DURK PEARSON, et al., Plaintiffs, v. TOMMY G. THOMPSON, et al., Defendants.

Civil Action No. 00-2724 (GK)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2001 U.S. Dist. LEXIS 6560

May 7, 2001, Decided

May 9, 2001, Filed

DISPOSITION:
[*1] Defendants' Motion for Reconsideration denied.

COUNSEL:
For DURK PEARSON, SANDY SHAW, AMERICAN PREVENTIVE MEDICAL ASSOCIATION, JULIAN M. WHITAKER, M.D., PURE ENCAPSULATIONS, INCORPORATED, XCEL MEDICAL PHARMACY, LTD., plaintiffs: Jonathan Walker Emord, EMORD & ASSOCIATES, P.C., Washington, DC.

For DONNA E. SHALALA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, JANE E. HENNEY, M.D., FOOD & DRUG ADMINISTRATION, UNITED STATES OF AMERICA, federal defendants: Mark T. Quinlivan, Susan Leslie Strawn, U.S. DEPARTMENT OF JUSTICE, Washington, DC.

JUDGES:
Gladys Kessler, United States District Judge.

OPINIONBY:
Gladys Kessler

OPINION:

MEMORANDUM OPINION

I. Introduction

Plaintiffs are designers, sellers, and manufacturers of dietary supplement formulations containing folic acid. n1 They bring this action against Defendants Tommy G. Thompson, Secretary, United States Department of Health and Human Services ("HHS"), in his official capacity; HHS; Bernard A. Schwetz, Acting Principal Deputy Commissioner, Food and Drug Administration ("FDA"), in his official capacity; the FDA; and the United States of America. n2

n1 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. [*2]

n2 Defendants Thompson and Schwetz have been substituted for Donna Shalala and Jane E. Henney, respectively.

Plaintiffs previously filed a motion for a preliminary injunction, seeking to enjoin the implementation of an FDA decision which prohibited them from including on their dietary supplements' labels the following health 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" ("Folic Acid Claim").

On February 2, 2001, this Court granted Plaintiffs' motion, finding that Defendants had violated the First Amendment in refusing to approve Plaintiffs' Folic Acid Claim, with or without disclaimers, and ordering that the case be immediately remanded to the FDA "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." See Pearson v. Shalala, 130 F. Supp. 2d 105, 121 (D.D.C. 2001) ("Pearson II"). The Court suggested that the FDA consider two disclaimers in particular, [*3] and

anticipated that the agency would "complete its task within 60 days." Id. at 120 & n.34. n3

n3 For a detailed statutory and factual background of this case, see Pearson II, 130 F. Supp. 2d at 107-112.

On February 16, 2001, Defendants filed a Motion for Reconsideration of the Court's February 2, 2001 Order. n4 This Motion is now before the Court. Upon consideration of the Motion, Opposition, Reply, and the entire record herein, for the reasons stated below, Defendants' Motion for Reconsideration [# 29] is denied.

n4 On April 3, 2001, Defendants submitted a proposed disclaimer, as required by Pearson II. See Defendants' Status Report. Plaintiffs have indicated they will accept Defendants' proposed disclaimer. See Notice to Court of Pls.' Adoption of Disclaimer for Folic Acid Claim and Pls.' Acceptance of that Disclaimer. Defendants have not, however, withdrawn their Motion for Reconsideration.

[*4]

II. Legal Standard

Defendants bring their motion for reconsideration pursuant to Fed. R. Civ. P. 59(e). Such motions should be granted only if the Court "finds that there is an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." Firestone v. Firestone, 316 U.S. App. D.C. 152, 76 F.3d 1205, 1208 (D.C. Cir. 1996) (internal citations and quotations omitted). In other words, Defendants must show "new facts or clear errors of law which compel the court to change its prior position." National Ctr. for Mfg. Sciences v. Department of Defense, 339 U.S. App. D.C. 294, 199 F.3d 507, 511 (D.C. Cir. 2000) (internal citation omitted). A motion for reconsideration will not be granted if a party is simply attempting to renew factual or legal arguments that it asserted in its original briefs and that were already rejected by the Court. See State of 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).

