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 REPLY TO
DEFENDANTS' OPPOSITION TO
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Plaintiffs, by counsel, hereby submit this reply to the Defendants' opposition to Plaintiffs' motion for summary judgment. There is no genuine issue of material fact and as a matter of law judgment should be entered in Plaintiffs' favor.

The Defendants ignore the controlling authority of Pearson v. Shalala, 164 F.3d 650 (D.C.Cir. 1999), which governed how the agency was to evaluate this case on remand. The Pearson Court adjudged FDA's suppression of the claim here in issue under the First Amendment standard of Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of NY, 447 U.S. 557 (1980), not under the more deferential standard of the Administrative Procedure Act (APA). The Court expected the agency to reevaluate the Plaintiffs' claim under that high standard, faulting it for rejecting--contrary to the third prong of Central Hudson--the "far less restrictive means" of disclaimers. 164 F.3d at 658. The Court expected the agency either to authorize the claim with corrective disclaimers or establish, based on empirical evidence, that the claim's misleadingness could not be cured with corrective disclaimers, a condition precedent to satisfaction of the agency's First Amendment burden of proof. FDA did neither. The FDA failed to conduct the First Amendment analysis prescribed by Pearson, and DOJ has not supplied

any justification for why (after eighteen months of delay in reaching a decision) FDA has failed to do so. Instead, DOJ urges this Court to readjudicate the question of what standard to apply, arguing against the authority of Pearson that this is not a First Amendment case; that FDA is not required to evaluate the Plaintiffs' claim under the First Amendment standard prescribed in Pearson; and that this Court may ignore Pearson's mandate and apply a more deferential standard of review. DOJ would have this Court commit reversible error by applying the wrong standard based chiefly on inapposite FTC precedent.[1]

I. THE FIRST AMENDMENT STANDARD OF PEARSON V. SHALALA GOVERNS

In their Opposition ("Opp."), the Defendants state, "[t]his is not a First Amendment case." Opp. at 1. That statement is remarkable because it contradicts FDA's statements during the past eighteen months that it would apply Pearson's First Amendment standard,[2] and it contradicts the Defendants' admission to the Court of Appeals that the First Amendment does apply.[3] It reveals that the Defendants are not above extra-legal argument, not above readjudicating the governing law. The Defendants had an opportunity to appeal Pearson but elected (or, should we say the Solicitor General elected) not to do so. Rather than accept Pearson as the governing law, FDA has clung to the very position that it argued unsuccessfully before the Court of Appeals: i.e., that this is not a First Amendment case; that it is not required to comply with the First Amendment standard; and that the issue of FDA's blanket suppression of a health claim is an administrative one to which it is due judicial deference, not a constitutional one subject to the three part Central Hudson test. In short, the Defendants would have this Court

[1] This Court should not be fooled by Defendants' call for greater deference but should follow the mandate of Pearson. The question of whether the high First Amendment or a more deferential standard of review ought to apply to FDA suppression of health claims is not open to debate. It was put to rest in Pearson. 164 F.3d at 658.
[2] JR 12 at 161.

rule as if Pearson were never decided. They would have this Court roll back the clock and decide in favor of the very legal propositions that the Court of Appeals rejected in a 3-0 panel decision and in a 11-0 en banc decision. Consistent with stare decisis, this Court cannot do what the Defendants ask of it.

Having utterly failed to evaluate whether any of a number of conceivable disclaimers could eliminate any potential to mislead (and having failed to adduce empirical evidence of misleadingness), FDA nonetheless retained its blanket ban on all claims that one source and amount of folic acid is superior to another.[4] It has thus not satisfied its First Amendment burden. Having failed to satisfy that burden, the normal order of the First Amendment (its barrier to government speech suppression) applies and FDA cannot maintain for a day more its unlawful suppression of the folic acid claim. Having not met its burden, FDA has no power or authority under the Constitution to stand between Plaintiffs' claim and the market.

As explained more fully below, the FDA's arguments fail because they variously (1) conflict with the Pearson mandate; (2) rely upon inapposite precedent; (3) ignore apposite precedent; and (4) lack evidentiary support.

(1) FDA's insistence that this is not a First Amendment case and that it is not required to satisfy the three part Central Hudson First Amendment standard is the very argument the Pearson Court rejected. Likewise, FDA's argument that the folic acid claim is "inherently misleading" is also one that the Court of Appeals rejected (deeming it "almost frivolous"), holding the folic acid

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[3] The Pearson decision reflects that admission. The Court wrote: "It is undisputed that FDA's restrictions on appellants' health claims are evaluated under the commercial speech doctrine." Pearson, 164 F.3d 655 (emphasis added).

[4] The FDA's pre-market prohibition on Plaintiffs' claim denies Plaintiffs (and everyone else for that matter) the right to place on labels and in labeling of dietary supplements any claim that one source and amount of folic acid is superior to another. The First Amendment cases the Pearson Court applied to FDA's pre-market suppression of Plaintiffs' claims were are all ones involving so-called "blanket bans" on commercial speech. See, e.g., In re R.M.J., 455 U.S. 191, 203 (1982); Ibanez v. Florida Dep't of Business and Prof'l Regulation, 512 U.S. 136, 144-46

claim (and, indeed, all three other original Pearson claims) not "inherently misleading" and thus not suppressible outright but ones that were at worst "potentially misleading" and thus ones that had to be allowed if disclaimers could render them nonmisleading. 164 F.3d at 658-659.

(2) FDA's insistence that this is not a First Amendment case and that it is not required to satisfy the First Amendment standard is unsupported by the FTC precedent upon which it erroneously relies. FDA would have this Court substitute for the controlling law of Pearson precedent arising in cases evaluating FTC post-market enforcement orders where no pre-market blanket speech bans are present. Unlike FDA's regime, under FTC's an advertiser may enter the market and propound any advertising claim it desires without agency pre-approval. Once the advertisement is made, however, FTC can act against it if it finds evidence that the ad is likely to mislead consumers, acting reasonably under the circumstances, in a material respect. Although the specific deceptive advertising can be prohibited by FTC following an adjudication of its misleadingness wherein FTC takes into account the totality of all relevant evidence (consumer surveys, expert testimony, scientific evaluations, etc.), FTC's prohibition affects only the specific speech in issue. The advertiser is free at all times to employ substitute advertising that is accurate. By contrast, under FDA's regime no health claim of any kind may enter the market without advance FDA approval. Thus, FDA's regime imposes a blanket ban while FTC's does not.

