IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DURK PEARSON, et al.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**No. 00-2724 (GK)**
	)	
TOMMY G. THOMPSON, et al.,	)	
	)	
Defendants.	)	

MEMORANDUM IN OPPOSITION
TO
DEFENDANTS' MOTION FOR RECONSIDERATION

Plaintiffs, by counsel, hereby oppose the Defendants' Motion for Reconsideration ("Motion"). That Motion seeks reconsideration of this Court's February 2, 2001 Memorandum Opinion and Order granting Plaintiffs' application for preliminary injunction, Pearson v. Shalala, No. 00-2724, 2001 U.S. Dist. LEXIS 1253 (D.D.C. 2001) (hereinafter referred to as "Pearson II"). The Defendants' Motion fails to satisfy this Court's high standard for reconsideration. United States v. Philip Morris, Inc., No. 99-2496, U.S. Dist. LEXIS 1173, at *6 (D.D.C. 2000). The Motion wrongly presents reargument of facts and law already well pled before this Court, an impermissible basis for reconsideration. Id. The motion should therefore be denied.

In its Motion, FDA presents no new evidence or law justifying reconsideration. Instead, FDA reargues record evidence and legal points that the Defendants already presented to this Court (and which this Court already considered) in advance of Pearson II's issuance. On that basis, this Court may deny the Motion summarily. United States v. Philip Morris Inc., No. 99-2496, U.S. Dist. LEXIS 1173, at *6 (D.D.C. 2000) ("A motion for reconsideration will not be granted if a party is simply attempting to renew legal

arguments that have already been rejected by the Court. . . In general, 'reconsideration . . . is an extraordinary remedy which should be used sparingly'") citing New York v. United States, 880 F.Supp. 37, 38 (D.D.C. 1995); Assassination Archives and Research Ctr. V. United States Dep't of Justice, 828 F.Supp. 100, 101-102 (D.D.C. 1993); quoting 11 WRIGHT ET AL., FEDERAL PRACTICE AND PROCEDURE § 2810.1, at 124 (2d ed. 1995); see also Alexis v. District of Columbia, No. 98-0151, 1999 U.S. Dist. LEXIS 13482, at *22 (D.D.C. 1999) ("the parties' arguments are mere recitations of points previously stated and rejected. As such they do no warrant reconsideration of the court's Opinion").[1]

Reliance on reargument in the face of a well-reasoned decision disrespects the Court's authority and disserves the administration of justice: delaying compliance without good cause. Here, the injustice is particularly unwelcome. Every day that passes without Plaintiffs' Folic Acid Claim in the market is another in which a fertile woman unaware of that claim remains at an unnecessarily heightened risk of giving birth to a child afflicted with neural tube defects (NTDs). Rather than devote its energies to disclosure of that health information, properly disclaimed, the Defendants invest their time and our tax dollars in a futile quest to suppress the claim in its entirety—a belated effort to rewrite the law of the First Amendment to exclude the FDA. But Pearson v. Shalala, 164 F.3d 650 (D.D.C. 1999)(hereinafter referred to as "Pearson I"), makes those attempts unlawful and, whether the Defendants like it or not, Pearson I is final; it is the

[1] In the context of an order granting injunctive relief, reconsideration should be particularly disfavored because injunctive relief is designed to protect the moving party at the earliest possible moment from the imposition of hardships during the pendency of the litigation. In this case, the hardships concerned arise from FDA's continuing violation of the First Amendment rights of Plaintiffs for which the Supreme Court has held immediate relief required. See Elrod v. Burns, 427 U.S. 347, 343 (1976).

law. It is long past the time for this agency to respect the authority of Pearson I and uphold the law as the Court of Appeals and this Court have interpreted it.

If this Court elects to delve further into the Motion, there are ample additional reasons why it falls far short of the mark.