[*5] **III. Analysis**

Defendants concede that there has not been an intervening change in relevant law nor has new evidence been discovered in this case. Rather, they argue that reconsideration is warranted because the Court has committed "clear error" in two ways: first, by "assigning undue weight" to a particular clinical study and failing to consider the relevant scientific evidence in totality; and second, by creating a legal standard which is inconsistent with the Court of Appeals decision in Pearson v. Shalala, 334 U.S. App. D.C. 71, 164 F.3d 650 (D.C. Cir. 1999) ("Pearson I"). Defendants also request clarification as to how they should apply this legal standard.

The Court finds that neither of Defendants' alleged bases for reconsideration establishes that the Court committed clear error or otherwise makes the requisite showing necessary to warrant reconsideration of the Court's February 2, 2001 Opinion. Indeed, the arguments contained in the motion for reconsideration further demonstrate Defendants' reluctance to fully comply with Pearson I, as will be explained in Section III.B below.

A. Conclusions Relating to the Cziezel Study

Defendants' first [*6] suggested basis for reconsideration is that the Court should "reconsider the [administrative] record evidence relevant" to its conclusion that the FDA failed to adequately consider the Cziezel Study, a 1992 human clinical intervention trial conducted on Hungarian women, n5 in evaluating the accuracy of Plaintiffs' Folic Acid Claim. Defs.' Mem. in Supp. of Mot. for Recons. ("Defs.' Mot.") at 3-4. Defendants make essentially two arguments in support of their first basis for reconsideration.

n5 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).

Defendants first argue that, "contrary to the Court's conclusion, the record does suggest that other vitamins in a multivitamin supplement [like the one given to pregnant women in the Cziezel Study] might have provided some of the protective effect ascribed by the Court" (i.e., a further reduction in the [*7] occurrence of neural tube defects "NTDs"). Id. at 4. In other words, Defendants question the validity of the Cziezel Study because it failed to isolate the effects of the various vitamins and minerals contained in the dietary supplements studied, and because it failed to prove that the reduction in NTD incidence was due exclusively to folic acid rather than other substances.

Defendants had ample opportunity to make this argument at the appropriate time, namely, in their opposition to Plaintiff's motion for a preliminary injunction. They did not. As the Court pointed out in its February 2, 2001 decision, "the FDA does not suggest [in its legal briefs] any other nutrients or vitamins in the multivitamin/multimineral supplements [used in the Cziezel Study] which could be responsible for decreased NTD risk besides folic acid." Pearson II, 130 F. Supp. 2d at 116. Defendants do not contest the accuracy of this statement in their motion for reconsideration briefs. Instead, they make a new argument, without any justification for having failed to raise it before, after the Court has thoroughly considered and decided Plaintiffs' motion for a preliminary injunction. [*8] Since Defendants do not present a new fact or clear error of law that would compel the Court to change its position, this argument will not now be considered when presented for the first time in a motion for reconsideration. See National Ctr. for Mfg. Sciences, 199 F.3d at 511. n6

n6 It is important to note that this case involves complex scientific and technical issues, and it is not the Court's institutional role to sua sponte consider arguments not raised by the parties. Rather, it is the parties' burden to make what they consider their best arguments when they submit their respective briefs. Therefore, the mere fact that the record material Defendants now refer to in support of their (new) argument was included in the original administrative record, see Defs.' Mot. at 4-6, is of no import.

Defendants also argue that no federal scientific or professional medical organization which has "considered the issue of periconceptional use of folic acid for reduction in risk of NTDs . . [*9] . recommends more than 400 mcg folic acid per day." Defs.' Mot. at 6-7. They argue that, given this fact, any statement which states or suggests that 800 mcg n7 is more effective than 400 mcg is inherently misleading because it cannot be made non-misleading through the use of disclaimers. Id. at 7-8.

n7 800 mcg or ug (micrograms) is equivalent to 0.8 mg.