None of the FTC cases involves the imposition of a blanket, pre-market ban on an entire category of commercial speech (e.g., in this case all speech which claims superiority of one source and amount of folic acid over another, whether or not disclaimed). None involves judicial deference to FTC in the presence of such a blanket ban; indeed, Kraft, Inc. v. FTC, 970 F.2d 311

(1994); Peel v. Attorney Registration and Disciplinary Comm'n of Illinois, 496 U.S. 91, 99-111 (1990); Bastes v. State Bar of Arizona, 433 U.S. 350, 375 (1977); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996).

(7th Cir. 1992) cited by Defendants expressly distinguishes the "individualized" enforcement orders used by the FTC from the kind of blanket bans held unconstitutional in the Supreme Court precedent relied upon in Pearson. Compare Pearson,164 F.3d at 658, with Kraft, 970 F.2d 311 at 317-318. None of the precedent cited by Defendants involves suppression of speech held potentially, rather than inherently, misleading. None involves the government's refusal to employ corrective disclaimers as a less restrictive alternative to outright suppression. None involves a decision upholding a blanket speech ban in the absence of empirical evidence, and--even in the FTC's post-market enforcement context--none excuses FTC from producing evidence of misleadingness. None involves suppression of speech after the Court of Appeals reasoned that "credible evidence" supported that speech. Pearson, 164 F.3d at 658.

(3) FDA's insistence that this is not a First Amendment case and that it is not required to satisfy the First Amendment standard conflicts with apposite Supreme Court precedent holding blanket bans on potentially misleading commercial speech unconstitutional unless the agency doing the censorship satisfies all three parts of the Central Hudson test. See In re R.M.J., 455 U.S. 191, 203 (1982); Ibanez v. Florida Dep't of Business and Prof'l Regulation, 512 U.S. 136, 144-46 (1994); Peel v. Attorney Registration and Disciplinary Comm'n of Illinois, 496 U.S. 91, 99-111 (1990).

(4) FDA's insistence that this is not a First Amendment case and that it is not required to satisfy the First Amendment standard conflicts with the decision in 44 Liquormart and with the Pearson Court's rejection of Lungren, to wit: Deference to the agency's conclusory assertion of

misleadingness is not due and the basis for the agency's finding of misleadingness must be subjected to scrutiny to determine if the harm recited by the agency is real.[5]

A. PEARSON REJECTED FDA'S ARGUMENT THAT THE FIRST AMENDMENT DOES NOT APPLY

The Defendants argue that FDA's prohibition on Plaintiffs' folic acid 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," must not be reviewed under the First Amendment standard but under the APA arbitrary and capricious standard. Opp. at 2-3. They also argue that "it is well-settled . . . that misleading speech may be prohibited without analysis under Central Hudson"). Opp. at 2. They argue that FDA's scientific review must be accorded substantial deference (in substance total deference), Opp. at 3, and they argue that FDA need not obtain empirical evidence to corroborate misleadingness. Opp. at 3.

Breaking Defendants' argument into parts, it is: (1) that the First Amendment standard does not apply to FDA suppression of Plaintiffs' claim; (2) that the APA substantial evidence standard applies to FDA suppression of Plaintiffs' claim; (3) that speech the FDA deems misleading based on its scientific review may be suppressed outright without undertaking the Central Hudson analysis and without evaluating whether disclaimers could cure misleadingness; and (4) that FDA is not required to adduce empirical evidence of misleadingness to support a blanket speech ban. Each proposition conflicts with the Pearson decision and the precedent upon which that Court relied.

Defendants' argument that the First Amendment does not apply is contrary to the position they took before the Court of Appeals. There they accepted that the First Amendment does

[5] See Pearson, 164 F.3d at 657-58, rejecting Association of Nat'l Advertisers v. Lungren, 44 F.3d 726, 736 (9th Cir. 1994) and citing 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 509-10 (1996) (which, in turn, rejected in pertinent part Posadas de Puerto Rico Assocs. V. Tourism Co. of Puerto Rico, 478 U.S. 328, 344 (1986)).

apply to agency restrictions on the Plaintiffs' claims, a proposition unremarkable to the Court of Appeals. As that Court recorded in Pearson: "It is undisputed that FDA's restrictions on appellants' health claims are evaluated under the commercial speech doctrine. See Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 67-68 (1983)." 164 F.3d at 655. The Court rejected reliance on any more deferential standard of review. See id.

Defendants' argument that the APA substantial evidence standard applies to FDA restrictions on Plaintiffs' claim was also rejected by the Court of Appeals. At the outset, the Court made clear that it would not subsume its evaluation of FDA's restrictions on Plaintiffs' claims under the APA standard but would evaluate those restrictions separately under the First Amendment standard.[6]

Defendants' argument that speech FDA deems misleading based on its scientific review may be prohibited outright without undertaking the Central Hudson analysis and without evaluating whether disclaimers could cure misleadingness was also flatly rejected by the Court of Appeals.[7]

Although the Court rejected the notion that Plaintiffs' health claims were "inherently

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[6] The Pearson Court wrote:

> We invert the normal order here to discuss first appellants' most powerful constitutional claim, that the government has violated the First Amendment by declining to employ a less draconian method—the use of disclaimers—to serve the government's interests, because the requested remedy stands apart from appellants' request under the APA that the FDA flesh out its standards. That is to say, even if [FDA's scientific review standard] were given a more concrete meaning, appellants might be entitled to make health claims that do not meet that standard—with proper disclaimers.

164 F.3d at 654.

[7] The Pearson Court stated:

> . . . [E]ven if "significant scientific agreement" were given a more concrete meaning, appellants might be entitled to make health claims that do not meet that standard—with proper disclaimers.
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> As best we understand the government, its . . . argument runs along the following lines: that health claims lacking "significant scientific agreement" [FDA's scientific standard] are inherently misleading . . . . We think this contention is almost frivolous . . . We reject it. . . . Under Central Hudson, we are obliged to evaluate a government scheme to regulate potentially misleading commercial speech by applying a three-part test.

