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Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: First Amendment Issues
Docket No. 02N-0209
67 Fed. Reg. 34942 (May 16, 2002)

The attached comments are submitted on behalf of the Grocery Manufacturers of America (GMA) specifically to address the First Amendment requirement that FDA permit in conventional food labeling the same qualified disease claims that the agency permits in dietary supplement labeling. GMA will submit additional comment on other First Amendment issues prior to July 30, 2002.


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The D.C. Circuit's Opinion in Pearson v. Shalala
and the First Amendment to the U.S. Constitution
Require FDA to Permit in Conventional Food Labeling
the Same Qualified Disease Claims
That It Permits in Dietary Supplement Labeling

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The D.C. Circuit's Opinion in Pearson v. Shalala
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Require FDA to Permit in Conventional Food Labeling
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That It Permits in Dietary Supplement Labeling

This white paper explains that the opinion of the United States Court of Appeals for the District of Columbia in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), rehearing denied, 172 F.3d 72 (D.C. Cir. 1999) (en banc), and decisions in proceedings subsequent to remand, such as Pearson v. Shalala, 130 F. Supp. 2d 105 (D.D.C. 2001) (Memorandum Opinion), and the First Amendment of the United States Constitution, require the Food and Drug Administration (FDA) to permit in conventional food labeling the same disease claims¹ that it permits in dietary supplement labeling. It also explains that the Agency has both the obligation and the authority to interpret and

¹ FDA generally refers to claims authorized by section 403(r)(1)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as "health" claims. We refer to them as "disease" claims to distinguish them from structure/function claims and because section 403(r)(1)(B) defines such claims as characterizing "the relationship of any nutrient . . . to a disease . . ."

apply the Federal Food, Drug, and Cosmetic Act (FD&C Act)² in a constitutional manner.

Section I explains the governing law and the FDA decisions to permit qualified disease claims on dietary supplement labeling under an "enforcement discretion" policy announced on October 6, 2000.³ Section II explains that FDA must permit these qualified disease claims on conventional food labeling, pursuant to Pearson v. Shalala. Failure to approve the qualified disease claims for conventional food labeling would contravene the decision in Pearson and would violate the First Amendment to the United States Constitution. Section III explains that FDA has the obligation to interpret and apply the statute in a constitutional manner, that the exercise of enforcement discretion in this instance lies within the Agency's discretion, and that it has precedent in the Agency's past practices.

The claims at issue are the following:

- Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect. The Institute of Medicine of the National Academy of Sciences recommends that

² 52 Stat. 1040 (1938), as amended, 21 U.S.C. § 301 et seq.

³ 65 Fed. Reg. 59855 (October 6, 2000).

women capable of becoming pregnant consume 400 mg of folate daily from supplements, fortified foods, or both, in addition to consuming food folate from a varied diet.⁴

- 0.8 mg folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form. FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic and daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects.⁵
- The scientific evidence about whether omega-3 fatty acids may reduce the risk of coronary heart disease (CHD) is suggestive, but not conclusive. Studies in the general population have looked at diets containing fish and it is not known whether diets or omega-3 fatty acids in fish may have a possible effect on a reduced risk of CHD. It is not known what effect omega-3 fatty acids may or may not have on risk of CHD in the general population.⁶
- Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is scientific evidence supporting the claim, the evidence is not conclusive.⁷

⁴ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (October 10, 2000). "'Folate' is the generic term for all forms of the vitamin and includes both naturally occurring 'food folate' and the synthetic form of 'folic acid' that is added to fortified food and dietary supplements." Id.

⁵ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (April 3, 2001) (Docket No. 91N-100H).

⁶ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (October 31, 2000) (Docket No. 91N-1013).

⁷ Letter from Christine J. Taylor (FDA) to Jonathan W. Emord (February 8, 2002) (Docket 91N-0103).

- It is known that diets low in saturated fat and cholesterol may reduce the risk of heart disease. The scientific evidence about whether folic acid [folate], vitamin B₆, and vitamin B₁₂ may also reduce the risk of heart disease and other vascular diseases is suggestive, but not conclusive. Studies in the general population have generally found that these vitamins lower homocysteine, an amino acid found in the blood. It is not known whether elevated levels of homocysteine may cause vascular disease or whether high homocysteine levels are caused by other factors. Studies that will directly evaluate whether reducing homocysteine may also reduce the risk of vascular disease are not yet complete.⁸
- As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B₆ and Vitamin B-12 may reduce the risk of vascular disease. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.⁹

I. Background

A. **The Nutritional Labeling and Education Act of 1990 Required FDA to Permit Disease Claims on Dietary Supplements and Conventional Foods.**

The Nutrition Labeling and Education Act of 1990 (NLEA)¹⁰ amended the FD&C Act to permit the use of disease

⁸ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (November 28, 2000) (Docket No. 99P-3029).

⁹ CFSAN Office of Nutritional Products, Labeling, and Dietary Supplements, "Settlement Reached for Health Claim Relating B Vitamins and Vascular Disease" (May 15, 2001), available at <http://www.cfsan.fda.gov/~dms/ds-hclbv.html>.

¹⁰ 104 Stat. 2353 (1990).

claims in food labeling. For these purposes, a disease claim is a claim in the label or labeling of a food that "expressly or by implication . . . characterizes the relationship of any nutrient . . . to a disease . . ." ¹¹

Under the NLEA, FDA must approve a disease claim for conventional food if it finds that "based on the totality of the publicly available scientific evidence . . . there is significant scientific agreement, among experts, . . . that the claim is supported by such evidence." ¹² A conventional food manufacturer may not use an NLEA disease claim in its labeling unless and until FDA promulgates a regulation authorizing that claim. ¹³ (Use of a disease claim in the absence of an authorizing regulation constitutes misbranding under section 403 of the Act.) The NLEA did not define "significant scientific agreement."

While the NLEA prescribed a standard for FDA's review of disease claims for conventional foods, it did not prescribe a standard for disease claims in dietary supplement labeling. Instead, Congress provided that such

¹¹ FD&C Act § 403(r)(1)(B), 21 U.S.C. § 343(r)(1)(B).

¹² FD&C Act § 403(r)(3)(B), 21 U.S.C. § 343(r)(3)(B).

¹³ FDA has authorized twelve disease claims under the "significant scientific agreement" standard. These claims may be made in both conventional food labeling and dietary supplement labeling. 21 C.F.R. §§ 101.72-101.83.

a claim would be "subject to a procedure and standard" established by FDA in a regulation.¹⁴

B. FDA Chose to Apply the Same "Significant Scientific Agreement" Standard to Both Conventional Food and Dietary Supplements.

FDA split the rulemaking on conventional food disease claims from the rulemaking on dietary supplement disease claims after enactment of the Dietary Supplement Act of 1992.¹⁵

Foods. In January 1993, FDA adopted final regulations implementing the NLEA with respect to disease claims on conventional foods.¹⁶ In these regulations, FDA explained briefly what was meant by the "significant scientific agreement" standard and how it would assess conformity to that standard.¹⁷ In particular, FDA stated that it would authorize a disease claim only if it determined:

based on the totality of publicly available scientific evidence

¹⁴ FD&C Act § 403(r)(5)(D), 21 U.S.C. § 343(r)(5)(D).

¹⁵ The Dietary Supplement Act of 1992 (DS Act), 106 Stat. 4491, 4500 (1992), imposed a moratorium on implementation of NLEA with respect to dietary supplements until December 15, 1993. NLEA had directed FDA to consider ten specific disease claims. These claims were exempt from the moratorium.

¹⁶ 58 Fed. Reg. 2478 (January 6, 1993).

¹⁷ Id. at 2503-2509.

(including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles) that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.¹⁸

Rather than flesh out the evidentiary requirement, FDA announced it would "make case-by-case determinations."¹⁹ FDA stated that it would not permit disease claims "based only on preliminary data," even if those claims accurately disclosed the preliminary nature of the data.²⁰ FDA lacks the authority, the Agency claimed, to permit preliminary disease claims "that are qualified by an explanation that a difference of scientific opinion exists."²¹

Dietary Supplements. In the rulemaking addressing the general requirements for disease claims in dietary supplement labeling, FDA decided to use the same "significant scientific agreement" standard -- and associated procedures -- as applied by statute to

¹⁸ Id. at 2503; 21 C.F.R. § 101.14(c).

