Mot. at 34-36.) The Agency states that it eliminated the van den Brandt and Knekt studies because they were conducted on Dutch and Finnish populations whose average baseline selenium levels (53.9 to 62.5 µg/L in blood and .5 µg/g in toenail clippings, respectively) are significantly lower than the levels observed in the "vast majority of the U.S. population."[26] (FDA Resp. at AR 001979.) Indeed, it appears that the van den Brandt and Knekt studies focused on populations whose members suffer from a selenium deficiency, since "nutritional adequacy of

[25] Plaintiffs cite four studies as "credible evidence" supporting the lung/respiratory tract claim that were improperly discounted by the FDA. (Pls.' Mot. at 34-36.) However, plaintiffs maintain that this is not a "comprehensive list of articles" they submitted in support of this claim and urge the Court to review the Administrative Record for all such materials. (*Id.* at 34 n.47.) In reviewing the nearly 4,000-page record, the Court encountered multiple articles that evaluated or discussed a possible relationship between selenium and lung cancer. But the Court is not in the position, nor is it the Court's role, to independently assess whether these publications, many of which are highly technical and discuss interactions at a bio-molecular level (*see, e.g.*, AR 001844 (Poerschke et al., *Modulation of redox status in human lung cell lines by organoselenocompounds: Selenazolidines, selenomethionine, and methylseleninic acid*, 22 Toxicology in Vitro 1761-1767 (2008)), constitute "credible evidence" in support of plaintiffs' claim. As such, the Court will limit its consideration to the four articles relied on by plaintiffs to assess whether the Agency's evaluation is inconsistent with the standards outlined in its current Guidance Document, irrational, and/or arbitrary and capricious. *See Whitaker*, 248 F. Supp. 2d at 11 (reviewing FDA's evaluation of scientific evidence to ensure Agency conducted a "process of reasoned decision-making" and that decision was not arbitrary and capricious).

[26] By comparison, according to a 2003 study, blood serum selenium concentrations in the U.S. population range from 91 µg/L (1st percentile) to 168 µg/L (99th percentile). (FDA Resp. at AR 001977.) From this, the FDA concluded that "populations [with] blood selenium concentrations of less than 90 µg/L are not applicable to the general U.S. population." (*Id.*) Similarly, studies from 1995 and 1998 indicate that toenail selenium concentration in the U.S. population is around .86 µg/g, with the lowest quintile ranging from .66 to .72 µg/g. (*Id.* at AR 001978.)

selenium is defined as the amount of selenium that is needed to saturate selenium enzyme activities; this occurs at blood selenium concentrations of 70-90 µg/L." (*Id.* at AR 001977.) The Agency's elimination of the van den Brandt and Knekt studies is thus consistent with the 2009 Guidance Document, which states that "[s]cientific conclusions cannot be drawn from studies conducted in countries or regions where inadequate intake of the substance is common since a response to the intake of the substance may be due to the correction of a nutrient deficiency for which health claims are not intended." (Guidance Document at AR 3521.) In fact, the Knekt study noted that "the serum selenium level of the present population was about 60 percent of the levels generally observed in other Western countries" and found only that "individuals with a low serum selenium concentration had an elevated risk of lung cancer." (AR 001569-001570.) The study further noted that "[h]igher serum selenium was associated with a reduced risk only at low alphatocopherol levels." (AR 001570.) Similarly, the van den Brandt found an inverse association between toenail selenium content and the risk of lung cancer, but it noted that selenium levels in the Netherlands are "intermediate between those reported from New Zealand and the United States." (AR 003170.) As such, the FDA's decision not to extrapolate from these studies to the U.S. population is both rational based on the studies' conclusions and consistent with the Agency's evaluation criteria.

