IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DURK PEARSON, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**No. 00-2724 (GK)**
	)	
DONNA E. SHALALA, et al.,	)	
	)	
Defendants.	)	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

Plaintiffs, by counsel and pursuant to Fed.R.Civ. P. 12(b)(6) and LCvR 7.1(b), hereby file their memorandum in opposition to Defendants' motion to dismiss ("MD"). In a separate pleading to be filed on December 22, 2000, Plaintiffs will submit a cross-motion for summary judgment.[1] For the following reasons, Defendants' MD should be denied and Plaintiffs' cross-motion for summary judgment should be granted.

I. STANDARD FOR REVIEW OF MOTION TO DISMISS

The Defendants state in their MD at 26 that this case may be determined as a matter of law exclusively on facts that are part of the administrative record.[2] Plaintiffs agree. We part company on what decision should be made on the record. Based on the record facts, summary judgment should be granted in Plaintiffs' favor in light of the fact that FDA's letter ruling (1) violates the Plaintiffs' First Amendment free speech rights and the constitutional mandate of the

[1] Defendants' MD has been filed consolidated with an opposition to Plaintiffs' motion for preliminary injunction. In light of the differing standards of review for the respective motions and to avoid delay in action on the motion for preliminary injunction, the Plaintiffs have uncoupled that consolidation by a pleading separate from this one entitled, "Plaintiffs' Memorandum in Reply to Opposition to Application for Preliminary Injunction," filed on December 20, 2000.

[2] Defendants filed a "joint record" ("JR") with its MD, noting that Plaintiffs reserved their right to file additional excerpts of record if necessary. Wherever possible herein Plaintiffs cite to Defendants' JR submission. Where those excerpts omit documents of record upon which Plaintiffs wish to rely, they cite to additional excerpts of record ("AER") filed herewith.

United States Court of Appeals in Pearson v. Shalala, 164 F.3d 650, 656 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir. 1999); (2) violates the Fifth Amendment Due Process Clause; (3) violates the Supremacy Clause; (4) violates the Food, Drug and Cosmetic Act, 21 U.S.C. § 343(r)(5)(D); and (5) violates the Administrative Procedure Act's prohibition on arbitrary and capricious agency action, 5 U.S.C. § 706(2)(A).

Under the motion to dismiss standard, the Court's focus is on the face of the complaint and whether it alleges facts that, when assumed true, are nonetheless ones for which there is no cognizable legal remedy. A motion to dismiss for failure to state a claim does not test whether the plaintiff will prevail on the merits, only whether plaintiff has properly stated a claim. Johnson v. Heyman, 2000 U.S. Dist. LEXIS 12785 (D.D.C. 2000); Price v. Crestar Sec. Corp., 44 Supp. 2d 351, 353 (D.D.C. 1999). In determining whether a plaintiff fails to state a claim, the court may consider only the facts alleged in the complaint and must accept the plaintiffs' factual allegations as true and draw all reasonable inferences in favor of the plaintiffs. See Maljack Prods. v. Motion Picture Ass'n, 52 F.3d 373, 375 (D.C. Cir. 1995); Ramirez de Alrellano v. Weinberger, 745 F.2d 1500, 1506 (D.C. Cir. 1984). To prevail on a motion to dismiss, the moving party must show "beyond doubt that the plaintiff can prove no set of facts in support of [his or her] claim which would entitle [him or her] to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957); see also Hishon v. King & Spalding, 467 U.S. 69, 73 (1984); Atchinson v. D.C., 73 F.3d 418, 421 (D.C. Cir. 1996). Decision under Rule 12(b)(6) must be made on the face of the complaint alone. Tele-Communication of Key West, Inc. v. United States, 757 F.2d 1330, 1335 (D.C. Cir. 1985). As explained below, under the motion to dismiss standard, Defendants' MD must be denied.

II. PLAINTIFFS HAVE STANDING TO SUE

In Steel Company v. Citizens for a Better Environment, 523 U.S. 83, 103 (1998), the Supreme Court held that three elements must be met to establish standing to sue: (1) injury in fact; (2) a connection between that injury and the complained of conduct; and (3) a likelihood that the requested relief will redress the injury alleged. The Defendants do not challenge Plaintiffs' standing to assert their First Amendment and Fifth Amendment claims but do challenge Plaintiffs' standing to assert Supremacy Clause, health claims statutory, and Administrative Procedure Act (APA) violations. Defendants contend that Plaintiffs cannot identify any injury fairly traceable to the alleged illegalities. As explained below, Defendants are in error. Direct and palpable injuries are directly connected to each of the violations alleged and will be remedied in toto if the relief requested is granted.

This case is a proceeding on remand from a judgment by the United States Court of Appeals, Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), reh'g, en banc denied 172 F.3d 72 (D.C. Cir. 1999). In that case, the Court of Appeals held the very claim Plaintiffs wish to make on labels and in labeling of the dietary supplements they license and sell ("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" (hereinafter "Folic Acid Claim")) not "inherently misleading" but protected under the First Amendment against outright suppression. 164 F.3d at 658-59. The Court also held FDA's refusal to favor the constitutionally preferred remedy of disclosure over suppression and allow the claim with a corrective disclaimer a violation of the First Amendment. 164 F.3d at 659.[3] Finally, the Court held FDA's refusal to define its standard for review of health claims ("significant scientific agreement") in a way that explains what it means or, at

[3] On First Amendment grounds, the Court held invalid the FDA's rule that prohibited Plaintiffs' Folic Acid Claim, 21 C.F.R. § 101.79(c)(2)(i)(G).

