UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JULIAN M. WHITAKER, M.D., et al.,	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Case No. 1:99CV03247 (GK)**
	)	
DONNA E. SHALALA, et al.,	)	
Defendants.	)	

PLAINTIFFS' MEMORANDUM OF POINTS AND AUTHORITIES

Plaintiffs Julian M. Whitaker, M.D.; Pure Encapsulations, Inc.; Durk Pearson and Sandy Shaw; and the American Preventive Medical Association (APMA) submit this memorandum in support of their Motion for Summary Judgment. They seek an order from this Court declaring FDA's refusal to process the Plaintiffs' dietary supplement health claim petition under 21 U.S.C. § 343(r)(5)(D), and refusal to implement the constitutional mandate of *Pearson v. Shalala*, 164 F.3d 650 *reh'g denied en banc*, 172 F.3d 72 (D.C. Cir. 1999), in evaluation of that claim, a violation of Section 403(r)(1)(B) of the Federal Food, Drug and Cosmetic Act (Act); of the Administrative Procedure Act (APA), 5 U.S.C. § 706 (2) (A-D); of the First Amendment to the United States Constitution; and of the canons of statutory construction and the Supremacy Clause of the Constitution. They also seek an injunction barring FDA from enforcing its Order of May 26, 2000 and an order that FDA process the Plaintiffs' health claim petition under 21 U.S.C. § 343(r)(5)(D). A draft order is attached. See Exh.1.[1]

I. SUMMARY

[1] The parties have stipulated to a single set of record exhibits in three volumes (listed herein as I, II, and III) filed with the Court in this proceeding. The parties have also agreed that they may use additional documents as exhibits appended to their memoranda in support of their respective cross motions. In this memorandum reference to "RE" refers to the record exhibits previously filed with the Court and reference to "Exh" refers to the exhibits appended to this memorandum.

Over the last sixty years the peer-reviewed scientific journals have amassed tens of thousands of articles on the actual and potential health benefits of foods and dietary supplements. That information is vital to consumers who seek to distinguish nutritional products in the marketplace and separate false claims from true ones. Since 1990, with rare exception, the FDA has forbade the public from receiving at the point of sale truthful and nonmisleading nutrient-disease information (see Exh. 2 at 23) and has tried to reclassify dietary supplements as drugs (see Exh. 2 at 22-26). It has done so in violation of the First Amendment, the Act, and the intent of Congress. See Exh. 2 at 14-17; 21-26.

As explained below, the Senate Committee on Labor and Human Resources held hearings on FDA's actions in 1994 and found them to reveal a pattern of "bias" against dietary supplements and against health claims, a bias that had hindered, rather than fostered, dissemination of nutrient-disease information against the will of Congress. See Exh. 2 at 23. The Committee found evidence that FDA had engaged in a persistent effort to reclassify dietary supplements as drugs. Exh. 2 at 22-26. The Committee concluded that "FDA has attempted to twist the statute in . . . a result-oriented effort to impede the manufacture and sale of dietary supplements" and that FDA's "actions discredit the agency and bring the law into disrepute, and has led to harassment and hardship for companies forced to defend themselves against this inappropriate regulatory strategy." Exh. 2 at 22.

The subject of this case, the agency's decision to disallow review of a Saw Palmetto extract health claim under the statutory provisions for health claims and to treat the underlying product instead as a drug subject to the Act's drug authorization provisions is but the latest example of FDA's "twist[ing of] the statute" to achieve a reclassification of dietary supplements as drugs.

Truth be told, this agency is engaged in an anti-competitive enterprise, protecting its drug approval process from competition that arises naturally when the health claim provisions of the Act are effectuated. It has admitted as much. See RE II at 730; 65 Fed Reg. 1000, 1040 (Jan. 6, 2000). Without question, approval of a nutrient-disease relationship claim (whether to prevent, cure, treat or mitigate disease) involves a relationship that was, until NLEA, possible only for a drug. Congress understood this and created a "safe harbor" from drug status to allow dietary supplements to carry nutrient-disease claims without becoming drugs.[2] But the statutory "safe harbor" from drug status FDA views as anathema to its control over drug approval and labeling content—a by-product of its historic, monopoly rent-content control *quid pro quo* struck with the pharmaceutical industry at the outset of drug regulation in America. It therefore refuses to effectuate the health claims provision and, on this point, has become a law unto itself, accountable neither to Congress nor to the courts.

It is, of course, this agency's legal duty to implement the Act fully and faithfully. Congress has statutorily required the approval standard for dietary supplement health claims be less rigorous than that for drugs. Exh. 2 at 24. It did so recognizing that while synthetic or xenobiotic substances, routinely approved as drugs, often carry potentially serious adverse effects that require physician prescription and supervision, most foods and dietary supplements have a long history of safe ingestion, without need for physician prescription and supervision.

FDA's refusal to follow the law has deprived the market of a mass quantity of nutrient-disease information. Consumers have been kept in the dark at the point of sale about the science documenting the influence of nutrients on disease, thereby rendering them more susceptible to

[2] The Court of Appeals has held that the Act's health claim provisions "create[] a safe harbor from designation as a 'drug' for certain dietary supplements whose labels or labeling advertise a beneficial relationship to a disease or health-related condition: If the FDA authorizes a label claim under 21 U.S.C.A. § 343(r), the product is not considered a drug under 21 U.S.C.A. § 321(g)(1)." *Pearson v. Shalala*, 164 F.3d at 652.

fraud rather than less as good counsels (i.e., truthful claims) concerning the potential health benefits of supplements are suppressed through FDA's prior restraint and as bad counsels (i.e., fraudulent claims) continue to proliferate largely left unchecked by the agency, forming a huge black market. FDA's restriction is most powerful for the law-abiding because it prevents them from communicating truthful nutrient-disease information at the point of sale, on labels and in labeling, where consumers look most to evaluate food and dietary supplement products.[3]

In this case FDA endeavors to suppress information concerning, and to reclassify as a drug, a dietary supplement lawfully sold in this country for hundreds of years, Saw Palmetto extract. See Exh. 3; RE I at 12-14. The health information Plaintiffs seek to convey concerns the effect of the supplement on symptoms of a condition common in over 50% of men over age 60, mild benign prostatic hyperplasia. RE I at 11.

Mild benign prostatic hyperplasia is a condition that involves inflammation of the prostate; although benign it is a source of irritation, causing reduced urine flow, nocturia (excessive urination at night), and voiding urgency. If adult males were to learn that 320 mg/day of a botanical extract could help reduce certain symptoms of mild benign prostatic hyperplasia (BPH), they would be able to choose a relatively inexpensive dietary approach without adverse effects to assist in their management of mild BPH, a benign condition. FDA aims to keep that information from the marketplace, thereby protecting its drug regime from competition[4] at the expense of the Act, the intent of Congress, the First Amendment rights of

[3] *See Pearson*, 164 F.3d at 658 n.7, citing John E. Calfee & Janis K. Pappalardo, "How Should Health Claims for Foods Be Regulated?" 26-27 (Bureau of Economics, Federal Trade Commission, 1989).

[4] FDA has approved five xenobiotic substances (flomax; proscar; minipress; hytrin; and cardura) for treatment of BPH. It has approved none specifically for mild BPH. OFFICE OF MANAGEMENT, DIVISION OF DATABASE MANAGEMENT, FOOD & DRUG ADMINISTRATION, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (20TH ED. 2000). Each approved drug has severe potential adverse effects including sudden loss of consciousness; hypotension; tachycardia; and impotence. See PHYSICIANS' DESK REFERENCE (MEDICAL ECONOMICS DATA PRODUCTION COMPANY 52nd ed. 1998). By contrast, Saw Palmetto extract for symptoms of mild BPH has no such adverse effects. See Exh. 17.

sellers and purchasers of this product, including the Plaintiffs, and those who suffer from mild BPH.

As explained below, FDA's actions violate the plain, literal meaning of 21 U.S.C. § 343(r); violate the intent of Congress concerning interpretation of that provision; violate the Administrative Procedure Act, 5 U.S.C. § 706 (2) (A-D); violate the First Amendment to the United States Constitution; and violate the Supremacy Clause and the canons of statutory construction.

II. FACTUAL BACKGROUND

The Plaintiffs include sellers and licensors of saw palmetto extract dietary supplements. The Plaintiffs also include an association (APMA) comprised of physicians who sell Saw Palmetto extract from their doctors' offices and of non-physicians who wish to receive from their doctors who sell Saw Palmetto extract dietary supplements the health claim that is the subject of Plaintiffs' health claim petition.

On May 25, 1999, the Plaintiffs filed a health claim petition with the FDA pursuant to 21 U.S.C. § 343(r)(5)(D) and 21 C.F.R. § 101.70. The health claim reads:

> **Consumption of 320 mg daily of Saw Palmetto extract may improve urine flow, reduce nocturia and reduce voiding urgency associated with mild benign prostatic hyperplasia (BPH).**

See RE I at 22. The Plaintiffs accompanied the petition with substantial peer-reviewed scientific evidence and expert opinion documenting the truthfulness of the claim and the safety of the dietary supplement. See RE I at 25-405.[5] The subject of the petition, saw palmetto extract, is the *n*-hexane lipidosterolic extract of the pulp and seed (fruit) of the dwarf American palm, *Seronoa*

[5]Despite its historic bias against supplements, even FDA has had to admit that Saw Palmetto does show effectiveness in treating symptoms of mild BPH. RE II at 1297 ("The results of these sutdies appear to suggest that [Saw Palmetto] may be useful in providing minimal relief of the symptoms of benign prostatic hypertrophy. The

repens. It is a mixture of free fatty acids and their esters, small quantities of phytosterols, and various other polyprenic compounds. RE I at 10. As such, the subject of the petition is an extract of a botanical naturally occurring and intended for ingestion as a dietary supplement. Saw Palmetto has been sold for centuries as a dietary supplement in the United States. See Wilt TJ, et al., "Saw Palmetto Extracts for Treatment of Benign Prostatic Hyperplasia: A Systematic Review," *Journal of the American Medical Association* 280:18, 1604-1609 (1998); Lowe F.C., et al., "Review of Recent Placebo-Controlled Trials Utilizing Phytotherapeutic Agents for Treatment of BPH," *Prostate,* 37:3, 187-93 (1998) (records from the 1700s indicate that Native Americans prepared "nutritional tonics" from the berries of saw palmetto plants); see Exh. 3;4. It has a long history of safe use. RE I at 12-14. There is no credible scientific evidence calling into question the safety of saw palmetto at the dose levels recommended but there is substantial evidence, in addition to its long history of safe use, corroborating its safety. RE I at 12-14; Exh. 3; 4; 17.[6]

In their petition, the Plaintiffs expressly requested that FDA implement *Pearson*, 164 F.3d 650, by authorizing the claim with such disclaimer or disclaimers as FDA reasonably deemed necessary to avoid a potentially misleading connotation. RE I at 10. The Plaintiffs have stated repeatedly that they will accept any reasonable disclaimer designed to avoid misleading

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data suggest that the drug probably has an effect that minimally improves the ability to empty the bladder and minimally improves the symptoms of outlet obstruction").

