UNITED STATES DISTRIC COURT FOR THE DISTRICT OF COLUMBIA

JULIAN M. WHITAKER, M.D., et al.,	)	
	)	
Plaintiffs,	)	
	)	**Civil Action**
v.	)	
	)	**No. 99-3247**
TOMMY G. THOMPSON, Secretary,	)	
	)	
Department of Health and Human Services, et al.,	)	
	)	
Defendants,	)	
	)	

ORDER

This matter is before the court on Plaintiffs' Motion for Summary Judgment [#19] and Defendants' Motion to Dismiss [#20]. Upon consideration of Defendants

And Plaintiffs' Motions, Oppositions, Replies, the October 28, 2002, Motions Hearing, and the entire record herein, for the reasons stated in the accompanying Memorandum Opinion, it is this 3rd day of January, 2003, hereby **ORDERED**, that the Defendants' Motion to Dismiss [#20] is **granted**; and it is further **ORDERED**, that the Plaintiff's Motion for Summary Judgment [#19] is **denied**.

/S/Gladys Kessler
Gladys Kessler
United States District Judge

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Defendants,	)	
	)	

MEMORANDUM OPINION

Plaintiffs are individuals and companies with a direct financial interest in dietary supplements containing saw palmetto extract as well as a non-profit therapeutic health organization composed of physician members who sell dietary supplements containing saw palmetto extract.[1] They bring this action against the Food and Drug Administration ("FDA"), Jane E. Henney, Commissioner of the FDA[2] the Department of Health and Human Services ("HHS"), Tommy G. Thompson, Secretary of the HHS, and the United States of

[1] Plaintiffs are Julian M. Whitaker, M.D., Pure Encapsulations, Inc., Durk Pearson, Sandy Shaw, and the American Association for Health Freedom (previously known as the American Preventive Medical Association).

[2] While the FDA Commissioner's post is now vacant, Jane E. Henney was the acting Commissioner at the time this case was filed.

America. Plaintiffs challenge the FDA's denial of a health claim application for saw palmetto.

This matter is before the Court on Plaintiffs' Motion for Summary Judgment and Defendants' Motion to Dismiss. Plaintiffs claim the FDA's decision violates the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq. (1972), the Administrative Procedure Act ("APA"), 5 U.S.C. § 706 et seq. (1996), the First Amendment, canons of statutory interpretation, and the Supremacy Clause. Defendants move to dismiss for failure to state a claim upon which relief can be granted, Fed. R. Civ.P. 12(b) (6), arguing that the FDA properly denied Plaintiffs' health claim application based on its classification of the saw palmetto claim as a drug claim. Upon consideration of Plaintiffs' and Defendants' Motions, Oppositions, Replies, the October 28, 2002, Motions Hearing, and the entire record herein, for the reasons discussed below, Defendants' Motion to Dismiss is granted, and Plaintiffs' Motion for Summary Judgment is denied.

I. Background

A. Statutory and Regulatory Framework

Prior to November 8, 1990, the FDCA provided that dietary supplements—including the saw palmetto supplements at issue in this case –would be regulated as a food, unless

their intended use was as a drug.[3] In other words, if a dietary supplement's label contained a disease-specific claim,[4] that supplement was subject to the FDA's drug approval and drug labeling requirements. See H.R. Rep. No. 101-538, at 9 (1990) ("House Rep."); 21 U.S.C. §§ 321 (g) (1) (B) and 355 (1996).

However, during the mid-1980s companies began making disease-specific claims about foods with increasing frequency and without the approval of the FDA. See House Rep. At 9. In response, Congress amended the FDCA through enactment of the Nutrition Labeling and Education Act ("NLEA") on November 2, 1990. Pub. L.No. 101-535, 104 Sat. 2353 (1990). Passage of NLEA was intended to address concerns that the FDA had brought "virtually no enforcement actions" against the types of claims it had previously prohibited by clarifying and strengthening "the [FDA's] legal authority…to establish the circumstances under which claims may be about the nutrients in foods." House Rep. At 7,9.

