Qualified Health Claims: Creatures of Case Law

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Many foods today bear labeling claims that describe the relationship between the food or its ingredient(s), and the reduced risk of particular diseases or health-related conditions. Such "health claims" can be divided into three categories:

(1) health claims supported by significant scientific agreement and approved by the Food and Drug Administration (FDA)[1] (SSA claims);

(2) qualified health claims (QHCs) with disclaimers describing the state of emerging scientific data and approved by FDA; and

(3) notified health claims based on an authoritative statement of a U.S. governmental scientific body and notified to FDA at least 120 days prior to use.[2]

The legal authority for SSA claims and notified health claims derives directly from the Federal Food, Drug, and Cosmetic Act (FDCA) and the implementing FDA regulations. By contrast, QHCs are *not* defined or described in the FDCA or FDA regulations. Rather, the legal basis for QHCs is grounded in First Amendment law as interpreted and applied by the federal courts to rein in FDA.

Historically, including health- or disease-related information on food labels caused a food to be deemed a drug as defined in the FDCA: "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease … ."[3] In October 1984, Kellogg's launched a bold advertising campaign informing consumers of the relationship between its All-Bran® cereal and a reduced risk of certain cancers. The campaign marked the beginning of a long struggle with FDA over the use of food labeling to communicate meaningful health-related information to consumers in an effort to encourage healthy dietary choices.

Three years later, FDA was persuaded to publish proposed rules to allow limited health-related messages in food labeling.[4] Before FDA could complete its rulemaking, however, Congress stepped in and enacted the Nutrition Labeling and Education Act of 1990 (NLEA),[5] which allowed food and dietary supplements to bear health claims—without requiring approval as a new drug—provided FDA approved the claim. The NLEA granted FDA the authority to promulgate regulations authorizing health claims for foods if, "based on the totality of publicly available scientific evidence … 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."[6] The NLEA also permitted health claims for dietary supplements "subject to a procedure and standard, respecting the validity of such claim[s]," promulgated by FDA.[7] Pursuant to this authority, FDA decided to apply the SSA standard to health claims for either foods or dietary supplements.[8]

FDA implemented its SSA standard in 1993 without explaining the standard's meaning to the food and dietary supplement industries.[9] Additionally, the agency rejected comments submitted during the rulemaking process that the SSA standard violates the First Amendment.[10] Congress again intervened and enacted The Food and Drug Administration Modernization Act of 1997 (FDAMA),[11] to allow notified health claims for foods but not dietary supplements.

In 1998, a dietary supplement marketer asked FDA to authorize four separate health claims: 1) consumption of antioxidant vitamins to a possible reduction of risk of certain cancers; 2) consumption of fiber to a possible reduction of risk of colorectal cancer; 3) consumption of omega-3 fatty acids to a possible reduction of risk of coronary heart disease; and 4) a higher level of folic acid than is found in foods in common form to a possible reduction of risk of

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neural tube defects. FDA evaluated these four health claims pursuant to its SSA standard and concluded that the evidence supporting the claims failed to meet SSA.[12]

The dietary supplement marketers challenged FDA's SSA regulations. This first legal challenge to FDA's SSA standard—*Pearson v. Shalala* (*Pearson I*)[13]—gave rise to QHCs as they are known today. In *Pearson I*, the dietary supplement marketers argued that FDA's denial of the four health claims impaired their First Amendment rights, and that FDA's SSA standard should be clearly defined.

It is uncontested that a health claim constitutes commercial speech that is protected by the First Amendment, but can be restricted by the government, in this case FDA, if certain conditions are met. The Supreme Court's decision in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*[14] presents a four-part test to determine whether such government restriction is permitted. If the speech concerns a lawful activity and is not misleading (the first part of the test), it is protected by the First Amendment. The government can restrict lawful and not misleading commercial speech, however, if the government interest in the speech is substantial; the regulation restricting the speech directly advances the government interest; and the regulation is not more extensive than necessary to serve that interest.[15]

In *Pearson I*, FDA argued that the four proposed health claims were inherently misleading, thus failing the first part of the *Central Hudson* test, and were not protected by the First Amendment. The U.S. Court of Appeals for the D.C. Circuit disagreed and determined that the proposed health claims were only "*potentially* misleading" and therefore passed the first prong of the *Central Hudson* test. Applying the second and third parts of the *Central Hudson* test, the court agreed that FDA had an essential interest in protecting against consumer fraud, and that FDA's SSA standard advanced this interest. The court determined that FDA's SSA standard failed the final part of the test, however, because it was more extensive than necessary to serve the government's interest. Therefore, FDA's regulations impermissibly restricted commercial speech.

