

THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

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Assessing Consumer Perceptions )  
of Health Claims; Public Meeting; )  
Request for Comments )  
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Docket No. 2005N-0413

Comments of

Center for Science in the Public Interest

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Division of Dockets Management  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland

**Re: Assessing Consumer Perceptions of Health Claims; Public Meeting;  
Request for Comments (Docket No. 2005N-0413)**

The Center for Science in the Public Interest (CSPI)<sup>1</sup> wishes to respond to the request for comments relating to the Food and Drug Administration (FDA)'s public meeting on "Assessing Consumer Perceptions of Health Claims."<sup>2</sup> As discussed below, the results of consumer research conducted by both the FDA and the International Food Information Council (IFIC)<sup>3</sup> indicate that disclaimers similar to those proposed by the court in *Pearson v. Shalala*<sup>4</sup> do not cure the deception created by health claims based on emerging science. Given the inadequacy of disclaimers, the FDA should rescind its prior authorizations of qualified health claims and refrain from further authorizations.

This proceeding emanates from the Agency's five-year attempt to comply with the opinion of the U.S. Court of Appeals for the District of Columbia Circuit addressing

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<sup>1</sup> CSPI is a non-profit consumer advocacy and education organization that focuses on food safety and nutrition issues. It is supported principally by the 900,000 subscribers to its *Nutrition Action Healthletter* and by foundation grants.

<sup>2</sup> 70 Fed. Reg. 60749 (Oct. 19, 2005).

<sup>3</sup> International Food Information Council, *Qualified Health Claims Consumer Research Project Summary* (Mar. 2005).

<sup>4</sup> 164 F.3d 650 (D.C. Cir. 1999).

the issue of whether the misleading nature of preliminary health claims for dietary supplements can be cured by the addition of a qualifying statement or disclaimer. In *Pearson v. Shalala*, the Court held the FDA could not prohibit health claims for dietary supplements that are not supported by “significant scientific agreement” [as required by the Nutrition Labeling and Education Act (NLEA) for foods], if a disclaimer or qualifier could cure the potential to mislead. The Court stated that if a disclaimer – such as “The evidence in support of this claim is inconclusive” – could cure any such potential, then the government could not prohibit companies from making the claim.<sup>5</sup> The Court also determined that health claims could be prohibited outright based on health or safety concerns, or where the quality or quantity of the evidence against the claim outweighed the evidence in support of it.<sup>6</sup>

The Court criticized the FDA for failing to support its contention that the disclaimers would “create confusion among consumers.” Nevertheless, it stated that “while we are skeptical that the government could demonstrate with empirical evidence that disclaimers similar to the ones we suggested above would bewilder consumers and fail to correct for deceptiveness, we do not rule out that possibility.”<sup>7</sup>

#### **I. *Pearson* Does Not Apply to Health Claims for Foods**

Initially, the FDA took the position that the *Pearson* decision applied only to dietary supplements. With a change in Administration, however, the FDA reversed its position. In so doing, the Agency ignored the legislative history of the NLEA and

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<sup>5</sup> *Pearson* at 659-60.

<sup>6</sup> *Id.* at 656 & n. 6, 659 & n. 10.

<sup>7</sup> *Id.* at 659-60.

Congress' decision in the Act to require that health claims for foods be based on "significant scientific agreement."<sup>8</sup> Congress was well aware that food health claims – both valid and specious – had become increasingly common.<sup>9</sup> "[W]hen the FDA relaxed enforcement of regulation during the [1980s], it lost control of the marketplace, and many unfounded claims began being used for foods."<sup>10</sup>

It is important to note that Congress did not address claims involving dietary supplements during the hearings leading up to the enactment of the NLEA because supplements were not covered by the legislation as it was originally introduced. Thus, while Congress specifically required that health claims for foods be based on "significant scientific agreement," it left it up to the FDA to determine the appropriate standard for supplements.<sup>11</sup>

Accordingly, we do not believe that foods come within the scope of the *Pearson* decision. Indeed the FDA agreed with this view from 1999 to 2002. In any event, no Court has ever held that *Pearson* applies to health claims on foods, and the Supreme Court has not yet decided this important issue.

