UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JULIAN M. WHITAKER, M.D.,	)	
Whitaker Wellness Institute	)	
4321 Birch Street, Suite 100	)	
Newport Beach, CA 92623;	)	
	)	
PURE ENCAPSULATIONS, INC.,	)	
490 Boston Post Road	)	
Sudbury, MA 01776;	)	
	)	
DURK PEARSON and SANDY SHAW,	)	
P.O. Box 2160	)	
Tonopah, NV 89049;	)	
	)	
and the AMERICAN PREVENTIVE	)	
MEDICAL ASSOCIATION,	)	
9912 Georgetown Pike,	)	
Suite D2,	)	
Great Falls, VA 22066,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 1: 00CV00123**
	)	
DONNA E. SHALALA, SECRETARY,	)	**Date: 1/19/2000**
UNITED STATES DEPARTMENT OF	)	
HEALTH AND HUMAN SERVICES,	)	**Judge Gladys Kessler**
Sixth Floor, 200 Independence Avenue,	)	
S.W., Washington, D.C. 20201;	)	
	)	
UNITED STATES DEPARTMENT OF	)	
HEALTH AND HUMAN SERVICES,	)	
200 Independence Avenue,	)	
S.W., Washington, D.C. 20201;	)	
	)	
JANE E. HENNEY, M.D.,	)	
COMMISSIONER OF FOOD AND	)	
DRUGS, FOOD AND DRUG	)	
ADMINISTRATION, 5600 Fishers	)	
Lane, Room 1471, Rockville, MD 20857;	)	
	)	
JOSEPH A. LEVITT,	)	
DIRECTOR OF THE CENTER	)	
FOR FOOD SAFETY AND	)	

APPLIED NUTRITION, FOOD	**)**
AND DRUG ADMINISTRATION,	**)**
Federal Building 8, Room 6815,	**)**
200 C Street, S.W.,	**)**
Washington, D.C. 20204;	**)**
	)
ELIZABETH A. YETLEY, Ph.D.,	**)**
DIRECTOR OF THE OFFICE OF	**)**
SPECIAL NUTRITIONALS,	**)**
FOOD AND DRUG	**)**
ADMINISTRATION,	**)**
Federal Building 8, Room 2804C,	**)**
200 C Street, S.W.,	**)**
Washington, D.C. 20204;	**)**
	)
FOOD AND DRUG	**)**
ADMINISTRATION,	**)**
5600 Fishers Lane,	**)**
Rockville, MD 20857;	**)**
	)
and the UNITED STATES	**)**
OF AMERICA,	**)**
	)
Defendants.	**)**

COMPLAINT
SEEKING REVIEW OF ADMINISTRATIVE AGENCY ACTIONS,
DECLARATORY JUDGMENT,
AND
INJUNCTIVE RELIEF

Plaintiffs Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; Durk Pearson and Sandy Shaw; and the American Preventive Medical Association hereby file this Complaint against Defendants Donna E. Shalala, Secretary, United States Department of Health and Human Services; the United States Department of Health and Human Services; Jane E. Henney, M.D., Commissioner of Food and Drugs, Food and Drug Administration; Food and Drug Administration; Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration; Elizabeth A. Yetley, Ph.D., Director, Office of Special Nutritionals, Food and Drug Administration; and the

United States of America, seeking review of the November 30, 1999 and January 11, 2000 denials of two health claim petitions (hereinafter "B-Vitamin Health Claim Denial" and "E-Vitamin Health Claim Denial," respectively), declaratory judgment, and preliminary and permanent injunctive relief.

The actions taken by the agency are in contumacious disobedience of the constitutional orders of the United States Court of Appeals for the D.C. Circuit in *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir 1999); are in violation of the First Amendment rights of the Plaintiffs; are in violation of the Supremacy Clause of the United States Constitution; are in violation of the Nutrition Labeling and Education Act of 1990; and are in violation of the Administrative Procedure Act's prohibition on arbitrary, capricious, and unlawful agency action. Moreover, by causing FDA to take the unconstitutional actions here in issue, FDA Commissioner Jane E. Henney, M.D.; FDA Center for Food Safety and Applied Nutrition Director Joseph A. Levitt; and FDA Office of Special Nutritionals Director Elizabeth A. Yetley, Ph.D. have violated their legal obligation to support and defend the Constitution of the United States.[1]

The B-Vitamin Health Claim Denial prohibits the Plaintiffs for an indefinite future period from communicating on labels and in labeling the scientifically corroborated statement (hereinafter "B-Vitamin Health Claim"):

> **As part of a well-balanced diet, rich in fresh whole fruits and vegetables, daily intake of at least 400 ug of folic acid, 3 mg of vitamin B6, and 5 ug of vitamin B12 may reduce the risk of vascular disease.**

[1] All elected or appointed civil servants are required pursuant to 5 U.S.C. § 3331 to swear a solemn oath to support and defend the Constitution and to well and faithfully discharge the duties of their offices.