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[3] "Food" is defined, in part, as "articles used for food or drink." 21 U.S.C. § 321 (f) (1). "Drugs" are defined, in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease." 21 U.S.C. § 321 (g) (1) (B).

[4] A "label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321 (k)

The NLEA liberalized the FDCA to permit health claims to be "made in the label or labeling of [a] food which expressly or by implication…characterizes the relationship of any nutrient…to a disease or a health-related condition." 21 U.S.C. § 343 (r) (1) (B). However, Congress clearly stated that the NLEA and FDA regulatory standards were to concern "only nutrients or substances in foods that 'nourish' and…[not] other, non-nutritive substances in foods." House Rep. At 7. Congress delegated to the FDA the task of developing a procedure and standard for approving health claims for dietary supplements, providing the health claims

> made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances…shall be subject to a procedure and standard, respecting the validity of such a claim, established by regulation of the Secretary.

21 U.S.C. § 343 (r) (5) (D). Thus, under the NLEA, a dietary supplement health claim is not automatically subject to the FDCA's far more extensive and demanding approval and labeling requirements for drugs so long as the claim is made in accordance with other sections of the statute, including 21 U.S.C. § 343 (r) (5) (D).

In 1993, the FDA responded to the NLEA by promulgating 21 C.F.R. §§ 101.70, which explained the standards and

procedures for FDA consideration of nutrient-disease claims. The FDA chose the same standard for authorizing dietary supplement health claims as the NLEA prescribed for authorizing food health claims—significant scientific agreement. See 21 C.F.R. §§ 101.14.[5] In requesting authorization for a health claim, a party first submits a petition with the proposed health claim, accompanied by supporting evidence. See id. §§ 101.70.(a)-(i). The FDA must then notify the applicant within 100 days whether the request will be denied or else "filed" for further review. See id. § 101.70 (j) (2). If further review is warranted, within the next 90 days the FDA must either deny the petition or publish a proposed regulation authorizing the health claim. See id. § 101.70 (j) (4).

In 1994, Congress passed the Dietary Supplement Health and Education Act of 1994 ("DSHEA"), Pub. L. No. 103-417,

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[5] In 1999, The court of Appeals for the District of Columbia ordered the FDA to further define the "significant scientific agreement" standard for evaluating dietary supplement health claims. Pearson v. Shalala, 164 F. 3d 650, 655 (D.C. Cir. 1999). In response, the FDA issued "Guidance for the Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements." Available at http://www.cfsan.fda.gov/`dms/ssaguide.html ("Guidance Report"). The Guidance Report stated that significant scientific agreement meant "the validity of the relationship is not likely to be reversed by new and evolving science, although the exact nature of the relationship may need to be refined." Id. At 2.

108 Stat. 3425 (1994), to further recognize "the importance of nutrition and the benefits of dietary supplements to health[6] promotion and disease prevention. " Id. At § 2 (2). The DSHEA clarified the FDA's role in authorizing health claims by creating a "rational Federal framework…to supersede the current ad hoc, patchwork regulatory policy on dietary supplements" to protect consumers' right of access to "safe dietary supplements…to promote wellness." ID. At § 2 (15). Passage of the DSHEA attempted to further clarify the authorization of dietary supplement health claims by

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[6] The FDCA definitions of "drug," and "dietary supplement," as amended by the NLEA and the DSHEA, are set forth in § as follows:

> (g) (1) THE term "drug" means…(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals…A food or dietary supplement for which a claim, subject to…sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343 (r) of this title is not a drug solely because the label or the labeling contains such a claim.
>
> (ff) The term "dietary supplement"—
> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:…(C) an herb or other botanical…
> Except for purposes of [drug definition at §321 (g)], a dietary supplement shall be deemed to be a food within the meaning of this Act.

including within the FDCA a dietary supplement definition and an amended drug definition.[7]