The FDA contends that it eliminated the Zhuo publication from its evaluation because the article "only reviewed lung cancer studies" and did not purport to provide "scientific evidence" in support of plaintiffs' claim. (Defs.' Mot. at 41.) Moreover, the Agency generally excludes such review articles because they "'do not contain sufficient information on the individual studies reviewed' from which scientific conclusions can be drawn." (*Id.* (quoting FDA Resp. at AR 001968).) Based on its review of the article, the Court concludes that the Agency's decision

to exclude the article from its evaluation was not arbitrary and capricious. While the article discusses 16 studies (some of which are also included in the record), it is not apparent from the article that the Agency had sufficient information from the Zhuo article to determine whether these studies contained design flaws. Moreover, many of the populations studied have low selenium levels that may not be the case in the U.S. population. (AR 003799.) Indeed, the article concludes that "[w] e found evidence that selenium could have protective effects; however, based on this analysis and other evidence, these effects apparently occur primarily in populations where overall selenium levels are low." (AR 003803.) The FDA's findings regarding the van den Brandt and Knekt studies suggest that even had the Agency considered the Zhuo article as providing scientific evidence, that evidence is not sufficiently credible to support plaintiffs' claim.

Finally, the Agency rejected the SU.VI.MAX study because the study "did not confirm that all subjects were free of the cancers of interest prior to the intervention" and therefore may have involved subjects who already had cancer at the time the study began. (FDA Resp. at AR 001971.) Because of this omission, the FDA stated that it could not draw scientific conclusions from the study. (*Id.*) However, the SU.VI.MAX study states that one of the criteria for participation in the study was "lack of disease likely to hinder active participation or threatened [sic] 5-year survival." (AR 001660.) The study participants were intermittently examined, and participants were asked to report any health events monthly. (*Id.*) Whenever a possible adverse event, including "cancer of any kind," was reported from whatever source, records were collected and included in study data. (*Id.*) The Agency also appears to have overlooked a later report on the SU.VI.MAX study population concerning prostate cancer, which noted that three participants were excluded at the start of the study *because* they had prostate cancer, indicating

that some sort of cancer screening process was conducted at the study's outset. (AR 001669.) As such, the Agency's stated reason for its disregard of the study is unsupported by the record. And the FDA provided no response to the plaintiffs' argument regarding the results of the study, namely that "in men, the incidence of respiratory cancers was reduced from 88 per 100,000 for the control group to 37 per 100,000 for the supplemented group," while in women, the "incidence of respiratory tract cancers was reduced from 21 per 100,000 in the control group to only 12 per 100,000 in the supplemented group." (Pls.' Mot. at 31; AR 01665.)

In sum, while the Court concludes that the Agency's exclusion of the van den Brandt, Knekt, and Zhuo publications on the basis of its Guidance Document was not irrational or arbitrary and capricious, the exclusion of the SU.VI.MAX study on the basis that it did not screen participants for cancer is not supported by the record. To the extent that the FDA is concerned about possible limitations of the SU.VI.MAX study protocol and/or results, it must remedy such limitations with disclaimers. *See Pearson I*, 164 F.3d at 658 (suggesting disclaimer for antioxidant claim to address Agency's concerns about study limitations). Accordingly, the Court remands the lung/respiratory tract claim to the Agency to determine an appropriate disclaimer in light of the SU.VI.MAX study.

C. Plaintiffs' Colon and Digestive Tract Claim

As with the lung/respiratory tract claim, the FDA concluded that there is no credible evidence for a claim about selenium supplements and reduced risk of colon or other digestive tract cancers. (FDA Resp. at AR 001989; Defs.' Mot. at 43.) After eliminating various studies from which it determined no scientific conclusions could be drawn, including studies it relied upon in the evaluation of other of plaintiffs' claims, the FDA reviewed three prospective observational studies that it found reported no significant relationship between selenium

concentration and the risk of colorectal cancer. (FDA Resp. at AR 001983-001985.) Plaintiffs challenge the FDA's conclusions regarding one of these studies (the Peters et al. study) and cite additional publications they contend were wrongly excluded from the FDA's evaluation of their colon and digestive tract claim: the Clark et al. study; the Ghadirian et al. study; the Fernandez-Banares et al. study; the Jaskiewicz et al. study; the Das et al. review article; the Schrauzer et al. study; and the Wei et al. study. (Pls.' Mot. at 36-38.)