The E-Vitamin Health Claim Denial prohibits the Plaintiffs for an indefinite future period from communicating on labels and in labeling the scientifically corroborated statements (hereinafter "E-Vitamin Health Claims"):

> **As part of a healthy diet low in saturated fat and cholesterol, 400 IU/day of Vitamin E (d-alpha-tocopherol or dl-alpha-tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.**
>
> **As part of a healthy diet low in saturated fat and cholesterol, 100 – 400 IU/day of natural Vitamin E (d-alpha-tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.**
>
> **As part of a healthy diet low in saturated fat and cholesterol, 200 – 800 IU/day of synthetic Vitamin E (dl-alpha-tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E.**

INTRODUCTION

Over one year ago, on January 15, 1999, the United States Court of Appeals for the D.C. Circuit held the Food and Drug Administration's practice of refusing to authorize health claims with corrective disclaimers unconstitutional under the First Amendment. *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir 1999) . The Court ordered FDA to authorize health claims with corrective disclaimers as the required, constitutional alternative to outright suppression of claims that are potentially (rather than inherently) misleading. *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir 1999) *distinguishing Friedman v. Rogers*, 440 U.S. 1 (1979) (hereinafter referred to as the "*Pearson* Disclaimer Requirement").

The mandate of this Court to the agency compelling implementation of *Pearson* issued on April 14, 1999. *Pearson* is a final and binding order of the Court of Appeals.

Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir 1999). Because it is a constitutional mandate, FDA's duty to implement the Court's order is immediate and omnipresent. That duty may not be delayed, denied, or avoided.

Officers of the Food and Drug Administration, like all officers of the Executive Branch, swear an oath of office to support and defend the Constitution of the United States and to well and faithfully execute the duties of their offices. See 5 U.S.C. § 3331. Even were such an oath not required, the Constitution defines the limits of federal power and of the lawful exercise of that power by officers and employees of the Executive Branch. FDA Commissioner Jane E. Henney, M.D.; FDA Director of the Center for Food Safety and Applied Nutrition Joseph A. Levitt; and FDA Director of the Office of Special Nutritionals Elizabeth A. Yetley, Ph.D., the officers responsible for the health claim denials, have flagrantly violated their constitutional duties in order to effectuate an indefinite suppression of the health claims here in issue against the plain contrary command of *Pearson v. Shalala* and the First Amendment rights of the Petitioners. Those officers appear motivated by an illegitimate desire to protect pharmaceutical product claims from competition arising from dietary supplement products that bear therapeutic claims in accordance with the dietary supplement health claims provision of the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343(r) *et seq*.

In contumacious disobedience of *Pearson*'s constitutional mandate, those officers and the Food and Drug Administration that employs them have denied the health claims that are the subject of this Complaint, resulting in the outright and indefinite suppression of protected commercial and scientific speech.

This Complaint asks this Court to invalidate those unlawful agency actions; rebuke the officers of the agency for violating the constitutional mandate in *Pearson* and the First Amendment rights of the Plaintiffs; order those officers to fulfill their constitutional duties; and compel authorization of the claims with corrective disclaimers at the earliest possible moment.

For an agency of this Government to disobey any Court order is a matter warranting judicial sanction and correction, but for an agency to disobey a Court order to implement a constitutional mandate (one designed to end First Amendment rights violations) is of even greater magnitude and urgency because it involves not only insolence and contumacious conduct in the face of the Court's order but also disrespect for the Supreme Law. Such insolence, contempt and disrespect warrants expedited review and the complete redress called for herein.

FACTUAL BACKGROUND AND BRIEF STATEMENT OF THE CASE

1. The Plaintiffs wish to communicate on labels and in the labeling of dietary supplements containing at least 400 ug of folic acid; 3 mg of Vitamin B6; and 5 ug of Vitamin B12 that they sell, license for sale, and plan to sell the following health claim: "As part of a well-balanced diet, rich in fresh whole fruits and vegetables, daily intake of at least 400 ug of folic acid, 3 mg of vitamin B6, and 5 ug of vitamin B12 may reduce the risk of vascular disease."

2. The Plaintiffs wish to communicate on labels and in the labeling of dietary supplements containing natural and synthetic forms of Vitamin E, the following health claims respectively: (1) "As part of a healthy diet low in saturated fat and

cholesterol, 400 IU/day of Vitamin E (d-alpha-tocopherol or dl-alpha-tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E;" (2) "As part of a healthy diet low in saturated fat and cholesterol, 100 – 400 IU/day of natural Vitamin E (d-alpha-tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E;" and (3) "As part of a healthy diet low in saturated fat and cholesterol, 200 – 800 IU/day of synthetic Vitamin E (dl-alpha-tocopherol) may reduce the risk of heart disease. Individuals who take anticoagulant medicine(s) should consult their physicians before taking supplemental Vitamin E;"

3. On May 25, 1999, the Plaintiffs filed a petition for approval of the B-Vitamin Health Claim with the Food and Drug Administration (FDA) pursuant to Section 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (FDCA) (21 USC § 343(r)(5)(D)) and Section 101.70 of the FDA's Rules (21 CFR § 101.70) (collectively, the "Health Claims Rules"). In the petition, the Plaintiffs requested that FDA authorize the claim with corrective disclaimers, if FDA reasonably deemed them necessary, in accordance with *Pearson v. Shalala*.