¹⁹ 58 Fed. Reg. at 2504; id. at 2506.

²⁰ Id. at 2504.

²¹ Id. at 2505.

conventional foods.²² FDA has consistently characterized that decision as a decision to adopt "the same standard" for both types of food.²³ Indeed, to support its decision to use the same standard, FDA cited both the need to eliminate consumer confusion²⁴ and the need for "fairness" as between dietary supplement and conventional food manufacturers.²⁵

²² 59 Fed. Reg. 395 (January 4, 1994) (final rule); 56 Fed. Reg. 60537 (November 27, 1991) (first proposed rule); 58 Fed. Reg. 33700 (June 18, 1993) (second proposed rule). The first disease claims proposal pertained to dietary supplements as well as to conventional foods. After Congress passed the DS Act in 1992, FDA finalized the rule as to conventional foods and issued a new proposal pertaining to dietary supplements.

²³ E.g., Brief for Appellees in Pearson v. Shalala (No. 98-5043) (D.C. Cir.) at 6 ("FDA proposed using the same standard for dietary supplements that Congress in the NLEA mandated for all other foods -- i.e., the 'significant scientific agreement'"); id. at 8 (In 1992, "the Agency reissued proposed regulations for dietary supplement health claims, again proposing to use the same standard -- significant scientific agreement . . . "); id. ("The Agency concluded that 'subject[ing] dietary supplements to the same standard that applies to foods in conventional form . . . strikes the appropriate balance.'").

²⁴ 56 Fed. Reg. at 60540 ("FDA believes that there would be significant potential for consumer confusion when confronted with a situation in which there would be health claims for substances when they are present in supplements but not when they are present in conventional foods.").

²⁵ 56 Fed. Reg. at 60540 ("FDA has an obligation to treat all segments of the regulated food industry with fairness. If dietary supplements were subject to different rules, whether with respect to the procedure for assessment of conformity with the scientific standard or to the manner in which claims are made, there is a possibility that (continued . . .)

C. FDA Chose to Apply the Same "Significant Scientific Agreement" Standard When the Food and Drug Administration Modernization Act Authorized Disease Claims for Conventional Foods Based on "Authoritative Statements."

In the Food and Drug Administration Modernization Act of 1997 (FDAMA),²⁶ Congress created an alternative to the NLEA process for approval of disease claims in conventional food labeling. The new disease claims provision permits conventional food manufacturers to make disease claims based on "authoritative statements" of qualified federal scientific bodies. So-called "authoritative statement claims" may be made after premarket notification to FDA, rather than approval by FDA. FDA is not required to prescribe the language of the permitted claim, nor is it required to promulgate a regulation authorizing the claim.²⁷

In June 1998, FDA by regulation "overruled" the Congressional mandate of FDAMA, by declaring that it would not permit disease claims on the basis of an "authoritative

supplements could be made to appear somehow superior to conventional foods that contain the same nutrient. Such an appearance would not only be untrue, it would be unfair to firms producing conventional foods.").

²⁶ 111 Stat. 2296 (1997).

²⁷ To date, two authoritative statement disease claims have been permitted.

statement" alone.²⁸ Instead, it wrote, it would incorporate the "significant scientific agreement" standard into the "authoritative statement" premarket notification process. Specifically, FDA stated that it intended "to determine whether the standard of significant scientific agreement is met by a health claim based on an authoritative statement."²⁹ This standard, FDA wrote, would not allow for a claim based on "findings characterized as preliminary results, statements that indicate research is inconclusive, or statements intended to guide further research."³⁰

Although the FDAMA "authoritative statement" standard applies only to conventional foods, FDA has proposed extending it to dietary supplements.³¹

D. In Pearson v. Shalala, the D.C. Circuit Held that FDA May Not Ban Disease Claims Simply Because They Fail to Meet the Significant Scientific Agreement Standard.

The Pearson case established unequivocally that FDA regulation of food labeling is subject to the First Amendment commercial speech doctrine. A disease claim that

²⁸ "Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body" (June 11, 1998).

²⁹ Id. at 2.

³⁰ Id. at 3.

³¹ 64 Fed. Reg. 3520 (January 21, 1999).

does not satisfy the "significant scientific agreement" standard is not inherently false and misleading. The First Amendment does not permit FDA to ban such claims categorically.

The Pearson case arose from FDA's decision not to approve four disease claims for dietary supplements. (The claims were among the ten as to which Congress had mandated a decision in the NLEA.)

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

In January 1993, FDA rejected all four claims for conventional food labeling, based on the lack of significant scientific agreement.³² In October 1993, FDA proposed not to authorize three of the four claims for the

³² 58 Fed. Reg. 2622 (January 6, 1993) (anti-oxidants and cancer); 58 Fed. Reg. 2537 (January 6, 1993) (dietary fiber and cancer); 58 Fed. Reg. 2682 (January 6, 1993) (omega-3 fatty acids and coronary heart disease); 58 Fed. Reg. 2606 (January 6, 1993) (folic acid and neural tube defects).

labeling of dietary supplements.³³ It proposed to authorize a claim relating folic acid to a reduced risk of neural tube defects, for dietary supplements and for foods, although not the comparative claim requested.³⁴ On December 31, 1993, both proposals became final.³⁵ The folic acid regulation, applicable both to foods and to dietary supplements, was modified in 1996.³⁶ The final regulation provides that:

The claim shall not state that a specified amount of folate per serving from one source is more effective in reducing the risk of neural tube defects than a lower amount per serving from another source.

Following the January 1994 denial of the four original claims, the Pearson plaintiffs brought suit in federal district court. They alleged that FDA's final regulations (denying all four claims) were unconstitutional prior restraints in violation of the First Amendment, that they violated the First Amendment commercial speech doctrine, and that they were overbroad in violation of the

³³ 58 Fed. Reg. 53296 (October 14, 1993).

³⁴ 58 Fed. Reg. 53254 (October 14, 1993).

³⁵ 59 Fed. Reg. 395 (January 4, 1994) (dietary fiber, antioxidant vitamins, and omega-3 fatty acids); 59 Fed. Reg. 433 (January 4, 1994) (folate).

³⁶ 61 Fed. Reg. 8750 (March 5, 1996).

First Amendment. Plaintiffs also argued that the final regulations were void for vagueness under the Fifth Amendment. Finally, the Pearson plaintiffs argued that FDA had violated the Administrative Procedure Act³⁷ by failing to adopt a defined standard for "significant scientific agreement" and by arbitrarily and capriciously denying all four claims.

The District Court granted FDA's Motion to Dismiss and denied the Plaintiffs' Motion for Summary Judgment.³⁸ In a strongly worded opinion, the U.S. Court of Appeals for the District of Columbia Circuit reversed the District Court and confirmed that FDA's labeling and advertising regulations are subject to the First Amendment commercial speech doctrine.³⁹ It is "undisputed," the court wrote, "that FDA's restrictions on appellants' health claims are evaluated under the commercial speech doctrine."⁴⁰ FDA conceded as much, but argued in the alternative (1) that disease claims lacking "significant scientific agreement" are inherently misleading and thus entirely outside the protection of the First Amendment, or

³⁷ 5 U.S.C. § 706.

³⁸ Pearson v. Shalala, 14 F. Supp.2d 10 (D.D.C. 1998).

³⁹ Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999).

⁴⁰ Id. at 655.

(2) that even if such claims are only potentially misleading, under the test set forth in Central Hudson Gas & Electric Corp. v. Public Service Commission of New York⁴¹ the government is not obligated to consider requiring disclaimers in lieu of an outright ban.

The D.C. Circuit dismissed the first argument as "almost frivolous."⁴² "We reject it," the court wrote.⁴³ As to the second, the court wrote, protection of public health and prevention of consumer fraud -- the cited bases for the ban -- are admittedly "substantial" government interests.⁴⁴ Nevertheless, "the government's regulatory approach" fails the final two prongs of Central Hudson.⁴⁵

While suppression of disease claims might protect consumers from fraud, it does not directly advance the government's interest in protecting the public health,

⁴¹ 447 U.S. 557 (1980).

⁴² 164 F.3d at 655.

⁴³ Id.

⁴⁴ Id. at 656.