B. Procedural History

On May 25, 1999, Plaintiffs filed a health claim petition with the FDA seeking approval for the labels of saw palmetto supplements [7] to include the following health claim:

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

Administrative Record (A.R.") at 21-22. In accordance with FDA regulations, Plaintiffs included scientific evidence supporting their claim. See A. R. at 121-397. Plaintiffs also requested that the FDA "approve the claim with such disclaimer or disclaimers as the agency reasonably deemed necessary to avoid any potentially misleading connotation." A.R. at 10; see Pearson v. Shalala, 164 F3d 650 (D.C. Cir. 1999) (Because the First Amendment favors speech disclosure over speech suppression, the FDA many not completely ban potentially misleading health claims but sho8uld allow such claims with an appropriate disclaimer.).

[7] Specifically, the saw palmetto in Plaintiffs' dietary supplements is the n-hexane lipidosterolic extract of the pulp and seed (fruit) of the dwarf American palm, Seronoa repens. A.R. at 10.

On June 7, 1999, the FDA acknowledged receipt of the Plaintiffs' health claim petition, and on September 1, 1999, the FDA accepted the petition for filing. See A. R. at 398, 406. The Plaintiffs' petition was denied under operation of law on December 1, 1999, because the FDA allowed 90 days to pass without issuing a decision. See A.R. at1175. The FDA stated that the denial was necessary because the prescribed time frame was insufficient to resolve the "important and novel issue…whether health claims for foods (including dietary supplements) may encompass [a claim of an effect on an existing disease] or whether such a claim is appropriate only on a product that has been shown to meet the safety and efficacy requirements for drugs." Id.

On December 7, 1999, the Plaintiffs filed this suit seeking declaratory and injunctive relief in light of the FDA's denial of their health claim petition. The action was stayed pending FDA reconsideration of its decision, and on April 4, 2000, the FDA held public hearings to determine whether the Plaintiffs' saw palmetto claim was a health claim or a drug claim under the FDCA. Upon consideration of the hearings and other comments, the FDA issued a formal letter on May 26, 2000, providing further explanation of its refusal to process the Plaintiffs' saw palmetto petition. See A.R> at 721.

The FDA concluded that "claims about effects on existing diseases do not fall within the scope of the health claims provision in 21 U.S. C. § 343(r) and therefore may not be the subject of an authorized health claim." A.R. at 723. With regard to Plaintiffs' proposed health claim, the FDA found that

> [The] petition clearly identifies the intended use of saw palmetto extract products bearing that proposed claim as the treatment of the urinary symptoms of BPH. The proposed model claim explicitly describes the mitigation of disease by treating its symptoms and establishes the intended use of products bearing the claim as drugs.

A.R. at 728. The FDA stated that its decision was based on the language and legislative history of the FDCA, prior agency interpretations of claims to treat disease, and concern that men would miss early diagnosis of prostate cancer by self-medicating with saw palmetto.

II. Standard of Review

A complaint should not be dismissed for failure to state a claim "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957); Davis v. Monroe County Bd. of Educ., 526 U.S. 629, 654 (1999). To that end, the complaint is construed liberally in the plaintiffs' favor, and the court grants plaintiffs the benefit of all inferences that can be

derived from the facts alleged. Shear v. National Rifle Ass'n. of Am., 606 F.2d 1251, 1253 (D.C. Cir. 1979). However, the court need not accept inferences drawn by plaintiffs if such inferences are unsupported by the facts set out in the complaint, nor must the court accept legal conclusions cast in the form of factual allegations. Kowal v. MCI Communication Corp., 16F.3d 1271, 1276 (D.C. Cir. 1994) (internal citation omitted).

III. Analysis

Plaintiffs argue that the central issue in this case is whether the FDA may deny their petition and indefinitely suppress the saw palmetto health claim. Plaintiffs contend that the FDA's refusal to evaluate the claim under 21 U.S. C. § 343 (r)(5)(D) violated both the FDCA and the APA and constitutes a blanket ban on commercial speech in violation of the First Amendment. Plaintiffs argue that a claim made n accordance with § 343 (r) (5) (D) is a health claim for a dietary supplement and cannot be regulated by the FDA as a drug claim because Congress clearly intended health claims to include any nutrient-disease claim not just risk reduction claims.