[6] In its Order, FDA disingenuously cites to a final rule denying OTC status to Saw Palmetto as evidence of a purported lack of proof of safety for the product. Drug petitioners bear the burden of proof on safety (21 U.S.C. § 355(d); *Washington Legal Foundation v. Shalala et al.*, 202 F.3d 331, 332 (D.C. Cir. 2000)) and thus must present specific safety studies to FDA to prove safety (a lack of adequate studies equates with a lack of safety, a determination that does not mean *per se* that the product is in fact unsafe). Unlike drugs, dietary supplements are presumed safe (21 U.S.C. § 342(f)(1); Exh. 2 at 3) based on their history of ingestion in foods and dietary supplements. By statute, dietary supplements are treated differently; FDA, not the petitioners, bears the burden of proof on safety and may not deem them injurious to health absent empirical evidence proving that conclusion. 21 U.S.C. § 342(f)(1); Exh. 2 at 3.

the public (that would include warnings that men should have annual prostate exams to screen for prostate cancer).

On June 7, 1999, FDA forwarded a letter acknowledging receipt of Petitioners' Saw Palmetto Health Claim petition. See RE I at 398-399. On September 1, 1999, FDA accepted the petition for filing. See RE I at 406. On December 1, 1999, FDA denied and suppressed the health claim. RE II at 1175. It did so without processing the claim under 21 U.S.C. § 343(r)(5)(D), without reviewing the scientific evidence supporting the claim and its safety, and without implementing the disclaimer approach mandated in *Pearson*. RE II at 1175. Rather, FDA summarily denied and suppressed the claim because, it argued, the claim "goes beyond risk reduction to claim an effect on an existing disease" which FDA deemed may only be approved "on a product that has been shown to meet the safety and efficacy requirements for drugs." RE II at 1175. FDA cited no authority as a basis for its decision.

On December 7, 1999, the Plaintiffs filed this suit seeking declaratory and injunctive relief. On February 11, 2000, the Plaintiffs filed a motion for summary judgment. On February 24, 2000, on the eve of its deadline for response to the motion, the Government said it would reconsider its order. On February 25, 2000, the parties filed a joint motion to stay the proceedings until May 26, 2000, to afford the FDA time to reconsider its decision. The Court granted the motion on February 25, 2000. Instead of reconsidering its decision, however, on May 26, 2000 the FDA announced no change in its prior ruling and promulgated a further explanation for its refusal to process the health claim under 21 U.S.C. § 343(r)(5)(D) (hereinafter "FDA Order"). RE II at 721.

On April 4, 2000, the FDA held public hearings on whether the saw palmetto claim was a health claim or a "drug" claim. RE II at 793-923. By a notice in the Federal Register, 65 Fed

Reg 1429 (2000), FDA solicited comments. The transcript of the hearing and the comments received are of record in this proceeding. RE II at 793-1024; 1039-1174; 1198-1262.[7]

In the FDA Order, the agency (1) refuses to process the Plaintiffs' health claim under 21 U.S.C. § 343(r)(5)(D) and instead defines the claim to be a "drug claim" which may only be processed under 21 U.S.C. § 355(d) and (2) refuses to allow the claim to be made with a disclaimer, as necessary, to avoid a misleading connotation. RE II at 721.

FDA states that it has never authorized health claims "to relieve [disease] symptoms." RE II at 721. It argues that "FDA has consistently taken the position, in notice and comment rulemaking, that claims to treat disease cannot be made as health claims for foods under the NLEA." RE II at 727.

FDA's position illogically treats disease "prevention" claims as health claims but disease "treatment, cure, or mitigation" claims as drug claims when the statutory drug definition includes the former and the latter: 21 U.S.C. § 321(g)(1)(B), "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." Moreover, contrary to the representation in the Order, FDA has in fact previously authorized claims, akin to Plaintiffs' health claim, for reduction in disease symptoms. For example, on January 6, 1993, 58 Fed Reg 2552 (1993), codified at 21 C.F.R. § 101.77(e)(2) (emphasis added), the following authorized health claim appears:

> Development of heart disease depends on many factors. Eating a diet low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber *may lower blood cholesterol levels* and reduce your risk of heart disease.

FDA has defined elevated blood cholesterol as a characteristic symptom of heart disease and has held blood cholesterol lowering a heart disease treatment claim. See 55 Fed Reg. 5176, 5178

[7] On May 26, 2000, following issuance of the FDA Order, the parties filed a joint motion to establish a procedural schedule. The Plaintiffs withdrew their originally filed motion to permit a resubmission in light of the FDA Order.

(1990) (a claim of "reducing serum cholesterol, and thus reducing the risk of coronary heart disease, would go beyond the concept of health messages and enter the realm of drug claims . . ."); 65 Fed. Reg. 1000, 1015 (Jan. 6, 2000) (". . . a statement would be considered a disease claim if it explicitly or implicitly claimed an effect . . . on one or more signs or symptoms . . . of a specific disease . . . [S]uch disease claims [include]: 'lowers cholesterol'"); 65 Fed. Reg. at 1017 (". . . elevated cholesterol [is] a disease [itself], with subsequent events (heart attack, stroke) the late consequences of [the] disease[]").

"A claim to relieve the symptoms of an existing disease," FDA states in its Order, is one to treat and/or mitigate disease, within the meaning of 21 U.S.C. § 321(g)(1)(B), "which encompasses articles 'intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.'" RE II at 722. While the statutory drug definition includes "prevention of disease," FDA conveniently omits analysis of that part of the definition, focusing only on the "treat, mitigate, or cure" language. RE II at 721-731. Disease prevention necessarily includes ingesting substances that reduce the risk of disease. Disease risk reduction claims thus fall squarely within the statutory definition of "drugs." FDA has recognized that fact. See, e.g., 55 Fed. Reg. 5176, 5184 ("The agency ". . . recognizes that a claim that a product 'may reduce the risk' or 'may forestall the premature onset' of a particular chronic disease is arguably a claim that it will prevent or mitigate the disease and thus a drug claim"); 63 Fed Reg 56802 (Oct. 23, 1998) (codified at 21 C.F.R. § 343.80) (FDA approves as drug synthetic substance designed to reduce the risk of death, nonfatal stroke, vascular mortality, and sudden death) and 60 Fed Reg 52507 (Oct. 6, 1998) (FDA approves drug for prevention of dental caries).[8] FDA therefore takes the

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The Court granted the motion and issued the scheduling order on May 26, 2000.

[8] On January 5, 1999, FDA granted a new indication for the drug Mepron (atovaquone) for prevention of pneumocystis larinii penumonia, and on October 29, 1998, FDA approved a new indication for the drug Nolvadex (tamoxifen citrate) to reduce the risk of breast cancer in women at high risk of contracting that disease.

incongruous position in this litigation that disease risk reduction claims are health claims, not "drug" claims, despite the fact that disease risk reduction claims, i.e., prevention claims, and disease symptom reduction claims, i.e., mitigation claims, are equally a part of the "drug" definition and are equally the subject of approved "drug" claims.

In addition, the agency conveniently omits from its Order the following portion of the definition for "drug" in 21 U.S.C. § 321(g)(1):

> A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim.

That portion reveals in plain English that Congress created a "safe harbor" from drug status for food and dietary supplements that bear health claims, provided, of course, that the petitioners in question submit their claims for pre-approval under the health claims provisions of the Act. Embedded in the statutory definition of "drug," this safe harbor provision renders stark the conflict between the position FDA takes in its Order and the statute's plain meaning.

FDA argues that in the Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 21 U.S.C. § 321 et seq., Congress adopted FDA's definition of health claim from its 1990 reproposed rule, 55 Fed Reg 5176 (Feb. 13, 1990).[9] FDA is wrong. While Congress included within the statute a definition of "significant scientific agreement" similar to (but not identical to) the one FDA included in its 1990 reproposed rule, Congress did not include within the statute the definition given to health claims (referred to there as "health messages") in FDA's 1990 reproposed rule. As FDA notes in its Order: "[t]he regulatory text of the 1990 proposed rule would have explicitly limited acceptable health claims to claims about 'the value that

[9] In its Order, FDA states that the NLEA legislative history "evidences no Congressional intent to expand the scope of health claims beyond what FDA had envisioned in its 1990 proposal. . . See House Report at 9, reprinted in 1990 U.S.C.C.A.N. at 3338-39." RE II at 725.

ingestion (or reduced ingestion) of a dietary component may have in either lowering the risk, or forestalling the premature onset, of a particular chronic disease.' 55 Fed. Reg. at 5192." RE II at 723.[10] But while FDA proposed to define health claims in this way, Congress did not. Fully cognizant of the reproposed rule, as FDA admits (RE II at 726) and as the legislative record confirms (See "Nutrition Labeling and Education Act of 1990," House Report 101-538 at 21 (Exh. 6 at 21)), Congress adopted a different, far broader definition for health claim: "characterizes the relationship of any nutrient . . . to a disease or a health-related condition." 21 U.S.C. § 343(r)(1)(B). That definition nowhere appears in the FDA's rules or proposed rule leading up to NLEA enactment. Moreover, after Congress enacted the NLEA with its broad definition of health claim, FDA responded not by promulgating an implementing rule with the limited regulatory definition contained in its 1990 reproposed rule (i.e., "the value that ingestion (or reduced ingestion) of a dietary component may have in either lowering the risk, or forestalling the premature onset, of a particular chronic disease"). No indeed FDA responded by superseding its 1990 reproposed rule "in all respects" with a new rule containing not the limited health claim definition but the broader definition Congress codified in the NLEA. FDA replaced the definition in the reproposed rule with the following, mirroring the language in 21 U.S.C. § 343(r)(1)(B): "*Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . characterizes the relationship of any substance to a disease or health related condition." 56 Fed Reg 60537, 60542 (1991); 21 C.F.R. § 101.14(a)(1).