4. On July 6, 1999, the Plaintiffs filed a petition for approval of the E-Vitamin Health Claims with the FDA pursuant to the Health Claims Rules. In the petition, the Plaintiffs requested that FDA authorize the claims with corrective disclaimers, if FDA reasonably deemed them necessary, in accordance with *Pearson v. Shalala*.

5. In an unprecedented move and in light of the overwhelming scientific evidence corroborating the claims, on May 25, 1999, Senator Tom Harkin, Senator Orrin

Hatch, and Congressman Peter De Fazio, ranking members of the U.S. Senate Republican and Democratic and U.S. House of Representatives Republican and Democratic leadership held a press conference in the Senate Swamp to endorse the B-Vitamin and E-Vitamin claims that are the subject of this Complaint and to call upon FDA to authorize the claims with corrective disclaimers, if necessary, as mandated by *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir 1999).

6. On September 1, 1999, the FDA filed the B-Vitamin Petition for comprehensive review in accordance with the procedures in Section 101.70(j)(2) of the FDA's Rules (21 CFR § 101.70(j)(2)). See Attachment A.

7. On October 13, 1999, the FDA filed the E-Vitamin Petition for comprehensive review in accordance with the procedures in Section 101.70(j)(2) of the FDA's Rules (21 CFR § 101.70(j)(2)). See Attachment B.

8. On November 30, 1999, the FDA denied the B-Vitamin claim on administrative law grounds, electing not to implement the *Pearson* Disclaimer Requirement. FDA stated that it would not consider whether it had to authorize the claim with a disclaimer until such time as it completed a general health claims rulemaking. The agency gave no date by which it would commence or complete the rulemaking, thus causing an indefinite suppression of the B-Vitamin Claim. See Attachment C.

9. On December 1, 1999, 64 Fed. Reg. 67291, the FDA published a Notice in the Federal Register. In its Notice, FDA stated that while it would evaluate the four health claims that were the subject of the *Pearson* remand under the *Pearson* Disclaimer Requirement, it would deny all other pending claims without evaluating them under the *Pearson* Disclaimer Requirement. Instead, FDA stated that it would consider

the First Amendment issue at an indefinite future date after it had completed a general health claims rulemaking proceeding. See Attachment D.

10. On December 22, 1999, the Plaintiffs filed a petition for reconsideration of the Notice and the B-Vitamin Health Claim Denial, demanding that FDA immediately implement *Pearson*'s Disclaimer Requirement, explaining that the failure to do so violated the Plaintiffs' First Amendment rights, constituted contumacious conduct in contravention of *Pearson*'s constitutional mandate, elevated administrative law and agency convenience above contrary constitutional law in violation of the Supremacy Clause, violated the plain and intended meaning of the health claims provisions of the Food, Drug and Cosmetic Act, violated the Administrative Procedure Act, and violated FDA officers' oaths of office to uphold the Constitution. FDA ignored both petitions and, instead, issued another order on January 11, 2000, denying the E-Vitamin Health Claim and again refusing to implement *Pearson*'s Disclaimer Requirement. See Attachment E.

11. FDA's B-Vitamin Health Claim Denial and its E-Vitamin Health Claim Denial violate (a) the First Amendment to the United States Constitution, U.S. CONST. amend. I; (b) the constitutional mandate of this Court for implementation of the *Pearson* Disclaimer Requirement; (c) the Supremacy Clause of the United States Constitution, U.S. CONST. art. VI, cl. 2; (d) the plain and intended meaning of the health claims provision of the Nutrition Labeling and Education Act, Under 21 U.S.C. § 343 (r) *et seq.*; (e) the prohibition on arbitrary and capricious administrative action in the Administrative Procedure Act, 5 U.S.C. § 706; and (f) the constitutional duties of officers

of the Food and Drug Administration whose actions caused the violation of the *Pearson* mandate.

JURISDICTION

12. This Court has jurisdiction over this matter pursuant to 5 U.S.C. §§ 702 and 706 (hereinafter the "Administrative Procedure Act"); 28 U.S.C. § 1331 (federal question jurisdiction); and 28 U.S.C. § 1361 (Action to compel an officer of the United States to perform his duty).

VENUE

13. This Court has venue over this action pursuant to 28 U.S.C. § 1391(e).

DESCRIPTION OF THE PARTIES

14. ***Julian M. Whitaker, M.D.*** Julian M. Whitaker, M.D. is a party to each of the Health Claim petitions that FDA has denied. He is a physician licensed to practice medicine in the states of California and Washington. He graduated from Dartmouth College in 1966 with a B.S. degree and from Emory University in 1970 with an M.D. degree. He received additional training in surgery as a resident at the University of California Medical School. From 1975 to 1976 he worked as a physician at the Pritikin Institute in California. Since that time he has been the Clinical Director of the Whitaker Wellness Institute in Newport Beach, California. He is the author of five books: Reversing Heart Disease (1985); Reversing Diabetes (1987); Reversing Health Risk (1989); Natural Healing (1994); and What Your Doctor Won't Tell You About Bypass (1995). Since August of 1991 he has been the editor of *Health & Healing*, currently the nation's largest single editor health newsletter. In 1998, *Health & Healing* had over 500,000 subscribers. Dr. Whitaker consults in the design and distribution of

pharmaceutical grade dietary supplements for human consumption. He receives royalties from the distribution and sale of several dietary supplements. Two supplement products in which Dr. Whitaker has a direct financial interest contain the B-Vitamins that are the subject of this Complaint and two supplement products in which Dr. Whitaker has a direct financial interest contain the E-Vitamins that are the subject of this Complaint. He would like to place the B-Vitamin Health Claim and the E-Vitamin Health Claims on those dietary supplements labels and in their labeling.