Not only have Defendants again failed to state a reason why the extraordinary relief of reconsideration is justified, they also fail to fully and accurately describe the record evidence. Despite Defendants' insistence that the scientific consensus is that 400 mcg, or 0.4 mg, (no more, no less) is the most effective dose at reducing NTD risk, numerous scientific and governmental bodies have indicated, either explicitly or implicitly, that doses of folic acid (i.e., synthetic folic acid and/or food folate) in excess of 400 mcg are beneficial. See Pls.' Mem. in Opp'n to Defs.' Mot. for Recons. ("Pls.' Opp'n") at 7-8. For example, the highly-respected [*10] 1998 study conducted by the Institute of Medicine of the National Academy of Sciences ("IOM/NAS Study") n8 states: "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." J.R. at 600 (emphasis added).

n8 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).

Defendants openly acknowledge that "all of the public health organizations recommend 0.4 mg [of folic acid] in addition to" a certain amount of food folate. Defs.' Reply to Pls.' Opp'n to Mot. for Recons. ("Defs.' Reply") at 9 (emphasis in original). However, their argument seems to be that, because "Plaintiffs' customers also eat food, including food containing folate," id., those individuals would obtain the recommended total amount [*11] of folic acid (both synthetic folic acid and food folate) by consuming a supplement containing 0.4 mg of folic acid and otherwise eating normally.

Defendants' (new) argument is purely speculative: while many foods are indeed fortified with folic acid (and some contain it naturally), Defendants have never suggested--and certainly have never submitted evidence--that Americans currently obtain a sufficient amount of food folate in their diets.

Accordingly, Defendants' first suggested basis for reconsideration is rejected. The basis is questionable, at best, on the merits, and Defendants certainly fail to make the requisite showing (new facts, intervening change in law or clear error) that would justify reconsideration of the Court's earlier decision. n9

n9 Defendants also contend that, under Pearson I, they are permitted to totally ban the Folic Acid Claim because the "totality of the evidence" does not support the superiority of 800

> mcg to 400 mcg, and thus the "weight" of the scientific evidence is "against" this claim. Defs.' Mot. at 9-10 (citing Pearson I, 164 F.3d at 659). The Court has already addressed, and rejected, this precise argument. See Pearson II, 130 F. Supp. 2d at 115 ("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.").

[*12]

B. The Court's Application of the Pearson I Standard

Defendants contend that this Court's decision in Pearson II held or implied that "the FDA must authorize a [health] claim whenever any 'credible evidence' supports that claim." Defs.' Reply at 13. Defendants seek reconsideration and/or clarification of this statement, which they maintain misstates, or is inconsistent with, the holding of Pearson I.

Notwithstanding Defendant's statement to the contrary, this Court did not hold, or otherwise indicate, that the FDA must approve all health claims supported by some "credible evidence."

As an initial matter, it is important to quote in full the relevant portion of Pearson I (which Pearson II cites and which Defendants claim this Court interpreted incorrectly):

> 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] [*13] 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). It is noteworthy that this is the only instance in Pearson I in which the Court of Appeals expressly addresses and comments on the substance of the Folic Acid Claim.

First, in citing this passage, Pearson II uses the term "credible evidence" with respect to only one sub-claim (the superiority of synthetic folic acid over food folate), which Pearson II makes clear was not dispositive by itself of the resolution of Plaintiff's motion for a preliminary injunction. n10

> n10 Defendants also criticize another relevant passage in Pearson II:
>
> The [Pearson I] 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.
>
> Pearson II, 130 F. Supp. 2d at 114 (emphasis added). However, as with the other relevant passage, this passage correctly summarizes the import of Pearson I.

[*14]

Second, and more importantly, Plaintiff's characterization of the relevant Pearson II passage is simply incorrect, especially when that passage is evaluated in context. The full passage reads as follows:

> However, as the Pearson [I] 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 [*15] the need for a well-drafted disclaimer, which the FDA has steadfastly thus far refused to even consider.