minimum, what it does not mean a violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). 164 F.3d at 660-61. The Court held invalid FDA's interpretation of its general health claims regulation, 21 C.F.R. § 101.14. Id. The Court remanded the case to FDA to reconsider Plaintiffs' health claims. On remand, for a period of eighteen months, FDA left the invalid agency rule on the books by not revoking it until October 3, 2000. See generally 65 Fed. Reg. 58917. In its revocation order, FDA substantively retained the rule by announcing that no party could use the Folic Acid Claim until FDA completed its reconsideration of the claim. On October 10, 2000, FDA issued a letter ruling on reconsideration of the Folic Acid Claim ("Letter Ruling"), again prohibiting it. The agency ruled that the claim was "inherently misleading" but adduced no empirical evidence that the claim actually misleads consumers, nor did FDA explain why no disclaimer could prevent potential misleadingness. The Pearson Court prescribed the Central Hudson test for the evaluation of Plaintiffs' Folic Acid Claim on remand, but FDA did not comply with that test in its Letter Ruling. Despite the Pearson decision FDA has kept in place a blanket ban on use of Plaintiffs' Folic Acid Claim from March 5, 1996, until the present and has not satisfied its First Amendment burden of proof to justify that act of suppression. FDA has adopted no procedural safeguards to protect the Folic Acid Claim from suppression despite the Pearson decision.

As set forth in the Complaint, each of the Plaintiffs license or sell multivitamin dietary supplements that contain .8 mg of folic acid per daily serving. Plaintiffs Durk Pearson, Sandy Shaw, and the American Preventive Medical Association originally proposed use of the Folic Acid Claim and were victors in Pearson v. Shalala. The history of their pursuit of the claim is set forth in Pearson. See 164 F.3d at 653-54. On remand, they were joined by Plaintiffs Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; and XCEL Medical Pharmacy, Ltd., each of whom

also license and sell multivitamin dietary supplements containing .8 mg of folic acid per daily serving. In timely filed comments before the agency on remand (JR 39 and 40), all of the Plaintiffs explained their desire to use the claim and expressed their willingness to accept any reasonable disclaimer designed to cure a proven misleading connotation arising from the claim.

Injury (speech suppression). The FDA's prohibition on the Folic Acid Claim causes the Plaintiffs to suffer an injury in fact that is concrete. The Supreme Court has held violation of a First Amendment right, even for a very short period of time, an irreparable injury without proof of more. See Elrod v. Burns, 427 U.S. 347, 373 (1976) (plurality opinion) ("The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury") *quoted in* Jackson v. City of Columbus, 194 F.3d 737, 747 (6th Cir. 1999); Iowa Right to Life Comm., Inc. v. Williams, 187 F.3d 963, 969 (8th Cir. 1999); Brownsburg Area Patrons Affecting Change v. Baldwin, 137 F.3d 503, 507 (7th Cir. 1998); New York Magazine v. Metropolitan Transportation Authority, 136 F.3d 123, 127 (2nd Cir. 1998); see also Lakewood v. Plain Dealer Publishing Co., 486 U.S. 750, 758 (1988); Washington Free Community v. Wilson, 426 F.2d 1213, 1218 (D.C. Cir. 1969). The Plaintiffs also suffer economic injury attendant to the loss of sales of folic acid-containing dietary supplements that would otherwise be purchased by women informed of the superior effectiveness over food folate of the synthetic folic acid in those supplements.

Injury (denial of Due Process). Plaintiffs' First Amendment right to communicate the Folic Acid Claim on labels and in labeling of their dietary supplements is a liberty right (and a property interest[4]) that may not be deprived for indefinite periods after a Court order recognizing

[4]Plaintiffs' Folic Acid Claim informs female consumers that 0.8 mg of folic acid in a dietary supplement is more effective in reducing neural tube defects than a lower amount in foods in common form. That claim is a value comparison that enables female consumers of childbearing age to discern why it would be better to get their folic acid from a dietary supplement every day than to rely exclusively on food folate in foods in common form (what

that right. The process that is due in such circumstances requires (1) immediate revocation of the rule held invalid and unconstitutional; (2) adoption of a definite deadline within which FDA must complete any secondary review of the scientific evidence that is *far less lengthy* than the time for its original review; and (3) issuance of an interim agency order (for the period between the time of the Court's mandate invalidating the speech suppressive rule until completion of any additional FDA scientific review on whether disclaimers can correct any perceived misleading connotation) that permits use of the claim held unconstitutionally suppressed accompanied by standard disclaimers such as: "The Food and Drug Administration has not approved this claim. The evidence in support of it is inconclusive and is undergoing further FDA review." This situation differs greatly from the one in Nutritional Health Alliance v. Shalala, 144 F.3d 220, 227-28 (2nd Cir. 1998), where the Court held the health claim review process in excess of 540 days a violation of the First Amendment prohibition on prior restraints. That decision concerned *the initial review of science for a health claim*. Here, by contrast, the agency reviewed the science for the health claim, denied the claim unconstitutionally, and then proceeded to reconsider the additional science concerning the claim after a federal court held its first assessment and claim denial unconstitutional under the First Amendment. While 540 days may arguably be a reasonable period of time to review anew scientific evidence first filed with the agency, 540 days is not a reasonable period of time to review an updated scientific record after an initial and complete scientific analysis of the evidence supporting a claim. Otherwise the incredible length of time involved (100 days for the initial review; over two years for Court review of the agency's action; and 540 days for re-evaluation) will result in extraordinary delays that deprive First Amendment rights for years (in this case over six years). Such burdens on

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FDA terms "conventional foods"). Disallowing Plaintiffs to convey that information to consumers deprives them of the economic benefit that would accrue to them were consumers to choose their dietary supplements based on the

speech will make it all but impossible for health claimants to receive timely protection for their First Amendment rights. Such burdens are also accompanied by extraordinary costs to the health claimant above and beyond the costs for the hiring of experts, expert review of the scientific literature, development of health claims, filing of the petitions and then prosecution of the matter before FDA and the courts.