I. DEFENDANTS' MOTION RESTS ON A LEGALLY ERRONEOUS PREMISE

The major premise underlying FDA's re-argument is the very position this Court (and Pearson I) rejected. That premise, that it is incumbent upon the Plaintiffs to prove their claim conclusively true as a condition precedent to its allowance, is directly contradicted by the law of the First Amendment. The First Amendment places the burden squarely on the Defendants to justify health claim suppression by proving inherent misleadingness with empirical evidence and by establishing that the claim cannot be rendered non-misleading through the addition of a corrective disclaimer. Pearson I, 164 F.3d at 659. That the Defendants did not do. To be more precise, it is not enough for FDA to complain that scientific evidence for Plaintiffs' claim is inconclusive. The Pearson I Court did, after all, recognize inconclusiveness as a basis for disclaimer use, not claim suppression; Defendants choose to forget that the Pearson Court's suggested disclaimer language in reference to the Folic Acid Claim was: "The evidence in support of this claim is inconclusive." Id. at 658). Rather, to suppress the claim without resort to disclaimers, FDA must prove based on empirical evidence that which it has not proven (and cannot prove on this record), namely that the claim misleads and that it cannot be rendered non-misleading through the addition of disclaimers.

The record below contains no competent scientific evidence to support a finding

of inherent misleadingness, and Defendants' cite none in their Motion. Defendants have never proven that .8 mg of folic acid is an ineffective dose or that .8 mg of folic acid is not more effective than .4 mg of folic acid (Plaintiffs' claim is that .8 mg is more effective than a lower amount in foods in common form; foods in common form contain naturally occurring food folate, not synthetic folic acid). To the contrary, FDA in its Motion merely speculates based on scientifically inconclusive evidence that .8 mg may not be more effective than .4 mg (and that .8 mg in a multivitamin may be effective based on the--as yet--unproven proposition that other vitamins reduce neural tube defects).

Under Pearson I, inconclusiveness is not a basis for health claim suppression; it is a basis for disclaimer if, and only if, there is in fact a demonstrable misleading connotation in need of disclaimer. In the agency proceedings below, FDA utterly failed to satisfy its burden of proof, so much so that this Court found FDA's position arbitrary and capricious in addition to failing to satisfy the Pearson I standard. See Pearson II, 2001 U.S. Dist. LEXIS 1253 at *29. In its Motion, the Defendants blithely presume, as they have throughout these proceedings, that they do not have to meet any burden to justify speech suppression, that their interpretation of the scientific data is enough, and that they are entitled to total deference from this Court for their decisions to suppress a health claim. The Defendants position is not simply one of arrogance, it is in contumacious disregard of the governing law, Pearson I. They make no argument that Pearson II conflicts with Pearson I; nor do they argue that Pearson II conflicts with the First Amendment precedent upon which Pearson I is based; nor can they rightly make such arguments. The Defendants' argument is thus incompetent because it does not establish any "clear error" by this Court as would warrant reconsideration. FDA's

supposition is emphatically not the law of the case; the rule of the First Amendment as explained in Pearson I is that the Defendants "must . . . meet [their] burden of justifying a restriction on speech," 164 F.3d at 659, and that this demonstration must be achieved "with empirical evidence that disclaimers similar to the ones [the Court] suggested . . . would bewilder consumers and fail to correct for deceptiveness," Id.(emphasis added). Having not met that burden, FDA must adhere to this Court's order and rely on short, succinct, and accurate disclaimers as its remedy for provable misleadingness.

II. DEFENDANTS' MOTION RESTS ON THE ERRONEOUS CONTENTION THAT CONCLUSIVE PROOF, AS OPPOSED TO CREDIBLE EVIDENCE, IS REQUIRED UNDER THE PEARSON I STANDARD AS A CONDITION PRECEDENT TO CLAIM ALLOWANCE

As the record evidence demonstrates, the Folic Acid Claim is supported by credible evidence. That was the finding of the Court of Appeals based on the record before it (Id. at 654) and that was the holding of this Court based on the record before it (20001 U.S. Dist. LEXIS 1253, at *36-37). There is no proof, let alone conclusive scientific proof, that .8 mg of folic acid is an ineffective dose, but there is a large-scale, well-designed clinical trial involving ingestion of .8 mg of folic acid by 2,104 women who had not before suffered a neural tube defect birth that yielded 100% effectiveness in reducing NTD risk among that large population, the Czeizel study (cited by the Court at Pearson II, 2001 U.S. Dist. LEXIS 1253 at *33-34). In its Motion, FDA refers to variable risk reduction effects in other studies that did not involve ingestion of .8 mg of folic acid, citing a small, not well-designed study of women who had a prior NTD involving consumption of 360 mcg that yielded a 86% risk reduction; a well-designed study of women who had a prior NTD involving 4,000 mcg that yielded a 60% risk reduction; and several studies of differing levels of reliability in which women consumed 400 mcg and