Pearson II, 130 F. Supp. 2d at 118 (emphasis added). When this entire passage is considered as a whole, it is clear that it accurately describes the import of Pearson I, in which the Court of Appeals states, among other things: "we suspect that a clarifying disclaimer could be added [to the Folic Acid Claim] to the effect that "the evidence in support of this claim is inconclusive." 164 F.3d at 659 (emphasis added).

To the extent that there is one single "holding" in Pearson II (i.e., a passage which resolves the dispositive

legal and factual issues implicated in Plaintiff's motion for a preliminary injunction), it is as follows:

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 [*16] 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.

Pearson II, 130 F. Supp. 2d at 118-19 (emphasis added). Significantly, in their motion for reconsideration Defendants do not challenge the accuracy of this holding, which is dispositive of Plaintiff's motion for a preliminary injunction.

Finally, it must be remembered that the Court's Opinion in Pearson II concluded that Defendants failed to comply with Pearson I, in which the Court of Appeals

(1) considered the precise Folic Acid Claim at issue here and rejected Defendants' previous argument that the claim was inherently misleading;

(2) suggested two disclaimers for Defendants to examine, one of which Defendants ignored and the other of which Defendants summarily dismissed as inadequate; n11

n11 The relevant passage from Pearson II bears repeating:

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.

Pearson II, 130 F. Supp. 2d at 118 (emphasis in original).

[*17]

(3) indicated that Defendants must "demonstrate with empirical evidence that disclaimers similar to the [two it] suggested ... would bewilder consumers and fail to correct for deceptiveness," n12 which Defendants have yet to do; and

n12 Pearson I, 334 U.S. App. D.C. at 80-81, 164 F.3d at 659.

(4) established a very heavy burden which Defendants must satisfy if they wish to totally suppress a particular health claim.

Given Defendants continuing failure to comply with these and other essential aspects of Pearson II, the Court must deny Defendants' motion for reconsideration.

With respect to Defendants' request for clarification, which asks under what circumstances the FDA may totally ban a health claim, this issue is adequately addressed when Pearson II is considered in conjunction with Pearson I. Pearson I indicates that "the FDA [may] impose 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 claim [*18] rests on only one or two old studies" or "where evidence in support of a claim is outweighed by evidence against the claim." 164 F.3d at 660 & n.10 (emphasis in original). Pearson II fleshes out the term "against": "The mere absence of significant affirmative evidence in support of a particular claim ... does not translate into negative evidence 'against' it. 130 F. Supp. 2d at 115. The Court finds that additional clarification of its Opinion or the applicable legal standard, without benefit of a concrete factual context, would be inappropriate.

IV. Conclusion

In moving for reconsideration, Defendants again seem to ignore the thrust of Pearson I. While that decision might leave certain specific issues to be fleshed out in the course of future litigation, the philosophy underlying Pearson I is perfectly clear: that the First Amendment analysis in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557, 65 L. Ed. 2d 341, 100 S. Ct. 2343 (1980), applies in this case, and that if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression. In its [*19] motion for reconsideration, the FDA has again refused to accept the reality and finality of that conclusion by the Court of Appeals.

For these reasons and the additional reasons stated above, Defendants' Motion for Reconsideration is **denied**.

An Order will issue with this Opinion.

May 7, 2001
Date

Gladys Kessler

United States District Judge

ORDER

This matter is before the Court on Defendants' Motion for Reconsideration of the Court's February 2, 2001 Opinion [# 29]. Upon consideration of the Motion, Opposition, Reply, and the entire record herein, for the reasons stated in the accompanying Memorandum Opinion, it is this 7th day of May 2001

ORDERED, that Defendants' Motion for Reconsideration **[# 29]** is **denied**.

This is a final appealable Order. See Fed. R. App. P. 4(a).

Gladys Kessler

United States District Judge