Thus the actual history of Congressional and agency action directly contradicts the position FDA has taken. Had FDA in truth believed the intent of Congress to be a ratification of

[10] The actual definition in the reproposed rule reads as follows: "The label statement is limited to describing the value that ingestion (or reduced ingestion) of a dietary component, as part of a total dietary pattern, may have in

the limited definition in its 1990 reproposed rule, it surely would not have superseded "in all respects" the limited definition in the reproposed rule with the broader one just quoted. Likewise, had Congress intended to restrict the meaning of its broadly worded health claims definition in 21 U.S.C. § 343(r)(1)(B) to the one FDA argues for now, *post hoc*, it surely would have adopted that limited definition or, at a minimum, would have explained why the literal and plain meaning of the broad language it chose was not intended. One searches in vain to find such an explanation in the legislative history.

FDA's error is a classic one, *post hoc, ergo propter hoc*: FDA argues that its superseded and defunct 1990 reproposed rule contains the proper interpretive meaning to be given the different, broader language in 21 U.S.C. § 343(r)(1)(B), merely because its 1990 reproposed rule occurred earlier in time. The nexus to proof of congressional intent is non-existent.

The agency also states that "nowhere in the legislative history are there any statements of Congressional intent to promote the *treatment* of disease with foods." RE II at 726 (emphasis in original). FDA is wrong again, as the statements quoted below from the Committee reports plainly reveal.

As explained below, the language of the Act is clear and, thus, under *Chevron* Step 1, the plain meaning governs without need to resort to the legislative history. Even were this court to find the language unclear, however, the legislative history underlying the NLEA and subsequent amendments to that Act show clearly that Congress has understood the term "health claim" to have the broad, literal meaning conveyed by the Act's plain language. Because the plain language and apparent meaning convey one and the same meaning, the onus is upon FDA to show that a contrary meaning was intended by reference to express text in the legislative history to that effect. FDA has cited no such text and, indeed, none exists.

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either lowering the risk, or forestalling the premature onset, of a chronic disease condition." 55 Fed Reg at 5192.

FDA's principal justification for its action appears at the end of the Order. FDA seeks to protect from competition, arising naturally from full implementation of the health claim provisions, its drug approval process. The statements contained in the Order are similar to ones in another FDA order wherein it refused to implement the *Pearson* First Amendment disclaimer requirement, again for anti-competitive reasons. See 65 Fed Reg 1000, 1040 (Jan. 6, 2000). In the Order, the agency writes in pertinent part:

> Many pharmacologically active substances with possible uses in disease treatment could qualify as dietary ingredients for use in dietary supplements because they are botanicals and otherwise meet the definition of 'dietary ingredient' in 21 U.S.C. § 321(ff)(1). Likewise, there are a number of substances found in conventional foods that are pharmacologically active. Therefore, if health claims for treatment of disease were permitted, there would be a serious danger that dietary supplements and food components would undermine the . . . regulatory requirements for drugs. Given the time and expense necessary to bring a new drug to market, it is unlikely that manufacturers would seek drug approval from FDA for any product containing a substance that could be characterized as a dietary supplement or conventional food component, but rather would take the health claim route. For that reason, the protections of the drug approval system and other regulatory requirements applicable to drugs would be lost for a large number of products used to treat disease. . .

RE II at 730.

Thus, FDA has established an anti-competitive position, designed to favor the drug approval provisions of the Act at the expense of the health claim provisions of the Act and, thus, to produce the result of denying the consuming public access to scientific information on the full effects of nutrients and other dietary supplements on disease.[11]

FDA's decision to disallow truthful and nonmisleading health claims if they concern disease treatment, disease mitigation, or disease cure and to limit them to disease prevention (i.e.,

[11] In 65 Fed. Reg. at 1040, FDA again stated its protectionist premise:

> Permitting disease claims under section 403(r)(6) of the act as long as they are accompanied with a disclaimer . . . would be an untenable alternative. If companies could avoid the time and expense of complying with the new drug provisions of the act merely by attaching a disclaimer to a disease treatment or prevention claim, the longstanding system of drug regulation in this country would be eviscerated . . .

risk reduction) ensures that an enormous quantity of scientific information will not reach consumers at the point of sale. FDA's decision forces health claims concerning disease treatment, disease mitigation, or disease cure to be processed as drug claims, establishing a regime of censorship, because few, if any, who possess the tens of millions of dollars needed for drug approval would dare invest when authorization for a dietary supplement under the "substantial evidence" drug standard is virtually impossible and when recoupment of investment for unpatentable dietary supplements is likewise virtually impossible. See Exh. 7.

To prepare, file, and prosecute a new drug approval application for saw palmetto extract will require a minimum of $58 million dollars. See Exh. 7; 5. None of the plaintiffs has that kind of money. Exh. 8;9;10;11. FDA's new drug application filing fee alone is a non-refundable $256,338. 21 U.S.C. § 379h(b) (2000); Exh. 8;9;10;11. Moreover, given the market price for saw palmetto extract, and the fact that it is unpatentable, it would be all but impossible to recoup any such investment. Exh. 7;16. Indeed, even multi-billion dollar pharmaceutical companies that file drug applications for patentable synthetic compounds, xenobiotics, complain that the length of their patent protection may not be enough for them to recoup the enormous costs associated with preparing, filing, and prosecuting new drug applications (and that in a monopoly pricing environment). Exh. 12; 7. Furthermore, the demographics of the dietary supplement marketplace show that the costs imposed by FDA's reclassification locks out virtually every such company from the process. Exh. 13; *see also* note 19 *infra*.

FDA admits, "[a]s a practical matter, food products are not likely to be able to meet the adequate directions for use requirement or to have disease prevention claims substantiated in a manner necessary for approval of a new drug application." 52 Fed Reg 28843, 28845 (1987). In the Order itself, FDA admits: "Given the time and expense necessary to bring a new drug to

market, it is unlikely that manufacturers would seek drug approval from FDA for any product containing a substance that could be characterized as a dietary supplement or conventional food component, but rather would take the health claim route." RE II at 730. FDA has also stated that it intends to limit the application of *Pearson* to the dietary supplement context (See Exh. 14 at 6); thus ensuring that truthful claims that failed FDA's near conclusive proof, "substantial evidence," standard for drugs would be suppressed in violation of the First Amendment.

FDA's Order to reclassify food and dietary supplement health claims to treat, mitigate, or cure disease as drug claims thus ensures suppression forever of an enormous quantity of truthful and nonmisleading labeling information vital indispensable for consumers to exercise informed choice in the market.[12]

III. LEGAL STANDARDS

The following general legal standards apply to the evaluation of this motion. Additional specific legal standards appear under each heading below.

Standing to Sue; Jurisprudential Concerns. The Plaintiffs, health claim petitioners, are aggrieved by the Order, which denies their petition and causes them to suffer lost sales to those with mild BPH who would otherwise buy the product if they knew of its mild BPH symptom reducing effects. The Plaintiffs are also willing speakers and, in the case of APMA (willing speakers and listeners), whose right to communicate and receive protected speech has been violated. When Plaintiffs have suffered an injury in fact that is caused by, or is fairly traceable to, the defendant's alleged unlawful conduct and their injury can be redressed by a favorable court decision, they have standing to sue. See, e.g., *Beehive Telephone Co., Inc. v. FCC,* 179 F.3d 941 (D.C. Cir. 1999) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992));

[12] See John E. Calfee & Janis K. Pappalardo, "How Should Health Claims for Foods Be Regulated?" 26-27 (Bureau of Economics, Federal Trade Commission, 1989).

see also American Trucking Assoc. Inc. v. United States, 627 F.2d 1313, 1320 n.24 (D.C. Cir. 1959) (denial of a petition for rulemaking constitutes an injury in fact when economic interests of petitioner are adversely affected). On jurisprudential grounds, the Court should not refrain from evaluating a case on the merits when an administrative decision has been formalized and its effects are being felt in a concrete way by the Plaintiffs. See, e.g., *Abbott Labs, Inc. v. Gardner*, 387 U.S. 136, 148-9 (1967).

When Government suppresses protected speech harm is presumed because the action violates the First Amendment. See *City of Lakewood v. Plain Dealer Publishing Co.,* 486 U.S. 750, 758 (1988); *Washington Free Community v. Wilson,* 426 F.2d 1213, 1218 (D.C. Cir. 1969). Moreover, when Government violates First Amendment rights, judicial review must occur at the earliest possible moment; delay involving speech suppression is intolerable. "Speakers . . . cannot be made to wait for years before being able to speak with a measure of security." *Riley v. National Federation of the Blind,* 784 U.S. 781, 793-94 (1988) (internal quotes omitted). Delay will "chill speech in direct contravention of the First Amendment's dictates." *Id.* at 794.

Summary Judgment. The court shall grant summary judgment when no genuine issues of material fact exist and judgment may be entered as a matter of law. See Fed.R.Civ.P. § 56(c). "Only disputes of facts that might affect the outcome of the suit . . . will properly preclude the entry of summary judgment." *Cook v. Babbitt,* 819 F.Supp. 1, 10-11 (D.D.C. 1993).

Injunction. This court has stated, "[t]he standards governing grant of a permanent injunction are clear. The Court must look at the interests of the parties who might be affected by the decree and must also examine whether the facts and the relevant law indicated that an injunction clearly should be granted or denied apart from any countervailing interest." *Universal Shipping Co. Inc. v. United States*, 652 F.Supp. 668, 675-676 (D.D.C. 1987). If the Court

determines that equitable relief is warranted, it has great discretion as to its appropriate scope. *Id.* at 676.