experienced between 40% and 80% risk reductions. Those studies are interesting but they do not establish that .8 mg of folic acid is less effective than .4 mg of folic acid in reducing neural tube defect risk. No such .8 mg to .4 mg head to head comparison was made in any of the studies. Furthermore, there is no large-scale placebo controlled clinical trial, like Czeizel, that reveals .8 mg of folic acid to yield less than 100% effectiveness in reducing NTDs among women with no prior NTD history. To be sure, we can speculate that .8 mg may in some women be less effective than .4 mg, but the empirical evidence isn't there. Czeizel remains unrebutted and, as this Court wrote in Pearson II, "[w]hen considered in conjunction with other studies of folic acid, the implication of the Czeizel Study is that 0.8 mg of folic acid is more effective than 0.4 mg at reducing the incidence of NTDs." Id. at *34.[2]

[2]The Defendants' Motion distorts the Court's evaluation of the Czeizel Study and exaggerates the significance to its ultimate holding of the Court's Czeizel analysis. Pearson II did not place "undue weight" on the Czeizel study nor did this Court base its rejection of FDA's "inherently misleading" conclusion "largely on the Court's interpretation of the Czeizel study," as the Defendants state in their Motion. Motion for Reconsideration at 1,3. The Court's ultimate conclusion rests primarily on FDA's failure to comply with Pearson's First Amendment mandate, not on the Court's analysis of Czeizel: "[I]t 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." Pearson II, 2001 U.S. Dist. LEXIS 1253, at * 19. The Court's analysis properly evaluated Czeizel within the context of all record studies and found FDA's claim that the evidence was "against" the superior effectiveness of .8 mg of folic acid a claim not supported by the entire record. The Court wrote:

> 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.
>
> 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. More importantly, in the Czeizel Study—a clinical 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 implicat8on of the Czeizel Study is that 0.8 mg of folic acid is more effective than 0.4 mg at reducing the incidence of NTDs.

Id. at * 31-32.

It is thus decidedly not the case that the Court placed sole or undue reliance on Czeizel, as the Defendants' mistakenly contend. Rather, the Court properly considered Czeizel within the context of the entire body of studies in the record and found Czeizel to be unrebutted, credible evidence.

Moreover, FDA cites to preliminary scientific evidence for the proposition that other vitamins in a multivitamin preparation may yield a reduction in NTD risk, attempting to muddy the waters on folic acid. Note well that if this argument were accepted it would undermine FDA's existing, authorized .4 mg folic acid claim because that claim authorization was based in no small part on multivitamin studies. This Court recognized this point in Pearson II, writing: "[T]he 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; J.R. at 89." The Defendants' argument is in so many respects an artifice. There remains no scientific proof that .8 mg of folic acid in a multivitamin supplement is any more effective than .8 mg alone, but there is a multivitamin study that revealed there to be no difference in effectiveness of folic acid in a multivitamin supplement and folic acid alone, the Medical Research Council study (cited by the Court at Pearson II at *31). In addition, as this Court found FDA has accepted multivitamin studies in the past as proof of the effectiveness of folic acid alone without questioning the contribution of the other vitamins to that effectiveness. Finally, as Plaintiffs pled to the Court in their pleadings, the point is an academic one given the fact that Plaintiffs' .8 mg folic acid-containing dietary supplements are multivitamins.

In its Motion, the Defendants argue that .4 mg of folic acid (i.e., 400 mcg) is the only dose level all federal public health agencies and the IOM endorse, suggesting all march in lock step with the FDA, Motion at 7, but they do not march in lock step. Even were all to join FDA in a single public recommendation, that would not establish that .8 mg is an ineffective dose, nor would that establish the existence of a scientific consensus

on .4 mg as the only effective dose, it would merely reflect the fact that all agencies of the federal government could agree on at least the .4 mg dose level as a public recommendation. But, truth be told, FDA is unique among several of its sister agencies in holding .4 mg (and no more) to be the only effective dose.

