

Before the  
FOOD AND DRUG ADMINISTRATION  
Rockville, MD

In re: Guidance on Applying )  
The Structure/Function Rule; ) Docket No. 01D-0058  
Request for Comments )

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COMMENTS OF  
PURE ENCAPSULATIONS, INC.;  
WELLNESS LIFESTYLES, INC. d/b/a AMERICAN LONGEVITY;  
DURK PEARSON and SANDY SHAW;  
AMERICAN PREVENTIVE MEDICAL ASSOCIATION;  
WEIDER NUTRITION GROUP INC.;  
LIFE PRIORITY INC.;  
LIFE ENHANCEMENT PRODUCTS INC.;  
LIFE EXTENSION FOUNDATION BUYERS CLUB INC.; and  
LIFE SERVICES SUPPLEMENTS

Pure Encapsulations, Inc.; Wellness Lifestyles Inc. d/b/a American Longevity; Durk Pearson and Sandy Shaw; the American Preventive Medical Association; Weider Nutrition Group Inc.; Life Priority Inc.; Life Enhancement Products Inc.; Life Extension Foundation Buyers Club Inc.; and Life Services Supplements (collectively, "Joint Commenters"), hereby submit their comments in response to the agency's solicitation of comments in the above-referenced docket. See 66 Fed. Reg. 11172 (2001).

**BACKGROUND OF THE JOINT COMMENTERS**

*Pure Encapsulations, Inc.* Pure Encapsulations, Inc. ("Pure") is a Massachusetts corporation engaged in the business of manufacturing, distributing, and selling pharmaceutical grade dietary supplements for human and companion animal consumption. Pure uses structure/function claims on its dietary supplement products' labels and in their labeling. Pure sells two dietary supplements containing saw palmetto extract and wants to place on the labels and in the labeling of those products: "helps to maintain normal urine flow in men over 50 years

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old.” Pure sells six dietary supplements containing calcium and wants to put on the labels and in the labeling of those products: “helps maintain normal bone density in post-menopausal women.” Pure also sells three dietary supplements containing alpha-lipoic acid, chromium, and gymnema sylvestre and wants to place on the label and in the labeling of those products: “helps maintain a healthy blood sugar level.” Pure also sells five dietary supplements containing sitosterols, garlic, EPA/DHA fish oils, niacin, and soy isoflavones and soy proteins and wants to place on the label and in the labeling of those products: “promotes normal cholesterol levels” and “promotes normal cholesterol metabolism and clearance.” Pure sells approximately twelve products that contain glucosamine, chondroitin, MSM (methylsulfanone methane), and/or shark cartilage and wants to place on the label and in labeling of those products: “helps to relieve joint pain.” Pure also sells two products that contain potassium, magnesium and hawthorne and wants to place on the label and in labeling of those products: “promotes normal blood pressure.” Under FDA’s current construction of its rules, each could not be made as a structure/function claim based on an alleged disease implication. However, FDA can and, to fulfill its First Amendment duty, must mandate use of a disclaimer, eliminating the disease connotation as a less restrictive alternative to claim restriction. Pure thus joins these comments to recommend a rule of innocent construction and use of disclaimers to eliminate implied disease claims in lieu of claim restriction. Pure also wants to use in labels and in labeling citations to scientific literature that may contain words referring to disease or disease conditions. It urges FDA to avoid restriction of its use of scientific citations for the edification of consumers and to rely instead on a disclaimer, eliminating the disease connotation, as a less restrictive alternative to restricting citation use.

*American Longevity*. Wellness Lifestyles Inc. d/b/a American Longevity (hereinafter “AL”) is a California corporation engaged in the business of manufacturing, distributing, and selling dietary supplements for human and animal companion consumption. AL uses structure/function claims on its dietary supplement products’ labels and in their labeling. Thus, it has a keen interest in FDA’s application of the structure/function claim rule. In particular, AL sells two dietary supplements containing saw palmetto extract and wants to place on the labels and in the labeling of those products: “helps to maintain normal urine flow in men over 50 years old.” AL sells six dietary supplements containing calcium and wants to put on the labels and in the labeling of those products: “helps maintain normal bone density in post-menopausal women.” AL also sells one dietary supplement containing chromium, vanadium, and gymneum and wants to place on the label and in the labeling of those products: “helps maintain a healthy blood sugar level.” AL sells six dietary supplements containing niacin, EPA/DHIA fish oils, soy isoflavones, and soy proteins and wants to place on the label and in the labeling of those products: “promotes normal cholesterol levels” and “promotes normal cholesterol metabolism and clearance.” AL sells approximately four products that contain glucosamine and chondroitin sulfate and wants to place on the label and in labeling of those products: “helps to relieve joint pain.” AL also sells four products that contain choline, potassium, magnesium and arginine and wants to place on the label and in labeling of those products: “promotes normal blood pressure.” AL thus joins these comments to recommend a rule of innocent construction and use of disclaimers to eliminate implied disease claims in lieu of claim restriction. AL also wants to use in labels and in labeling citations to scientific literature that may contain words referring to disease or disease conditions. It urges FDA to avoid restriction of its use of scientific citations

for the edification of consumers and to rely instead on a disclaimer, eliminating the disease connotation, as a less restrictive alternative to restricting citation use.

***Durk Pearson and Sandy Shaw.*** Durk Pearson and Sandy Shaw (“Pearson and Shaw”) are scientists residing in Nevada. 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 dietary supplements that use structure/function claims on dietary supplement products’ labels and labeling. Thus, they have a keen interest in FDA’s application of the structure/function claim rule. In particular, Pearson and Shaw license a dietary supplement formulation containing calcium and want to put on the labels and in the labeling of those products that contain the formulation: “helps maintain normal bone density in post-menopausal women.” Pearson and Shaw also license a dietary supplement formulation containing arginine, choline, and Vitamin B5 and want to place on the label and in labeling of those products that contain the formulation: “promotes normal blood pressure.” Under FDA’s current construction of its rules, each would be prohibited as a structure/function claim based on an alleged disease implication. However, FDA can and, to fulfill its First Amendment duty, must mandate use of a disclaimer, eliminating the disease connotation as a less restrictive alternative. Pearson and Shaw thus join these comments to recommend a rule of innocent construction and use of disclaimers to eliminate implied disease claims in lieu of claim restriction. Pearson and Shaw also want to use in labels and in labeling citations to scientific

literature that may contain words referring to disease or disease conditions. They urge FDA to avoid restriction of their use of scientific citations that edify consumers (a violation of their First Amendment rights) and to rely instead on a disclaimer, eliminating the disease connotation, as a less restrictive alternative to restricting citation use.

***American Preventive Medical Association.*** The American Preventive Medical Association (“APMA”) is a non-profit organization in Virginia. 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. Several APMA practitioner members sell dietary supplements and use structure/function claims on the labels and in the labeling of those supplements. In addition, APMA and its practitioner members and their hundreds of thousands of patients benefit from the use of structure/function claims because those claims enable them to communicate and receive non-misleading health information essential to the exercise of informed patient choice. APMA’s physician members seek to use the structure/function claims listed herein disclaimed as necessary to avoid a disease implication.

***Weider Nutrition Group Inc.*** Weider Nutrition Group Inc. (“Weider”) is a Utah corporation engaged in the business of manufacturing, distributing, and selling dietary supplements for human and animal companion consumption. Weider uses structure/function claims on its dietary supplement products’ labels and in their labeling. In particular, Weider sells a dietary supplement product containing calcium and wants to place on labels and in labeling the following claim: “calcium helps maintain normal bone density in post-menopausal women.” Weider also sells several products containing glucosamine and chondroitin sulfate and wants to use on labels and in labeling for those products: “helps relieve joint pain.” Under FDA’s current construction of its rules, each would be prohibited as a structure/function claim based on an

alleged disease implication. However, FDA can and, to fulfill its First Amendment duty, must mandate use of a disclaimer, eliminating the disease connotation as a less restrictive alternative. Weider thus joins these comments to recommend a rule of innocent construction and use of disclaimers to eliminate implied disease claims in lieu of claim restriction. Weider also wants to use in labels and in labeling citations to scientific literature that may contain words referring to disease or disease conditions. It urges FDA to avoid restriction of its use of scientific citations for the edification of consumers and to, instead rely on a disclaimer, eliminating the disease connotation, as a less restrictive alternative to restricting citation use.

*Life Priority Inc.* Life Priority, Inc. ("LifeP") is a Kansas corporation engaged in the business of distributing and selling dietary supplements for human and companion animal consumption. LifeP uses structure/function claims on its dietary supplement products' labels and labeling. LifeP sells a dietary supplement containing saw palmetto extract, pygeum extract, and pumpkin seed oil extract and wants to place on the labels of this product: "helps to maintain normal urine flow in men over 50 years old." LifeP sells a dietary supplement containing calcium and wants to put on the labels and in the labeling of those products: "helps maintain normal bone density in post-menopausal women." LifeP sells a dietary supplement containing quercetin, niacin, EPA/DHA fish oils and wants to place on the label and in the labeling of those products: "promotes normal cholesterol levels" and "promotes normal cholesterol metabolism and clearance." LifeP sells dietary supplements that contain glucosamine hydrochloride and chondroitin sulfate and wants to place on the labels and in the labeling of those products: "helps to relieve joint pain." LifeP sells dietary supplements that contain choline, arginine, and Vitamin B5 and wants to place on the label and in the labeling of those products: "promotes normal blood pressure." Under FDA's current construction of its rules, each would be prohibited as a

structure/function claim based on an alleged disease implication. However, FDA can and, to fulfill its First Amendment duty, must mandate use of a disclaimer, eliminating the disease connotation as a less restrictive alternative. LifeP thus joins these comments to recommend a rule of innocent construction and use of disclaimers to eliminate implied disease claims in lieu of claim restriction. LifeP also wants to use in labels and in labeling citations to scientific literature that may contain words referring to disease or disease conditions. It urges FDA to avoid restriction of its use of scientific citations for the edification of consumers and to rely instead on a disclaimer, eliminating the disease connotation, as a less restrictive alternative to restricting citation use.

***Life Enhancement Products Inc.*** Life Enhancement Products Inc. (LEP) is a Nevada corporation engaged in the business of manufacturing, distributing and selling dietary supplements for human and companion animal consumption. LEP uses structure/function claims on its labels and in its labeling. LEP sells two dietary supplements containing saw palmetto extract and wants to place on the labels and in the labeling of those products: “helps to maintain normal urine flow in men over 50 years old.” LEP sells two dietary supplement containing calcium and wants to put on the labels and in the labeling of those products: “helps maintain normal bone density in post-menopausal women.” LEP sells more than 10 dietary supplement containing glutamine, alpha lipoic acid, vanadium, chromium, and American ginseng and wants to place on the label and in the labeling of those products: “helps maintain a healthy blood sugar level.” LEP also sells four dietary supplements containing sitosterols, niacin, red yeast rice, Omega-3 fish oils, garlic, and soy and wants to place on the label and in the labeling of those products: “promotes normal cholesterol levels” and “promotes normal cholesterol metabolism and clearance.” LEP sells three dietary supplements that contain glucosamine and chondroitin

and wants to place on the labels and in the labeling of those products: “helps to relieve joint pain.” LEP sells eight dietary supplements that contain potassium, magnesium, choline, and arginine and wants to place on the labels and in the labeling of those products: “promotes normal blood pressure.” Under FDA’s current construction of its rules, each would be prohibited as a structure/function claim based on an alleged disease implication. However, FDA can and, to fulfill its First Amendment duty, must mandate use of a disclaimer, eliminating the disease connotation as a less restrictive alternative. LEP thus joins these comments to recommend a rule of innocent construction and use of disclaimers to eliminate implied disease claims in lieu of claim restriction. LEP also wants to use in labels and in labeling citations to scientific literature that may contain words referring to disease or disease conditions. It urges FDA to avoid restriction of its use of scientific citations for the edification of consumers and to rely instead on a disclaimer, eliminating the disease connotation, as a less restrictive alternative to restricting citation use.

