



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

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Dockets Management Branch
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Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Guidance for Industry: Significant Scientific Agreement in the Review of Health Claims for Conventional Foods and Dietary Supplements (64 Federal Register 71794 (December 22, 1999) [DOCKET NO. 99D-5424].

Re: Notice: Strategy For Implementation of Pearson Court Decision (64 Fed. Reg. 67289 (December 1, 1999) [DOCKET NOS. 91N-0101, 91N-0098, 91N-0103, and 91N-100H].

Dear Sir or Madam:

These comments are submitted on behalf of International Dairy Foods Association (IDFA) and its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. The approximately 850 member companies of these associations operate more than 1550 processing and manufacturing plants, which account for 85% of dairy products consumed in the United States. IDFA and its members have substantial direct experience with FDA's "significant scientific agreement" standard, which governs health claim authorization, in developing product labeling claims, and in pursuing formal health claim approval. In addition, IDFA's experience arises from its work as a contractor in developing claims and claims substantiation in support of the "Milk Mustache" campaigns sponsored by the Milk Processor Education Program, and conducted under the supervision of the U.S. Department of Agriculture. In these capacities, IDFA and its member companies have experienced first hand the substantial barrier to truthful, nonmisleading, and fully substantiated health claims that is imposed through the application of the "significant scientific agreement" standard articulated in the above referenced industry guidance. Most fundamentally, it is FDA's application of this standard that gave rise to the First Amendment violations the court found in the landmark decision in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999).

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The Pearson v. Shalala Decision

The Pearson decision constitutes the first time a court ever subjected FDA's standard for health claim approval to close scrutiny under the First Amendment. In a strongly worded opinion, the court firmly rejected FDA's argument that it should be accorded greater latitude to regulate health claims in food labeling than applies to commercial speech generally. *Id.* at 655. The court held that FDA's ban of four specific health claims under the "significant scientific agreement" standard, without regard to whether these claims could be accurately stated in a more qualified manner in view of the weight of substantiating evidence, violated the First Amendment. Although the court also held that FDA had violated the Administrative Procedure Act by failing to explain what FDA requires to satisfy the "significant scientific agreement" standard, the court noted that, even if better defined, properly worded health claims may nonetheless be permitted under the First Amendment "that do not meet that standard . . ." *Id.* at 654 (emphasis added).

The implications of the Pearson decision are far reaching. FDA's ban of the specific health claims at issue in Pearson did not reflect an aberration in FDA's approach, but rather served vividly to illustrate how FDA has instituted a categorical ban on all qualified health claims under the "significant scientific agreement" standard. While FDA has insisted that the suppression of such qualified claims is necessary to serve government policy objectives, these arguments were marshaled by FDA lawyers in Pearson, and were found wanting. The Pearson court flatly rejected FDA arguments that legitimate public health objectives could be served through the suppression of truthful, nonmisleading health claims. Relying on a substantial body of Supreme Court case law, the Pearson court emphasized that this is precisely the kind of choice the U.S. Constitution makes for us. The government cannot justify a ban on truthful speech merely because it sees some advantage to public ignorance of the actual facts. *Id.* at 655. Moreover, since qualified health claims of the kind contemplated by the court in Pearson are routinely employed in consumer advertising and promotions in full conformance with the "reasonable basis" standard of the Federal Trade Commission (FTC) – and the huge body of undergirding antideception case law, FDA's argument that its standard is necessary to prevent consumer deception lacks credibility.

"Health claims," like all other health messages, are permitted in food and dietary supplement advertising and promotions regulated by the FTC, provided they are truthful, and nonmisleading in view of the weight of the substantiating scientific evidence. The standards that must be satisfied to ensure a claim is nondeceptive and substantiated have been developed through antideception case law, and are founded on foundational common law principles. In its most recent policy statement on health-related claims for foods, FTC described its substantiation standard as a

"truth-in-advertising law [which] can be boiled down to two common-sense propositions: (1) advertising must be truthful and not misleading; and (2) before disseminating an ad, advertisers must have adequate substantiation for all product claims."

FTC Bureau of Consumer Protection, Dietary Supplements: An Advertising Guide for Industry 3 (November 1998) ("Advertising Guide"). See also Deception Policy Statement, 103 F.T.C. 174 (1983); Substantiation Statement, 104 F.T.C. 839 (1984); Food Advertising Enforcement Policy Statement, 59 Fed. Reg. 28388 (June 1, 1994).

