

99N-0554

May 21, 1999

Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 12A-16  
Rockville, Maryland 20852

**Re: How to Use Health Claims and Nutrient /Content Claims in Food Labeling;  
Public Meeting [Docket No. 99N-0554]**

The Center for Science in the Public Interest (CSPI)<sup>1</sup> is filing these comments in support of the Food and Drug Administration's framework for implementing Section 303 and 304 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) which was announced at the May 11, 1999 public hearing on authoritative statements. These comments include and supplement our oral presentation.

**I. Introduction**

In enacting the Food and Drug Administration Modernization Act (FDAMA), Congress made a procedural change to the means by which manufacturers could legally market products containing health claims. In lieu of petitioning the FDA for a regulation to permit the use of a new health claim or nutrient content claim, manufacturers may now make such claims without going through the rulemaking process. Such claims are permitted so long as the claims are based on "an authoritative statement" from a scientific agency of the U.S. government or the National Academy of Sciences (NAS), and FDA does not object. Although Congress created a

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<sup>1</sup> CSPI is a non-profit consumer organization supported by more than 1,000,000 members that has worked since 1971 to improve national health policies.

streamlined alternative to the rulemaking route, the Senate Committee Report makes it clear that this legislation “maintains the rigorous scientific standard health claims must meet under existing law.”<sup>2</sup> The House report appears to permit the FDA to apply an even higher standard than the existing scientific agreement standard. The report states that the FDA must determine “whether the authoritative statement upon which the notification is based is supported by scientific consensus to the extent the Secretary considers appropriate to allow the claim.”<sup>3</sup>

Congress provided limited guidance as to what constitutes an authoritative statement -- it must be a published statement by a scientific body of the U.S. with health and nutrition responsibilities or the NAS, must be currently in effect, cannot be the work of an individual in his own capacity, and must concern the relationship between a nutrient and a disease or health-related condition. Congress further concluded that the statement must be based on a deliberative review by the scientific body of the scientific evidence.<sup>4</sup> Statements meeting these criteria are subject to a presumption of validity.<sup>5</sup>

Congress did not, however, specify the point at which a statement from a qualifying agency becomes authoritative. Nor did it specify whether the FDA or the agency responsible for the statement should determine whether the statement is “authoritative.” And, it also did not address coordination issues that are raised when more than one agency is involved in making a

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<sup>2</sup> S. Rep. 105-43, at 49 (1997).

<sup>3</sup> H.R. Rep. 105-306 (1997).

<sup>4</sup> H.R. Rep. No. 105-306, at 16; S. Rep. No. 105-43, at 49 (1997).

<sup>5</sup> H.R. Rep. No. 105-306, at 16.

determination as to the permissibility of a particular claim. These comments will address those issues.

**II. A statement is authoritative when it meets the criteria set forth by Congress and the FDA.**

Because Congress did not define the point at which a statement by a qualifying scientific agency becomes “authoritative,” it is the role the role of the FDA to make this determination. As the Supreme Court has stated, “ The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly by Congress.”<sup>6</sup>

In determining the point at which a published statement by a qualifying federal agency constitutes an “authoritative statement,” the FDA must consider the definitiveness of the statement. The dictionary definition of “authoritative” is “official. . . entitled to credit or acceptance: conclusive.”<sup>7</sup> Finality appears to be the key. For example, if an agency issues a *final* executive regulation interpreting an ambiguous statute, this is considered to be an “*authoritative statement* from the executive.”<sup>8</sup>

Similarly, a decision by the Supreme Court is considered authoritative because it is the court of last resort. As the Supreme Court has stated “[i]t is this Court’s responsibility to say what a statute means, and once the Court has spoken, it is the duty of other courts to respect that

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<sup>6</sup> *Chevron, U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837 (1984).

<sup>7</sup> *Webster’s New Collegiate Dictionary* 76 (1977).

<sup>8</sup> *In the matter of: Appletree Marks, Inc. v. South Central United Food & Commercial Workers Union and Employers Health & Welfare Trust*, 19 F.3d 969 ( 5th Cir. 1994)(emphasis added).

understanding of the governing rule of law. A judicial construction of a statute is an *authoritative statement*” on the meaning of the statute.<sup>9</sup>

In analogous regulatory proceedings, other agencies have provided concrete examples of what makes a statement authoritative. For example, in a discussion of a proposed rule governing refrigerants, the Environmental Protection Agency (EPA) cited a report by the Intergovernmental Panel on Climate Change as being authoritative.

The first IPCC report was developed by 170 scientists from 25 countries and was peer-reviewed by an additional 200 scientists. Since that time, the number of scientists developing and reviewing the report has grown. This group comprises most of the active scientists working in the field today, and therefore the report is an *authoritative statement* of the views of the international scientific community at this time.<sup>10</sup>

The FDA has appropriately drawn the line between authoritative and preliminary statements in its actions surrounding the rejection of nine petitions for health claims filed by Weider Nutrition International. Press releases, progress reports on specific projects, and analyses conducted on behalf of a particular agency by an outside contractor do not reflect the kind of deliberative study that Congress envisioned when it adopted the “authoritative statement” requirement. Congress intended the authoritative statement process to provide an alternative to an FDA rulemaking proceeding only if another agency with scientific expertise had thoroughly addressed the issues that would otherwise need to be raised in a petition.

Congress wanted FDA to be able to rely on data from other agencies that was comparable to the data the FDA would rely on in its own regulatory proceeding to justify the

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<sup>9</sup> *Rivers v. Roadway Express, Inc.*, 114 S. Ct. 1510 (1994) (emphasis added).

