**UNITED STATES DISTRICT COURT**
**DISTRICT OF CONNECTICUT**

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| **FLEMINGER, INC.,** | : | |
| **PLAINTIFF,** | : | |
| | : | **CIVIL ACTION NO. 3:10cv855 (VLB)** |
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| **v.** | : | **FEBRUARY 23, 2012** |
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| **U.S. DEPARTMENT OF HEALTH AND** | : | |
| **HUMAN SERVICES, ET AL.,** | : | |
| **DEFENDANTS** | : | |

**MEMORANDUM OF DECISION GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND GRANTING IN PART AND DENYING IN PART DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT [Dkt. ## 36, 37]**

**Plaintiff, Fleminger, Inc. ("Fleminger"), a manufacturer and retailer of green tea brings this action against the U.S. Department of Health and Human Services ("DHHS"), Kathleen Sebelius in her official capacity as Secretary of DHHS, the U.S. Food and Drug Administration ("FDA"), and Margaret Hamburg, M.D., in her official capacity as Commissioner of the FDA. Fleminger filed a petition with the FDA for authorization of certain qualified health claims regarding green tea on its products labeling. The FDA exercised its enforcement discretion requiring Fleminger to include a modified disclaimer to its qualified health claim that drinking green tea "may reduce the risk of breast or prostate cancer." Fleminger alleges that Defendants violated its commercial speech rights under the First Amendment by requiring Fleminger to include the modified disclaimer to its health claim. Both Fleminger and Defendants have moved for summary judgment. For the foregoing reasons, Plaintiff's motion for summary judgment is**

**granted in part and denied in part and Defendants' cross motion for summary judgment is granted in part and denied in part.**

## I. Background

**The current case challenging the FDA's regulation of marketing claims regarding the health benefits for food under the First Amendment is closely related to a progression of similar cases challenging the FDA's regulation of health claims for dietary supplements under the First Amendment in the District of Columbia. In response to these cases, the FDA has developed a system for considering so called "qualified health claims" which it applies to both food products and dietary supplements. [Dkt. #37, Def. Mem. at 6].**

**This is a case of first impression in this Circuit as neither party cites and this Court has not found any Second Circuit authority on point analyzing the FDA's qualified health claim process under the First Amendment. The D.C. Circuit and district court cases provide the most pertinent analysis and guidance on this rather unique issue. Before turning the particular facts and issues in dispute in the present case, it is necessary to first review these prior D. C. Circuit and district court cases as well as the statutory and regulatory framework underlying the FDA's power to regulate such health claims.**

### *i. Legal Standard for Evaluating Commercial Speech Claims*

**Since health claims regarding both food products and dietary supplements are commercial speech, the FDA's regulation of such claims is evaluated under the multi-step framework established in *Central Hudson Gas &***

***Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557 (1980) and as later elaborated in *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002). As a "threshold matter," the Court must determine "whether the commercial speech concerns unlawful activity or is misleading. If so, then the speech is not protected by the First Amendment." *Western States*, 535 U.S. at 367.**

**However, 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 the government interest is substantial, then the Court must determine "whether the regulation directly advances the governmental interest asserted" and finally "whether [the regulation] is not more extensive than is necessary to serve that interest." *Id.* (quoting *Central Hudson*, 447 U.S. at 566). The last step requires an evaluation of "whether the fit between the government's end and the means chosen to accomplish those ends is not necessarily perfect, but reasonable." *Pearson I*, 164 F.3d at 656 (internal quotation marks and citation omitted). A "reasonable fit" is not a "least restrictive means" test, *Clear Channel Outdoor, Inc. v. City of New York*, 594 F.3d 94, 104 (2d Cir. 2010), and thus courts do not ask where there is "no conceivable alternative" but instead require that the "regulation not burden substantially more speech than is necessary to further the government's interests." *Bd. of Trs. of the State Univ. of N.Y. v. Fox*, 492 U.S. 469, 478 (1989). "[I]f the Government c[an] achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Western States*, 535 U.S. at 371. 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." *Alliance II*, 786 F.Supp.2d at 13 (quoting *Western States*, 535 U.S. at 371).**

**Plaintiff argues that the Supreme Court's recent decision in *Sorrell v. IMS Health Inc.*, 131 S.Ct. 2653 (2011) altered or modified the traditional framework for evaluating commercial speech. *See* [Dkt. # 41, Pl. Opposition Mem. at 9, 9 n.5]. Plaintiff argues that under *Sorrell* the government must demonstrate more than just a reasonable fit between the government's ends and the means chosen to accomplish those ends and suggests that *Sorrell* overturned the Supreme Court's prior holding in *Fox*. In *Fox*, the Supreme Court expressly rejected the proposition that government restrictions on commercial speech need to be the absolute least restrictive means to achieve the desired end and instead held that such restrictions require only a reasonable fit. *Fox*, 492 U.S. at 477-78. Plaintiff bases its argument solely on the fact that the majority in *Sorrell* never used the word "reasonable" in connection with its analysis of the fit between the government's means and ends and at one point noted that the statute at issue "at least" must directly advance the substantial government interest. [Dkt. #41, Pl. Opposition Mem at 0, 9 n.5].**

**The Court is not persuaded that the Supreme Court's decision in *Sorrell* altered the traditional scrutiny applied under the *Central Hudson* framework and overturned *Fox*'s holding. The majority's opinion in *Sorrell* expressly relied on the Supreme Court's prior articulation of the standard for evaluating commercial speech claims in *Central Hudson*, *Western States* and *Fox*. *See Sorrell*, 131.Ct. at**

**2667-68 ("To sustain the targeted, content-based burden § 4631(d) imposes on protected expression, the State must show at least that the statute directly advances a substantial government interest and that the measure is drawn to achieve that interest. There must be a 'fit between the legislature's ends and the means chosen to accomplish those ends.'") (quoting *Fox*, 492 U.S. at 480). The majority in *Sorrell* cited to *Fox* for the proposition that "there must be a fit between the legislature's end and the means chosen to accomplish those ends." *Sorrell*, 131 S.Ct. at 2667-68. The fact that the majority did not use the word "reasonable" when it cited to *Fox* for the proposition that there must be a fit between the government's means and ends does not indicate that the Supreme Court mutely overturned well-established and long standing precedent. Moreover, the *Sorrell* court's focus was on the subject restrictions lack of neutrality and lack of any fit reasonable or otherwise with its stated purpose.**

**Further, under the traditional framework as articulated in *Central Hudson*, *Western States* and *Fox*, the government's restriction on speech must directly advance the governmental interest asserted. The use of the words "at least" by the majority in *Sorrell* does not alter or change any part of the traditional commercial speech analysis under this long standing precedent. *See Fox*, 492 U.S. at 474 (noting that under *Central Hudson*, the Court "must determine whether the regulation directly advances the governmental interest asserted"). Moreover, it is unlikely that the Supreme Court would directly overturn a prior holding and drastically alter the level of scrutiny afforded under a foundational constitutional analysis without a thorough and comprehensive discussion heralding such an**

**elemental change to the long standing and well-established constitutional framework. The decision in *Sorrell* did not impact the traditional framework for evaluating commercial speech under the First Amendment and accordingly the government must demonstrate a reasonable fit between its ends and the means chosen to accomplish those ends. The government is therefore not obligated to demonstrate that its restriction is the least restrictive means to achieve its ends.**

***ii. Statutory and Regulatory Framework***

**To determine the disputed issues, the Court must consider the statutory and jurisprudential context in which they arise. In 1990, Congress enacted the Nutrition Labeling and Education Act of 1990 ("NLEA") Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified as amended at 21 U.S.C. §§ 301, 321, 337, 343, 34-1, 345, 371) which amended the Food, Drug and Cosmetic Act ("FDCA") to provide the FDA with authority to regulate health claims on food including dietary supplements. Before NLEA was enacted, a food intended for use in the diagnosis, cure, mitigation, treatment or prevention of a disease would fall within the FDCA's definition of a drug and become subject to the FDA's requirements for drug approval and labeling. *See Pearson v. Shalala*, 164 F.ed 650, 652-3 (D. C. Cir. 1999) ("*Pearson I*"); 21 U.S.C. § 321 (g)(1)(B). NLEA created a "safe harbor" from drug designation for foods labeled with health claims. *See Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp.2d 48, 41 (D.D.C. 2010) ("*Alliance I*"); *see also* 21 U.S.C. § 343(r)(1). "Under NLEA, 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." *Alliance for Natural Health U.S. v. Sebelius*, 786 F.Supp.2d 1, 4 (D.C.C. 2011) ("*Alliance II*") (quoting 21 U.S.C. § 343(r)(3)(B)(i)). The FDA subsequently promulgated a regulation adopting NLEA's "significant scientific agreement" standard for food health claims to dietary supplement claims. *Id.* (citing 21 C.F.R. §101.14(c)).**

