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**FDA PUBLIC MEETING ON IMPLEMENTING THE PEARSON COURT  
DECISION AND OTHER HEALTH CLAIM ISSUES**

**PANEL III:**

**“SHOULD HEALTH CLAIMS GO BEYOND CLAIMS ABOUT REDUCING THE RISK OF A DISEASE TO INCLUDE CLAIMS ABOUT MITIGATION OR TREATMENT OF AN EXISTING DISEASE, OR ARE SUCH CLAIMS DRUG CLAIMS? WHERE IS THE BOUNDARY, IF ANY, BETWEEN THESE CLAIMS?”**

**PREPARED REMARKS OF  
CLAUDIA A. LEWIS-ENG, ESQ<sup>1</sup>**

On December 1, 1999, FDA summarily denied a health claim filed by my firm's clients associating saw palmetto (an herbal dietary supplement) with a reduction in the symptoms of mild benign prostatic hyperplasia.<sup>2</sup> It did so without following the procedure for dietary supplement health claims review specified in the Nutrition Labeling and Education Act and without following the First Amendment requirements of *Pearson v. Shalala*.

FDA based its refusal to follow the governing law on the view that the claim “goes beyond risk reduction to claim an effect on an existing disease” which FDA surmises may only be made if the dietary supplement is granted new drug approval under the Act's drug approval provisions, 21 U.S.C. § 355(d). See Attachment. Based on FDA's refusal to process the health claim under the Act's health claims provision and under the *Pearson* standard, my firm filed suit against FDA seeking declaratory and injunctive relief.

The questions posed to the panel arise out of FDA's summary denial of the Saw Palmetto claim. The questions suggest that FDA wants the scope of the NLEA health claims provision to be construed narrowly, reaching not all nutrient-disease relationship claims but only those that concern disease risk reduction. But the plain language of the NLEA health claims provision and its underlying history make it undeniable that

<sup>1</sup> Claudia A. Lewis-Eng is an attorney with Emord & Associates, P.C. who practices constitutional and administrative law before the federal courts and agencies. Emord & Associates, P.C. represented the Plaintiffs in *Pearson v. Shalala*.

<sup>2</sup> The claim reads: “Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH).”

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Congress meant for all dietary supplement claims that associate a nutrient with a disease to be subject to the NLEA health claims provision. FDA's attempt to restrict the scope of the health claims definition, causing dietary supplement health claims to be redefined as drug claims, is a rather obvious attempt to hinder, rather than foster, the dissemination of dietary supplement nutrient-disease information. It is also an anti-competitive move designed to protect the drug approval process from competition arising from full implementation of the NLEA health claims provision. That attempt violates the NLEA. It violates Congress's intent. It violates the First Amendment, and it violates the Administrative Procedure Act's prohibition on arbitrary and capricious agency action.

In 1994, Congress reviewed FDA's implementation of the health claims provision of NLEA. S. Rep. No. 103-410. Congress concluded that FDA has "a long history of bias against dietary supplements." S.Rep. No. 103-410, at 14. Congress faulted FDA for "hindering, rather than fostering, the dissemination of truthful and nonmisleading information about the nutrient/disease relationship." S.Rep. No. 103-410, at 23. Congress concluded that FDA "has . . . acted to restrict the information that the public may receive about dietary supplements." S.Rep.No. 103-410. The United States Court of Appeals for the D.C. Circuit similarly found in *Pearson v. Shalala*, 164 F.3d 650, 654 (1999), that "[i]n general, the FDA appears quite reluctant to approve health claims on dietary supplements . . ."

FDA's current attempt to say that health claims do not include disease treatment and mitigation claims is yet another effort to block full implementation of the NLEA health claims provision. If FDA redefines health claims to exclude disease mitigation and treatment claims, it would defeat the essential purpose of the NLEA health claims provision. In 1990, the President signed the NLEA into law. Prior to its adoption, FDA treated as drugs all food and dietary supplements that included disease treatment claims. See H.R. Rep. 101-538 (1990). NLEA was designed to make it possible for dietary supplements to carry disease claims without having to become approved drugs, without having to satisfy the "substantial evidence," near conclusive proof, pre-market drug approval standard in 21 U.S.C. § 355. See S.Rep. No. 103-410, at 24. Congress expressly rejected the "drug certainty" standard as a legal condition for dietary supplement health claim approval. S. Rep. No. 103-410, at 24.

If FDA redefines health claims to exclude disease mitigation and treatment claims, it will effectively prohibit those claims all together. Under 21 U.S.C. § 379h(b)(1), those who wish to file a new drug application must pay the FDA the hefty and anti-competitive sum of \$256,338 per application (in 2000). In addition, proof of drug efficacy is required, i.e., proof to a near certain degree under the "substantial evidence" drug standard. 21 U.S.C. § 255(d). In adopting the NLEA health claims provision, Congress intended to avoid this heavy burden for dietary supplements. Congress wanted disease claims to be possible on dietary supplements without having to obtain drug approval for them.

FDA has no statutory authority to define health claims in a manner contrary to the NLEA. NLEA defines dietary supplement health claims broadly to include "[ones which] characterize[] the relationship of any nutrient . . . to a disease or health-related condition . . ." 21 U.S.C. § 343(r)(1)(B). Note well that Congress has used the broadest possible language: any "*relationship*" between a nutrient and a disease or health-related condition. The term "relationship" in its ordinary sense and meaning refers

to a “connection” of one thing to another, without restriction. WEBSTER’S NEW UNIVERSAL UNABRIDGED DICTIONARY, p. 1525 (2d ed. 1983). Disease treatment and disease mitigation are plainly within the universe of nutrient-disease relationships. To prove that Congress intended something other than the plain meaning of the statutory language requires proof in legislative history that the plain language was not intended. You will look in vain, however, to find any basis in the legislative history to support FDA’s position. Congress never stated any intention to define nutrient-disease relationships to exclude statements that associate nutrients with disease treatment or mitigation.