In its response to plaintiffs' petition, the Agency stated that the Peters study was of "high methodological quality" (FDA Resp. at AR 001984), which is the highest ranking the FDA gives to human intervention and observational studies, which in turn are the two types of studies the Agency considers most reliable. (*Id.* at AR 001961; *see also* AR 003523-003526.) However, the Agency concluded that because "[t]here was no significant difference in the overall incidence of adenomatous colorectal polyps (a surrogate endpoint for colorectal cancer) between the five quintiles of serum selenium [levels]," the study did not provide evidence of a relationship between selenium and a reduced risk of colorectal cancer. (FDA Resp. at AR 001984.) Upon review of this study, the Court concludes that the FDA's determination that this study does not constitute credible evidence in support of plaintiffs' claim is unreasonable and unsupported by the findings of the study. The study concluded that "[o]verall, higher serum selenium levels were inversely associated with reduced risk of advanced colorectal adenoma." (AR 002910.) In particular, the authors noted that men in "the highest quintile of selenium had 43% lower risk for advanced colorectal adenoma compared with men in the lowest quintile." (AR 002909.) The authors later stated that "[f]indings from our study [and another study] particularly support inverse association [between selenium and] advanced adenoma." (AR 002912.) These findings are squarely at odds with the FDA's conclusion that the study showed no significant difference

in adenomas across the various levels of selenium. Therefore, the Court finds that the Peters study was unreasonably discounted as credible evidence.

The Agency excluded several studies because they are "retrospective," meaning that they measured selenium intake after the subjects "had already been diagnosed with the disease." (Defs.' Mot. at 43.) Because the health status of subjects can have an effect on selenium measurements, the FDA concluded that it could not determine whether the lowered selenium levels observed in these studies were caused by the cancer or by the participants' nutrient intake. (*Id.*) The Court defers to the FDA's position with respect to retrospective studies generally and its determinations regarding the Clark, Fernandez-Barnares, and Jasckiwicz studies, which appear reasonable and consistent with the Agency's Guidance Document. However, the Agency's explanation for exclusion is inapposite with respect to the Ghadrian study. There, the authors measured toenail selenium because it is "the best measure of assessing long-term dietary selenium." (AR 003844.) They then noted that in their study, "toenail selenium represents the dietary selenium intake *prior to the diagnosis* of cancer, as toenails were collected mainly before the final diagnosis or major treatment." (*Id.* (emphasis added).) The study found a "significant inverse association . . . between toenail selenium levels and the risk of colon cancer." (AR 003841.) The Court concludes that the FDA's exclusion of this study from its evaluation of plaintiffs' claim because it is retrospective was unreasonable, given the clear representations in the study as to the nature of the selenium intake observed.

The FDA's rejection of the Schrauzer, Das, and Wei publications is consistent with the Agency's guidance, discussed previously, regarding review articles and studies of nutritionally-deficient populations. However, it is difficult to discern the logic in the FDA's decision to exclude from its evaluation of plaintiffs' digestive tract claim studies the Agency relied on for

scientific conclusions concerning other of plaintiffs' claims (*e.g.*, the Criqui et al. study; the Ringstad et al. study, and the Willet et al. study). (FDA Resp. at AR 001983-001985.) Although the Criqui and Willet studies showed an inverse relationship between selenium and gastrointestinal cancer (AR 002248, 003278), the FDA excluded them from consideration of plaintiffs' claim because they do not include information about the site-specific gastrointestinal cancers measured. (FDA Resp. at AR 001983-001984.) "Gastrointestinal" cancers are "digestive tract" cancers, at least according to the National Institutes of Health's National Cancer Institute (NCI), on which the FDA relies heavily in defining and categorizing cancers. (*See id.* at AR 001962 ("Cancer is categorized into different types based on specific organ and tissue sites (National Cancer Institute).") NCI defines "digestive tract" as "[t]he organs through which food and liquids pass when they are swallowed, digested, and eliminated. These organs are the mouth, esophagus, stomach, small and large intestines, and rectum and anus."[27] NCI's definition of gastrointestinal ("[r]efers to the stomach and intestines")[28] thus suggests that gastrointestinal cancers are a subset of digestive tract cancers, meaning that a reduced risk of gastrointestinal cancers necessarily constitutes a reduced risk of digestive tract cancers. Therefore, the failure of the Criqui and Willet studies to specify the gastrointestinal cancers observed is irrelevant to whether they are credible evidence in support of plaintiffs' claim.[29] The Court therefore finds that the FDA erred when it excluded these studies.