**Under the FDCA, a food labeled with an unauthorized health claim may be considered a misbranded food. See 21 U.S.C. § 343(r)(1)(B) (providing that a food shall be deemed to be misbranded if its "(1) labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title."). A product labeled with a claim that is false or misleading is subject to seizure and the FDA may enjoin the product's distribution or seek criminal penalties against its manufacturer. *See Alliance II*, 786 F.Supp.2d at 5 (citing 21 U.S.C. §§ 331(a), 332, 334, 352(a)).**

***iii. Pearson I***

**After enactment of NLEA, the FDA declined to authorize petitions for health claims that did not meet the significant scientific agreement ("SSA") standard. The FDA reasoned that if a health claim was not supported by significant scientific agreement such claim was "inherently misleading and thus entirely outside the protection of the First amendment" as commercial speech. *See Pearson I*, 164 F.3d at 655. The D.C. Circuit in *Pearson I* considered whether the FDA had violated the First Amendment because it had precluded "the approval of**

**less-well supported claims accompanied by a disclaimer." *Id.* at 654. The FDA had declined to consider the alternative of requiring corrective disclaimers for claims that did not meet the SSA standard arguing that even if the proposed disclaimers were only potentially misleading under *Central Hudson* the government was "not obligated to consider requiring disclaimers in lieu of an outright ban on all claims that lack significant scientific agreement." *Id.* at 655.**

**Applying the commercial speech test set forth in *Central Hudson, the Pearson I* Court concluded 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" which was the rejection of a proposed health claim without consideration of a corrective disclaimer. *Pearson I*, 164 F.3d at 656-58. The D.C. Circuit's rationale was based on its conclusion that under the commercial speech doctrine there "was a preference for disclosure over outright suppression" and for the "less restrictive and more precise means" of regulating commercial speech. *Id.* at 656-58. In analyzing recent Supreme Court precedent in similar arenas, the *Pearson I* court concluded that "disclaimers [were] constitutionally preferable to outright suppression." *Id.* at 657.**

**The FDA was therefore required under the First Amendment to consider the adequacy of possible disclaimers which would have the effect of preventing consumer confusion and present claims in a way that was not deceptive. *Id.* at 656-60. The court concluded that well-drafted disclaimers could remedy any supposed weakness in the proposed claims.**

**The *Pearson I* court proposed several examples of such corrective disclaimers in connection with the appellants' proposed claims at issue in *Pearson I*. Appellant's first proposed claim was that "[c]onsumption of antioxidant vitamins may reduce the risk of certain kinds of cancer." *Id.* at 658. The FDA had determined that this claim lacked significant scientific agreement "because existing research had examined only the relationship between consumption of foods containing these components and the risks of these diseases. The FDA logically determined that the specific effect of the *component* of the food constituting the dietary supplement could not be determined with certainty." *Id.* (emphasis in the original). The court suggested that this concern could be accommodated by "adding an appropriate disclaimer to the label along the following lines: 'The evidence is inconclusive because existing studies have been performed with *foods* containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods.'" *Id.***

**The *Pearson I* court also suggested a clarifying disclaimer for appellants' fourth proposed claim that "'0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form'" which the FDA had concluded was not supported by significant scientific agreement because "'the scientific literature does not support the superiority of any on source [of folic acid] over others.'" *Id.* at 658-9. The *Pearson I* court stated that they "suspect[ed] that a clarifying disclaimer could be added to the effect that 'The evidence in support of this claim is**

**inconclusive.'" In addition, the court suggested that if the FDA is concerned that the "consumers might assume that a claim on a supplement's label is approved by the government" then the FDA might "require the label to state that 'The FDA does not approve this claim.'" *Id.***

**However, the D.C. Circuit did not create a safe harbor. Instead it stated that it did not "presume to draft precise disclaimers" for the proposed claims itself and instead expressly left that "task to the agency in the first instance." *Id.* at 660. The court also recognized 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." *Id.* at 659. In addition, it saw "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.**

**Lastly, the court considered whether the Administrative Procedures Act ("APA") required the FDA to "explain why it rejects [] proposed health claims [and whether] to do so adequately necessarily implies giving some definitional content to the phrase 'significant scientific agreement.'" *Id.* at 660. The court concluded that "[i]t simply will not do for a government agency to declare-without explanation-that a proposed course of private action is not approved" and held that the "FDA must explain what it means by significant scientific agreement, or at minimum what it does not mean." *Id.* at 661.**

### *iv. Pearson II*

**After considering the *Pearson I* decision, the FDA issued a guidance document regarding significant scientific agreement. The FDA also issued a subsequent decision stating that it would not authorize a proposed folic acid claim even with clarifying disclaimers because it had found the claim to be inherently misleading as the weight of scientific evidence was against the claim. *See Pearson v. Shalala*, 130 F.Supp.2d 105, 107 (D.D.C. 2001) ("*Pearson II*"). In *Pearson II*, the court found that the FDA had failed to comply with the constitutional guidelines outlined in *Pearson I* when it concluded that the weight of evidence was against the proposed claim and could not be corrected by an appropriate disclaimer. *Id.* at 112,114. After reviewing the scientific data, the court concluded that the proposed claim was not inherently misleading since "[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. Lastly, the court indicated that the "question that must be answered under *Pearson* [*I*] is whether there is any 'credible evidence'" in support of the proposed claim. *Id.* at 114, 118. The court reasoned that if there was any "credible evidence" unless such evidence was "outweighed by evidence against the claim" or is "qualitatively weaker" than evidence against the claim, the claim could "not be absolutely prohibited." *Id.* at 114-15. The court therefore found that the FDA's conclusion that the proposed claim could not be remedied by appropriate disclaimers was arbitrary and capricious and remanded the case to the FDA to**

**"draft one or more appropriately short, succinct, and accurate disclaimers." *Id.* at 120.**

***v. Whitaker v. Thompson***

**In June 2001, the plaintiffs in *Pearson* filed another lawsuit challenging the FDA's decision to not authorize an antioxidant claim that had been at issue in *Pearson I*. *Whitaker v. Thompson*, 248 F.Supp.2d 1 (D.D.C. 2002). The FDA had concluded that "the weight of the scientific evidence against the relationship [between cancer and and antioxidant vitamins] was greater than the weight of evidence in favor of the relationship." The FDA reasoned that such claim was therefore "inherently misleading" and could not be cured with a disclaimer. *Id.* at 7. After reviewing the relevant scientific data, the court found that the proposed claim was not "inherently misleading" and that the "FDA ha[d] failed to carry its burden of showing that suppression of Plaintiffs' Antioxidant Vitamin Claim is the least restrictive means of protecting consumers against the potential of being misled by the Claim." *Id.* at 8. The *Whitaker* Court suggested 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." *Id.* at 11. The Court directed the FDA to "draft and submit one or more alternative disclaimers, one of which may be selected by designers, sellers and manufacturers of dietary supplements containing antioxidant vitamins" noting that the FDA's decision to**

**entirely suppress the claim did not "comport with the First Amendment's clear preference for disclosure over suppression of commercial speech." *Id.* at 8, 15.**

***vi. The FDA's Response to Pearson I, Pearson II and Whitaker***

**In response to the decisions rendered in *Pearson I, Pearson II* and *Whitaker*, the FDA developed a system for evaluating proposed health claims. Under this system, the FDA first determined whether the proposed health claim was supported by significant scientific agreement. If it was, the FDA considered the claim to be "unqualified" and it approved the claim without requiring the addition of any corrective disclaimers. However, if the claim was not supported by significant scientific agreement, but there was credible evidence in support of the claim, the FDA considered the claim to be "qualified" and would require the addition of corrective disclaimers to the claim to reflect the scientific record. Since the FDA is only authorized to approve claims that are supported by significant scientific agreement under NLEA and the FDA's regulations, it does not "approve" qualified health claims but instead "exercises enforcement discretion" to allow such claims to made with the additional of corrective disclaimers. *See* [Dkt. #37, Def. Mem. at 6].**

**The FDA also issued a guidance document which describes its process for evaluating the scientific support for both qualified and unqualified health claims. *See* Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation for Health Claims (Jan. 2009) ("Guidelines").[1] According to the**