Health Claims/Protected Commercial Speech. Health claims on labels and in labeling are protected forms of scientific speech; restrictions upon them are subject to evaluation under either strict scrutiny (*Burson v. Freeman*, 504 U.S. 191 (1992)) applied to scientific speech or intermediate scrutiny (*Central Hudson Gas & Electric Corp. v. Public Service Comm'n*, 447 U.S. 557 (1980); *Pearson*, 164 F.3d 650 at 655; *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 482 (1995)) applied to commercial speech. The FDA may not deny and suppress health claims outright but must authorize them with such disclaimer as is, or such disclaimers as are, reasonably necessary to avoid a misleading connotation. *Pearson* at 659.[13] Government must authorize health claims with corrective disclaimers because it "may not place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive." *Pearson* at 655 (citing *In re R.M.J.*, 455 U.S. 191, 203 (1982)). Government may not presume that health claims will mislead but must meet its burden of proof with empirical evidence documenting that, in fact, consumers will be misled. *Id.* (citing *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994)).

Review of an Agency Statutory Construction. Under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 81 L.Ed.2d 694, 104 S.Ct. 2778 (1984), agency statutory construction is subjected to a two-step test. The court must first determine whether

[13] Commercial speech, including a health claim, may only be denied and suppressed outright if it is inherently misleading, *Pearson*, 164 F.3d at 655, and cannot be rendered non-misleading through the addition of a disclaimer. *Pearson*, 164 F.3d at 657-58. The burden is upon government to prove based on empirical evidence that the speech in issue is inherently misleading and cannot be corrected through disclaimer. *Pearson* at 659, citing *Ibanez v. Florida Dep't of Business and Prof'l Regulation*, 512 U.S. 136, 146 (1994). Health claims that are *inconclusive* are not inherently misleading by that fact alone and must therefore be authorized with corrective disclaimers. *Pearson*, 164 F.3d at 658-59. Health claims that are not backed by "significant scientific agreement" are not inherently misleading by that fact alone and must therefore be authorized with corrective disclaimers. *Pearson*, 164 F.3d at 658.

Congress has spoken to the precise question at issue. *Id.* at 842-843. If it has, that is the end of the matter: The court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. *Id.* at 843. If the statute is silent or ambiguous with respect to the specific issue, the court must determine whether the agency's answer is based on a permissible construction. *Id.* A court will not disturb an agency's choice that is "a reasonable accommodation of conflicting policies . . . unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned." *Id*. at 844 citing *U.S. v. Shimer*, 367 U.S. 374, 382-383 (1961).

To determine Congress' intent the courts "emplo[y] the traditional tools of statutory construction: We examine the statute's text, structure, and legislative history, and apply the relevant cannons of interpretation." *Kachanis v. Dept. of Treasury*, No. 99-3157, 2000 U.S.App. LEXIS 9549, at * 13 (Fed. Cir. May 9, 2000) (citing *Delverde, SRL v. U.S.*, 202 F.3d 1360, 1363 (Fed. Cir. 2000)); *See also*, *Intrac Arms Int'l v. Albright*, 1998 U.S. Dist. LEXIS 21858 at *23, No. 97-1464 (D.D.C. Dec. 28, 1998) (citing *Southern Cal. Edison Co. v. FERC,* 116 F.3d 507, 511 (D.C. Cir. 1997)). If Congress has expressed its intent on the precise question, that intention is the law and must be given effect, and the only issue is whether the agency acted in accordance with that intent. *Kachanis*, at 13(citations omitted).

No deference is due agency interpretations at odds with the plain language of the statute. Even contemporaneous and longstanding agency interpretations must fall to the extent they conflict with statutory language. *Legal Environmental Ass. Foundation Inc. v. U.S. EPA*, 118 F.3d 1467, 1477 (11th Cir. 1997) (citing *Public Employees Retirement Sys. v. Betts*, 492 U.S. 158, 171, 109 S.Ct. 2854, 2863, 106 L.Ed.2d 134 (1989)). "A reviewing Court should not defer to an agency position which is contrary to an intent of Congress expressed in unambiguous

terms." *Id.* citing (*K mart Corp. v. Cartier Inc.*, 486 U.S. 281, 291, 100 L.Ed.2d 313, 108 S.Ct. 1811 (1988); *Chevron*, 467 U.S. at 842-843.)

Canons of Statutory Construction. It is incumbent upon the court to avoid an unconstitutional construction of a statute, whenever possible. *See DeBartolo Corp. v. Florida Gulf Coast Building & Construction Trades Council, et al.*, 484 U.S. 568, 574-576 (1988) *citing NLRB v. Catholic Bishop of Chicago*, 440 U.S. 490, 499-501 (1979).

APA Arbitrary and Capricious/Abuse of Discretion Standard. Administrative agency actions that are arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law; contrary to constitutional right, power, privilege, or immunity; in excess of statutory jurisdiction, authority, or limitations; or short of statutory right violate the APA. 5 U.S.C. § 706 (2)(A-D) (1999); *see, e.g., JSG Trading Corp. v. USDA*, 176 F.3d 536 (D.C. Cir. 1999).

IV. SAW PALMETTO IS A DIETARY SUPPLEMENT UNDER DSHEA WITH AN ESTABLISHED RECORD OF SAFETY

In 21 U.S.C. § 321(ff), a dietary supplement is "a product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: . . . an herb or other botanical; . . . or a[n] extract . . . of any [such] ingredient . . ." The Plaintiffs' products are botanical extracts intended for ingestion as dietary supplements. RE I at 10; 28. Saw Palmetto extract has been sold for hundreds of years in this country. RE I at 28; Exh. 3; 4. There is no credible scientific evidence calling into question the safety of saw palmetto extract in doses equal to or exceeding the 320 mg/day recommended by Plaintiffs; it has a long history of safe use. RE I at 28; 30-38; 119; Exh. 3;4;5. Under Section 4 of the DSHEA, the Government bears the burden of proof to show that, in fact, a dietary supplement is unsafe before it may restrict its

marketability. 21 U.S.C. § 342(f)(1).[14] The Government's Order does not review the scientific evidence presented by the petitioners concerning saw palmetto's safety.

V. THE MEDICAL FOOD PROVISIONS OF THE ACT DO NOT APPLY

In its Order, FDA argues that the statute provides clear evidence that products containing claims for dietary management of disease are medical foods and that Congress did not intend an overlap between medical foods and dietary supplement and food health claims. RE II at 726. The argument is misleading.

The establishment of the medical foods category does not cause the NLEA health claim provisions to be limited to "prevention" claims. Indeed, the medical foods provision does not apply to Plaintiffs' saw palmetto products or claim. In 1988 Congress amended the Orphan Drug Act and provided a definition of a medical food.[15] 21 U.S.C. § 360ee(b)(3). The Orphan Drug Act and the medical foods category were to provide incentives for companies to develop drugs, medical foods, and devices specifically to compensate for incapacities to ingest, absorb, or metabolize ordinary foods or nutrients as a result of **rare** diseases and conditions.[16] 21 U.S.C. § 360ee; *see also* 134 Cong. Rec. S 3685 at 6210-6213 (March 31, 1988).

Medical foods must be administered under the supervision of a physician and used for the dietary management of a disease. As such they are distinctive formulations tailored to unique physiological conditions of single patients. A food that meets the extensive FDA criteria[17] for

[14] See also Exh. 2 at 21: "Under present law, a dietary supplement, as with any food, is presumed to be safe. It therefore may be lawfully marketed, unless and until the FDA, by a preponderance of the evidence, shows that the supplement is 'injurious to health.'"

[15] A medical food is a food which is formulated to be consumed or administered enterally, under the supervision of a physician, and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. 21 U.S.C. 360ee(b)(3).

[16] Under the Orphan Drug Act the term rare condition in the case of a medical food means any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical for such disease will be developed without assistance. 21 U.S.C. § 360ee(b)(2).

[17] A product that is to be marketed as a medical food must meet the following requirements:

such foods is exempt from health claim requirements; otherwise those requirements apply. 21 U.S.C. §§ 343(q)(5)(A)(iv) and (r)(5)(A).

Foods that bear health claims, by contrast, need not be administered under a physician's supervision nor provide for unique nutrient needs that result from impaired capacities to ingest, absorb or metabolize ordinary foods or nutrients. Thus FDA errs in its interpretation of the medical foods provisions. As the statute's plain language, and that of 21 CFR § 101.9(j)(8) reveal, the two regulatory schemes were designed to address two different public health issues. Congress created the medical foods category to address the special needs of Americans with rare diseases who suffer ingestion or absorption incapacities and are under physician supervision. See 134 Cong. Rec. S 3685 at 6210-6213 (March 31, 1988). Congress created the NLEA health claims provision to provide the public with information about the nutrient-disease relationship on the labels and in labeling of foods and dietary supplements sold over-the-counter without physician supervision. House Report 101-538, 101st Cong., 2nd Sess. 20 (June 13, 1990).

Plaintiffs' saw palmetto products and claim is appropriate for evaluation under the NLEA health claims provision. BPH is not a rare condition (it affects over 50% of all men over age 60) and Plaintiffs' products are not intended to be administered under a physician's supervision for

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(i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
(ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;
(iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
(iv) It is intended to be used under medical supervision; and
(v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

21 CFR § 101.9(j)(8).

patients with impaired abilities to ingest, absorb, or metabolize foods or nutrients, as required by the medical foods regulations. Consequently, FDA's argument is entirely misleading and misplaced.

VI. FDA'S DEMAND THAT THE SAW PALMETTO CLAIM BE EVALUATED AS A DRUG CLAIM VIOLATES 21 U.S.C. § 343 (r)(5)(D) AND THE INTENT OF CONGRESS

Chevron Step 1. Under *Chevron* step 1 if the relevant language of the statute is unambiguous that is the end of the inquiry; the plain meaning governs. *Chevron,* 467 U.S. at 843. *See also, Meredith v. Federal Mine Safety & Health Review Comm.*, 177 F.3d 1042 (D.C.Cir. 1999). Under 21 U.S.C. § 343(r)(1) a health claim for a food, including a dietary supplement, is defined as that which "expressly or by implication . . . characterizes the relationship of any nutrient . . .in the label or labeling of the food to a disease or health-related condition." FDA adopted virtually identical language in its rules following passage of the NLEA, 21 C.F.R. § 101.13(a)(1);(2):

> any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . characterizes the relationship of any substance to a disease or health-related condition . . . .