(1) FDA has not adopted any reasonable deadlines for action on the constitutional remand. Plaintiffs first presented their Folic Acid claim to FDA in 1996. In the advent of the Pearson decision, for over eighteen months and continuing to the present, the FDA has assiduously refused (against Plaintiffs repeated demands to the contrary, AER 19, 20 and 21) to adopt any reasonable deadlines for agency action.

(2) FDA has not adopted any procedure for ensuring immediate compliance with the Court of Appeals' order (or any federal court's order) by rapid revocation of the unconstitutional speech suppressive rules in question. In this case FDA waited eighteen months before it published a notice in the Federal Register revoking the rules the Court of Appeals held invalid and, even then, continued to enforce the substantive prohibitions of those rules (including the prohibition on the Folic Acid Claim) thereafter (and to the present and into the indefinite future).

(3) FDA has not adopted any procedure for prompt notification to the health claimants in question that it will refrain on an interim basis from taking enforcement action against them if they place on labels and in labeling the claims held unconstitutionally suppressed conditioned on use of interim disclaimers such as those described above. FDA has rejected Plaintiffs pleas that it rely on interim disclaimers to allow the claim into the market at the earliest possible moment; to the contrary, it has insisted on continuing enforcement of the substantive prohibition contained

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claim over exclusive reliance on foods as a way to maximize neural tube defect risk reduction.

in the constitutionally invalidated rule here in issue for a period of over eighteen months. That failure caused Plaintiffs' First Amendment rights here in issue to be suppressed for over eighteen months before a substantive ruling on whether it would allow the claim issued. During that time (and continuing to the present), the Plaintiffs have suffered a continuing deprivation of their First Amendment rights despite the holding of the Court of Appeals. Likewise, they have suffered a deprivation of their Fifth Amendment due process rights because the process due them was not provided. The failure of FDA to adopt procedural safeguards to protect from suppression of health claims held unconstitutionally suppressed by the federal courts pending FDA's further review of science concerning those claims constitutes a present harm to Plaintiffs that is capable of repetition yet would evade review unless this Court holds that failure of due process a violation of Plaintiffs First and Fifth Amendment rights.

Injury (Supremacy Clause). The FDA has chosen to elevate demand for compliance with its interpretation of the regulatory prohibition on unauthorized health claims above the contrary requirements of the First Amendment, as construed by the Pearson Court. FDA takes the position that its continuing prohibition on Plaintiffs' Folic Acid Claim following the revocation of the rule prohibiting the Folic Acid Claim arises from its codified obligation not to permit unauthorized health claims. That construction violates the Supremacy Clause and the First Amendment to the United States Constitution by elevating agency rules and interpretation above the supreme law of the First Amendment. That action causes Plaintiffs to suffer injury by depriving them of their First Amendment right to communicate the Folic Acid Claim on labels and in labeling of their .8 mg folic acid-containing dietary supplements.

Injury (Violation of 21 U.S.C. § 343(r)(5)(D)). The FDA has chosen to interpret its statutory duty to mean that it must find established to a near conclusive degree a *relationship*

between a nutrient and a disease as a condition precedent to claim approval. By regulation it has adopted the same standard for review of dietary supplements as is statutorily prescribed for foods. See 21 U.S.C. § 343(r)(3)(b) and (5)(D). The statute, however, directs FDA to determine whether there exists significant scientific agreement, among experts qualified to evaluate the claim, "that the claim," *not the relationship*, "is supported by such evidence." Separate and apart from its noncompliance with the First Amendment, FDA's statutory interpretation is at odds with the plain and intended meaning of the statute and deprives the Plaintiffs of the statutory right of review for health claims to which they are entitled.

Injury (APA Violation). As petitioners who filed comments before the FDA advocating its application of a defined standard of "significant scientific agreement" that complied with the requirements of the statute, 21 U.S.C. § 343(r)(5)(D), and who sit in the regulated class that has and will continue to file petitions for health claim approval, they are aggrieved in no manner less than the original Pearson plaintiffs by FDA's continuing refusal to define a coherent standard of review for the regulated class. Moreover, they are particularly aggrieved by the FDA Letter Ruling because FDA did not perform a required Pearson evaluation (in reliance on Central Hudson's three-part test) of its claim suppression separate and apart from its evaluation under the rubric of "significant scientific agreement" but, instead, based its decision to suppress the Folic Acid Claim (without resort to disclaimers) on the conclusions reached under its "significant scientific agreement" review.

Thus, for the foregoing reasons, Plaintiffs suffer direct, concrete, immediate, and continuing injury. The harms are the direct result of FDA action or inaction. The declaratory and injunctive relief requested by the Plaintiffs will afford complete relief for the foregoing injuries. Accordingly, Plaintiffs have standing to assert all of their claims.

III. PLAINTIFFS HAVE STATED CLAIMS FOR RELIEF UNDER THE FIRST AND FIFTH AMENDMENTS AND UNDER THE SUPREMACY CLAUSE OF THE UNITED STATES CONSTITUTION

Defendants argue that Plaintiffs' First Amendment cause of action cannot prevail because (1) the Folic Acid Claim is "actually misleading" and (2) the weight of the scientific evidence is against it. Premised on that same argument, the Defendants contend that Plaintiffs' cause of action for agency failure to implement the constitutional mandate of the Pearson Court; failure to comply with the due process requirements of the Fifth Amendment; and failure to comply with the Supremacy Clause fails. As explained below, the Defendants' argument lacks persuasive power when FDA's Letter Ruling and the evidence from the record below are carefully examined.