15. ***Pure Encapsulations, Inc.*** Pure Encapsulations, Inc. (Pure) is one of the parties to the Health Claim Petitions denied by FDA. Pure is a Massachusetts corporation engaged in the business of manufacturing, distributing, and selling pharmaceutical grade dietary supplements for human and companion animal consumption. Three of the supplement products manufactured, distributed, and sold by Pure contain the B-Vitamins that are the subject of this Complaint. Five of the supplement products manufactured, distributed, and sold by Pure contains the E-Vitamins that are the subject of this Complaint. Pure would like to place B-Vitamin Health Claim and E-Vitamin Health Claims on those dietary supplements labels and in their labeling.

16. ***Durk Pearson and Sandy Shaw.*** Durk Pearson and Sandy Shaw are scientists residing in Nevada. They are two of the parties to the Health Claims Petitions denied by FDA. They design dietary supplement formulations and license them to manufacturing and retailing companies. They are authors of four books on aging and age-related diseases, including the #1, million plus copy best seller Life Extension: A Practical Scientific Approach (1982). They have also published three other health books, two of which were best sellers: The Life Extension Companion (1984); the Life

Extension Weight Loss Program (1986); and Freedom of Informed Choice—FDA Versus Nutrient Supplements (1993). Pearson and Shaw license for sale two dietary supplements that contain the B-Vitamins and two dietary supplements that contain the E-Vitamins that are the subject of this Complaint. They wish to place the B-Vitamin Health Claim and E-Vitamin Health Claims on the labels and in the labeling of those dietary supplements.

17. ***American Preventive Medical Association***. The American Preventive Medical Association (APMA) is a non-profit organization in Great Falls, Virginia. APMA is one of the parties to the Health Claim Petitions denied by FDA. APMA was founded in October of 1992 and is dedicated to ensuring consumer access to preventive therapies and the rights of health care providers to offer those therapies, including dissemination and receipt of information concerning the health benefits of the B-Vitamins and E-Vitamins that are the subject of this Complaint. Several APMA physicians, including its over 450 physician members and its 14 physician board members, sell dietary supplements that contain the B-Vitamins and E-Vitamins that are the subject of this Complaint. APMA and its practitioner members and its practitioner board members along with their hundreds of thousands of patients would benefit from approval of the Health Claims because such approval would enable them to communicate and receive at the point of sale nonmisleading health information on the labels and in the labeling of their B-Vitamin and E-Vitamin containing dietary supplements.

18. ***Donna E. Shalala, Secretary, United States Department of Health and Human Services; United States Department of Health and Human Services; Jane E. Henney, M.D., Commissioner of Food and Drugs, Food and Drug Administration;***

Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition, Food and Drug Administration; Elizabeth A. Yetley, Ph.D., Director, Office of Special Nutritionals, Food and Drug Administration; Food and Drug Administration; and the United States of America. Donna E. Shalala (sued in her official capacity only) is the Secretary of the United States Department of Health and Human Services, the executive department having jurisdiction over the Food and Drug Administration. Jane E. Henney, M.D. (sued in her official capacity only) is the Commissioner of the Food and Drug Administration. Joseph A. Levitt (sued in his official capacity only) is the Director of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration. Elizabeth A. Yetley, Ph.D. (sued in her official capacity only) is the Director of the Office of Special Nutritionals of the Food and Drug Administration. The Food and Drug Administration is that administrative agency granted authority by Congress to regulate the interstate manufacture, sale, and distribution of foods, drugs, cosmetics, biologics, medical devices, and dietary supplements in the United States. The Department of Health and Human Services and the Food and Drug Administration are part of the executive branch of the United States government.

CAUSE OF ACTION I: VIOLATION OF THE FIRST AMENDMENT

19. Plaintiffs reallege and restate paragraphs 1 through 18 and incorporate them herein.

20. FDA's B-Vitamin Health Claim Denial and its E-Vitamin Health Claim Denial violate the First Amendment to the United States Constitution. Those denials unconstitutionally suppress protected commercial speech that conveys factual

information important to those who wish to reduce their risks of vascular and heart disease.

21. The B-Vitamin Health Claim and the E-Vitamin Health Claims are endorsed by the opinion of leading scientists who study the nutrient-disease relationships, are supported by substantial scientific evidence (including the results of human clinical, epidemiological, and animal trials), and accurately reflect the state of current scientific information.

22. Government may not suppress either truthful and nonmisleading commercial and scientific speech or potentially misleading commercial speech. With regard to the latter, it may not suppress such speech but may require corrective disclaimers to avoid misleading connotations.

