UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

MEMORANDUM OPINION

Plaintiffs are designers, sellers, and manufacturers of dietary supplement formulations containing folic acid.[1] They bring this action against Defendants Donna E. Shalala, Secretary, United States Department of Health and Human Services ("HHS"), in her official capacity; HHS; Jane E. Henney, M.D., Commissioner of Food Drugs, Food and Drug Administration ("FDA"), in her official capacity; the FDA; and the United States of America.

Plaintiffs challenge an FDA decision prohibiting them from including on their dietary supplements' labels a particular folic acid health claim, contending that the FDA's decision violates the First Amendment, Fifth Amendment, and Supremacy Clause of the United States Constitution, as well as the Food, Drug and Cosmetic Act, 21 U.S.C. § 343(r)(5)(D), and the Administrative Procedure Act ("APA"), 5 U.S.C. §

[1] Plaintiffs are Durk Pearson and Sandy Shaw, the American Preventive Medical Association, Julian M. Whitaker, M.D., Pure Encapsulations, Inc., and XCEL Medical Pharmacy, Ltd.

706. Plaintiffs seek a preliminary injunction enjoining the FDA from taking any action which would prevent Plaintiffs from using their desired folic acid health claim.

This matter is before the Court on Plaintiffs' Motion for a Preliminary Injunction [#3]. Upon consideration of the Motion, Opposition, Reply, the Excerpts of Record, the arguments of counsel during the motions hearing, and the entire record herein, for the reasons discussed below, Plaintiffs' Motion for a Preliminary Injunction is **granted.**

I. Statutory Framework and Procedural History

Prior to November 8, 1990, dietary supplements[2]--including the multi-vitamin supplements containing folic acid at issue in this case--were regulated as a "food," unless their intended use was as a "drug."[3] In other words, if a dietary supplement's label[4] contained a health

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[2] A "dietary supplement" is defined, in part, as a "product . . . intended to supplement the diet" which contains a vitamin, mineral or other enumerated substance. 21 U.S.C. § 321(ff).

[3] "Food" is defined, in part, as "articles used for food or drink." 21 U.S.C. § 321(f)(1). "Drugs" are defined, in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

[4] A "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). For purposes of this Opinion, the Court does not see a need to distinguish between "labels" and "labeling," the latter of which is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Id. § 321(m).

claim,[5] that supplement became subject to the FDA's strict drug approval and drug labeling requirements. See 21 U.S.C. §§ 321(g)(1)(B) and 355.

On November 2, 1990, Congress enacted the Nutrition Labeling and Education Act ("NLEA" or "the Act"),[6] which amended the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq. The NLEA liberalized the FFDCA, creating a "safe harbor" from "drug" designation for dietary supplements and foods that make health claims. See 21 U.S.C. § 343(r)(1)(B). So long as a health claim is made in accordance with 21 U.S.C. § 343(r)(3), for foods in conventional form, or in accordance with 21 U.S.C. § 343(r)(5)(D), for dietary supplements, the claim is not subject to the FFDCA's far more extensive and demanding approval and labeling requirements for drugs. See 21 U.S.C. § 321(g)(1)(B).

The NLEA also established the procedure under which the FDA would authorize and evaluate health claims for foods and dietary supplements. The Act directed that health claims for conventional foods shall be approved

> only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence

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[5] "Health claims" are statements that describe a relationship between a nutrient, such as calcium, and a disease or health-related condition, such as osteoporosis. See 21 U.S.C. § 343(r)(1)(B).

[6] Pub. L. No. 101-535, 104 Stat. 2353, codified as amended at 21 U.S.C. §§ 301, 321, 337, 343, 371 (1990).

> from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

21 U.S.C. § 343(r)(3)(B)(i) (emphasis added). Health claims for dietary supplements received a different authorization procedure, however. Instead of mandating a particular standard as it did for conventional foods in § 343(r)(3)(B)(i), Congress broadly delegated to the FDA the task of developing an appropriate procedure for evaluating and authorizing health claims for dietary supplements. The relevant section provides simply that health claims

> made with respect to a dietary supplement . . . shall be subject to a procedure and standard, respecting the validity of such a claim, established by regulation of the Secretary.

21 U.S.C. § 343(r)(5)(D). In addition, Congress specifically directed the FDA to consider whether health claims could be authorized for a number of specified nutrient-disease relationships, including the connection between folic acid[7] and neural tube defects ("NTDs").[8] See

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[7] "Folic acid, also known as pteroylmonoglutamic acid, is a synthetic compound used in dietary supplements and fortified foods." Compl. ¶ 2.

[8] "Neural tube defects ("NTDs"), specifically spina bifida and anencephaly, affect approximately 4,000 live births and pregnancies each year in the United States . . . . These spinal cord malformations are associated with serious developmental disabilities, including muscle weakness and/or paralysis, bowel and bladder incontinence, and intellectual impairment." Compl. ¶ 1.

21 U.S.C. § 343(r)(5)(D); NLEA, Pub. L. 101-535, § 3(b)(1)(A)(x).

The FDA responded to section 343(r)(5)(D) by promulgating 21 C.F.R. § 101.14, which applied the NLEA-prescribed procedure for food health claims (i.e., "significant scientific agreement") as the authorization procedure for dietary supplement health claims. The FDA responded to section 343(r)(5)(D) by publishing a proposed rule in the Federal Register on November 27, 1991, proposing not to authorize any health claim linking folic acid with a reduction in the risk of neural tube defects.

On January 6, 1993, the FDA adopted a final rule prohibiting claims associating folic acid with NTDs. See 58 Fed. Reg. 2606 (Jan. 6, 1993). On October 14, 1993, however, the FDA reversed its position and proposed authorizing certain claims associating folic acid with a reduction in the risk of NTDs. See 58 Fed. Reg. 53254 (Oct. 14, 1993).[9]

On January 28, 1994, Plaintiffs Durk Pearson and Sandy Shaw and the American Preventive Medical Association ("Pearson Plaintiffs") filed comments asking the FDA to authorize the following claim: ".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" (the "Folic Acid Claim"). Plaintiffs wished to use this claim on the labels and in the labeling of their dietary supplements. Compl. ¶

[9] The FDA did not actually issue final regulations authorizing such claims to be made until approximately two and a half years later. See 61 Fed. Reg. 8752 (March 5, 1996).