*Life Extension Foundation Buyers Club Inc.* Life Extension Foundation Buyers Club Inc. (“LEFBC”) is a Nevada corporation engaged in the business of formulating, distributing and selling dietary supplements for human and animal companion consumption. LEFBC uses structure/function claims on its dietary supplement products’ labels and in their labeling. LEFBC sells three dietary supplements containing saw palmetto extract and wants to place on the labels and in the labeling of those products: “helps to maintain normal urine flow in men over 50 years old.” LEFBC sells five dietary supplements containing calcium and wants to place on the labels and in the labeling of those products: “calcium helps maintain normal bone density in post-menopausal women.” LEFBC also sells 5 dietary supplements containing glutamine, alpha lipoic acid, vanadium, and chromium that are high in protein or low in carbohydrates (and low in

fat) and wants to place on the label and in the labeling of those products: “helps maintain a healthy blood sugar level.” LEFBC also sells six dietary supplements containing sitosterols, niacin, and soy and wants to place on the label and in the labeling of those products “promotes normal cholesterol levels” and “promotes normal cholesterol metabolism and clearance.” LEFBC sells five dietary supplements containing chondroitin and glucosamine and wants to place on labels and in the labeling of those products: “helps to relieve joint pain.” LEFBC also sells seven dietary supplements containing potassium, magnesium, and arginine and wants to place on the labels and in the labeling of those products: “promotes normal blood pressure.” Under FDA’s current construction of its rules, each would be prohibited as a structure/function claim based on an alleged disease implication. However, FDA can and, to fulfill its First Amendment duty, must mandate use of a disclaimer, eliminating the disease connotation, as a less restrictive alternative. LEFBC thus joins these comments to recommend a rule of innocent construction and use of disclaimers to eliminate implied disease claims in lieu of claim restriction. LEFBC also wants to use in labels and in labeling citations to scientific literature that may contain words referring to disease or disease conditions. It urges FDA to avoid restriction of its use of scientific citations for the edification of consumers and to rely instead on a disclaimer, eliminating the disease connotation, as a less restrictive alternative to restricting citation use.

***Life Services Supplements.*** Life Services Supplements (“LSS”) is a New Jersey corporation engaged in the business of manufacturing dietary supplements for human consumption. LSS uses structure/function claims on its dietary supplement products’ labels and in their labeling. LSS sells two dietary supplements containing saw palmetto extract and wants to place on the labels and in the labeling of those products: “helps to maintain normal urine flow

in men over 50 years old.” LSS sells two dietary supplements containing calcium and wants to place on the labels and in the labeling of those products: “calcium helps maintain normal bone density in post-menopausal women.” LSS also sells more than 80 dietary supplements containing glutamine, alpha lipoic acid, glucosol (extract of *Lagerstroemia speciosa L.*), vanadium, chromium, and are high in protein and/or low in carbohydrates and wants to place on the label and in the labeling of those products: “helps maintain a healthy blood sugar level.” LSS also sells four dietary supplements containing sitosterols, niacin, and soy and wants to place on the label and in the labeling of those products “promotes normal cholesterol levels” and “promotes normal cholesterol metabolism and clearance.” LSS sells five dietary supplements containing chondroitin and glucosamine and wants to place on labels and in the labeling of those products: “helps to relieve joint pain.” LSS also sells three dietary supplements containing potassium and magnesium and wants to place on the labels and in the labeling of those products: “promotes normal blood pressure.” Under FDA’s current construction of its rules, each would be prohibited as a structure/function claim based on an alleged disease implication. However, FDA can and, to fulfill its First Amendment duty, must mandate use of a disclaimer, eliminating the disease connotation as a less restrictive alternative. LSS thus joins these comments to recommend a rule of innocent construction and use of disclaimers to eliminate implied disease claims in lieu of claim restriction. LSS also wants to use in labels and in labeling citations to scientific literature that may contain words referring to disease or disease condition. It urges FDA to avoid restriction of its use of scientific citations for the edification of consumers and to rely instead on a disclaimer, eliminating the disease connotation, as a less restrictive alternative to restricting citation use.

## INTRODUCTION

The agency's request invites parties to supply comments not only on the content of a structure/function claim guidance but also on "additional topics for inclusion in the guidance" and "any other issue appropriate for this guidance." 66 Fed. Reg. 1000. Since FDA's January 6, 2000 Final Rule, the United States District Court for the District of Columbia has published two additional First Amendment decisions that expound further upon the restrictions the Constitution imposes on this agency's regulation of commercial speech, Pearson v. Shalala, 130 F.Supp.2d 105 (D.D.C. 2001) ("Pearson II") and Pearson v. Thompson, No. 00-2724 (GK) (D.D.C. May 9, 2001) ("Pearson III").

As explained below, the First Amendment forbids FDA from restricting protected commercial speech: (1) FDA may not restrict use of a structure/function claim on the basis that one claim implication is arguably that the dietary ingredient or nutrient is intended to cure, treat, mitigate, or prevent a disease; (2) FDA may not restrict use of any accurate citation on grounds that the title or content of the cited work associates a dietary ingredient or nutrient with disease cure, treatment, mitigation, or prevention; and (3) FDA may not preclude use of a product, trade, or company name on grounds that it arguably implies disease cure, treatment, mitigation, or prevention unless before imposing any such restriction it proves, based on empirical evidence, that the less restrictive alternative of a mandatory disclaimer cannot suffice to eliminate the disease connotation.

The constitutional doctrine taught by the Pearson cases compels this agency to avoid imposing a burden or restriction on commercial speech if the less restrictive alternative of a disclaimer can suffice to serve a legitimate government's objective. FDA must heed those decisions and adopt in its guidance (1) an innocent construction rule, as explained below, and (2)

use of disclaimers as a less restrictive alternative to imposition of restraints on commercial speech.

When FDA issues a "courtesy letter" to a party that submits a structure/function claim notice, pursuant to 21 C.F.R. § 101.93, it in effect informs the party that the claim may not be made in the secure knowledge that it is lawful without either (1) the approval of a health claim petition or (2) the approval of a new drug application. In the experience of the Joint Commenters, the cost of a health claim petition ranges from approximately \$35,000 to \$75,000, depending on the nature of the claim and the relative level of complexity of the science supporting it. See Exhibits 1-10. The typical cost of a new drug application is approximately \$52 million to \$300 million, again depending on the complexity of the submission. See Exhibit 11. This agency rarely authorizes or allows health claims and has explained that dietary ingredients are unlikely to be granted new drug approval. See 52 Fed. Reg. 28843, 28845 (Aug. 4, 1987). Thus, the effective burdens on speech that may not be made without FDA health claim or new drug approval are great. Accordingly, FDA may not shirk its First Amendment obligation in its review of structure/function claims and must rely on less restrictive alternatives that favor disclosure over suppression of (1) health information, (2) citations, and (3) product and company names that arguably imply, but do not state, nutrient-disease associations.

#### **BACKGROUND OF AGENCY NOTICE**

Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect a structure or function in humans, characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describe general well-being from consumption of a nutrient or dietary ingredient. 21 U.S.C. § 343(r)(6)(A). The manufacturer of a dietary supplement bearing a structure/function claim must have substantiation

that the claim is truthful and not misleading and the statement must appear with the following disclaimer, prominently displayed in boldface type:

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Id. at §343(r)(6)(B; C). In addition, within 30 days after first marketing the dietary supplement containing the structure/function claim the manufacturer, packer or distributor of the dietary supplement must file a notice with FDA concerning use of the claim on the label and in labeling. 21 C.F.R. § 101.93(a)(1).

On January 6, 2001, before Judge Gladys Kessler's two recent First Amendment decisions (Pearson v. Shalala, 130 F.Supp.2d 105 (D.D.C. 2001) ("Pearson II"); Pearson v. Thompson, No. 00-2724 (GK) (D.D.C. May 9, 2001) ("Pearson III") the FDA published a rule governing the use of structure/function claims for dietary supplements (hereinafter "January 6<sup>th</sup> Rule"). 65 Fed. Reg. 1000 (21 C.F.R. § 101.93). In the January 6<sup>th</sup> Rule FDA states that dietary supplement labels or labeling may bear structure/function claims provided that such statements are not express or implied disease claims under (g) of that section. Id. (21 C.F.R. § 101.93(f)). If the label or labeling of a product marketed as a dietary supplement bears an express or implied disease claim as defined in paragraph (g) of 21 C.F.R. § 101.93<sup>1</sup>, the product will be subject to regulation as a drug unless the claim is an authorized health claim. Id. at 101.93(f).

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<sup>1</sup> 21 C.F.R. § 101.93(g) states:

(1) For purpose of 21 U.S.C. 343(r)(6), a "disease" is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g. cardiovascular disease) or a state of health leading to such dysfunctioning (e.g. hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition).

(2) FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under 21 U.S.C. 343(r)(6) if it meets one or more of the criteria listed below. These criteria are not intended to classify as disease claims statements that refer to the ability of a product to maintain healthy structure or function, unless the statement implies disease prevention or treatment. In determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

In the January 6<sup>th</sup> Rule FDA stated that it would later provide a guidance for industry that gave examples of labeling claims that would and would not be considered disease claims (65 Fed. Reg. at 1009), give examples of permissible and impermissible product names (Id. at 1022), and address the use of citations to a publication or reference that implies the treatment or prevention of disease (Id. at 1025).<sup>2</sup>

Under the above docket, FDA asks for comment on those guidance topics proposed in the January 6<sup>th</sup> Rule and for suggestions for additional topics for inclusion in the guidance. See 66

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- (i) has an effect on a specific disease or class of diseases;
  - (ii) has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;
  - (iii) has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;
  - (iv) has an effect on a disease or diseases through one or more of the following factors
    - (a) the name of the product;
    - (b) a statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;
    - (c) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;
    - (d) Use of the term "disease" or "diseased," except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of disease or to a specific product or ingredient; or
    - (e) Use of pictures, vignettes, symbols, or other means;
  - (v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;
  - (vi) Is a substitute for a product that is a therapy for a disease
  - (vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;
  - (viii) Has a role in the body's response to a disease or to a vector of disease
  - (ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or
  - (x) Otherwise suggests an effect on a disease or diseases.

<sup>2</sup> In its call for comments concerning the proposed guidance, FDA states that the issue of substantiation of structure/function claims will not be addressed in the proposed guidance but will be a separate guidance.

Fed. Reg. 11172. In addition, FDA asks for comments addressing any other issues appropriate for the guidance. Id.

Since FDA's adoption of the January 6<sup>th</sup> Rule, the United States District Court for the District of Columbia has issued two decisions explaining the First Amendment principles governing FDA's restrictions on health claims. Those First Amendment principles are of general applicability and govern all instances in which FDA presumes to restrict or burden commercial speech (including, therefore, structure/function claims). In particular, the Pearson decisions teach that when commercial speech contains a potentially misleading connotation (such as an unintended implied claim to treat disease) it is the duty of this agency to employ a less restrictive alternative to its speech restriction, i.e. a disclaimer. The overarching First Amendment presumption in favor of disclosure over suppression (the same one that imposes on this agency a First Amendment burden of proof in the health claim context) compels this approach.

### SUMMARY

The proposed guidance should instruct FDA's agents on how to evaluate structure/function claims in accordance with the protections of the First Amendment. The First Amendment requires the Government to employ a less restrictive alternative to commercial speech restriction unless, based on empirical evidence, it can prove the alternative incapable of correcting misleadingness. In accordance with the First Amendment, FDA should apply an "innocent construction presumption" in analyzing dietary supplement structure/function claims that contain an implied disease treatment claim. FDA must begin with the unbiased presumption that a structure/function claim that arguably implies disease cure, treatment, prevention, or mitigation is intended (based on the regulatee's notice filing) to convey a non-disease connotation. To avoid the implied, yet unintended, disease connotation, FDA should give the

party serving notice of the claim the option of using a disclaimer that eliminates the disease connotation rather than a “courtesy letter” limited to explaining that the claim is capable of lawful use only if it is first approved in response to a health claim petition or approved as part of a new drug application – two costly and often unattainable options.