A. THE B-VITAMIN CLAIM IS NOT INHERENTLY MISLEADING AND MAY NOT BE CONSTITUTIONALLY SUPPRESSED

23. The B-Vitamin Health Claim Petition is predicated on more than one hundred scientific studies from peer-reviewed journals and a detailed scientific affidavit endorsing the claim from one of the nation's leading authorities on B-Vitamins and vascular disease, Kilmer McCully, M.D. The evidence revealed that B-Vitamins may reduce homocysteine levels in the blood and that homocysteine levels, in turn, are an independent risk factor for vascular disease. Thus, the claim represents that B-Vitamins may reduce the risk of vascular disease by reducing an independent risk factor for the disease.

24. FDA admits that there exists a "sound basis for associations between

homocysteine levels and folic acid and – to a lesser extent – vitamins B6 and B12," B-Vitamin Health Claim Denial at 9, but stated that there was an absence of conclusive proof of the causal association between a reduction in homocysteine levels and a lowering in the risk of vascular disease. B-Vitamin Health Claim Denial at 9. Contrary to FDA's position, the United States Center for Disease Control and Prevention, that agency charged by Congress with identifying risk factors for disease, concurs with the scientific findings relied upon by Plaintiffs, and publicly announced two weeks before the B-Vitamin Health Claim Denial that homocysteine is an independent risk factor for vascular disease. See CDC, Morbidity and Mortality Weekly Report, November 12, 1999.

25. The B-Vitamins here in issue have been lawfully sold over-the-counter since the 1930's and have been safely consumed in the United States and around the world for the past seventy years.

B. THE B-VITAMIN CLAIM IS PROTECTED COMMERCIAL SPEECH AND MUST BE AUTHORIZED

26. The B-Vitamin Claim conveys scientific information concerning the association between B-Vitamins and vascular disease risk that is valuable to consumers. The claim is either truthful and nonmisleading or, at worst, potentially misleading. As for the latter kind of speech, Government may not suppress truthful and nonmisleading and potentially misleading commercial speech. Government may use a corrective disclaimer to eliminate a perceived potential to mislead.

27. In their B-Vitamin Health Claim Petition, the Plaintiffs have invited the FDA to employ any reasonable disclaimer reasonably deemed necessary to avoid a potentially misleading connotation arising from the claim. They have offered to make

any FDA evaluation of the claim available to consumers of products bearing the claim (via an 800 number reference and internet site and/or to include any reasonable disclaimer with the claim). In this way the consuming public can best discern how to evaluate scientific information at the point of sale free of the agency's current blanket refusal to allow any Health Claim except that which has been established to its satisfaction and to a conclusive degree. FDA has unconstitutionally rejected use of disclaimers in favor of suppressing the claims outright for an indefinite future period.

C. THE E-VITAMIN CLAIM IS NOT INHERENTLY MISLEADING AND MAY NOT BE CONSTITUTIONALLY SUPPRESSED

28. The E-Vitamin Health Claim Petition is predicated on more than 120 scientific studies from peer-reviewed journals and a detailed scientific affidavit endorsing the claim from one of the nation's leading authorities on E-Vitamins and heart disease, William A. Pryor, Ph.D. The evidence revealed that E-Vitamins may reduce the risk of heart disease by inhibiting LDL oxidation and platelet aggregation and adhesion, commonly associated with heart disease.

29. FDA has approved an entire class of drugs as cardiovascular disease (CVD) event preventives and treatments based primarily on those drugs inhibition of platelet aggregation and adhesion. FDA has approved indications for aspirin as a heart disease preventive, 63 Fed. Reg. 56802, 56814-56815 (October 23, 1998) and Pletal (Jan. 15, 1999), Persantine (Dec. 13, 1990), Ticlid (March 24, 1993), Plavix (Nov. 17, 1997), Aggrastat (May 14, 1998), Integrilin (May 18, 1998), and Aggrenos (Nov. 22, 1999) as CVD preventives and therapeutics, based primarily on evidence that those drugs inhibit platelet aggregation, understood to be a characteristic sign or symptom of those diseases. FDA has recognized that inhibiting and decreasing platelet aggregation is a well

recognized therapy for the prevention of heart attack – an obvious endpoint of CVD. 65 Fed. Reg. 1000, 1016 (Jan. 6, 2000). Yet, despite accepting such evidence as indicative of the cardiovascular disease risk preventive and therapeutic effects of drugs, FDA refused to consider the evidence presented by the Plaintiffs documenting the inhibitory effects of Vitamin E on platelet adhesion and aggregation. FDA also refused to evaluate certain other scientific evidence presented by the Plaintiffs because it deemed the evidence not conclusive. FDA attempted to justify its refusal to evaluate the evidence on the basis that it did not find conclusive proof of causality between Vitamin E and overall CVD risk. E-Vitamin Health Claim Denial at 7.

30. FDA required conclusive proof of causality between Vitamin E consumption and overall CVD risk reduction as a condition precedent for considering scientific evidence of Vitamin E's inhibitory effects on platelet aggregation, a known contributing factor to the development and progression of heart disease. Likewise, while FDA reviewed evidence associating oxidized LDL with increased risk of CVD, it found that evidence not to "establish," conclusively, a causal nexus between Vitamin E induced reduction in oxidized LDL and CVD risk. FDA deemed the evidence insufficient despite the fact that it was supplied with eighty-two supporting articles from peer-reviewed scientific journals on the role of oxidized LDL in CVD development and progression. See Attachment F. Those eighty-two scientific journal articles are a subset of more than 300 on the subject. See Attachment G.