⁴⁵ Id. As explained by the D.C. Circuit, under Central Hudson a court evaluates a government scheme to regulate potentially misleading speech by applying a three-part test. First, the court asks whether the asserted government interest is substantial. Second, the court determines whether the regulation directly advances the government interest asserted. Third, the court determines whether the fit between the government's ends and the means chosen to accomplish those ends is reasonable. 164 F.3d at 655-656.

since FDA does not claim the products themselves are harmful.⁴⁶ And "the difficulty with the government's consumer fraud justification," the court wrote, "comes at the final Central Hudson factor."⁴⁷ There is not a reasonable fit between the government's stated goal (prevention of fraud) and the means chosen to advance it (outright suppression of any disease claims). FDA argued that the commercial speech doctrine does not embody a preference for disclosure over outright suppression. "Our understanding of the doctrine," the court wrote, "is otherwise."⁴⁸ Under Central Hudson, FDA must consider a disclaimer in lieu of an outright ban.⁴⁹ The court invalidated 21 C.F.R. § 101.71(a), 21 C.F.R. § 101.71(c), 21 C.F.R. § 101.71(e), and 21 C.F.R. § 101.79(c)(2)(i)(G), the regulations governing the four disease claims at issue.⁵⁰

⁴⁶ Id.

⁴⁷ Id. at 657.

⁴⁸ Id.

⁴⁹ See also Thompson v. Western States Medical Center, 535 U.S. ____ (2002), where the Court observed that even where there is a substantial risk of patient confusion, the Government must consider whether labeling can alleviate that risk before it imposes an outright ban on accurate and nonmisleading advertising. Slip op. at 18. The Western States decision is discussed in Part II.B.2, *infra*.

⁵⁰ Pearson, 164 F.3d at 661.

The Court of Appeals also held that the Administrative Procedure Act requires FDA to "give some definitional content" to the phrase "significant scientific agreement."⁵¹ On remand, the court held, "FDA must explain what it means by significant scientific agreement, or, at minimum, what it does not mean."⁵²

The Court of Appeals denied rehearing,⁵³ and FDA did not seek review in the Supreme Court.

E. FDA Has Been Slow to Implement the Pearson Ruling.

FDA has been slow to implement the Pearson decision. In addition, at every step it has refused to apply the First Amendment aspects of the ruling to conventional foods.

Announcement of Strategy. On December 1, 1999, over seven months after the mandate issued from the District Court to FDA, FDA announced a "strategy" to implement Pearson.⁵⁴ First, FDA would update the scientific evidence on the four claims at issue in Pearson. Second, FDA would issue a guidance clarifying the "significant

⁵¹ Id. at 660.

⁵² Id. at 661.

⁵³ 172 F.3d 72 (D.C. Cir. 1999).

⁵⁴ 64 Fed. Reg. 67289 (December 1, 1999).

scientific agreement" standard. Third, FDA would hold a public meeting to solicit input on changes to FDA's general disease claim regulation for dietary supplements, 21 C.F.R. § 101.14, that might be warranted in light of Pearson. Fourth, FDA would initiate a rulemaking to reconsider the general disease claim regulation for dietary supplements that might be warranted in light of Pearson. Fifth, FDA would initiate a rulemaking on each of the Pearson claims. FDA also stated that it would deny all other pending disease claims without prejudice if they failed to meet the significant scientific agreement standard, until the disease claim regulation was revised.⁵⁵ FDA made no mention of conventional foods.

Significant Scientific Agreement Guidance. More than seven months after the mandate issued, FDA published a guidance addressing the meaning of "significant scientific agreement."⁵⁶ This document defines the phrase as it applies to disease claims on both dietary supplements and

⁵⁵ 64 Fed. Reg. at 67290.

⁵⁶ 64 Fed. Reg. 71794 (December 22, 1999) (announcing availability of guidance); "Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements" (December 22, 1999).

conventional foods.⁵⁷ Key to this guidance is FDA's insistence that there be significant scientific agreement about the substance/disease relationship rather than significant scientific agreement about the actual claim being made. This is an incorrect interpretation of the disease claim provisions of the FD&C Act and a more narrow restriction of speech than Congress intended. Section 403(r)(3)(B)(i) requires only that a disease claim be supported by significant scientific agreement. It does not require that the relationship between the food substance and the disease condition be established by significant scientific agreement (except to the extent that the claim characterizes the relationship). FDA applies this incorrect guidance to both dietary supplements and conventional foods.

Letter to Congress. In the spring of 2000, FDA took the position in a letter to a Member of Congress that it will not apply the Pearson ruling to conventional foods absent a direct court order. In a letter to Representative David M. McIntosh dated May 16, 2000, FDA wrote:

⁵⁷ Id. at 3 ("This standard applies to conventional foods health claims by statute; FDA applied the same standard to dietary supplement health claims by regulation.")

The claims that were the subject of Pearson were for dietary supplements. The court's mandate did not direct FDA to reconsider any health claims for conventional foods. There is a statutory requirement that FDA authorize health claims for conventional foods only when there is significant scientific agreement that the nutrient-disease relationship is valid. Therefore, absent a court ruling finding the statute unconstitutional, FDA does not have authority to authorize health claims for conventional foods when such a claim would require a disclaimer to render it truthful and nonmisleading. For these reasons, the Pearson implementation strategy announced in the December 1, 1999, Federal Register did not address health claims for conventional foods.⁵⁸

Public Meeting. In April 2000, FDA held a public meeting to solicit comments on two topics pertaining to disease claims in food and dietary supplement labeling. The first issue was whether a disease claim relating to an existing disease (not simply a claim of risk reduction) could properly be authorized under the NLEA disease claim

⁵⁸ Letter from Melinda K. Plaisier (FDA) to the Honorable David M. McIntosh (U.S. House of Representatives) (May 16, 2000). Other statements by FDA officials confirm this to be FDA's stance. For instance, Joseph Levitt, Director of the Center for Food Safety and Applied Nutrition, told a reporter in October 2000 that Pearson and the new interim standard of proof apply only to dietary supplements. "FDA to Allow Dietary Supplement Claims Failing to Meet its 'Gold Standard' Proof," Dietary Supplement and Food Labeling News 1, 8 (October 11, 2000).

process. As to this issue, FDA wrote, its decision would apply to dietary supplements and to conventional foods.⁵⁹ The second issue was how to implement the aspect of Pearson requiring FDA to consider the use of qualified disease claims. As to this issue, FDA wrote, its decision would only apply to dietary supplements:

Unlike the statutory provision for the use of health claims on dietary supplements Section 403(r)(3)(B)(i) of the act provides that FDA may authorize health claims on conventional foods only when there is significant scientific agreement among qualified experts that the totality of publicly available scientific evidence support the claim. As a result of this statutory requirement for conventional foods and because the Pearson case involved only dietary supplements, this portion of the public meeting will be restricted to health claims on dietary supplements.⁶⁰

New Interim Strategy. On October 3, 2000, FDA revoked its regulations codifying its decision not to authorize the Pearson claims.⁶¹ On October 6, 2000, FDA announced a new strategy for disposition of pending dietary

⁵⁹ FDA later determined that such claims are not permissible NLEA disease claims. Letter from Joseph A. Levitt (FDA) to Jonathan W. Emord (Docket No. 99P-3030) (May 26, 2000).

⁶⁰ 65 Fed. Reg. 14219, 14221 (March 16, 2000).

⁶¹ 65 Fed. Reg. 58917 (October 3, 2000).

supplement disease claims.⁶² FDA announced it would use its "enforcement discretion" to decline to take action against a dietary supplement disease claim provided the following conditions are met: (a) the disease claim petition meets FDA requirements for such petitions; (b) the scientific evidence supporting the claim outweighs the scientific evidence against the claim; (c) consumer health and safety are not threatened; and (d) the claim meets the general requirements for a disease claim (i.e., except for the significant scientific agreement standard and the requirement that the claim be made in accordance with an authorizing regulation). If these criteria are satisfied, FDA explained, the Agency will send a letter to the petitioner outlining the Agency's rationale for its determination that the evidence does not meet the significant scientific agreement standard and stating the conditions under which the Agency will ordinarily expect to exercise enforcement discretion regarding the claim.⁶³ FDA stated that this implementation of the Pearson mandate will only apply to disease claims on dietary supplements.

⁶² 65 Fed. Reg. 59855 (October 6, 2000); see also FDA Talk Paper T00-51 (October 11, 2000).