164 F.3d at 654, 655.

misleading" based on FDA's scientific review, the Court did find more credence in the argument that "health claims on dietary supplements should be thought at least potentially misleading," 164 F.3d at 655, and thus expected the agency to evaluate on remand whether the less restrictive alternative of disclaimers could eliminate potential misleadingness. Id at 658 ("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 659 ("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").

Moreover, the disclaimers the Court proposed to FDA[8] reveal quite plainly that the Court did not accept the absence of scientific conclusiveness or the lack of FDA approval for the claim as a basis for prohibiting it outright. Id. at 659. Indeed, concerning the Plaintiffs' folic acid claim, the Court advised: "We suspect that a clarifying disclaimer could be added to the effect that 'The evidence in support of this claim is inconclusive.'" Id. The Pearson court also advised that FDA could employ the disclaimer, "The FDA does not approve this claim." Id. These disclaimers reveal that the Court was unwilling to accept FDA's disagreement with or uncertainty about the extent of scientific support for a claim as a basis for claim suppression but, rather, considered those factors a basis for an appropriate disclaimer.[9]

[8] The Court proposed the following disclaimers to FDA: "The evidence is inconclusive . . .;" "The evidence in support of this claim is inconclusive;" "The FDA did not approve this claim." 164 F.3d at 658-659.

[9] To be sure, the Court did state that when a claim was "incurable by disclaimer" it could be banned outright, as when a "claim is outweighed by evidence against the claim," citing as an example a hypothetical Vitamin E/Alzheimer's claim for which there was said to be "*no* evidence" in support, 164 F.3d at 659. Only when the claim is "inherently misleading," i.e., incurable by disclaimer, can it be banned outright. Thus, in instances where there is sound scientific evidence to support the claim, as here, and the issue is one of semantics (how to avoid conveying that information in a misleading manner), the solution is a disclaimer. Recall the Supreme Court's admonition, cited at the start of Pearson: ". . . the States may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive." Pearson, 164 F.3d at 655 citing In re R.M.J., 455 U.S. 191, 203 (1982). The Pearson Court repeatedly emphasized that the Constitution favors disclosure over suppression: ". . . 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

Defendants' argument that FDA is not required to adduce empirical evidence of misleadingness is also directly contrary to the Court of Appeals decision. The Court of Appeals rejected the notion that conclusory assertions that consumers will be misled satisfy the agency's burden of proof. The Court made clear that it expected FDA not to rely on such conclusory assertions but instead to ascertain misleadingness upon a foundation of empirical evidence. 164 F.3d at 659, 660 (". . . here the FDA's conclusory assertion falls far short" and ". . . we are skeptical that the government could demonstrate with empirical evidence that disclaimers . . . fail to correct for deceptiveness"). In short, the FDA was expected to support conclusions of misleadingness with empirical evidence as required by the First Amendment commercial speech standard. See Ibanez, 512 U.S. at 146; Edenfield v. Fane, 507 U.S. 761, 771 (1993).[10]

Before the Court of Appeals the Defendants argued points substantively indistinguishable from those reargued here. They argued that health claims failing to satisfy the agency's scientific standard of review were by that fact alone ***inherently*** misleading. 164 F.3d at 655.

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less restrictive' means." 164 F.3d at 658. In short, if it can be rendered nonmisleading through the addition of disclaimers, it must be.

[10] The Court wrote:

> The government disputes that consumers would be able to comprehend appellants' proposed health claims in conjunction with the disclaimers we have suggested—this mix of information would, in the government's view, create confusion among consumers. But all the government offers in support is the FDA's pronouncement that "consumers would be considerably confused by a multitude of claims with differing degrees of reliability." 59 Fed. Reg. at 405. Although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech—here the FDA's conclusory assertion falls far short. See 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") (citations and internal quotation marks omitted); Edenfield, 507 U.S. at 771 (invalidating a ban on in-person solicitation by accountants where the government failed to present "studies" or "anecdotal evidence" showing that such solicitation posed dangers of fraud, overreaching, or compromised independence).
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> . . . [W]hile we are skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones we suggested above would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility.

They called upon the Court to defer to the agency's judgment on the science and accept that judgment as dispositive of the question of misleadingness. This, in effect, is the same argument the Defendants press before this Court. The Defendants also argued that even if the claims were only potentially misleading, FDA still did not have to permit them with corrective disclaimers. Id. Those arguments were rejected in Pearson, Id. at 658, and, thus, are not appropriate for argument here. The Defendants' reiteration of them must once again fail.

B. DEFENDANTS' SUBSTANTIAL RELIANCE ON FTC PRECEDENT IS MISPLACED

This case on remand is quite plainly governed by Pearson. Even were Pearson not the governing law, however, the cases cited by DOJ do not stand for the proposition that a more deferential APA review applies to FDA pre-market suppression of health claims. The cited cases involving FTC enforcement actions do not concern pre-market blanket bans on an entire category of speech (e.g., all claims that one source of folic acid is superior to another). That is not how FTC operates. Rather, they all concern post-market enforcement against deceptive advertising content, allowing for alternative or disclaimed ads that eliminate deceptiveness. Another set of cases, those involving the FDA, do not involve judicial review of acts of FDA health claims suppression and thus are entirely inapposite. In short, none of the cases cited excuse the Defendants from their duty to comply with the Pearson constitutional mandate.

DOJ cites Henley v. FDA, 77 F.3d 616, 620 (2d Cir. 1996) for the proposition that the APA arbitrary and capricious standard applies. Opp. at 5. In Henley, the Plaintiff did not assert a First Amendment cause of action against the government. Indeed, Henley did not involve FDA suppression of a claim the Plaintiff desired to make on the label or in the labeling of her own product. Rather, Henley involved the charge that FDA was arbitrary and capricious (the APA

Pearson 164 F.3d at 659-60.

standard) in its refusal to compel the placement of a warning statement on the labels of oral contraceptive products made by others. Thus, the case has no applicability to the facts present here. It did not involve a willing speaker attempting to vindicate his or her own speech rights.