31. In short, FDA refused to consider, and rejected, extensive peer-reviewed published scientific evidence associating consumption of Vitamin E with a reduction in factors known to affect the development and progression of CVD. FDA instead

demanded, and did not find, conclusive proof that Vitamin E reduces the overall risk of CVD, despite the fact that the claim in issue is a "may reduce the risk of" rather than a "will reduce the risk of" claim.

32. The E-Vitamins here in issue have been sold over-the-counter since the 1930's and have been safely consumed in the United States and around the world for over sixty years.

D. THE E-VITAMIN CLAIM IS PROTECTED COMMERCIAL SPEECH AND MUST BE AUTHORIZED

33. The E-Vitamin Claim conveys scientific information concerning the association between E-Vitamins and heart disease risk that is valuable to consumers. The claim is either truthful and nonmisleading or, at worst, potentially misleading. Government may not suppress truthful and nonmisleading and potentially misleading commercial speech. As for the latter kind of speech, Government may use a corrective disclaimer to eliminate a perceived potential to mislead.

34. In their E-Vitamin Health Claim Petition, the Plaintiffs have invited the FDA to employ any reasonable disclaimer deemed necessary to avoid a potentially misleading connotation arising from the claim. They are willing to make FDA's evaluation of the claim available to consumers of products having labels or labeling bearing the claim (via an 800 number reference and via an internet site and/or to include any reasonable disclaimer with the claim). In this way the consuming public can best discern how to evaluate scientific information at the point of sale free of the agency's current blanket refusal to allow any Health Claim except that which has been established to its satisfication and to a conclusive degree. FDA has unconstitutionally rejected use of disclaimers in favor of suppressing the claims outright for an indefinite future period.

E. THE *PEARSON* DISCLAIMER REQUIREMENT IS THE AGENCY'S CONSTITUTIONALLY REQUIRED ALTERNATIVE TO SUPPRESSION OF THE B-VITAMIN AND E-VITAMIN CLAIMS

35. Under *Pearson*, health claims that are not the subjects of conclusive scientific proof, but are backed by scientific evidence, must be authorized with corrective disclaimers that alert consumers to the absence of conclusiveness. FDA may not suppress scientific information on the existence of the associations that the petitioners seek to convey. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir 1999). Thus, *Pearson* called upon FDA to consider authorizing each of the four claims there in issue with disclaimers that read as follows: "The evidence is inconclusive because existing studies have been performed with *foods* containing antioxidant vitamins, and the effect of those boods on reducing the risk of cancer may result from other components in those foods;" "The evidence in support of this claim is inconclusive;" and "The FDA does not approve this claim."

36. In light of the exensive peer-reviewed published scientific evidence supporting an association between B-Vitamins and a reduced risk of vascular disease and E-Vitamins and a reduced risk of heart disease, FDA violated *Pearson*'s Disclaimer Requirement by suppressing the B-Vitamin and E-Vitamin Health Claims outright instead of authorizing the claims with disclaimers reasonably designed to alert consumers to FDA's concerns about the level of proof present to support the claims.

F. FDA ENGAGED IN CONTUMACIOUS CONDUCT BY REFUSING TO IMPLEMENT *PEARSON*'S DISCLAIMER REQUIREMENT

37. *Pearson* ordered FDA to favor disclosure of health claims over suppression and compelled the agency not to deny potentially misleading claims but to authorize them with corrective disclaimers. In its B-Vitamin Health Claim Denial and in its E-Vitamin

Health Claim Denial, FDA contumaciously violated *Pearson* by suppressing the health claims instead of implementing the *Pearson* Disclaimer Requirement.

CAUSE OF ACTION II: VIOLATION OF THE SUPREMACY CLAUSE

38. Plaintiffs reallege and restate paragraphs 1 through 18 and incorporate them herein.

39. Under the Supremacy Clause of the Constitution, the Constitution and the laws made in pursuance of it are Supreme. U.S. CONST. art. VI, cl. 2. In our constitutional order, administrative law and agency convenience cannot be deemed supreme over a constitutional mandate from a federal court or the First Amendment to the United States Constitution.

40. The *Pearson* Court prohibited FDA from denying potentially misleading health claims on administrative grounds that violate First Amendment disclosure requirements. Instead, the *Pearson* Court ordered the agency to authorize potentially misleading health claims with corrective disclaimers. FDA violated the Supremacy Clause by refusing to implement that constitutional mandate and by insisting on adherence to its administrative rules to the contrary.

CAUSE OF ACTION III: VIOLATION OF THE NUTRITION LABELING AND EDUCATION ACT OF 1990

41. Plaintiffs reallege and restate paragraphs 1 through 18 and incorporate them herein.

42. FDA's demand for conclusive proof as a condition precedent to approval of a health claim is contrary to Congress's express intent for interpretation of "significant scientific agreement" in the Nutrition Labeling and Education Act of 1990 and contrary to the plain meaning of the statute, 21 U.S.C. § 343 (r) *et seq*.