⁶³ 65 Fed. Reg. at 59856.

Application of Interim Standard. Since October

2000, FDA has applied this "interim standard" four times -- in each case, in response to a petition (or lawsuit) from a dietary supplement manufacturer.

1. Fiber. On October 10, 2000, it denied the fiber claim.⁶⁴ This decision has not been challenged.

2. Folic Acid. On October 10, 2000, FDA concluded that the folic acid claim was "inherently misleading" and it declined to authorize the claim even with clarifying disclaimers. Instead, it stated that it would exercise "enforcement discretion" as to the following four alternative claims, each of which recommends that women capable of becoming pregnant consume 0.4 mg (400 mcg) folate daily to reduce the risk of neural tube defects.⁶⁵

Example 1: Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. The Institute of Medicine of the National Academy of Sciences recommends that women capable of becoming pregnant consume 400 mcg folate daily from supplements, fortified foods, or both, in addition to consuming food folate from a varied diet.

⁶⁴ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (Docket No. 91N-0098) (October 10, 2000).

⁶⁵ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (October 10, 2000) (Docket No. 91N-100H).

Example 2: Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. The scientific evidence that 400 mcg folic acid daily reduces the risk of such defects is stronger than the evidence for the effectiveness of lower amounts. This is because most such tests have not looked at amounts less than 400 mcg folic acid daily.

Example 3: Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. Women capable of becoming pregnant should take 400 mcg folate/day from fortified foods and/or a supplement, in addition to food folate from a varied diet. It is not known whether the same level of protection can be achieved by using only food that is naturally rich in folate. Neither is it known whether lower intakes would be protective or whether there is a threshold below which no protection occurs.

Example 4: Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. Women capable of becoming pregnant should take 400 mcg of folate per day from a supplement or fortified foods and consume food folate from a varied diet. It is not known whether the same level of protection can be achieved by using lower amounts.

The petitioners challenged FDA's decision in court. On February 2, 2001, the United States District Court for the District of Columbia concluded in a sharply worded opinion that FDA's denial of the folic acid claim

violated the First Amendment.⁶⁶ The court observed that "FDA simply failed to comply with the constitutional guidelines in Pearson. Indeed, the Agency seems to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals opinion."⁶⁷ The district court declared that FDA's October 10 denial of the folic acid claim violated the First Amendment. The court ordered FDA to draft "one or more short, succinct, and accurate alternative disclaimers" to accompany the folic acid claim.⁶⁸ In a letter dated April 3, 2001, FDA reversed itself and stated it would allow the following claim and disclaimer.

0.8 mg folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form. FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic acid daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects.⁶⁹

⁶⁶ Pearson v. Shalala, 130 F. Supp. 2d 105 (D.D.C. 2001) (Memorandum Opinion).

⁶⁷ Id. at 112.

⁶⁸ Id. at 120 (Order). The court also stated that FDA should respond within 60 days of the decision. Id. at 120.

⁶⁹ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (April 3, 2001) (Docket No. 91N-100H).

3. Omega-3 Fatty Acids. On October 31, 2000, FDA determined that there was no significant scientific agreement as to the relationship between omega-3 fatty acids in dietary supplements and lowered risk of coronary heart disease, and announced that it would exercise "enforcement discretion" as to certain qualified claims describing that relationship.⁷⁰ It offered the following as a sample qualified claim.

The scientific evidence about whether omega-3 fatty acids may reduce the risk of coronary heart disease (CHD) is suggestive, but not conclusive. Studies in the general population have looked at diets containing fish and it is not known whether diet or omega-3 fatty acids in fish may have a possible effect on a reduced risk on CHD. It is not known what effect omega-3 fatty acids may or may not have on risk of CHD in the general population.

Plaintiffs asked the Agency to revisit its October 31 decision in lieu of further litigation. In a response dated February 8, 2002, FDA reversed itself and agreed to modified language.

Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease. FDA evaluated the data and determined that, although there is

⁷⁰ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (October 31, 2000) (Docket No. 91N-0103).

scientific evidence supporting the claim, the evidence is not conclusive.⁷¹

4. Antioxidants. On May 4, 2001, FDA denied the fourth Pearson claim, relating to antioxidant vitamins and cancer, and stated that it would not permit qualified claims under Pearson.⁷² This decision has not been challenged.

5. Folic Acid/B Vitamins. On November 28, 2000, FDA determined that there was no significant scientific agreement about a disease claim submitted after Pearson -- concerning the relationship between folic acid, vitamin B₆, and vitamin B₁₂, in dietary supplements, and the risk of heart disease and other vascular disease. FDA announced that it would exercise "enforcement discretion" as to certain claims describing that relationship.⁷³ It offered the following as a sample qualified claim.

It is known that diets low in saturated fat and cholesterol may reduce the risk of heart disease. The scientific evidence about whether folic acid [folate], vitamin B₆, and vitamin B₁₂ may also reduce the risk of heart disease

⁷¹ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (February 8, 2002) (Docket 91N-0103).

⁷² Letter from Christine Lewis (FDA) to Jonathan W. Emord (Docket No. 91N-0101) (May 4, 2001).

⁷³ Letter from Christine J. Lewis (FDA) to Jonathan W. Emord (November 28, 2000) (Docket No. 99P-3029).

and other vascular diseases is suggestive, but not conclusive. Studies in the general population have generally found that these vitamins lower homocysteine, an amino acid found in the blood. It is not known whether elevated levels of homocysteine may cause vascular disease or whether high homocysteine levels are caused by other factors. Studies that will directly evaluate whether reducing homocysteine may also reduce the risk of vascular disease are not yet complete.

After litigation, FDA and plaintiffs in a companion case to Pearson (Whitaker v. Thompson) filed a joint notice of dismissal in which FDA once again reversed itself and agreed to permit the following claim.

As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6 and Vitamin B-12 may reduce the risk of vascular disease. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.

F. FDA Has Steadfastly Refused to Apply the Pearson Ruling to Conventional Foods.

1. FDA Ignored GMA's Citizen Petition Arguing that Pearson Must be Applied to Conventional Food Labeling.

In April 2000, the Grocery Manufacturers of America (GMA) submitted a citizen petition arguing that FDA must apply the Pearson ruling to all foods, not just to dietary supplements. The Pearson decision, we pointed out,

arose under the same standard for approval of disease claims as applies to all food under the NLEA. FDA's implementation strategy perpetuates FDA's suppression of truthful and nonmisleading information about food and dietary supplements and inhibits GMA members from disseminating important nutrition and health information to consumers. We argued that FDA must conform its regulation of food labeling to Pearson's First Amendment standards by taking six actions.

1. FDA must withdraw and revise its proposed strategy to implement the Pearson decision.
2. FDA must apply Pearson to all food, including but not limited to dietary supplements, because the Pearson case interpreted the NLEA standard for approval of disease claims for food (which FDA extended without change to dietary supplements).
3. FDA must withdraw the significant scientific agreement guidance because it does not allow FDA to authorize all truthful, nonmisleading claims (including claims for which the level of scientific support can be set forth meaningfully in disclaimers or other explanatory information).
4. FDA must withdraw the authoritative statement guidance because it indicates that FDA will use its unconstitutional interpretation of "significant scientific agreement" to determine whether a statement is "authoritative."
5. FDA must amend all existing disease claim regulations (both procedural and substantive) in 21 C.F.R. § 101.14 and 21 C.F.R. Part E to comply with Pearson.

6. FDA must immediately suspend all enforcement action against claims that are truthful, accurate, and not misleading.

FDA has not responded to this petition.

2. FDA Refused GMA's Disease Claim Petition.

Because FDA would not respond to the first GMA petition, on March 14, 2001, GMA submitted a disease claim petition pursuant to section 403(r)(4) of the FD&C Act and 21 C.F.R. § 101.70 seeking approval for conventional food labeling of the specific qualified claims permitted by FDA pursuant to Pearson in dietary supplement labeling. GMA incorporated by reference the entire docket for each original disease claim at issue and conceded that each claim lacked significant scientific agreement, as FDA defined the standard. GMA explained that both Pearson and the First Amendment require FDA to treat all food similarly -- permitting the same qualified claims for conventional foods as for dietary supplements. FDA responded to the petition on June 22, 2001, raising what were essentially technical objections and refusing to address the petition on the merits. FDA first asserted that GMA's incorporation by reference of materials in the dietary supplement disease claim dockets was inadequate insofar as GMA did not make "specific reference" to the precise "location" of required information. FDA also suggested that the scientific

considerations for dietary supplements and conventional foods are not identical, even though both are "food" under the statute, both are subject to the same "significant scientific agreement standard," and claims on both are equally protected by the First Amendment.