DOJ cites Novartis Corp. v. FTC, 223 F.3d 783, 786 (D.C. Cir. 2000) for the proposition that FDA health claim suppression is reviewable under the APA standard. Opp. at 5-6. Novartis was a post-market enforcement action based on evidence of deceptiveness from the marketplace. The case did not involve an FDA pre-market blanket ban on speech but an FTC post-market enforcement order requiring the Plaintiff to cease deceptive advertising but allowing Plaintiff to use new ads with corrective disclaimers. In Novartis, the Plaintiff did not challenge on First Amendment grounds FTC's determination that its ad was likely to mislead; indeed, it did not dispute that finding at all. Id. at 786. The Plaintiff in Novartis merely raised a First Amendment challenge to the disclaimer remedy imposed, which the Court in fact evaluated not under the APA standard but under the First Amendment Central Hudson test. Thus, contrary to Defendants' argument, the case is inapposite and the only First Amendment challenge in the case was in fact evaluated under the First Amendment standard, not the more deferential standard of the APA. DOJ also mistakenly relies on FTC v. Brown & Williamson Tobacco Corp., 778 F.2d 35 (D.C. Cir. 1985). That case involved not a pre-market speech ban but a post-market enforcement decision by the FTC to seek injunctive relief against deceptive advertising not of a health claim but of a tar content disclosure on Brown & Williamson cigarettes. See Id. B & W refused to use the accepted testing methodology for ascertaining tar levels and thus was able to report a lower tar amount than otherwise would be the case. The post-market enforcement order was not a blanket ban, like FDA's pre-market prohibition, and this caused the Court to avoid

reliance on the same First Amendment precedent relied upon by the Pearson Court. Brown & Williamson Tobacco, 778 F.2d at 43-44.[11]

DOJ cites Community Nutrition Inst. v. Block, 749 F.2d 50 (D.C. Cir. 1984) again for the proposition that deferential review applies to FDA label claim suppression. As in Henley, so too in Block, the Plaintiff did not even bring a First Amendment challenge. In Block, the Plaintiff brought an APA challenge to regulations that prescribed standards of identity (not health claims) for meats. The case is thus entirely inapposite.

DOJ relies heavily on Kraft, Inc. v. FTC, 970 F.2d 311 (7th Cir. 1992) for the proposition that agency findings of deceptiveness are always reviewed under the substantial evidence standard. The case involves a post-market FTC enforcement action against Kraft for a deceptive nutrient content claim wherein Kraft advertising associated the amount of calcium in its cheese singles with that in five ounces of milk, when in fact the amount of calcium in its cheese singles was 30% less than that in five ounces of milk.[12] Thus, the claim was false on its face. Moreover, Kraft conceded the falsity of the associations were they implied, but argued that the claims were not implied. Again, as in Novartis, the Court found the FTC's post-market enforcement not a blanket ban on an entire category of speech, as are the FDA's bans, but an enforcement action aimed at prohibiting only the deceptive content of the ad.[13] Note well that

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[11] The following passage from the decision reveals why the Court held the ban not a blanket one: "Contrary to the appellant's implication, the lower court did not impose a 'sweeping prohibition' or 'blanket injunction' against any milligram tar claim, subject *only* to the discretion of the FTC. . . . In fact, the district court explicitly stated that 'B & W is . . . free to advertise B & W as containing 3-7 mg. Tar, the estimate which the FTC currently accepts.'" Brown & Williamson Tobacco, 778 F.2d at 44 citing 580 F.Supp. 981, 990 n.53 (D.D.C. 1983). Thus, unlike here, no blanket ban was imposed on a category of speech.

[12] In pertinent part, the ad stated: ". . . Imitation slices use hardly any milk. Kraft has five ounces per slice. Five ounces. So her little bones get calcium they need to grow." Id. at 314.

[13] The Kraft Court wrote:

> Most important, the restriction in Peel is a completely different animal than the one challenged here. In Peel, the issue was whether a prophylactic regulation applicable to all lawyers, completely prohibiting an entire category of potentially misleading commercial speech, passed constitutional muster. . . . Here, by contrast, the issue is whether an individualized FTC cease and desist order, prohibiting a particular set of deceptive ads, passes constitutional muster. . . . We find the restricting at issue in Peel and the one here

while Kraft found Peel inapplicable, the Pearson Court applied Peel to FDA's suppression of Plaintiffs' claims, including the folic acid claim. See Pearson, 164 F.3d at 655, 657.

DOJ (Opp. at 7) erroneously cites two cases FTC v. Colgate-Palmolive Co., 380 U.S. 374 (1965) and United States v. 95 Barrels (Apple Cider Vinegar), 265 U.S. 438, 442-43 (1924) for the proposition that deferential review is appropriate in evaluating FDA suppression of label claims. Those cases cannot be used to interpret the propriety of First Amendment application to FDA health claim suppression because they precede the extension of First Amendment protection to commercial speech in Virginia Pharmacy Bd. v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 770 (1976) and the adoption of the modern test for evaluation of restrictions on commercial speech relied on in Pearson, i.e., the three part test in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 477 U.S. 557, 566 (1980). Thus, the citations are not to prevailing authority.

DOJ cites American Home Products Corp. v. FTC, 695 F.2d 681, 686 (3d Cir. 1983) again for the proposition that the high standard of the First Amendment should not be applied to review of FDA suppression of a health claim. Opp. at 7. In American Home Products, the Plaintiff argued a denial of administrative due process; the Plaintiff did not challenge FTC on First Amendment grounds. The case is inapposite.

DOJ cites Truth in Labeling Campaign v. Shalala, 999 F.Supp. 1289, 1300 (E.D. Mo. 1998) in support of its call for deferential review. Opp. at 7. The case does not involve a First Amendment challenge to FDA suppression of a health claim; rather, it is an administrative law challenge to FDA's failure to include an MSG warning label on other parties' products. The case did not involve a willing speaker attempting to vindicate his or her own speech rights.