In the 1990 committee report from the House Committee on Energy and Commerce, Congress emphasized that the NLEA health claims provision applied to “any disease claim” and never once stated that the provision was meant to apply only to those claims that refer to disease risk reduction as opposed to disease treatment or disease mitigation. Congress stated with respect to the NLEA:

**Section 403(r)(3) regulates disease claims. It prohibits any disease claim . . . unless the claim meets the requirements of regulations promulgated by the Secretary. The requirement applies to any disease claim that is made with respect to required nutrients and other nutrients in food.**

H.Rep. 101-538 at 20.

Reflecting upon the NLEA health claims provision, Congress in 1994 again made clear that Congress intended the NLEA to permit authorization of all manner of nutrient-disease relationship claims, not just disease risk reduction claims. Moreover, it made clear that dietary supplements were expressly intended to bear health claims without having to be separately approved as drugs:

**One of the salutary purposes of the Nutrition Labeling and Education Act was to allow claims for nutrient/disease relationships to reflect current science, without bringing food within the drug definition of the Federal Food, Drug, and Cosmetic Act. A clear purpose of the NLEA was to assure that the public would be provided with clear information about the relationship of nutrient to disease, and to ascertain that that information would be accurate and not misleading.**

S.Rep. No. 103-410, at 23.

Congress was thus concerned that the nutrient-disease “relationship” be accurately characterized, not that the relationship be limited to exclude disease treatment and disease mitigation. Were it concerned that the naturally all-encompassing term “relationship” be interpreted in a less than all-encompassing way, we should expect to find evidence of that intent in the legislative history. There is none. Contrary to the position FDA tries to maintain, Congress sought to ensure that claims were accurately stated. If claims were artificially limited to exclude treatment and mitigation and include only risk reduction, the result would necessarily be a mass suppression of accurately stated nutrient-disease claims, ones that accurately reflect the disease treatment or disease mitigation effect of certain nutrients.

Following FDA's position would also produce the unconstitutional result of causing the NLEA health claims provision to conflict with the First Amendment by denying consumers access to scientifically accurate information that dietary supplements treat or mitigate disease symptoms. Consistent with the rules of statutory construction, FDA must not construe the NLEA to conflict with the First Amendment but must construe the two to be in harmony with one another. See *De Bartolo Corp. v. Florida Gulf Coast Building & Construction Trades Council, et al.*, 485 U.S. 490, 499-501 (1979).

Repeatedly in the legislative history Congress has emphasized that the NLEA health claims provision was designed to be flexible and was to embrace all manner of disease claims. The Congress wrote:

**In implementing the significant scientific agreement standard, FDA will be expected to take full advantage of the flexibility of the standard to maximize the availability on food and dietary supplement labels and labeling of disease-related information consumers can prudently use to affect their risk of disease.**

**This includes recognizing that there will nearly always be some remaining scientific uncertainty about the validity of any diet-related health claims; that some individual consuming or avoiding a nutrient in response to a health claim may benefit, while others may not; and that the benefit for any individual may consist not of absolutely avoiding a disease, but rather of reducing her or his risk of a disease,**

S. Rep. No. 103-410, at 24.

FDA's denial and suppression of the Saw Palmetto/BPH claim not only violates the NLEA health claims provision but also the First Amendment. Under *Pearson v. Shalala*, the health claim is protected commercial speech that may not be suppressed outright but must be authorized with such disclaimer or such disclaimers as FDA deems reasonably necessary to avoid a misleading connotation. Consistent with its commitment to the Court, FDA should reverse its position and evaluate the Saw Palmetto claim under the NLEA health claims provision and under the First Amendment standard established in *Pearson*. It should stop trying to do an end-run around the NLEA health claims provision and once and for all implement fully and faithfully consistent with the intent of Congress and with the First Amendment.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

December 1, 1999

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

RE: Petition for Health Claim: Saw Palmetto and Benign Prostatic Hyperplasia (Docket Number 99P-3030)

Dear Mr. Emord:

This responds to your health claim petition dated May 25, 1999, submitted to the Food and Drug Administration (FDA) on behalf of Julian Whitaker, M.D., Durk Pearson and Sandy Shaw, American Preventive Medical Association, and Pure Encapsulations, Inc., requesting that the agency authorize a health claim on the relationship between dietary supplements of saw palmetto extract (specifically the *n*-hexane lipidosterolic extract of the pulp and seed of the dwarf American palm, *Serona repens*) and benign prostatic hyperplasia. Your petition was filed for comprehensive review on September 1, 1999, in accord with the procedures in 21 CFR § 101.70(j)(2). Ninety days have passed since the petition was filed and FDA has not taken action to deny the petition or to publish a proposed regulation to provide for the requested use of the health claim; thus, the petition is deemed to be denied under 21 U.S.C. § 343(r)(4)(A)(i) and 21 CFR § 101.70(j)(3)(iii).

FDA has allowed your petition to be denied by operation of law because the agency has been unable to resolve an important and novel issue that the petition raises. All previous health claim petitions that met the eligibility requirements in 21 CFR § 101.14(b) have addressed reduction of the risk of a disease or health-related condition. Because your petition goes beyond risk reduction to claim an effect on an existing disease, the agency has had to consider seriously whether health claims for foods (including dietary supplements) may encompass this type of claim or whether such a claim is appropriate only on a product that has been shown to meet the safety and efficacy requirements for drugs. The agency has been unable to reach a decision on your petition within the time provided by statute and regulation, and has decided to seek public input on the important question it raises. We will continue to work diligently to resolve this issue and, when a resolution is achieved, the agency will, on its own initiative, reconsider your health claim petition.

