



THE ASSOCIATION FOR
**DRESSINGS
& SAUCES**

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September 13, 2002

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Re: Docket No. 02N-0209, Request for Comment on First Amendment Issues

Dear Sir or Madam:

The Association for Dressings and Sauces (ADS) represents manufacturers of salad dressing and condiment sauces and suppliers of materials and services to the industry. ADS assists members in fully complying with all currently applicable labeling and container requirements. ADS members are particularly interested in the changing climate of nutrient and health claims regulations, and the Food and Drug Administration's (FDA) role in overseeing this evolving area.

ADS commends FDA's willingness to consider the First Amendment implications of its current regulatory stance in light of recent court decisions clarifying the scope of commercial speech rights. We believe ADS members have a First Amendment right to include appropriate nutrient content and health claims on their product labeling, with appropriate disclosures, rather than total preclusion of such claims. We therefore encourage FDA to consider such claims in the context of the First Amendment related to current and future labeling regulations. For example, significant scientific evidence demonstrates the health benefits of Vitamin E. But, under current regulations, manufacturers of many fat-based products like dressings for salads or mayonnaise may not use the product label to inform consumers of the benefits of this healthful ingredient. Similarly, manufacturers cannot take advantage of existing health claims due to the fat content of traditional products.

A. The Governing Law

The Nutrition Labeling and Education Act of 1990 (NLEA), 104 Stat. 2353 (1990), amended the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §

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301 *et seq.*, to permit manufacturers of dietary supplements and conventional foods to include health claims in their product labeling. A health claim is a claim in the labeling of a food that “expressly or by implication . . . characterizes the relationship of any nutrient . . . to a disease.” 21 U.S.C. § 343(r)(1)(B). Under the NLEA, FDA must approve a health claim 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.” *Id.* § 343(r)(3)(B). The NLEA did not define the term “significant scientific agreement.” A conventional food manufacturer may not include a health claim in its labeling unless FDA has promulgated a regulation authorizing the claim.¹ Further, a manufacturer cannot make a health claim if FDA finds that a product contains “any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet-related, taking into account the significance of the food in the daily diet.” *Id.* § 343(r)(3)(A)(ii) (emphasis added). However, the statute gives FDA the authority to permit such a claim and require a labeling disclosure. *Id.*

The NLEA provided a standard for FDA’s review of health claims for conventional foods but not for dietary supplements, leaving the latter to FDA’s discretion. In 1994, FDA adopted the same “significant scientific agreement” standard to govern such claims for dietary supplements, citing the need to maintain “fairness” between dietary supplement and conventional food manufacturers. 56 Fed. Reg. 60537, 60540 (November 27, 1991) (proposed rule); 59 Fed. Reg. 395 (January 4, 1994) (final rule).

The Food and Drug Administration Modernization Act of 1997 (FDAMA), 111 Stat. 2296 (1997), created an alternative to the NLEA process for FDA approval of health claims in conventional food labeling. When qualified federal scientific bodies have issued “authoritative statements” supporting a qualified health claim, the manufacturer can include such a claim in its food labeling after providing premarket notification to FDA. FDA need not promulgate a regulation permitting the claim. After the passage of FDAMA, FDA issued a guidance document reflecting its intention to incorporate the “significant scientific agreement” standard into the authoritative statement premarket notification process.²

B. Recent Court Decisions Clarify the Scope of Commercial Speech

Subsequent to the passage of FDAMA and the issuance of the FDA guidance document on “authoritative statements,” the D.C. Circuit held in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), rehearing denied, 172 F.3d 72 (D.C. Cir. 1999) (*en banc*), that FDA may not ban a health claim simply because it fails to meet the significant scientific agreement standard. The court considered a challenge to FDA’s

¹ Currently authorized claims are found in 21 C.F.R. §§ 101.72 - 101.83.

² See “Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body” (June 11, 1998), at 2-3.

regulations by dietary supplement manufacturers who sought to include four different health claims on their products. After FDA rejected the claims, the Pearson plaintiffs challenged the denial on several grounds, including that it was a prior restraint of speech in violation of the First Amendment and an unconstitutional restriction on commercial speech.