First Amendment. The Plaintiffs challenge FDA's Letter Ruling for violating the First Amendment and the mandate of the Court of Appeals in Pearson v. Shalala. The Defendants argue essentially three points: (1) that the First Amendment challenge should not be evaluated under the First Amendment standard applied by the Court of Appeals in Pearson v. Shalala, but under the more facile arbitrary and capricious standard of the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A), *explained principally in* Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-843 (1984); (2) that while the Folic Acid Claim does not state that .8 mg of folic acid is more effective than .4 mg of folic acid, *it implies it* and that the implication is inherently misleading; and (3) that while the Folic Acid Claim does not state that folic acid in a dietary supplement is more effective than folic acid in a fortified food, *it implies it* and that the implication is inherently misleading. As explained here (and more fully in Plaintiffs' Memorandum in Reply to Opposition to Application for Preliminary

Injunction ("the PI Reply") which is incorporated here by reference), the Defendants' argument is entirely lacking in merit.

(1) The Proper Standard of Review Arises Under the First Amendment, Not the Administrative Procedure Act. The correct standard of review for Defendants' suppression of the Folic Acid Claim on remand is the one applied in Pearson v. Shalala, 164 F.3d at 653.[5] Pearson is the governing law for this case on remand from the Pearson Court decision. The Pearson Court's First Amendment standard of review is the one FDA was required to follow in the remand proceeding and is the one to which FDA is answerable before this Court. The Pearson Court evaluated FDA's suppression of the Folic Acid Claim and held the claim not "inherently misleading" but protected under the First Amendment. The review was *constitutional* first and foremost; the more deferential APA standard was not a part of the Court's evaluation of the health claim's suppression. Indeed, the Court compelled FDA to answer the Plaintiffs "most powerful constitutional claim, that the government has violated the First Amendment . . . ***because the requested remedy stands apart from appellants' request under the APA that the FDA flesh out its standards.***" 164 F.3d at 655 (emphasis added). The Pearson Court utterly rejected the view that precedent "mandates a more deferential review of government regulations on potentially misleading commercial speech," explaining that "[i]t is clear . . . that when government chooses a policy of suppression over disclosure—at least where

[5] Defendants cite two inapposite cases in support of their argument (Cf. Kraft, Inc. v. FTC, 970 F.2d 311 (7th Cir. 1992) and FTC v. Brown & Williamson Tobacco Corp., 778 F.2d 35 (D.C. Cir. 1985)). Both cited cases are FTC appeals that deal with marketed claims not with FDA's pre-market approval process. Plaintiffs' claim, by contrast, has never entered the market. In the FTC cases, the agency presented evidence from the market to show misleadingness. In this case FDA is *assuming* that the statements are misleading without a scintilla of evidence in support. Thus, the cited cases are not applicable to the facts present here. Moreover, under FTC's standard of review ("competent and reliable scientific evidence"), the agency does not *prohibit* the making of any claim before market, it merely requires for one to avoid an FTC challenge after market that the claim not be deceptive. Here, by contrast, FDA has barred from the market every claim that states that any specified amount of folic acid from one source is superior to any specific amount of food folate from another (or, for that matter, that states folic acid is superior to food folate).

there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means." Pearson, 164 F.3d at 658.

On remand, FDA was to act consistent with the Court of Appeals' decision, but FDA did not. FDA's Letter Ruling did not evaluate the Folic Acid Claim under the three-part Central Hudson test. FDA did not adduce any evidence that the Folic Acid Claim actually misleads consumers (it has not a single consumer survey to support its supposition that consumers would be misled). Instead, in a conclusory fashion, FDA's Letter Ruling makes that assertion. FDA failed to establish that *no* disclaimer could be added to the claim to cure any *proven* potential to mislead. It thereby violated the Pearson mandate.

Under the First Amendment standard, the Defendants, not the Plaintiffs, have the burden of proof. See Ibanez v. Florida Dep't of Business & Prof'l Regulation, 512 U.S. 136, 146 (1994); Edenfield v. Fane, 507 U.S. 761, 771 (1993). They cannot shift that burden to Plaintiffs. The First Amendment burden is a high one. See Ibanez, 512 U.S. at 143 ("The State's burden is not slight; the 'free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful," citing Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 646 (1985)); see also Pearson, 164 F.3d at 659, citing Ibanez, 512 U.S. at 146 ("If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree"), *and citing* Edenfield, 507 U.S. at 771. The Supreme Court has held that unsupported assertions and mere speculation or conjecture about harm and direct advancement of government interests are insufficient to justify speech suppression; the

government must adduce empirical evidence to *prove* misleadingness and to *prove* that its chosen means *will in fact* promote its interests in a *direct* and *material* way as a condition precedent to speech suppression. See Central Hudson, 447 U.S. at 566; see also Ibanez, 512 U.S. at 148; Edenfield, 507 U.S. at 771; Zauderer 471 U.S. at 648-49. On remand, FDA had that obligation but failed to meet it. Despite the passage of eighteen months, FDA has adduced *no* empirical evidence that consumers will be misled, or harmed in any way, by the Folic Acid Claim. FDA's conclusion that the claim is "inherently misleading" is thus entirely unfounded.

Despite the fact that Defendants have the burden, they argue that Plaintiffs, not they, were required to come up with an acceptable disclaimer on remand. To the contrary, FDA bears that burden both under the terms of the Pearson decision and under the First Amendment standard Pearson requires FDA to apply. See Pearson, 164 F.3d at 659; *citing* Ibanez, 512 U.S. at 146; and citing Edenfield, 507 U.S. at 771.[6] Plaintiffs, for their part, have repeatedly expressed a willingness to accept any *reasonable* disclaimer. JR 39 and 40. They have also stated that they will voluntarily accompany the Folic Acid Claim with the following disclaimer: "Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects."