However, Defendants argue that when reading the health claims provision in the context of the entire FDCA, Congress

never intended to limit the statute's central purpose of drug regulation. Thus, Defendants contend that the statute only allows health claims regarding disease prevention and mandates denial of any claims falling outside that scope—i.e, claims containing a non-preventative intent included in the FDCA's drug definition, such as providing treatment for an existing disease. Defendants argue that the FDA's statutory construction violates neither the FDCA nor the APA because the FDCA's definitions for dietary supplements and drugs are not mutually exclusive. Furthermore, Defendants argue that the FDA's decision to ban Plaintiffs' saw palmetto claim, a given its classification as a drug claim, is in accordance with First Amendment principles for government regulation of commercial speech.

A. The FDA's Determination That It May Authorize Only Those Health Claims Regarding Disease Prevention Violates Neither the FDCA Nor the APA.

Plaintiffs contend that the FDA's classification of the saw palmetto claim as a drug claim violates both the FDCA and the APA because the health claims provision in § 343 (r) (1) (B) precludes dietary supplement claims from being categorized as drug claims under § 321 (g) (1). This argument presents an issue of statutory interpretation governed by the well-known analytic framework set forth in Chevron USA inc., V. Natural Resources Defense Council,

Inc., 467 U.S. 837, 843-45 (1984). Accord Young v. Community Nutrition Institute, 476 U.S. 974, 980-811 (1986) applying Chevron analysis to the FDA's interpretation of the FDCA).

Under step one of the Chevron analysis, the court asks "whether Congress had directly spoken to the precise question at issue." Id., 467 U.S. at 842. If the intent of Congress is clear, "That is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id., 467 U.S. at 842-43. However, if the statute is "silent or ambiguous with respect to the specific issue," the court proceeds to step two of the Chevron analysis and asks "whether the agency's answer is based on a permissible construction of the statute." Id., 467 U.S. at 843. Thus, to hold the FDA's present interpretation of the FDCA erroneous, the court must "conclude that [the FDA's] interpretation either ran athwart a clear mandate of the Congress, or was an unreasonable one." Troy Corporation v. Browner, 120 F3d 277, 283 (D.C. Cir. 1997).

1. Chevron Step One

Turning to the first stage of the Chevron analysis, the Court must determine whether Congress expressed clear intent regarding the proper scope of health claims allowed under

the FDCA. In determining congressional intent, a court must employ "Traditional tools of statutory construction," including "the statute's text, legislative history, and structure, as well as its purpose." Bell Atlantic Telephone Companies v. F.C.C., 131 Fd 1044, 1047 (D.C. Cir. 1997).

The language of §343 (r) (1) (B) provides that a health claim for a dietary supplement is a claim that "characterizes the relationship of any nutrient…to a disease or health-related condition." 21 U.S.C. § 343 (r) (1) (B). Plaintiffs contend that by enacting U.S.C. § 343 (r) (1) (B), Congress clearly intended health claims for dietary supplements to include an nutrient-disease claim and did not intend to limit these claims to disease risk reduction claims. However, Defendants argue that, when read in the context to the whole FDCA, it is clear that Congress never intended U.S.C. § 343 (r) (1) (B) to limit the statute's core function of drug regulation. See F.D.A. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132-133 (2000) (When determining whether Congress has specifically addressed the question at issue, "the words of a statute must be read…with a view to their place in the overall statutory scheme.") (internal citation s and quotations omitted). Defendants thus argue that Congress intended the

FDA to evaluate the validity of a health claim under both the dietary supplement and drug provision of the FDCA.