[1] **Available at http://www.fda.gov/Food/GuidanceComplianceRegulatory**

**Guidelines, the FDA employs an evidence-based review system for the scientific evaluation of health claims. *See* Guidelines at §III.A. "After assessing the totality of the scientific evidence, FDA determines whether there is SSA to support an authorized health claim or credible evidence to support a qualified health claim." *Id.* "When the evidence for a substance-disease relationship is credible but does not meet the SSA standard, then the proposed health claim for the relationship should include qualifying language that identifies limits to the level of scientific evidence to support the relationship." *Id.* at III.H. The Guidelines indicate that the "health claim language should reflect the level of scientific evidence with specificity and accuracy. However, gaps in the scientific evidence may sometimes limit the information that can be included in the claims. For example, when the scientific evidence is limited but credible, it may not be possible for the qualified health claim to identify an amount of the substance that is associated with a reduced risk of the disease." *Id.***

***vii. Alliance I***

**In *Alliance I*, the plaintiffs challenged the FDA's rejection of certain health claims regarding cancer risk and selenium supplements. 714, F.Supp.2d at 57. The FDA outright banned several of plaintiffs' claims concluding there was no credible scientific evidence to support them and then exercised its enforcement discretion to permit modified versions of the claims that were supported by some credible evidence. *Id.* at 57-78.**

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**Information/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm**

**In connection with the FDA's decision to entirely ban certain health claims, the court reviewed the record to determine whether the FDA's determination that those claims at issue were not supported by credible scientific evidence was arbitrary and capricious. The Court concluded that while it was "obligated to conduct an independent review of the record and must do so without reliance on the Agency's determinations as to constitutional questions" that it should afford "deference to the Agency's interpretation of scientific information, provided such interpretation is reasoned and not arbitrary and capricious." *Id.* at 60. The Court found that certain aspects of the FDA's determinations were arbitrary and capricious while other aspects were not and remanded those back to the FDA for reevaluation and drafting of disclaimers where appropriate. *Id.* at 65, 72.**

**The plaintiffs also argued that the FDA's decision to modify one of their proposed claims by entirely replacing the proposed language with its own language violated the Supreme Court's mandate there be a reasonable fit between the government's goal and the restrictions it imposes on commercial speech. The plaintiffs had proposed the following claim "Selenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive." *Id.* at 57. The FDA rejected this 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 70-71. Consequently the FDA, in exercising its enforcement discretion, modified the claim to the following "'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.'" *Id.***

**The court agreed with the plaintiffs that there was not "a reasonable fit" because 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." *Id.* at 71 (internal quotation marks and citation omitted). The Court emphasized that the FDA had "replaced the 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 contradicts the claim and defeats the purpose of making it in the first place." *Id.* (internal quotation marks and citation omitted). The Court suggested that where there is some credible evidence for a substance-disease relationship the FDA "is obligated to at least consider the possibility of approving plaintiffs' proposed language with the addition of 'short, succinct, and accurate disclaimers.'" *Id.* (quoting *Pearson II*, 130 F.supp. 2d at 120). Consequently, the FDA was found to have "completely eviscerated plaintiffs' claim, with no explanation as to why a less restrictive approach would not be effective." *Id.***

**The *Alliance I* Court suggested the better approach might have been to alter the "convincing but not yet conclusive" portion of the proposed claim to "more accurately reflect[] the strength of the scientific evidence at issue. Such qualification would be a 'far less restrictive means' than negation of the plaintiffs'**

**claim." *Id.* In sum, the Court found that the "FDA's replacement of plaintiffs' claim with different and contradictory language is inconsistent with the spirit, if not the letter, of *Pearson I*" and that the "FDA ha[d] 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." *Id.* at 72. This claim was consequently remanded to the FDA for the purpose of drafting one or more short, succinct, and accurate disclaimers.**

***viii. Alliance II***

**The same plaintiffs in *Alliance I* raised a substantially identical challenge to the FDA's rejection of several different proposed health claims and the FDA's rewording of two of their proposed claims. The court in *Alliance II* again noted that since it "is not in the position, nor is it the Court's role, to independently assess, whether the scientific evidence evaluated by the FDA constitutes credible evidence in support of plaintiffs' claims," the court's inquiry into the propriety of the FDA's ban on several proposed claims was limited to "an assessment of whether the FDA's evaluation was inconsistent with its own standards, irrational or arbitrary and capricious." *Alliance II*, 786 F. Supp. 2d at 16. The Court concluded that the FDA's conclusion that plaintiffs proposed claims were not supported by credible evidence was reasonable and not arbitrary and capricious.**

**As was the case in *Alliance I*, the FDA had completely reworded and replaced two of plaintiffs' qualified health claims in an identical manner to the**

**claims at issue in *Alliance I*. The court found these modified claims failed for the same reasons as articulated in *Alliance I*. The *Alliance II* court emphasized that the FDA's replacement and complete rewording of Plaintiffs' claims made it "difficult to tell what the original health claims are and appears to disavow the FDA's own conclusions that those claims are supported by credible evidence." *Id.* at 24.**

**The court interpreted *Pearson* and its progeny as standing for the proposition that "[w]here the evidence supporting a claim is inconclusive, the First Amendment permits the claim to be made; the FDA cannot require a disclaimer that simply swallows the claim." *Id.* The court suggested that in such cases where there is some credible evidence supporting a possible substance-disease relationship that the FDA should allow the claim regarding the substance-disease relationship to be made. The FDA's role and focus should then be directed to drafting or modifying a disclaimer "regarding the strength or nature of the evidentiary support for [the] health claim." *Id.* at 24 n.22.**

## II. Factual and Procedural History

**Fleminger originally submitted a health claim petition to the FDA dated January 27, 2004 which was supplemented on May 21, 2004 requesting the FDA to authorize the following health claim: "Daily consumption of 40 ounces of typical green tea containing 710 µg/ml of natural (-) -epigallocatechin gallate (EGCG) may reduce the risk of certain forms of cancer. There is scientific evidence**

**supporting this health claim although the evidence is not conclusive." *See* (Administrative Record ("AR'") at 1, 2102).**

**On June 30, 2005, the FDA issued a response letter informing Fleminger that after its review it would exercise its enforcement discretion for qualified health claims regarding the consumption of green tea and a reduced risk of breast and prostate cancer. The FDA concluded that there was not "credible evidence to support a claim with respect to all other types of cancer." (AR 2216-2235).**

**In the response letter, the FDA evaluated the strength of the scientific evidence to support the substance-diseases relationship. With respect to breast cancer, the FDA explained that three studies provided information about whether green tea may reduce the risk of breast cancer. The FDA noted that "[a]lthough two Japanese cohort studies found no association between green tea consumption and breast cancer… one-case control study reported that, with green tea consumption, there was a reduction in breast cancer risk in Asian-Americans from California." (AR 2229). On the basis of these studies, the FDA concluded there was "very limited credible evidence for a qualified health claim specifically for green tea and breast cancer." The FDA noted that the reported findings of the one-case control study "had not been replicated" and explained that "replication of scientific findings is important to substantiate results." In addition, the FDA noted that "consistency of findings among similar and different study designs is important for evaluating the strength of scientific evidence." (*Id.*). The FDA also indicated that "prospectively designed studies provide**

**stronger evidence for an association than case-control studies since there are fewer forms of bias." (*Id.*). Based on its review of the "strength of the total body of publicly available scientific evidence for a claim about green tea and reduced risk of breast cancer, FDA rank[ed] this evidence as the lowest level for a qualified health claim" and concluded that it was "highly unlikely that green tea reduces the risk of breast cancer." (AR 2230).**

**With respect to prostate cancer, the FDA explained that two studies provided information about whether green tea may reduce the risk of prostate cancer. (*Id.*). The FDA noted that these studies involved two case-control studies from China and Japan and each of the studies "were small (fewer than 150 cases each) in size and both received high methodological quality ratings." (*Id.*). The Japanese study reported no association while the Chinese study "reported a decrease in prostate cancer risk with green tea intake." (*Id.*). Based on these two studies the FDA concluded there was "very limited credible evidence for a qualified health claim specifically for green tea and prostate cancer." (*Id.*). The FDA noted that the reported findings of the Chinese study have not been replicated and that prospectively designed studies provide for stronger evidence for an association than case-control or retrospectively designed studies since "there are fewer forms of bias." (*Id.*). Based on its review of the "strength of the total body of publicly available scientific evidence for a claim about green tea and reduced risk of prostate cancer, FDA rank[ed] this evidence as the lowest level for a qualified health claim" and concluded that it was "highly unlikely that green tea reduces the risk of prostate cancer." (*Id.*).**

**The FDA informed Fleminger that it would consider exercising enforcement discretion for the following qualified health claims:**

> **(i) Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer; and**
>
> **(ii) One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer.**

**(AR 2235).**

**In response, Fleminger sought administrative reconsideration on August 5, 2005 pursuant to 21 C.F.R. §10.33 asking the FDA to consider the following two qualified health claims:**