The court emphasized that, under the First Amendment, disclosure is preferable to outright suppression of speech. Therefore, instead of simply denying proposed health claims that lack SSA, FDA must consider use of clarifying disclaimers to negate the potential misleading nature of the claim.[16] The court realized that in some instances, however, a disclaimer might not validate a proposed health claim. The court concluded that FDA could ban claims lacking SSA outright when: 1) evidence in support of the claim is qualitatively weaker than evidence against the claim (e.g., when a claim is supported by only one or two old studies); and 2) evidence in support of the claim is outweighed by evidence against the claim.[17] With respect to the proposed dietary supplement claims at issue, the court found that a disclaimer could accommodate FDA's concerns about the first three claims. The court also found that "credible evidence" supported the fourth proposed claim—concerning folic acid—and that a clarifying disclaimer could be added to this claim.[18] Additionally, the court found that FDA's failure to define its SSA standard was arbitrary and capricious in violation of the Administrative Procedures Act.[19] The court instructed FDA to define its SSA standard, re-evaluate the proposed health claims at issue, and evaluate all proposed health claims on a case-by-case basis.

Nearly one year after the D.C. Circuit ordered FDA to define its SSA standard, and nine years after the NLEA created the standard, the agency issued a guidance for industry regarding SSA agreements (the 1999 Guidance).[20] In the 1999 Guidance, FDA stated that SSA "is met when the validity of the relationship is not likely to be reversed by new and evolving science, although the exact nature of the relationship may need to be refined over time."[21] The agency also published a notice in October 2000 indicating that it would not simply deny all health claims that did not meet the SSA standard; rather, FDA would "exercise enforcement discretion in the appropriate circumstances." One of these "appropriate circumstances" was when "the scientific evidence in support of [a] claim outweighs the scientific evidence against the claim, the claim is appropriately qualified, and all statements in the claim are consistent with the weight of the scientific evidence … ."[22]

Under this "weight of the scientific evidence" (WOSE) standard, FDA re-evaluated the folic acid health claim proposed by the plaintiffs in *Pearson I,* but again denied this claim. The agency issued a letter decision concluding that the WOSE was against the proposed claim, and that the claim was inherently misleading and could not be made nonmisleading with a disclaimer. The *Pearson I* plaintiffs filed a motion for preliminary injunction in *Pearson v. Shalala* (*Pearson II*)[23] arguing that FDA had misread and misapplied *Pearson I.*

The U.S. District Court for the District of Columbia agreed that FDA had failed to comply with the constitutional guidelines outlined in *Pearson I*, and stated that FDA has "continually refused to authorize … disclaimers … ."[24] The *Pearson II* court found that the proposed folic acid claim was not inherently misleading and that FDA erred by not drafting disclaimers to accompany it. The court noted that, under *Pearson I*, when "credible evidence" supports a claim,

the claim cannot be prohibited.[25] Both the *Pearson I* and *Pearson II* courts deemed the evidence supporting the folic acid claim credible; thus, it could not be banned outright. The *Pearson II* court repeated the *Pearson I* court's finding that FDA may ban a proposed health claim when evidence in support of the claim is outweighed by evidence against the claim. The *Pearson II* court then provided additional meaning for the term "against": "[t]he mere absence of significant affirmative evidence in support of a particular claim … does not translate into negative evidence 'against' it."[26]

Following *Pearson I* and *Pearson II*, FDA "shoulder[ed] a very heavy burden" in seeking to ban health claims.[27] In December 2002, the agency published a guidance for industry regarding QHCs and labeling (the 2002 Guidance) as part of its "continuing effort to comply with [*Pearson I*]."[28] In the 2002 Guidance, FDA re-articulated that it would allow QHCs claims when SSA is not present if the scientific evidence in support of the claim outweighed the scientific evidence against it.

After *Pearson I*, FDA continued to review proposed health claims on a case-by-case basis. Through a letter decision, the agency denied a proposed claim linking antioxidant vitamins in dietary supplements to a reduction of certain kinds of cancer. According to FDA, the claim failed to meet the SSA standard and the scientific evidence against the relationship was greater than the evidence in favor of the relationship. The claim was inherently misleading, therefore, and could not be made nonmisleading with a disclaimer.