40. The FDA rejected Plaintiffs' request, stating that "the scientific literature does not support the superiority of any one source [of folic acid] over others." 61 Fed. Reg. at 8760.

In a final rule, the FDA established the daily recommended intake ("RDI") for folate[10] to be 400 mcg (0.4 mg), and it identified 100% of the RDI as the "target intake goal." 21 C.F.R. § 101.79(b)(3), (c)(3)(iv).[11] The FDA also approved four "model" health claims, each of which essentially indicated that women who consume "healthful diets with adequate folate . . . may reduce their risk of having a child with birth defects of the brain or spinal cord."[12] 21 C.F.R. § 101.79; Joint

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[10] The term "folate" includes all compounds that have the vitamin properties of folic acid. It includes both synthetic folic acid (which is used in dietary supplements and in fortified foods) and naturally occurring food folate. See Compl. ¶ 3.

[11] Section 101.79(c)(3)(iv) actually uses the term "DV" ("daily value") instead of RDI, but the two terms appear to be used interchangeably in this context.

[12] The four "model" claims were:

> Example 1: Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. The Institute of Medicine of the National Academy of Sciences recommends that women capable of becoming pregnant consume 400 mcg folate daily from supplements, fortified foods, or both, in addition to consuming food folate from a varied diet.
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> Example 2: Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. The scientific evidence that 400 mcg folic acid daily reduces the risk of such defects is stronger than the evidence for the effectiveness of lower amounts. This is because most such tests have not looked at

Excerpts of Record ("J.R.") at 17. The FDA authorized foods and dietary supplements to carry any of these model claims on their labels if they qualify as a "good source" of folate. 21 C.F.R. § 101.79(c)(2)(ii). A food or dietary supplement qualifies as a "good source" of folate if it contains 10% of the RDI (i.e., 10% of 400 mcg, which equals 40 mcg or .04 mg).

The Pearson Plaintiffs contended that these model claims were themselves misleading and otherwise unsatisfactory, and that the FDA's refusal to authorize Plaintiffs' Folic Acid Claim violated the First Amendment, the APA and other laws. Accordingly, on November 16, 1995, the Pearson Plaintiffs brought suit against the FDA, arguing that the

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amounts less than 400 mcg folic acid daily.

> Example 3: Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect. Women capable of becoming pregnant should take 400 mcg of folate per day from a supplement or fortified foods and consume food folate from a varied diet. It is not known whether the same level of protection can be achieved by using only food that is naturally rich in folate. Neither is it known whether lower intakes would be protective or whether there is a threshold below which no protection occurs.
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> Example 4: Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. Women capable of becoming pregnant should take 400 mcg of folate per day from a supplement or fortified foods and consume food folate from a varied diet. It is not known whether the same level of protection can be achieved by using lower amounts.

J.R. at 17.

FDA had unlawfully suppressed their Folic Acid Claim and requesting that the court invalidate the FDA's decision.[13] On January 12, 1998, this Court upheld the FDA's decision and granted summary judgment in its favor. See Pearson v. Shalala, 14 F. Supp. 2d 10 (D.D.C. 1998) (Kessler, J.).

On January 15, 1999, the Court of Appeals for the District of Columbia Circuit reversed and remanded the case with instructions to remand it in turn to the FDA for reconsideration of Plaintiffs' Folic Acid Claim, among other health claims. See Pearson v. Shalala, 164 F.3d 650, 661 (D.C. Cir. 1999) ("Pearson" or "Court of Appeals Opinion").

The Court of Appeals strongly suggested, without declaring so explicitly, that Plaintiffs' Folic Acid Claim was only "potentially misleading," not "inherently misleading," and therefore the FDA's refusal to authorize the Folic Acid Claim (or to propose a disclaimer to accompany the Claim) violated the First Amendment. Specifically, the Court of Appeals stated:

> The FDA's concern regarding the fourth claim--"0.8 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"--is different from its reservations regarding the first three claims; the agency simply concluded that "the scientific evidence does not support the

[13] Plaintiffs also challenged the FDA's refusal to authorize three additional health claims (dietary fiber/cancer, antioxidant vitamins/cancer, and omega-3 fatty acids/coronary heart disease) but these are not at issue in the present action.

> superiority of any one source [of folic acid] over others." 61 Fed. Reg. at 8760. But it appears that credible evidence did support this claim [citation omitted], and we suspect that a clarifying disclaimer could be added to the effect that "the evidence in support of this claim is inconclusive."

164 F.3d at 659 (emphasis added). The Court of Appeals went on to state:

> We do not presume to draft precise disclaimers for each of appellants' four claims; we leave that task to the agency in the first instance. Nor do we rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright.

Id. at 659. In addition, the Court of Appeals held that the FDA failed to adequately define the standard for reviewing health claims that it had adopted pursuant to 21 U.S.C. § 343(r)(5)(D) ("significant scientific agreement"), and thus acted arbitrarily and capriciously in violation of the APA.

Accordingly, the Court of Appeals directed the FDA on remand: (1) to determine whether a disclaimer could be added to the Folic Acid Claim and other health claims to cure them of potentially misleading connotations, and (2) to explain "what it means by significant scientific agreement or, at minimum, what it does not mean." 164 F.3d at 655, 660.

On April 20, 1999, this Court remanded the case to the FDA, in accordance with the Court of Appeals Opinion. Thereafter, the Pearson Plaintiffs sent a series of letters to the FDA, asking by what "date

certain" the agency intended to comply with the Court of Appeals Opinion. Compl. ¶ 53. The Pearson Plaintiffs also asked if the FDA would be willing to authorize their Folic Acid Claim, accompanied by one of the disclaimers suggested by the Court of Appeals ("The evidence in support of this claim is inconclusive") or other appropriate disclaimers.