> **(i) Drinking green tea equivalent to that consumed by Asian Americans may reduce the risk of breast cancer in women. There is credible evidence supporting this claim although the evidence is limited; and**
> **(ii) Drinking green tea equivalent to that consumed by the residents living in Hangzhou, China may reduce the risk of prostate cancer. There is credible evidence supporting this claim although the evidence is limited."**

**(AR 2473).**

**The FDA responded to Fleminger on August 19, 2008 denying his petition for reconsideration concluding that the petition did "not satisfy the requirements for reconsideration because none of the issues raised in [Fleminger's] petition demonstrates that the agency failed to consider or adequately consider relevant information or views contained in the administrative record as required by 21 CFR §10.33(d)(1)." (AR 2495-2503).**

**On September 10, 2008, Fleminger responded in writing to the FDA's denial of its petition for reconsideration noting its disagreement with the FDA's determination. (AR 2504-2505). Fleminger indicated in its letter that it recognized that the clarification of the "FDA ruling reiterates a qualified green tea health claim language for the Agency's discretion enforcement consideration for the time being as follows: Green tea may reduce the risk of cancer of the break and the prostate. There is credible evidence supporting this claim although the evidence is limited." (*Id.*). However, Fleminger's response was not a formal submission seeking FDA authorization of the new claim and consequently the FDA did not consider or authorize Fleminger's new claim. [Dkt. # 37, Def. Mem. at 10].**

**On February 22, 2010, FDA issued a warning letter advising Fleminger that its websites contained marketing in violation of the FDCA including amongst other items the marketing of several unauthorized health claims. (AR 2590-93). The letter informed Fleminger that the use of unauthorized health claims which were false and misleading rendered the company's products misbranded and that failure to correct the identified violations could lead to enforcement action. (*Id.*). Fleminger responded to the warning letter explaining that it believed the claim "Green tea may reduce the risk of cancer of the breast and the prostate. The FDA has concluded that there is credible evidence supporting this claim although the evidence is limited" had been properly submitted to the FDA in its September 10, 2008 letter. Fleminger explained that since "[t]here have been no objections from the FDA or the FTC in the past 4.5 years since the letters were sent. The**

**undersigned believe[d] the language used in this claim is fully in compliance with the conclusions of the FDA." (AR2594-95).**

**Subsequently on May 27, 2010, the United States District Court for the District of Columbia issued its decision in *Alliance I* finding that the FDA's modified health claim violated the First Amendment. *See supra* Part I.vii. Since the modified health claim at issue in *Alliance I* was substantially similar to the modified health claim the FDA had authorized in the instant case, the *Alliance I* decision prompted the FDA to reconsider Fleminger's prior claim. After such reconsideration, the FDA issued an amended response on February 24, 2011. (AR 2617-50). In the amended response, the FDA concluded that the "scientific support between green tea and reduced risk of breast cancer is negligible, as is the scientific support for a relationship between green tea and reduced risk of prostate cancer." (AR 2637). In light of the recent *Alliance I* decision, FDA informed Fleminger that it would revise the qualified claim language it had previously authorized. The FDA found that Fleminger's proposed disclaimer that "There is credible evidence supporting this claim although the evidence is limited" did "not accurately convey the weakness of the scientific evidence regarding a relationship between green tea and a reduced risk of breast or prostate cancer." (AR 2638).**

**The FDA also explained that based on the presence of the claim "Drinking green tea may reduce the risk of breast or prostate cancer" in food labeling, the FDA was concerned that "consumers are likely to assume that FDA has endorsed the claim and that the claim is supported by reliable scientific evidence." (*Id.*).**

**The FDA pointed to its 2002 study which found that "35% to 57% of consumers, with or without use experience with dietary supplements, mistakenly believe that the government regulates the manufacturing and pre-approves the marketing of these products." (*Id.*). The FDA concluded that "this risk of consumer deception is particularly acute where, as here, the scientific support for the claim is scant, and thus there is a very low likelihood that the substance actually may reduce the risk of the disease. Under these circumstances, a strong disclaimer is essential in order to make clear that the FDA does not endorse the claim and that there is very little scientific evidence for the claim." (AR 2639). The FDA indicated that the proposed disclaimer which "characterizes the evidence as 'credible' but 'limited' is misleading because it suggests that the evidence is stronger than it really is."**

**Consequently, the FDA considered exercising its enforcement discretion for the following claim: "Green tea may reduce the risk of breast or prostate cancer. FDA does not agree that green tea may reduce the risk because there is very little scientific evidence for the claim." The FDA then explained the rationale for its proposed disclaimer language. The FDA indicated that the language "FDA does not agree" will prevent "consumers from erroneously assuming that the health claim reflects FDA's determination that scientific evidence, taken as a whole, shows that green tea is likely to reduce the risk of breast or prostate cancer." (AR 2640). In addition, the language "there is very little scientific evidence" according to the FDA "accurately conveys the strength of the scientific evidence because it helps consumers distinguish among claims that are**

**supported by different levels of scientific evidence. To be effective, the disclaimer must enable consumers to distinguish between the very limited level of scientific support for the green tea qualified health claim and the stronger level of scientific support for many other qualified health claims, and for health claims that FDA authorizes by regulation." (*Id.*).**

**After the FDA issued its amended response, Fleminger filed the instant action in federal court alleging that the FDA violated the First Amendment when it rejected Fleminger's proposed health claim that "Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded[2] that there is credible evidence supporting this claim although the evidence in limited" and instead modified the claim to the following "Green tea may reduce the risk of breast or prostate cancers. FDA does not agree that green tea may reduce that risk because there is very little scientific evidence for the claim."**

## III. Legal Standard

**Pursuant to Federal Rule of Civil Procedure 56, the Court will grant a motion for summary judgment "if the movant shows that there is no genuine**

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**[2] In the FDA's amended response, the FDA considered the version of Fleminger's proposed disclaimer that was presented by Fleminger in its response to the FDA's denial of its petition for reconsideration. *See* (AR 2504-05). The Court notes that Fleminger presented a slightly different version of the disclaimer in response to the FDA's warning letter. *See* (AR 2594-95). The main difference between the two versions is that the version presented in response to the warning letter includes the additional language that the "FDA has concluded" there is credible evidence supporting this claim although the evidence is limited. Fleminger's motion for summary judgment is predicated on the version of the proposed disclaimer which contains the additional language. Since the Court's analysis is not materially impacted by this additional language, the Court will consider Fleminger's disclaimer with the additional language.**

**dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In this case, there are no disputed issues of fact as each party seeks judgment as a matter of law based on the facts provided in the administrative record.**

**Although Fleminger states in its complaint, that it brings this action under the APA, Fleminger alleges a single cause of action for violation of the First Amendment. See [Dkt. #1, Compl.]. Fleminger argues in its memorandum in opposition to Defendants' cross motion for summary judgment that this case should not be evaluated under the APA's arbitrary and capricious standard and clarifies that its sole cause of action arises under the First Amendment. [Dkt. #42, Pl. Opposition Mem. at 7]. Further, Fleminger never argues that the FDA's conclusion that "there is very little scientific evidence" for the proposed health claim was arbitrary or capricious, it merely argues that its proposed language that "there is credible evidence supporting this claim although the evidence is limited" is better and more preferable and therefore the FDA's preclusion of its right to make the claim violates the First Amendment.**

**If Fleminger had argued that the FDA's determination that "there was very little scientific evidence" for the health claim that drinking green tea may reduce the risk of breast or prostate cancer was erroneous that challenge would be properly analyzed under Section 706(2) of the APA which provides that final agency action may only be set aside if arbitrary, capricious and an abuse of discretion. However, since Fleminger has not challenged the merits of the FDA's**

**assessment of the strength of scientific evidence supporting the proposed health claim, there is no question presented under the APA.**

**As described above, the Court's analysis with respect to whether the FDA violated Fleminger's commercial speech rights under the First Amendment is evaluated under the analytical framework articulated in *Central Hudson* and later elaborated by *Western States*. *See supra* Part I.i. As the *Alliance I* court acknowledged, the Court 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 … 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." 714, F.Supp.2d at 60 (citations omitted).**

**The Court is not in the position, nor is it the Court's role, to independently assess the highly technical scientific data to determine what amount of scientific evidence supports the proposed health claim at issue. Such a determination falls squarely within the ambit of the FDA's expertise and therefore the Court must give deference to the FDA's assessment of the strength of the scientific data at issue. *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."); *Baltimore Gas & Electric Co. v. NRDC*, 462 U.S. 87, 103 (1983) ("reviewing court must generally be at its most deferential" when examining "scientific determination [s]" by administrative agency "within its area of special**