---

[27] National Cancer Institute, Dictionary of Cancer Terms, *available at* http://www.cancer.gov/dictionary/?CdrID=46447 (last visited May 26, 2010).

[28] National Cancer Institute, Dictionary of Cancer Terms, *available at* http://www.cancer.gov/dictionary/?CdrID=45692 (last visited May 26, 2010).

[29] To the extent the Agency fears that consumers hoping to prevent a type of digestive tract cancer other than a gastrointestinal cancer will be misled by the claim, qualifying language can be used to limit the claim's scope. *See Pearson I*, 164 F.3d at 659 (government's interest in

In sum, based on its examination of the scientific literature and the FDA's response to plaintiffs' petition, the Court finds that the FDA's decision to ban plaintiffs' colon and digestive tract claim because there is no credible evidence in support of it "is unreasonable because it is not supported by a review of the available evidence or the FDA's own Guidance Report." *See Whitaker*, 248 F. Supp. 2d at 13. Indeed, it appears that credible evidence (*e.g.*, the Peters, Ghadrian, Criqui, and Willet studies) does support this claim. As such, complete suppression of the claim is unwarranted. *See Whitaker*, 248 F. Supp. 2d at 10; *see also Pearson I*, 164 F.3d at 658-59; *Pearson II*, 130 F. Supp. 2d at 114. The Court will remand this claim to the Agency for reconsideration and, if needed, appropriate qualifying language.

III. FDA'S QUALIFICATION OF PLAINTIFFS' PROSTATE CLAIM

After reviewing the scientific literature submitted with plaintiffs' petition, the FDA concluded that it could draw scientific conclusions regarding plaintiffs' prostate claim from eight observational studies and one intervention study. (FDA Resp. at AR 001989.) Of these, the Agency determined that two nested case-control studies suggested that selenium may reduce the risk of prostate cancer. (*Id.* at AR 001989-001990.) However, the FDA rejected plaintiffs' proposed claim because it found the characterization of the evidence in support of the claim as "convincing but not yet conclusive" to be false and misleading. (*Id.* at AR 001993.) Instead, the Agency stated that it would exercise enforcement discretion with respect to the following qualified health claim: "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

---

preventing labels that do not include material information "would seem to be satisfied-at least ordinarily-by inclusion of a prominent disclaimer").

risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer." (*Id.*)

The Court agrees with plaintiffs' contention that the FDA's proposed claim is at odds with the Supreme Court's mandate that there be a "reasonable fit" between the government's goal and the restrictions it imposes on commercial speech. *See Pearson I*, 164 F.3d at 656 n.5 (quoting *State University of New York v. Fox*, 492 U.S. 469, 480 (1989)). The Agency has not drafted a "precise disclaimer" designed to qualify plaintiffs' claim while adhering to the "First Amendment preference for disclosure over suppression," as mandated. *Pearson I*, 164 F.3d at 658-59. Rather, it has replaced plaintiffs' claim entirely. And the Agency's "qualification" effectively negates any relationship between prostate cancer risk and selenium intake. Indeed, the FDA's language is an example of a "disclaimer" that "contradict[s] the claim and defeats the purpose of making [it] in the first place." (Defs.' Reply at 11.) While such language might be appropriate were there no credible evidence in support of a positive relationship between prostate cancer risk and selenium intake, the Agency concedes that there is such evidence. (FDA Resp. at AR 001986, 001990.) As such, the FDA is obligated to at least consider the possibility of approving plaintiffs' proposed language with the addition of "short, succinct, and accurate disclaimers." *Pearson II*, 130 F. Supp. 2d at 120. Here, the FDA has completely eviscerated plaintiffs' claim, with no explanation as to why a less restrictive approach would not be effective. For instance, to the extent that the FDA takes issue with the proposed "convincing but not yet conclusive" claim, the Agency makes no attempt to demonstrate that this concern would not be accommodated by altering this portion of the claim with language that more accurately reflects the strength of the scientific evidence at issue. Such qualification would be a "far less restrictive means" than negation of plaintiffs' claim. *Pearson I*, 164 F.3d at 658.