The controlling principle in statutory construction is "the basic and unexceptional rule that courts must give effect to the clear meaning of statutes as written." *Estate of Floyd Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 476, 120 L.Ed.2d 379, 112 S.Ct. 2589 (1992). The ordinary and obvious meaning of a phrase is not to be lightly discounted. *INS v. Cardoza-Fonesca*, 480 U.S. 421, 431-432, 94 L.Ed.2d 434, 107 S.Ct. 1207 (1987) (citations omitted). The courts should assume that the legislative purpose is expressed by the ordinary meaning of the words used. *Id*. (citations omitted). The word "relationship" in its ordinary sense

encompasses a broad meaning. It refers to a "connection" of one thing to another. WEBSTER'S NEW UNIVERSAL UNABRIDGED DICTIONARY 1626 (1996). The plain meaning of the sentence would cause the relationship of any substance in a food, including a dietary supplement, to a disease or health-related condition to be properly the subject of a health claim petition under 21 U.S.C. § 343(r). The language does not include a restriction on the kind of nutrient-disease relationship such as the one appearing in FDA's 1990 reproposed rule (i.e., "lowering the risk, or forestalling the premature onset, of a particular chronic disease") that it argues for now in its Order. Indeed, interpreting "health claim" to have such a meaning would controvert the statute's plain meaning.

The agency states that its decision to define health claim to include disease prevention (risk reduction) but exclude disease cure, treatment, or mitigation (symptom reduction) is based on the drug definition in 21 U.S.C. § 321(g)(1). RE II at 722. The argument is in fact a *non sequitur*. The drug definition embraces in like manner "prevention" claims and "cure, treatment, and mitigation" claims. It reads in pertinent part: "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." Every health claim approved by the FDA thus far falls within the "drug" definition because every one concerns prevention or treatment of disease. It is impossible to argue, logically, based on the plain meaning of the Act's drug definition, that *any* health claim would be something other than a claim that meets the drug definition (i.e., a "drug claim"). There is, thus, no principled distinction to be made, based on the drug definition, between prevention claims (which FDA allows to be made as health claims) and cure, treatment, and mitigation claims (which it does not). Unlike FDA, the Court of Appeals correctly understood the Act's health claim provision to be a "safe harbor" for "drug claims"

when applied to dietary supplements.[18] The health claim "safe harbor" has a special pre-approval process meant for foods and dietary supplements that specifies a different standard and procedure than the standard and procedure for drugs. Contrast 21 U.S.C. § 343(r)(3)(B) and (r)(5)(D); 21 C.F.R. §§ 101.14; 101.70 with 21 U.S.C. § 355(d); 21 C.F.R. § 314 et seq.

Furthermore, the FDA's interpretation cannot stand when the statute is examined as a whole. The cardinal rule of statutory construction is that "a statute is to be read as a whole, *see Massachusetts v. Morash*, 490 U.S. 107, 115, 104 L.Ed. 2d 98, 109 S.Ct. 1668 (1989), since the meaning of statutory language, plain or not, depends on context." *Conroy v. Aniskoff*, 507 U.S. 511, 123 L.Ed.2d 229 113 S.Ct. 1562 (1993) citing (*King v. St. Vincent's Hospital*, 502 U.S. 215, 221, 116 L.Ed. 2d 578, 112 S.Ct. 570 (1991). It is clear from the Act's drug definition that claims that would otherwise meet the definition of a drug do not render the products drugs if the products are foods or dietary supplements and the claims are pursued under the health claims provisions of the Act; 21 U.S.C. § 321(g)(1) reads in pertinent part:

> A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) *is not a drug solely because the label or the labeling contains such a claim.*

21 U.S.C. § 321(g)(1) (emphasis added). "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Cardoza*, 480 at 432 citing *Russello v. U.S.*, 464 U.S. 16, 21 (1983) (citations omitted). "We do not start from the premise that [the statutory] language is imprecise. Instead we assume that in drafting

[18] The Court wrote: "Although there is apparently some definitional overlap between drugs and dietary supplements under the statute, it creates a safe harbor from designation as a 'drug' for certain dietary supplements whose labels or labeling advertise a beneficial relationship to a disease or health-related condition: If the FDA authorizes a label claim under 21 U.S.C.A. § 343(r), the product is not considered a drug under 21 U.S.C.A. § 321(g)(1)." *Pearson*, 164 F.3d at 652.

legislation, Congress said what it meant." *Legal Environmental Ass. Foundation Inc. v. U.S. EPA*, 118 F.3d 1467, 1474 (11th Cir. 1997) citing (*U.S. v. LaBonte*, 117 S.Ct. 1673, 1677, 137 L.Ed.2d 1001 (1997)).

Moreover, under 21 U.S.C. § 343(r)(3)(B)(i);(ii) FDA must promulgate regulations that describe "the relationship between a nutrient . . . and a disease or health-related condition" and "the significance of each such nutrient in affecting such disease or health-related condition." No limitation is included in this language concerning the nature of the effect on disease (i.e., Congress does not limit the effect to disease risk reduction). In addition, 21 U.S.C. § 343(r)(3)(B)(iii) provides that FDA shall "require such claim to be stated in a manner so that the claim is an accurate representation . . ." Thus, the nutrient-disease relationship and the claim must be *accurate*. If the science for a health claim reveals that the claim reduces the symptoms, but not the risk of, disease, FDA is statutorily required to ensure that the claim is accurately stated. In such a circumstance, compelling the claim to concern risk reduction exclusively would violate this section (and deceive the public).

In sum, then, the definition of health claim in 21 U.S.C. § 343(r)(1) is clear and applies to all claims for foods and dietary supplements that meet the drug definition. Under *Chevron* Step 1, the inquiry is at an end. The plain meaning governs.

Chevron Step 2. In this case, there is no justifiable basis for conducting a *Chevron* Step 2 analysis: the relevant statutory language is clear. Assuming *arguendo* that the court proceeds to Step 2, it would then evaluate the text in conjunction with the legislative history to discern the statute's meaning. *Chevron*, 467 U.S. at 843. There is no instance in the legislative history where a committee reporting on the bill, a bill sponsor, or a member discussing the bill expressly states a definition of the term "health claim." That definition appears only in the Act. Of the

legislative history available, the best sources showing congressional understanding of the Act's definition of "health claim" are those statements made in committee reports that were before both houses of Congress prior to voting on the bill. *See Vaughn v. Rosen*, 523 F.2d 1136, 142 (1975); K.Davis, Administrative Law Treatise § 3A.31, p. 175 (1970 Supp.). "The basic principle is quite elementary: the content of the law must depend upon the intent of both Houses not of just one." *Vaughn*, 532 F.3d at 1142-1143 citing Davis, supra, at 175.

The legislative history pre-dating adoption of the NLEA health claims provision reveals that the terms "disease treatment" and "disease prevention" are both used in reference to "health claims" along with disease risk reduction, contrary to FDA's assertion in its Order. In the Report of the House Committee on Energy and Commerce concerning the NLEA, House Report 101-538, 101st Cong., 2nd Sess. (June 13, 1990), a report before both houses of Congress prior to voting on the bill, the following passages reveal that Congress understood the term "health claim" to embrace not only prevention but also treatment.

> . . . [D]uring the mid-1980's, companies began making *health claims* on foods, even though the FDA had not approved the claims through the drug approval process. These statements claimed that the food was valuable in the *prevention or treatment of various diseases*. Subsequently, the FDA published proposed regulations that sanctioned this practice by permitting manufacturers to make disease-specific claims that had not met the FFDC Act's requirements applicable to drugs.

Exh. 6 at 9[19] (emphasis added). And again, from the same Report, the Committee writes:

> Moreover, there is a serious question as to whether the Agency has the legal authority to implement the program that it has proposed, *which would permit health claims regarding the usefulness of a food in treating a disease*, without also requiring that the claim meet the premarket approval requirements applicable to drugs.

Exh. 6 at 9 (emphasis added).

[19] This number corresponds with the page number of the actual report, not the USCCAN number also present on the pages of Exh. 6.

In that same Report, when discussing the meaning of the new Section 403(r)(3), the Committee does not include the limiting language on the meaning of health claims one would expect were Congress following FDA's 1990 reproposed rule definition. To the contrary, the Report states that the health claim provision applies to "any disease claim;" the Committee writes:

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

Exh. 6 at 20 (emphasis added).

In the Congressional Record, 101st Cong. 2nd Sess., 136 Cong. Rec. H 12951 at 12953 (October 26, 1990), the Statement of the House Floor Managers includes their expectation that dietary supplements should be subject to at least as strong a health claims standard as foods that contain "claims that the food will *treat* a disease or health condition."[20] Although the statement of the House Floor Managers was made after the Senate had completed its consideration of the bill, it is "certainly significant" in determining the congressional intent of the phrase "health claim." *Nat'l Ass'n of Greeting Card Publ. V. U.S.P.S.*, 462 U.S. 810, 833, 77 L.Ed.2d 195, 103 S.Ct. 2717 (1983) citing (*Vaughn*, 523 F.2d at 1142; Davis, *supra*, at 175).

In the Congressional Record, 101st Cong. 2nd Sess., 136Cong. Rec. S 16607 at 16610 (October 24, 1990), in joining Senator Metzenbaum in presenting amendments to the proposed House bill, Senator Hatch understood the health claims provision to create a procedure and standard for permitting health claims on dietary supplements without rendering them drugs. He

[20] In context the statement reads: "There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims. The potential is just as great for vitamins as it is for other products. In our view, vitamins and the other substances covered by this provision should be subject to at least as strong a standard as is applicable to other foods that contain claims that the food will *treat a disease or health condition."* Exh. 15 at 12953 (emphasis added).

thus contemplated that the health claims review procedure would result in "drug claims" on dietary supplements:

> The compromise thus incorporates what I consider to be an essential right of our citizens to have access to vitamins, minerals, herbs and other nutritional supplements without fear of their being branded unlawful drugs. Section 403(r)(5)(D) takes that further step by bringing the same protection to claims for dietary supplements—under the new section 201(g)(1), *a dietary supplement will not be considered a drug solely because it carries a valid health claim.*

Cong. Rec., 101st Cong., 2nd Sess., 136 Cong. Rec. S at 16611 (emphasis added).