On September 8, 1999, the FDA published a notice requesting that interested parties submit scientific data concerning the four substance-disease relationships at issue in Pearson, including the relationship between folic acid and NTDs.[14] 64 Fed. Reg. 48841 (Sept. 8, 1999); J.R. at 150. The FDA also contracted with a non-government entity "to conduct a literature review for the four claims to identify relevant scientific information that became available after the agency's initial review of these claims." Govt's Mem. in Opp'n to Pls.' Mot. for Prelim. Inj. ("Govt's Opp'n") at 6. As a result of these two information-gathering measures, the FDA received a large number of post-1992 scientific studies describing the relationship between folate and NTDs, including a 1998 study conducted by the

[14] The comment period was originally scheduled to close on November 22, 1999. Upon Plaintiffs' request, the period was re-opened until April 3, 2000. The FDA also held a public meeting on April 4, 2000, for the purpose of soliciting comments relating to the implementation of the Court of Appeals Opinion. The comment period for this meeting closed on April 19, 2000.

Institute of Medicine of the National Academy of Sciences[15] ("IOM/NAS Study")[16] and a 1999 follow-up study ("Berry Study")[17]. Govt's Opp'n at 7-8. The FDA received over 600 pages of scientific submissions from Plaintiffs, including documentation of a 1992 human clinical intervention trial conducted on Hungarian women ("Cziezel Study")[18]. Compl. ¶ 63-64.

On December 22, 1999, in response to the Court of Appeals' order that the FDA further define the "significant scientific agreement" standard for evaluating dietary supplement health claims, the FDA issued "Guidance for the Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements" ("Guidance Report") and announced its availability in the Federal Register. 64 Fed. Reg. 71794 (Dec. 22, 1999); J.R. at 163, 165-186.

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[15] The National Academy of Sciences is a private, non-profit organization which has been charged, since 1863, with the duty of advising the federal government on scientific and technical matters. Govt's Opp'n at 8 n.5.

[16] Inst. of Food, Med. and Nutrition Board, Nat'l Academy of Sciences, Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Panothenic Acid, Biotin and Choline (1998) (contained in J.R. at 580-624).

[17] R.J. Berry, et al., Prevention of neural tube defects with folic acid in China, 341 New Eng. J. Med. 1485 (1999) (contained in J.R. at 398-403).

[18] A.E. Cziezel and I. Dudas, Prevention of the first occurrence of neural-tube defects by periconceptional vitamin supplementation, 327 New Eng. J. Med. 1832 (1992) (contained in J.R. at 454-57).

On March 31, 2000, the Pearson Plaintiffs filed an application for a preliminary injunction before this Court, contending that the FDA's continuing refusal, subsequent to the Court of Appeals Opinion, to authorize Plaintiffs' Folic Acid Claim and the three other claims, with or without disclaimers, violated the First Amendment. On May 23, 2000, the Court denied the Pearson Plaintiffs' application, declaring, among other things, that "[b]ecause FDA has not yet exhausted the 540-day period within which they must make a final decision on Plaintiffs' health claims, . . . Plaintiffs have not suffered any First Amendment injury which this Court can address." Pearson v. Shalala, Civ. A. No. 95-1865, 2000 WL 767584, at *3 (D.D.C. May 24, 1999) (Kessler, J.).

On October 3, 2000, the FDA published a notice revoking the four rules held unconstitutional by the Court of Appeals in Pearson, over 18 months after that Court's decision. 65 Fed. Reg. 58917, 58918 (Oct. 3, 2000); J.R. at 158-159. The FDA continued to refuse to authorize Plaintiffs' Folic Acid Claim as well as the other three claims.

On October 10, 2000, having reviewed the new scientific studies submitted and having applied the "significant scientific agreement" standard as described in the Guidance Report and as modified by an October 6, 2000 Rule,[19] the FDA issued a letter decision ("Folic Acid

[19] On October 6, 2000, the FDA published a notice indicating that it had modified its "its approach to processing new health claim petitions for dietary supplements" on an interim basis. 65 Red. Reg.

Decision") in which it declared that it would not authorize Plaintiffs' Folic Acid Claim, even with clarifying disclaimers, because it deemed the Claim to be "inherently misleading." J.R. at 1-21. However, because the FDA also concluded that "an appropriately qualified claim would not threaten consumer health or safety," the agency exercised its enforcement discretion to propose four alternative claims, each of which recommended that women capable of becoming pregnant consume 0.4 mg (400 mcg) folate daily to reduce the risk of neural tube defects.[20] J.R. at 17.

On November 13, 2000, Plaintiffs filed the present lawsuit.

III. Analysis

Plaintiffs contend that the FDA's Folic Acid Decision fundamentally misread and misapplied the legal standard articulated by the Court of Appeals in Pearson, and that the FDA therefore acted in violation of the First Amendment.[21] Plaintiffs further contend that the

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59855, 59856; J.R. at 162. "Rather than denying all petitions that do not meet the significant scientific agreement standard pending completion of the general rulemaking," the FDA indicated its intention to "exercise enforcement discretion in the appropriate circumstances," such as when, among other things, "the scientific evidence in support of [a] claim outweighs the scientific evidence against the claim, the claim is appropriately qualified, and all statements in the claim are consistent with the weight of the scientific evidence . . ." Id.

[20] For the claims' actual language, see supra note 12.

[21] Plaintiffs contend that the FDA also violated Pearson by inadequately defining "significant scientific agreement," but the Court need not reach that issue for purposes of ruling on Plaintiffs' Motion for a Preliminary Injunction.