FDA and GMA now have two possible approaches to the matter. Either it can proceed to litigation or it can be resolved administratively. GMA is submitting this white paper in the hope that the matter can be resolved without the need for litigation.

II. Both the Pearson Ruling and the First Amendment Require FDA to Permit in Conventional Food Labeling the Same Disease Claims It Permits in Dietary Supplement Labeling.

Both the Pearson decision and the First Amendment require FDA to permit conventional food manufacturers to make qualified disease claims in their labeling just as the Agency permits dietary supplement manufacturers to make those claims in their labeling. Neither Pearson nor the First Amendment permits FDA to treat the speech of dietary supplement manufacturers differently from the speech of conventional food manufacturers.

A. The Ruling in Pearson Requires FDA to Permit the Proposed Claims in Conventional Food Labeling.

The Court of Appeals in Pearson applied the First Amendment commercial speech doctrine to FDA regulation of

product labeling. It is "undisputed," the court wrote, "that FDA's restrictions on appellants' health claims are evaluated under the commercial speech doctrine."⁷⁴ Indeed, FDA conceded as much. The claims that are the subject of this white paper are commercial speech, and FDA is therefore obliged under Pearson (and its own concessions in the case) to conform its regulation of these claims to the Central Hudson doctrine.

The Court of Appeals in Pearson unambiguously held that FDA's application of the significant scientific agreement standard to bar disease claims was unconstitutional. Indeed, FDA's argument that claims lacking "significant scientific agreement" were inherently misleading was deemed to be "almost frivolous." The "significant scientific agreement" standard applies to all foods, whether in conventional form or in dietary supplements. It would be unconstitutional (and similarly "frivolous") for FDA to bar disease claims on conventional foods because they lack significant scientific agreement. The Pearson ruling forecloses this option. Accordingly, under Pearson, FDA must consider other methods of assuring that disease claims in conventional food labeling are

⁷⁴ Pearson, 164 F.3d at 655.

truthful and non-misleading -- such as disclaimers, explanatory statements, and the like.

The court's holding is not limited to dietary supplements. The court expressly invalidated the disease claim regulations that apply to both dietary supplements and conventional foods. The court's reasoning is not limited to dietary supplements or to "statutory" standards rather than "regulatory" standards. If it is frivolous for FDA to argue that dietary supplement disease claims lacking in significant scientific agreement are inherently misleading, it is equally frivolous for FDA to argue that conventional food disease claims lacking in significant scientific agreement are inherently misleading. If suppression of disease claims on dietary supplements would not directly advance the government's interest in protecting the public health, suppression of disease claims on conventional foods would not directly advance the government's interest in protecting the public health. If there is no reasonable fit between the prevention of fraud and the outright suppression of disease claims on dietary supplements, there is no reasonable fit between the prevention of fraud and the outright suppression of disease claims on conventional foods.

The regulatory schemes for conventional foods and dietary supplements are identical. Dietary supplements are food under the FD&C Act. Rules that apply to dietary supplement disease claims also must apply to disease claims for food. The FDA disease claims regulation makes this clear when it states:

The requirements of this section apply to foods intended for human consumption that are offered for sale, regardless of whether the foods are in conventional food form or dietary supplement form.⁷⁵

The standard that FDA applies is the same. FDA recognized that the same standard applies to disease claims for dietary supplements and conventional foods when it issued the significant scientific agreement guidance following the Pearson decision and when it issued the guidance on authoritative body claims under the Food and Drug Administration Modernization Act of 1997. The commercial speech doctrine embodies a preference for disclosure over outright suppression. This is no less true as to conventional food labeling than it was as to dietary supplement labeling. Nothing in the Pearson ruling is even plausibly limited to dietary supplements.

⁷⁵ 21 C.F.R. § 101.14(g).

B. Even Had the Pearson Case Not Been Decided, the First Amendment Requires FDA to Permit the Proposed Claims in Conventional Food Labeling.

- 1. The Commercial Speech Proposed for Conventional Foods in this Petition is Entitled to Protection Under the Supreme Court's First Amendment Cases.**

The First Amendment to the United States Constitution protects "commercial speech," including food and dietary supplement labeling. Disease claims in food labeling also impart vital noncommercial information to consumers, such as the health risks and benefits of consuming a particular product. Food labels and labeling bearing a hybrid of commercial and noncommercial speech are entitled to a heightened form of intermediate scrutiny (i.e., an even more rigorous application of Central Hudson).⁷⁶ Even under conventional commercial speech doctrine, however, as explained below, FDA must approve the proposed disease claims.

⁷⁶ In recent cases involving hybrid speech, the Court has applied a rigorous form of Central Hudson. E.g., Greater New Orleans Broadcasting Association v. United States, 527 U.S. 173 (1999); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996); Rubin v. Coors Brewing Company, 514 U.S. 476 (1995). Cf. Bolger v. Youngs Drug Products Corp., 463 U.S. 60 (1983) (advertisements containing discussions of important public issues such as venereal disease and family planning); Consolidated Edison Co. v. Public Service Commission of New York, 447 U.S. 530 (1980) (inclusion in monthly bills of inserts discussing political issues).

Under conventional commercial speech doctrine, the government may not prohibit or restrict commercial speech unless it satisfies the four-part test in Central Hudson Gas & Electric Corp. v. Public Service Commission.⁷⁷

Under this four part test, the government may prohibit commercial speech only if the speech is inherently false or misleading or proposes an unlawful transaction. Otherwise, it may regulate commercial speech only if it has a significant interest in doing so, the regulation in question directly furthers that interest, and there is no less restrictive means of furthering that interest.

The Central Hudson test can be distilled into two principles. First, "only false, deceptive or misleading commercial speech may be banned."⁷⁸ Second, commercial speech that is not false, deceptive, or misleading may be restricted, but only if the government shows that there is a "reasonable fit" between its objectives and the degree of restriction that it uses to achieve its objectives.⁷⁹

⁷⁷ 447 U.S. 557 (1980).

⁷⁸ Ibanez v. Florida Department of Business and Professional Regulation, 512 U.S. 136, 142 (1994) (citing Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 638 (1985)).

⁷⁹ Board of Trustees of State Univ. of New York v. Fox, 492 U.S. 469, 480 (1989).

As to the first principle, FDA has the burden to establish that a disease claim is false or misleading, before it may ban that claim.⁸⁰ As to second principle, FDA has the burden "of identifying a substantial interest and justifying the challenged restriction."⁸¹ FDA may not satisfy its burden with speculation. It must present proof that its feared harm is real and that the intended statement will indeed harm the public.⁸²

The Supreme Court has repeatedly and emphatically rejected what it calls the "paternalistic" suppression of commercial speech. As the Court has explained:

The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good. That teaching applies equally to state attempts to deprive consumers of accurate information about their chosen products.⁸³

To the contrary, the Supreme Court clearly directs the government to give consumers information on which they can base their own decisions:

⁸⁰ Cf. Ibanez, 512 U.S. at 142.

⁸¹ Greater New Orleans Broadcasting, 527 U.S. at 174.

⁸² Ibanez, 512 U.S. at 143; Edenfield v. Fane, 507 U.S. 761, 770-771 (1993); Zauderer, 471 U.S. at 648-49.

⁸³ 44 Liquormart, 517 U.S. at 503.

information is not in itself harmful . . . people will perceive their own best interest if only they are well enough informed . . . the best means to that end is to open the channels of communication rather than to close them.⁸⁴

The Court made the same point in Central Hudson:

Even when advertising communicates only an incomplete version of the relevant facts, the First Amendment presumes that some accurate information is better than no information at all.⁸⁵

Finally, the restriction must be "narrowly tailored."⁸⁶ The "cost" of the restriction -- that is, the burden it imposes on the speech -- must be "carefully calculated."⁸⁷ That cost/benefit assessment in turn requires that "the regulation not 'burden substantially more speech than is necessary to further the government's legitimate interests.'"⁸⁸

2. The Supreme Court Strongly Reaffirmed Its Commercial Speech Principles in a Recent Decision.

In an opinion delivered in April, the Supreme Court had occasion to apply the Central Hudson principles

⁸⁴ Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 770 (1976).

