

that, on the administrative record compiled in the challenged rulemakings, the first amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably concludes that a disclaimer would not eliminate the potential deception.

The Appeals Court further stated that it did not “rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright.” (164 F. 3d at 659.) Also, the court saw “no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than the evidence against the claim.” *Id.* at 659 n.10. This language was the genesis of the “weight of the evidence” criterion discussed in this ANPRM.

In the **Federal Register** of October 6, 2000 (65 FR 59855), following the Appeals Court ruling in *Pearson*, FDA published a notice announcing its intention to exercise its enforcement discretion with regard to certain categories of dietary supplement health claims that may not meet the SSA standard currently endorsed in § 101.14(c).⁴ The October 6, 2000, notice identified circumstances in which the agency intended to consider exercising enforcement discretion for a qualified health claim in dietary supplement labeling. Included in the agency’s consideration was whether the scientific evidence in support of a given health claim outweighed the scientific evidence against it. In the **Federal Register** of December 20, 2002 (67 FR 78002), FDA published a notice of availability announcing that the agency was identifying qualified health claim enforcement discretion factors in the form of guidance and expanding its consideration of enforcement discretion

to include health claims in the labeling of conventional foods as well as dietary supplements.⁵

Six days after publication of the December 20, 2002, notice and the guidance, the U.S. District Court for the District of Columbia issued its decision in *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002) (*Whitaker*). In *Whitaker*, the district court, interpreting *Pearson*, found that “credible evidence,” rather than “weight of the evidence,” is the appropriate standard for FDA to apply in evaluating qualified health claims. *Whitaker*, 248 F. Supp. 2d at 10. In light of *Whitaker*, FDA believes that the weight of the evidence standard in the October 6, 2000, **Federal Register** notice and the December 20, 2002, guidance must be tempered by the test of credible evidence (68 FR 41387 at 41388–41389).

Also in December 2002, FDA announced a major new initiative, the Consumer Health Information for Better Nutrition Initiative, to make available more and better information about conventional foods and dietary supplements to help consumers improve their health and decrease the risk of contracting diseases by making sound dietary decisions. Under this initiative, the agency established the Task Force on Consumer Health Information for Better Nutrition (the Task Force). The Task Force was charged with, among other things, reporting on how the agency can improve consumer understanding of the health consequences of dietary choices and increase competition by product developers in support of healthier diets. This charge includes how the agency should evaluate scientific evidence for qualified health claims, as well as developing a framework for regulations that will give these principles the force and effect of law.

FDA announced the availability of the Task Force report (Ref. 1), in a notice published in the **Federal Register** of July 11, 2003 (68 FR 41387). The notice also announced the availability of two guidances entitled “Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data” (Ref. 2) and “Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements” (Ref. 3) that further updated the agency’s approach on how it intends to implement the *Pearson* decision. Further, the notice stated that FDA intended to publish an ANPRM to solicit comments on the regulatory approaches and topics addressed in the

Task Force report. This ANPRM is that document.

As of September 1, 2003, the agency has implemented the evidence-based ranking system and the procedures for qualified health claims⁶ on an interim basis. However, FDA recognizes the need for transparent, long-term procedures that have the force and effect of law.⁷ Such procedures would benefit both the industry and the consumer, provided they result in well-reasoned, science-based decisions that facilitate the communication of truthful and non-misleading information to the consumer. To this end, the agency is issuing this ANPRM to solicit comment on various approaches the agency might adopt to regulate qualified health claims in the labeling of conventional foods and dietary supplements.⁸

Although the Task Force focused primarily on the issue of qualified health claims, its discussions were enriched by considerations related to promoting partnerships with sister public health agencies and others, with the goal of increasing the quantity and improving the impact of health messages⁹ on conventional human foods

⁶ FDA is using the term “qualified health claim” to refer to health claims that do not meet the current SSA standard. This is in contrast to FDA’s use of the term “unqualified health claim” to refer to health claims that meet the current SSA standard and are or could be authorized under the NLEA and regulations issued under the act, including 21 CFR 101.70.

⁷ Since the October 2000 **Federal Register** notice and under the December 2002 guidance, when FDA decides to exercise its enforcement discretion with respect to a qualified health claim, it so notifies the petitioner by letter. This process was developed as a short-term response to the court decisions described above and does not provide for public participation.

⁸ In accordance with the recommendation of the Task Force, FDA is also conducting consumer research to determine whether potentially misleading health claims can be cured by disclaimers in at least some cases. The agency does not have such data for conventional foods or dietary supplements. Within the next year, the agency will be completing research in this area. FDA’s rulemaking will be informed by the results of this research, as well as the agency’s evaluation and consideration of the regulatory alternatives and public comment.

⁹ In the **Federal Register** of November 27, 1991 (56 FR 60537 at 60538), FDA stated that for consistency with the NLEA, the agency was using the term “health claim” in place of “health message,” which was used in pre-NLEA **Federal Register** documents (i.e., proposed rule of August 4, 1987 (52 FR 28843); ANPRM of August 8, 1989 (54 FR 32610); and re-proposed rule of February 13, 1990 (55 FR 5176)) that discussed disease-related information on food labeling. Thus, the use of the term “health message” in those previous documents was roughly equivalent to the use of the term “health claim” in post-NLEA **Federal Register** documents. In recent documents (e.g., the December 2002 guidance, the Task Force report), including this ANPRM, however, FDA is using the term “health message” in a broader context than solely to

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rehearing on April 2, 1999 (172 F.3d 72 (D.C. Cir. 1999)).

⁴ In the **Federal Register** of December 1, 1999 (64 FR 67289), FDA published a notice to inform the public of the steps FDA planned to follow to carry out the *Pearson* decision. In the **Federal Register** of December 22, 1999 (64 FR 71794), FDA published a notice of availability of guidance clarifying the SSA standard in light of *Pearson*. The October 2000 notice announced FDA’s revisions to the 1999 implementation strategy.

⁵ FDA decided to apply the enforcement discretion factors to conventional foods to promote consistency in health messages, to enable consumers to learn about important health information even if it may not necessarily meet the current SSA standard, and to avoid further litigation over the constitutionality of the health claims provisions of the NLEA applicable to conventional food labeling to the extent that these provisions do not permit qualified claims (68 FR 41387 at 41389).