Under its policy, FTC has emphasized that its "substantiation standard is a flexible one that depends on many factors. When evaluating claims about the efficacy and safety of foods . . . the FTC has typically applied a substantiation standard of competent and reliable scientific evidence." Advertising Guide at 3. FTC considers "all forms of competent and reliable scientific research when evaluating substantiation." *Id.* at 10.

Implications of Pearson For the Significant Scientific Agreement Standard

The Pearson decision means that FDA no longer can continue to ban or restrict the use of health claims in food labeling that are stated in a truthful, nonmisleading manner in view of the weight of the substantiating evidence. While the First Amendment requirements articulated in Pearson and the large body of case law upon which the decision is founded might quite readily be satisfied under a "reasonable basis" standard, Pearson raises doubt whether these requirements can be satisfied within the existing statutory definition of "significant scientific agreement" at section 403(r)(3)(B)(i). In any case, FDA's obvious misreading of the statutory standard, as reflected in the present guidance, has only magnified the constitutional difficulties presented.

Under section 403(r)(3)(B)(i), FDA must authorize a health claim when it finds, "based on the totality of publicly available scientific evidence . . . there is significant scientific agreement, among [qualified] experts . . . , that the claim is supported by such evidence." 21 U.S.C. 343(r)(3)(B)(i)(emphasis added). There is no rational legal basis for FDA to avoid review of specific qualified claims, and apply this standard to the generic question of whether a particular diet/disease relationship has been established as "scientifically valid." Industry Guidance at page 16. Qualified experts clearly could agree that a particularly worded health claim accurately characterizes a diet/disease relationship in view of the weight of the supporting scientific evidence, without necessarily agreeing that the relationship has been proved "valid." The statutory standard focuses on the accuracy of the claim. By focusing instead on relationship "validity" – FDA ventures down a path that is met with all the hazards that accompany any pursuit of ultimate truth.

The history of science and medicine proves that, despite the objective standards of the best scientific method, the meaning of scientific results at a given point in time is a matter upon which free minded experts may disagree. The result of FDA's approach is that, regardless of the accuracy of a specific claim in reflecting the weight of the evidence, it is not allowed unless it conforms with the version of truth that is held by those empowered to make that decision. This danger to free speech is made worse by the off-the-record consultations on health claim petitions in which FDA engages with government scientists, who are not held publicly accountable for the views they may express on a health claim petition. Concerns over the Administrative Procedure Act violations caused by this backdoor process was the subject of an IDFA petition filed in 1996, addressing an FDA

health claim ruling that was not supported by the administrative record. See IDFA Petition for Reconsideration [96P-0047].

Moreover, since FDA's entire regulatory approach attempts to conform health messages with the official dietary guidance issued by the federal government, this means that to be approvable, it is not sufficient that a health claim be truthful, it must fit with the official guidance. Adding all this up, FDA's health claim approval process imposes an insurmountable burden on free speech. At the very heart of the problem is FDA's focus on whether a diet/disease relationship has been established as "scientifically valid" under the "significant scientific agreement" standard rather than simply assessing the more limited question of the truthfulness of a given claim.

Beyond the legal and political problems presented by FDA's approach, are the scientific problems in attempting to "freeze frame" reality by determining the nature of diet/disease relationships that are "valid" and codifying them in a rule. FDA's approach leaves little room to accommodate the forward march of science, which obligates both FDA and those making claims constantly to review new findings and adjust understandings. The history of science and medicine is filled with theories that once were embraced as "valid" but were later shown to be unfounded. While modern medicine has brought miracle discoveries that should silence any proponent of "miasma" or "bleeding" therapy, it is dangerous ever to exalt current knowledge as "valid," presuming it cannot be toppled by future research. Surely, the nutritionists of the past would be surprised to see the importance of dietary cholesterol intake downplayed today as a contributor to serum cholesterol levels. They would be surprised to see the milk-based diets used to treat ulcer patients abandoned in favor of antibiotic therapy. They would undoubtedly be surprised to see the current emphasis on dietary constituents like flavonoids and fatty acid fractions to enhance health, even though these have no formal scientific recognition as "nutrients." It is a fact of life that science marches on in an industrialized country like ours, and topples even the most well established theories when they prove to be untrue. The government's theories are not exempt.

Even when the government has anointed a diet/disease relationship as "valid," it cannot insulate its determination from future research findings. For example, there is a strong body of evidence showing that FDA's sodium/hypertension health claim focuses on an isolated dietary factor that has little impact on the blood pressure levels for most people. The persistence of this questionable claim, while maintaining standards that block other meaningful claims leaves the public with a misleading picture of the relative importance of dietary factors that influence blood pressure control. It is hard to see how this furthers public health.