Failure to adopt an innocent construction presumption and use of a disclaimer clarifying a non-disease meaning as a less restrictive alternative to claim restriction unlawfully burdens protected speech. That failure imposes financial burdens and delays in communication that are impermissible restraints. Simon & Schuster v. Members of the New York State Crime Victims Board, 502 U.S. 105, 115 (1991) citing Leathers v. Medlock, 499 U.S. 439, 437, 113 L.Ed.2d 494, 111 S.Ct. 1438 (1991) (impermissible financial burden on the First Amendment); Elrod v. Burns, 427 U.S. 347, 49 L.Ed.2d 547, 96 S.Ct. 2673 (1976)(citations omitted)(loss of First Amendment freedoms for minimal amounts of time is irreparable injury). FDA’s insistence on burdening commercial speech in this way when it has readily available the less restrictive alternative of a clarifying disclaimer (that no disease connotation is intended) violates the First Amendment to the United States Constitution.

## **ARGUMENT**

### **I. THE FIRST AMENDMENT REQUIRES AN INNOCENT CONSTRUCTION PRESUMPTION FOR STRUCTURE/FUNCTION CLAIM ANALYSIS**

It is FDA’s constitutional duty to begin any analysis of a dietary supplement’s structure/function claims free of content bias. “Regulations which permit the Government to discriminate on the basis of the content of the message cannot be tolerated under the First Amendment.” Simon & Schuster v. Members of the New York State Crime Victims Board, 502 U.S. 105, 116 (1991) citing Regan v. Time, Inc., 468 U.S. 641, 648-9, 82 L.Ed.2d 487, 104

S.Ct. 3262 (1984); see also Police Dept. of Chicago v. Mosley, 408 U.S. 92, 95, 33 L.Ed.2d 212, 92 S.Ct. 2286 (1972)). Implicit in a party's filing of a structure/function claim is its intention to convey a non-disease treatment message. It is thus appropriate for FDA to take reasonable steps short of claim restriction to effectuate that intent by relying on reasonable disclaimers that eliminate the treatment connotation should it perceive what the filer has not.

FDA's restrictions on structure/function claims must comply with the First Amendment commercial speech doctrine. See Pearson v. Shalala, 164 F.3d 650, 655 (D.C. Cir. 1999) (application of the commercial speech doctrine to FDA's restrictions on dietary supplement health claims) (citing See Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 67-68, 77 L. Ed. 2d 469, 103 S. Ct. 2875 (1983)).

Truthful advertising related to lawful activities is entitled to the protections of the First Amendment. But when the particular content or method of the advertising suggests that it is inherently misleading or when experience has proved that in fact such advertising is subject to abuse, the States may impose appropriate restrictions. Inherently misleading advertising may be prohibited entirely. But the States may not place an absolute prohibition on ... potentially misleading information ... if the information also may be presented in a way that is not deceptive.

Id. citing (In re R. M. J., 455 U.S. 191, 203, 102 S. Ct. 929, 71 L. Ed. 2d 64 (1982)); see also Ibanez v. Florida Dep't of Business and Prof'l Regulation, 512 U.S. 136, 144-46, 129 L. Ed. 2d 118, 114 S. Ct. 2084 (1994); Peel v. Attorney Registration and Disciplinary Comm'n of Illinois, 496 U.S. 91, 99-111, 110 L. Ed. 2d 83, 110 S. Ct. 2281 (1990)).

A government scheme to regulate commercial speech must meet the three-part test articulated by the Supreme Court in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557, 566, 65 L. Ed. 2d 341, 100 S. Ct. 2343 (1980): (1) whether the asserted government interest is substantial; (2) whether the regulation directly advances the governmental interest asserted; and (3) whether the fit between the government's ends and the means chosen to accomplish those ends is reasonable. Central Hudson, 447 U.S. at 566; See also

Board of Trustees of the State University of New York v. Fox, 492 U.S. 469, 480, 106 L. Ed. 2d 388, 109 S. Ct. 3028 (1989) (discussing Central Hudson, 447 U.S. at 564-66); See also Pearson, 164 F.3d. at 655-656.

It is not enough to justify restriction of speech that FDA's interest in the restriction is the protection of the public's health and safety when a less restrictive alternative is readily available that can also achieve that objective. "We have long recognized that even regulations aimed at proper governmental concerns can restrict unduly the exercise of rights protected by the First Amendment." Simon & Schuster, 502 U.S. at 117 citing Minneapolis Star & Tribune Co. v. Minnesota Comm'r of Revenue, 460 U.S. 575, 592, 103 S.Ct. 1365, 75 L.Ed.2d 295 (1983).

Application of the structure/function rule without an innocent construction presumption makes the regulation unduly restrictive and burdensome in violation of the First Amendment. A regulation is not "narrowly tailored" where a substantial portion of the burden on speech does not serve to advance content-neutral goals. Simon & Schuster, 502 U.S. at 122 citing Ward v. Rock Against Racism, 491 U.S. 781, 105 L.Ed.2d 661, 109 S.Ct. 2746 (1989). If the purpose of the structure/function claim is to enable consumers to develop and maintain healthy dietary practices and be informed of data about the effect of a dietary ingredient or nutrient on a body structure or function, the restriction must directly advance that goal. Suppression and restriction of structure/function claims that imply disease treatment but also an effect on a structure or function unnecessarily burdens speech that could be allowed without any further restriction by the simple expedient of disclaimer, disclaiming the disease treatment connotation.

The Joint Commenters wish to make the following claims which FDA has previously deemed, in its January 6<sup>th</sup> Rule, impermissible, implied disease claims:

Claim 1. Saw Palmetto extract helps to maintain normal urine flow in men over 50 years old.

Claim 2. Calcium helps maintain normal bone density in post-menopausal women.

Claim 3. Alpha lipoic acid, chromium, and gymnea sylvestre help maintain a healthy blood sugar level.

Claim 4. Niacin, sitosterols, garlic, EPA/DHA fish oil, soy isoflavones, and soy proteins help promote normal cholesterol levels.

Claim 5. Niacin, sitosterols, garlic, EPA/DHA fish oil, soy isoflavones, and soy proteins help promote normal cholesterol metabolism and clearance.

Claim 6. Glucosamine, chondroitin sulfate, and MSM (methylsulfane methane) help relieve joint pain.

Claim 7. Potassium and magnesium [or in the alternative arginine, choline, and Vitamin B5] promote normal blood pressure.

FDA contends that Claim 1 implies that the product is a treatment for benign prostatic hyperplasia (BPH) – a benign condition that FDA considers a disease. To comply with the First Amendment, rather than prohibit the claim except upon approval of a new drug application or a health claim petition,<sup>3</sup> FDA ought to allow its use with a clarifying disclaimer (such as, “This product is not intended for use in the treatment of Benign Prostatic Hyperplasia”).

FDA contends that Claim 2 implies that the product is a treatment for osteoporosis. To comply with the First Amendment, rather than prohibit the claim except upon approval of a new drug application or a health claim petition, FDA ought to allow its use with a clarifying disclaimer (such as, “This product is not intended for use in the treatment of osteoporosis”).

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<sup>3</sup> FDA has stated that it will not accept a health claim petition for any claim of treatment of an existing disease. See Exhibit 12.

FDA contends that Claim 3 implies that the product is a treatment for diabetes. To comply with the First Amendment, rather than prohibit the claim except upon approval of a new drug application or a health claim petition, FDA ought to allow its use with a clarifying disclaimer (such as, "This product is not intended for use in the treatment of diabetes").

FDA contends that Claims 4 and 5 imply that the product is a treatment for hypercholesterolemia or cardiovascular disease. To comply with the First Amendment, rather than prohibit the claims except upon approval of a new drug application or a health claim petition, FDA ought to allow their use with a clarifying disclaimer (such as, "This product is not intended for use in the treatment of hypercholesterolemia or cardiovascular disease").

FDA contends that Claim 6 implies that the product is a treatment for arthritis. To comply with the First Amendment, rather than prohibit the claim except upon approval of a new drug application or a health claim petition, FDA ought to allow its use with a clarifying disclaimer (such as, "This product is not intended for use in the treatment of arthritis").

FDA contends that Claim 7 implies that the product is a treatment for hypertension or cardiovascular disease. To comply with the First Amendment, rather than prohibit the claim except upon approval of a new drug application or a health claim petition, FDA ought to allow its use with a clarifying disclaimer (such as, "This product is not intended for use in the treatment of high blood pressure or cardiovascular disease").

FDA also objects to use of citations that include in their titles reference to diseases on the theory that consumers will comprehend the citation to imply that the nutrient or dietary ingredient treats those diseases. To comply with the First Amendment, rather than prohibit the use of a full and accurate citation, the FDA should allow citation use along with a disclaimer that makes clear that the nutrient or dietary ingredient is not intended for use in the treatment of the

disease in question. For example, use of a citation such as “Houpt J.B. et al., Effect of glucosamine hydrochloride in the treatment of pain of osteoarthritis of the knee, J. Rheumatol. 26(11):2423-30 (Nov. 1999)” could be allowed with a disclaimer on the cite page which reads: “Product X is not intended for use in the treatment of osteoarthritis.” The Joint Commenters plan to use numerous scientific references in their labeling. For example “Rindone, J.P. et al. Randomized, controlled trial of glucosamine for treating osteoarthritis of the knee. West J. Med. 172 (2):91-4 (Feb. 2000);” “Delafuente J.E., Glucosamine in the treatment of osteoarthritis, Rheum. Dis. Clin. North Am. 25(1):1-11, vii (Feb. 2000);” and “McAlindon T.E., et al., Glucosamine and chondroitin for treatment of osteoarthritis: a systematic quality assessment and meta-analysis. JAMA 283(11):1469-75 (March 15 2000).” Each can be disclaimed with: “This product is not intended to treat osteoarthritis.” The Joint Commenters would accept any reasonable disclaimer but will not accept prohibition of communication of truthful scientific literature citations because that violates their First Amendment rights.

#### **B. A DISEASE DISCLAIMER IS A LESS RESTRICTIVE ALTERNATIVE**

Almost all structure/function claims and product names that arguably imply, but do not state, a disease claim can be clarified by an appropriate disclaimer, eliminating the risk that a reasonable consumer would interpret their intended utility to be for disease treatment. In fact, the current disclaimer, “This product is not intended to diagnose, treat, cure, or prevent any disease,” required by Congress to be used in conjunction with each structure/function claim already performs this role, thus revealing that Congress understood and accepted the disclaimer as a preferable alternative to claim restriction. Consistent with congressional intent, FDA must do the same.

Disclaimers are constitutionally preferable to commercial speech restriction. See Pearson, 164 F.3d at 657 citing Peel, 496 U.S. at 110; R.M.J., 455 U.S. at 206 n.20; Shapero, 486 U.S. 466 at 478, 100 L. Ed. 2d 475, 108 S. Ct. 1916. When government favors speech restriction in lieu of disclosure--at least where there is no showing that disclosure would not suffice to cure misleadingness--government disregards a "far less restrictive" means. Pearson, 164 F.3d at 658.

As stated by 21 C.F.R. 101.93(g), "in determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented." The context of a potentially misleading structure/function claim includes the required disease disclaimer that must accompany that claim: "This product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 343(r)(6)(C). The disease disclaimer specifically states that the product is not intended to have an effect on disease. FDA may require further clarification, as explained above, by requiring use of a more specific disease disclaimer. The constitutional limitation on agency disclaimers is that they be reasonable. See Pearson 164 F.3d at 658-659.

For example, "promotes normal blood pressure," "promotes normal cholesterol levels," and "helps to maintain normal urine flow in men over 50 years old" are all statements identified in the January 6<sup>th</sup> rule as implied disease claims. Blood pressure and cholesterol levels are measurements of the health status of the human body and, in and of themselves, are not diseases. When examined from an innocent construction presumption and in the context of the disease disclaimer they reasonably do not convey a disease treatment connotation. Nonetheless, FDA could require the addition of more specific disclaimers such as those mentioned above, or similar reasonable disclaimers, and indeed it must do so as a less restrictive alternative to claim restriction. The First Amendment compels resort to the less restrictive alternative.