FDA's continued refusal to authorize their Folic Acid Claim, even with disclaimers, causes them irreparable harm, thus necessitating the issuance of a preliminary injunction. Defendants respond that the Folic Acid Claim is "inherently misleading" and that no clarifying disclaimer can cure that defect. Accordingly, they maintain that the Claim is not protected speech and that the FDA's decision to prohibit the Folic Acid Claim was neither arbitrary nor capricious.

To obtain a preliminary injunction, Plaintiffs must show (1) a substantial likelihood of success on the merits; (2) a substantial threat that they will suffer irreparable injury if the injunction is not granted; (3) that the threatened irreparable injury outweighs the threatened harm that the injunction would cause Defendants and third parties; and (4) that granting the preliminary injunction would be in the public interest. See Mova Pharm. Corp v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998); Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841 (D.C. Cir. 1977).

Applying these four criteria, the Court concludes that a preliminary injunction is warranted in this case. As will be explained below, it is clear that the FDA simply failed to comply with the constitutional guidelines outlined in Pearson. Indeed, the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the

Court of Appeals Opinion. However, given that it is not the Court's institutional role to draft accurate, adequate, and succinct health claim disclaimers, see Pearson, 164 F.3d at 659, the Court will permit the FDA to draft and submit one or more alternative disclaimers which may be chosen by designers, sellers, and manufacturers of dietary supplements. Because the Court is granting only limited relief to Plaintiffs at this time, see Order, Plaintiffs will not be authorized to design, sell, or manufacturer their dietary supplements without disclaimers.[22]

A. Substantial Likelihood of Success on the Merits

The FDA's refusal to authorize Plaintiffs' proposed claim must be subjected to the analytical standard established by the U.S. Supreme Court in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557 (1980), and elaborated upon by our Court of Appeals in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999).

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[22] Plaintiffs request that the Court "issue an immediate preliminary injunction barring FDA from taking any action to prohibit them from including on the labels and in the labeling of their dietary supplements (that contain recommended daily doses of 0.8 mg of folic acid)" Plaintiffs' Folic Acid Claim. Pls.' Application for Prelim. Inj. ("P.I. Mot.") at 37-38. Plaintiffs indicate that they will "voluntarily accompany" their 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." Id. Because the Court finds the Folic Acid Claim to be "potentially misleading," it cannot grant Plaintiffs' request in its entirety; rather, the FDA must be given the opportunity, "in the first instance," to draft a clarifying disclaimer. Pearson, 164 F.3d at 659.

If information is "inherently" misleading, it may be banned entirely. See Pearson, 164 F.3d at 655 (citing In re R.M.J., 455 U.S. 191, 203 (1982)). In the case of "potentially misleading commercial speech," a court reviewing a challenge to such a government regulation must employ a three-part test. 164 F.3d at 655. The first question is "whether the asserted government interest is substantial." Pearson, 164 F.3d at 655 (citing Central Hudson, 447 U.S. at 566). Next, a court must ask "whether the regulation directly advances the governmental interest asserted" and "whether the fit between the government's ends and the means chosen to accomplish those ends is . . . reasonable." Pearson, 164 F.3d at 655 (internal citations and quotations omitted).

Having considered the very Folic Acid Claim which is at issue in this case, the Pearson Court provided additional guidance on application of the Central Hudson test to the concrete factual scenario currently before this Court.[23] Our Court of Appeals noted that the test's first prong (whether there is a governmental interest in the

[23] With respect to the relevant First Amendment analysis, Defendants ask the Court to consider a number of decisions other than Pearson, including decisions from other circuits, older D.C. Circuit decisions, and a 1924 U.S. Supreme Court decision. See Govt's Opp'n at 13-14. However, not only is Pearson the most recent decision in this Circuit on this issue, but it is clearly the law of the case, since it has already examined the precise health claim at issue here (Plaintiffs' Folic Acid Claim) in the context of the precise situation at issue here (the FDA's refusal to authorize the Claim, even with disclaimers).

regulatory scheme) is easily satisfied by the FDA's decision to deny approval for certain health claims, such as the Folic Acid Claim. Simply stated, the governmental interest implicated is the "protection of public health and prevention of consumer fraud." 164 F.3d at 655-56. The Court went on to conclude that Central Hudson's second prong is also satisfied, because the FDA's regulation of dietary supplement health claims directly advances its interest in "protecting against consumer fraud," by ensuring that consumers have accurate and non-misleading information about the health products they contemplate purchasing. Pearson, 164 F.3d at 655. In the present case, then, there can be no doubt that the FDA has satisfied the first two prongs of the Central Hudson test.

The more difficult analytical inquiry concerns the test's third prong (whether there is a reasonable fit between the government's goals and the means it has chosen to achieve them). In reviewing the relevant U.S. Supreme Court decisions, the Pearson Court singled out one legal principle of particular importance: disclaimers are "constitutionally preferable to outright suppression," Pearson, 164 F.3d at 657 (internal citations omitted); in other words, more disclosure rather than less is the preferred approach, so long as advertising is not inherently misleading. Id. at 657 (citing Bates v. State Bar of Arizona, 433 U.S. 350, 376 (1977). With this guidance in mind, the Court went on to state: "It is clear, then, that when

government chooses a policy of suppression over disclosure--at least where there is no showing that disclosure would not suffice to cure misleadingness--government disregards a 'far less restrictive means.'" Id. at 658. Employing these legal standards, the Court of Appeals strongly suggested that Plaintiffs' Folic Acid Claim was not "inherently misleading," but rather only "potentially misleading." For that reason, the Court "suspect[ed] that a clarifying disclaimer could be added to the effect that 'the evidence in support of this claim is inconclusive'" or that "[t]he FDA does not approve this claim." 164 F.3d at 659.