43. Congress has repeatedly faulted this agency for applying a more stringent standard than Congress intended. Congress did not intend for there to be a requirement of conclusive proof of a health claim for dietary supplements as a condition precedent to claim approval. Rather, Congress expected health claims to be approved under "significant scientific agreement" "when a significant segment of scientists having relevant expertise agree, based on relevant scientific evidence, that consumers are reasonably likely to obtain the claimed health benefit." S. Rep. No. 103-410, at 24 (1994). Congress plainly did not contemplate that the drug pre-approval certainty standard would be applied. Rather, Congress defined "NLEA's goal" as that of "assuring that consumers have access on food and dietary supplement labels to health claims that are scientifically supported, without having to wait until the degree of scientific certainty contemplated by the drug standard has been achieved." S. Rep. No. 103-410 at 24 (1994).

44. Congress has severely criticized FDA for harboring an institutional bias against approval of dietary supplement health claims and for interpreting its health claims approval standard in a way that hinders, rather than fosters, the dissemination of scientific information and that limits consumer access to important information on diet and health. S. Rep. No. 103-410 at 14, 16, 23, 24, 30 (1994); S. Rep. No. 105-43 at 49 (1997); H. Rep. No. 105-306 at 16 (1997).

45. FDA's demand of conclusive proof as a condition precedent for approval of the B-Vitamin Health Claim and the E-Vitamin Health Claims violates the plain and intended meaning of the NLEA section concerning health claims approval.

CAUSE OF ACTION IV: VIOLATION OF THE ADMINISTRATIVE PROCEDURE ACT

46. Plaintiffs reallege and restate paragraphs 1 through 18 and incorporate them herein.

A. FDA'S DECISION TO IMPLEMENT THE *PEARSON* DISCLAIMER REQUIREMENT ON THE FOUR *PEARSON* CLAIMS BUT NOT ON ALL OTHER PENDING CLAIMS CONSTITUTES ARBITRARY AND CAPRICIOUS AGENCY ACTION

47. In its Notice, 64 Fed. Reg.67289 at 67290, the FDA announced that it would implement the *Pearson* disclaimer requirement when considering authorization of all four health claims at issue in *Pearson v. Shalala* but stated that it would deny every other pending claim without implementing *Pearson*'s Disclaimer Requirement. Rather, the claims would be suppressed for an indefinite future period; after FDA completed a general health claims rulemaking proceeding, it would then, and only then, "consider" the First Amendment issue.

48. FDA's implementation of the *Pearson* Disclaimer Requirement on the four *Pearson* claims but not on any others, when all are submitted for evaluation under 21 U.S.C. § 343 (r), constitutes an arbitrary and capricious agency action in violation of the Administrative Procedure Act, 5 U.S.C. § 706. The action inexplicably and impermissibly delays implementation of the *Pearson* Court's First Amendment mandate in favor of FDA's contrary administrative rules and its convenience.

B. THE ACTION OF FDA'S OFFICERS IN ISSUING THE NOVEMBER 30 B-VITAMIN HEALTH CLAIM DENIAL AND THE JANUARY 11, 2000 E-VITAMIN HEALTH CLAIM DENIAL VIOLATES THEIR CONSTITUTIONAL DUTIES AS OFFICERS AND EMPLOYEES OF THE EXECUTIVE BRANCH, *PEARSON*'S CONSTITUTIONAL MANDATE, AND THE FIRST AMENDMENT, AND THEREBY CONSTITUTES ARBITRARY AND CAPRICIOUS AGENCY ACTION

49. FDA Commissioner Jane E. Henney, M.D.; FDA Director of the Center

for Food Safety and Applied Nutrition Joseph A. Levitt; and FDA Director of the Office of Special Nutritionals Elizabeth A. Yetley, Ph.D. are officers of the agency, an executive branch of government, and are obligated to uphold the Constitution of the United States. The actions of each of those officers, acting separately and in concert, to cause the issuance of the B-Vitamin Health Claim Denial and the E-Vitamin Health Claim Denial without implementing the *Pearson* Disclaimer Requirement violate their constitutional duties, violate the *Pearson* Court's constitutional mandate, and violate the First Amendment rights of the Plaintiffs.

50. Actions by FDA officers in violation of their constitutional duties, in violation of the *Pearson* Court's constitutional mandate, and in violation of the First Amendment rights of the Plaintiffs constitute arbitrary and capricious actions contrary to law. They thus violate the Administrative Procedure Act, 5 U.S.C. § 706.

C. FDA'S VIOLATIONS OF THE *PEARSON* COURT'S MANDATE, THE FIRST AMENDMENT, AND THE NLEA ALSO VIOLATE THE APA

51. The APA prohibits agency action that is contrary to law. Accordingly, FDA's violation of the First Amendment, the *Pearson* constitutional mandate, and the Nutrition Labeling and Education Act health claims provision also violates the Administrative Procedure Act, 5 U.S.C. § 706.