Likewise, when the urine flow claim is examined from an innocent construction presumption (and in the context of the disease disclaimer) it is clear that a reasonable consumer would not presume that the claim implied that the product had an effect on a disease or disease condition. Nonetheless, FDA could require the addition of the disclaimer mentioned above or similar reasonable disclaimers (all of which, if reasonable, the Joint Commenters would accept) and must do so if its other course would be to restrict the claim. The First Amendment compels resort to the less restrictive alternative.

**C. FAILURE TO IMPLEMENT THE INNOCENT CONSTRUCTION PRESUMPTION AND TO RELY ON DISEASE DISCLAIMERS AS A LESS RESTRICTIVE ALTERNATIVE IMPOSES UNREASONABLE FINANCIAL BURDENS ON SPEECH**

When FDA states that a claim is not a permissible structure/function claim but may only be made following agency approval of a health claim petition or a new drug application, it is effectively informing the regulatee that its preferred speech cannot be made without (1) payment of considerable sums of money and (2) FDA acquiescence, that -- based on agency history -- is unlikely to occur and, even if it does, will undoubtedly take more than a year. "A statute is presumptively inconsistent with the First Amendment if it imposes a financial burden on speakers because of the content of their speech." Simon & Schuster, 502 U.S. at 115 citing Leathers v. Medlock, 499 U.S. 439, 437, 113 L.Ed.2d 494, 111 S.Ct. 1438 (1991). As in Simon & Schuster, without an innocent construction presumption the structure/function rule "plainly imposes a financial disincentive only on speech of a particular content." Id. at 116. Moreover, "the loss of First Amendment freedoms, for even minimal periods of time, unquestionable constitutes irreparable injury." Elrod v. Burns, 427 U.S. 347, 49 L.Ed.2d 547, 96 S.Ct. 2673 (1976)(citations omitted). Because of the risk of prosecution for misbranding and distribution

and sale of an unapproved drug (21 U.S.C. § 343; 355), speakers will be apt to refrain from speaking (perhaps indefinitely) rather than communicate a structure/function claim FDA argues implies disease treatment.

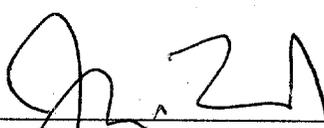
## CONCLUSION/RECOMMENDATION

For the foregoing reasons, the proposed guidance for application of the structure/function claim rule should provide that any structure/function claim that implies (but does not expressly state) disease treatment will be given an innocent construction by the agency and may be required to bear a reasonable agency drafted disclaimer to eliminate a disease treatment connotation. Likewise, the proposed guidance should provide that any citation or product or company name that may imply a disease treatment claim will be given an innocent construction by the agency and may be required to bear a reasonable, agency drafted disclaimer to eliminate any potential disease treatment connotation. Both such approaches must be used in lieu of claim restriction or citation limitation to avoid violation of the commercial speech doctrine as explained in the Pearson decisions and cases cited therein. See 164 F.3d 650 (“Pearson I”); Pearson v. Shalala, 130 F.Supp.2d 105 (D.D.C. 2001)(“Pearson II”); Pearson v. Thompson, No. 00-2724 (GK) (D.D.C. May 9, 2001) (“Pearson III”).

Respectfully submitted,

PURE ENCAPSULATIONS, INC.;  
WELLNESS LIFESTYLES INC. D/B/A AMERICAN LONGEVITY;  
DURK PEARSON and SANDY SHAW;  
AMERICAN PREVENTIVE MEDICAL ASSOCIATION;  
WEIDER NUTRITION INTERNATIONAL INC.;  
LIFE PRIORITY INC.;  
LIFE ENHANCEMENT PRODUCTS INC.;  
LIFE EXTENSION FOUNDATION BUYERS CLUB INC.; and  
LIFE SERVICES SUPPLEMENTS

By

  
Jonathan W. Emord  
Andrea G. Ferrenz  
Counsel for Joint Commenters

Dated: May 23, 2001

# **EXHIBIT 1**

MAY-21-01 03:57PM FROM-PURE ENCAPSULATIONS

978-443-9664

T-296 P.01/01 F-992

**Before the  
FOOD AND DRUG ADMINISTRATION  
Rockville, MD**

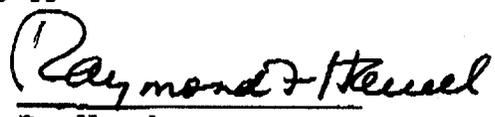
**In re: Guidance on Applying )  
The Structure/Function Rule; ) Docket No. 01D-0058  
Request for Comments )**

**AFFIDAVIT**

1, Ray Hamel, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am the Chief Executive Officer of Pure Encapsulations Inc. ("Pure").
2. Pure has been a party to four health claim petitions filed with the Food and Drug Administration (FDA).
3. The cost of legal and scientific fees associated with the preparation and prosecution of each of these petitions before the FDA has been approximately \$35,000 to \$75,000, depending on the complexity and quantity of scientific corroboration present.
4. In each case where FDA has evaluated the health claim petition in its entirety, the FDA has taken at least 540 days to complete its review and issue a decision.
5. Pure does not possess, nor am I aware of any dietary supplement company that possesses the financial wherewithal to pay between \$50 million and \$350 million to finance the costs associated with a new drug application.

Dated: May 21, 2001

  
Ray Hamel  
Pure Encapsulations Inc.

## **EXHIBIT 2**

05/21/2001 13:57 6195751493

GIC

PAGE 01

Sent By: EMORD & ASSOCIATES, P.C.;

2024668938;

May-21-01 4:18PM;

page 1 of 1

**Before the  
FOOD AND DRUG ADMINISTRATION  
Rockville, MD**

**In re: Guidance on Applying  
The Structure/Function Rule;  
Request for Comments**

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)  
)

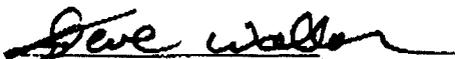
**Docket No. 01D-0058**

**AFFIDAVIT**

I, Steve Wallach, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am the Executive Director of American Longevity (the d/b/a of Wellness Lifestyles Inc.) ("AL").
2. AL has never filed a health claim petition with the Food and Drug Administration (FDA).
3. AL understands that the cost of legal and scientific fees associated with the preparation and prosecution of a health claim petition before the FDA is typically approximately \$35,000 to \$75,000, depending on the complexity and quantity of scientific corroboration present.
4. AL understands that typically when FDA evaluates a health claim petition in its entirety, the FDA takes at least 540 days to complete its review and issue a decision.
5. AL does not possess, nor am I aware of any dietary supplement company that possesses the financial wherewithal to pay between \$50 million and \$350 million to finance the costs associated with a new drug application.

Dated: 05-21-01

  
Steve Wallach  
American Longevity

# EXHIBIT 3

**Before the  
FOOD AND DRUG ADMINISTRATION  
Rockville, MD**

**In re: Guidance on Applying )  
The Structure/Function Rule; ) Docket No. 01D-0058  
Request for Comments )**

**AFFIDAVIT**

I, Durk Pearson, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I have been a party to four health claim petitions filed with the Food and Drug Administration (FDA).

2. The cost of legal and scientific fees associated with the preparation and prosecution of each of these petitions before the FDA has been approximately \$35,000 to \$75,000, depending on the complexity and quantity of scientific corroboration present.

3. In each case where FDA has evaluated the health claim petition in its entirety, the FDA has taken at least 540 days to complete its review and issue a decision.

4. I do not possess, nor am I aware of any dietary supplement company that possesses the financial wherewithal to pay between \$50 million and \$350 million to finance the costs associated with a new drug application.

Dated: 21 May 2001

  
Durk Pearson

# **EXHIBIT 4**

Sent By: HP LaserJet 3100;  
Sent By: EMORD & ASSOCIATES, P.C.;

7754825184;  
2024666938;

May-21-01 13:18;  
May-21-01 3:29PM;

Page 1/2  
Page 2/3

**Before the  
FOOD AND DRUG ADMINISTRATION  
Rockville, MD**

**In re: Guidance on Applying  
The Structure/Function Rule;  
Request for Comments**

)  
)  
)

**Docket No. 01D-0058**

**AFFIDAVIT**

I, Sandy Shaw, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I have been a party to four health claim petitions filed with the Food and Drug Administration (FDA).

2. The cost of legal and scientific fees associated with the preparation and prosecution of each of these petitions before the FDA has been approximately \$35,000 to \$75,000, depending on the complexity and quantity of scientific corroboration present.

3. In each case where FDA has evaluated the health claim petition in its entirety, the FDA has taken at least 540 days to complete its review and issue a decision.

4. I do not possess, nor am I aware of any dietary supplement company that possesses the financial wherewithal to pay between \$50 million and \$350 million to finance the costs associated with a new drug application.

Dated: 5-21-01

  
Sandy Shaw

# EXHIBIT 5



# **EXHIBIT 6**

MAY-22-2001 TUE 08:40 AM EXECUTIVE

FAX NO. 8019726532

P. 02

Before the  
**FOOD AND DRUG ADMINISTRATION**  
Rockville, MD

In re: Guidance on Applying )  
The Structure/Function Rule; ) Docket No. 01D-0058  
Request for Comments )

**AFFIDAVIT**

I, De Lois Shelton, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am the Director of Regulatory Affairs of Weider Nutrition Group, Inc. ("Weider").

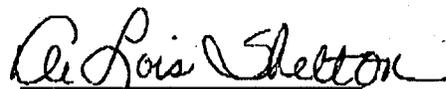
2. Weider has never filed a health claim petition with the Food and Drug Administration (FDA).

3. Weider understands that the cost of legal and scientific fees associated with the preparation and prosecution of a health claim petition before the FDA is typically approximately \$35,000 to \$75,000, depending on the complexity and quantity of scientific corroboration present.

4. Weider understands that when FDA evaluates a health claim petition in its entirety, the FDA typically has taken at least 540 days to complete its review and issue a decision.

5. Weider does not possess, nor am I aware of any dietary supplement company that possesses, the financial wherewithal to pay between \$50 million and \$350 million to finance the costs associated with a new drug application.

Dated: 5-22-01

  
De Lois Shelton  
Weider Nutrition Group, Inc.

# **EXHIBIT 7**

5-22-201 8:36PM

FROM LIFE PRIORITY 9134385444

P. 1

Sent By: EMORD & ASSOCIATES, P.C.;

2024666938;

May-22-01 8:00PM;

Page 2

**Before the  
FOOD AND DRUG ADMINISTRATION  
Rockville, MD**

**In re: Guidance on Applying  
The Structure/Function Rule;  
Request for Comments**

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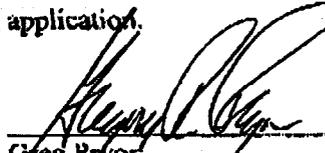
**Docket No. 01D-0058**

**AFFIDAVIT**

I, Greg Pryor, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am the President of Life Priority (LP).
2. LP has never filed a health claim petition with the Food and Drug Administration (FDA).
3. LP understands that the cost of legal and scientific fees associated with the preparation and prosecution of a health claim petition before the FDA is typically approximately \$35,000 to \$75,000, depending on the complexity and quantity of scientific corroboration present.
4. LP understands that typically when FDA evaluates a health claim petition in its entirety, the FDA takes at least 540 days to complete its review and issue a decision.
5. LP does not possess, nor am I aware of any dietary supplement company that possesses the financial wherewithal to pay between \$50 million and \$350 million to finance the costs associated with a new drug application.

Dated: 5/23/01

  
Greg Pryor  
Life Priority

# **EXHIBIT 8**

FROM :

PHONE NO. :

May. 22 2001 10:32AM P3

Before the  
FOOD AND DRUG ADMINISTRATION  
Rockville, MD

In re: Guidance on Applying )  
The Structure/Function Rule ) Docket No. 01D-0058  
Request for Comments )

AFFIDAVIT

I, Will Block, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information and belief;

1. I am the Chief Executive Officer of Life Enhancement Products (LEP),

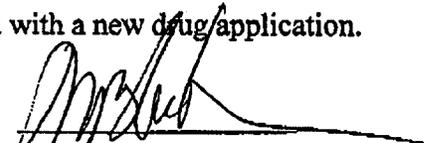
2. LEP has never filed a health claim petition with the Food and Drug Administration (FDA).