> sufficiently distinct to justify differing levels of appellate review. Accordingly, we decline to review *de novo* the FTC's findings and, with the substantial evidence test in mind, turn to the facts . . .

DOJ cites Serono Lab, Inc. v. Shalala, 158 F.3d 1313, 1320 (D.C. Cir. 1998); Thompson Medical Co., Inc. v. FTC, 791 F.2d 189, 196 (D.C. Cir. 1986); Trio-Bio Lab, Inc. v. United States, 836 F.2d 135, 142 (3d Cir. 1987); and Bristol-Myers Squibb Co. v. Shalala, 923 F.Supp. 212, 216-18 (D.D.C. 1996) for the proposition that the standard applicable to FDA's suppression of Plaintiffs' claim is "great deference to the agency's determination." Opp. at 8. None of those cases stand for that proposition. None arises in the context of a First Amendment challenge to suppression of a health claim by FDA. In Serono Lab, Inc. v. Shalala, the Plaintiff challenged a district court decision preliminarily enjoining approval by FDA of a generic drug; the case has no relevance whatsoever to FDA health claim suppression. Thompson Medical Co., Inc. v. FTC does not stand for the general proposition for which DOJ cites it: that great deference is due to FDA in a decision to suppress a dietary supplement health claim. Opp. at 8. Thompson Medical does not involve a First Amendment challenge but instead a series of jurisdictional and administrative law challenges to FTC's deceptive advertising order. Again, the case is inapplicable. In Trio-Bio Lab, Inc. v. United States, the Plaintiff did not bring a First Amendment challenge to an FDA labeling ban; it sued the agency alleging that FDA's conclusion that a substance was a new animal drug was unreasonable. The case is again wholly inapposite. In Bristol-Myers Squibb Co. v. Shalala, the Plaintiff did not bring a First Amendment challenge to FDA suppression of a health claim. The case involved a challenge to an FDA drug approval based on the Plaintiffs' contention that the scientific evidence supporting the approval was not adequate. Again, the case has no application in the context of agency suppression of a health claim.

DOJ cites National Comm'n on Egg Nutrition, 570 F.2d 161 (1977); Resort Car Rental System, Inc. v. FTC, 518 F.2d 962 (9th Cir. 1975); and Bakers Franchise Corp. v. FTC, 302 F.2d

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Id. at 317-18.

258 (1962) for the proposition that advertising capable of being interpreted in a way that is misleading may be suppressed outright. Aside from the fact that the cases are inapposite because they concern post-market FTC enforcement, they also precede the adoption of the three part Central Hudson test, the test relied upon by the Pearson Court to assess FDA's suppression of speech. They cannot serve as substitutes for the modern commercial speech test used to adjudge the propriety of FDA speech suppression in Pearson.[14]

C. DEFENDANTS' BLANKET BAN CANNOT WITHSTAND SCRUTINY BECAUSE IT IS BASED ON SPECULATIVE HARM, NOT EMPIRICAL EVIDENCE

The Defendants state that they rely on a "common sense determination" that consumers will be misled as a substitute for the adduction of empirical evidence to support that proposition. They say that they are "not aware of any case in which extrinsic evidence has been required to show misleadingness under the FDCA, even for felony convictions." Opp. at 8. But, alas, they are aware of Pearson and therein the Court made clear that the First Amendment burden of proof upon FDA required the agency to come up with empirical evidence to support its claim of misleadingness. 164 F.3d at 659, 660 (citing "the [government's] burden to demonstrate that the harms it recites are real" and expressing skepticism that FDA "could demonstrate with empirical evidence that disclaimers . . . would . . . fail to correct for deceptiveness . . .").

Under the constitutional precedent speculation as to harm is inadequate; would-be regulators must prove that the harms they recite are real and that their regulatory means will advance the government's interests in a direct and material way. Ibanez, 512 U.S. at 146. In Pearson, the Court told the Defendants that they "must still meet [their] burden of justifying a restriction on speech—here the FDA's conclusory assertion falls far short." 164 F.3d at 659,

[14] Moreover, DOJ's interpretation of the cases conflicts directly with the more recent precedent cited by the Pearson Court concerning disclaimers, to wit: ". . . the State may not place an absolute prohibition on . . . potentially

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"). Indeed, the Court fully expected FDA on remand to adduce empirical evidence concerning both misleadingness and the extent to which disclaimers could eliminate alleged misleading connotations, expressing doubt that the evidence would prove disclaimers insufficient. 164 F.3d at 660. The fact is FDA adduced *no* evidence that Plaintiffs' claim actually misleads, yet concluded that Plaintiffs' claim is "inherently misleading," and FDA evaluated no disclaimers. The agency's determination of misleadingness is based on sheer speculation about consumer reaction. Although the Defendants rely heavily on the inapposite FTC cases, not even in those cases do the federal courts permit FTC to avoid adduction of empirical evidence of deceptiveness. Indeed, even in FTC cases involving conspicuous implications (cited by Defendants), market evidence must still be presented to support a claim of deceptiveness albeit not necessarily consumer survey evidence. There is nothing in "0.8 mg of folic acid in a dietary supplement is more effective than a lower amount in foods in common form" that conspicuously implies that .8 mg of folic acid is more effective than .4 mg of folic acid or that dietary supplement folic acid is more effective than similar amounts of folic acid in a fortified food. Nevertheless, the Defendants argue that those invisible claims are "conspicuous." Indeed, what is it about ".8 mg" or the term "lower amount" that logically implies the number .4 mg?[15] The Defendants' enemy is imaginary but the First Amendment precedent applicable to

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misleading information . . . if the information also may be presented in a way that is not deceptive." 164 F.3d at 655, citing In re R.M.J., 455 U.S. 191, 203 (1982) (citations omitted).

[15] As for the Defendants' contention that consumers will understand "foods in common form" to include fortified foods, there are, of course, numerous and obvious far less restrictive means than suppression to dispel that perceived connotation. Why, for example, didn't FDA simply require that the words "unfortified foods" be used in place of "foods in common form"? Plaintiffs would have had no objection to that requirement. Alternatively, they could

Defendants is very real and compels evidence of misleadingness as a condition precedent to censorship; appeals to "common sense," without more, will not do.