FDA applies its relationship "validity" standard not only in determining whether claims can be made at all, but in formulating specific "model claims" and the requirements that must be included in each iteration of the approved claim in food labeling. This means that FDA's view of what is scientifically "valid" results in a formulaic health claim message which must be used without regard to the particular labeling context, or target consumer. This, of course, makes the false assumption that the best way to communicate with

consumers is to convey to them a standardized description of the diet/disease relationship that FDA has deemed "valid," using the most scientifically precise terms possible. There is no place in FDA's system to account for the ever changing consumer. The experts in consumer communications, advertisers and marketers, tell us that nothing could be less effective in reaching a varied spectrum of consumers than a boilerplate message meant for all people and all contexts. To really reach consumers, it is necessary to tailor the message to meet their frames of reference, interests, and needs. FDA's standard eliminates the opportunity for creative health messages even concerning relationships FDA has deemed "valid."

By setting up a relationship "validity" standard, and codifying it in health claim regulations, FDA's policy blocks truthful speech, and too rigidly controls the messages even concerning relationships it deems "valid." FDA's "validity" standard unavoidably institutes an inflexible system of speech banning rules that are destined for obsolescence and cannot be changed readily or efficiently enough to keep pace with advancing science. The policy ultimately means that labeling can only state health claims in accordance with the government's prescribed message, even though it is outdated and ineffective in reaching consumers.

FDA's regulation of calcium/osteoporosis health claims illustrates the point. 21 C.F.R. 101.72. While FDA's factual findings recognize that both men and women are at risk for developing osteoporosis, and that maintaining adequate calcium intake throughout life is a key to reducing the risk of osteoporosis,¹ FDA's cramped specifications for what must be stated in an actual claim ignore these basic facts. Regardless of the nature of the product or the context in which a claim would be used, FDA rules prohibit osteoporosis claims (assertedly as misleading) unless they specify the special needs of subpopulations, with such terms as "white and Asian women," "menopausal women" and "elderly men."² Needless to

¹ "Peak bone mass is the total quantity of bone present at maturity, and experts believe that it has the greatest bearing on whether a person will be at risk of developing osteoporosis and related bone fractures later in life. Another factor that influences total bone mass and susceptibility to osteoporosis is the rate of bone loss after skeletal maturity. An adequate intake of calcium is thought to exert a positive effect during adolescence and early adulthood in optimizing the amount of bone that is laid down. However, the upper limit of peak bone mass is genetically determined. The mechanism through which an adequate calcium intake and optimal peak bone mass reduce the risk of osteoporosis is thought to be as follows. All persons lose bone with age. Hence, those with higher bone mass at maturity take longer to reach the critically reduced mass at which bones can fracture easily. The rate of bone loss after skeletal maturity also influences the amount of bone present at old age and can influence an individual's risk of developing osteoporosis. Maintenance of an adequate intake of calcium later in life is thought to be important in reducing the rate of bone loss particularly in the elderly and in women during the first decade following menopause."

21 C.F.R. 101.72(a).

² "A health claim associating calcium with a reduced risk of osteoporosis may be made on the label or labeling of a food describe in paragraph (c)(2)(ii) of this section, provided that:

say, these kinds of qualifiers do not entice advertising executives whose career success depends on reaching real consumers. To the contrary, while concise, attractive, and even clever osteoporosis claims are used in FTC regulated advertising like the "Milk Mustache" advertising campaign (a campaign in which even Secretary Donna Shalala has participated, sporting her own celebrity milk mustache), there is precious little use of osteoporosis claims on food labels in the dairy industry – even though such products are among the best dietary sources of calcium there are. This is because FDA's claim is cumbersome and racially sensitive. FDA's "our-way-or-no-way" regulatory approach leaves marketers with no real alternative but to abandon health claims in labeling. There is no question that FDA's approach chills truthful speech, even with respect to diet/disease relationships approved as "valid."

The relationship "validity" objective around which FDA's entire "significant scientific agreement" methodology is framed, ultimately cannot be squared with the mandates of the First Amendment. The Pearson decision and the body of case law on which it is founded requires that FDA abandon its focus on the "validity" of diet/disease relationships and focus instead on the truth of the actual claim a manufacturer wishes to make in view of the weight of substantiation.