The D.C. Circuit first confirmed that FDA's labeling and advertising regulations are subject to the First Amendment commercial speech doctrine. 164 F.3d at 655. Therefore, such regulations are properly analyzed using the test laid out in Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York, 447 U.S. 557 (1980). As explained by the D.C. Circuit, truthful and nonmisleading commercial speech is analyzed by a three-part Central Hudson test.³ First, the court asks whether the asserted government interest is substantial. Second, the court determines whether the regulation directly advances the asserted interest. Finally, the court determines whether there is a reasonable fit between the government's interest and the means chosen to advance that interest. 164 F.3d at 655-656. After applying the three-part test, the court invalidated the four regulations denying the challenged health claims.

More recent jurisprudence likewise favors disclosure over suppression of speech. In Thompson v. Western States Medical Center, 535 U.S. ___, 122 S.Ct. 1497 (2002), a case arising in a slightly different context, the Supreme Court observed that even where there is a substantial risk of consumer confusion, the Government must consider whether labeling can alleviate that risk before it imposes an outright ban on accurate and nonmisleading commercial speech. 122 S.Ct. at 1508. A group of pharmacies engaged in the compounding of prescription drugs challenged a provision of FDAMA that, as part of a statutory scheme for regulating compounding, prohibited a pharmacy, pharmacist, or physician from advertising that it could compound any particular drug or category of drugs. 21 U.S.C. § 353a(a), 353a(c). The plaintiffs argued that the provision violated their First Amendment right to advertise their services in a truthful and nonmisleading manner. The Court was willing to assume FDA might be able to demonstrate a substantial government interest for a restriction on advertising. However, the Court concluded FDA had not shown that the advertising prohibition was narrowly tailored to advance that interest. As the Court remarked, "[i]f the First Amendment means anything, it means that regulating speech must be a last -- not first -- resort." 122 S.Ct. at 1507. Even if patients might be confused about the risks of compounded drugs, the Court observed that "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." Id. at 1508.

In Pearson, the D.C. Circuit cited Central Hudson for the proposition that the commercial speech doctrine embodies a preference for disclosure over outright

³ The court curtly rejected the FDA argument that lack of FDA approval rendered claims inherently misleading.

suppression of speech. 164 F.3d at 657. The decision in Western States likewise reflects a preference to provide consumers with more, rather than less, information about a product. Permitting truthful, appropriately qualified health claims allows consumers to make informed choices and assess the benefits and risks of choosing the product for themselves, rather than the government performing the assessment on their behalf. The courts have consistently rejected governmental barriers to the dissemination of truthful commercial information when the asserted goal is preventing the public from making bad decisions with the information. See 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996); Virginia Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 770 (1976).

However, FDA has not fully and properly implemented the Pearson ruling. As it began to reconsider its stance on the proper standard for evaluation of health claims, FDA stated that it viewed the scope of the Pearson holding as limited to dietary supplements and would not include conventional foods in its reconsideration. 65 Fed. Reg. 14219, 14221 (March 16, 2000). We believe this is an incorrect interpretation of the Pearson decision. Although the specific facts presented in the case concerned dietary supplements, the D.C. Circuit interpreted – and found wanting – the NLEA standard for approval of health claims for food that FDA had adopted, unchanged, for dietary supplements.

FDA has suggested no credible basis for limiting the Pearson holding to dietary supplements. There is no reason to believe consumers process information about dietary supplements differently from information about conventional foods, for example. Thus, for legal and practical reasons, the First Amendment principle articulated in Pearson is fully applicable to conventional foods.

C. ADS Members Seek to Include Truthful Claims in Their Labeling

Today, ADS members may label their products with truthful information about nutrient content of their products if they disclose, as appropriate, the fat content of the product. However, FDA regulations do not permit ADS members to make truthful claims about the health benefits of the same nutrients, even if the claims are clearly qualified with disclosures. This inconsistent treatment of nutrient content claims and health claims violates the First Amendment.