Accordingly, the Court must examine not only the language of U.S.C. § 343 (r) (1) (B) but also the provision regarding the FDA health claim approval and other relevant definitions. Approval of a dietary supplement health claim "shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary [of the FDA]." U.S.C. § 343 (r) (5) (d). A dietary supplement is a product "intended to supplement the diet that bears or contains…an herb or other botanical" that will be deemed a food "[e]xcept for purposes of [the drug definition at § 321 (g)]." U.S.C. § 321 (ff) (1) (c). A drug is a product "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321 (g) (1) (B). While § 343 (r) (5) (d) clearly indicates that the FDA has authority to determine the standards regarding health claims for dietary supplements, it is unclear how those standards affect the approval of health claims for products that treat an existing disease.

Plaintiffs argue that if the dietary supplement definition is not read to supersede the drug definition, all health claims could be regulated as drugs given their

intended use for "prevention of disease." However, Congress rejected Plaintiffs' view when it refused to add a provision onto the DSHEA's drug definition stating that, subject to certain exceptions, "[t]he term 'drug' does not include a dietary supplement as defined in paragraph (ff)…" 140 Cong. Rec. S11706 (daily ed. Aug. 13, 1994). See also U.S. v. Ten Cartons, More or Less, of an Article Ener-B Vitamin B-12, 72 F.3d 285, 287 (2d Cir. 1995) (A product deemed a dietary supplement under § 321 (ff) could also be classified a s a drug under § 321 (g) (1) because Congress considered and rejected the provision to exclude dietary supplements from drug classifications.). Thus, Plaintiffs' argument has little force. See INS v. Cardoza-Fonseca, 480 U.S. 442-43 (1987) ("Few principles of statutory construction are more compeling than the poposition that Congress does not intend sub silentio to enact statutory language that it has earlier discarded in favor of thoer language.") (internal citations and quotations omitted).

Plaintiffs also contend that congressional intent to restrict health claims from classification as drug claims is found in other language added to the drug definition by the DSHEA, stating that

> A food or dietary supplement of which a claim, subject to…sections 343 (r) (1) (B) and 343 (r) (5) (D) of this title, is made in accordance with the requirements of

> section 343 (r) of this title is not a drug solely because the label or the labeling contains such a claim.

21 U.S.C. § 321 (g) (1). However, Defendants argue that the term "solely" indicates that Congress still intended the FDA to retain its long-established discretion to classify a claim as a drug claim if it provided adequate grounds for the classification.

In this case, the FDA has provided a further explanation for its decision to classify Plaintiffs' claim as drug claim—i.e., the proposed claim goes beyond risk reduction and purports to treat a disease. The FDA argues that because FDCA's definitions for dietary supplements and drugs are not mutually exclusive, it is authorized to determine that health claims for dietary supplements are actually drug claims when the claim is directed at disease treatment. See Bell Atlantic Telephone Co., 131 F.3d at 1048 (When attempting to understand "the relationship between tow different provision within the same statute, [a court] must analyze the language of each to make sense of the hole [statute]."). Congress' intent regarding the scope of health claims is not clear on the face of the FDCA, as amended by the NLEA and the DSHEA, given the interconnectedness of the statute's provision.

Unfortunately, the legislative histories of the FDCA, NLEA, and DSHEA do not demonstrate a clear congressional intent with regard to the appropriate scope of health claims. There is no question that the legislative intent behind enactment of the original FDCA was to protect the p8blic from unsafe drugs. See U.S. v. Undetermined Quantities of…Veterinary Drug, 22F.3d 235, 238 (10th Cir. 1994) (citing U.S. v. Article of Drug…Bacto-Unidisk, 394 U.S. 784, 789 (1969) (Provisions of the FDCA are to liberally construed consistent with the Act's overriding purpose of protecting public health.).

In amending the FDCA through the NLEA, Congress created a framework for authorization of health claims but also delegated full authority to the FDA to adopt whichever standard the agency deemed most appropriate for approving such claims. See 136 Cong. Rec. H12953 (Oct. 26, 1990) (The House Floor Manager stated that "the FDA is given the discretion to define both the procedure and the standard [for approving health claims] because the principals in the Senate could not agree."). While the NLEA provided the statutory authority for authorizing health claims, it clearly gave the FDA wide discretion in approving such claims. See House Rep. At 8 (Health claims "may not be made

unless [they are] consistent with a final regulation issued by the FDA.").