FDA takes the position that Congress knew of the existence of the 1990 reproposed rule and intended to adopt the meaning expressed there as the meaning for "health claim" appearing in the Act at 21 U.S.C. § 343(r)(1)(B). RE II at 724-725. FDA's contention concerning the intent of Congress is not corroborated by the legislative record, however; indeed that record belies the contention, as does FDA's own response to the adoption of the NLEA health claims provision. In its 1990 reproposed rule FDA defined the term as "the value that ingestion (or reduced ingestion) of a dietary component may have in either lowering the risk, or forestalling the premature onset, of a particular chronic disease." 55 Fed Reg at 5192. RE III at 1292. Contrary to FDA's argument, fully cognizant of that definition in the reproposed rule (FDA admits this, RE II at 724, and the legislative record confirms this, Exh. 6 at 21), Congress instead adopted the following far broader definition: "characterizes the relationship of any nutrient . . . to a disease or a health-related condition." 21 U.S.C. § 343(r)(1)(B). That definition nowhere appears in the FDA's rules or proposed rule leading up to the enactment of the NLEA. But after the Congress enacted NLEA with its broad definition of health claim, FDA responded not by promulgating an implementing rule with the limited regulatory definition of its 1990 reproposed rule. No, indeed, FDA responded by causing its 1990 reproposed rule to be "superseded in all respects" by a new rule containing not the limited health claim definition in its 1990 reproposed

rule but instead the broader definition Congress codified in the NLEA. 56 Fed Reg 60537, 60538 (1991); 21 C.F.R. § 101.14(a)(1). FDA replaced the definition in the reproposed rule with the following, broader definition, which mirrors the statutory language: "*Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication . . . characterizes the relationship of any substance to a disease or health related condition." 56 Fed Reg at 60563; 21 C.F.R. § 101.14(a)(1).

Had FDA in truth believed the intent of Congress to be a mere ratification of the limited definition in its 1990 reproposed rule, it surely would not have superseded the definition in the reproposed rule with the broader one just quoted. Likewise, had Congress intended to restrict the meaning of its broadly worded health claims definition in 21 U.S.C. § 343(r) to the one FDA argues for now, *post hoc*, it surely would have adopted that limited definition or, at a minimum, would have explained why the literal and plain meaning of the broad language it chose was not intended. One searches in vain to find such an explanation in the legislative history. The FDA's error in interpretation is a classic one, *post hoc, ergo propter hoc*: FDA argues that its superseded and defunct 1990 reproposed rule contains the proper interpretive meaning to be given the different, broader language in 21 U.S.C. § 343(r), merely because its 1990 reproposed rule occurred earlier in time. The necessary nexus of proof of intent is non-existent.

The bi-partisan report of the Senate Committee on Labor and Human Resources accompanying the DSHEA, Senate Report 103-410, 103d Cong., 2nd Sess., October 8, 1994 (Exh. 2), with amendments to the drug definition and the health claims sections of the Act, reveals additional legislative intent concerning the meaning of the health claim provisions.

In particular, the Committee understands the NLEA health claims provision to create a "safe harbor" for nutrient/disease relationship claims which would otherwise constitute "drug

claims." As explained above, this is the same understanding that the Court of Appeals derived from its review of the statutes in *Pearson v. Shalala*. *See* 164 F.3d at 652-653. The Committee writes:

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

S. Rep. 103-410 at 22-23; Exh. 2 at 22-23.

In that same report, the Committee discusses various nutrient-disease relationships supported by scientific evidence. Its listing is not limited to those involving disease risk reduction. Among the direct treatment associations the Committee favorably reviews are those for garlic reducing serum blood cholesterol (S. Rep. 103-410 at 11; Exh. 2 at 11); ginger relieving nausea and stomach distress (S. Rep. 103-410 at 11; Exh. 2 at 11); the bioflavonoid quercitin reducing the allergy-inflammatory response (S. Rep. 103-410 at 14; Exh. 2 at 14); and glucosamine sulfate repairing damaged joints (S. Rep. 103-410 at 14; Exh. 2 at 14).

Finally, adoption of the limited definition FDA advocates would undermine the objective Congress seeks to achieve with the health claims provision: "A clear purpose of the NLEA was to assure that the public would be provided with clear information about the relationship of nutrition to disease, and to ascertain that that information would be accurate and not misleading" and "NLEA's goal [is to] assur[e] that consumers have access on food and dietary supplement labels to health claims that are scientifically supported, without having to wait until the degree of scientific certainty contemplated by the drug standard has been achieved." Exh. 2 at 23, 24. As explained below, FDA's reclassification of the saw palmetto extract claim from the category of dietary supplement to the category of drug claims imposes a regime of censorship involving such

severe restrictions on the right to communicate on labels and in labeling as to effectively prohibit that right.

VII. FDA'S DEMAND THAT THE SAW PALMETTO CLAIM BE EVALUATED AS A DRUG CLAIM VIOLATES THE FIRST AMENDMENT

In its Order, FDA states that, to be *considered*, Plaintiffs' claim must be part of a new drug application for saw palmetto extract under 21 U.S.C. § 355(d) and 21 C.F.R. § 314 et seq. Drug approval for saw palmetto extract is, however, a virtual impossibility as FDA well knows. FDA has already denied approval for Saw Palmetto as an OTC drug. 55 Fed Reg 6926 (1990). Moreover, it has stated that drug approval would be virtually impossible for any food under the rigid standards it imposes on drugs. The agency has written, "[a]s a practical matter, food products are not likely to be able to meet the adequate directions for use requirement or to have disease prevention claims substantiated in a manner necessary for approval of a new drug application." 52 Fed Reg at 28845.

In its Order, FDA admits that the time and expense would militate against seeking new drug approval, writing: "Given the time and expense necessary to bring a new drug to market, it is unlikely that manufacturers would seek drug approval from FDA for any product containing a substance that could be characterized as a dietary supplement or conventional food component, but rather would take the health claim route." RE II at 730. FDA has also stated that it intends to limit the application of *Pearson* to the dietary supplement context (Exh. 14 at 6), thus ensuring that truthful claims that failed FDA's near conclusive proof, "substantial evidence," standard for drugs (21 U.S.C. § 355(d)) would be suppressed in violation of the First Amendment. It is therefore the case that FDA's Order to reclassify health claims to treat, mitigate, or cure disease as drug claims ensures that an enormous quantity of truthful and nonmisleading labeling

information about the Saw Palmetto/mild BPH nutrient-disease relationship will be suppressed forever.

Even were the prospect of drug approval for saw palmetto realistic, the costs of the process ensure that virtually no company that manufactures, sells, or distributes Saw Palmetto (or any other dietary supplement for that matter) could afford to apply. Estimates of the costs for achieving drug authorization range from $300 million to $500 million dollars from start to finish. See Exh. 5; 12. Experienced in the economic evaluation of drug markets, and a former expert for FDA, economist Paul H. Rubin estimates that the costs necessary for preparing and prosecuting Plaintiffs' saw palmetto extract under the drug approval provisions would be at least $58 million. See Exh. 7. The lower cost is based on the fact that the product is an identified one (preliminary scientific search costs may therefore be eliminated). The cost is nevertheless prohibitive not only for Plaintiffs but also for virtually every other company in the entire dietary supplement industry.[21]

The annual gross revenues received by the companies that sell the Plaintiffs Saw Palmetto products are $3,301,296 for Dr. Whitaker and $354,000 for Pure Encapsulations. Exh. 8; 11. Thus, the combined gross revenues do not even approach the $58 million estimate. None of the Plaintiffs can afford to pay $58 million to pursue a drug application for saw palmetto. Even if they could pursue it, as explained above, they could not reasonably expect approval.

Finally, not even multibillion dollar pharmaceutical companies are willing to invest in drug applications unless the product is patentable. Exh. 12 (Jonathan L. Mezrich, "The Patentability and Patent Term Extension of Lifesaving Drugs: A Deadly Mistake," 6 J. of L. and

[21] Indeed, the published demographics for all United States manufacturers and marketers of dietary supplements reveals that only 16 companies have revenues exceeding $100 million; only 38 have revenues between $20 and $100 million; and fully 996 have revenues less than $20 million. Exh. 13. By contrast, the leading pharmaceutical

Health 111, 112 (1991-1992)). Saw palmetto extract, however, is a naturally occurring product with a long history of use in this country; it is thus unpatentable. See Exh. 16; 7. At the market rates charged for saw palmetto, it would be all but impossible for any company, let alone any of the Plaintiffs, to recoup a $58 million investment. Even were it patentable, to recoup their investment the Plaintiffs would have to charge an above-market rate for the product; yet, because saw palmetto is sold across the United States in grocery stores, pharmacies, etc. by numerous companies, those companies would be able to continue selling their products at market rates yet enjoy increased sales due to the spill over effect of Plaintiffs' health claim labeling.

Thus, as a practical matter, FDA's decision to move the saw palmetto health claim from the health claim category to the drug category ensures that no truthful and nonmisleading speech will be communicated to the public at the point of sale concerning the mild BPH symptom reducing benefits of this dietary supplement.[22]

Moreover, the agency's Order virtually ensures that no food or dietary supplement product will be able to place any nutrient/disease claim (concerning treatment, mitigation, or prevention) on the label of any food or dietary supplement, because all such claims of every kind imaginable may only now be made pursuant to an FDA drug approval. The agency has thus achieved in one Order a massive suppression of truthful and nonmisleading speech that it has endeavored to achieve for decades against the will of Congress and the Courts. See Exh. 2.

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companies in the United States have revenues ranging from $5.07 billion (Schering-Plough) to $14.51 billion (Merck). *See* 1998 Med.Ad.News, v. 18, n.5, 990500 at 30.