D. IOM, CDC, BDDD, AND NCEH RECOGNIZE EFFECTIVENESS FOR AMOUNTS OF FOLIC ACID IN EXCESS OF .4 MG; .4MG IS NOT FOR THEM A STATIC IDEAL AS IT IS FOR FDA

DOJ argues that FDA's ban on Plaintiffs' claim is based on the agency's determination that the evidence in support of the claim is outweighed by the evidence against it. That argument is based on a false predicate. FDA never evaluated Plaintiffs' actual claim or any disclaimers that could be used with that claim. Based on the scientific record before the Court of Appeals, that Court observed that "credible evidence did support [the] claim." 164 F.3d at 658. Not once in its arguments pre-Pearson did FDA contend that Plaintiffs' claim implied that .8 mg of folic acid was more effective than .4 mg of folic acid or that folic acid in a dietary supplement was more effective than the same amount of folic acid in a fortified food. On remand, rather than evaluate Plaintiffs' actual claim and disclaimers that might be used to eliminate any proven potential to mislead, FDA invented its "implied claim" theory. It presumed Plaintiffs' claim to convey to consumers implications nowhere found on the face of the claim and nowhere mentioned by it in prior argument.[16] FDA's construct is a transparent artifice. There is no evidence of any kind that consumers understand Plaintiffs' claim either to mean that .8 mg of folic acid is more effective than .4 mg of that same synthetic substance or to mean that folic acid-

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have come up with a disclaimer similar to that offered 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."

[16] DOJ strains credulity when it argues that the disclaimers Plaintiffs are willing to use with the claim should be ignored because they were not raised before the agency. The agency never explained its wholly unfounded position that the Plaintiffs' claim includes two "implied claims" before its letter ruling and, thus, Plaintiffs were neither given an opportunity to comment upon those counterintuitive implications or to recommend disclaimers in response to them. Moreover, it is FDA, not Plaintiffs, who have the First Amendment burden of proof and under that burden it was FDA's duty, not Plaintiffs, to evaluate all possible disclaimers as less restrictive alternatives to outright suppression. Plaintiffs proceeded as far as they needed by informing the agency that they would accept any reasonable disclaimer. FDA violated its constitutional duty by not evaluating disclaimers before reaching its conclusion that Plaintiffs' claim was "inherently misleading."

containing dietary supplements are more effective than folic acid-containing fortified foods. Furthermore, it is not Plaintiffs intention to convey those messages. Plaintiffs have said they would accept any reasonable disclaimer, including (1) "In some women .4 mg of folic acid may be as effective in reducing neural tube defect risk as .8 mg" and (2) "Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects." On its face, the Plaintiffs' claim compares .8 mg of folic acid in a dietary supplement with a lower amount in foods in common form.[17] Immediately we are discussing a comparison between folic acid in an almost 100% bioavailable form (dietary supplement folic acid) with food folate that is only ½ as bioavailable—an IOM conclusion (Appl. for PI Exh. 7 at 210; JR 23 at 601; JR 43 at 835)--that FDA has not refuted.[18] Thus, the actual claim concerns not a comparison between .8 mg of folic acid in a dietary supplement and .8 mg of folate in a food in common form (i.e., a comparison between .8 mg of folic acid and .4 mg of food folate equivalent to folic acid) but a comparison between .8 mg of folic acid in a dietary supplement and a lower amount (i.e., less than .8 mg) in a food in common form (i.e., a comparison between .8 mg and *less than* .4 mg. of food folate equivalent to folic acid because food folate is only ½ as

[17] The Defendants argue semantics, that foods in common form include foods fortified with folic acid. Semantic meanings are perhaps ones most curable by disclaimer. Although fortified foods are uncommon because they naturally do not include synthetic folic acid but have supplements of synthetic folic acid added to them, the fact remains that FDA had the burden of proof on remand to rely on disclaimers wherever possible to eliminate a misleading connotation. Had it believed consumers would be misled, it could have simply included a disclaimer like the one Plaintiffs have crafted that would make clear that foods fortified with "similar amounts of folic acid" may be equally effective. DOJ misconstrues even this disclaimer. Plaintiffs do not say the "same" amount of folic acid in the disclaimer, they say "similar," making it clear that they contemplate not precise equivalence in amount.

[18] The Defendants present a tortured argument that bioavailability does not equal effectiveness or potency. They do this on the erroneous assumption that bioavailability is "the rate" of absorption. Opp. at 35. It is not. It is the percentage of absorption. Neuhouser et al (Appl. for PI Exh. 21 at 626) made the point well:

> Brown and colleagues found that women who used vitamin supplement pills containing folic acid were able to increase their red blood cell folate levels associated with a decreased risk of neural tube defects . . . . In sum, these studies have shown that supplemental folic acid as pteroylglutamic acid is more effective at increasing red cell folate levels than naturally occurring food sources of folate.

Please note Plaintiffs' memorandum in support of the motion erroneously cites this as JR 23 at 2.

bioavailable). The claim by its plain meaning thus does not compare the effectiveness of .8 mg with .4 mg of folic acid.

The Defendants argue redundantly that .4 mg of folic acid is the only dose level all federal public health agencies and the IOM endorse, suggesting all march in lock step with the FDA, Opp. at 24, but they do not march in lock step.[19] While all federal agencies have recognized .4 mg to be effective, FDA is unique in its insistence that .4 mg is the only effective dose. The others understand safe and effective doses to range from .4 mg to over .8 mg.[20] The others recognize that range for women who have not suffered a prior NTD-affected pregnancy. In those who have suffered a prior NTD-affected pregnancy, they recommend 4 mg (i.e., 4,000 mcg) (JR 43 at 836; JR 21 at 477; Appl. for PI Exh. 19); only in the case of prior NTD-affected pregnancies do they all recommend a static amount.