D. FDA'S DEMAND FOR CONCLUSIVE PROOF AKIN TO THE DRUG CERTAINTY STANDARD IS ARBITRARY AND CAPRICIOUS FOR THE DIETARY SUPPLEMENT "MAY" CLAIMS HERE IN ISSUE

52. The claims here in issue are worded as "may reduce the risk of" claims instead of "will reduce the risk of" claims. They thus depend upon evidence that nutrients affect certain biological factors and mechanisms associated with disease endpoints in ways that reduce those factors and mechanisms, thereby making it

reasonably likely that disease risk reduction will result. Under the NLEA, Congress expressly does not demand conclusive proof of causality for dietary supplement health claims. Despite that fact, FDA arbitrary and capriciously has demanded conclusive proof of causality (the so-called drug pre-approval certainty standard) as a condition precedent to claim approval. That demand for conclusive proof is not only contrary to the plain language of the NLEA's health claims approval provisions and the intent of Congress but also to basic logic. A "may" claim does not require sufficient evidence to conclude that a change in the dietary intake of a substance will result in a change in a disease endpoint, only that it may do so (in the words of Congress, "that consumers are *reasonably likely* to obtain the claimed health benefit"). FDA's demand for conclusive proof is, thus, arbitrary and capricious and contrary to law.

RELIEF REQUESTED

53. The Plaintiffs respectfully request that this Honorable Court:

Declare in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act) that the FDA's November 30, 1999 Denial of the B-Vitamin Health Claim Petition and the FDA's January 11, 2000 Denial of the E-Vitamin Health Claim Petition are invalid; in particular, they request that this Court declare:

(a) that the FDA's November 30, 1999 Denial of the B-Vitamin Health Claim Petition and January 11, 2000 Denial of the E-Vitamin Health Claim Petition violates the First Amendment to the United States Constitution;

(b) that the FDA's November 20, 1999 Denial of the B-Vitamin Health Claim Petition and January 11, 2000 Denial of the E-Vitamin Health Claim Petition

constitute contumacious conduct by the agency in disobedience of the *Pearson* Court's constitutional mandate;

(c) that the FDA's November 30, 1999 Denial of the B-Vitamin Health Claim Petition and January 11, 2000 Denial of the E-Vitamin Health Claim Petition violates the Supremacy Clause of the United States Constitution by elevating administrative law and agency convenience above the First Amendment and the *Pearson* Court's constitutional mandate;

(d) that the FDA's November 30, 1999 Denial of the B-Vitamin Health Claim Petition and January 11, 2000 Denial of the E-Vitamin Health Claim Petition constitutes arbitrary and capricious agency action, an abuse of discretion, and actions contrary to law in violation of the Administrative Procedure Act, 5 U.S.C. § 706; and

(e) that the FDA's November 30, 1999 Denial of the B-Vitamin Health Claim Petition and January 11, 2000 Denial of the E-Vitamin Health Claim Petition violates the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343(r)(1)(B).

Order in accordance with the *Pearson* Court's constitutional mandate and the First Amendment that FDA authorize the B-Vitamin Health Claim and the E-Vitamin Health Claims forthwith with such disclaimer or such disclaimers as are reasonably necessary to avoid a potentially misleading connotation in accordance with the requirements of the First Amendment as mandated by this Court in compliance with the decision of the United States Court of Appeals for the D.C. Circuit 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).

Declare in accordance with 28 U.S.C. § 2201 (the Declaratory Judgment Act) and 28 U.S.C. § 1361 (to compel an officer of the United States to perform his duty) that FDA Commissioner Jane E. Henney, M.D.; FDA Director of the Center for Food Safety and Applied Nutrition Joseph A. Levitt; and FDA Director of the Office of Special Nutritionals Elizabeth A. Yetley, Ph.D., the FDA officers responsible for drafting and issuing the orders denying the B-Vitamin and E-Vitamin Health Claim Petitions, have violated their oaths of office to uphold the Constitution of the United States.

Order in accordance with 28 U.S.C. § 1361 (to compel an officer of the United States to perform his duty) that FDA Commissioner Jane E. Henney, M.D.; FDA Director of the Center for Food Safety and Applied Nutrition Joseph A. Levitt; and FDA Director of the Office of Special Nutritionals Elizabeth A. Yetley, Ph.D. fulfill their constitutional duties by immediately authorizing the B-Vitamin Health Claim and the E-Vitamin Health Claims with such disclaimer or such disclaimers as are reasonably necessary to avoid a potentially misleading connotation in accordance with the requirements of the First Amendment as mandated by this Court in compliance with the decision of the United States Court of Appeals for the D.C. Circuit 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).

Order in accordance with this Court's inherent judicial authority to ensure that its orders are implemented and 18 U.S.C. § 401 that the Defendants FDA and FDA Commissioner Jane E. Henney, M.D.; FDA Director of the Center for Food Safety and Applied Nutrition Joseph A. Levitt; and FDA Director of the Office of Special Nutritionals Elizabeth A. Yetley, Ph.D. are in Contempt of Court for violating the *Pearson* Court's constitutional mandate.

Declare in accordance with this Court's inherent judicial power to ensure that its orders are implemented and 18 U.S.C. § 401 that any Defendant who causes, aids in, abets, or countenances any continued failure to implement fully and faithfully the constitutional mandate of the United States Court of Appeals for the D.C. Circuit 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) shall be subject to further judicial sanction, including, but not limited to, monetary sanctions for noncompliance.

Retain jurisdiction over this matter to ensure prompt compliance with the *Pearson* Court's constitutional mandate and this Court's order that FDA authorize the B-Vitamin Health Claim and E-Vitamin Health Claims with reasonable disclaimers.

Respectfully submitted,

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Dated: January 19, 2000