Given that the FDA has continually refused to authorize the disclaimers suggested by the Court of Appeals--or any disclaimer, for that matter--it is essential to carefully review its analysis in reaching that decision. First, the FDA divided Plaintiffs' proposed claim (".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") into essentially two sub-claims: (1) a comparison of the effectiveness of 0.8 mg of folic acid to that of lower amounts, especially 0.4 mg, and (2) a comparison of the effectiveness of folic acid found in dietary supplements to folate found in "foods in common form." J.R. at 8. Then, the FDA analyzed

each sub-claim separately.[24]

With respect to the first sub-claim, the FDA declared that "the weight of scientific evidence does not support the conclusion that 800 mcg folic acid/day is more effective than 400 mcg folic acid/day, or lesser amounts . . . in reducing the risk of NTDs." J.R. at 11. With respect to the second sub-claim, the FDA declared that "[t]here is no basis to believe that folic acid delivered by dietary supplements and folic acid delivered by fortified foods differ significantly in their ability to function metabolically as the folate vitamin." J.R. at 14.

Taking these two sub-claims together, the FDA concluded that, "based on the totality of the scientific evidence, there is not significant scientific agreement among qualified experts 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.'"

Id. The FDA further concluded, without elaboration, that "the weight

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[24] As a preliminary matter, Plaintiffs take issue with the FDA's decision to divide the Folic Acid Claim into the two sub-claims. According to Plaintiffs, the FDA makes an improper inference in so doing, reading into Plaintiffs' claim assertions they never intended to make (namely, the two sub-claims). However, to the extent that Plaintiffs are attempting to argue that the Folic Acid Claim is wholly non-misleading because it is capable of only one possible reading (i.e., that 0.8 mg of folic acid is more effective than some unspecified "lower amount" of food folate, and nothing more), such an argument is without support; there has been no suggestion that consumers will read the Folic Acid Claim in that way. At any rate, the FDA's chosen method of dissecting the Claim is neither arbitrary nor capricious. See 5 U.S.C. § 706(2)(A); Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971).

of the evidence is against both aspects of the proposed claim," and that the claim is "inherently misleading and cannot be made non-misleading with a disclaimer or other qualifying language." Id. at 16 (emphasis added) (citing Pearson, 164 F.3d at 659).

Upon reviewing not only the FDA's Folic Acid Decision, but also the scientific studies on which the FDA relied to reach its conclusion that the "weight" of evidence was against Plaintiffs' Folic Acid Claim, the Court concludes that the FDA has failed to comply with the Court of Appeals decision in Pearson and that Plaintiffs have a substantial likelihood of success on the merits of their First Amendment claim. The Court finds, as a matter of law, that Plaintiffs' Folic Acid Claim is not "inherently misleading," and the FDA therefore erred in not drafting disclaimers to accompany the Claim.

The Pearson Court established clear guidelines for the FDA in determining whether a particular health claim may be deemed "inherently misleading" and thus entirely banned. The Court implied, though it did not declare explicitly, that when "credible evidence" supports a claim, such as the Folic Acid Claim, that claim may not be absolutely prohibited. 164 F.3d at 659. The Court did not "rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright." Id. at 659. The Court also stated 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--for example, where the claims rests on only one or two old studies." Id. at 659 n.10.

Nevertheless, upon reviewing the Folic Acid Claim and the three other claims proposed by Plaintiffs, the Court indicated that it was "skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones [the Court] suggested above ["The evidence in support of this claim is inconclusive" or "The FDA does not approve this claim"] would bewilder consumers and fail to correct for deceptiveness," although the Court did not "rule out that possibility." Id. at 659-660.

In its Folic Acid Decision, the FDA seemed to recognize the import of Pearson, because it stated as its basis for prohibiting the Folic Acid Claim its conclusion that the "weight" of the scientific evidence was "against" the proposed claim; accordingly, the FDA determined that the disclaimer suggested by the Pearson Court ("The evidence in support of this claim is inconclusive") was "inadequate" to cure the misleading nature of the claim. J.R. at 16.

While the Court is mindful that it is generally "not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence," NRDC v. EPA, 824 F.2d 1211, 1216 (D.C. Cir. 1987), even a cursory examination of the scientific literature on which the FDA relied in its Folic Acid Decision demonstrates that the FDA's

conclusion that the "weight" of the evidence was against Plaintiffs' Folic Acid Claim was arbitrary, capricious and otherwise in violation of law.[25]

1. Whether 0.8 Mg of Folic Acid is Superior to 0.4 Mg

With respect to the first sub-claim (the superiority of 0.8 mg over 0.4 mg), despite the FDA's conclusory assertion to the contrary, the studies that it included in its Folic Acid Decision cannot be accurately described as being "against" the claim that 0.8 mg of folic acid is superior to 0.4 mg of folic acid.

First, it is undisputed that there is ample evidence that 0.4 mg of folic acid is highly effective in reducing the neural tube defect risk.[26] Second, it is true that there is not a scientific consensus which affirmatively supports Plaintiffs' assertion that 0.8 mg of folic acid is superior to 0.4 mg. See Govt's Opp'n at 15 ("FDA found that the best data available do not support the existence of a dose-

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[25] The parties argue at length about which legal standard the Court should apply in evaluating the FDA's decision to ban Plaintiffs' Folic Acid Claim--the agency-deferential standard ordinarily mandated by the APA or the much more Plaintiff-friendly First Amendment standard seemingly mandated by Pearson. Because the Court finds that the agency's conclusion would violate either standard, it need not reach this issue.

[26] In examining the effect of 0.4 mg of folic acid, one study cited by the FDA found a 72% reduced risk of NTDs, while other studies found reduced risks of 40%, 60%, 70% and 80%. See Govt's Opp'n at 17-18; J.R. at 9, 10, 736. To the extent that Plaintiffs suggest there is a scientific consensus that 0.4 mg results in a 50% reduction of NTDs, see P.I. Mot. at 10, they are incorrect.

dependent risk reduction in NTDs at doses greater than 400 mcg."). For these reasons, among others, the sub-claim is undoubtedly "potentially" misleading, because it reasonably implies that 0.8 mg has been proven more effective than 0.4 mg, which is far from true.