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- (A) The claim makes clear that adequate calcium intake throughout life is not the only recognized risk factor in this multifactorial bone disease by listing specific factors, including sex, race, and age that place persons at risk of developing osteoporosis and stating that an adequate level of exercise and a healthful diet are also needed;
 - (B) The claim does not state or imply that the risk of osteoporosis is equally applicable to the general United States population. The claim shall identify the populations at particular risk for the development of osteoporosis. These populations include white (or the term "Caucasian") women and Asian Women in their bone forming years (approximately 11 to 35 years of age or the phrase "during teen or early adult years" may be used). The claim may also identify menopausal (or the term "middle-aged") women, persons with a family history of the disease, and elderly (or "older") men and women as being at risk;
 - (C) The claim states that adequate calcium intake throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase "build and maintain good bone health" may be used to convey the concept of optimizing peak bone mass. When reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may also state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss;
 - (D) The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate calcium intake throughout life; and
 - (E) The claim states that a total dietary intake greater than 200 percent of the recommended daily intake (2,000 milligrams (mg) of calcium) has no further known benefit to bone health. This requirement does not apply to foods that contain less than 40 percent of the recommended daily intake of 1,000 mg of calcium per day or 400 mg of calcium per reference amount customarily consumed as defined in Sec. 101.12(b) or per total daily recommended supplement intake."

Id. at 101.72(c).

FDA's Pearson Implementation Plan

The Pearson decision is no aberration and must be taken seriously by FDA. It rests on a solid foundation of nearly 30 years of case law, and comes from a court well familiar with FDA. The time has come for FDA finally to embrace the constitutional standards to which its policies must conform. FDA cannot make the policy reforms mandated by Pearson, while it continues to hold fast to the "significant scientific agreement" standard articulated in the industry guidance.

IDFA makes three observations concerning FDA's response to the Pearson decision that have raised concern about the agency's readiness to fully embrace the court's ruling. First, FDA's issuance of "industry guidance" on "significant scientific agreement," without first addressing the First Amendment issues presented by Pearson, - assertedly to "promptly comply with the [Pearson] decision" (64 Fed. Reg. at 71794), raises serious concern. We fail to see how more fully articulating the very standard that resulted in the First Amendment violations in Pearson can be said to "comply" with the Pearson decision in any way. This maneuver addresses nothing more than "appearances," and suggests that FDA does not fully appreciate the integral connection between FDA's standard, which applies to all conventional foods and dietary supplements, and the specific First Amendment violations the Pearson court identified.

Second, IDFA observes that, while the specific claims at issue in Pearson concerned dietary supplement products, the First Amendment violations stemmed immediately from FDA's application of the "significant scientific agreement standard" to the health claims at issue. It is the same standard that FDA applies to health claims for all conventional foods and dietary supplements. Accordingly, the remedy of constitutional harms that is compelled by Pearson must extend beyond dietary supplement claims to include all conventional food claims also subject to that standard. While it is a matter of FDA discretion under section 403(r)(5)(D) of the FD&C Act that FDA has applied the "significant scientific agreement" standard to dietary supplement claims, it must be emphasized that the core violations found in Pearson arose under the First Amendment. Accordingly, there is no rational legal basis for FDA to purport to "implement" the Pearson decision, while limiting its focus to "dietary supplements," as the agency announced it intends to do in its December 1, 1999 implementation plan. IDFA will vigorously oppose any effort by FDA to exclude, limit, or postpone Pearson implementation with respect to conventional food health claims.

Third, there is no rational legal basis for FDA to attempt to push to closure any pending rulemaking procedures concerning health claims policy which affect conventional food, without a full airing of the First Amendment issues presented by Pearson. The CFSAN priorities stated for this year concerning pending proposed amendments to section 101.14, which obviously are implicated under Pearson, raise serious concerns in this regard. IDFA will strongly oppose any effort by FDA to modify health claim policies affecting conventional food without full scrutiny of such proposals under the principles of Pearson and the huge body of First Amendment case law upon which that decision is founded.

Conclusion

For the foregoing reasons, IDFA requests that FDA (1) immediately withdraw and suspend application of the "significant scientific agreement" standard articulated in the above industry guidance to health claims for conventional foods and dietary supplements, (2) in accordance with the principles of Pearson and the huge body of Supreme Court case law upon which it is founded, authorize all health claims that are stated in a truthful and nonmisleading manner that accurately reflects the nature and weight of the substantiating scientific evidence, and (3) revise its Pearson implementation plan to include health claims for conventional foods together with those for dietary supplements in all phases of reform.

Respectfully submitted,


Linwood Tipton
President and CEO
International Dairy Foods Association

CROSS FILE SHEET

FILE NO: 99D-5424/C9

SEE FILE NO: 91N-0101 /C179
91N-0098/C123
91N-0103/C123
91N-100H/C104