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<sup>8</sup> Congress's judgment was based on the voluminous record amassed in hearings leading up to the passage of the NLEA. See *FDA Proposals to Permit the Use of Disease-Specific Health Claims on Food Labels: Hearing Before a Subcomm. of the House Comm. on Gov't Operations*, 100<sup>th</sup> Cong., 1<sup>st</sup> Sess. (1987); *House Comm. on Gov't Operations, Disease-Specific Health Claims on Food Labels: An Unhealthy Idea*, H.R. Rep. No. 561, 100<sup>th</sup> Cong., 2d Sess. (1988); *FDA's Continuing Failure to Regulate Health Claims for Foods: Hearings Before the Subcomm. on Human Resources and Intergovernmental Relations of the House Comm. on Government Operations*, 101<sup>st</sup> Cong., 1<sup>st</sup> Sess. (1989); *House Comm. on Gov't Operations, FDA's Continuing Failure to Prevent Deceptive Health Claims for Food*, H.R. Rep. No. 980, 101<sup>st</sup> Cong., 2d Sess. (1990); *Health and Nutrition Claims in Food Advertising and Labeling: Hearings Before the Senate Comm. on Gov't Affairs*, 101<sup>st</sup> Cong., 2d Sess. (1990).

<sup>9</sup> See, e.g., 136 Cong. Rec. H5843 (daily ed. July 30, 1990) (statement of Rep. Madigan) ("Consumers today are confronted with a variety of labels that provide them with disjointed and confusing information.").

<sup>10</sup> 136 Cong. Rec. H12953 (daily ed. Oct. 26, 1990) (statement of Rep. Waxman).

<sup>11</sup> 136 Cong. Rec. S16607-09. (statement of Sen. Metzenbaum).

## II. Even if Pearson Applies to Foods, it Does Not Require the Use of Disclaimers

Assuming that the holding in *Pearson* does apply to health claims for foods, the FDA now has evidence of its own, as well as that from IFIC, which is funded by the food industry, demonstrating that disclaimers similar to those suggested by the court in *Pearson* are ineffective. In its report entitled “Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims,” the Agency reached the following conclusions:

- Consumers did not understand qualifying statements that used only words to convey the strength of the science underlying a claim.
- When report card graphics were used, consumers mistakenly believed that “B grade claims” – those based on a moderate amount of evidence that is not conclusive – were based on greater scientific certainty than claims based on significant scientific agreement.
- Consumer perceptions of product health benefits were not diminished by disclaimers indicating greater scientific uncertainty for a claim. In some cases, consumers had more negative perceptions of product health benefits when the claims were conveyed with more scientific certainty.<sup>12</sup>

Thus, the FDA now has “empirical evidence” demonstrating that qualified health claims can be misleading and confusing to consumers. But instead of announcing that it now has “empirical evidence” that qualified health claims do not work, the FDA is continuing to approve such claims.

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<sup>12</sup> Brenda M. Derby, Alan S. Levy, *Working Paper: Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* (Sept. 2005); FDA, *Questions and Answers: Qualified Health Claims in Food Labeling Report on Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* (Sept. 28, 2005).

Since the completion of its research in May 2004,<sup>13</sup> the FDA has nonetheless approved claims for olive oil and coronary heart disease; omega-3 fatty acids and coronary heart disease; calcium and colon/rectal cancer and calcium and colon/rectal polyps; chromium picolinate and insulin resistance; calcium and hypertension, pregnancy-induced hypertension and preeclampsia; green tea and prostate and breast cancer; and tomatoes and prostate, ovarian, gastric and pancreatic cancer. The FDA authorized claims with such weak supporting evidence that it had to require disclaimers indicating that “it is highly unlikely”<sup>14</sup> or “highly uncertain”<sup>15</sup> that the claim is valid. Even *Pearson* does not require approval in such cases.<sup>16</sup>

The FDA bases its approval of such claims on a subsequent district court decision, *Whitaker v. Thompson*.<sup>17</sup> That case concerned the FDA’s denial of a petition seeking authorization to claim that antioxidant vitamins help prevent cancer. In *Whitaker*, the court held that where a health claim for a dietary supplement was supported by some

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<sup>13</sup> Although the FDA completed its research in May 2004, it did not release its own study until September 28, 2005 following a successful appeal of the Agency’s denial of a Freedom of Information Act request submitted by CSPI. Prior to that, FDA had refused to release copies of the raw data to members of Congress. Response of Dr. Lester Crawford to question 14 from Sen. Kennedy during his confirmation hearings. IFIC – whose study protocol and results paralleled those of the FDA – released its own results in March 2005.

<sup>14</sup> Green tea and prostate and breast cancer; calcium and hypertension and preeclampsia.; tomatoes and pancreatic cancer.

<sup>15</sup> Chromium picolinate and insulin resistance; tomatoes and ovarian cancer.