The Defendants' argument also presumes without the slightest evidentiary support that .8 mg is not a very effective dose and that somehow women who consume Plaintiffs' .8 mg-containing folic acid supplements will be led to believe that .4 mg folic acid containing foods and supplements are ineffectual or undeserving of consumption.[21] That argument is too extreme to be credible as indeed the Defendants repeated resort to hyperbolic invective would suggest (hyperbole is a feeble substitute for reasoned argument). Were the Defendants' argument valid,

[19] As Plaintiffs' quotations from IOM and CDC, NCEH, and BDDD make clear, unlike FDA, these other entities recognize and communicate to the public that dose levels in excess of .4 mg are effective in NTD-risk reduction.

[20] There is simply no other explanation for why IOM recommends thrice in the IOM Report the option of 400 mcg from fortified foods daily and 400 mcg from supplements daily plus food folate (a total of over 800 mcg): "To reduce the risk of neural tube defects for women capable of becoming pregnant, the recommendation is to take 400 ug of folic acid daily from fortified foods, supplements, **or both**, **in addition to** consuming food folate from a varied diet." Appl. For PI Exh. 7 at 196; 246; 259. See also Appl. For PI Exh. 19 (quoted in the text supra); JR 43 at 836-38.

[21] The Defendants make a belated attempt to raise a safety issue, arguing that high doses (presumably meaning .8 mg or more albeit .8 mg is not a high dose) may make testing for a vitamin B12 deficiency difficult (i.e., may mask such a deficiency). That "safety concern" appears nowhere in the agency's letter ruling on Plaintiffs' claim and with good reason. See JR 1A. Indeed, FDA has set a safe single dose upper limit for dietary supplements of 1,000 mcg, 21 C.F.R. § 101.79(c)(i)(F), cognizant of the fact that those who take the supplements would also eat folate

then FDA's sister agencies, CDC, BDDD, and NCEH, and the IOM would be equally guilty of "misleading" the public because they invite the public to consume over .4 mg, including amounts of .8 mg or more daily. The Defendants distort the statements of these other entities to suggest that they only recommend .4 mg. That is simply not the case. They join in FDA's recommendation of .4 mg, but they recognize, as FDA does not, that .8 mg (or more) is also an effective dose. In Application for Preliminary Injunction Exh. 7 (IOM Report Page 258), the **IOM writes**:

> **To summarize the data, a reduced risk of NTD has been observed for women who took a folate supplement of 360 to 800 ug/day in addition to dietary folate intake of 200 to 300 ug/day.**

Clearly IOM contemplates a range of consumption for effectiveness that involves total daily amounts (with the food folate added in) of between 460 mcg/day to 950 mcg/day of folic acid. It also defies credulity for the Defendants to read the straightforward recommendation of CDC, NCEH, and BDDD to endorse a static .4 mg amount. In Appl. for PI Exh. 19 at the CDC Internet Page entitled "Preventing Neural Tube Birth Defects: A Prevention Model and Resource Guide" at Internet page number 1-2, **the CDC, NCEH, and BDDD include the following over .8 mg daily folic acid dosing amount among their recommendations**:

> **Increase consumption of foods fortified with folic acid (e.g., "enriched" cereal, bread, rice, pasta, and other grain products) in addition to consuming food folate from a varied diet (e.g., orange juice and green vegetables). 1. Take a vitamin supplement with 400 micrograms of folic acid daily.**

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containing foods and might add 100 to 150 mcg or more of folic acid equivalent to the total. Accordingly, Plaintiffs' .8 mg supplement is well within the safe zone.

Among its sister agencies only FDA takes the position that .4 mg of folic acid daily is an ideal one-size-fits-all dose. Its sisters admit a range of effective dosing: .4 mg to over .8 mg. They communicate that range to the public.[22]

Moreover, the Defendants reveal naivete when they assert that Plaintiffs' claim comparing dietary supplement folic acid with foods in common form is Plaintiffs' attempt to control the folate marketplace. As the Defendants well know, once FDA allows Plaintiffs' claim it may be used by any company that sells .8 mg of folic acid in a dietary supplement, not just Plaintiffs. There is simply no competitive advantage to be derived for any one party. All who sell folic acid will benefit from the folic acid claim, including those who sell fortified cereals containing .4 mg per serving (people may elect to eat two servings if they prefer that over a supplement) and those who sell single ingredient, .4-mg containing folic acid dietary supplements (they may add to use directions the option of .8 mg daily consumption levels).[23]

The Defendants argue strenuously that greater bioavailability of synthetic folic acid does not equal greater effectiveness. Their argument conflicts with basic logic (only folic acid taken into the blood stream is effective in reducing NTDs) and with the agency's own equation of bioavailability with potency in 1993: "Estimates of the increased bioavailability ('potency') of

[22] The Defendants' extensive discussion (Opp. at 26-29) of the "potential" NTD risk reduction role of other vitamins in a multivitamin preparation has no bearing on the admitted effectiveness of synthetic folic acid. The fact remains FDA approved its original folic acid claim based in no small part on studies involving folic acid containing multivitamins (61 Fed. Reg. 8,752); it did not question the effectiveness of folic acid in those supplements. Moreover, as Plaintiffs explained in their memorandum in support of their motion (see footnote 12 thereto), plaintiffs' folic acid-containing supplements are all multivitamins, rendering the discussion entirely academic.

[23] In the Opp. at 36 fn.13, FDA errs when it says, "labeling claims for folate amounts must be based on the amount in the food as prepared, e.g., canned good labels take into account losses from cooking and canning. Therefore a woman considering labeled amounts of folate will not be misled." To the contrary, that statement is belied by the fact that canned food labels take into account only the amount los in the manufacturers' cooking and processing, not in the consumers' preparation of the food. Thus, women are in fact still misled; only supplemental folic acid provides reliable dosing.

free folic acid relative to food folates range from at least twofold to fourfold or greater . . .” JR 3 at 60.[24]

Finally, we should all be so lucky if every woman of childbearing age in the United States consumed .8 mg of folic acid in a dietary supplement every day. The consequence of accepting Plaintiffs’ claim is that women may actually be led by the information to consume .8 mg folic acid-containing dietary supplements during their childbearing years. The overwhelming scientific evidence establishes that if they were to do so the horrible affliction of neural tube defect births and NTD abortions would be reduced in America. That result we can surely live with; indeed, people of good conscience should demand it.[25]