3 LEP understands that the cost of legal and scientific fees associated with the preparation and prosecution of a health claim petition before the FDA is typically approximately \$35,000 to \$75,000 depending on the complexity and quantity of scientific corroboration present.

4. LEP understands that typically when FDA evaluates a health claim petition in its entirety the FDA takes at least 540 days to complete its review and issue a decision.

5 LEP does not possess, nor am I aware of any dietary supplement company that possesses the financial wherewithal to pay between \$50 million and \$350 million to finance the costs associated with a new drug application.

Dated: May 22, 2001

  
Will Block  
Life Enhancement Products

# **EXHIBIT 9**

05/22/2001 15:34 4679762  
EMORD & ASSOCIATES, P.C.

2024666938; CUSTOMER SERVICE  
May-22-01 4:21PM;

PAGE 01  
Page 2/2

**Before the  
FOOD AND DRUG ADMINISTRATION  
Rockville, MD**

**In re: Guidance on Applying )  
The Structure/Function Rule; ) Docket No. 01D-0058  
Request for Comments )**

**AFFIDAVIT**

I, Ronald Keys, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am the Product Advisor Supervisor of Life Extension Foundation Buyers Club Inc. (LEFBC).

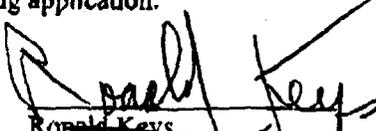
2. LEFBC has never filed a health claim petition with the Food and Drug Administration (FDA).

3. LEFBC understands that the cost of legal and scientific fees associated with the preparation and prosecution of a health claim petition before the FDA is typically approximately \$35,000 to \$75,000, depending on the complexity and quantity of scientific corroboration present.

4. LEFBC understands that typically when FDA evaluates a health claim petition in its entirety, the FDA takes at least 540 days to complete its review and issue a decision.

5. LEFBC does not possess, nor am I aware of any dietary supplement company that possesses the financial wherewithal to pay between \$50 million and \$350 million to finance the costs associated with a new drug application.

Dated: MAY 22, 2001

  
Ronald Keys  
Life Extension Foundation Buyers Club Inc.

# **EXHIBIT 10**

Before the  
FOOD AND DRUG ADMINISTRATION  
Rockville, MD

In re: Guidance on Applying )  
The Structure/Function Rule; ) Docket No. 01D-0058  
Request for Comments )

AFFIDAVIT

I, Dan Maiullo, declare under penalty of perjury that the following is true and correct to the best of my knowledge, information, and belief:

1. I am the Vice President of Life Services Supplements. ("LSS").
2. LSS has never filed a health claim petition with the Food and Drug Administration (FDA).
3. LSS understands that the typical cost of legal and scientific fees associated with the preparation and prosecution of health claim petitions before the FDA is approximately \$35,000 to \$75,000, depending on the complexity and quantity of scientific corroboration present.
4. LSS understands that the FDA typically takes at least 540 days to complete its review and issue a decision on a health claim petition.
5. LSS does not possess, nor am I aware of any dietary supplement company that possesses the financial wherewithal to pay between \$50 million and \$350 million to finance the costs associated with a new drug application.

Dated: 5-21-01

  
Dan Maiullo  
Life Services Supplements

# EXHIBIT 11

## ANALYSIS OF THE ECONOMIC IMPACT OF FDA PROHIBITION OF PROPOSED HEALTH CLAIMS

Paul H. Rubin  
Department of Economics and School of Law  
Emory University  
Atlanta, GA 30322-2240  
Voice: 404-727-6365  
Fax: 630-604-9609  
Email: prubin@Emory.edu  
<http://www.Emory.edu/COLLEGE/ECON/Rubi.htm>

This is an analysis of the economic impact of the FDA refusal to authorize one or more of the health claims pending before the agency, and instead to compel as a condition for approval an NDA or NDA-equivalent degree of proof for these claims.

The nutrients in question are: 1) Three B vitamins (folic acid, B6 and B12) considered together for reduction of vascular disease; 2) Vitamin E for reduction of heart disease; 3) Folic Acid for reducing neural tube defects; 4) Omega-3 Fatty Acids for reduction of coronary heart disease risk; 5) Antioxidants (Vitamins A, C, E, beta-carotene, lycopene and lutein) for reduction of cancer risk; and 6) Fiber for reduction of colorectal cancer. The proposed health claims (perhaps with appropriate disclaimers) are: 1) "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) "As part of a healthy diet low in saturated fats 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." 3) ".8 mg of folic acid in a dietary supplement is more effective at reducing neural tube defects than a lower amount in foods in common form;" 4) "Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease;" 5) "Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer;" and (6) "Consumption of fiber may reduce the risk of colorectal cancer."

In performing this analysis, I use the standard of maximization of consumer welfare, the general standard used by economists in evaluating public policy decisions.

## Professional Background

I am a Professor of Economics and Law at Emory University in Atlanta and editor in chief of *Managerial and Decision Economics*. I am an Adjunct Scholar at the American Enterprise Institute and the Georgia Public Policy Foundation; former Vice President of the Southern Economics Association; and a Fellow of the Public Choice Society. I have been Senior Staff Economist at the President's Council of Economic Advisers, Chief Economist at the U.S. Consumer Product Safety Commission, Director of Advertising Economics at the Federal Trade Commission, and vice-president of Glassman-Oliver Economic Consultants, Inc., a litigation consulting firm in Washington. I have taught economics at the University of Georgia, City University of New York, VPI, and George Washington University Law School. I have written or edited seven books, and published over one hundred articles and chapters on economics, law, and regulation, in journals including the *American Economic Review*, *Journal of Political Economy*, *Quarterly Journal of Economics*, *Journal of Legal Studies*, *Journal of Law and Economics*, and the *Yale Journal on Regulation*, and I sometimes contribute to the *Wall Street Journal* and other newspapers. My work has been cited in the professional literature over 1300 times. Recent books include *Managing Business Transactions*, Free Press, 1990 and *Tort Reform by Contract*, AEI, 1993. I have consulted widely on litigation and regulation related matters, and have addressed numerous business, government, professional, policy and academic audiences. I received my B.A. from the University of Cincinnati in 1963 and my Ph.D. from Purdue University in 1970.

I have written several professional journal articles on the regulation of information by the FDA. I wrote one of the first articles advocating direct-to-consumer advertising,<sup>2</sup> and the FDA cited this article in its decision to remove the moratorium on this form of advertising. I have also written articles advocating removal of the requirement for the "brief summary" on television advertising.<sup>3</sup> and this policy has also been adopted. I testified before the FDA on the beneficial effects of this policy, and the FDA has chosen to continue the policy.

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<sup>1</sup> There are also proposed labels for d- $\alpha$ -tocopherol and dl- $\alpha$ -tocopherol separately.

<sup>2</sup> Alison Masson and Paul H. Rubin, "Matching Prescription Drugs and Consumers: The Benefits of Direct Advertising," *New England Journal of Medicine*, Aug. 22, 1985, 513-5; also, "Reply," Feb. 20, 1986, 524.

## Investment in Pharmaceutical Research

The FDA has required a degree of proof to support health claim approval for supplements that is equivalent to the degree of proof required for approval of new pharmaceuticals:

A causal relationship exists when data show that the consumption of a substance increases or decreases the probability of developing or not developing a particular disease or health-related condition. Causality can be best established by interventional data, particularly from randomized, controlled clinical trials, that show that altering the intake of an appropriately identified and measured substance results in a change in a valid measure of a disease or health-related condition. In the absence of such data, a causal relationship may be inferred based on observational and mechanistic data through strength of association, consistency of association, independence of association, dose-response relationship, temporal relationship, effect of dechallenge, specificity, and explanation of a pathogenic mechanism or a protective effect against such a mechanism (biological plausibility). Although these features strengthen the claim that a substance contributes to a certain health outcome, they do not prove that eating more or less of the substance will produce a clinically meaningful outcome. In many cases (for example, if the intake of the substance has not been or cannot be assessed adequately in available observational studies because it has not been commonly consumed or its intake cannot be assessed independently of other substances), controlled clinical trials are necessary to establish the validity of a substance/disease relationship.<sup>4</sup>

This level of proof is essentially equivalent to the requirement of the new drug approval (NDA) process that pharmaceuticals must undergo for approval. Indeed, for two of the claims at issue, the FDA has made this explicit. For the claims involving three B vitamins (folic acid, B6 and B12) considered together for reduction of vascular disease the FDA has specifically indicated that "These findings strongly suggest that well designed and controlled clinical studies are necessary to establish whether folic acid, vitamin B6 and vitamin B12 may reduce the risk of vascular disease."<sup>5</sup> Similarly, for

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<sup>3</sup> Paul H. Rubin, "Economics of Prescription Drug Advertising," *Journal of Research in Pharmaceutical Economics*, 1991, 29-41.

<sup>4</sup> U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition Office of Special Nutritionals, December 22, 1999, Guidance for Industry Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements, available at <http://vm.cfsan.fda.gov/~dms/ssaguide.html>, p. 14-15, Online version.

<sup>5</sup> Letter of November 30, 1999, from Elizabeth A. Yetley, Director, Office of Special Nutritionals, Center for Food Safety and Applied Nutritionals, FDA, to Jonathan W. Emord, regarding Petition for Health Claim: Folic Acid, Vitamin B6, and Vitamin B12 Dietary Supplement and Vascular Disease, p. 11.

claims involving Vitamin E and heart disease, the FDA has indicated that "One reason for the insufficient evidence from the primary prevention studies is that none of the studies were designed to measure the association between Vitamin E and reduced risk of CVD."<sup>6</sup> Thus, it is apparent that the FDA now requires a level of proof for health claims equivalent to that required for pharmaceuticals.

However, the economics of the drug approval process and of the nutritional supplements industry, and the requirements of patent law, interact in such a way that no one will obtain such approval. Therefore, should the FDA require such a standard for approval, the result would be that the health claims would not be made. The basic point is this: Drug approval or its equivalent is quite expensive. Naturally occurring products such as those at issue here, which have been in use for a substantial period of time, cannot be patented. The supplement industry is highly competitive. Therefore, there is no way for any producer to earn a return on the investment that would be needed to obtain approval, and so no producer would spend the resources to obtain such an approval. Therefore, the effect of an FDA decision would not be to induce producers to undertake the research needed to obtain approval. It would merely be to deny consumers the valuable information that would be available if the health claims could be made. I now develop this analysis in detail.

#### Costs of Drug Approval

Costs of drug approval are quite high. DiMasi and his co-authors provide useful estimates of the costs of drug development.<sup>7</sup> Their analysis enables me to break down the costs in a way relevant for estimating the expected costs of obtaining approval for supplements, if someone would be willing to undertake such an investment. A major part of the cost of obtaining a new drug approval is the "preclinical" phase, or general research expenditures of pharmaceutical firms, which cannot be attributed to any one drug. In the DiMasi analysis, these costs represent over half of the total expenditures.<sup>8</sup> I

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<sup>6</sup> Letter of January 11, 2000, from Elizabeth A. Yetley, Director, Office of Special Nutritionals, Center for Food Safety and Applied Nutritionals, FDA, to Jonathan W. Emord, regarding Petition for Health Claim: Vitamin E dietary Supplements and Heart Disease, p. 7-8.

<sup>7</sup> Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, and Louis Lasagna, "Costs of Innovation in the Pharmaceutical Industry," *Journal of Health Economics*, 10 (1991), 107-142.

<sup>8</sup> This is because the preclinical expenditures occur very early in the development process, and the capitalization process adds a substantial amount to these costs.

assume that there are no preclinical costs attributable to these products, since the products and their properties are well known.