As the record reveals IOM, CDC, NCEH, and BDDD have all communicated to the public dose levels in excess of .4 mg as effective in NTD-risk reduction. While those federal agencies have recognized .4 mg to be effective, and have joined FDA in advocating it, FDA is unique in its insistence that .4 mg is the only effective dose. IOM recommends, no fewer than three times in the IOM Report (of record in this proceeding) (the very report FDA heralds as authoritative), the option of 400 mcg from fortified foods daily and 400 mcg from supplements daily plus food folate (a total of over 800 mcg) daily, writing: "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; JR 43 at 836-38. . In Appl. for PI Exh 7 (IOM Report Page 258)(emphasis added), **the IOM also 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 effectiveness that involves total daily amounts (with food folate added in) of between 460 mcg/day to 950 mcg/day of folic acid.

The CDC, BDDD, NCEH, and IOM have published to the public a recommendation of over .4 mg of folic acid, including amounts of .8 mg or more daily (recommendation # 3 in the indented quote below). In Appl. for PI Exh. 19 at the CDC

Internet Page entitled "Preventing Neural Tube Defects: A Prevention Model and Resource Guide" at Internet page number 1-2 (emphasis added), **the CDC, the NCEH, and the BDDD include the following (see recommendation # 3) recommending over .4 mg daily folic acid daily:**

> **There are three ways women can get enough folic acid to prevent spina bifida and anencephaly. They can choose to:**
>
> **1. Take a vitamin supplement containing 400 micrograms of folic acid daily.**
>
> **2. Eat a fortified breakfast cereal daily which contains 100% of the recommended daily amount of folic acid (400 micrograms)**
>
> **3. 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.**

In sum, FDA's argument has failed utterly to identify any clear error warranting reconsideration.

III. THE DEFENDANTS' MISCONSTRUE THE COURT'S "CREDIBLE EVIDENCE" FINDING

The Defendants try to induce this Court to commit reversible error. They ask the Court to hold that it applied a standard of review in this case other than the three-part Central Hudson test. They do this by asking the Court to make a choice among false alternatives (a Hobson's Choice): to explain whether its standard is the "credible evidence" language appearing at 164 F.3d at 658 n.7 or the "weighing" of evidence for and against a claim language appearing at Id. at 659. The argument is based on the false premise that these terms contained in Pearson I and II's reasoning in aid of construction of the First Amendment are a substitute for the First Amendment standard itself. The

Defendants wrongly construe the "weighing" verbiage in Pearson I, 164 at 659 , to be the sum total of the Court's "standard" of review rather than a tool in aid of construction when clearly in the context of Pearson I it is the latter, not the former. The argument is also a red herring: neither in Pearson I nor in Pearson II are the "credible evidence" and the "weighing" terms inconsistent or in conflict when used therein in aid of construction; rather, they are complementary. Moreover, the Defendants wrongly beg the Court to reverse its decision predicated on speculation about application of the First Amendment standard in future cases not before the Court, an enterprise void of standing, essentially seeking a declaratory judgment without a live case or controversy. That "elucidation" the Court cannot provide and, were it to do so, would again afford Defendants a basis for argument on appeal.

Pearson I used both above-quoted terms as a part of its analysis in aid of construction of the First Amendment standard. Id. at 658 n.7 ("But it appears that credible evidence did support this claim [in reference to Plaintiffs' Folic Acid Claim]); Id. at 659 ("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"). This Court did the same thing in Pearson II, 2001 U.S. Dist. LEXIS 1253, at *12-13.

The "standard" of review under the First Amendment and as applied in Pearson I to the claim here in issue is the three-part Central Hudson test. That is the standard articulated in Pearson I and Pearson II. Under the third prong of Central Hudson (the means-ends fit), the assessment includes whether there are obvious less restrictive alternatives to outright suppression. In connection with that prong, the Supreme Court

has held: ". . . 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." In re R.M.J., 455 U.S. 191, 203 (1982), cited in Pearson I, 164 F.3d at 655. To comply with the third prong of Central Hudson, the Court of Appeals and this Court have held that the Defendants must adduce empirical evidence of misleadingness and must establish, as a condition precedent to claim suppression, that no disclaimer can correct a misleading connotation.