We will communicate with you shortly to advise you further regarding the procedure and process that we will use to make our decision.

Sincerely,

Elizabeth A. Yetley, Ph.D.  
Director  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

DURK PEARSON, ET AL.,

Plaintiffs

v.

DONNA E. SHALALA, SECRETARY,  
UNITED STATES DEP'T OF HEALTH  
AND HUMAN SERV., ET AL.,

Defendants.

Civil Action No. 95-1865 (GK)

APPLICATION FOR PRELIMINARY INJUNCTION  
AND REQUEST FOR EXPEDITION

Durk Pearson, Sandy Shaw, and the American Preventive Medical Association, by counsel and pursuant to LCvR 65.1(c), this Court's inherent power to enforce its own judgments, and the All Writs Act, 28 U.S.C. § 1651, hereby apply to this Honorable Court for a preliminary injunction. The Plaintiffs respectfully request that the Court issue a preliminary injunction to bar FDA from enforcing four rules held invalid in *Pearson v. Shalala*, 164 F.3d 650, 661 (D.C. Cir. 1999) (holding unconstitutional under the First Amendment 21 C.F.R. §101.71(a), (c), (e) and 101.79(c)(2)(i)(G)), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir. 1999), so long as the health claims unlawfully suppressed by those rules are accompanied by the disclaimers found acceptable to the *Pearson* Court. 164 F.3d at 658-659. The Plaintiffs ask that the injunction remain in place until such time as FDA adopts final rules authorizing the four health claims with the disclaimers specified by the *Pearson* court or with such other disclaimers as the agency reasonably deems necessary.

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For over fourteen months after the Court's January 15, 1999 decision and for almost one year after this Court issued its April 20, 1999 mandate to FDA, FDA has continued to enforce the rules *Pearson* invalidated. FDA has done so despite repeated entreaties from the Plaintiffs that the agency abide by the Court's constitutional order and authorize--with the disclaimers specified by the *Pearson* Court--the health claims FDA unconstitutionally suppressed. FDA has refused to state a reasonable date certain by which it will authorize the claims with disclaimers. FDA's refusal to state a date certain ensures continued violation of the *Pearson* Court's order, indefinite denial of the Plaintiffs' claims, indefinite violation of the Plaintiffs' First Amendment rights, and indefinite postponement of the relief granted the Plaintiffs by the *Pearson* Court.

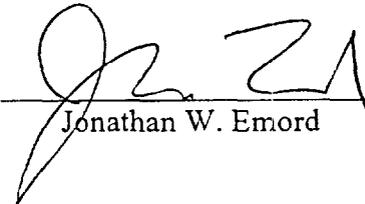
The Plaintiffs attach hereto a Memorandum of Points and Authorities and affidavit and documentary evidence in support of their Application. In accordance with LCvR 65.1, the Plaintiffs respectfully request a hearing on this application no later than twenty days after the March 31, 2000 filing date, unless the Court earlier decides the motion on the papers. Good cause exists for expedition. As the facts set forth in the Memorandum of Points and Authorities establish, the Plaintiffs have spent the better part of an entire year urging this agency to obey the law and implement the Court's constitutional mandate—all to no avail. The FDA has expressly refused to discontinue enforcement of the four invalidated rules. The FDA has refused to permit the health claims that the Court held unconstitutionally suppressed, with the disclaimers the Court recommended. The FDA has failed to set any date certain by which it will abide by the Court's constitutional order. Thus, unless this Court enjoins FDA from continuing to enforce the constitutionally invalid rules, the Court's order will go unfulfilled, the

Plaintiffs will not receive the relief they were granted by the *Pearson* Court, and the Plaintiffs will not receive the protection for their First Amendment liberties that is their right. Indeed, to the contrary, the First Amendment violations that begot the *Pearson* Court's decision will continue unabated.

For the foregoing reasons explained in greater detail in the attached memorandum, the Plaintiffs respectfully request the grant of expedited review (draft order attached) and the grant of their Application for Preliminary Injunction (draft order attached) at the earliest possible moment.

Respectfully submitted,

DURK PEARSON,  
SANDY SHAW,  
and the AMERICAN PREVENTIVE  
MEDICAL ASSOCIATION,

By   
Jonathan W. Emord

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Dated: March 31, 2000

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

DURK PEARSON, ET AL., )  
 )  
 Plaintiffs )  
 )  
 v. ) Civil Action No. 95-1865 (GK)  
 )  
 DONNA E. SHALALA, SECRETARY, )  
 UNITED STATES DEP'T OF HEALTH )  
 AND HUMAN SERV., ET AL., )  
 )  
 Defendants. )

MEMORANDUM OF POINTS AND AUTHORITIES  
IN SUPPORT OF APPLICATION FOR PRELIMINARY INJUNCTION

Durk Pearson, Sandy Shaw, and the American Preventive Medical Association, by counsel and in accordance with (1) LCvR 65.1(c), (2) this Court's inherent power to enforce its own judgments, and (3) the All Writs Act, 28 U.S.C. § 1651, hereby submit their Memorandum of Points and Authorities, affidavits, and documentary evidence in support of their Application for Preliminary Injunction. The Plaintiffs respectfully request that this Honorable Court issue a preliminary injunction to bar FDA from enforcing four rules held constitutionally invalid in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir. 1999) so long as the health claims in issue are accompanied by the disclaimers the *Pearson* Court found acceptable. 164 F.3d at 658-659. The Plaintiffs ask that the injunction remain in place until such time as FDA adopts final rules authorizing the four health claims with the disclaimers specified by the *Pearson* Court or with such other disclaimers as the agency reasonably deems necessary.

