UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DURK PEARSON, ET AL.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 00-2724RWR**
	)	
DONNA E. SHALALA, SECRETARY, UNITED STATES DEP'T OF HEALTH AND HUMAN SERV., ET AL.,	)	
	)	
Defendants.	)	

APPLICATION FOR PRELIMINARY INJUNCTION
AND REQUEST FOR EXPEDITION

Plaintiffs Durk Pearson; Sandy Shaw; the American Preventive Medical Association; Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; and XCEL Medical Pharmacy, Ltd., by counsel and pursuant to LCvR 65.1(c) and (d) and Fed.R.Civ.P. 65, hereby apply for a preliminary injunction to block enforcement of a speech ban imposed on them by the Food and Drug Administration (FDA).

The Plaintiffs seek a preliminary injunction barring FDA from taking any action to prohibit them from including on the labels and in the labeling of their dietary supplements (that contain recommended daily doses of 0.8 mg of folic acid) the following truthful and nonmisleading scientific statement**: "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."**[1] The United States Court of Appeals for the D.C. Circuit held that FDA unconstitutionally suppressed that statement in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), recon. denied, 172 F.3d 72 (D.C. Cir. 1999). On

January 15, 1999, the Court invalidated FDA's rule prohibiting the statement and ordered FDA to reconsider its decision to disallow the claim. FDA did not remove the invalidated rule from the Federal Register until October 6, 2000. FDA did not issue its decision on reconsideration until October 10, 2000 (on that date, 18 months after the Pearson remand, it issued a letter ruling reaffirming its denial of the claim). FDA has continued to enforce its ban on the statement without cessation from the date of the Pearson decision (January 15, 1999) to the date of its October 10, 2000 letter ruling and to the present.

FDA now admits, having earlier suppressed the claim, that folic acid reduces the risk of neural tube defect births (including spina bifida and anencephaly), 21 C.F.R. § 101.79.[2] The FDA refuses to permit, however, any truthful claim that one source of folic acid is superior to any other. For example, FDA refuses to permit the truthful claim that synthetic folic acid (found in a dietary supplement and in folic acid-fortified food) is more bioavailable than natural food folate, yet that statement has been demonstrated true, scientifically, to the satisfaction of the United States Centers for Disease Control and Prevention; the National Center for Environmental Health; the National Council on Folic

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[1] Plaintiffs will voluntarily accompany the statement with the following disclaimer: "Foods fortified with similar amounts of folic acid may be as effective as dietary supplements in reducing the risk of neural tube defects."

[2] FDA's admission is a reluctant one brought about in part by political pressure, in part by the insistence of the United States Centers for Disease Control and Prevention that women of childbearing age needed to consume .4 mg of folic acid daily to reduce their risk of having an NTD birth by an estimated 50 percent, and in part by the Plaintiffs' earlier suit against the agency for denying the claim. The United States Senate Committee on Labor and Human Resources evaluated FDA's actions and concluded:

> Without appropriately accounting for the CDC recommendation, FDA promulgated a rule in January 1993, prohibiting claims concerning the relationship. In the wake of controversy concerning FDA's action, and despite the absence of any change in the scientific evidence, the Agency reversed course, proposing to authorize such claims in October, 1993. Final regulations authorizing the claim were promulgated in March 1996. ***Undoubtedly, many children suffered from preventable neural tube defects as a result of FDA's delay in authorizing health claims based on the 1992 CDC recommendation.***

Acid; and the Food and Nutrition Board of the Institute of Medicine among other federal health agencies. As a consequence, American women are denied at the point of sale information indispensable to their exercise of consumer choice in the selection of folic acid sources best able to reduce the risk of having an NTD-affected birth. FDA's currently authorized (21 C.F.R. § 101.79) and allowed (see October 10, 2000 letter) claims convey the false impression that food folate and synthetic folic acid are fungible, i.e., equally effective. American women have undoubtedly been misled by relying on those FDA authorized and permitted claims which suggest that adequate protection from neural tube defects can be achieved simply by eating a healthful diet (with foods labeled as helping to prevent NTDs that contain as little as 10 percent of the RDI of folic acid or equal amounts of less effective natural food folate) or by consuming grains fortified with .14 mg (140 mcg) of folic acid per 100 grams of grain product (21 C.F.R. § 101.79(c)(2)(i)(G))—sources that have never been demonstrated scientifically to provide reliable or substantial protection against NTDs.

As explained in the attached Memorandum, affidavits, and documents in support[3], the United States Centers for Disease Control and Prevention, the National Center for Environmental Health, and the Institute of Medicine have concluded that the bioavailability of synthetic folic acid is approximately twice that of food folate and that the evidence for a protective effect from folic acid supplements is much stronger than for food folate. The FDA refuses to allow the Plaintiffs' statement on labels and in labeling

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"Food and Drug Administration Modernization and Accountability Act of 1997," Senate Report 105-43, July 1, 1997 (105th Cong., 1st Sess.) at 50 (emphasis added).

[3] With the exception of Plaintiffs' affidavits corroborating that the documents appended to Plaintiffs' memorandum are from the rulemaking docket before the FDA, every exhibit to the attached memorandum is a document from the record below, reviewed by FDA before its issuance of the October 10, 2000 letter ruling that is the subject of this application.

despite the foregoing findings of the other federal health agencies and despite substantial scientific evidence corroborating the statement.

In a letter ruling, dated October 10, 2000, the FDA prohibited Plaintiffs' statement from appearing on the labels and in the labeling of dietary supplements containing .8 mg of folic acid per daily dose. As explained in the attached Memorandum, affidavits, and documentary evidence in support, FDA's speech ban violates the First Amendment to the United States Constitution and threatens the health and welfare of all fertile American women and newborns.

Every day that passes with FDA's speech ban in place is a day in which Plaintiffs' First Amendment rights are violated and American women are denied health information that can enable them to reduce reliably and substantially their risk of having an NTD-affected birth. Indeed, if women rely on the FDA's authorized and permitted claims, they may believe themselves adequately protected by eating diets that yield less than the RDI of .4 mg of folic acid daily, despite the fact that no scientific evidence corroborates a reliable protective effect with less than .4 mg of folic acid daily. The evidence reliably demonstrates only a 50 percent NTD risk reduction with .4 mg of folic acid daily, and reveals that women may experience as much as a 100 percent reduction in NTD risk from consumption of .8 mg of folic acid daily.

To end the violation of Plaintiffs' First Amendment rights and to help protect American women of childbearing age from preventable NTD-affected births, the Plaintiffs respectfully urge this Honorable Court to grant the requested injunctive relief at the earliest possible moment. In accordance with LCvR 65.1, the Plaintiffs respectfully request a hearing on this application no later than 20 days after the filing date, unless

the Court earlier decides the motion on the papers. Good cause exists for expedition in light of the First Amendment violations present and the risks of harm to American women and their newborns. The full extent of those violations and risks of harm are explained in the attached Memorandum.

Respectfully submitted,

DURK PEARSON;
SANDY SHAW;
AMERICAN PREVENTIVE
MEDICAL ASSOCIATION;
JULIAN M. WHITAKER, M.D.;
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By counsel:

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