**expertise"); *City of New York v. United States Department of Transportation*, 715 F.2d 732, 645 (2d Cir. 1983) (citing *Baltimore Gas* as defining the "standards circumscribing our role"); *Smith v. Potter*, 187 F.Supp.2d 93, 97 (S.D.N.Y. 2001) ("'It is not the court's role to second-guess scientific judgments of' a governmental agency that is responsible for protecting public health) (quoting *Mazur v. Merck & Co.*, 964 F.2d 1348, 1350 n.1 (3d Cir. 1992)).**

**Although the Court is obligated to give deference to the FDA's assessment of the strength of the scientific evidence for the proposed health claim, such deference does not extend to the determination of whether the FDA's modified disclaimer violated Fleminger's commercial speech rights.**

## IV. Analysis

**Fleminger principally argues that the FDA violated its commercial speech rights because the FDA's interests in regulating its speech are not substantial. Fleminger argues that there are two asserted governmental interests at stake the first being the interest in "accurately conveying the strength of the scientific evidence" and second in "preventing the mistaken assumption that the FDA endorses the claim." *See* [Dkt. # 36, Pl. Mem. at 8]. Fleminger alternatively suggests that there is not an appropriate fit between the government's goal and the restriction it imposed on its commercial speech which in this case is the FDA's revised disclaimer language. Defendants argue that the FDA has a substantial interest in preventing consumer confusion and protecting public health and that the fit between the restriction it imposed on Fleminger's**

**commercial speech and its interest in preventing consumer confusion and public health was reasonable.**

***i. Analysis of whether the government's interests are substantial***

***a. FDA has a substantial interest in preventing consumer confusion and protecting public health***

**Fleminger argues that the FDA's interest in "accurately conveying the strength of scientific evidence" is not substantial in this case because its proposed disclaimer that "[t]here is credible evidence supporting this claim although the evidence is limited" does accurately convey the strength of scientific evidence. *See* [*Id.* at 10]. However this particular argument is misplaced and reflects a misunderstanding of the *Central Hudson* framework. The argument that Fleminger's proposed language does accurately convey the strength of the scientific evidence rather relates to whether there is a reasonable fit between the government's interest in accurately conveying the strength of scientific evidence and the means chosen to accomplish that end as opposed to whether the asserted governmental interest is substantial in the first place. If Fleminger's proposed language already appropriately advanced the asserted governmental interest then the restriction of replacing Fleminger's proposed language with the FDA's modified language is more extensive than necessary to serve that interest. Consequently, Fleminger's argument that the governmental interest in accurately conveying the strength of scientific evidence is not substantial is unpersuasive as it is really an argument that goes to the fit between the government's ends and the means chosen to accomplish those ends. Accordingly, the Court will consider Fleminger's argument that its proposed**

**disclaimer accurately conveys the strength of scientific evidence in its analysis of whether there is a fit between the FDA's ends and the means chosen to accomplish such ends.**

**Although, Fleminger's characterizes the interest as "accurately conveying the strength of the scientific evidence" this interest is more commonly characterized as preventing consumer confusion and protecting public health. It is beyond doubt that the FDA's interest in preventing consumer confusion and protecting public health is a substantial interest which justifies the FDA's imposition of appropriate disclaimers in connection with qualified health claims. The D.C. Circuit in *Pearson I* found that the FDA's substantial interests in protecting public health and preventing consumer fraud were "undeniable" and noted that the "significant questions under *Central Hudson*" concerned the fit between the government interest asserted and the means chosen to accomplish the end. *Pearson I*, 164 F.3d at 656.**

**The FDA's substantial interests in preventing consumer confusion and protecting public health are underscored by the legislative history of NLEA in which Congress expressly granted the FDA authority to approve health claims made on food which were supported by "significant scientific agreement." Congress specifically identified three main governmental interests underlying NLEA: (i) prevention of consumer fraud; (ii) improving public health; and (iii) ensuring that substance-disease claims were supported by significant scientific agreement. Congress expressly stated that the "need for legislation regarding health claims on foods is equally compelling" and noted that "during the mid-**

**1980's, companies began making health claims on foods, even though the FDA had not approved the claims through the drug approval process" which led to a plethora of "unfounded health claims in the marketplace." H.R.Rep.No. 101-538, at 3338-9 (1990). Congress concluded that "legislation with respect to health claims is [] both desirable and necessary." Id. Such legislation was desirable and necessary because there was "a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims." 136 Cong.Rec. H12951-02, 12953 (statement of Rep. Waxman).**

**The Court finds that the FDA has asserted a substantial interest in ascertaining the validity and truthfulness of health-related claims on food and in drafting appropriate disclaimers which reflect the level of scientific evidence for a particular health claim in order to prevent consumer confusion and protect public health. The FDCA's and NLEA's express grant of authority to the FDA to ensure that only truthful and accurate health claims supported by reliable scientific evidence are permitted in the marketplace reflects the substantial interest the government has in regulating such claims and in ensuring that such claims not supported by significant scientific agreement contain succinct disclaimers which accurately convey the strength of scientific evidence. Consequently, the Court finds that the government has asserted an interest in preventing consumer confusion and protecting public health which is undeniably substantial.**

***b. FDA has a substantial interest in preventing the assumption that the FDA endorses the claim***

**Fleminger also argues that the FDA's concern that consumers might mistakenly believe that the FDA endorses the qualified health claim is speculative and unfounded. Fleminger suggests that since the FDA does not as extensively regulate the sale of food as it does with drugs, its concern that consumers will assume that FDA approves health claims made on food is unfounded. The Federal Circuit has embraced this notion. *See Pearson* I, 164 F.3d at 659 (acknowledging the FDA's "general concern, given the extensiveness of government regulation of the sale of drugs, consumers might assume that a claim on a supplement's label is approved by the government").**

**Indeed, Fleminger's argument is contrary to our longstanding laws and regulations and the FDA's longstanding practice. The FDA has for over seventy years been empowered by Congress to regulate the sale and marketing of foods that were intended for use in the diagnosis, cure, mitigation, treatment or prevention of a disease. *See* FDCA 21 U.S.C. §§ 301. For over twenty years Congress has mandated that the FDA approve only those health claims made on food which were supported by "significant scientific agreement." *See* NLEA Pub. L. No. 101-535, 104 Stat. 2353 (1990). The FDA has therefore historically and extensively regulated any food which bears a substance-disease related marketing claim. Contrary to Fleminger's arguments, a claim on a box of Quaker Oats indicating that "Oatmeal can reduce cholesterol" is exactly the type of health claim that has for over seventy years fallen squarely within the parameters of the FDA's regulatory authority as mandated under the FDCA and then later under NLEA. *See* [Dkt. # 41, Pl. Opposition Mem. at 13 n.8]. Since the statutory**

**and regulatory framework for health claims made on food is pervasive and long established, the Court finds that the FDA's concern that consumers might mistakenly assume that the FDA approves such health claims to be more than well founded. A consumer would likely assume that the FDA approves such claims by the virtue of the fact that Congress has indeed legislated that the FDA only approve health claims made on food which are supported by significant scientific agreement.**

**Fleminger also argues that FDA has little evidence that consumers will mistakenly believe that FDA approves health claims regarding food. Fleminger emphasizes that the 2002 study the FDA cited in its amended response which indicated that "35% to 57% of consumers, with or without use experience with dietary supplements, mistakenly believe that the government regulates the manufacturing and pre-approves the marketing of these products" is not relevant or applicable to food claims since it only analyzed dietary supplements. *See* (AR 2638). The Court agrees that since the 2002 study focused on dietary supplements it is not as relevant to establishing the significance of the FDA's purported concern and interest with respect to food claims. However as discussed above, the statutory and regulatory framework mandating the FDA to approve health claims made on food products amply establishes the fact and significance of this interest.**

**Fleminger, relying on the Supreme Court's decisions in *Edenfield v. Fane*, 507 U.S. 761. 771 (1993) and *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146 (1994), suggests that the government must provide empirical**

**evidence establishing that its asserted interest is substantial and real. However Fleminger's reliance on these cases is misplaced. In *Edenfield*, the Supreme Court recognized that the government's asserted interest in protecting consumers from fraud was substantial but found that there was no reasonable fit between the government's ends in preventing fraud and the means chosen, namely the total prohibition of truthful speech. 507 U.S. at 762, 769. The Supreme Court's concern that there were no studies or anecdotal evidence factored into the Court's analysis of the fit between the government's ends in preventing fraud and the means chosen to pursue that end. Ultimately, the Supreme Court held that the restriction on speech at issue in *Edenfield* did not directly advance any of the state's substantial interests. *Id.* at 762, 771.**