⁸⁵ Central Hudson, 447 U.S. at 562.

⁸⁶ Fox, 492 U.S. at 480.

⁸⁷ Id. at 480.

⁸⁸ Id. at 478.

in a case involving advertising of FDA-regulated products. In Thompson v. Western States Medical Center,⁸⁹ a group of pharmacies engaged in the practice of compounding prescription drugs challenged a provision of FDAMA that allowed compounding only in response to an "unsolicited" prescription and prohibited a pharmacy, pharmacist, or physician from advertising that it could compound any particular drug or category of drugs.⁹⁰ The pharmacies argued that the FDAMA provision violated their First Amendment right to advertise their services in a truthful and nonmisleading manner. The Government responded that advertising was "'a fair proxy for actual or intended large-scale manufacturing,'"⁹¹ an activity viewed by Congress as violating FDA's new drug approval process.

In an opinion authored by Justice O'Connor, the Supreme Court agreed with the pharmacies and held that the provision unconstitutionally limited legitimate commercial speech. The Government conceded -- and all nine justices agreed -- that the First Amendment applies to FDA, thereby definitively abandoning FDA's pre-Pearson arguments on that

⁸⁹ 535 U.S. ____ (2002).

⁹⁰ 21 U.S.C. §§ 353a(a), 353a(c).

⁹¹ Western States, slip op. at 12.

score. Thus, in the wake of Western States, it is clear that any speech restriction imposed by FDA must be assessed within the Central Hudson framework.

In Western States, the Government did not defend the challenged FDAMA provision on the ground that the pharmacists' advertising promoted an unlawful activity or would be misleading.⁹² Instead, the Government -- and the Court -- focused on the final three prongs of the Central Hudson test, which require the Government to demonstrate that its interest is substantial, that the challenged provision directly advances that interest, and that the provision "is not more extensive than is necessary to serve that interest."⁹³ The Court was willing to assume that the Government might be able to demonstrate a substantial enough interest in "[p]reserving the effectiveness and integrity of the [FD&C Act's] new drug approval process,"⁹⁴ although the Court expressed skepticism that the Government had given sufficient weight to its contrary interest in ensuring the continued access of needy patients to suitable

⁹² Id. at 10.

⁹³ Id. at 9 (quoting Central Hudson, 447 U.S. at 566).

⁹⁴ Id. at 11.

compounded medications.⁹⁵ Still, assuming the Government's interest was sufficient, the Court was also willing to assume that large-scale marketing of drugs requires advertising.⁹⁶

However, the Court flatly rejected the Government's contention that it had satisfied the final prong of the Central Hudson test. The Court's past precedent clearly established that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."⁹⁷ Yet here, the Court found that the advertising restriction was not narrowly tailored to advance the claimed interest. As the Court stated,

If the First Amendment means anything, it means that regulating speech must be a last -- not first -- resort. Yet here it seems to have been the first strategy the Government thought to try.⁹⁸

The Court characterized the dissent's arguments as "a fear that people would make bad decisions if given truthful

⁹⁵ Id.

⁹⁶ Id. at 13.

⁹⁷ Id.

⁹⁸ Id. at 15.

information about compounded drugs,"⁹⁹ a rationale for speech restrictions the Court had rejected in prior cases:

We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information.¹⁰⁰

The Court suggested several non-speech-related ways in which the Government might draw the line between legitimate compounding and unauthorized large-scale manufacturing. More importantly, it also noted that even if the Government had a legitimate fear that advertising would create patient confusion about compounded drugs' risks, as the dissent implied, "this interest could be satisfied by the far less restrictive alternative of requiring each compounded drug to be labeled with a warning that the drug had not undergone FDA testing and that its risks were unknown."¹⁰¹ In Western States, the Government did not contend that the advertising was misleading, precluding a colorable argument that patients might be confused. But even if the Government believes consumer confusion is a possibility,

⁹⁹ Id. at 16.

¹⁰⁰ Id. (citing Virginia Bd. of Pharmacy, 425 U.S. at 769).

¹⁰¹ Id. at 18.

the Court's opinion makes clear that before it institutes a blanket ban on the speech, the Government is obligated to establish that a qualification in the labeling will not reduce that risk.

3. Application of These Principles to the Qualified Disease Claims at Issue Dictates that FDA Permit Their Use in Conventional Food Labeling.

The qualified disease claims at issue are truthful and nonmisleading. FDA has conceded this by permitting them in dietary supplement labeling.¹⁰² Thus, under Central Hudson and Western States, FDA may not categorically ban the claims on conventional foods. Rather, it must satisfy a heavy burden of justifying any restriction on the claims, and it may not rely on "paternalistic" assumptions about the ability of consumers to interpret qualified claims. Nor may it arbitrarily argue that consumers may understand qualified claims on dietary supplements but not the same claims on conventional foods.

A "public health" justification would not support suppression of the qualified disease claims. The

¹⁰² The FD&C Act prohibits a manufacturer from including in its labeling a disease claim that is false or misleading. FD&C Act § 403(a)(1), 21 U.S.C. § 343(a)(1); see also 21 C.F.R. § 101.14(d)(2)(iii).

conventional foods at issue are concededly safe. Nor would a "consumer fraud" justification support suppression of the qualified disease claims. The claims, as qualified, are accurate and nonmisleading. The First Amendment does not permit FDA to assume consumers are incapable of understanding qualifications and caveats. The Supreme Court's commercial speech cases lead to the same conclusion the Pearson court reached. FDA must consider qualified disease claims in conventional food labeling.

III. FDA Has Both the Authority and the Obligation to Apply the FD&C Act in A Way that Protects, Rather than Violates, the First Amendment Rights of Conventional Food Manufacturers.

FDA claims in its letter to Representative McIntosh that it is "required" to apply the "significant scientific agreement" standard to conventional foods, because the food standard is embodied in a statute, while the dietary supplement standard was merely embodied in a regulation. A federal statute is subject to the same constitutional standard as an agency regulation. If FDA may not by regulation categorically ban from food labeling disease claims lacking significant scientific agreement, neither then may Congress do so by statute. Moreover, it is incumbent on FDA to interpret section 403(r)(4) in a way that comports with the Constitution. As an instrument of

the Federal Government, whose officers are sworn to uphold the Constitution, FDA may not simply shrug its shoulders and claim that it has no choice but to knowingly violate the Constitution.

A. FDA Can and Should Revise its Interpretation of the "Significant Scientific Agreement" Standard.

FDA is not bound to its current interpretation of the "significant scientific agreement" standard in the FD&C Act but may amend that interpretation. The point at which scientific agreement becomes "significant" is inherently ambiguous and an insufficient guideline for judicial review, under the Administrative Procedure Act. It is FDA's Guidance policies that clarify the meaning of the term, and FDA may amend its policies.¹⁰³

The statute instructs FDA to issue a regulation permitting a manufacturer to make a disease claim only when the claim meets the statutory requirements, as articulated by FDA. The Administrative Procedure Act requires that agencies give content to their enforcement policies, so as to prevent arbitrary and capricious enforcement

¹⁰³ FDA's interpretations must, of course, comport with the relevant statutory provisions. See Heckler v. Chaney, 470 U.S. 821, 833 n.4 (1985). As this section demonstrates, the operative statutory language in this case affords more than one reasonable interpretation.

decisions.¹⁰⁴ Without question, the language in Section 403(r)(3)(B)(i) is clear in one regard. FDA may not promulgate a new regulation for a claim that lacks "significant scientific agreement." However, as the D.C. Circuit has suggested, the statutory language alone may not create a sufficiently clear standard to guide a court's review of FDA's exercise of enforcement discretion.¹⁰⁵

The D.C. Circuit suggested in Pearson v. Shalala¹⁰⁶ that the operative statutory language on significant scientific agreement, standing alone, may not pass muster under the APA. FDA argued in Pearson that its

¹⁰⁴ 5 U.S.C. § 706(2)(A). Arguably, FDA's decision to explicate the meaning of the significant scientific agreement standard via a Guidance Document violated the administrative law requirement that legislative rules be promulgated pursuant to formal rulemaking procedures, which FDA did not follow in this case.