## FACTUAL BACKGROUND

On December 13, 1993, the Plaintiffs first filed comments with FDA asking the agency to approve the following four health claims at issue in the *Pearson* decision:

- (1) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers."
- (2) "Consumption of fiber may reduce the risk of colorectal cancer."
- (3) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease."
- (4) ".8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form."

The Plaintiffs explained to the FDA that if the agency believed the claims harbored a potential to mislead that it was incumbent upon FDA under the First Amendment to authorize the claims with corrective disclaimers (what they termed the "split label approach").

In 59 Fed. Reg. 405, FDA rejected out of hand the Plaintiffs proffered disclaimer approach.

In 58 Fed. Reg. 53,302 (1993), the FDA prohibited the antioxidant vitamins/cancers claim. That order resulted in the promulgation of 21 C.F.R. § 101.71(c). That rule reads in pertinent part: "**Health claims: claims not authorized.** Health claims not authorized . . . for dietary supplements of vitamins, minerals, herbs, or other similar substances: (c) Antioxidant vitamins and cancer."

In 58 Fed. Reg. 53,298 (1993), the FDA prohibited the fiber/colorectal cancer claim. That order resulted in the promulgation of 21 C.F.R. § 101.71(a). That rule reads in pertinent part: "**Health claims: claims not authorized.** Health claims not authorized .

. . for dietary supplements of vitamins, minerals, herbs, or other similar substances: (a) Dietary fiber and cancer.”

In 58 Fed. Reg. 53,304 (1993), the FDA prohibited the omega-3 fatty acids-coronary heart disease claim. That order resulted in the promulgation of 21 C.F.R. § 101.71(e). That rule reads in pertinent part: “**Health claims: claims not authorized.** Health claims not authorized . . . for dietary supplements of vitamins, minerals, herbs, or other similar substances: (e) Omega-3 fatty acids and coronary heart disease.”

In 61 Fed. Reg. 8760 (1996), the FDA prohibited the claim that .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. That order resulted in the promulgation of 21 C.F.R. § 101.79(c)(2)(i)(G). That rule reads in pertinent part: “The claim shall not state that a specified amount of folate per serving from one source [of folate] is more effective in reducing the risk of neural tube defects than a lower amount per serving from another source.”

Thus, from 1993 to the present (in the case of the first three above-listed health claims) and from 1996 to the present (in the case of the last above-listed health claim), the FDA has enforced each of the above-referenced rules that prohibit use of the four health claims on labels and in labeling. On January 15, 1999, a unanimous three-judge panel of the United States Court of Appeals for the D.C. Circuit held each of the FDA rules invalid under the First Amendment to the United States Constitution. *Pearson v. Shalala*, 164 F.3d at 661. In response to the Government’s petition for rehearing, a unanimous eleven members of the United States Court of Appeals refused rehearing. 172 F.3d 72 (D.C. Cir. 1999).

The *Pearson* Court rejected the FDA's argument that the above-listed four health claims were "inherently misleading" and, thus, entirely outside the protection of the First Amendment.<sup>1</sup> Based on voluminous scientific evidence contained in the record, the pleadings, and oral argument, the Court reasoned that the Government's "inherently misleading" argument was "almost frivolous" and rejected it. 164 F.3d at 655. Instead, the Court reasoned that the claims were, at worst, only "potentially misleading" finding plausible the Government's argument that consumers might "have difficulty in independently verifying these claims" or "might actually assume that the government has approved such claims."<sup>2</sup> *Id.* Consistent with a long line of Supreme Court cases dating from *In re R.M.J.*, 455 U.S. 191, 203 (1982) to *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 144-46 (1994), the Court held that the constitutionally permissible remedy for potentially misleading commercial speech is not absolute suppression but disclosure with disclaimers designed to eliminate the misleading connotation. The Court recognized "disclaimers as constitutionally preferable to outright suppression" consistent with the Supreme Court's admonition in First Amendment commercial speech cases that Government favor disclosure over suppression, that "the preferred remedy is more disclosure, rather than less," 164 F.3d at 657 (citing *Bates v. State Bar of Arizona*, 433 U.S. 350, 376 (1977)).

The Court considered each of the Government's grounds for "supposed weaknesses in the claims," 164 F.3d at 658: (1) that the antioxidants, fiber, and omega-3

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<sup>1</sup> The Supreme Court has held that "[i]nherently misleading [commercial speech]. . . may be prohibited entirely" but that "potentially misleading" commercial speech may not be prohibited "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). *See also* 164 F.3d at 655 (and additional cases cited therein).

<sup>2</sup> At no time during the five years of litigation involving the above-listed health claims did FDA once argue that the products, which are legally sold throughout the United States, threatened consumer health or safety.

fatty acids health claims were based on evidence of the effect of those ingredients when consumed as foods in common form and not based specifically on evidence of the effect of the ingredients outside those foods; (2) that the folic acid health claim was not conclusively supported by scientific evidence documenting the superiority of any one source of folic acid over others; and (3) that consumers might assume that a claim on a dietary supplement label is approved by FDA even if FDA harbors reservations about the claim. 164 F.3d at 658-659. The Court determined that each FDA concern could be addressed appropriately with a disclaimer and then proceeded to offer the agency precise language that it deemed capable of eliminating each concern. Concerning the antioxidant, fiber, and omega-3 fatty acids health claims, the Court wrote:

But certainly [the Government's] concern could be accommodated, in the first claim for example, by adding a prominent disclaimer to the label along the following lines: "The evidence is inconclusive because existing studies have been performed with foods containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods." A similar disclaimer would be equally effective for the latter two claims [meaning, the fiber and omega-3 fatty acids claims].