**Similarly in *Ibanez*, the Supreme Court suggests without expressly stating that the state has a substantial interest in preventing consumer fraud but found that the restriction at issue, once again the articulation of undeniably truthful statements on a mere suspicion that the statements were made for an improper purpose, did not directly serve that interest. 512 U.S. at 137, 144 (reasoning that "[a]s long as Ibanez holds an active CPA license from the Board we cannot imagine how consumers could be misled by her truthful representation to that effect" and finding that "[o]n the bare record made in this case, the Board has not shown that the restrictions burden no more of Ibanez' constitutionally protected speech than necessary"). The Supreme Court's admonishment that the we cannot allow rote invocation of the words 'potentially misleading' to supplant the Board's burden to demonstrate that the harms it recites are real and that its**

**restriction will in fact alleviate them to a material degree does not suggest as Plaintiff contends that the government must present empirical evidence establishing that its asserted interest is substantial. Instead, the Supreme Court' admonishment is more aimed at the analysis with respect to the reasonable fit between the government's ends and the means chosen by the government to advance those ends. Moreover, in *Ibanez* the court noted the absence of both empirical or anecdotal evidence.**

**Lastly, the Court notes that Fleminger's proposed disclaimer includes a positive statement that "*The FDA has concluded* that there is credible evidence supporting this claim although the evidence is limited." [Dkt. #36, Pl. Mem. at 4] (emphasis added). Fleminger's proposed invocation of FDA approval creates the very substantial interest in the accuracy of the claim Fleminger challenges.**

**In addition, the FDA is authorized by legislation to only approve those health claims made on food which meet the SSA standard. To imply that the FDA has approved a particular health claim where the claim is not supported by significant scientific evidence would run afoul of NLEA's mandate to the FDA. Accordingly, this Court finds that the FDA has a substantial interest in preventing consumers from assuming the FDA has approved the qualified health claim.**

**Further, it would be wholly inappropriate for the Court to command the FDA to allow a disclaimer in which its name and reputation were expressly invoked where it did not agree with the content of the disclaimer. Fleminger cannot use the auspices of the First Amendment to put words into the mouth of**

**the FDA. For a marketing claim to include a specific reference to the "FDA's conclusions" the content of that claim must come from the FDA itself. If not, such a claim would undoubtedly be misleading and false and would arguably fall outside the protection of the First Amendment altogether. Absent the FDA's express agreement, a proposed health claim cannot include specific reference to the "FDA" in its marketing.**

***ii. Analysis of fit between the government's end and the means chosen to accomplish those ends***

***a. Fleminger's proposed disclaimer is misleading and inaccurate***

**Fleminger's argument that its proposed disclaimer that "[t]he FDA has concluded that there is credible evidence supporting this claim although the evidence is limited" accurately conveys the strength of scientific evidence is really an argument regarding reasonable fit and whether the speech restriction advances the asserted governmental interests. Essentially, Fleminger's argument is that since its proposed disclaimer accurately conveys the strength of scientific evidence the FDA's replacement of its disclaimer with its own version cannot possibly advance the FDA's interest in preventing consumer fraud and protecting public health. Fleminger has carefully avoided challenging the FDA's conclusion that "there is very little scientific evidence" for the claim and instead simply argues that its articulation of the level of scientific evidence supporting the green tea health claim is appropriate.**

**As discussed above the assessment of the level of scientific evidence in support a substance-disease relationship falls squarely within the ambit of the**

**FDA's expertise and the Court must give deference to both the FDA's own assessment and articulation of the level of scientific evidence supporting the green tea claim and the FDA's determination that Fleminger's articulation of the level of scientific evidence was inaccurate and misleading. *See e.g., Federal Power Commission v. Florida Power & Light Co.*, 404 U.S. 453, 463 (1972) ("Particularly when we consider a purely factual question within the area of competence of an administrative agency created by Congress, and when resolution of that question depends on 'engineering and scientific' considerations, we recognize the relevant agency's technical expertise and experience, and defer to its analysis unless it is without substantial basis in fact."); *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) (finding that FDA's "judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's expertise and merit deference from us"), *cert. denied,* 516 U.S. 908 (1995).**

**In both the FDA's original response letter and its amended response letter, the FDA explained its rationale for concluding that Fleminger's proposed disclaimer that there was credible but limited scientific evidence for both the prostate and breast cancer claim was inaccurate and misleading. *See* (AR 2216-2235, 2627-50). With respect to breast cancer, there was only one study that found an association between drinking green tea and a reduction in the risk of breast cancer. (AR 2229). That study's result have not been replicated and utilized a scientific methodology, a case-control study method, which the FDA considered to be weaker as it is susceptible to more forms of bias then**

**prospectively designed studies. (*Id.*). The FDA also identified two cohort studies which found no association between drinking green tea and a reduction in the risk of breast cancer and noted that these studies utilized the stronger prospectively designed methodology. (*Id.*). Considering that two stronger studies found no association and only one weaker non-replicated study found an association, the FDA concluded that the level of scientific evidence for the breast cancer claim was "very little" and that Fleminger's assessment of the scientific evidence as credible but limited was not accurate and therefore misleading. The Court agrees with the FDA's conclusion that "credible but limited evidence" signals to consumers a higher level of scientific support then is accurately reflected by a single non-replicated study whose results were undermined by two stronger studies finding no association.**

**The word "credible" is defined as "offering reasonable grounds for being believed." Merriam Webster Online Dictionary, http://www.merriam-webster.com/dictionary/credible (last visited January 17, 2012). An average consumer would likely then interpret "credible but limited evidence" to mean evidence which offers a reasonable ground for believing that a purported health claim is true. The Court agrees with the FDA's assessment that one weaker un-replicated study finding a positive association between drinking green tea and a reduced risk of breast cancer and two stronger studies finding no such association does not offer a reasonable ground for believing that the proposed health claim is true. Since the weight of scientific evidence for the breast cancer claim does not offer**

**a reasonable ground for believing the claim to be true, it would be misleading to label the level of evidence in support of such claim as "credible but limited."**

**Similarly, the Court agrees with the FDA's conclusion that "credible but limited evidence" is an inaccurate and misleading description of the level of scientific evidence in support of the proposed prostate cancer claim. The FDA identified two studies relevant to whether drinking green tea may reduce the risk of prostate cancer. (AR 2230). Both studies were smaller case-control studies. One study found a positive association between drinking green tea and a reduced risk of prostate cancer while the other study found no association. (*Id.*). The one study finding a positive association has not been replicated. (*Id.*). For the same reasons as the proposed breast cancer claim, the Court agrees with the FDA's assessment that one relatively weak and un-replicated study finding a positive association and another relatively weak study finding no association does not provide a reasonable ground for believing the claim to be true. Since the weight of scientific evidence for the prostate cancer claim also does not offer a reasonable ground for believing that claim to be true, it would be likewise misleading to label the level of evidence in support of such claim as "credible but limited."**

**The Court acknowledges that in *Pearson II* the D.C. District court concluded that "[t]he mere absence of significant affirmative evidence in support of a particular claim ... does not translate into negative evidence 'against' it" and therefore found that the proposed folic acid claim was not inherently misleading. *Pearson II*, 130 F.Supp.2d at 115. The court in *Pearson II* was considering**

**whether the FDA's assessment of the level of scientific data supported the outright suppression of the proposed health claim. Unlike in *Pearson II*, the FDA in the instant matter has concluded that it cannot outright suppress the proposed health claim entirely on the basis of the one case-control study finding an association with the reduced risk of breast cancer and the one case-control study finding an association with the reduced risk of prostate cancer. Therefore, the *Pearson II* court's analysis is not fully applicable to these particular facts and circumstances. Moreover unlike in *Pearson II*, in the present case there were three studies which affirmatively found no association between drinking green tea and the reduced risk of breast or prostate cancer which undermined the two studies that did find such an association. The application of *Pearson II* court's reasoning to the facts of the present case only suggests that the FDA cannot outright suppress the green tea health claim in the first instance, which the FDA has acknowledged that it cannot do. The *Pearson II* court instructed that the appropriate response under the First Amendment was to allow the folic acid claim at issue to be made with the inclusion of appropriate disclaimers that "could cure the alleged misleading nature of the Folic Acid Claim" which is exactly what Defendants have tried to do in the present case. *Id.* at 119.**

**Fleminger also argues that its proposed disclaimer of "credible but limited evidence" is accurate because it tracks the language of the FDA's own Guidelines for finding a "qualified health claim." Fleminger points out that the FDA will only exercise its enforcement discretion to permit a qualified health claim when it finds that "there is credible evidence to support" such a claim. *See* Guidelines at**

**§III.H. Fleminger essentially argues that since the FDA has found that the proposed health claim should be considered a qualified claim it has necessarily found there to be credible evidence in support of the proposed claim and therefore its disclaimer is accurate and not misleading. Fleminger suggests that if there wasn't credible evidence in support of the proposed claim, then the FDA would have outright banned the claim in its entirety which it has not done.**