Moreover, in light of its review of the scientific literature, the Court finds that the Agency's "disclaimer" is inaccurate. For example, the FDA concluded that the Li et al. study showed "no significant difference in plasma selenium levels between cancer-free controls . . . and prostate cancer cases" and "no significant relationship between plasma selenium levels and prostate cancer risk." (FDA Resp. at AR 001986.) Yet, the studies' authors stated that they "found a statistically significant inverse association between pre-diagnostic plasma selenium levels and the risk of advanced prostate cancer." (AR 001697.) Further, among men with "increased PSA levels at baseline," the authors found that "higher levels of selenium were associated with a reduced risk of all prostate cancer." (*Id.*) The FDA argues that the Li study does not support plaintiffs' claim because the statistically significant relationship between selenium and cancer risk appeared only when the investigators "stratified the subjects into five groups based on the pre-diagnostic plasma selenium levels and compared the highest group to the lowest." (Defs.' Mot. at 38.) Yet, the purported absence of a significant difference in cancer risk "between the five quintiles of serum selenium" was the very reason the Agency excluded a study in the evaluation of plaintiffs' colon and digestive tract claim. (FDA Resp. at AR 001984.) Such inconsistency is unreasonable. Even if the FDA determines the study evidences only a limited reduction in risk in certain subgroups (Defs.' Mot. at 38), the Court concludes that the Agency erred in finding that the study "show[s] no reduction in [prostate cancer] risk."

In short, the FDA's replacement of plaintiffs' claim with different and contradictory language is inconsistent with the spirit, if not the letter, of *Pearson I*. The FDA has failed to justify the complete substitution of new language for plaintiffs' proposed claim, especially since it appears that the Agency's central objection to the claim concerns the nature of the qualifying language, not the underlying relationship claim. Additionally, although the Court has not

conducted a complete review of the Agency's analysis of the scientific evidence submitted in support of this claim,[30] the Agency's replacement claim mischaracterizes at least one study (Li et al), suggesting that the FDA's proposed claim is inaccurate. As such, the Court will remand plaintiffs' prostate claim to the FDA for the purpose of reconsidering the scientific literature and drafting one or more short, succinct, and accurate disclaimers in light of that review.

CONCLUSION

Plaintiffs' motion for summary judgment is granted in part and denied in part, and defendants' cross-motion for summary judgment is denied. This case is remanded to the FDA for the purpose of 1) drafting one or more disclaimers to accompany plaintiffs' certain cancers, anticarcinogenic, and prostate claims, or, alternatively, setting forth empirical evidence that any disclaimer would fail to correct the claims' purported misleadingness; 2) determining an appropriate disclaimer to accompany plaintiffs' lung and respiratory tract claim in light of the SU.VI.MAX study; and 3) reevaluating plaintiffs' colon and digestive tract claim and drafting one or more disclaimers.

The Court denies plaintiffs' motion to the extent it seeks an order enjoining the FDA from precluding plaintiffs from placing their proposed health claims on dietary supplement labeling. (Pls.' Mot. at 43.) It is not for this Court to pass judgment on the validity of plaintiffs' proposed qualifying language in the first instance, *see Pearson I*, 164 F.3d at 659, nor can the Court rule out the possibility that "the government could demonstrate with empirical evidence that disclaimers . . . would bewilder consumers and fail to correct for deceptiveness." *Id.* at 659-60. To that end, the Court remands the claims at issue to the Agency for further review and

[30] Because the Court remands this claim to the FDA on the basis of the Agency's complete substitution of plaintiffs' proposed claim, it did not need to review all of the studies excluded or relied on by the FDA in evaluating plaintiffs' claim.

action consistent with this Memorandum Opinion. Although the Court is limited in its ability to mandate that the Agency act by a specific date, *see Consumer Fed'n of Am. and Pub. Citizen v. United States Dep't of Health and Human Servs.*, 83 F.3d 1497, 1506-07 (D.C. Cir. 1996), the Court expects that the FDA will act with reasonable speed in reviewing the proposed claims and drafting disclaimer language. *See Whitaker*, 248 F. Supp. 2d at 17 n.20.

/s/
ELLEN SEGAL HUVELLE
United States District Judge

DATE: May 27, 2010