In *Whitaker v. Thompson* (*Whitaker I*),[29] a new group of plaintiffs argued that, in denying the antioxidant vitamin claim, FDA had misread and misapplied *Pearson I*. The U.S. District Court for the District of Columbia found that—as in the previous *Pearson* cases—the antioxidant claim was not inherently misleading. Applying the *Central Hudson* test, as well as the conclusions of *Pearson I* and *Pearson II*, the court concluded that FDA had "once again failed to comply with the constitutional guidelines outlined in *Pearson I*."[30]

The *Whitaker I* court interpreted *Pearson I* as identifying the narrow circumstances under which a complete ban of a health claim as inherently misleading would be reasonable: 1) when FDA determines that no evidence supports the claim, or 2) when FDA determines that evidence in support of claim is qualitatively weaker than evidence against claim (e.g., only one or two old studies support the claim) *and* FDA demonstrates with empirical evidence that disclaimers would bewilder consumers and fail to correct for deceptiveness. In the case at hand, FDA reviewed more than 150 studies concerning the relationship between antioxidant vitamins and a reduction of certain kinds of cancer. One-third of these studies supported the relationship. The court contrasted this number of studies against the "one or two old studies" hypothesized by the *Pearson I* court as grounds for banning proposed health claims outright, and concluded that FDA failed to follow *Pearson I* as well as its own 1999 Guidance.[31] Once again FDA was instructed to draft disclaimers that could accompany the proposed health claim.

Like the *Pearson* plaintiffs, the *Whitaker* plaintiffs challenged FDA's decisions a second time. FDA also had denied a proposed health claim for saw palmetto supplements that stated that consumption of saw palmetto extract may improve symptoms associated with mild benign prostatic hyperplasia (BHP). FDA concluded that BHP was a disease and that claims about effects on existing diseases do not fall within the scope of health claims and, therefore, could not be the subject of an authorized health claim.

In *Whitaker v. Thompson* (*Whitaker II*),[32] the U.S. District Court for the District of Columbia again applied First Amendment law to evaluate FDA's denial of the claim. A more crucial analysis in *Whitaker II*, however, was one of statutory interpretation. The court applied the analytic framework set forth in *Chevron USA Inc. v. Natural Resources Defense Council, Inc.*[33] to determine whether FDA's decision to limit approved health claims to those involving disease risk reduction was lawful.

Chevron provides courts with a two-step test to determine whether they should defer to an agency's interpretation of a statute. Under the first step, the court asks whether Congress has "directly spoken to the precise question at issue."[34] If the statute is "silent or ambiguous," the court proceeds to step two and asks whether the agency's interpretation of the statute is "based on a permissible construction of the statute."[35] The *Whitaker II* court determined that the FDCA, the NLEA, the Dietary Supplement Health and Education Act of 1994 (DSHEA),[36] and their respective legislative histories, did not demonstrate a clear congressional intent with respect to the appropriate scope of health claims. The court noted that the NLEA created a framework for the authorization of health claims for dietary supplements, but delegated full authority to FDA to adopt an appropriate standard for approving such claims. Thus, Congress' intent with respect to the appropriate scope of health claims was ambiguous.[37]

Applying step two of the *Chevron* analysis, the *Whitaker II* court needed only to find that FDA's decision to limit health claims to those involving disease risk reduction was rational. Because Congress had relied on reports that focused on the role of diet in reducing disease risk, not in treating existing disease,

the court found that FDA had acted rationally.[38] FDA's decision to limit approved health claims to those involving disease risk reduction—and, consequently, its determination that the saw palmetto claim was unlawful—was permissible and reasonable. Because the saw palmetto claim was unlawful, it failed the first part of the *Central Hudson* test and was not protected by the First Amendment. Consequently, FDA's denial of the claim did not violate the First Amendment.[39]

Meanwhile, in light of *Whitaker I*, FDA established a new threshold for evaluating evidence and deciding whether to allow qualified health claims. The agency modified the WOSE standard articulated in its 2002 Guidance with a test of "credible evidence." Under an interim guidance regarding QHCs and labeling (2003 Interim Guidance), which is still in effect today, FDA requires that petitions for proposed health claims explain how "credible evidence" supports the claim.[40]

FDA's 2003 Interim Guidance has been challenged in court. In *Center for Science in the Public Interest v. FDA*,[41] two public interest organizations alleged that the 2003 Interim Guidance set forth a new regulatory regime in which FDA would allow "certain claims about purported health benefits of foods, without following the procedural requirements or meeting the substantive standard of the [NLEA]."[42] The plaintiffs could not point to a food label that was inaccurate or misleading as a result of the 2003 Interim Guidance, however, because only one qualified health claim had been submitted to FDA under the 2003 Interim Guidance, and it had not yet been reviewed. Thus, the plaintiffs had not yet suffered an injury in fact and did not have standing to bring the suit. Additionally, the court held that the issue was not ripe for review because the alleged procedural violation applied to an interim guidance. FDA's 2003 Interim Guidance is not final agency action, but a nonbinding pre-enforcement policy statement that allows FDA to exercise enforcement discretion until such time as regulations can be promulgated by notice-and-comment rulemaking. The court found that to suffer an injury in fact, not only would FDA have to decide to permit a particular QHC, but also the QHC must be so misleading that the members of the public interest groups wrongly relied on the QHC and were adversely affected as a result.