**However, the FDA's use of the term "credible evidence" within the context of the FDA's Guidelines and its regulatory framework has a unique and technical meaning which is substantially different from the meaning of "credible evidence" within a consumer marketing context. As discussed above within a consumer marketing context "credible evidence" connotes that there is a reasonable basis to believe that the claim is true. Here the FDA has made clear that it does not interpret "credible evidence" within its regulatory framework to mean that there is a reasonable basis to believe that proposed health claim is true, but rather it appears the lower threshold namely that there is some nominal or even negligible support that the claim might be true. For example although the FDA concluded there was "credible evidence" to support the classification of Fleminger's proposed health claim as "qualified," the FDA also explained that on the basis of this so called "credible evidence" that it concludes, based on the totality of the scientific evidence, that it was "highly unlikely" that green tea reduces the risk of breast or prostate cancer. *See* (AR 2229-30). Consequently, the meaning of "credible evidence" within the FDA's regulatory context cannot be translated over into the consumer marketing context as Fleminger suggests is appropriate. The**

**classification of a claim as "qualified" does not reflect the FDA's determination that the evidence in support of such "qualified claim" provides a reasonable basis for believing that claim to be true.**

**In fact, the determination that there is a reasonable basis for believing that a proposed health claim is true appears to be better aligned with the FDA's classification of unqualified health claims under the "significant scientific agreement" standard rather than its classification of qualified health claims under its "credible evidence" standard. The FDA has indicated that "[s]ignificant scientific agreement refers to the extent of agreement among qualified experts in the field. On the continuum of scientific evidence that extends from very limited to inconclusive evidence, SSA lies closer to consensus. FDA's determination of SSA represents the agency's best judgment as to whether qualified experts would likely agree that the scientific evidence supports the substance/disease relationship that is the subject of a proposed health claim. The SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship." *Id.* at §III G. Therefore the "significant scientific agreement" standard and not the "credible evidence" standard as articulated in the Guidelines better reflects the FDA's assessment of what is a reasonable basis for believing that a proposed health claim is true. Consequently, the Court finds that the Fleminger's proposed language that there is "credible but limited" evidence is misleading as the FDA's "credible evidence" standard for classification of qualified health claims does not comport with a consumer's common sense understanding of the term "credible evidence."**

**If the Court adopted Fleminger's argument that the description of "credible but limited" is appropriate on the basis of the FDA's Guidelines and the FDA's invocation of its Guidelines in its response letter to Fleminger then the FDA would be obligated to label the level of scientific support as "credible" for every qualified health claim for which it exercised its enforcement discretion. This would undermine the public interest in food labeling. As the FDA indicated in its amended response to Fleminger for the disclaimers to be effective in preventing consumer confusion and protecting the public health the "disclaimer must enable consumers to distinguish between the very limited level of scientific support for the green tea qualified health claim and the stronger level of scientific support for many other qualified health claims, and for health claims that FDA authorizes by regulation." (AR 2640). The FDA must have the ability to draft specific disclaimers tailored to the particular health claim at issue in order to allow the FDA to advance the public's interests in preventing consumer confusion and protecting public health in a manner which does not burden substantially more speech than is necessary to further those interests. In fact, the FDA Guidelines indicate that the "health claim language should reflect the level of scientific evidence with specificity and accuracy." *See* Guidelines at III.H. The First Amendment therefore requires that the FDA draft specific disclaimers tailored to the particular health claim at issue which reflects the specific level of scientific support for that health claim.**

**Since Fleminger's proposed disclaimer is inaccurate and misleading, under the applicable FDA nomenclature, the FDA is not obligated under the First**

**Amendment to allow Fleminger to use such language in its marketing. Instead the FDA is obligated to draft short, succinct and accurate disclaimers "regarding the strength or nature of the evidentiary support for [the] health claim." *Alliance II*, 786 F. Supp. 2d at 24 n.22.**

***b. The FDA is not required to provide empirical evidence demonstrating the Fleminger's proposed language is misleading or that consumers will assume the FDA approves health claims made on food on the bases asserted by the Plaintiff***

**Fleminger argues that under *Ibanez* and *Edenfield* the FDA is required under the First Amendment to prove empirically that Fleminger's proposed disclaimer language is misleading and that consumers will assume that the FDA approved the health claim in order to justify its modification of the disclaimer. The Supreme Court's admonishment in *Ibanez* that "[w]e cannot allow rote invocation of the words 'potentially misleading' to supplant the Board's burden to "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree," 512 U.S. at 146, and its concern in *Edenfield* that there must be some basis for validation of the government's supposition that the restriction on speech advances its interests in any direct and material way, 507 U.S. at 771, do not stand for the proposition that the government is obligated to conduct an empirical analysis to justify its restrictions. These Supreme Court cases do not require empirical data. Instead, they really stand for the proposition that there must be some actual or real validation that the speech restriction does in fact advance the government's interest. In fact, the Supreme Court noted in *Edenfield* that this basis for validation does not require empirical evidence but rather could be predicated on anecdotal evidence. 506 U.S. at 771 ("The Board**

**has not demonstrated that, as applied in the business context, the ban on CPA solicitation advances its asserted interests in any direct and material way. It presents no studies that suggest personal solicitation of prospective business clients by CPA's creates the dangers of fraud, overreaching, or compromised independence that the Board claims to fear. The record does not disclose any *anecdotal* evidence, either from Florida or another State, that validates the Board's suppositions.") (emphasis added).**

**Conversely, the statutory and regulatory framework mandating FDA approval for health claims made on food and the FDA's expert assessment and analysis of the level of scientific evidence at issue provide a sufficient basis for validation that meets the Supreme Court's edicts in *Edenfield* and *Ibanez*. First, the FDA's conclusion that Fleminger's proposed disclaimer is inaccurate and misleading is validated by the FDA's expert analysis and assessment of the level of scientific evidence at issue which was thoroughly articulated in the FDA's response and amended response to Fleminger's petition. *See* (AR 2216-35, 2617-50). This expert analysis provides real validation that the restriction on speech actually advances the FDA's interests in preventing consumer confusion and protecting public health.**

**The case at bar is inapposite to both *Edenfield* and *Ibanez*. In both of those cases, relied upon by the Plaintiff, the speech sought to be precluded was undeniably truthful. This is not the case here. In the case at bar there are three relevant scientific studies on which the FDA formed its opinion. One was a limited study supporting Fleminger's claim and two were more efficacious**

**studies tending to undermine Fleminger's claim. Thus the factual support for the FDA's restriction on Fleminger's speech is more than anecdotal if not empirical.**

**If the FDA like the defendants in *Ibanez* and *Edenfield* had merely stated without explaining the basis for its conclusion that Fleminger's proposed disclaimer was inaccurate and misleading that would have been the "rote invocation of the words 'potentially misleading' that the Supreme Court warned against. However the FDA did not merely rely on the rote invocation of these words. Instead, it relied upon and provided a thorough review and analysis of all of the scientific evidence at issue and a comprehensive articulation of its rationale in concluding that Fleminger's proposed disclaimer was inaccurate and misleading. Consequently, the FDA has more than provided a real and not speculative basis for the Court to find that the FDA's restriction in modifying the disclaimer to accurately reflect the level of scientific support for the claim advanced the public's interests.**

**Second as discussed above, the FDA's concern that consumers will assume it approved the health claim is validated by the long standing statutory and regulatory framework authorizing the FDA to only approve health claims on food that are supported by significant scientific agreement. Consequently, the statutory and regulatory framework provide a real and not speculative basis for finding that the FDA's restriction in modifying the disclaimer to convey that the FDA has not approved the health claim advanced its interests.**

**The Court also notes that the *Pearson I* and *Whitaker* courts considered the issue of empirical evidence. In *Pearson I*, the D.C. Circuit stated that "while we are skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones we suggested above would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility." 164 F.3d at 659-60. The *Whitaker* court interpreted *Pearson I* to stand for the proposition 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." 248 F.Supp.2d at 11. However, both the *Pearson I* and *Whitaker* courts only considered the need for empirical evidence in connection with the government's outright ban of the proposed health claim as opposed to the FDA's prerogative to draft short, succinct and accurate disclaimers as to the level of scientific support for a qualified health claim. The *Pearson I* and *Whitaker* court's analysis should therefore be confined to the circumstances where the government is seeking to outright ban the proposed health claim entirely as opposed to the present circumstance where the government allows the health claim to be made but drafts an appropriate disclaimer to remedy the weaknesses in the proposed claim. Accordingly, the First Amendment does not require the FDA in every case to conduct an empirical study in connection with a petition for a qualified health claim demonstrating that the petitioners' proposed disclaimer language is**