164 F.3d at 658. Concerning the folic acid health claims, the Court wrote:

The FDA's concern regarding the fourth claim . . . is different from its reservations regarding the first three claims; the agency simply concluded that "the scientific literature does not support the superiority of one source [of folic acid] over others," [citations omitted]. But it appears that credible evidence did support this claim, [citations 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 658-659. Concerning FDA's fear that consumers might think FDA "approved" of (as opposed to "authorized" with disclaimers) the health claims, the Court wrote:

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The *Pearson* Court explained: "It is important to recognize that the government does not assert that appellants' dietary supplements in any fashion threaten consumer's health and safety." 164 F.3d at 656.

The government's general concern that . . . consumers might assume that a claim on a supplement's label is approved by the government, suggests an obvious answer: The agency could require the label to state that "The FDA does not approve this claim."

164 F.3d at 659.

In the final paragraph of the decision, the Court recites its essential holdings. In that paragraph, the Court expressly holds invalid the four FDA sub-regulations upon which FDA relied to suppress the claims. 164 F.3d at 661. The Court remanded the case to the district court for further remand to the FDA for reconsideration of the health claims in light of its findings. *Id.* Exhibit A.

On July 19, 1999, counsel for the Plaintiffs wrote to the FDA (to the agency's Chief Counsel Margaret Jane Porter and to the Director of the FDA Center for Food Safety and Applied Nutrition (CSFAN) Joseph A. Levitt), complaining that FDA had "not acted to implement the decision." Plaintiffs' counsel "request[ed] word from the agency on the date by which we may expect it to authorize the four claims held unconstitutionally suppressed." The letter further stated:

As you are no doubt aware, when a First Amendment violation is found, the Court expects government redress without delay. *See generally New York Times Company v. United States*, 403 U.S. 713 (1971). Considerable time has passed since issuance of the mandate yet the agency has not acted to authorize the four claims. . . . We urge the agency to act promptly to avoid countenancing the very constitutional violations the Court ordered be rectified.

On behalf of the parties in *Pearson*, we ask when we may expect FDA action to implement the decision. We also seek to determine if, in the interim, the FDA will refrain from taking action against plaintiffs if they commence use of the four above-referenced claims on labels and in labeling with the disclaimers specified by the Court. As we read *Pearson*, any action by FDA to prevent use of the claims with the reasonable disclaimers the Court has specified will constitute a continuing First Amendment violation.

Exhibit B.

On September 17, 1999, the CSFAN Director, Joseph Levitt, responded. Levitt assured the Plaintiffs that FDA had made implementation of the decision a “priority” but let the Plaintiffs know in no uncertain terms that the very rules the Court held invalid under the First Amendment would continue to be enforced by the agency against the Plaintiffs into the indefinite future. He wrote:

... [T]he use of any of the four claims, with or without disclaimers, would violate the Federal Food, Drug, and Cosmetic Act and would subject products bearing such claims to enforcement action.

Exhibit C.

Plaintiffs’ counsel wrote again to the agency’s responsible officers on September 23, 1999, urging compliance with the Court’s constitutional mandate and explaining that compliance with that mandate takes precedence over agency administrative convenience.

Exhibit D. In a letter dated October 5, 1999, Levitt responded:

... [W]e agree that the court’s decision requires FDA to reconsider not only whether each of the four claims meets the significant scientific agreement standard, but also, even if that standard is not met, whether the addition of a disclaimer to the claim could render it non-misleading. If the answer to either question is yes, we will authorize the claim.

Exhibit E. Nevertheless, Levitt did not commit to authorize any of the claims and did not agree to any date certain by which the agency would authorize them.

Fully eight months after this Court issued its constitutional mandate, in December of 1999, the FDA for the first time published in the federal register “its strategy to implement . . . *Pearson* . . .” 64 Fed Reg. 67289 (1999). Exhibit F. The agency recognized that the “court held in *Pearson* that . . . the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the

potential deception.” *Id.* at 67290. Further, the FDA also recognized that it had an “obligation to implement the court decision promptly.” *Id.* Despite those admissions, FDA did not discontinue enforcing the four rules invalidated by the court, did not even commit to authorize the claims with disclaimers by a date certain, and in fact did not commit to authorize any of the claims with or without disclaimers. Instead, the agency presented a cumbersome and extensive list of regulatory steps it intended to take in a deliberately slow process toward addressing the Court’s order. At the end of this long train stands not a commitment by FDA to stop enforcement of the invalidated rules and authorize the claims with disclaimers but equivocation: FDA describes its ultimate action as involving a decision on *whether* to authorize the claims, thus holding out the possibility that it in the end it may never stop enforcing the rules and may never authorize the claims. FDA’s deliberately slow, protracted approach of delay accompanied by claim denial ensures continued suppression of the claims for years to come, absent grant of the injunctive relief Plaintiffs request.