Having not met its burden of proof under the First Amendment standard, FDA cannot prevail on the merits.

(2) The Scientific Evidence Confirms the Veracity of the Folic Acid Claim; the Claim Is Not "Inherently Misleading" The Defendants argue against the weight of the evidence (a) that food folate is as effective as synthetic folic acid (MD at 9; Letter Ruling at 14) and (b)

[6] It is of course indisputable (absent proof of mind reading) that only the FDA knows, at the time of its decision, what it finds misleading about any particular claim. Only FDA, therefore, can logically craft a disclaimer for use by its decision date.

that the greater bioavailability of synthetic folic acid over food folate (i.e., the greater absorption of folic acid by intestinal cells) does not correlate with greater effectiveness in reducing NTDs (MD at 22). As explained more fully in the PI Reply at 9-13, entities no less expert in the scientific evaluation of folic acid than the United States Centers for Disease Control and Prevention (CDC); the National Center for Environmental Health (NCEH); the National Council on Folic Acid (NCFA); the Food and Nutrition Board of the Institute of Medicine (IOM); and the American Academy of Pediatrics (AAP) have all concluded, identically, that the scientific evidence does not demonstrate that food folate is as effective as synthetic folic acid in reducing NTDs. See JR 45 at 259, 23 at 14 and 18 and 48 at 320.

The Defendants' contention that the proven greater bioavailability of folic acid (the kind found in supplements and fortified foods) does not equal greater effectiveness is absurd. In addition to its illogic, the contention conflicts with FDA's own prior statements as explained in Plaintiffs PI Reply at 11-13. Bioavailability, as Webster's Dictionary explains, means "the extent to which a nutrient or medication can be used by the body." To suggest that a nutrient not absorbed by the cells of the body is as effective as a nutrient that is absorbed is patently ridiculous. FDA has already recognized in its decision granting a health claim for the association between folic acid and NTD risk that greater bioavailability does equal greater "*potency*," i.e., effectiveness. See the PI Reply at 11-12.[7]

(3) The Folic Acid Claim Does Not State That .8 mg of Folic Acid Is More

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[7] Examine FDA's own words from its 1993 folic acid decision authorizing a claim: "It is well recognized," said FDA, "that the bioavailability of free folic acid, the form included in fortified foods and in dietary supplements, is severalfold higher than that of naturally occurring food folates. Estimates of the increased bioavailability ('potency') of free folic acid relative to food folates range from at least twofold to fourfold or greater." 58 Fed. Reg. 53273 (emphasis added). Note well FDA's association between bioavailability and potency. That association is the very one the Defendants now say does not exist.

Effective than .4 mg of Folic Acid and Does Not State That Folic Acid in a Dietary Supplement Is More Effective than Folic Acid in a Fortified Food, Either Expressly or Impliedly. The Defendants are reduced to arguing, for the first time here, that the Folic Acid Claim *implies* two specific misleading connotations. *Ab initio*, this Court should recognize that *even if* misleading connotations were implied (albeit no empirical evidence exists to establish that they are)[8] under the First Amendment standard, FDA is to resort to use of disclaimers to eliminate those misleading connotations, not outright suppression. Thus, having failed to do so, it cannot meet its First Amendment burden even if the Folic Acid Claim *impliedly* misleads.[9]

The Folic Acid Claim does not compare folic acid in a dietary supplement or a fortified food with a lesser amount in a dietary supplement or a fortified food. Instead, the claim compares folic acid in a dietary supplement with a lower amount in foods in common form. Thus, it compares folic acid with lesser (usually far less), naturally occurring amounts of food folate.[10] Without question, relying on the IOM's determination that folic acid and food folate are not bioequivalent (See Plaintiffs PI Reply at 14), it takes about twice as much food folate to equal the potency of a given amount of synthetic folic acid (the kind found in dietary supplements and fortified foods). JR 23.

[8] Such evidence is legally required; presumptions are not enough. See generally Ibanez v. Florida Dep't of Business & Prof'l Regulation, 512 U.S. 146 (1994); Edenfield v. Fane, 507 U.S. 771 (1993).

[9] Even if the Folic Acid Claim were properly deemed *impliedly* misleading on either of these two grounds, FDA has not presented any evidence to establish why a reasonable disclaimer could not suffice to cure misleadingness. For example, FDA could have required use of the disclaimer, "In some women, .4 mg of folic acid may be as effective in reducing neural tube defect risk as .8 mg.," and FDA could have required use of the disclaimer, "Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects," or both. Plaintiffs would have accepted such a requirement without hesitation. Yet, FDA chose the draconian (and unconstitutional) approach of outright suppression, contumaciously rejecting the constitutional standard prescribed for it by the Pearson Court.

[10] Without any empirical evidence to show consumers understand the term "foods in common form" to mean "fortified foods," the Defendants argue that in fact this is implied. Semantics aside, FDA could certainly correct this perceived "misleading" connotation as to the meaning of "foods in common form" in the Folic Acid Claim by simply accepting a reasonable qualification as offered by the Plaintiffs: "Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects."