1. FDA's Regulations Permit Nutrient Content Claims, With Disclosures, But Not Health Claims

FDA's regulations permit a food manufacturer to label its product with nutrient content claims, as long as the label also discloses certain other information. If a food contains more than 13.0 grams of fat, 4.0 grams of saturated fat, 60 milligrams of cholesterol, or 480 milligrams of sodium per reference amount, per serving, or per 50 grams, depending on the product, it “must bear a statement disclosing that the nutrient

exceeding the specified level is present in the food,” e.g., “See nutrition information for fat content.” 21 C.F.R. § 101.13(h)(1).⁴ This policy is in keeping with the case law and First Amendment principles, because it permits a manufacturer to highlight certain nutrient levels in a product while advising consumers that the product contains an elevated level of another nutrient.

FDA’s regulations treat health claims quite differently. The FDCA permits FDA to bar a health claim if the product contains a level of any nutrient that “increases the risk of a disease or health-related condition,” but FDA must assess the level of that nutrient in light of “the significance of the food in the total daily diet.” 21 U.S.C. § 343(r)(3)(A)(ii). If a health claim would “assist consumers in maintaining healthy dietary practices,” FDA may permit the claim along with an appropriate disclosure. *Id.* FDA has chosen fat, saturated fat, cholesterol, and sodium as the four nutrients which “increase the risk of a disease or health-related condition.” Thus, unless specifically exempted by FDA, a health claim is disqualified if it pertains to a product with a level of fat, saturated fat, cholesterol, or sodium that exceeds the thresholds listed above. 21 C.F.R. § 101.14(a)(4). The manufacturer cannot include the claim on its label, even if accompanied by a clear disclosure of the, e.g., fat level of the product. As applied by FDA, this policy deprives consumers of valuable product information and robs them of the opportunity to weigh the nutritional qualities of the product for themselves.

2. FDA Has Not Articulated a Legitimate Basis for Suppressing Truthful Health Claims

FDA’s implementing regulation does not directly advance interests in protecting public health or preventing consumer fraud, nor is there a reasonable fit between those interests and the means chosen by the agency. Thus, in light of the decision in Pearson, FDA should permit ADS members to include health claims on their products.

For example, vegetable oils are an excellent food source of vitamin E, an antioxidant which studies have suggested may prevent or delay the development of cardiovascular disease and cancer. Vegetable oils are also fat-based ingredients, exceeding FDA’s regulatory threshold of 13.0 grams of fat per 50-gram sample. Vegetable oil products (e.g., mayonnaise and salad dressings) have therefore been subject to FDA’s blanket ban on health claims, thus eliminating any incentive on the part of marketers of products that are good or rich sources of vitamin E from sponsoring research in this area or pursuing health claims with FDA for which they believe there is significant scientific agreement.

The D.C. Circuit in Pearson made clear that disclosures are favored over outright suppression of speech. 164 F.3d at 657. Before it can suppress speech, FDA

⁴ An exception involves a prohibition on making “cholesterol” claims if a serving of the food contains 2 or more grams of saturated fat. 21 C.F.R. § 101.62(d).

must demonstrate that suppression directly advances a substantial interest -- and that there is a reasonable fit between that interest and the means FDA has chosen to advance it. Id. at 655-656. In other words, FDA must show that its policy prohibiting a manufacturer from making a health claim for a valuable nutrient provided by vegetable oil in a product which exceeds FDA's threshold for fat content, promotes a legitimate, substantial interest that a label disclosure cannot advance.