[22] "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, Inc. v. Members of the New York State Crime Victims Board*, et al., 502 U.S. 105, 115, 116 L.Ed.2d 476, 112 S.Ct. 501 (1991) citing (*Leathers v. Medlock*, 499 U.S. 439, 447, 113 L.Ed.2d 494, 111 S.Ct. 1438 (1991)). "This notion is so engrained in our First Amendment jurisprudence that last Term we found it so 'obvious' as to not require explanation." *Simon & Schuster*, 502 U.S. at 115-116 citing *Leathers*, 499 U.S. at 447. "[T]he government's ability to impose content-based burdens on speech raises the specter that the government may effectively drive certain ideas or viewpoints from the marketplace." *Simon & Schuster*, 502 U.S. at 116 citing *Leathers*, 499 U.S. at 448-449.

The regulatory reclassification to drug causes a greater restriction on the Plaintiffs' health claim than would occur were the claim evaluated under the less stringent standards for health claims and under *Pearson v. Shalala* (which compels that FDA allow claims that can be corrected for potential misleadingness through the addition of a disclaimer even if those claims fail to satisfy FDA's health claims review standard). See 164 F.3d 650.

The health claim here in issue is of a very high order. It was drafted by independent scientific consultants to the Plaintiffs and worded with care to reflect accurately the current state of scientific evidence on the nutrient-disease relationship. RE I at 22. The Plaintiffs have agreed to allow the claim to be disclaimed with any reasonable disclaimer designed to cure potential misleadingness. RE I at 10. As such, the claim conveys scientific information concerning symptom relief for a condition that afflicts over 9 American men[23] and over 50% of men over the age of 60.[24] It is scientific speech no different from that contained in the scientific literature from which it is derived. The body of scientific support for it is immense and of record in this proceeding. RE I at 1-397. As such, FDA regulations restricting it should be subjected to strict scrutiny. Under the First Amendment strict scrutiny standard, FDA could only justify its regulation were it to prove (1) that it has a compelling governmental interest for requiring the claim to undergo the requirements of the drug approval process rather than the health claim review process for dietary supplements and (2) that it has employed the least restrictive means to effectuate its interest. *See, e.g., Riley v. Nat'l Fed. Of the Blind of NC,* 487 U.S. 781 (1988).

Even if this Court holds that the Government's restrictions and burdens on the health claim should be evaluated under the First Amendment commercial speech standard, FDA must

[23]U.S. Bureau of the Census, "Resident Population of the US, by Age & Sex, Dec. 28, 1998; Jacobson et al., "New Diagnostic and Treatment Guidelines for Benign Prostatic Hyperplasia, Potential Impact in the United States," Arch Intern. Med., 155: 477-481, 1995.

still satisfy a high burden of proof to justify its restriction. *Central Hudson*, 447 U.S. 557. Under that standard, before FDA may impose any such restriction it must first determine whether its restriction satisfies the three-part *Central Hudson* test, as modified by its progeny. FDA must prove (1) that its interest is substantial; (2) that its restriction *directly* advances its interest; and (3) that the fit between the government's ends and the means chosen to accomplish those ends is reasonable. See *Pearson v. Shalala*, 164 F.3d at 655-656; *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 482 (1995). FDA bears the burden of proof under the commercial speech standard. It must prove with empirical evidence that the harms it recites are real and that its regulatory means will alleviate those harms to a material degree. *Pearson*, 164 F.3d at 659; *Edenfield v. Fane*, 507 U.S. 761, 771 (1993) ("This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree"). The Government's burden is a "heavy" one. *Peel v. Atty Regis. & Disciplinary Comm. Of Illinois*, 496 U.S. 91, 109 (1990).

In its Order, FDA articulates three governmental interests: (1) its public health concern that men with prostate cancer may "lose precious time by self-medicating under the illusion that they are treating a benign, non-life-threatening condition;" (2) its concern that "the protections of the drug approval system and other regulatory requirements applicable to drugs would be lost for a large number of products used to treat disease;" and (3) its concern that "incentives to perform research would be diminished, since less research is necessary to obtain authorization of a health claim than to meet the new drug approval standard." RE II at 730.

[24]Agency for Health Care Policy and Research (AHCPR), "Treating Your Enlarged Prostate," AHCPR Publication No. 940584, 1994.

FDA has adduced no empirical evidence whatsoever to support any of these contentions of harm. Its harms are thus entirely speculative, based on conjecture. As such, they fail *ab initio* because FDA has not met its burden of proving that the harms it recites are real.

State Interest. The interests articulated in the Order are misplaced and, therefore, neither compelling nor substantial. First, the saw palmetto extract product is not offered as a treatment for prostate cancer, and the Plaintiffs have stated that they will accept any reasonable disclaimer FDA deems necessary (that would include one alerting men of the need for annual prostate exams). RE I at 10.[25] Thus, the interest in protecting males with prostate cancer is not implicated by the Plaintiffs' health claim. Second, the health claim provision applies only to those products that satisfy the definitions of foods and dietary supplements in 21 U.S.C. § 321(f);(ff). There is no change to the status quo ante defined by the FDCA. Thus, the interest in protecting the applicability of the drug approval provisions to drugs is not affected by the Plaintiffs' health claim for a dietary supplement. Third, the interest in protecting the incentives to perform research for either drugs or dietary supplements are not affected by the Plaintiffs' health claim. Only products that satisfy the definitions of foods and dietary supplements in 21 U.S.C. § 321(f);(ff) are eligible for use of the health claims provision. There is no change in the status quo ante defined by the FDCA. Thus, the interest in protecting the research incentives for drug products and the different research incentives for food and dietary supplement products are unchanged, unaffected by Plaintiffs' health claim. In short, none of the Government's articulated interests are applicable to the Plaintiffs' health claim.

While the Government's statement of interests in the Order do not apply, there is an illegitimate Government interest that does (indeed, it is FDA's true motive): to protect the drug

regime from competition arising from full implementation of the Act's health claims review provisions. That interest is illegitimate because (1) it causes the drug approval provisions to envelop almost all health claims for foods and dietary supplements when Congress intended the health claim provisions to be a "safe harbor" from drug classification and (2) it thereby grants monopoly protection for drugs beyond that intended by Congress. Accordingly, the Government's interest in protecting the drug approval regime from competition is neither compelling nor substantial but is irrational, illegitimate, and in frustration of the statutory scheme.

Least Restrictive Alternatives. The Government has not employed the least restrictive means to effectuate its interests. As explained above the FDA has achieved by fiat a reclassification that effectively prevents the communication of any nutrient-disease relationship information to the public, including the Plaintiffs' health claim, on the labels of foods and dietary supplements if that information concerns disease treatment, cure, or mitigation. Rather than favor such massive suppression of speech, the Government can simply rely on disclaimers to address its public health concerns. In the case of the saw palmetto claim, the Government can mandate disclaimers on the Plaintiffs labels and in their labeling warning men to seek annual prostate exams. The Plaintiffs have stated that they will accept any reasonable disclaimer. The disclosure of more information is a far less restrictive alternative to the severe restriction imposed by the FDA's effective ban on all truthful and nonmisleading labeling of vital need for those who suffer from mild BPH.

The protections for the drug approval system are unaffected by the Plaintiffs' health claim. Those protections continue to apply with equal force to drugs as intended by Congress.

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[25] The *Pearson* Court favors this approach. The Court wrote: "[T]he government's interest in preventing the use of labels that are true but do not mention adverse effects would seem to be satisfied—at least ordinarily—by inclusion

The protections for the drug approval system do not apply to dietary supplements and foods, however, even when those products carry health claims; that too is the statutory scheme. Thus, a far less restrictive alternative is to follow the statutory scheme and rely upon the health claims pre-approval requirements, 21 U.S.C. § 343(r) and the extant food and dietary supplement safety provisions, 21 U.S.C. §§ 342; 343, that already afford FDA full regulatory authority to deny approval to, or remove from the market, any product injurious to health.

The incentives for drug research are unaffected by the Plaintiffs' health claim. Nevertheless, under the standard that applies to food and dietary supplement health claims, incentives for research remain the same.[26] Thus a far less restrictive alternative is to recognize that the market already includes substantial incentives for all companies to prove that their products are safe and effective, not least of which are those arising from the desire to achieve market share and reduce products liability risks. Moreover, a far less restrictive alternative is to recognize that the statute remains unaffected by the Plaintiffs' health claim. The same incentives exist ex ante as ex post for proving drug safety and efficacy.[27] Those incentives differ for xenobiotic substances because the substances are alien to the human body; foods and dietary supplements are derived from substances commonly consumed. In the case of Saw Palmetto extract, the product has served as a nutritional tonic in America for several hundred years. Its safety is demonstrated by its history of safe use. Finally, the Government could (and does) directly subsidize research on drugs, foods, and dietary supplements; that too is a far less

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of a prominent disclaimer setting forth those adverse effects." 164 F.3d at 659.

[26] Drug patent protection, not FDA regulation, is ultimately responsible for the billions spent on drug research. Monopoly rents from those patents fund research; those rents are not available to the unpatentable Saw Palmetto extract. *See* Exh. 12.

[27] The agency's bias against health claim approval creates a tremendous disincentive for food and dietary supplement research. If *Pearson* is fully implemented, and FDA's bias is eliminated, incentives for research will increase because food and dietary supplement companies will come to learn that the prospects for claim approval are real rather than ephemeral.

restrictive alternative to suppression. See, e.g., 42 U.S.C. §§ 287c-21; 287c-11; *see also* Pub. L. No. 105-78 at 1482 (Congress appropriates $7 million to Office of Alternative Medicine, NIH, for peer-reviewed complementary and alternative medicine research grants).

Direct Advancement. The Government's reclassification of health claims does nothing to advance its interest in causing men with cancer to obtain proper treatment for prostate cancer. Indeed, the suppression of Plaintiffs' health claim and the refusal to use disclaimers is likely to cause those having prostate problems to be less aware of the significance of them and of the need for annual cancer screenings than were they to read Plaintiffs' health claim and an FDA disclaimer alerting them to the wisdom of annual cancer screenings. See Exh. 7. That health claim and disclaimer would provide more information to more men about the need for attention to mild BPH and to cancer screenings than suppression of point of sale information altogether.

The Government's reclassification will also leave entirely unaffected the respective (and differing) existing incentives for drug research and food and dietary supplement research; that is because the underlying product is a dietary supplement, not a xenobiotic or synthetic drug. The latter are patentable and it is the monopoly rents achieved through patent protection that induce the many billions spent on drug research, not the FDA's categorization of health claims. See Exh. 12.