Finally, as explained in the PI Reply at 19 – 22, FDA's existing authorized and allowed folic acid claims are misleading to the public. Without the benefit of Plaintiffs' Folic Acid Claim appearing in the market at the point of sale, FDA's misleading permitted label claims will continue to lead women of childbearing age to believe that food folate, containing as little as 20 mcg of folic acid equivalent (an amount never proven to have any NTD risk reduction benefit), is effective in reducing NTD risk and will deprive women of the vital information that folic acid in a dietary supplement (or in a fortified food) in amounts equal to or greater than 650 mcg can reduce the risk of NTD-affected pregnancies by 50% or higher. FDA has thus authorized Folic Acid/NTD claims that mislead women in a way that contributes to, rather than lessens, ignorance concerning the use of folic acid to reduce the incidence of neural tube defects.

Viewing all factual inferences in Plaintiffs' favor (consistent with the motion to dismiss standard) and viewing the law applicable to the facts in accord with precedent, there can be no question that Plaintiffs have stated a claim under the First Amendment and the Pearson decision.

Fifth Amendment. The Plaintiffs' challenge FDA's actions on remand as failing to apply the process that is due after a final adjudication has held FDA's suppression of a health claim unconstitutional under the First Amendment. In particular, FDA has not acted promptly to revoke rules held unconstitutional; has not by a reasonable date certain re-evaluated the claim in light of additional scientific evidence following remand; and has not adopted an "up front standard" to allow the claim held unconstitutionally suppressed to be made on labels and in labeling for an interim period bearing interim disclaimers. Moreover, FDA has continued to enforce the unconstitutional rule even after officially "revoking" it.[11] Under the circumstances,

[11] In Pearson, 164 at 660, at fn 12, the Court of Appeals explained that just such a Fifth Amendment challenge could arise after remand to the agency and that it would not be subsumed under an APA analysis but would, like the First Amendment analysis above, be subject to the *constitutional*, not the APA, standard. The Court of Appeals wrote:

those actions deprive Plaintiffs of the process that is due them following a final and binding constitutional remand from the federal courts. The Supreme Court has explained that "procedural due process imposes constraints on governmental decisions which deprive individuals of 'liberty' or 'property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendments." Mathews v. Eldridge, 424 U.S. 319, 332 (1976).[12] The Court has held that

> identification of the specific dictates of due process generally requires consideration of three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Id. at 334-335 (1976). Concerning the third factor, the Supreme Court has warned that "[f]inancial cost alone is not a controlling weight in determining whether due process requires a particular procedural safeguard prior to some administrative decision." Id. at 348. Rather, "[t]he ultimate balance involves a determination as to when, under our constitutional system, judicial-type procedures must be imposed upon administrative action to assure fairness." Id. At root, here, the extraordinary government delays in action, the inexplicable refusal to revoke invalidated rules for over a year and six months after the Court of Appeals held them invalid, FDA's continuing enforcement of the revoked, unconstitutional rule, and the utter refusal to adopt interim procedural safeguards to allow a claim held unconstitutionally suppressed

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> To be sure, there could be some differences between an APA analysis and a First or Fifth Amendment analysis. It is possible that a standard may be sufficiently well-delineated to satisfy the APA but not the First or Fifth Amendment. And, the APA may allow the agency to provide guidance in implementation, whereas the First or Fifth Amendment may require the agency to define its standard up front. Neither of these issues is presently before us (they could only conceivably arise after remand to the agency), and we leave them for another day.

[12] See also Sacramento v. Lewis, 523 U.S. 833, 845-846 (1998): "We have emphasized time and again that the 'touchstone of due process is protection of the individual against arbitrary action of government . . ."

epitomize unfairness and lack of due process. The factual record reveals proof of due process violation under each of the three parts of the Mathews test.

(1) The Private Interest. There are two private interests at stake. One is Plaintiffs' First Amendment right, judicially recognized. Thus, Plaintiffs have an undoubted First Amendment right in their Folic Acid Claim. A second is Plaintiffs' economic interest in communicating the value comparison message conveyed by the Folic Acid Claim. That claim ("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") conveys to female consumers information they can use to maximize their reduction in neural tube defect births. If communicated in the market on Plaintiffs' .8 mg folic acid-containing multivitamin dietary supplements, the claim would have the effect of encouraging women to rely on those supplements as a means of reducing neural tube defect births. It thus is in Plaintiffs' economic interest that the claim be communicated. Deprivation of that right to communicate thus also redounds to Plaintiffs' economic detriment.

(2) The Risk of Erroneous Deprivation of that Interest and the Probable Value of Additional or Substitute Procedural Safeguards. On remand, FDA failed to revoke the rules held invalid and unconstitutional by the United States Court of Appeals for a period of over eighteen months after the Court's mandate issued and retains them in force to this day. In addition, FDA refused to specify (and has not specified) any *reasonable* deadline for definitive agency action on whether to allow the claim in question on remand from a federal court order holding the agency's suppression of the claim unconstitutional. Finally, against Plaintiffs' demands to the contrary, FDA has assiduously refused to issue or adopt any interim measure to inform the Plaintiffs that it would refrain from taking enforcement against them if they used the Folic Acid claim held unconstitutionally suppressed with interim disclaimers pending the outcome of FDA re-

evaluation of additional scientific evidence concerning the health claim. In the advent of a federal court decision holding suppression of Plaintiffs' Folic Acid Claim unconstitutional, the refusal of FDA to take the foregoing actions wrongfully deprived Plaintiffs for an excessively long period (indeed, a period longer than any other federal agency delay in implementing a final and binding constitutional mandate from a federal court)—over eighteen months and continuing—of their First Amendment right to communicate the Folic Acid Claim and of their economic interest in making that value comparison in the marketplace. Accordingly, the Court has ample grounds for holding FDA's actions on remand a violation of the Fifth Amendment Due Process Clause based on findings that (1) FDA's failure to publish within two weeks of issuance of the Court of Appeals' mandate a revocation of the Folic Acid rule deprived Plaintiffs of the process that was due; (2) FDA's failure to adopt a reasonable date certain for dispositive action on the Folic Acid Claim within 120 days after issuance of the Court of Appeals' mandate to re-evaluate any additional scientific evidence deprived Plaintiffs of the process that was due; (3) FDA's failure to notify Plaintiffs within one week after the remand order issued that they could use the Folic Acid Claim accompanied by interim disclaimers (in place until FDA completed its re-evaluation of the science) deprived Plaintiffs of the process that was due; and (4) FDA's continued enforcement of the revoked, unconstitutional rule. Moreover, there is extraordinary value to such findings because they will have the effect of forcing this agency to put in place procedural safeguards that will arrest in future (for the benefit of the health claimants here in issue[13] both now and in the future as they file new claims) the harms inflicted on Plaintiffs (and all others similarly situated) as a result of agency inaction in the face of a constitutional mandate.