FDA has stated that it would: (1) solicit more science from the public concerning the claims, (2) would conduct four rulemakings (one for each claim) concerning the science, (3) would thereafter re-evaluate the claims under its health claims review standard, (4) would thereafter “proceed to consider whether there is any qualifying language that could render the claim nonmisleading,” (5) would thereafter “propose to authorize the claim; otherwise, the agency will propose not to authorize it;” and (6) would thereafter publish a final rule to authorize or deny the claim. *Id.* This process ensures claim suppression for years to come and gives no assurance that after the passage of those years FDA will in the end allow the claims with or without disclaimers. In short,

the agency has chosen obfuscation, delay, and equivocation over immediate, full, and faithful compliance with the *Pearson* Court's constitutional mandate to end a First Amendment rights violation. It contumaciously refuses to discontinue enforcement of the constitutionally invalidated rules and further upsets the constitutional order by causing its administrative convenience and preferences to take preference over the orders of this Court and the Court of Appeals.<sup>3</sup>

Fully ten months after this Court issued its constitutional mandate, in January of 2000, the FDA published its "Dietary Supplement Strategy (Ten Year Plan)" in which it stated its intent to complete regulatory action on certain matters by the year 2010. Exhibit G. Under the title "Overall Ten-Year Goal," and under the subtitle "Labeling," appears "Pearson v. Shalala." Thus, FDA has publicly announced its expectation that it will finally implement the Court's constitutional order by 2010 – a total of eleven years after the Court of Appeals held invalid under the First Amendment FDA's four rules prohibiting the Plaintiffs health claims. Based on the procedural course FDA has chosen, a decade may well pass before it finally decides whether it will allow the health claims the Court held unconstitutionally suppressed (and there is no guarantee that it will allow the claims even then). The last FDA health claims rulemaking (to implement the health claims provision of the NLEA) was commenced on November 27, 1991 (65 Fed. Reg. 60566) and was not completed until four years and four months later on March 5, 1996

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<sup>3</sup> It should be obvious that under the Supremacy Clause, it is the Constitution and laws in pursuance of it are supreme; laws contrary to the Constitution notwithstanding. To quote Justice Marshall: "Certainly all those who have framed written constitutions contemplate them as forming the fundamental and paramount law of the nation, and consequently the theory of every such government must be, that an act of the legislature, repugnant to the constitution, is void. Those then who controvert the principle that the constitution is to be considered, in court, as paramount law, are reduced to the necessity of maintaining that courts must close their eyes on the constitution, and see only the law. This doctrine would subvert the very foundation of all written constitutions. It would declare that an act, which, according to the principles and

(61 Fed. Reg. 8752) (FDA therein suppressed all dietary supplement health claims before it but one).

On January 19, 2000, counsel for the Plaintiffs wrote again to the agency, once more imploring that FDA take immediate action to comply with the *Pearson* Court's constitutional order. That letter stated in pertinent part:

. . . . One year has passed since the United States Court of Appeals held unconstitutional FDA's suppression of the four claims at issue in *Pearson*. The Court rejected FDA's position that the claims were inherently misleading. The Court accepted the plaintiffs' argument that, at worst, the claims were only potentially misleading and had to be authorized with reasonable disclaimers. The Court commanded FDA to implement that First Amendment disclaimer requirement forthwith, and the United States District Court's mandate to FDA compelling implementation of the decision issued on April 14 [sic: 20], 1999.

As a constitutional order to this agency, the Court of Appeals' mandate takes precedence over any contrary administrative rule and, certainly, over administrative convenience. This agency may not lawfully delay, deny, or avoid implementation of the constitutional mandate. This agency is neither a law unto itself nor exempt from constitutional limits on its powers. As officers charged with the duty of supporting and defending the Constitution and seeing that your duties are well and faithfully executed, you are duty bound to ensure compliance with the constitutional mandate. Compliance is now long past due. More time than is reasonably necessary to authorize the claims with disclaimers has passed. Agency inaction constitutes contumacious conduct.

Instead of implementing *Pearson's* First Amendment disclaimer requirement, for over a year after the decision FDA has continued to suppress the four claims there in issue choosing not to implement the disclaimer requirement. That suppression constitutes a continuing First Amendment violation.

The purpose of this letter is simple. As parties whose First Amendment rights have been violated by this agency for a decade, my clients believe they are entitled to immediate answers to the following questions: (1) Does FDA plan to authorize the four claims at issue in *Pearson* with disclaimers? (2) If so, by what date will the agency authorize the claims?

Please provide me with a written response to this inquiry on or before February 19, 2000.

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theory of our government, is entirely void; is yet, in practice, completely obligatory . . . *Marbury v. Madison*, 5 U.S. 137, 177-178 (1803).

Exhibit H.

On February 17, 2000, Levitt responded for FDA, writing in pertinent part:

It would be premature for the agency to make a commitment to authorize the four claims or, conversely, to state an intention not to authorize them. As I said in my October 5, 1999, letter to you, the court's decision requires FDA to reconsider not only whether each of the four claims meets the significant scientific agreement standard, but also, even if that standard is not met, whether the addition of a disclaimer to the claim could render it non-misleading. If the answer to either question is yes, FDA will authorize the claim.

Exhibit I.

Noticeably absent from the letter was any direct response to the simple questions posed: (1) Does FDA plan to authorize the four claims at issue in *Pearson* with disclaimers? (2) If so, by what date will the agency authorize the claims?

Again on February 18, 2000, counsel for the Plaintiffs wrote to Levitt asking him to commit to a date certain by which FDA would comply with the Court's constitutional mandate, writing, in pertinent part:

The essential problem with the agency's response is that it presumes it proper to maintain denial and suppression of the four claims without committing to action by a reasonable date certain. Over a year has passed since *Pearson* was decided and yet still we have no definitive response from FDA on the Court's constitutional mandate. In other words, as it now stands, the claims are being denied and suppressed indefinitely without regard to the mandate. In light of the Court's holding that the agency's denial and suppression of the claims violates the First Amendment, it would behoove the agency either to commit to act definitively on them by a reasonable date certain (the earliest possible date) or to issue promptly an interim final rule authorizing the claims with the disclaimers the *Pearson* Court recommended and then later decide whether tailoring of those disclaimers would be warranted.