In footnote 10 to Defendants’ pleading, they misleadingly compare studies of differing scientific validity (e.g., case controlled studies that are of lesser weight with double-blind placebo controlled clinical trials that are of greater weight) and studies involving subjects without prior NTDs (such as in the Czeizel study) with those having prior NTDs involving much greater resistance to the NTD-risk reducing effects of folic acid (such as the Medical Research Council study). By doing so they try to lead this Court to believe that .8 mg of folic acid would not be more effective than lower amounts in foods in common form. That contention is not established scientifically. But more importantly, in light of the fact that Plaintiffs’ claim

[24] The Defendants would have the Court believe that when IOM concludes that synthetic folic acid is twice as bioavailable as food folate, it is making no statement that synthetic folic acid is more effective than food folate in reducing NTD risk. Opp. at 33-34. The Defendants are wrong. Joseph Mulinare and J. David Erickson of the Birth Defects and Genetics Diseases Branch, BDDD, NCEH, CDC have written (JR 46 at 912):

> Dietary improvement is the least proven approach . . . Epidemilogic studies have attempted to determine whether dietary folates by themselves were effective in preventing NTDs are not definitive. For the short term, it would not be an effective measure.

Scientists from academia concur. Barber et al. (JR 49 at 924) state: “. . . [P]ericonceptional supplementation of the material diet with a multivitamin containing folic acid is the only identified factor which has been definitively shown to have a significant relationship to NTD risk in a large scale clinical trial.”

[25] Defendants misapprehend their First Amendment duty. Theirs is not to compel Plaintiffs to propound only that public health message they themselves propound (the mantra in favor of a static .4 mg per day). Their duty, unfulfilled, is to determine whether Plaintiffs’ claim is false and incapable of being cured through disclaimer.

compares .8 mg of folic acid in a dietary supplement with a lower amount in foods in common form, the unalterable fact remains that there is not one single study of diet-derived food folate that establishes such folate to be effective in reducing neural tube defect risk, not a single one. That accounts for the reason why, unlike FDA, IOM, CDC, NCEH, and BDDD have stated that a protective effect from food folate "remains to be demonstrated." JR 23 at 259 (IOM); JR 45 at 14 (CDC, NCEH, and BDDD).

II. THE DEFENDANTS' HAVE VIOLATED THE FIFTH AMENDMENT AND THE APA

The Defendants misconstrue Plaintiffs' Fifth Amendment argument. Plaintiffs do contend that FDA's continuing failure after over eighteen months of delay to implement the Pearson mandate violates the Fifth Amendment by denying them the process that was due, but Plaintiffs also contend much more than that. In the face of the Court of Appeals decision, FDA had to implement the Pearson constitutional mandate; it did not. FDA had to follow the three-part Central Hudson test; it did not. FDA had to evaluate all potential disclaimers upon a foundation of empirical evidence; it did not. FDA had to revoke the invalidated rules; it did not for eighteen months and even then it kept the substantive prohibitions contained in those rules in place. It thereby violated the Fifth Amendment Due Process Clause.

The Defendants have violated the APA and the Pearson Court's order. Neither FDA's Guidance, JR 13, nor its action on the folic acid claim provides anyone with meaningful guidance on the level, degree, quality, or quantity of scientific evidence the agency will find acceptable.[26] Indeed, FDA's decision, post-Pearson to raise its "implied claims" argument for

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Plaintiffs have no lawful duty to parrot FDA's mantra; indeed, compelling that speech raises its own First Amendment issues. See Wooley v. Maynard, 430 U.S. 705 (1976).

[26] in its folic acid decision [JR1A at 3], FDA spells out no criteria for evaluation of the claim, belying its contention that defined criteria exist and were applied. It has proceeded ad hoc with considerable subjectivity and no discernible criteria to permit even remotely predictable outcomes.

the first time within its letter ruling reveals the extent to which factors not scientific (i.e., factors semantic and political) predominate over straightforward scientific evaluation. FDA has yet to explain its evaluative criteria with sufficient detail to enable the regulated class to discern what FDA expects to satisfy its "significant scientific agreement" standard. That is no less true today than it was before the Pearson Court admonished FDA to come up with a defined standard.

III. FDA HAS VIOLATED PLAINTIFFS' STATUTORY RIGHTS UNDER 21 U.S.C. § 343(r)(5)(D)

As explained above, FDA's action on the Plaintiffs' folic acid claim does not comply with the statute. The statute calls upon FDA to focus on whether the "claim" is supported by scientific evidence. In this case, FDA ignored the actual claim before it and focused on implied claims nowhere present in the language of the actual claim. FDA did so demanding proof to a near conclusive degree that .8 mg of folic acid was more effective than .4 mg and that folic acid in a dietary supplement was more effective than folic acid in a fortified food, when neither of those implications arise from the plain meaning of the claim. It thereby violated the statute.

IV. CONCLUSION

For over six years, FDA has invested enormous resources in favoring suppression over disclosure, doing everything it can to stop women from receiving the simple message that .8 mg of synthetic folic acid is more effective in reducing neural tube defects than a lower amount in foods in common form. Rather than follow the mandate of the Court of Appeals by evaluating all possible disclaimers and disclosing the truth to the public instead of suppressing the entire claim, rather than find ways to make sure all women can appreciate in the market the superior effectiveness of synthetic folic acid, and rather than act with alacrity and dispatch in the face of a constitutional mandate and public health necessity, the FDA has invested its time, energy, and resources in tactics of delay, in semantic games, and in suppressing every bit of information on

the superiority of .8 mg of synthetic folic acid over lower amounts of food folate. That effort, reminiscent of its earlier effort to deprive the country of any folic acid-NTD claim for three long years, is a shameful legacy that is leaving those unaware of the benefits of synthetic folic acid at unnecessarily heightened risk of NTDs. Indeed, it is not too much to state (as the Congress of the United States stated) that "undoubtedly, many children suffered from preventable neural tube defects as a result of FDA's delay in authorizing" these claims. See Senate Report 105-43, July 1, 1997 (105th Cong., 1st Sess.) at 50. For the sake of American women, their children, and the Plaintiffs' right of free speech, this Court should bring FDA's legacy of suppression to an end.

Respectfully submitted,

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