[13] The Plaintiffs here have pending before the agency at this time additional health claims and plan to file more health claims with the agency in the future.

Viewing all factual inferences in Plaintiffs' favor (consistent with the motion to dismiss standard) and viewing the law applicable to the facts in accord with precedent, there can be no question that Plaintiffs have stated a claim under the Fifth Amendment's Due Process Clause and are entitled to their requested relief.

Supremacy Clause. As explained above, the FDA on remand did not undertake the three-part test prescribed in Pearson (and in Central Hudson). Satisfaction of all elements of that test is a condition precedent to suppression of speech that is, at worst, only potentially misleading. Moreover, FDA relied upon the scientific findings reached under its ill-defined "significant scientific agreement" standard as a basis for suppressing the Folic Acid Claim. FDA did not evaluate any disclaimers to use with Plaintiffs' Folic Acid Claim but rejected the claim outright. Under these circumstances, FDA has elevated its ill-defined "significant scientific agreement" standard above the contrary requirements of the First Amendment to the United States Constitution. That action violates the Supremacy Clause of the United States Constitution. Under the plain and intended meaning of the statutory language, FDA should have approved the Folic Acid Claim.[14] Approval of a health claim is permanent by rule until that rule is revoked by rulemaking. Allowance of a health claim through the exercise of enforcement discretion is temporary because that discretion may be revoked at any time without resort to a rulemaking proceeding. Thus, protection is less certain in the enforcement discretion context than when a formal rule authorizes the claim. Moreover, in this case FDA blurred and

[14] FDA's general health claims rule (the agency's interpretation of which was held unconstitutional in Pearson, 164 F.3d at 660-61), 21 C.F.R. §§ 101.14 and 101.70, codifies for dietary supplements the same standard of review contained in the Food Drug and Cosmetic Act for foods, 21 U.S.C. § 343(r)(3)(B)(i). That Section requires FDA to determine as a condition precedent to health claim authorization whether a health "claim is supported by [scientific] evidence," i.e., whether it accurately describes the present state of scientific understanding, not whether the nutrient-disease *relationship* underlying the claim is established to a near conclusive degree. The plain and intended meaning of the statutory language comports with the First Amendment. FDA's interpretation of it in its Letter Ruling does not.

inextricably intertwined its analysis such that its condemnation of the claim under its health claim review standard served as a basis for its decision to refuse to refrain from taking enforcement action against the claim. Thus, in the Letter Ruling, FDA impermissibly elevated its unconstitutional administrative decision above the contrary dictates of the First Amendment to the United States Constitution in violation of the Supremacy Clause.

Viewing all factual inferences in Plaintiffs' favor (consistent with the motion to dismiss standard) and viewing the law applicable to the facts in accord with precedent, there can be no question that Plaintiffs have stated a claim under the Supremacy Clause and are entitled to their requested relief.

IV. PLAINTIFFS HAVE STATED CLAIMS FOR RELIEF UNDER THE HEALTH CLAIMS PROVISION OF THE STATUTE AND UNDER THE ADMINISTRATIVE PROCEDURE ACT

The Defendants rather blithely contend that Plaintiffs have failed to state claims for violation of 21 U.S.C. § 343(r)(5)(D) and under the Administrative Procedure Act, 5 U.S.C. § 706 because they lack standing (refuted above) and depend upon the presumption that the Folic Acid claim is not "inherently misleading" but is protected speech. While both of those points are dealt with above, we here proceed out of an abundance of caution to explain the rationale underlying each of Plaintiffs' arguments under the statutory provisions. As should be quite clear, Plaintiffs have indeed stated claims for which relief can be granted under each of the statutory provisions.

21 U.S.C. § 343(r)(5)(D). As explained above, the evaluation used by FDA to support denial of the Folic Acid Claim arose under its health claims review standard and did not involve analysis of compliance with the three-part First Amendment test prescribed by the Pearson Court for speech that is, at worst, only potentially misleading. Although FDA purports to have adopted

for dietary supplement health claims the same standard of review used for food health claims (articulated in 21 U.S.C. § 343(r)(3)(B)(i)), it in fact evaluates not whether a dietary supplement health "claim is supported by [scientific] evidence," as required by Section 343(r)(3)(B)(i), but whether the nutrient-disease *relationship* is established to a near conclusive degree, a level of proof comparable to that required for pre-market authorization of a new drug, even though Congress expressly rejected use of the new drug standard. See Senate Report 103-410 at 23-24 (103d Cong., 2d Sess.) AER 27. FDA requires, as explained in its guidance, near conclusive proof of causality between the nutrient and the disease effect, focusing not on whether the claim description is accurate, but on whether the underlying relationship has been established. See GUIDANCE FOR INDUSTRY SIGNIFICANT SCIENTIFIC AGREEMENT IN REVIEWING HEALTH CLAIMS FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS (Dec. 1999) ("Guidance"). That latter interpretation of the general health claims rule, 21 C.F.R. § 101.14, is not prescribed for foods by the Act and denies authorization to claims, such as Plaintiffs', which are accurate. That latter interpretation violates the intended meaning of the Nutrition Labeling and Education Act and the First Amendment. See Senate Report 103-410 (103d Cong., 2d Sess.) AER 27 wherein Congress condemns FDA's failure to authorize health claims supported by scientific evidence and explains that it did not intend for the drug standard of review to govern the evaluation of health claims but that, instead, it expected all health claims to be allowed under the following circumstances:

> In implementing the significant scientific agreement standard, FDA will be expected to take advantage of the flexibility of the standard to maximize the availability on food and dietary supplement labels and labeling of disease-related information consumers can prudently use to affect their risk of disease.
>
> This includes recognizing that there will nearly always be some remaining scientific uncertainty about the validity of any diet-related health claim; that some individuals consuming or avoiding a nutrient in response to a health claim may benefit, while others may not; and that the benefit for any individual may consist not of absolutely avoiding a disease, but rather of reducing her or his risk of a disease.

> The endpoint for evaluation of the adequacy of support for a claim should not be definitive proof that the nutrient has the stated effect for all populations, but that the nutrient will produce the stated effect in the majority of a target population the majority of the time. In addition, the scientific evidence supporting a claim should not be held to the same standard used in evaluating new drug applications.

S. Rep. 103-410 at 24.[15]

Thus, in its Letter Ruling denying Plaintiffs' Folic Acid Claim, FDA did not follow the statutorily prescribed and intended method for evaluating "significant scientific agreement." It therefore violated Plaintiffs' statutory right to that review under 21 U.S.C. § 343(r)(5)(D).

APA. The Court of Appeals gave FDA the opportunity to "flesh out its standards" on a case by case basis (sub-regulation by sub-regulation). FDA published a "guidance" document as a response to the Court of Appeals' demand eight months after the remand issued. See 64 Fed. Reg. 71794 (Notice announcing availability of the document). The Guidance does no more than reiterate the essential ranking of different kinds of scientific studies that appeared in the rule on "significant scientific agreement" before the Court's order. *Compare* 21 U.S.C. § 343(r)(3)(B)(i) (where FDA explains the various levels of scientific evidence it will consider), *with* GUIDANCE FOR INDUSTRY SIGNIFICANT SCIENTIFIC AGREEMENT IN REVIEWING HEALTH CLAIMS FOR CONVENTIONAL FOODS AND DIETARY SUPPLEMENTS at 4-16. The Court ordered FDA to "explain what it means by significant scientific agreement or, at minimum, what it does not mean" such that the regulated class could "perceive the principles which are guiding agency action." 164 F.3d at 661. Nowhere in the Guidance or in the Letter Ruling does FDA explain the meaning of the term "significant scientific agreement" such that the regulated class can "perceive the principles" which guide its decision. FDA provides no evaluative criteria to enable the regulated

[15] The Committee of Congress that issued this report stated that it should not be used as legislative intent when interpreting the Dietary Supplement Health and Education Act (DSHEA). See Statement of Agreement 140 Cong.

class to know whether any studies other than randomized, double-blind, placebo controlled intervention clinical trials (FDA's so-called "gold standard" which was designed for new drug approvals) will be deemed acceptable (will be deemed evidence of the presence of "significant scientific agreement") to the agency. Even in the case of the "gold standard" studies, FDA provides no explanation of the circumstances under which such studies will be accepted or rejected. FDA does not explain precisely what factors present in the "gold standard" cases will be taken into account in assessing whether the study is "well-designed." For example, in the Folic Acid Claim, the "gold standard" Czeizel study (JR at 19) is not accepted by FDA as dispositive, yet its basis for coming to that determination is largely hidden from view. While in the Letter Ruling FDA discounts the study for being a "multivitamin study," JR 1A at 9, it has itself in the past relied on just such "multivitamin" studies as support for the efficacy of folic acid. See 61 Fed. Reg. 8752 (wherein FDA relies on multivitamin studies in support of its authorization of folic acid-NTD risk reduction claim). Indeed, in Defendants' MD, Defendants now retreat from that "multivitamin" argument. See MD at 16-17. Likewise, while FDA says that it will take into account studies it regards as less than the "gold standard," e.g., epidemiological or observational studies, it again does not define the evaluative criteria it applies to assess the merits of those kinds of studies. Thus, because the agency has not explained its evaluative criteria (both the kinds of studies it will find acceptable as evidence of significant scientific agreement and the factors it weighs in evaluating each study), it remains impossible for the regulated class to "perceive the principles which are guiding agency action." FDA has therefore not complied with the Pearson remand's requirement that it define "significant scientific agreement." FDA's failure to comply with the remand requirement is, thus, a

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Rec. S 14801 (Oct. 7, 1994). The Committee did not, however, articulate any such restriction on use of the report in interpreting the Nutrition Labeling and Education Act and that is the use to which Plaintiffs put it here.

continuing violation of the APA and constitutes arbitrary, capricious, and unlawful agency action and an abuse of agency discretion.

Viewing all factual inferences in Plaintiffs' favor (consistent with the motion to dismiss standard) and viewing the law applicable to the facts in accord with precedent, there can be no question that Plaintiffs have stated a claim under 21 U.S.C. § 343(r)(5)(D) and under 5 U.S.C. § 706.

V. CONCLUSION

For the foregoing reasons, the Plaintiffs respectfully request that this Honorable Court deny the Defendants' motion to dismiss and, in the alternative, grant Plaintiffs' motion for summary judgment filed under separate cover simultaneous herewith.

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