Means/Ends Fit. The means-ends fit is not reasonable, it is irrational. There is no evidence to suggest that any consumer given enough information would mistake Plaintiffs' product as a treatment for prostate cancer. Moreover, there is no evidence that the constitutional presumption in favor of more information would not fully suffice to cure any possible misperception. Disclosing on the label the need for a prostate cancer exam is a rational, less

restrictive way to achieve the Government's ends; suppressing all such information at the point of sale does nothing to achieve the ends, provides no reasonable fit.

Thus, under either strict scrutiny or the commercial speech test, FDA has failed to meet its burden of proof. Its Order thus violates the First Amendment and should be held invalid.

VIII. FDA'S DEMAND THAT THE SAW PALMETTO CLAIM BE EVALUATED AS A DRUG CLAIM VIOLATES THE APA, CONSTITUTES AN ABUSE OF DISCRETION, AND AN ARBITRARY AND CAPRICIOUS AGENCY ACTION

FDA's Order violates the APA in eight different ways. (1) As explained above, the FDA has reclassified the Plaintiffs' health claim as a drug claim in violation of the NLEA health claims provision; actions contrary to law violate the APA, 5 U.S.C. § 706(2)(A). (2) As explained above, FDA has irrationally, without reasoned explanation, caused health claims that involve "prevention" within the meaning of the drug definition in 21 U.S.C. § 321(g)(1) to be deemed "health claims" under the Act while simultaneously causing health claims that involve "cure, treatment, or mitigation" within the meaning of the drug definition in 21 U.S.C. § 321(g)(1) to be deemed "drug claims" under the Act, violating the APA's prohibition on arbitrary and capricious agency action, 5 U.S.C. § 706(2)(A). (3) As explained above, FDA's Order effectively ensures that the Plaintiffs may not communicate (and in the case of APMA's non-physician members, receive) their health claim thus imposing a restriction in violation of the First Amendment; actions contrary to constitutional right violate the APA, *Id*. at 706(2)(B). (4) As explained below, FDA has elevated its speech restrictive Order above the contrary requirements of the First Amendment in violation of the Supremacy Clause of the Constitution; unconstitutional actions violate the APA, *Id.* at 706(2)(B). (5) FDA has rejected, without reasoned explanation, Plaintiffs' request for use of a reasonable disclaimer and has not explained why such a disclaimer would not suffice to alert consumers of the need for prostate cancer

screening exams or such other information as FDA reasonably deems necessary for public health protection. (6) FDA has reclassified the Plaintiffs' health claim as a drug claim without conducting a notice and comment rulemaking to change the meaning of its existing health claims definition in 21 C.F.R. § 101.14(a), thus creating a new rule of general applicability that conflicts with an existing codified definition without notice and comment rulemaking to change the codified rule in violation of the APA, 5 U.S.C. § 706(2)(D). (7) As explained above, FDA has approved a claim for fiber that concerns reduction in the symptoms of disease but refuses to approve the Plaintiffs' health claim although it too concerns reduction in symptoms of disease, thus acting in an arbitrary and capricious manner in violation of the APA, *Id.* at 706(2)(A). (8) Here, as in times past, FDA, as Congress has found (DSHEA Committee Report at 14-17; 21-26; Exh. 2 at 14-17; 21-26), is motivated by a pervasive and historic bias against dietary supplements and dietary supplement health claims that is unscientific and seeks to protect its drug regime from a competition that arises naturally from full effectuation of the health claims provisions of the NLEA; those actions are irrational and illegitimate in light of the legislative scheme; such unprincipled and unreasoning agency action violates the APA's prohibition on arbitrary and capricious agency action, 5 U.S.C. § 706(2)(A).

IX. FDA'S DEMAND THAT THE SAW PALMETTO CLAIM BE EVALUATED AS A DRUG CLAIM VIOLATES THE SUPREMACY CLAUSE

Under the Supremacy Clause of the United States Constitution, U.S. CONST. art. VI, cl. 2, it is axiomatic that FDA possesses no lawful power to take unconstitutional actions. By issuing Orders and compelling adherence to them when those Orders are contrary to the First Amendment, FDA violates not only the First Amendment but also the Supremacy Clause of the Constitution. A law repugnant to the Constitution cannot stand without rendering the Constitution no better than the law, but the Constitution is Supreme law and, thus, a law

"repugnant to the constitution, is void." *Marbury v. Madison,* 5 U.S. 137, 177-178 (1803). Thus, FDA's insistence on an Order repugnant to the Constitution violates the Constitution's Supremacy Clause.

X. FDA'S REFUSAL TO IMPLEMENT THE *PEARSON* DISCLAIMER APPROACH VIOLATES THE FIRST AMENDMENT

In *Pearson*, the Court of Appeals held FDA's decision to favor suppression over disclosure with disclaimers (to the extent necessary to cure misleadingness) a violation of the First Amendment. 164 F.3d 650. In this case, FDA commits the same First Amendment violation by refusing to allow the Plaintiffs' health claims to be made with such disclaimers as are reasonably necessary to avoid a misleading connotation. The *Pearson* Court faulted FDA for rejecting out of hand disclaimers as a less restrictive alternative to outright suppression. In the Order, FDA rejects disclaimers out of hand once again; this time the agency has the temerity not even to mention the subject in its Order. The agency's refusal to rely on disclaimers as a less restrictive alternative to outright suppression of the health claim violates the First Amendment. *See Pearson*, 164 F.3d at 658-660.

XI. FDA CAN, AND THEREFORE MUST, INTERPRET THE NLEA HEALTH CLAIMS PROVISION TO EFFECT A CONSTITUTIONAL RESULT

In its Order FDA interprets the NLEA to produce an unconstitutional result. Instead of interpreting the NLEA health claims provision consistent with the plain meaning of its statutory language, recognizing every statement that characterizes the relationship of a nutrient to a disease to be a health claim, FDA has chosen to regard some of those statements as health claims and others as "drug claims," the latter constituting claims that are effectively suppressed by FDA forever. By interpreting the NLEA health claims provision in this way, FDA causes the provision to yield an unconstitutional result: the suppression of truthful and nonmisleading

claims concerning the effect of nutrients upon the symptoms of an existing disease, the treatment of disease, the mitigation of disease, and the cure of disease. Moreover, because FDA has announced that it will restrict the First Amendment protections for commercial speech announced in *Pearson* to dietary supplement health claims (Exh. 14), there is no means within the drug regime for truthful and nonmisleading claims that fail to satisfy FDA's "substantial evidence" drug standard to appear with disclaimers (curative of misleading connotations) on labels and in labeling; to wit, the very First Amendment violation found in *Pearson* recurs.

There is an alternative to FDA's interpretation of the NLEA health claims provision. That alternative is to interpret the provision consistent with its plain meaning (as explained above, which is consistent with its legislative history). By doing so, every dietary supplement and food for which a claim is made that relates a nutrient to a disease (whether the claim concerns prevention, treatment, mitigation, or cure) would be processed under the NLEA health claims provision and would be eligible to receive First Amendment protection consistent with *Pearson v. Shalala*.

It is incumbent upon the federal courts to avoid an unconstitutional construction of a statute wherever possible. *DeBartolo Corp. v. Florida Guild Coast Building & Construction Trades Council, et al.,* 485 U.S. 568, 574-576 (1988) *citing NLRB v. Catholic Bishop of Chicago,* 440 U.S. 490, 499-501 (1979). If the court construes the statute as FDA has, the court will effect an unconstitutional suppression of truthful and nonmisleading health information. By construing the statute as the law requires, the court will arrive at a constitutional outcome, preserving the statute. Accordingly, the Court should (and, consistent with the canons, must) construe the NLEA health claims provision to encompass the Plaintiffs' health claim and hold FDA's contrary interpretation a violation of the statute and the Constitution.

XII. SUMMARY JUDGMENT SHOULD BE GRANTED IN PLAINTIFFS' FAVOR

There are no genuine issues of material fact that are the subject of dispute. The facts all arise from the administrative record below and from the agency's Order. The issues in the case are ones of law, centering on statutory interpretation, administrative law, and the Constitution. Consistent with Fed.R.Civ.P. § 56(c), this case is ripe for summary judgment. There are no disputes of fact that would affect the outcome and summary judgment affords an efficient method for resolving legal issues without need of trial. *Cook v. Babbitt,* 819 F.Supp. 1, 10-11 (D.D.C. 1993). Accordingly, for this reason and those articulated above and supported by the exhibits hereto, the court should grant summary judgment in Plaintiffs' favor.

XIII. AN INJUNCTION SHOULD BE GRANTED TO PRECLUDE FDA ENFORCEMENT OF ITS ORDER

As the legal analysis above reveals, Plaintiffs have a substantial likelihood of success on the merits. In addition, the deprivation of their First Amendment right to communicate on labels and in labeling the vital health information contained in their health claim constitutes an irreparable injury. *See Elrod v. Burns,* 427 U.S. 347, 373 (1976). The public interest and hardship factors lie in their favor because the public is best served by having access to truthful and nonmisleading health information essential to freedom of informed choice in the market and the Government retains the power to evaluate the health claims in issue under the health claims review procedure prescribed in 21 U.S.C. § 343(r). Accordingly, this Court should impose a permanent injunction against the Government, barring it from enforcing the Order.

XIV. CONCLUSION

For the foregoing reasons, the Plaintiffs respectfully request that this Honorable Court grant their motion for summary judgment by declaring FDA's refusal to process the Plaintiffs' dietary supplement health claim petition under 21 U.S.C. § 343(r)(5)(D) and refusal to

implement the constitutional mandate of *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) in evaluation of that claim, a violation of Section 403(r)(1)(B) of the Act; of the Administrative Procedure Act (APA), 5 U.S.C. § 706 (2) (A-D); of the First Amendment to the United States Constitution; and of the canons of statutory construction and the Supremacy Clause of the Constitution. They also ask this Honorable Court to grant them an injunction barring FDA from enforcing its Order and an order that FDA process the Plaintiffs' health claim petition under 21 U.S.C. § 343(r)(5)(D).

Respectfully submitted,

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