<sup>10</sup> 63 Fed. Reg. 34023, 34048 n.3 (June 11, 1998).

issuance of rules permitting health claims or nutrient content claims. The fact that Congress determined that authoritative statements must be based on thorough scientific analyses is demonstrated by the fact that the statute gives the FDA final approval authority over health claims based on the findings in another agency’s authoritative statement. In modifying or prohibiting a health claim based on authoritative statements, the FDA is *required* to evaluate the claim to determine whether 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.”<sup>11</sup>

**III. The FDA should be the ultimate arbiter of whether a statement is authoritative.**

To facilitate the determination of whether a statement is authoritative, we would recommend as follows:

- Manufacturers who wish to make a claim based upon an authoritative statement should submit a notification letter to the FDA. The notification should include labeling information regarding the amount of the substance that needs to be consumed to have the desired effect and, where relevant, “do not exceed levels.”
- FDA, after verifying that the notification is complete, should submit it to the agency whose “authoritative statement” is the basis for the claim.
- The notification should be promptly placed on the public docket and indicate the date of referral to the relevant government agency. To facilitate review by the public, notifications should be placed in a single public docket labeled “Health and Nutrient

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<sup>11</sup> 21 U.S.C. § 403(3)(D)(i).

Content Claims Based Upon Authoritative Statements.”

- The agency to whom the notification is sent should determine whether it can certify that:
  - (a) The statement is the result of a thorough and extensive investigation by the agency of the relevant scientific issues and represents the authoritative opinion of the agency;
  - (b) that if a report was conducted by an outside contractor, the agency has adopted the contractor’s findings as its own; and
  - (c) the manufacturers’s claim can reasonably be based on the authoritative statement of the agency;
- Following the receipt of a written notification from the agency that reviewed the authoritative statement, FDA will determine: (1) whether it agrees with the determination of the other agency and (2) whether the label claim needs to be modified to comply with the terms of §§ 101.13 or 101.14 of the FDA’s regulations.

**IV. The Use of Qualifying Statements Should Not be Permitted.**

Authoritative statements should not be qualified, as suggested by Annette Dickenson, Ph.D., a panelist representing the Council for Responsible Nutrition. The use of qualified authoritative statements is a contradiction in terms. If a statement is authoritative, it is definitive. It defies logic, therefore, to assert that an authoritative statement can state that there is sufficient evidence to justify a recommendation but that more research is needed. Dr. Dickenson’s suggestion that the decision in *Pearson v. Shalala*<sup>12</sup> requires such a result is without merit. That decision applies only to health claim petitions filed by dietary supplement manufacturers under

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<sup>12</sup> 164 F.3d 650 (D.C. Cir. Jan. 15, 1999) (reh’g den. Apr. 2, 1999).

the Nutrition Labeling and Education Act. Moreover, no further action should be taken as a result of the *Pearson* decision until the government decides whether to ask the Supreme Court to hear the case. If a petition for a writ of *certiorari* is filed and granted, the FDA should not act until the Court renders its decision.

In addition, permitting the use of qualifiers could ultimately have a chilling effect on statements by scientific bodies concerning research and the publication of newly emerging theories. Researchers and scientific bodies would be reluctant to share their ideas and results, fearing that they would be taken out of context or exploited commercially before there is an adequate scientific basis.

Moreover, consumers would be thoroughly confused. CSPI has always encouraged manufacturers to provide consumers with adequate information so that they can make informed choices. Promoting the concept of the consumer right to know has been one of our underlying themes. But if scientists themselves are divided, or research is incomplete, consumers cannot make an informed choice. For example, consumers would not be aided by a statement that the Surgeon General believes that substance X *might* be helpful to your health, but that more research needs to be conducted. Such statements could well undermine the respect now given to the Surgeon General's recommendations.<sup>13</sup> Consumers respect statements from the Surgeon General such as those that appear on alcoholic beverages<sup>14</sup> and cigarette packages<sup>15</sup> because they

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<sup>13</sup> For example, "Surgeon General's Warning: Quitting smoking now greatly reduces serious risks to your health" or "Smoking Causes Lung Cancer, Heart Disease, Emphysema and May Complicate Pregnancy."

<sup>14</sup> The following statements must appear on the labels of alcoholic beverages:  
GOVERNMENT WARNING: (1) According to the Surgeon General, women should not

are aware that such statements are authoritative and not based on preliminary scientific findings.

**V. It is premature to determine whether FDAMA should apply to dietary supplements.**

As we stated in our comments to the FDA with respect to the proposal to apply FDAMA to dietary supplements, such action is premature. Numerous issues need to be addressed in light of the *Pearson* case, including whether dietary supplements should be regulated the same as or differently from foods making health claims.

**VI. Conclusion**

In conclusion, there is no doubt that Congress intended to provide an alternative procedural route for manufacturers to obtain approval to make legitimate health and nutrient content claims. But providing an alternative route is not synonymous with providing a less stringent standard for claims. If another agency has thoroughly addressed an issue, manufacturers should be permitted to rely on another agency's findings. But if another agency has not thoroughly addressed an issue, the FDA cannot view its statements as "authoritative." To do so would make a mockery of a statute that is designed to protect the consumer from false and misleading statements.

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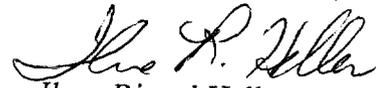
drink alcoholic beverages during pregnancy because of the risk of birth defects.

(2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

27 C.F.R. § 16.22.

<sup>15</sup> Under the Federal Cigarette Labeling and Advertising Act of 1966, manufacturers must label products with one of four warning from the Surgeon General about the health effects of smoking on the smoker and unborn babies. 15 U.S.C. § 1333.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ilene R. Heller". The signature is written in a cursive, flowing style with a prominent initial "I".

Ilene Ringel Heller  
Senior Staff Attorney