Nor do the DSHEA amendments demonstrate any clear congressional intent with respect to the specific scope of health claims. Here too, the legislative history is ambiguous. It is clear that Congress intended the FDA to establish a more principled regulatory framework for authorizing health claims in order to provide consumers with more access to such information. Pub. L. No. 103-417, 108 Stat. 4325 at § 2 (15). However, Congress specifically stated that the amendments were added to recognize "the Benefits of dietary supplements to health promotion and disease prevention." Id.at § 2 (2) (emphasis added).

Furthermore, Congress issued a Statement of Agreement for the DSHEA that compromised the amendments' "entire legislative history." 140 Cong. Rec. § 14801 (Oct. 7, 1994). The sponsors of the bill intended "that no other reports or statements be considered as legislative history for the bill." Id. Because the Statement of Agreement provides explanations for only four DSHEA amendments and does not include any statement regarding the appropriate scope of health claims, the Court finds that the Statement of Agreement further demonstrates an overall lack of specific intent regarding the meaning of the DSHEA

amendments in the context of the whole FDCA. See also Pharmanex v. Shalala, 221 F3d 1151, 1158 (10th Cir. 2000) (The court found that the meaning of DSHEA provision were "not elucidated, but rather [became] less clear" by the Statement of Agreement.).

In this case, the Court finds an absence of a clear congressional intent with respect to the appropriate scope of health claims. Given the ambiguity inherent in the FDCA's intertwined definitions for drugs and dietary supplements, the lack of decisive legislative history, and the FDCA's S dual function of regulating both drugs and dietary supplements, the Court determine that "Congress has [not] directly spoken to the precise question at issue." Chevron, 467 U.S. at 842.

2. Chevron Step Two

Because the Court has determined that the intent of Congress with respect to the scope of health claims is ambiguous, analysis of the FDA's decision under the second stage of Chevron is required. In the second stage, a court must evaluate the same text, history, and purpose used in the first stage, but instead of determining "whether these convey a plain meaning that requires a certain interpretation," the court will determine "whether these permit the interpretation chosen by the agency." Bell

Atlantic Telephone Co., 131 F3d at 1049 (emphasis in original). At stage two, a court "need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question originally had arisen in a judicial proceeding." Chevron, 467 U.S. at 843 n.11. The court need merely find that the agency's choice is a rational one. See Young, 467 U.S. at 981 (The FDA's interpretation of an ambiguous FDCA provision was sufficiently rational "To preclude a court from substituting its judgment for that of the FDA.").

Courts have long upheld FDA decisions to classify products a drugs based on their intended use. See Action on Smoking and Health v. Harris, 655 F2d 235 (D.C. Cir. 1980) (The FDA's refusal to classify cigarettes as a drug was not arbitrary and capricious because Plaintiffs had failed to prove that the manufacturers had expressed an intent covered by the FDCA's drug definition.); National Nutritional Foods Assoc. v. Mathews, 557 F2d 325, 333 (2d Cir. 1977) (The "vendor's intent in selling the product to the public is the key element" in the FDCA drug definition.).

Furthermore, courts have found that because the FDCA definitions of dietary supplements and drugs are not mutually exclusive, FDA regulation may properly focus on

intent. See Ten Cartons…Ener-B Vitamin B-12, 72 F.3d at 287 (The FDA may regulate an article as a drug pursuant to § 321 (g) (1) © whether or not is a "dietary supplement" within the meaning of § 321 (ff).); U.S. v. Writers & Research, Inc., 113 F.3d 8 (2d Cir. 1997) (A homeopathic substance is subject to FDCA requirements for drugs if it is promoted as a treatment or cure for an existing disease.).