However, neither of the two statements described above lead to the conclusion that the "weight" of the scientific evidence is "against" the superiority of 0.8 mg over 0.4 mg--which is what the FDA must show to remove the Folic Acid Claim from First Amendment protection. The mere absence of significant affirmative evidence in support of a particular claim (i.e., the superior effectiveness of 0.8 mg over 0.4 mg of folic acid) does not translate into negative evidence "against" it.[27]

No study has concluded that doses between 0.4 mg and 0.8 mg are harmful, or that 0.8 mg is demonstrably less effective than 0.4 mg of folic acid.[28] More importantly, in the Cziezel Study--a clinical

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[27] In the legal brief filed on its behalf, the FDA seems to now recognize this distinction. It no longer contends that the "weight" of the scientific evidence is "against" the Folic Acid Claim, as it did in the Folic Acid Decision, but instead argues simply that "the scientific evidence does not support a claim that 800 mcg is a necessary, recommended, or more effective dose . . ." Govt's Opp'n at 15, and that "the weight of the scientific evidence does not support the claim that 800 mcg is more effective than 400 mcg or lesser amounts . . ." Id. at 18 (emphasis added).

[28] In October 1993, the FDA "tentatively decided to use 1 mg (1,000 ug)/day of total folate intake as the safe upper limit," admitting that its conclusion was "not without controversy." 58 Fed. Reg. 53273 (Oct. 14, 1993); J.R. at 60. However, a scientist reporting the findings of a 1997 workshop sponsored by a standing committee of the Food and

intervention trial involving 2,104 Hungarian women taking multivitamin supplements containing 0.8 mg of folic acid (the results of which were published in the New England Journal of Medicine in 1992)--0.8 mg of folic acid yielded a 100% reduction in the incidence of NTDs. When considered in conjunction with other studies of folic acid, the implication of the Cziezel Study is that 0.8 mg of folic acid is more effective than 0.4 mg at reducing the incidence of NTDs.[29]

The FDA tries to discount the significance of the findings of the Czeizel Study because the agency places "lesser weight on the outcome of randomized clinical trials in which the test substance, i.e folic acid, is fed as part of a multivitamin/multimineral supplement." J.R. at 9. However, the FDA has previously relied on numerous studies involving multivitamin supplements containing folic acid, without questioning the validity of those studies. See 61 Fed. Reg. at 8752;

Nutrition Board, Institute of Medicine, stated that "[d]uring this workshop it became apparent that consensus has been reached among the scientific community [that] folate and folic acid are completely without adverse effects in any population or subgroup at intakes up to 5000 ug/d [5 mg per day]." P.I. Mot., Ex. 25 at 92. At any rate, the FDA has never contended that a dosage of less than 1 mg is harmful.

[29] In the Cziezel Study, women planning a pregnancy were randomly given either a multivitamin supplement containing 0.8 mg of folic acid or a "trace-element supplement" containing no folic acid. J.R. at 454. Of the women in the first group (taking 0.8 mg of folic acid), none gave birth to infants with NTDs; of the women in the second group, six gave birth to infants with NTDs. See J.R. at 454-57. The Cziezel Study did not evaluate the effectiveness of 0.4 mg of folic acid, but reputable studies have found its effectiveness to range from 40% to 80%. See supra note 26.

J.R. at 89. Further, the FDA does not suggest any other nutrients or vitamins in the multivitamin/ multimineral supplements which could be responsible for decreased NTD risk besides folic acid. Indeed, one of the studies the FDA relies on as presenting the "strongest data" associating folic acid and decreased NTD risk examined the effects of both multivitamin supplements and folic acid taken separately, and concluded that it was only the folic acid--not any other substance in the multivitamins--which was responsible for the decreased incidence of NTDs. See J.R. at 9 (citing MRC Vitamin Study Research Group, Prevention of neural tube defects: Results of the Medical Research Council Vitamin Study, 338 Lancet 131 (July 1991), contained in P.I. Mot., Ex. 4).

When the affirmative findings of the Cziezel Study are taken into account, in conjunction with the lack of evidence that doses in excess of 0.4 mg of folic acid are ineffective or harmful, it is clear that the first sub-claim is only "potentially" misleading. Consequently, the Court concludes that the FDA erred in determining that the sub-claim is inherently misleading.

2. Whether Folic Acid is Superior to Folate Found in "Foods in Common Form"

With respect to the second sub-claim, the FDA similarly concluded in its Folic Acid Decision that the "weight" of the scientific evidence was against the superiority of folic acid over folate occurring in

foods. The FDA relied primarily on the following two criticisms of the sub-claim:

a. whether folic acid is superior to naturally occurring food folate

To begin with, the FDA concedes that "[i]t is well-recognized 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; J.R. at 60. The FDA also acknowledges that, based on the findings of the 1998 IOM/NAS Study, "the available evidence for protective effect from folic acid is much stronger than that for food folate." J.R. at 14.

Indeed, countless scientific bodies have expressed skepticism that food folate is as effective at reducing NTDs as is folic acid, including the Centers for Disease Control ("CDC"), the Food and Nutritional Board of the Institute of Medicine ("IOM"), and the National Center for Environmental Health ("NCEH"). See, e.g., P.I. Mot., Ex. 19 ("The body can absorb and use the folic acid found in vitamin supplements and fortified foods more efficiently than it can convert the food folate into a usable form. Synthetic folic acid is about twice as absorbable as naturally occurring food folate."); see

also Pls.' Submission of Record Citations for Footnote 9 to Pls.' Reply Mem. at 1-4.