For new chemical entities (NCEs) that are ultimately approved, the mean clinical period costs (including Phases I, II, and III, and animal studies) is \$43 million, with a 95% confidence interval of \$43; the median is  $\$40.9 \pm \$11.3$  million (that is, from \$29.6 to \$52.2 million), all in 1987 dollars.<sup>9</sup> If we use the mean, \$43 million, then, in 1999 dollars, this is \$58 million. This is the best estimate of the expected cost of approval for a NCE that is ultimately approved.<sup>10</sup> This is the amount per substance that someone would have to be willing to invest to obtain approval. No one would undertake such an investment unless they expected to be able to recoup it. But there is no way in which a producer could expect such recoupment. This is because a) any firm obtaining approval for any of these supplements would be unable to obtain a useful patent; and b) the supplements industry is highly competitive and therefore recoupment of the needed investment would be impossible without a patent.

Many of the six supplements at issue here are aggregations of more than one entity. The B vitamins considered for reduction of vascular disease include folic acid, B6 and B12; the Antioxidants for reduction of cancer risk include Vitamins A, C, E, beta-carotene, lycopene and lutein; and the Fiber for reduction of colorectal cancer includes both soluble and non-soluble fiber. In its consideration of the petition regarding the B vitamins for reduction of vascular risk the FDA considered each vitamin separately.<sup>11</sup> I assume therefore that if someone were to seek approval through NDA-level studies, the FDA would require separate analysis for each component. Table 1 indicates the cost of seeking approval for each health claim. These costs range from \$58 million to \$348 million.

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<sup>9</sup> DiMasi et al., p. 130 and Table 7.

<sup>10</sup> The equivalent figure for marketed NCEs is \$75.2 million in 1987 dollars, or \$101.5 million in 1999 dollars. The difference is that this latter figure includes costs of both successful and unsuccessful drugs, with the costs of unsuccessful drugs allocated to successes. I use the lower number for all of the substances at issue. It is possible that some would not be approved, but since this would not be known, I assume that all would be approved. Alternatively, I could use the higher number and infer the probability that some would not be approved; the results would be the same.

<sup>11</sup> Letter of November 30, 1999, from Elizabeth A. Yetley, Director, Office of Special Nutritionals, Center for Food Safety and Applied Nutritionals, FDA, to Jonathan W. Emord, regarding Petition for Health Claim: Folic Acid, Vitamin B6, and Vitamin B12 Dietary Supplement and Vascular Disease.

**Table 1: Estimated Cost of Seeking NDA Level Approval for Each Health Claim**

Claim	Cost Of NDA-Level Approval (1999 Dollars)
Three B vitamins considered together for reduction of vascular disease: folic acid, Vitamin B6 and Vitamin B12	\$174 Million
Vitamin E for reduction of heart disease	\$58 Million
Folic Acid for reducing neural tube defects	\$58 Million
Omega-3 Fatty Acids for reduction of coronary heart disease risk	\$58 Million
Antioxidants for reduction of cancer risk: Vitamins A, C, E, beta-carotene, lycopene and lutein	\$348 Million
Fiber for reduction of colorectal cancer: Soluble and non-soluble fiber	\$116 Million

Source: Calculated by author from data in Joseph A. DiMasi, Ronald W. Hansen, Henry G. Grabowski, and Louis Lasagna, "Costs of Innovation in the Pharmaceutical Industry," *Journal of Health Economics*, 10 (1991), 107-142.

## Patentability<sup>12</sup>

As to patentability: First, a requirement for receiving a valid patent is that the product be "novel." None of the supplements at issue here are novel. All are readily available from numerous sources and have been available for many years. Obviously, a product that has been in use for decades cannot be novel. Additionally, patent laws distinguish between "discovery" and "invention," and only inventions are patentable.<sup>13</sup>

More specifically, "products of nature," are not patentable.<sup>14</sup> Thus, if anyone were to spend the resources needed to obtain approval for these supplements, they could not obtain patent protection. All of these supplements are natural products. The Three B vitamins (folic acid, B6 and B12) are found in many foods; Vitamin E is found in foods; Folic Acid is available in foods; Omega-3 Fatty Acids come from seafoods; Antioxidants are readily available in foods; and Fiber is available from wheat bran and other foods. Thus, all of these supplements are products of nature and not novel, and so are not patentable.

## Industry Competitiveness

If a manufacturer of supplements could have protection from competition from sources other than patent law, then the investment in obtaining approval of health claims could be worthwhile. However, there is no source of such protection. The supplements industry is highly competitive. I have a list of 40 companies in the industry and their annual sales for 1997.<sup>15</sup> I have calculated total sales for the 40 firms at \$4,511 billion. The largest firm has sales of \$425 million, about 9% of the total. The largest four firms account for only 30% of the total, a low number and one sign of a competitive industry. More specifically, economists commonly use the HHI index to measure the competitiveness of an industry.<sup>16</sup> I have calculated the HHI for the supplements industry

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<sup>12</sup> For a discussion of these issues, a useful source is Shayana Kadidal, "Plants, Poverty, and Pharmaceutical Patents," 103 *Yale Law Journal* 223, October 1993.

<sup>13</sup> Kadidal, at 238.

<sup>14</sup> Kadidal, at 237.

<sup>15</sup> The Hartman Group, 1998 Industry Overview, *Nutrition Business Journal*, September 1998, 18-19.

<sup>16</sup> This is the Herfindahl-Hirschman Index. It is used by the Federal Trade Commission and the Department of Justice Antitrust Division in evaluating mergers. As defined in the FTC-DOJ 1992 Merger Guidelines (<http://www.ftc.gov/bc/docs/horizmer.htm>), footnote 17: "For example, a market consisting of four firms with market shares of 30 percent, 30 percent, 20 percent and 20 percent has an HHI of 2600 ( $30^2 + 30^2 + 20^2 + 20^2 = 2600$ ). The HHI ranges from 10,000 (in the case of a pure monopoly) to a number approaching

as 445 (Table 2.) Additionally, a private firm called The Vitamin Shoppe lists in their catalog 280 suppliers whose products they carry.<sup>17</sup> Sales are not given, so I cannot use this data to modify the HHI index. However, addition of small firms would reduce the calculated index even further. This is a highly unconcentrated industry.<sup>18</sup> In other words, the supplements industry is competitive.

In a competitive industry, market forces will assure that price will generally be equal to marginal costs. A sunk cost such as the cost of obtaining approval for a NCE will not and cannot effect price. Thus, in this industry, there is no way that any producer who spent the \$58-\$348 million needed to obtain approval would be able to earn this money back. Any firm spending resources to obtain such approval would be forced to price its product at the same price as any firm that did not spend resources obtaining approval, and this price would not reflect the costs of obtaining approval. As a result, no rational firm would spend this money. Therefore, if these claims are not granted, then no research will be performed, and the health claims will not be made.

The assumption made by the FDA in the two letters to Jonathan Emord mentioned in notes 5 and 6 cited above is that if the petition is denied, then manufacturers will seek approval of these nutrients thorough an NDA equivalent process. But this will not occur, for reasons discussed above. Therefore, the effect of denying the petitions will be that fewer consumers will learn of the benefits of the products. Therefore, by denying the petition, the FDA is denying truthful information to the marketplace. If the manufacturers are not allowed to make the desired claims, then the result will be that some consumers will not learn of these benefits, and this will cause a net harm to consumers. This is not a socially desired outcome.

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zero (in the case of an atomistic market). Although it is desirable to include all firms in the calculation, of information about small firms is not critical because such firms do not affect the HHI significantly."

<sup>17</sup> August 2000 Catalog, available from The Vitamin Shoppe, 4700 Westside Ave., North Bergen, New Jersey, 07407, 800-223-1216.

<sup>18</sup> "The Agency divides the spectrum of market concentration as measured by the HHI into three regions that can be broadly characterized as unconcentrated (HHI below 1000), moderately concentrated (HHI between 1000 and 1800), and highly concentrated (HHI above 1800)." (Merger Guidelines.)

**Table 2: Calculation of HHI for Supplements Industry**

Sales, \$millions	Sales/Total sales (4511)	Percentage of Total (x100) Squared
\$425	.09	81
340	.08	64
325	.07	49
291	.06	36
281	.06	36
260	.06	36
219	.05	25
213	.05	25
170	.04	16
152	.03	9
120	.03	9
110	.02	4
109	.02	4
108	.02	4
100	.02	4
98	.02	4
90	.02	4
90	.02	4
88	.02	4
70	.02	4
70	.02	4
65	.01	1
55	.01	1
50	.01	1
50	.01	1
50	.01	1
49	.01	1
45	.01	1
43	.01	1
40	.01	1
40	.01	1
35	.01	1
35	.01	1
34	.01	1
34	.01	1
33	.01	1
32	.01	1
32	.01	1
30	.01	1
30	.01	1
\$4511 Total Sales		445 HHI

Source: Calculated from The Hartman Group, 1998 Industry Overview, *Nutrition Business Journal*, September 1998, 18-19.

## A Tax on Speech

Petitioners in this matter and other manufacturers of legitimate and legal food supplements desire to make true health claims for these products. There are many true claims that can be made about these supplements without having the supplements undergo an NDA or NDA-equivalent process. The FDA desires to allow only two levels of claims: either no claim at all, or a claim supported by NDA-level documentation. But there are many true statements that can be made with a lesser amount of proof. Manufacturers do not desire to make untruthful statements, or to claim a higher level of proof for their statements than is appropriate. Rather, they desire to make claims that are supported by the available evidence. For example, most of the claims at issue here include the word "may," so that these are hedged and nuanced claims. Moreover, manufacturers have expressed willingness to include further disclaimers if the FDA decides that these are needed. Indeed, the court in *Pearson v. Shalala* itself provided some suggestions for disclaimers.<sup>19</sup>

A requirement for an NDA-level of proof before allowing any claim at all is equivalent to imposing a tax of \$58-\$348 million on truthful speech. That is, the FDA's position is equivalent to requiring a large payment to allow a firm to exercise its free speech rights. Since no one will find it worthwhile to undertake this investment, as discussed above, the FDA's tax is a prohibitive tax, and will effectively tax some truthful speech out of the market. That is, the effect will be to suppress truthful speech.

Of course, this also means that consumers will be denied the right to hear truthful statements about these products. One result will be that consumers will simply have less true information about supplements. Another result may be that unscrupulous sellers may provide untrue or fraudulent information about some supplements or nutrients. If consumers desire health information about supplements but legitimate sellers are denied the right to provide such information, then a "black market" in untrue information may

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<sup>19</sup> *Durk Pearson And Sandy Shaw, American Preventive Medical Association and Citizens For Health, Appellants V. Donna E. Shalala, Secretary United States Department Of Health And Human Services, et al., Appellees, For the District of Columbia Circuit, Argued December 1, 1998, Decided January 15, 1999, No. 98-5043 Consolidated with 98-5084, Appeals from the United States District Court for the District Of Columbia (95cv01865).*

develop. As a result, consumers may ultimately use less healthful products. In either case, the result will be reduced health for consumers. Rather than improving the market for information, the FDA's actions have effectively shut down part of this market.

### Summary

The FDA in denying the several petitions has assumed that manufacturers will seek approval for these nutrients under an NDA-equivalent process. But the economics of the drug approval process and the supplement industry and the requirements of patent law interact in a way to ensure that no one will find it worthwhile to seek such approval. Rather, the result of denying the petitions is that consumers will simply be denied valuable and beneficial information about useful preventatives. The FDA has imposed a tax on truthful speech, and the level of the tax is sufficiently high so as to be prohibitive. The FDA has closed part of the market for true information, and this will result in reduced health for consumers.

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Ph.D., Economics, Purdue University, 1970  
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## PROFESSIONAL EXPERIENCE

### ACADEMIC

Professor of Economics and Law, Emory University, beginning 1999; Professor of Economics, 1991-1999; Acting Chair, Economics, 1993-94.  
Adjunct Professor: VPI, 1984; George Washington University Law Center, 1985-89.  
Professor, Baruch College and the Graduate Center, CUNY, 1982-83.  
Assistant, Associate and Full Professor of Economics, University of Georgia, 1968-82.

### NONACADEMIC

Vice President, Glassman-Oliver Economic Consultants, 1987-1991.  
Chief Economist, U.S. Consumer Product Safety Commission 1985-87 (Senior Executive Service).  
Director of Advertising Economics, Federal Trade Commission, 1983-85.  
Senior Staff Economist, President's Council of Economic Advisers, 1981-82.