Plaintiffs argue that the FDA has already interpreted the FDCA to allow health claims for disease treatment. For example, one f five model health claims suggested by the FDA for the dietary fat and cholesterol-coronary heart disease relationship states that a "healthful diet low in saturated fat, total fat, and cholesterol…may lower blood cholesterol levels and may reduce the risk of hear disease." 21 C.F.R. 101.75 (e) (3) (2002). Plaintiffs contend that this health claim goes beyond risk prevention because it includes a claim to lower blood cholesterol, which is treating an existing disease. See also 21 C.F.R. 101.77 (E)(2) (2002) (A model dietary fiber-coronary heart disease health claim also states that eating a diet high in dietary fiber "may lower blood cholesterol levels and reduce your risk of heart disease."). However, Defendants argue that these claims are primarily concerned with risk reduction of heart disease, not the treatment of an existing disease. In fact, the

FDA's rulemaking clearly stated that these claims liked "dietary factors to heart disease risk via the intermediate mechanism of reducing blood LDL-cholesterol levels." 58 Fed.Reg. 2552, 2573 (1993) (emphasis added).

Moreover, report relied upon by Congress in enacting the NLEA clearly focused on the role of diet in reducing disease risk, not in treating an existing disease. See House Rep. At 9 (referring to the Surgeon General's "Report on Nutrition and Health" (1988) for the argument that certain diets "can reduce the risk of chronic disease") and 13-14 (relying upon the National Research Council's "Diet and Health Implications for Reducing Chronic Disease Risk" (1989) (emphasis added).

In this case, the FDA concluded that the Plaintiff's health claim indicated that saw palmetto's intended use was purely pharmacological. The proposed claim addresses only BHP symptom treatment and does not include any claim of disease prevention, bolstering FDA concerns that approval of the claim would not provide an adequate level of protection to vulnerable consumers. In fact, the FDA previously withdrew over-the-counter approval for saw palmetto by concluding the while "saw palmetto 'probably' provides some 'minimal' [BHP] symptomatic relief" it was concerned that "as long as only the symptoms of the disease [were]

relieved, men with BHP may be lulled into a false sense of security" and postpone medical examinations necessary for treatment of BHP, diagnosis of secondary complications, and screening for prostate cancer. A.R. at 729 (citing to 55 Fed. Reg. 6929 (1990)).

The FDCA, as amended by the NLEA and the DSHEA, establishes both the FDA's authority to regulate drugs and dietary supplements and the FDA's responsibility to protect consumers. The FDA has decided that approval oaf a health claim with a purely pharmacological al purpose would not provide an adequate level of consumer protection. AS the language, structure, and legislative history of the FDCA do not clearly state the appropriate scope of health claims for dietary supplements, the Court finds the FDA's decision to limit approved health claims to those involving disease risk reduction is both permissible and reasonable under the second stage of the Chevron analysis.

3. The APA

Under the APA, an agency's action may be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not accordance with law." 5 U.S.C. § 706 (2) (A). In making this finding, the court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of

judgment." Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 401, 416 (1971). The court's role is to ensure that the agency's decision was based on relevant factors and not a "clear error of judgment," not substitute its judgment for that of the agency. Id., 401 U.S. at 416. If the "agency's reasons and policy choices…conform to certain minimal standards of rationality…the rule is reasonable and must be upheld." Small Refiner Lead Phase-Down Task Force v. EPA, 705 F2d 506, 521 (D.C. Cir. 1983) (citation omitted.) This standard presumes the validity of agency action. Ethyl Corp. v. EPA, 541 F3d 1, 34 (D.C. Cir. 1976) (en banc), cert. Denied, 426 U.S. 941 (1976).

As explained above, the FDA has provided an adequate rationale for its determination that the FDCA, as amended by the NLEA and the DSHEA, authorizes the FDA to deny health claims aimed primarily at treatment for an existing disease. There, the FDA's decision to deny the saw palmetto claim as a drug claim, given it intended treatment of BHP, was neither arbitrary nor capricious. In addition, since the FDA's interpretation of the FDCA was permissible under the two-step analysis of Chevron, its decision was not contrary to law. Accordingly, the FDA did not violate the APA in denying Plaintiffs' saw palmetto health claim petition.