The FDA does not seriously challenge any of these findings. Instead, it questions whether synthetic folic acid's superior bioavailability necessarily makes it a "more effective delivery vehicle" in reducing NTDs. J.R. at 11.[30] Again, the FDA misreads the Court of Appeals decision in Pearson. The Court stated:

> The FDA's concern regarding the fourth claim--"0.8 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"--is different from its reservations regarding the first three claims; the agency simply concluded that "the scientific evidence does not support the superiority of any one source [of folic acid] over others." 61 Fed. Reg. at 8760. But it appears that credible evidence did support this claim, see, e.g., Diet and Health: Implications for Reducing Chronic Disease Risk 67 (Committee on Diet and Health, Food and Nutrition Board 1989) (concluding that "[l]osses [of folic acid] in cooking and canning [foods] can be very high due to heat destruction"), and we suspect that a clarifying disclaimer could be added to the effect that "the evidence in support of this claim is inconclusive."

164 F.3d at 659 (emphasis added).

In attacking the Court of Appeals' observation ("it appears that credible evidence did support this claim"), the FDA noted, among other things, that "many foods that are good source of food folate are

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[30] The FDA isolated two distinct "aspects" of the sub-claim: "a) compositional issues, e.g., dietary supplements contain more of the vitamin or are subject to fewer losses of th vitamin than are foods, and b) issues of physiologic effectiveness, e.g., the folic acid ingredient in dietary supplements is physiologically superior to the naturally occurring folate in foods." J.R. at 11.

minimally processed or eaten raw," and concluded that the putative problem identified by the Court of Appeals--that folic acid may be destroyed when certain foods are cooked--is therefore insignificant. J.R. at 12. The FDA conceded that "some vitamins, minerals and other nutrients may be lost from some foods during home cooking," but concluded, without any scientific or empirical support, that the cooking labels accompanying such foods (e.g., "To retain vitamins do not rinse before or drain after cooking") would solve that potential problem. Id. at 12-13.

However, as the Pearson opinion strongly suggests, the FDA may not ban the Folic Acid Claim simply because the scientific literature is inconclusive about whether synthetic folic acid is superior to naturally occurring food folate. See Pearson, 164 F.3d at 658. The question which must be answered under Pearson is whether there is any "credible evidence" that synthetic folic acid is superior to naturally occurring food folate. See id. (observing that "it appears that credible evidence did support" the Folic Acid Claim). There clearly is such evidence, as the FDA itself acknowledged. J.R. at 14 ("IOM/NAS (1998) did note that the available evidence for a protective effect from folic acid is much stronger than that for food folate."). Consequently, the agency erred in concluding otherwise. In short, even if the FDA's criticism of the sub-claim is valid, this criticism does not make the Claim inherently misleading; rather, it suggests the need

for a well-drafted disclaimer, which the FDA has steadfastly thus far refused to even consider.

b. whether the term "foods in common form" includes fortified foods

A second complaint the FDA levels against the second sub-claim is that it implies that folic acid in dietary supplements is more effective than the folic acid used to fortify foods. The FDA presently considers foods in "common form" to include fortified foods. It argues that there is no scientific evidence that the folic acid found in dietary supplements is any better than the folic acid found in fortified foods. Accordingly, the FDA contends that Plaintiffs' Folic Acid Claim, by asserting the superiority of folic acid over "foods in common form," is inaccurate and misleading. J.R. at 15.

While the parties can reasonably disagree about whether fortified foods should be considered "foods in common form," Plaintiffs correctly focus their argument on the only relevant legal question: assuming the inference is to be fairly drawn, and assuming that the claim is misleading, can the Folic Acid Claim be made non-misleading through a clarifying disclaimer? Pls.' Mem. in Reply to Govt's Opp'n at 17. The FDA patently refused to consider any such disclaimers, including what appears to be a reasonable one recently suggested by Plaintiffs: "Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects." Id.

The Pearson Court clearly ruled that the FDA may not prohibit a health claim unless it first makes a "showing" that the claim's alleged "misleadingness" could not be cured through the use of a disclaimer or other types of disclosure. 164 F.3d at 658. The FDA has not made such a showing, and its decision to classify the second sub-claim as inherently misleading is therefore erroneous.

3. Plaintiffs' Folic Acid Claim Considered in Totality

In sum, the FDA has simply failed to adequately consider the teachings of Pearson: that the agency must shoulder a very heavy burden if it seeks to totally ban a particular health claim. With respect to the two disclaimers which the Pearson Court suggested might cure all potential misleadingness, the FDA did not consider one of them at all, and summarily rejected the other in a single sentence. Nor did the FDA "demonstrate with empirical evidence that disclaimers similar to the ones" suggested by the Court of Appeals would "bewilder consumers and fail to correct for deceptiveness." Pearson, 164 F.3d at 659-60. Indeed, the FDA did not consider any other disclaimers, except for "The FDA has not evaluated this claim," a disclaimer no one has suggested and which is obviously inaccurate. See J.R. at 16.

For the reasons expressed above, the FDA's determination that the Folic Acid Claim is "inherently misleading" and cannot be cured by disclaimers is arbitrary and capricious, whether the two sub-claims are examined in isolation or together. Consequently, the Court concludes

that the FDA did not undertake the necessary analysis required by Pearson, especially as evidenced by its failure to consider clarifying disclaimers that could cure the alleged misleading nature of the Folic Acid Claim. For all the forgoing reasons, the Court concludes that there is a substantial likelihood that Plaintiffs will prevail on the merits of their claim.

B. The Substantial Threat of Irreparable Harm

The case law makes it very clear that Plaintiffs are harmed by the FDA's suppression of the Folic Acid Claim. "The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." Elrod v. Burns, 427 U.S. 347, 373 (1976) (plurality opinion) (citing New York Times Co. v. United States, 403 U.S. 713 (1971)); see also Lakewood v. Plain Dealer Publ'g Co., 486 U.S. 750, 758 (1988) (noting that "opportunities for speech," if suppressed, "are irretrievably lost"). The FDA's actions in violation of the First Amendment thus constitute irreparable harm.[31]

C. The Injury to Third Parties

Defendants contend that the Folic Acid Claim will mislead and harm third parties (namely, consumers) and therefore is not beneficial to

[31] Defendants imply that Elrod and its progeny apply only to political, and not commercial, speech, see Govt's Opp'n at 25, but they do not make any argument as to why one type of First Amendment violation should be judged differently than another. Morever, Defendants have not pointed to any case law in support of such a distinction.

the public. The Court is aware of the vital role the FDA plays in protecting vulnerable consumers from fraud in the labeling and marketing of foods and dietary supplements. However, under the governing analysis set forth in Pearson, even if Plaintiffs' Folic Acid Claim is in some respects "potentially misleading," the resulting injury that could flow to consumers cannot compare, as a matter of law, with the First Amendment injury Plaintiffs have continually borne in the two yeas since Pearson was decided.