### ADDITIONAL PROFESSIONAL AFFILIATIONS

Adjunct Scholar: American Enterprise Institute; Georgia Public Policy Foundation; Cato Institute, 1992-1998.  
Editor In Chief: *Managerial and Decision Economics*.

## RESEARCH AND TEACHING AREAS

Law and Economics (Economics Departments, Law Schools, and Practicing Attorneys); Industrial Organization and Antitrust; Transactions Cost Economics; Government and Business (Economics and MBA Students); Public Choice; Economics of Advertising and Safety; Regulation and Cost-Benefit Analysis; Price Theory; Law in Post-Communist Economies; Biological Evolution and Economics.

## PROFESSIONAL RECOGNITION

Over 1300 citations to published work in *Social Science Citation Index*; about 60-75 per year.

“Why Is the Common Law Efficient?” *Journal of Legal Studies*, 1977, over 250 citations;  
Reprinted seven times, in English, Spanish and French.

“Self Interest, Ideology and Logrolling in Congressional Voting,” *Journal of Law and Economics*, 1979, with James Kau, over 160 citations; Reprinted once.

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Fellow, Public Choice Society

Member, Institute of Justice task force on “Consumer Freedom”

Asked to write entries for *Encyclopedia of Law and Economics* and for *New Palgrave Dictionary of Economics and the Law*.

Senior lecturer, World Bank Conference on Private Sector Development, Trest, Czech Republic, November 1994.

First Vice-President, Southern Economics Association, 1994-1996

Vice-President, Georgia Chapter, National Association of Scholars, 1994-2000.

Chairman's Award, Consumer Product Safety Commission, 1987.

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Several course adoptions; selected by the Executive Book Club.

Guest editor, special issue of *Managerial and Decision Economics*, March 1993,  
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8. "Growing a Post-Communist Legal System," in Terry Anderson and P. J. Hill, editors, *The Privatization Process: A Worldwide Perspective*, Rowman & Littlefield, 1996, 57-81.
9. "Pricing, Entry, Service Quality, and Innovation Under A Commercialized Postal Service: A Comment," in Gregory Sidak, editor, *Governing the Postal Service*, AEI Press, 1994.
10. "FDA Advertising Restrictions: Ignorance is Death," in Robert Higgs, editor *Hazardous to Our Health? FDA Regulation of Health Care Products*, Independent Institute, 1995.
11. "Economic Analysis of Deception Standards," Introduction to *Advertising Law Anthology*, July-December, 1994, xv-xxv.
12. "Increasing Liability, Increasing Risk," in Patrick B. McGuigan, editor, *Law, Economics and Civil Justice: A Reform Agenda for the '90s*, Free Congress Foundation, Washington, 1994, 39-47.

13. "Costs and Benefits of the MFJ," Introduction to *Deregulating Telecommunications: The Baby Bells Case for Competition*, Wiley, 1995, with Richard Higgins.
14. "Courts and the Tort-Contract Boundary in Product Liability," in Frank Buckley, editor, *The Fall and Rise of Freedom of Contract*, Duke University Press, 1999, 119-139.
15. "Ideology" in William F. Shughart II and Laura Razzolini, editors, *Elgar Companion to Public Choice*, Edward Elgar, in press.
16. "Ignorance is Death: The FDA's Advertising Restrictions," in Roger D. Feldman, Editor, *American Health Care: Government, Market Processes, and the Public Interest*, The Independent Institute and Transaction Publishers, 2000, 285-311.

### REPRINTED ARTICLES

"Why Is the Common Law Efficient?," in:

1. Jules Coleman and Jeffrey Lange, editors, *The International Library of Essays in Law and Legal Theory: Law and Economics*, 1992.
2. Maxwell Stearns, editor, *Public Choice and Public Law: Readings and Commentary*, Anderson Publishing Co., 1997.
3. Kenneth Dau-Schmidt and Thomas Ulen, editors, *Law and Economics Anthology*, Anderson Publishing Co., 1998.
4. Richard Posner and Francesco Parisi, editors, *The International Library of Critical Writings in Economics, Law and Economics*, Edward Elgar, 1997.
5. Michael Arnheim, editor, *The International Library of Essays in Law and Legal Theory: The Common Law*, Dartmouth Publishing Co., 1994.
6. Andres Roemer and Hugo Garduno, Editors, *Law and Economics: A Literature Survey (Derecho y Economía: una revisión de la literatura)*, Fondo de Cultura Económica, Mexico, 2000, in press.
7. Louis Vogel, *Law and Economics (in French)*, in press.

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9. Alper and Hellman, editors, *The Economics of Crime: A Reader*, Simon and Schuster, 1988.
10. "A Paradox Regarding the Use of Time," in J. King, editor, *Readings in Labor Economics*, Oxford University Press, 1980.
11. "The Impact of Labor Unions on the Passage of Economic Legislation," with J. Kau, in J. Baderschneider, editor, *The Collective Bargaining Process*, BPI, 1982.
12. "A Socioeconomic Model of National Olympic Performance," in J. Loy, et al., editors, *Sport, Culture, and Society: A Reader on the Sociology of Sport*, Lea and Febinger, Philadelphia, with R. Grimes and W. Kelly, 1982.
13. "Matching Prescription Drugs and Consumers" with Alison Masson, in *Chemical Dependency*, Greenhaven Press, 1989.
14. "The Economics of Civil RICO," with Robert Zwirb, in *Corporate Practice Commentator*, Spring, 1988.

15. "Consequences of Damage Awards for Hedonic and Other Nonpecuniary Losses," in John O. Ward, editor, *A Hedonic Primer for Economists and Attorneys*, Lawyers and Judges Publishing Co., 1992; second edition, Thomas R. Ireland and John O. Ward, editors, 1996; with John Calfee.
16. "Self Interest, Ideology and Logrolling in Congressional Voting," in Charles Rowley, editor, *Library of Critical Writings in Economics: Public Choice Theory*, Edward Elgar Publishing Co., 1992, with James Kau.
17. "Are Pharmaceutical Ads Deceptive?" in *Advertising Law Anthology*, July-December, 1994.
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19. "Economics of Prescription Drug Advertising," in Mickey Smith, editor, *Studies in Pharmaceutical Economics*, Haworth Press, 1996, 405-413.
20. "Promises, Promises: Contracts in Russia and Other Post-Communist Economies," in Charles Rowley, editor, *Classical Liberalism and Civil Society*, Edward Elgar and the Locke Institute, 1998.
21. "The Theory of the Firm and the Structure of the Franchise Contract," in Martin Carter, Mark Casson and Vivek Suneja, editors, *The Economics of Marketing*, Edward Elgar, 1998.
22. "Common Law and Statute Law," in Andres Roemer and Hugo Garduno, Editors *Law and Economics: A Literature Survey (Derecho y Economía: una revisión de la literatura)*, Fondo de Cultura Económica, Mexico, 2000, in press.

## REVIEWS, ENCYCLOPEDIA ENTRIES, OP-ED AND MAGAZINE ARTICLES, TRIBUTES, MISCELLANEOUS PUBLICATIONS

### Book Reviews

1. Richard Nelson and Sidney Winter, *An Evolutionary Theory of Economic Change*, in *Journal of Political Economy*, August 1983.
2. William Shughart, *Antitrust Policy and Interest Group Politics*, in *Regulation*, Winter, 1991.
3. Richard McKenzie and Dwight Lee, *Quicksilver Capital*, in *Regulation*, Summer, 1991.
4. Kip Viscusi, *Reforming Products Liability*, in *Cato Journal*, Fall, 1991.
5. Gerald W. Scully, *Constitutional Environments and Economic Growth*, in *Cato Journal*, Fall, 1992.
6. Nicholas Mercuro, Editor, *Taking Property and Just Compensation: Law and Economics Perspectives on the Takings Issue* in *Public Choice*, 1994.
7. Donald Drake and Marian Uhlman, *Making Medicine, Making Money* in *The Journal of Research in Pharmaceutical Economics*, 1995, 103-107 and in *Journal of Pharmaceutical Marketing and Management*, 1995, 47-49.
8. Melvin J. Hinich and Michael C. Munger, *Ideology and the Theory of Political Choice* in *Public Choice*, October 1995, 195-198.
9. Keith T. Poole and Howard Rosenthal: *Congress: A Political-Economic History of Roll Call Voting*, in *Public Choice*, Vol. 100, No. 1-2, July 1999, 135-137.
10. Elliott Sober and David Sloan Wilson, *Unto Others: The Evolution and Psychology of Unselfish Behavior*, in *Journal of Bioeconomics*, Vol. 1, No. 1, 1999, 115-117.

### Encyclopedia Entries:

1. Legal Reform in Eastern Europe, *New Palgrave Dictionary of Economics and the Law*, Peter Newman, Editor, Macmillan, 1998, Vol. 2, 549-559.
2. "Judge Made Law", *Encyclopedia of Law and Economics* edited by Boudewijn Bouckaert and Gerrit de Geest, Edward Elgar, 2000, Vol. V, *The Economics of Crime and Litigation*, 543-558.
3. "Information Regulation, (Including Regulation of Advertising)," *Encyclopedia of Law and Economics*, edited by Boudewijn Bouckaert and Gerrit de Geest, Edward Elgar, 2000, Vol. III, *The Regulation of Contracts*, 271-295.

### Op-Ed Articles

1. "The Dangers of Overstating Safety Risks," *Wall Street Journal*, Oct. 8, 1987, p. 30.
2. "The Lawyer-Economist Battle," *Legal Times*, November 9, 1987.
3. "Punishments Must Fit the 'Crime,'" *New York Times*, Sunday January 31, 1988, Financial Section.
4. "The Pitfalls of Hedonic Value Use," *National Law Journal*, Jan. 16, 1989, 15-16.
5. "The Next American Tort Crisis," *Wall Street Journal*, December 28, 1989, p. A8.
6. "Sudafed's the Last Thing to Be Afraid Of," *Wall Street Journal*, March 13, 1991, p. A14. Reprinted in *Consumers Research*, May, and *Michigan Food News*, 1991.
7. "Curbing Consumer Drug Information?" *Washington Times*, Sun., Feb. 16, 1992, B4.
8. "New Study on Drug Ads Misleads," *Wall Street Journal*, June 4, 1992, p. A8.
9. "FDA's Advertising Regs Cost Lives," *Investor's Business Daily*, October 20, 1995.
10. "The High Cost of Lawsuits," *Investor's Business Daily*, March 1, 1996.
11. "Costs of the Tort System," Notable and Quotable, *Wall Street Journal*, April 17, 1996, p. A20.

### Magazine Articles

1. "Plugs for Drugs," *Regulation*, Sept. 1986, 37-43, 53, with Alison Masson; reprinted in *Journal of Pharmaceutical Marketing and Management*, Winter, 1986, 29-43.
2. "Cost-Benefit Analysis and Voluntary Standards," *Standardization News*, June 1987.
3. Editorial, *RICO Law Reporter*, December 1987, with Robert Zwirb.
4. "Risky Products, Risky Stocks," *Regulation*, 1988, No. 1, 35-39, with Gregg Jarrell and R. Dennis Murphy.
5. "What the FDA Doesn't Want You to Know," *American Enterprise*, May 1991.
6. "Managing Transactions to Enhance Corporate Performance," *National Productivity Review*, Fall, 1991, pp. 519-531.
7. "Why Regulate Consumer Product Safety?" *Regulation*, 1991, 58-63.
8. "Tort Reform by Contract," *The American Enterprise*, January 1993.
9. "Price Controls for Drugs," *Journal of the Medical Association of Georgia*, March 1995.
10. "Fundamental Reform of Tort Law," *Regulation*, 1995, Number 4, 26-33.
11. "Treatment Decisions: Tort or Contract," *Regulation*, No. 1, 1999, 25-30.
12. "The 1<sup>st</sup> Nuisance," *Regulation*, No. 1, 1999, 3.