As stated succinctly by Justice O'Connor in *Thompson vs. Western States Medical Center*, "[i]f the First Amendment means anything, it means that regulatory speech must be a last- not first-resort."[43] FDA has reluctantly acquiesced to the principles of First Amendment law applied by the federal courts in *Pearson I* and its progeny over the last seven years. Disclaimers devised by FDA for QHCs range from "scientific evidence suggests but does not prove" to "FDA concludes that it is highly unlikely." Caution should be exercised when requesting FDA approval for a QHC. Not only must the proposed claim be couched in terms of risk reduction for disease to avoid denial as an illegal drug claim, but also the WOSE, tempered by the credible evidence test, must be sufficiently strong to avoid an "FDA concludes that it is highly unlikely" disclaimer.

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1 21 U.S.C. § 343(r)(1)(B), (3)(A); *see also* 21 C.F.R. § 101.14, 101.70(a)(1) (defining a "health claim" as "any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, … characterizes the relationship of any substance to a disease or health related condition.").

2 21 U.S.C. § 343(r)(3)(C).

3 *Id.* § 321(g)(1)(B).

4 *See* 52 Fed. Reg. 28,843 (Aug. 4, 1987); 55 Fed. Reg. 5176 (Feb. 13, 1990).

5 Pub. L. No. 101-535, 104 Stat. 2253 (1990).

6 21 U.S.C. § 343(r)(3)(B)(i).

7 *Id.* § 343(r)(5)(D).

8 21 C.F.R. § 101.14(c).

9 *See* 58 Fed. Reg. 2478, 2533 (Jan. 6, 1993).

10 59 Fed. Reg. 395, 422-23 (Jan. 4, 1994).

11 Pub. L. No. 105-115, 111 Stat. 2296 (1997).

12 Pearson v. Shalala, 164 F.3d 650, 653 (D.C. Cir. 1999), *reh'g en banc*, *denied*, 172 F.3d 72 (1999) [hereinafter *Pearson I*] (*citing* 21 C.F.R. §§ 101.71(a), (c), (e), 101.79(c)(2)(i)(G) 1998)).

13 *Id.*

14 447 U.S. 557 (1980).

15 *Id.* at 566.

16 *Pearson I,* 164 F.3d at 659.

17 *Id.*

18 *Id.* at 658.

19 Pub. L. No. 89-554, 80 Stat. 381 (1966).

20 FDA, Center for Food Safety and Applied Nutrition (CFSAN), Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (Dec. 22, 1999) [hereinafter the 1999 Guidance], *available at* http://www.cfsan.fda.gov/~dms/ssaguide.html (last visited Sept. 22, 2005).

21 *Id.* at sec. E.

22 65 Fed. Reg. 59,855, 59,856 (Oct. 6, 2000).

23 130 F. Supp. 2d 105 (D.D.C. 2001).

24 *Id.* at 114.

25 *Id.* (*citing Pearson I,* 164 F.3d at 659).

26 *Id.* at 115.

27 *Id.* at 118.

28 FDA, CFSAN, Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements (Dec. 2002) [hereinafter the 2002 Guidance], *available at* http://www.cfsan.fda.gov/~dms/hclmgui2.html (last visited Sept. 23, 2005).

29 248 F. Supp. 2d 1 (D.D.C. 2002).

30 *Id.* at 8.

31 *Id.* at 11-12.

32 239 F. Supp. 2d 43 (D.D.C. 2003) [hereinafter *Whitaker II*].

33 467 U.S. 837 (1984).

34 *Id.* at 842.

35 *Id.* at 843.

36 Pub. L. No. 103-417, 108 Stat. 4325 (1994).

37 *Whitaker II*, 239 F. Supp. 2d at 50, 51.

38 *Id.* at 52 (*citing* H.R. Rep. No. 101-538, at 9 (1990)).

39 *Id.* at 54.

40 FDA, CFSAN, Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements (July 10, 2003) [hereinafter the 2003 Interim Guidance], *available at* http://www.cfsan.fda.gov/~dms/hclmgui3.html (last visited Sept. 23, 2005).

41 2004 U.S. Dist. LEXIS 18541 (D.D.C. 2004).

42 *Id.* at *2.

43 535 U.S. 357, 373 (2002).