¹⁰⁵ FDA recognizes this ambiguity in its Guidance Document on significant scientific agreement, where it observes that:

Significant scientific agreement does not require a consensus or agreement based on unanimous and incontrovertible scientific opinion. However, on the continuum of scientific discovery that extends from emerging evidence to consensus, it represents an area on the continuum that lies closer to the latter than to the former.

Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements, December 22, 1999, available at <http://www.cfsan.fda.gov/~dms/ssaguide.html>.

¹⁰⁶ 164 F.3d 650 (D.C. Cir. 1999).

regulation requiring significant scientific agreement for dietary supplements was justified merely because Congress chose the same term in the statute. The D.C. Circuit squarely rejected that claim, and suggested a broader implication:

we are quite unimpressed with the government's argument that the Agency is justified in using this standard without definition because Congress used the same standard in [the statute]. Presumably -- we do not decide -- the FDA in applying that statutory standard would similarly be obliged under the APA to give it content.¹⁰⁷

Federal statutes are "to be construed so as to avoid serious doubts as to their constitutionality."¹⁰⁸ FDA's current interpretation and enforcement of the "significant scientific agreement" standard infringe food manufacturers' First Amendment right to make non-deceptive claims about their products. FDA can remedy this by adopting a constitutionally valid interpretation of the "significant scientific agreement" standard. For example, FDA should acknowledge that scientific agreement may be "significant" even though the scientific community

¹⁰⁷ Id. at 660-61.

¹⁰⁸ Communications Workers of America v. Beck, 487 U.S. 735, 762 (1988).

continues to research and debate various details of a claim. Such a standard would carry out Congress's intent of providing accurate consumer information while not infringing on manufacturers' legitimate speech concerns.

In short, on its own and without further explication from FDA, the statutory provision arguably does not contain sufficient "law to apply" to guide FDA's enforcement actions.¹⁰⁹ For APA purposes, an FDA regulation or guidance on significant scientific agreement is needed to flesh out the meaning of the term and give content to the statutory prohibition before FDA can enforce it fairly. Today, however, the Agency's interpretation of the statutory standard represents an unconstitutional infringement on food manufacturers' commercial speech rights. The solution is clear. FDA should issue and enforce a new guidance or regulation that interprets the statutory term "significant scientific agreement" in a manner that does not unconstitutionally restrict food manufacturers' speech rights.

¹⁰⁹ Chaney, 470 U.S. at 834; see also United States v. Juvenile No. 1, 118 F.3d 298 (5th Cir. 1997) (holding that the statutory phrase "substantial federal interest" does not provide a justiciable standard).

B. FDA Has an Obligation to Interpret and Apply the FD&C Act Constitutionally.

Federal agencies have an independent obligation to uphold the Constitution, which is the supreme law of the land.¹¹⁰ Cases dating from the earliest years of the republic establish that a congressional enactment that conflicts with the Constitution is not a "law." As such, an executive branch agency is not required to enforce it.

In Marbury v. Madison, Justice Marshall explained the proposition that courts have an obligation to overturn statutes and other official acts that conflict with the Constitution. The theory of a constitutional government must be that "an act of the legislature repugnant to the constitution is void."¹¹¹ Marbury addressed the power of the judiciary to invalidate a congressional enactment on the basis on a conflict with the Constitution. However, the principle underlying Marbury v. Madison leads to the logical conclusion that the executive branch has an identical obligation to uphold the superior source of law

¹¹⁰ U.S. Const. art. VI, § 2.

¹¹¹ 5 U.S. (1 Cranch) 137, 177 (1803). See also The Federalist No. 78, at 467 (Alexander Hamilton) (Clinton Rossiter ed., 1961) ("[E]very act of a delegated authority, contrary to the tenor of the commission under which it is exercised, is void. No legislative act, therefore, contrary to the Constitution, can be valid.").

in the United States. In short, an executive branch agency must uphold the Constitution even when it conflicts with a statutory directive.¹¹²

This point was made during the debates that led to the adoption of the Constitution. At the Philadelphia Convention in 1787, James Wilson argued that the Constitution imposed significant restraints on the power of the legislature.¹¹³ In his view, the power of the Constitution is paramount to the power of the legislature; just as a judge may consider constitutional principles in assessing the legitimacy of a legislative enactment, "the same manner, the President of the United States could shield himself, and refuse to carry into effect an act that violates the Constitution."¹¹⁴

In the present context, of course, FDA is acting on behalf of the President.¹¹⁵ Upon taking the oath of office, the president vows to "preserve, protect and defend

¹¹² Id. at 180 ("a law repugnant to the constitution is void, and . . . courts, as well as other departments, are bound by [the Constitution]") (emphasis added).

¹¹³ Statement of James Wilson on December 1, 1787 on the Adoption of the Federal Constitution, reprinted in 2 Jonathan Elliot, Debates on the Federal Constitution 418 (1836).

¹¹⁴ Id. at 446.

¹¹⁵ "The executive Power shall be vested in a President." U.S. Const. art. II, § 1(1).

the Constitution of the United States."¹¹⁶ As agents of the president, FDA's Commissioner and staff likewise have an obligation to uphold the tenets set forth in the Constitution, including the First Amendment.

C. A Decision to Decline Enforcement of the Misbranding Prohibition on First Amendment Grounds Lies Within the Agency's Discretion and is not Unprecedented at the Agency.

1. A Decision to Decline Enforcement of the Misbranding Provision in this Instance Lies Within the Agency's Discretion.

FDA has the discretion to decline to proceed for misbranding against a nonmisleading disease claim that lacks an authorizing regulation. The FD&C Act states that the Secretary "shall" promulgate regulations authorizing disease claims,¹¹⁷ and further states that disease claims "may only be made" if, among other things, they meet the requirements of those regulations.¹¹⁸ Nowhere does the Act state that FDA "must" enforce violations of the latter provision. The relevant cases fully support the conclusion that FDA may decide not to do so.

¹¹⁶ U.S. Const. art. II, § 1(8).

¹¹⁷ FD&C Act § 403(r)(3)(B)(i), 21 U.S.C. § 343(r)(3)(B)(i).

¹¹⁸ FD&C Act § 403(r)(3)(A), 21 U.S.C. § 343(r)(3)(A).

The Supreme Court's decision in Heckler v. Chaney¹¹⁹ upheld FDA's enforcement discretion and suggested that such a decision not to enforce will not be judicially reviewable in the absence of a clear statutory standard for review. In Chaney, prison inmates challenged FDA's decision not to take enforcement action against the unapproved use of certain drugs for administration of the death penalty by lethal injection. The D.C. Circuit held that FDA's decision was reviewable and overturned FDA's decision as arbitrary and capricious.¹²⁰

In a unanimous decision, the Supreme Court reversed. It held that an action is committed to agency discretion where "no judicially manageable standards are available for judging how and when an agency should exercise its discretion."¹²¹ Section 706 of the Administrative Procedure Act limits a court's ability to set aside an agency action to situations where the action was "arbitrary, capricious, and abuse of discretion, or otherwise not in accordance with law."¹²² In all other cases, however, section 701(a)(2) precludes a court's

¹¹⁹ Heckler v. Chaney, 470 U.S. 821 (1985).

¹²⁰ Chaney v. Heckler, 718 F.2d 1174 (D.C. Cir. 1983).

¹²¹ Chaney, 470 U.S. at 830.

¹²² 5 U.S.C. § 706(2)(A) (1994).

review over matters "committed to agency discretion by law."¹²³ The Court explained that there can be no judicial review if the exercise of discretion is such that "a court would have no meaningful standard against which to judge the agency's exercise of discretion."¹²⁴

An enforcement decision is a prototypical example of a decision committed to an agency's absolute discretion. In these cases, courts' "recognition of the existence of discretion is attributable in no small part to the general unsuitability for judicial review of agency decisions to refuse enforcement."¹²⁵ Such decisions are unsuitable for judicial review because a court is ill-equipped to second-guess the factors that led to the agency's decision, which may be peculiarly within the agency's expertise.¹²⁶ An agency's non-enforcement decision is essentially equivalent to a prosecutor's decision not to indict a suspect.¹²⁷ The latter class of decisions has "long been regarded as the special province of the Executive Branch, inasmuch as it is

¹²³ 5 U.S.C. § 701(a)(2).