B. The FDA's Decision to Deny Plaintiffs' Health Claim Does Not Violate the First Amendment

Plaintiffs argue that the saw palmetto claim is either scientific or commercial speech protected by the First Amendment. However, it is "undisputed that [] restrictions on [] health claims are evaluated under the commercial speech doctrine. " Pearson, 164 F.3d at 655 (citing Bolger v. Youngs Drug Prod. Corp., 463 U.S. 60, 67-68 (1983)). Therefore, the FDA's refusal to authorize Plaintiffs' proposed claim must be evaluated under the analytical framework established in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York, 447 U.S. 557 (1980). See also Thompson v. Western States Med. Ctr., U.S., 122 S.Ct. 1497 (2002) (applying the Central Hudson analysis to FDA regulations concerning advertising and promotion of compounded drugs).

Under Central Hudson, the reviewing court must conduct a four-part analysis for evaluating legislative restrictions on commercial speech. First, the court must determine whether the expression is protected by the First Amendment – i.e., whether "The speech concerns lawful activity and is not misleading." Western States, 122 S.Ct at 1504. A complete ban on commercial speech is only appropriate where the government proves the "The expression itself was flawed

in some way, either because it was deceptive or related to unlawful activity." Central Hudson, 477 U.S. at 566 n.9. If the speech is protected, the court must determine "whether the asserted government interest is substantial, the court must determine "whether the regulation directly advances the governmental interest asserted." Central Hudson, 447 U.S. at 566. Finally, the court must determine "Whether [the regulation] is not more extensive than is necessary to serve that interest." Central Hudson, 447 U.S. at 566.

Plaintiffs argue that the FDA's denial of the Saw palmetto health claim cannot meet the Central Hudson test as articulated by Pearson, because it impermissibly restricts commercial speech by not allowing "the Plaintiffs' health claims to be made wit such disclaimers as are reasonably necessary to avoid a misleading connotation." Pls.' Mot. For Summary J. at 42. While the Pearson decision did restrict FDA regulation of potentially misleading speech in health claims, Plaintiffs mistakenly construe the FDA's current decision to deny the saw palmetto health claim petition as a decision base on misleadingess. In this case, the court has determined that the FDA has reasonably interpreted the FDCA to conclude "claims about the effects on existing disease do not fall within the scope of the

health claim provision in 21 U.S. C. § 343 (r) and therefore may not be the subject of an authorized health claim." A.R. at 723. Because the FDA determined that the saw palmetto claim was drug claim for disease treatment, it concluded that the claim was an unlawful health claim and thus denied Plaintiffs' petition.

As there is no doubt that unlawful speech can be banned under the first step of the Central Hudson analysis, the FDA's prohibition of Plaintiffs' saw palmetto claim does not violate the First Amendment. See id., 447 U.S. at 563-64 ("[T]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban…commercial speech related to illegal activity."); 44 Liquormart, Inc. v. Rhode Island, 517 U.S> 484, 497 n.7 (1996) ("[T]he First Amendment does not protect commercial speech about unlawful activities.").

IV. Conclusion

The FDA's denial of Plaintiffs' saw palmetto claim did not violate the FDCA, APA, or First Amendment. The FDA's interpretation of the various provisions of the FDCA to permit only disease prevention health claims was reasonable given the ambiguity of the statute; therefore, its decision

to deny Plaintiffs' claim based on this interpretation is neither arbitrary nor capricious nor contrary to law. For the reasons discussed above, Plaintiffs' Motion for Summary Judgment is **denied** and Defendants' Motion to Dismiss is **granted.** An Order will issue with this Opinion.

January 3, 2003
Date

/s/Gladys Kessler
Gladys Kessler
United States District Judge

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