It is especially important to recognize that, in the present case, the potential harm to consumers from deception is severely limited. By the FDA's own admission, consumers who purchase and consume multivitamin supplements containing 0.8 mg of folic acid, such as the ones marketed by Plaintiffs, will not suffer any adverse health effects. See Pearson, 164 F.3d at 656 (noting that "the government does not assert that [the Pearson Plaintiffs'] dietary supplements in any fashion threaten consumer's health and safety"). At worst, any deception resulting from Plaintiffs' health claim will result simply in consumers spending money on a product that they might not otherwise have purchased, or perhaps spending more money on a product with a higher folic acid content. This type of injury, while not insignificant, cannot compare to the harm resulting from the unlawful suppression of speech.

D. The Public Interest

The public interest would be served in two ways by the issuance of an injunction. First, it is clearly in the public interest to ensure that governmental agencies, such as the FDA, fully comply with the law, especially when that law concerns the parameters of a party's First Amendment rights to effectively communicate its health message to consumers.

Second, the public health risk from neural tube defects is undeniably substantial. NTDs occur in approximately 1 of every 1,000 live births in the United States. See P.I. Mot., Ex. 22 at 325. Approximately 2,500 babies are born every year with an NTD. Id. Of the children born with NTDs, most do not survive into adulthood, and those who do experience severe handicaps. The lifetime health costs associated with spina bifida, the most common NTD, exceed $500,000, and the yearly costs in Social Security payments exceed $82 million.[32] See P.I. Mot., Ex. 26 at 2, 6.

Given that the scientific consensus, even as acknowledged by the FDA, confirms that taking folic acid substantially reduces a woman's risk of giving birth to an infant with a neural tube defect, the public interest is well served by permitting information about the folic acid/NTD connection to reach as wide a public audience as possible. Plaintiffs' Folic Acid Claim, regardless of whether it is ideally worded or entirely free from misleadingness, communicates this vitally

[32] Defendants did not dispute any of Plaintiffs' statistics.

important message.

IV. Conclusion

For the reasons stated, the Court finds that the FDA's decision to classify Plaintiffs' Folic Acid Claim as "inherently misleading" was arbitrary, capricious, and an abuse of discretion. Plaintiffs' proposed Claim is only potentially misleading, and therefore subject to First Amendment protection. Accordingly, the Court concludes that the FDA acted unconstitutionally, and particularly in violation of the Court of Appeals decision in Pearson v. Shalala, in suppressing Plaintiffs' Claim rather than proposing a clarifying disclaimer to accompany the Claim. Accordingly, the Court **grants** Plaintiffs' Motion for a Preliminary Injunction insofar as it requests a declaration that the FDA's refusal to authorize the Folic Acid Claim violated the First Amendment.[33]

However, because it is the FDA's, rather than the Court's, institutional role to draft accurate, adequate, and succinct health claim disclaimers, the Court hereby **remands this case to the FDA**, instructing the agency to draft one or more appropriately short, succinct, and accurate disclaimers.[34] The Court strongly suggests the

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[33] See supra note 22.

[34] The Court is aware that there are certain constraints on its ability to mandate specific time limits for agency action. See Consumer Fed'n of Am. and Pub. Citizen v. United States Dep't of Health and Human Servs., 83 F.3d 1497 (D.C. Cir. 1996). Because of those constraints, the Court will not impose an absolute time limit for the

agency consider the two disclaimers suggested by the Pearson Court ("The evidence in support of this claim is inconclusive" and "The FDA does not approve this claim"), as well as the disclaimer put forth by Plaintiffs ("Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects").

An Order will issue with this Opinion.

_____ _____
Date Gladys Kessler
United States District Judge

Copies to:

Jonathan W. Emord
Emord & Associates, P.C.
1050 Seventeenth Street, NW
Suite 600
Washington, DC 20036

Susan Strawn
Drake Cutini
Office of Consumer Litigation
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044

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drafting of disclaimers. However, there is no question that the agency has acted with less than reasonable speed in this case; for example, it waited for more than 18 months before revoking rules declared unconstitutional by our Court of Appeals. Further, as discussed above, the health risks to the public from neural tube defects, as well as the economic consequences, are very substantial. Consequently, the Court anticipates that the agency will complete its task within 60 days.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

O R D E R

This matter is before the Court on Plaintiffs' Motion for a Preliminary Injunction [#3] and Defendant's Motion to Dismiss [#9]. For the reasons stated in the accompanying Memorandum Opinion, it is this _____ day of February 2001

ORDERED, that Plaintiffs' Motion for a Preliminary Injunction **[#3]** is **granted** only insofar as it requests a declaration that the Food and Drug Administration's October 10, 2000 denial of Plaintiffs' Folic Acid Claim (".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") violates the First Amendment of the U.S. Constitution; and it is further

ORDERED, that this case is **remanded**, effective immediately, to the Food and Drug Administration, for the purpose of drafting one or more short, succinct, and accurate alternative disclaimers, which may be chosen by Plaintiffs to accompany their Folic Acid Claim, consistent with the accompanying Memorandum Opinion.

_____
Gladys Kessler
United States District Judge

Copies to:

Jonathan W. Emord
Emord & Associates, P.C.
1050 Seventeenth Street, NW
Suite 600
Washington, DC 20036

Susan Strawn
Drake Cutini
Office of Consumer Litigation
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044