In using the term "credible evidence" in support of Plaintiffs' Folic Acid Claim, this Court (2001 U.S. Dist. LEXIS 1253, at *27-28) and the Court of Appeals (164 F.3d at 658 n.7) did not articulate a "standard." No, indeed, both courts made factual findings that the Folic Acid Claim was backed by credible evidence – a finding of fact, not a standard of law. That did not resolve the issue under Central Hudson's third prong (the actual standard). Rather, it made clear that FDA had to present empirical evidence to satisfy its burden of proof by demonstrating no disclaimer to be sufficient to cure any provable potential to mislead. That duty FDA did not satisfy; indeed, FDA evaluated no disclaimers before it suppressed Plaintiffs' claim outright. In connection with the evaluation of a hypothetical health claim, the Court of Appeals in aid of construction explained that it could not draft disclaimers for FDA on each of the four claims there in issue and that the Court would not rule out the possibility that empirical evidence could be found to demonstrate that no disclaimer could cure misleadingness but left it incumbent upon the FDA to adduce empirical evidence as a condition precedent to claim suppression. Thus, the "standard" in issue was, again, the overall First Amendment standard in Central Hudson and, in particular, the third prong of that test. The "standard"

was not the "weighing" language in aid of construction offered by the Pearson I Court or the "credible evidence" findings of both Courts. That fact becomes readily apparent in the context of the decision, where the Pearson I Court relies on a hypothetical claim to illustrate its point:

> 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 disclaimer and ban it outright. For example, if the weight of the evidence were against the hypothetical claim that "Consumption of Vitamin E reduces the risk of Alzheimer's disease," the agency might reasonably determine that adding a disclaimer such as "the FDA has determined that *no* evidence supports this claim" would not suffice to mitigate the claim's misleadingness . . . . Finally, while we are skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones we suggested above would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility.

164 F.3d at 659.

Note well that the Court of Appeal's reasoning that the "preferred remedy" is always disclosure over suppression (Id. at 657 citing Bates v. State Bar of Arizona, 433 U.S. 350, 376 (1977): "the preferred remedy is more disclosure, rather than less" and reciting that "the [Supreme] Court has reaffirmed this principle, repeatedly pointing to disclaimers as constitutionally preferable to outright suppression") combined with the Court's skepticism about the ability of FDA to prove no disclaimer effectual in eliminating misleadingness with respect to the four claims before it leads ineluctably to the conclusion that claims that accurately reflect the scientific evidence (even when the evidence is inconclusive) may have a potential to mislead but are not suppressible outright so long as disclaimers can render them nonmisleading.

This Court's statement that the claim in issue is backed by credible evidence is a finding of fact, just as its determination that the evidence in favor of the claim outweighs

the evidence against it is also a finding of fact. The findings are complimentary, not inconsistent, and the findings do not substitute for, nor are they intended to substitute for, the operative First Amendment standard of review. Let there be no mistake, this Court made factual findings of both the presence of credible evidence and of the evidence for outweighing the evidence against the claim ("[E]ven 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," Pearson II, 2001 U.S. Dist. LEXIS 1253, at * 29; and, "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 . . . There clearly is such evidence . . .," Id. at 38).

In sum, then, FDA's attempt to induce this Court to deem findings of fact a "standard" is a transparent invitation to error this Court should decline to accept. This Court correctly determined the standard to be the First Amendment standard applied by the Pearson Court. In the context of both decisions, it is clear that both the credible evidence finding and the weighing determinations are findings of fact in aid of construction of the operative standard, not standards themselves.

IV. CONCLUSION

For the foregoing reasons, the Defendants have utterly failed to establish a new legal or factual basis for reconsideration of this Court's opinion and have, instead,

impermissibly reargued matters already well pled before the Court's opinion was issued.

Accordingly, this Court should deny the Defendants' Motion without further ado.

Sincerely,

DURK PEARSON;
SANDY SHAW;
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