A public health rationale would not justify an outright ban on the health claim. FDA has not argued that vegetable oil consumption is harmful to consumers. Indeed, in its Federal Register notice announcing the health claims regulation, the agency recognized that "[i]n appropriate amounts, such nutrients [as fat] have a necessary or useful place in the total daily diet." 58 Fed. Reg. 2478, 2490 (January 6, 1993). Further, FDA acknowledged that "[i]t is the total diet, consisting of a number of foods consumed over time, that has the potential to increase disease risk." 58 Fed. Reg. at 2490. The FDCA directs FDA to consider the level of fat in vegetable oils in light of "the significance of the food in the total daily diet." In this regard, it is clear that FDA's total regulatory disqualification of health claims for dressing and sauce products of this industry made with vegetable oil, which may comprise a small proportion of the total daily diet, is not narrowly tailored to advance a significant government interest. A carefully drafted disclosure could achieve the same goal without suppressing speech. For example, FDA could permit a health claim about vitamin E in vegetable oils but require a specific disclosure such as "see back panel for information about fat " as is now required in some cases for nutrient content claims. Such an approach would permit the speech while alleviating any risk of consumer confusion about dietary guidelines.

The total disqualification of health claims based on fat content has two other effects that do not comport with the Pearson decision. First, manufacturers are precluded from making currently approved health claims that might otherwise be appropriate for dressing and sauce products, such as those involving the inclusion of vegetable or fruit ingredients in food, the inclusion of fiber sources, or the inclusion of soy-protein-based ingredients. Second, the disqualification approach, in addition to affecting the development of health information based on the natural vitamin E content of vegetable oils, also inhibits the development of health information based on other traditional ingredients of dressings and sauces, such as garlic and other herbs. We use these only as examples as the health benefits of foods beyond basic nutrition continue to evolve, and it would prove difficult to encompass all ingredients with potential health benefits.

Dressings and sauces are a traditional means of adding flavor and attraction to foods, and thus are a useful means of adding valuable, health-benefiting ingredients to the diet. The disqualification position of the current regulations precludes the use of this class of foods to provide important information to consumers, who are able to balance that information with the knowledge of the fat content of the food, as used in the total diet.

The conclusion that FDA's policy does not comport with the directive in Pearson is also supported by the regulation's failure to consider the source of fat in the

food product, which leads FDA to treat all fats as equal disqualifiers. However, fats are not identical. Some scientific evidence suggests dietary fats from animal sources are more closely linked to diseases such as cancer than are fats derived from vegetable sources. For example, a vitamin E health claim, combined with an accurate disclosure statement, could encourage consumers to emphasize healthier fats in their diets. Again, this suggests there is not a reasonable fit between FDA's current regulation and its public health goal.

Nor would a consumer fraud or confusion justification support a ban on the health claim. ADS members seek to make accurate, nonmisleading claims about the health benefits of their products (e.g., the presence of vitamin E because of the use of vegetable oils as ingredients in dressing and sauce products). With proper disclosures, there can be no argument that some health claims would deceive consumers, who must be assumed to understand caveats and disclaimers. See Pearson, 164 F.3d at 657-659. This principle applies equally to labels of conventional foods and dietary supplements.

D. Conclusion

The Pearson court directed that when credible evidence supports a claim, such as the vitamin E claim discussed in these comments, as only one example, FDA may not absolutely prohibit that claim if a disclaimer could alleviate any danger of consumer confusion. 164 F.3d at 659. ADS believes this is such a situation. FDA's current regulation prohibiting ADS members from pursuing a health claim informing consumers of the benefits of vitamin E in vegetable oils violates the principle set forth in Pearson v. Shalala: that disclosure is preferred over suppression of speech, and the First Amendment requires that the government trust consumers' ability to sort out truthful information in making health choices. ADS urges FDA to permit its members to include accurate, properly qualified health claims in their product labeling.

We would be pleased to provide additional information upon request.

Sincerely,



Richard E. Cristol
President

Smith, Donna

From: Smith, Donna
Sent: Friday, September 13, 2002 9:46 AM
To: 'fdadockets@oc.fda.gov'
Subject: Docket No. 02N-0209, Request for Comment on First Amendment Issues



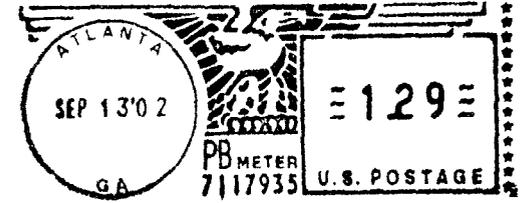
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