**misleading or inaccurate or that consumers will mistakenly believe that the FDA approved the proposed health claim.**

***c. The portion of the FDA's disclaimer stating there is "very little scientific evidence" strikes a reasonable fit between the government's ends and the means chosen to accomplish those ends***

**As the *Alliance I and II* court concluded the First Amendment requires that where there is some evidence supporting a possible substance-disease relationship, as is the case here, the FDA should allow the claim to be made in the first instance, which the FDA has done in the present case. The FDA's role then should be directed toward drafting or modifying a disclaimer "regarding the strength or nature of the evidentiary support for [the] health claim." *Alliance II*, 786 F. Supp. 2d at 24 n.22. Here, the FDA has followed the *Alliance* court's direction allowing the proposed health claim to be made in the first instance but also modifying a disclaimer which conveys "the strength or nature of the evidentiary support for the health claim." *Id.***

**The portion of the FDA's modified disclaimer stating that "there is very little scientific evidence" for the proposed health claim reflects a reasonable fit between the FDA's goal of preventing consumer confusion and protecting public health and the means chosen to accomplish that end as it permits the claim to be made while disclosing to the consumer contrary sound scientific evidence. As discussed above, the Court defers to the FDA's assessment of the strength of scientific evidence at issue as "very little" and notes that Fleminger has not argued that the FDA's assessment is arbitrary and capricious. In accord with *Pearson* and its progeny, the First Amendment requires that the FDA allow**

**Fleminger's claim that "drinking green tea may reduce the risk of breast or prostate cancer" be made with the addition of short, succinct and accurate disclaimers as to the level of scientific support for the proposed health claim. As discussed above since Fleminger's proposed disclaimer is inaccurate and misleading, the FDA is not obligated to permit the disclaimer to be made under the First Amendment. Instead the FDA has the obligation to draft a short, succinct and accurate disclaimer which reflects the strength or nature of the evidentiary support for the health claim. Since the drafting of disclaimers regarding the strength or nature of evidentiary support for a health claim falls well within the ambit of the FDA's expertise as well as its statutory and regulatory authority, the Court must necessarily defer to its analysis and judgment. As explained above, any challenge to the FDA's analysis and judgment as to the level of scientific support for a proposed claim is rather properly asserted under the APA as opposed to the First Amendment.**

**Since the portion of the FDA's modified disclaimer stating that "there is very little scientific evidence" accurately conveys the strength of the scientific evidence supporting the proposed health claim, it directly advances the FDA's interest in preventing consumer confusion and protecting public health. It also does not burden substantially more speech than is necessary to further that interest as the FDA has permitted the health claim to be made in the first instance thereby adhering to the First Amendment's "preference for disclosure over outright suppression" as well as the preference for the use of disclaimers over outright suppression. *See Pearson I*, 164 F.3d at 656-58. In addition, the fit is**

**reasonable because Fleminger's proposed disclaimer undermines the interest in preventing consumer confusion and protecting public health as it unequivocally did not accurately convey the strength of the scientific evidence for the proposed claim. Accordingly, the Court finds that the portion of the FDA's modified disclaimer stating that "there is very little scientific evidence" is an accurate statement of the scientific evidence and thus does not violate the First Amendment.**

***d. The portion of the FDA's disclaimer stating that the "FDA does not agree that green tea may reduce that risk" does not strike a reasonable fit between the government's ends and the means chosen to accomplish those ends***

**Although the portion of the FDA's disclaimer conveying the strength of scientific evidence supporting the health claim is appropriate under the First Amendment, the portion of the disclaimer stating that the "FDA does not agree that green tea may reduce that risk" suffers from the same constitutional infirmities as the modified disclaimers at issue in *Alliance I and II*. The placement of this language immediately after Fleminger's claim that "drinking green tea may reduce the risk of breast or prostate cancer" has the effect of negating any relationship between green tea and the reduction of breast or prostate cancer and therefore effectively swallows the entire claim. The negation of the proposed health claim with this portion of the disclaimer represents an impermissible restriction on Fleminger's commercial speech.**

**Here the portion of the FDA's disclaimer stating that "there is very little scientific evidence" sufficiently cures or remedies the weaknesses inherent in**

**Fleminger's proposed disclaimer as to the level of scientific support for the claim. Since the FDA's interest in preventing consumer confusion and protecting public health is sufficiently advanced by the portion of the disclaimer accurately conveying the strength of the scientific evidence, the portion of the disclaimer stating that the "FDA does not agree that green tea may reduce that risk" is rendered somewhat superfluous. Accordingly, the portion of the disclaimer stating that the "FDA does not agree that green tea may reduce that risk" does not directly advance the government's interest in preventing consumer confusion and protecting public health. Consequently, the inclusion of this language burdens more speech then is necessary to remedy the weaknesses of Fleminger's health claim with respect to its interests in preventing consumer confusion and protecting public health.**

**While the FDA does have a substantial interest in preventing the assumption that it has approved the health claim, the FDA's language burdens substantially more speech than is necessary to further that interest since the language effectively negates the substance-disease relationship claim altogether. There are less burdensome ways in which the FDA could indicate in a short, succinct and accurate disclaimer that it has not approved the claim without nullifying the claim altogether. As the Supreme Court instructed "[I]f the Government c[an] achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Western States*, 535 U.S. at 371. As the *Pearson I* court suggested the "agency could require the label to state that 'the FDA does not approve this claim.'" *Pearson I,* 164 F. 3d at 659.**

**Such a disclaimer would not have the same effect of negating Fleminger's proposed health claim in the first instance and would therefore allow the FDA to achieve its interest in a manner that restricts less speech.**

**The Court also suspects that the FDA's concern that consumers will assume it has approved the health claim could also be accommodated by changing the disclaimer along the following lines: "Green tea may reduce the risk of breast or prostate cancer although the FDA has concluded that there is very little scientific evidence to support the claim." Such a disclaimer would not have the effect of negating the substance-disease claim and would therefore represent a lesser restriction on Fleminger's commercial speech but also accommodate the FDA substantial interest in preventing the assumption that it has approved the claim. Accordingly, the portion of the disclaimer stating that the "FDA does not agree that green tea may reduce that risk" does not strike a reasonable fit between the Governments ends and the means chosen to accomplish those ends and therefore violates the First Amendment.**

**As the *Pearson I* court acknowledged it is not the role of the courts to draft precise declaimers but instead "leave[s] that task to the agency in the first instance." *Pearson I*, 164 F.3d at 659. The Court accordingly remands Fleminger's health claim to the FDA for the purpose of drafting appropriate disclaimers consistent with this Memorandum Opinion.[3]**

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[3] **Defendants encourage the Court to take into consideration the settlement reached in *Alliance I* in which the parties agreed to a disclaimer which stated that "Selenium may reduce the risk of prostate cancer. Scientific evidence**

**Although the Court has found that the portion of the disclaimer stating that the "FDA does not agree that green tea may reduce that risk" constitutes an impressible restriction on Fleminger's commercial speech rights, the Court questions whether this portion of the disclaimer might be permissible under certain circumstances. For example, Fleminger had affirmatively advertised on his website the health claim that "Green tea may reduce the risk of breast and prostate cancers. The FDA has concluded that there is credible evidence supporting this claim although the evidence in limited" which the FDA had not authorized. Considering that Fleminger had essentially advertised that the FDA had agreed with its claim that green tea may reduce the risk of breast and prostate cancer, the FDA might have an interest in requiring a retraction in the form of a disclaimer that rectified or clarified that it did not agree with that claim. Rectifying false advertisement may justify the imposition of the additional speech restriction. However Defendants have not argued that this language in the disclaimer was needed to ameliorate any consumer confusion that was caused by Fleminger's publication of the unauthorized health claim on its website and accordingly the Court need not decide this issue.**

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**concerning this claim is inconclusive. Based on its review, FDA does not agree that selenium may reduce the risk of prostate cancer." Although the Court recognizes the FDA's interest in using consistent disclaimer language, this disclaimer was not the subject of any court's review under the First Amendment and is not identical to the disclaimer at issue, and therefore the Court does not find the *Alliance I* settlement disclaimer to be relevant to its analysis in the present case.**

## Conclusion

**For the foregoing reasons, the Plaintiff's motion for summary judgment is GRANTED IN PART AND DENIED IN PART [Dkt. #36] and Defendants' cross motion for summary judgment [Dkt. #37] is GRANTED IN PART AND DENIED IN PART. Fleminger's qualified health claim is remanded to the FDA for further action consistent with this Memorandum Opinion and the other relief sought by the Plaintiff is denied. The Clerk is directed to close the file.**

**IT IS SO ORDERED.**

***/s/***

**Hon. Vanessa L. Bryant**

**United States District Judge**

**Dated at Hartford, Connecticut: February 23, 2012**