

any substance-disease relationship, no matter how weak or preliminary the evidence, would meet SSA as long as the claim accurately described the level of the evidence.

This approach may be vulnerable to a first amendment challenge because it applies the statutorily prescribed process for reviewing unqualified health claims to qualified health claims. The statutory process requires notice-and-comment rulemaking and permits FDA up to 540 days to complete its review of a health claim petition (see 21 U.S.C. 343(r)(4)(A)(i)). Although the United States Court of Appeals for the Second Circuit has held that a period of 540 days is not an unconstitutional prior restraint for unqualified health claims (see *Nutritional Health Alliance v. Shalala*, 144 F.3d 220 (1998), cert. denied, 525 U.S. 1040 (1998)), it is unclear whether it is too long to restrain qualified health claims in which the SSA standard is applied to the claim itself rather than the substance/disease relationship. FDA is concerned that this approach may be found to be unconstitutional because the value of commercial speech often depends upon its timeliness.

3. Option 3

A third option would be to treat qualified health claims as wholly outside the NLEA and regulate them on a postmarket basis under section 403(a)(1) of the act, which provides that food is misbranded if its labeling is false or misleading. Consistent with FDA's past practice, "false or misleading" would be defined to include lacking substantiation.

Under this approach, FDA could only evaluate and, where necessary, prohibit a claim after it appears on a product label (or in other product labeling). This is similar to the Federal Trade Commission's (FTC) approach, but with one significant difference: FTC has administrative subpoena power, allowing FTC to obtain a company's substantiating data, evaluate the data, and, where appropriate, take enforcement action with relative speed. In contrast, while FDA holds administrative subpoena power in some circumstances, the agency is not vested with such power for the investigation and enforcement of health claims in the labeling of conventional foods and dietary supplements.

As a result, the agency would have to build enforcement cases by first searching the literature and consulting with experts. Depending on the nature of the matter, FDA might also have to test how consumers would interpret the claim (where, for example, there was a

serious question about the existence of an implied claim). There is also a concern that this option would not afford FDA any role in reviewing or clearing claims before they appeared in labeling and would not provide any opportunity for public participation. Finally, this option could be inefficient and too resource intensive for FDA to be able to protect consumers from misleading claims that would already be in the labeling of products in the marketplace.

B. Issues Raised in the Task Force Report

In its report, the Task Force recommended that FDA seek comment on several additional topics: (1) Data and research on a substance/disease relationship, including incentives for SSA; (2) revised claim language for unqualified health claims; (3) interim final rules for unqualified health claims; (4) use of phrases such as "FDA authorized" in qualified and unqualified health claims; (5) consumer education; (6) evaluations of outside groups; and (7) competent and reliable evidence.

1. Data and Research on a Substance/Disease Relationship, Including Incentives for SSA

Although FDA intends to provide for the use of qualified health claims, the agency remains interested in authorizing unqualified health claims by regulation under the SSA standard. Based on the July 2003 interim evidence-based ranking guidance (Ref. 2), the level of scientific evidence to support the substance/disease relationship for an unqualified health claim would continue to be based on relevant, high quality studies, such as randomized, controlled intervention trials and prospective observational cohort studies, which minimize bias. FDA is requesting comments on how to provide incentives for manufacturers to develop the data needed to obtain SSA for an unqualified health claim. In addition, FDA is requesting comments on how to more effectively develop public-sponsored research on substance/disease relationships.

2. Revised Claim Language for Unqualified Health Claims

The health claim regulations require unqualified health claims to state that the substance "may" reduce the risk of the specified disease (e.g., "calcium may reduce the risk of osteoporosis") (§ 101.14(d)(2)(ii)). In the final rule on general requirements for health claims for conventional foods (58 FR 2478 at 2505), FDA explained that the agency's

use of the term "may" relates to the potential to reduce the risk of disease. The agency intended the use of the word "may" to convey to consumers that there is no guarantee that any one dietary practice will, in fact, reduce an individual's risk of a disease. FDA noted that absolute claims about diseases affected by diet generally are not possible because such diseases are almost always multifactorial, and that diet is only one factor that influences whether a person will get such a disease (58 FR 2478 at 2505). For example, in the case of calcium and osteoporosis, genetic predisposition (e.g., where there is a family history of fragile bones with aging) can play a major role in whether an individual will develop the disease. Id. Because of factors other than diet, some individuals may develop the disease regardless of how they change their dietary patterns to avoid the disease. Id. Thus, FDA intended the word "may" to alert consumers that there is no certainty that risk of disease will be reduced for each individual. However, it seems to the agency that in common practice the word "may" could be, and perhaps often is, interpreted as a reflection of the science supporting the claim rather than the certainty about the ability of a dietary practice to affect any one consumer. Thus, the word "may" leads to uncertainty about the science behind the claim, which was not FDA's intention.

The Task Force suggested that FDA consider removing the requirement for the word "may" from unqualified health claims to eliminate the uncertainty about the science underlying claims that meet SSA. FDA is requesting comments on whether the agency should make this change, whether there are alternatives to this change, and whether such a change would assist consumers in identifying the level of science supporting such health claims.

3. Interim Final Rules for Unqualified Health Claims

The Task Force recommended that FDA solicit comment on whether FDA should authorize unqualified health claims through interim final rules (IFRs) to expedite the availability of the health claim in food labeling. Before *Pearson*, the agency's general practice was to provide for the unqualified health claim through full notice-and-comment rulemaking, i.e., by issuing a proposed rule with a comment period, followed by a final rule authorizing the health claim (see section 403(r)(4)(A)(i) and § 101.70(j)). Although this practice has made for a relatively slow process, the comments received have proved useful to the agency (e.g., to more accurately