### Personal Tributes

1. "Ellen Rausen Jordan: Friend, Teacher, Co-Author", *U.C. Davis Law Review*, Spring, 1997, 621-622.
2. "Henry Manne, Network Entrepreneur," *Case Western Reserve Law Review*, Winter, 1999, 333-340.
3. "In Memoriam: Peter H. Aranson, 1943-1999," *Public Choice*, forthcoming.

### Miscellaneous Publications

1. "Law and Economics," Manhattan Institute, *Economic Policy*, New York, 1984.
2. Testimony, *All Terrain Vehicles*, U.S. House of Representatives, 1988, pp. 214-225.
3. Letter, "Advertising of Prescription Drugs," *New England Journal of Medicine* 319, 5 (August 4, 1988), p.314.
4. "Regulatory Relief or Power Grab: Should Congress Expand the FDA's Enforcement Authority?" Heritage Foundation *Backgrounder*, 1992.
5. "Medical Malpractice and Consumer Choice: How Do the Plans Measure Up?", Citizens for a Sound Economy, *Issues and Answers*, May 10, 1994.
6. Letter, "Pharmaceutical Promotion and Physician Requests to Hospital Formularies," *Journal of the American Medical Association*, Aug. 3, 1994, p. 355.
7. "Direct-to-Consumer Promotion," Progress and Freedom Foundation, *Future Insight*, 1995.
8. Letter, *Commentary*, May 1994.
9. Letter, *Commentary*, September 1996, comment on "Denying Darwin," p. 14-15.

## OTHER PROFESSIONAL ACTIVITIES

### PARTICIPATION IN PROFESSIONAL MEETINGS

American Association of Law Schools, 1985.

American Economics Association/Allied Social Science Associations, 1979, 1980, 1981, 1984, 1993, 1994, 1995, 1996, 1997, 1998, 1999.

American Law and Economics Association, 1993, 1994, 1995, 1996, 1997, 1998, 1999.

Association for Politics and the Life Sciences, 1999.

Canadian Law and Economics Association, 1999.

Econometric Society, 1970, 1971, 1974, 1975, 1977, 1978; European Meetings, 1978.

European Law and Economics Association, 1993, 2000.

International Society for Human Ethology, 2000.

International Society for New Institutional Economics, 1998.

Public Choice Society, 1977, 1978, 1979, 1980, 1981, 1983, 1985, 1989, 1992, 1993, 1994, 1996, 1998, 1999.

Society for Evolutionary Analysis in Law, 2000.

Southern Economic Association, 1971, 1976, 1977, 1978, 1979, 1980, 1981, 1984, 1985, 1987, 1991, 1993, 1994, 1995, 1996, 1997, 1998.

Southern Political Science Association, Invited Panel, 1998.

Western Economic Association, 1974, 1975, 1984, 1985, 1988, 1996, 1997.

### CONFERENCE ORGANIZED

"Economics of Consumer Protection," Georgetown University, Continuing Legal Education, 1985.

### INVITED PRESENTATIONS AND CONFERENCES

#### Presentations at Universities

Arizona State University, 2000; Auburn University, 1978, 1996; Berkeley, 1984; Boston University, 1984; Carnegie-Mellon, 1982; Case-Western Reserve University, 1986; CIRANO (Montreal), 1996; Clemson University, 1993; Columbia University, 1998; Cornell University, 1998; Duke University, 1981; Emory University, 1981; Florida State University, 1998; George Mason University, 1983, 1985, 1989, 1990, 1992, 1993, 1994, 1995, 1997, 1998; Harvard University, 1993, 1995; Hoover Institution, 1983; Lund University (Sweden), 1992; Montana State University, 1998; McMaster University, 1983; New York University, 1998; Northwestern University, 2000; Purdue University, 1991; Stanford University, 1995; Texas A & M, 1985; University of Chicago, 1978, 1979; University of Florida, 1989; University of Georgia, 1996; University of Kansas, 1995; University of Miami, 1979; University of Michigan, 1987; University of Pennsylvania, 1993; University of Toronto, 1984, 1995; Virginia Polytechnic Institute, 1983; Washington University, 1991, 1993; Western Ontario, 1984; York University, 1984.

### **Non-Academic Presentations**

Federal Trade Commission, 1983; Cato Institute, 1985, 1990, 1991; U.S. Department of Justice, Antitrust Division, 1986, 1988, 1995; National Association of Business Economists, 1988; Brookings Institution, 1986; American Medical Writers-Pharmaceutical Advertising Association, 1986; National Library of Medicine, 1986; American National Standards Institute, 1986; Jefferson Society, 1986; Drug Information Association, 1991; U.S. Commodities Futures Trading Commission, 1991, Distinguished Speaker, 1992; U.S. Chamber of Commerce, Washington, 1991; Milken Institute, 1992; Food and Drug Law Institute, 1992; Institute for International Research, 1992; Heritage Foundation, 1992; American Enterprise Institute, 1992, 1993, 1994, 1995; Coalition of Healthcare Communicators, 1992; Independent Institute, 1993, 1994; Political Economy Research Center, 1994; Ad-Hoc Committee on Pharmaceutical Economics, 1997; Employer's Managed Health Care Association, 1999; Mercatus Center (Capitol Hill), 2000.

### **Invited Conference Attendance**

Economics of Regulated Utilities, University of Chicago, 1975; Legal Institute for Economists, University of Miami, 1977; Private Alternatives to the Judicial System, University of Miami, 1978; Toward Liberty, VPI, 1978; Evolutionary Theory in Law and Economics, University of Miami, 1980; Guest, Nutter Memorial Lecture, Hoover Institution, 1981; Regulatory Authorities, Corporate Privacy, and the Corporate Attorney, Emory University, 1981; Carnegie Conference on Political Economy, Pittsburgh, 1982, 1983, 1984; Constitutional Economics, Heritage Foundation, 1982; Perspectives on Entrepreneurship, Political Economy Research Center, Denver, 1984; Critical Issues in Tort Law Reform, Yale, 1984; Valuing Health Risks, National Academy of Sciences, 1987; The Calculus of Consent After 20 Years, Santa Cruz, 1988; Political Economy Forum, Political Economy Research Center, Bozeman, Montana, 1990, 1998; Malpractice Reform, American Enterprise Institute, 1992; Health Care Policy and Regulation Workshop, Rutgers, 1994; Franchising, University of Michigan, 1994; Workshop on the Evolution of Utilities and Utility Functions, University College, London, 1997; Evolution and Legal Theory, Georgetown University, 1999.

**OUTSIDE PROMOTION AND TENURE REVIEWS:** Baruch College, CUNY; Brigham Young; Cornell; George Mason; George Washington; Florida State; Pennsylvania State University at Erie; University of Alabama; University of Kansas; University of Southern California; University of Minnesota; Vanderbilt.

### **DOCTORAL COMMITTEES CHAIRED:**

Susan Griffin, Emory, 1994, (Center for Disease Control); Todd Merolla, Emory, 1995; Kristine Principe, Emory, 1996; Raymond Atkins, Emory, 1998 (J.D., George Mason; Covington and Burling); John Yun, Emory, 1999 (Federal Trade Commission); Kari Jones, Emory, 1999 (University of Georgia); David Prince, 2000 (J.D., University of Michigan; Simpson, Thacher and Bartlett).

## **EDITORIAL**

### **Editor-in-Chief**

*Managerial and Decision Economics*, since 1994; editor, Special issue, "Transactions Costs and Management," 1993.

### **Editorial Boards**

*Public Choice; Regulation; Journal of Bioeconomics; Journal of Research in Pharmaceutical Economics; Journal of Real Estate Finance and Economics.*

### **Referee**

National Science Foundation; Research Council of Canada; *American Economic Review; American Journal of Political Science; American Law and Economics Review; American Political Science Review; Annals of Regional Science; Cato Journal; Contemporary Policy Issues; Eastern Economic Journal; Economic Inquiry; Economic Journal; Economics of Governance; Emory University Law Review; European Journal of Law and Economics; International Regional Science Review; International Review of Law and Economics; Journal of Corporate Finance; Journal of Economic Behavior and Organization; Journal of Economics and Business; Journal of Economics and Finance; Journal of Labor Research; Journal of Law and Economics; Journal of Law, Economics, and Organization; Journal of Legal Studies; Journal of Marketing; Journal of Political Economy; Journal of Public Economics; Journal of Real Estate Finance and Economics; Journal of Social and Biological Structures; Journal of the American Real Estate and Urban Economics Association; Managerial and Decision Economics; National Tax Journal; Politics and the Life Sciences; Public Choice; Public Finance Quarterly; Quarterly Journal of Economics; Review of Regional Studies; Social Science Quarterly; Southern Economic Journal; Marketing and Public Policy Conference, 1995.*

## CONSULTING

### ANTITRUST, INCLUDING MERGERS AND ACQUISITIONS

Appelton Papers; ARCO; Barclays Bank and Visa; Broadcast Music Inc.; Browning-Ferris Industries; Campbells; Coca-Cola Bottling Company of the Southwest; College Football Association; Columbian Chemical Company; Dresser Industries; First Hawaiian; Georgia-Pacific; General Motors; Juki; Kodak and Fuqua; Levi Strauss; McKesson; National Soft Drink Association; Nederlander; *Newsday*; *Olivetti*; Professional Golfers Association; Real estate industry, market definition; Regional Bell Operating Companies; Roppe; Sara Lee; Scripps; SmithKline-Beckman; Southern Natural Gas; Thomson; United Airlines; West Point Pepperell.

### OTHER MATTERS

Alamo Car Rental; Cemex; Ciba-Geigy; Dial Corp; Drug Emporium; Emerson Electric; for Hernando de Soto, on property rights in the informal sector of the Peruvian economy, cited in *The Other Path*; Ford Motor Company; National Propane Gas Association; Pfizer; Physicians Weight Loss; R.J. Reynolds, on advertising matters; Hedonic damages, several cases; U.S. Sentencing Commission; Texans Against Censorship, Inc.

### TESTIMONY

In the U. S. District Court, Eastern District of Texas, on lawyer advertising, for Texans Against Censorship, Inc., 1995.

For defendants in tort liability litigation, criticizing use of "hedonic" damages.

Congressional Committee, pro bono testimony, on recall of All Terrain Vehicles, 1988.

For the New York Power Authority, before the Nuclear Regulatory Commission on costs and benefits of the Indian Point Nuclear Reactor, 1983.

For the Pharmaceutical Manufacturers Association, before the Health Committee of the Georgia Senate, on bills to regulate pharmaceutical prices, 1994; 1995.

Before the Food and Drug Administration, on direct-to-consumer promotion of pharmaceuticals, sponsored by the Progress and Freedom Foundation, 1995.

For the State on New Mexico, regarding taxation of franchising, in an administrative proceeding.

## AFFIDAVITS FILED

Airline Antitrust Litigation, regarding the value of the settlement; cited favorably and found "credible" in *Order* of Marvin H. Shoob, Senior U.S. District Court Judge, 1992  
Motion of Bell Atlantic, Bellsouth, NYNEX and Southwestern Bell to vacate the Modified Final Judgment in the AT&T Case, 1994.

For Hoechst Celanese Corporation, in the class action regarding polybutylene plumbing, in Chancery Court for Obion County, Tennessee, regarding the fairness of the \$950 million settlement.

Willmann et al. v. GTE, U.S. District Court, Southern District of Illinois, class action regarding "Inside Wire", on the fairness of the settlement; cited favorable and found "credible" by the Court.

Folkerts et al. v. Illinois Bell Telephone Company and Todt et al. v. Ameritech, class action suits regarding "inside wire", on the fairness of the settlements. (There are no decision as yet in these matters; I had previously worked on liability and damage issues for plaintiffs.)

Eller Media v. City of Milwaukee, for Eller Media on the effects of advertising on smoking in First Amendment suit regarding City of Milwaukee ordinance restricting tobacco advertising on billboards. Settled.

Julian M. Whitaker, M.D. v. Donna E. Shalala, Secretary, regarding first amendment issues in the labeling of Saw Palmetto, a dietary supplement, June 8, 2000

# EXHIBIT 12



DEPARTMENT OF HEALTH & HUMAN SERVICES

7777  
Saw Palm  
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, *Serenoa 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