Exhibit J.

On behalf of the FDA, Levitt responded but again did not commit to authorize the claims with disclaimers, or even to act, by any date certain. Exhibit K.

Again in letters dated February 28, 2000 and March 3, 2000, 2000, counsel for the Plaintiffs sought a commitment from the agency of action to implement the Court's constitutional mandate by a date certain. Exhibit L. On March 30, 2000, the FDA responded that it would first "discuss" the plan for implementing disclaimers on or before April 17, 2000, but again refrained from agreeing to authorize the claims with disclaimers or to adopt a date certain by which it would do so. Exhibit M.

### LEGAL ANALYSIS

#### A. THIS COURT HAS LEGAL AUTHORITY TO ENSURE THAT ITS ORDERS ARE IMPLEMENTED

The United States District Courts rely upon two principal jurisdictional bases for post-judgment enforcement of their orders: (1) the inherent power of the court to enforce its judgments (see, e.g., *Root v. Woolworth*, 150 U.S. 401, 410-411 (1893); *Nat'l Org. for the Reform of Marijuana Laws v. Mullen*, 828 F.2d 536, 539 (9<sup>th</sup> Cir. 1987); *Adams v. Mathis*, 752 F.2d 553 (11<sup>th</sup> Cir. 1985)) and (2) the All Writs Act, 28 U.S.C. § 1651 (see, e.g., *Wesch v. Folsom*, 6 F.3d 1465 (11<sup>th</sup> Cir. 1993)).

In *Root*, the Supreme Court explained that it is "well settled that a court of equity has jurisdiction to carry into effect its own orders, decrees, and judgments, which remain unreversed, when the subject-matter and the parties are the same in both proceedings." 150 U.S. at 410-411. By the terms of the All Writs Act, ". . . all courts established by Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law." In particular, "the All Writs Act . . . empowers federal courts to issue injunctions to protect or effectuate their judgments." *Wesch*, 6 F.3d at 1470 (citing *Kelly v. Merrill Lynch, Pierce, Fenner & Smith Inc.*, 985 F.2d 1067, 1069 (11<sup>th</sup> Cir. 1993); *Kinnear-Weed Corp. v. Humble Oil &*

*Ref. Co.*, 441 F.2d 631, 637 (5<sup>th</sup> Cir.), cert denied 404 U.S. 941 (1971); *Ward v. Penn. New York Cent. Transp. Co.*, 456 F.2d 1046, 1048 (2<sup>nd</sup> Cir. 1972); *Olin Corp. v. Ins. Co. of No. America*, 807 F.Supp. 1143, 1152 (S.D.N.Y. 1992). The All Writs Act has been applied in constitutional cases, like *Pearson*, to compel compliance with a Court order designed to end practices that violate civil rights.

In *Davis v. Board of School Commissioners of Mobile Co.*, a case containing many parallels to FDA's failure to follow the law here, the Plaintiffs appealed the denial of their application for preliminary injunction to desegregate the county school system in accordance with the Fourteenth Amendment. 322 F.2d 356 (5<sup>th</sup> Cir. 1963). In addition to appealing the denial of the preliminary injunction, the Plaintiffs sought an order requiring the Mobile County schools to commence integration by a date certain. The Circuit Court granted the relief sought, noting that the Plaintiffs had tried unsuccessfully for nearly a year to get the school authorities to comply with their constitutional duties. *Id.* at 358. The school authorities had not "acknowledged that (a) the present system is constitutionally invalid or (b) there is any obligation on their part to make any changes at any time." *Id.* In granting injunctive relief, the Court stated that the plaintiffs--African-American children denied constitutional rights--were entitled to minimum effective relief. *Id.*<sup>4</sup> The Court held the All Writs Act its source of power to grant the Plaintiffs the requested relief.

Like the school administration in *Davis*, the FDA has yet to acknowledge that its four rules prohibiting Plaintiffs' health claims are invalid and that it has an obligation to discontinue enforcement of those rules immediately. Like the Plaintiffs in *Davis*, the

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<sup>4</sup> The First Amendment rights here in issue are as fundamental as those protected by the Fourteenth Amendment at issue in *Davis*.

*Pearson* Plaintiffs have struggled for months in vain to get the agency to implement the Court's constitutional order. Accordingly, the Plaintiffs are amply entitled under apposite precedent to the relief sought here.

**B. FOR OVER A YEAR THE FDA HAS VIOLATED THIS COURT'S ORDER BY ENFORCING FOUR RULES THE PEARSON COURT HELD CONSTITUTIONALLY INVALID**

FDA has continued to enforce all four rules the *Pearson* Court held invalid under the First Amendment. The Court held the claims not "inherently misleading" but, at worst, only "potentially misleading." Under apposite Supreme Court precedent cited by the Court, 164 F.3d at 655, potentially misleading commercial speech may not be suppressed outright but must be allowed with corrective disclaimers. 164 F.3d at 655-660.

FDA's statements to Plaintiffs' counsel reveal not only that it has no immediate intention to authorize the four health claims with the disclaimers provided by the Court but also that it clings to an unlawful assumption of unconstitutional power, stating that it may eventually decide (apparently years hence) to sustain its current prohibition of the claims, repeating the very First Amendment violation that begot *Pearson*.