¹²⁴ Chaney, 470 U.S. at 830.

¹²⁵ Id. at 831 (citations omitted).

¹²⁶ Id.

¹²⁷ National Milk Producers Federation v. Harris, 653 F.2d 339, 343 (8th Cir. 1981) (observing that in general, both enforcement and prosecutorial decisions by executive branch agencies are committed to agency discretion).

the Executive who is charged by the Constitution to 'take Care that the Laws be faithfully executed.'"¹²⁸ Given scarce FDA resources, a "court should not force the agency to funnel its efforts in any one direction."¹²⁹

The Court in Chaney further noted that an agency's decision to refrain from enforcement is qualitatively different from the usual decision reviewed by courts, which is a decision to take some action. When an agency chooses not to act, it "generally does not exercise its coercive power over an individual's liberty or property rights, and thus does not infringe upon areas that courts are often called upon to protect."¹³⁰

FDA has argued that Chaney gave it "wide latitude in matters of enforcement discretion."¹³¹ In Heterochemical Corporation v. FDA, for example, the plaintiff petitioned FDA to take regulatory action against its competitors. After investigating the matter, FDA declined to take enforcement action against the competitors, and the

¹²⁸ Chaney, 470 U.S. at 831 (quoting U.S. Const., Art. II, § 3).

¹²⁹ Robbins v. Reagan, 780 F.2d 37, 47 (D.C. Cir. 1985).

¹³⁰ Chaney, 470 U.S. at 832.

¹³¹ Food Labeling; Health Claims and Label Statements for Dietary Supplements; Update to Strategy for Implementation of Pearson Court Decision, 65 Fed. Reg. 59,855, 59,857 (October 6, 2000).

plaintiff brought suit. The court found that because the Agency had made extensive investigations into the matter, its refusal to take enforcement action was arguably arbitrary and capricious. The court therefore rejected FDA's argument that Chaney was fully dispositive on the issue. However, the court noted that Chaney clearly established one point. FDA is never required to investigate alleged violations of the FD&C Act and other statutes.¹³² The Supreme Court in Chaney "established a presumption that '[r]efusals to take enforcement steps' are not reviewable."¹³³

2. A Decision Not to Enforce the Misbranding Provision, Due to First Amendment Concerns, Would Not Break New Ground.

FDA has on prior occasions chosen to exercise enforcement discretion out of concern that enforcing a statutory provision would contravene constitutional rights.

For example, recognizing First Amendment limits on its authority, FDA has issued a Compliance Policy Guide detailing when it will institute a seizure action against books that constitute misleading labeling.¹³⁴ The FD&C Act

¹³² Heterochemical Corp. v. FDA, 644 F. Supp. 271, 273 (E.D.N.Y. 1986).

¹³³ Id. (quoting Chaney, 470 U.S. at 831).

¹³⁴ CPG 7153.13, Sec. 140.100 (revised 8/31/89).

regulates printed material that promotes the use of a product and "accompanies" the product. Such promotional labeling may not be false and misleading. If FDA finds that it is so, the Agency's general enforcement practice is to recommend seizure of both the product and the offending labeling in such cases. However, such regulation presents free speech concerns, and the burden on free speech is particularly troubling where the labeling takes the form of a book. Recognizing those concerns, FDA has announced that where the labeling is a book, rather than recommending outright seizure, the Agency will "consider filing a complaint for forfeiture against the product and an injunction to halt, after a hearing, the misuse of the book."¹³⁵

Similarly, at times FDA has chosen not to pursue an appeal of an adverse decision on the constitutionality

¹³⁵ Id. In another constitutional context, the D.C. Circuit restricted FDA's authority to seize literature in conjunction with an unapproved device. In Founding Church of Scientology v. United States, 409 F.2d 1146 (D.C. Cir. 1969), FDA seized several electrical instruments and a large quantity of literature owned by The Founding Church of Scientology of Washington, D.C. Because the appellants had made out a prima facie case that Scientology is a religion, the D.C. Circuit held that FDA could not seize general literature which merely sketched out the doctrinal theory of Scientology, even though it also discussed the unapproved electrical instruments.

of a statutory provision it enforces.¹³⁶ Finally, in other contexts with less bearing on constitutional rights, FDA likewise has exercised enforcement discretion.¹³⁷ These examples illustrate FDA's past willingness to refrain from enforcing a statutory provision for constitutional or other reasons. In light of the First Amendment implications of FDA's current policy, GMA asks FDA to exercise its discretion to permit conventional food manufacturers to make the same qualified disease claims that dietary supplement manufacturers may now make.

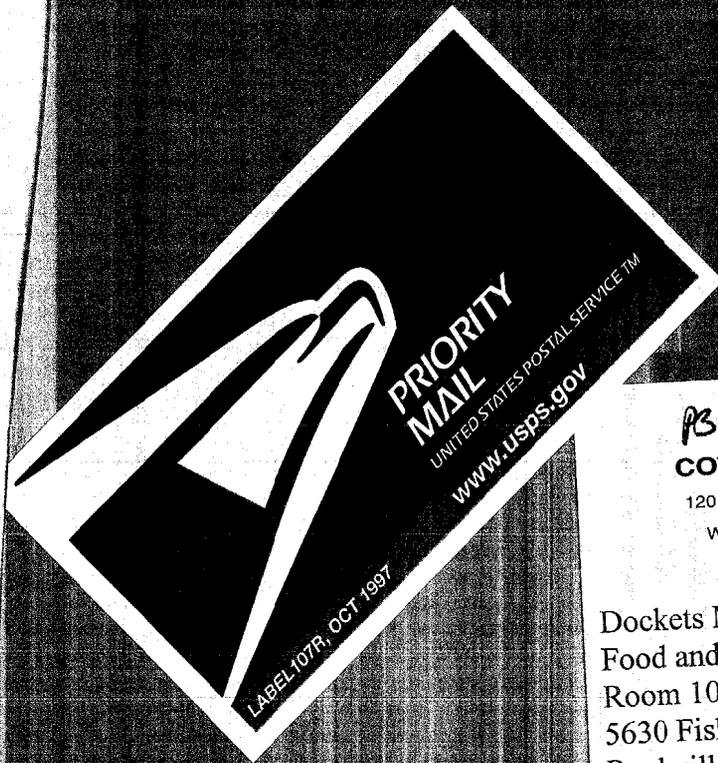
¹³⁶ FDA's decision not to appeal the holding in Milnot Co. v. Richardson, 350 F. Supp. 221 (S.D. Ill. 1972), illustrates this point. An Illinois District Court held the Filled Milk Act to be unconstitutional on due process grounds, ignoring earlier Supreme Court precedent upholding the Act. Although Congress never repealed the Act, FDA chose not to pursue its appeal and instead exercised its discretion to cease enforcing the Act. See Filled Milk Products, 38 Fed. Reg. 20,748 (Aug. 2, 1973).

¹³⁷ E.g., Extra-Label Policy Based on "Enforcement Discretion," FDA Says, Food Chemical News, January 26, 1987, at 9 (FDA allowed veterinarians to use animal drugs in an extra-label fashion); Guidance for Industry on Levothyroxine Sodium Products -- Enforcement of August 14, 2001, Compliance Date and Submission of New Applications; Availability, 66 Fed. Reg. 36,794 (July 13, 2001) (FDA allowed transition period during which unapproved product could be sold); CDRH Interim Policy Regarding Parents' Access to Tests for Drugs of Abuse, available at <http://www.fda.gov/cdrh/dsma/113.html> (FDA announced it would not take enforcement action against distributors or unapproved home drug test collection systems).

IV. Conclusion

The Pearson v. Shalala opinions and the First Amendment require FDA to permit in conventional food labeling the same disease claims that it permits in dietary supplement labeling. FDA's failure to permit qualified disease claims contravenes FDA's obligation to enforce the FD&C Act in a constitutional manner. FDA has the authority to permit manufacturers to make those claims; Heckler v. Chaney established that an agency's decision to enforce or not to enforce a statutory provision is committed to its discretion. The FD&C Act does not indicate any intent by Congress "to circumscribe agency enforcement discretion,"¹³⁸ and indeed FDA has often exercised enforcement discretion in the past. In short, FDA should now exercise its inherent authority to permit the qualified disease claims in conventional food labeling.

¹³⁸ Chaney, 470 U.S. at 834.



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