It is axiomatic that the rules held invalid by the Court are of no further force or effect. As Exhibit C reveals, FDA has continued to enforce the invalid rules for over a year, threatening the Plaintiffs with enforcement action if they use the claims with the disclaimers specified by the Court. FDA has denied the Plaintiffs the relief the Court of Appeals granted them. Indeed, FDA has adopted no date certain by which it will comply with the Court's constitutional order. Moreover, FDA has refused to allow the claims, even on an interim basis, with the curative disclaimers specified by the Court.

**C. THIS COURT SHOULD ISSUE A PRELIMINARY INJUNCTION TO  
BAR FDA FROM ENFORCING THE INVALIDATED RULES UNTIL  
SUCH TIME AS FDA COMPLETES ITS RULEMAKING ON PEARSON  
IMPLEMENTATION**

This Court has long held that a preliminary injunction is warranted when the following four elements are met: (1) the Plaintiffs will suffer irreparable injury absent the injunction; (2) the Plaintiffs are likely to prevail on the merits; (3) an injunction would not substantially impair the rights of the Defendants or other interested parties; and (4) an injunction would be in the public interest. See, e.g., *Search et al. v. Pena*, Case No. 95-1289 SSH, 1995 U.S. Dist. LEXIS 16583, at \*6 (D.D.C. July 31, 1995); *Sea Containers Ltd. v. Stena AB*, 890 F.2d 1205, 1208 (D.C. Cir. 1989); *Washington Metro Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 842-44 (D.C.Cir. 1977).

***Irreparable Injury.*** Because the matter in issue involves four rules that suppress constitutionally protected speech, the injury stemming from the continued unlawful enforcement of those rules is irreparable unless the requested preliminary injunction is granted. Indeed, the Supreme Court has held that violation of a First Amendment right, even for a very short period of time, constitutes irreparable injury without proof of more. See *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality opinion) (“The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury”) quoted in *Jackson v. City of Columbus*, 194 F.3d 737, 747 (6<sup>th</sup> Cir. 1999); *Iowa Right to Life Comm., Inc. v. Williams*, 187 F.3d 963, 969 (8<sup>th</sup> Cir. 1999); *Brownsburg Area Patrons Affecting Change v. Baldwin*, 137 F.3d 503, 507 (7<sup>th</sup> Cir. 1998); *New York Magazine v. Metropolitan Transportation Authority*, 136 F.3d 123, 127 (2<sup>nd</sup> Cir. 1998); see also *City of Lakewood v. Plain Dealer Publishing Co.*, 486 U.S. 750, 758 (1988); *Washington Free Community v. Wilson*, 426 F.2d 1213, 1218 (D.C. Cir.

1969). When Government violates First Amendment rights, the Supreme Court has held delay in eliminating the rights violation intolerable: “Speakers . . . cannot be made to wait for years before being able to speak with a measure of security.” *Riley v. National Federation of the Blind*, 784 U.S. 781, 793-94 (1988) (internal quotes omitted).

***Substantial Likelihood of Success.*** In light of (1) the *Pearson* Court’s order that the four rules Plaintiffs seek to enjoin are invalid under the First Amendment, thus rendering them of no further legal force or effect, and (2) that the speech in issue is protected under the First Amendment and cannot be suppressed outright but must be allowed with corrective disclaimers, there is undoubtedly a substantial likelihood of success on the merits.

***No Substantial Injury to Defendants or Others.*** Grant of the requested injunction would not cause any harm to the FDA or others. Indeed, it would ensure that the agency fulfills its constitutional obligations and it will ensure compliance with the *Pearson* Court’s mandate, thereby aiding the agency in fulfilling its duties and preventing a constitutional crisis begot by an agency contumaciously disobeying a federal court order. It would also cause FDA to comply with the intent of Congress that it stop hindering and start fostering the communication of accurate health information on labels and in labeling. See S.Rep.No. 103-410, at 23 (“FDA’s treatment of health claims on dietary supplements and its implementation of the health claims standard is hindering, rather than fostering, the dissemination of truthful and nonmisleading information about the nutrient/disease relationship”); see also S. Rep. No. 103-410, at 14-30; Exhibit N (bipartisan letters from members of Congress complaining about FDA’s failure to implement *Pearson*’s constitutional mandate).

*An Injunction Will Serve the Public Interest.* Grant of the injunction will ensure cessation of FDA's violation of First Amendment rights with respect to the four health claims held unconstitutionally suppressed in *Pearson*. Those claims provide vital health information for consumers that can aid consumers in making informed choices at the point of sale. In addition, grant of the injunction will restore the proper constitutional order, causing FDA to recognize that it is not a law unto itself but must obey federal court orders and ensure that its rules, policies, and procedures fall within constitutional limits. Accordingly, grant of the injunction would serve the public interest.

Based on the foregoing, and the evidence appended to this memorandum, this Court should grant the requested preliminary injunction at the earliest possible moment. The Court should bar FDA from enforcing the four rules held invalid by the *Pearson* Court so long as each of the above-referenced health claims is accompanied by the disclaimers found acceptable to the Court. The injunction should remain in place until such time as FDA adopts final rules authorizing the four health claims with the disclaimers specified by the *Pearson* Court or with such other disclaimers as the agency reasonably deems necessary.

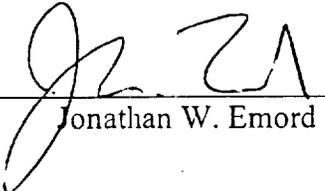
CONCLUSION

For the foregoing reasons, the Plaintiffs respectfully request that this Honorable Court issue the requested preliminary injunction at the earliest possible moment.

Respectfully submitted,

DURK PEARSON;  
SANDY SHAW;  
and the AMERICAN  
PREVENTIVE MEDICAL  
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By

  
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