<sup>16</sup> *Pearson* said that the FDA could impose an outright ban on a claim where evidence against the claim is quantitatively or qualitatively stronger than evidence for the claim. 164 F.3d at 659. Such claims would fall under Category B claims – moderate evidence that is not conclusive – under FDA’s *Guidance for Industry and FDA: Interim Evidence-Based Ranking System for Scientific Data; Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements*. 68 Fed. Reg. 41387 (July 11, 2003). Other Category B claims and all Category C and D claims are wholly unjustified by *Pearson*.

<sup>17</sup> 248 F. Supp. 2d 1 (D.D.C. 2002). See 68 Fed. Reg. 41388-89.

“credible evidence,” but not by the weight of the evidence, the FDA had to allow it, subject to an appropriate disclaimer.<sup>18</sup> *Whitaker*, however, did not involve foods, was not appealed, and went beyond *Pearson* by ordering the FDA to authorize a claim *contrary* to the weight of credible evidence. Its holding that commercial speakers have a constitutional right to make promotional health claims that are more likely than not to be *untrue* is unsupported either by the Supreme Court’s commercial speech jurisprudence or by the holding in *Pearson*. *Whitaker* thus fails to justify the scheme implemented by the FDA in 2003.

### **III. The FDA Should Rescind its Approvals of Qualified Health Claims and Not Consider Additional Applications**

In various public statements, the Agency has expressed its commitment to approving qualified health claims, even if the presumptions upon which the *Pearson* decision were based have been discredited. For example, the *Federal Register* notice announcing this meeting states that the Agency “intends to consider all pertinent information from this public meeting in any rulemaking related to alternatives for *regulating qualified health claims*. . . .”<sup>19</sup> Nowhere does the FDA question whether its research results should be used as the basis for terminating the qualified health claims initiative.<sup>20</sup> Given the results

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<sup>18</sup> 248 F. Supp. at 10 -11.

<sup>19</sup> 70 Fed. Reg. 60751 (emphasis added).

<sup>20</sup> Moreover, the FDA has not examined the consequences associated with the approval of qualified health claims. For example, although the qualified claim authorized for omega-3 fatty acids and the reduction of the risk of coronary heart disease establishes a maximum level of intake, no minimum is specified because “the scientific evidence for this relationship is not conclusive and does not support the establishment of a recommended daily dietary intake level or even a possible level of omega-3 fatty acids to be useful in achieving a reduction in the risk of CHD for the general healthy population.”<sup>20</sup> Numerous products are now boasting the fact that they contain omega-3 fatty acids. But consumers have no idea of whether they are getting an appropriate amount of the nutrient to trigger speculative benefits or too little or too much. Without such information, the label ensures profits for manufacturers, but “creates confusion among consumers,” a result *Pearson* wanted to prevent.

of its own survey, the FDA is obligated to cease authorizing qualified health claims for foods and to enforce the NLEA as enacted by Congress.

#### **IV. The Institute of Medicine Report Issued *After Pearson* Also Supports Discontinuation of Qualified Health Claims**

*Pearson* suggested that it likely would have reached a different result if FDA had articulated health or safety concerns stemming from preliminary health claims rather than asserting a “common sense judgment” that consumer health is advanced directly by barring claims not supported by significant scientific agreement.<sup>21</sup> FDA did not argue at the time that preliminary health claims could create a public health hazard. However, since the decision in *Pearson*, a report by the National Academies of Science Institute of Medicine urged FDA to take “a cautious approach” in permitting claims, explaining that:

Claims about nutrient-disease relationships are more easily made than scientifically supported. Because the *implications for public health are so important*, caution is urged prior to accepting such claims without supportive evidence from appropriately designed, typically large, clinical trials.<sup>22</sup>

Of particular concern to the IOM was the fact that some supplements may have harmful effects that are not readily apparent. For example, in 1989, the hypothesis that beta-carotene in foods could help prevent lung cancer was considered promising. Since that time, three significant clinical trials were undertaken to investigate that hypothesis. The trials not only “failed to substantiate a possible preventive role” for beta-carotene with regard to lung cancer, but in two trials involving supplement tablets, lung cancer incidence was significantly increased rather than reduced: for individuals who smoked or

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<sup>21</sup> *Pearson* at 656.

<sup>22</sup> National Academy of Sciences, Institute of Medicine, *Evolution of Evidence for Selected Nutrient and Disease Relationships* (2002) (emphasis added) 58.

had prior exposure to asbestos.<sup>23</sup> Thus, if food companies had been permitted to proclaim in 1989 that beta-carotene consumption could reduce the risk of lung cancer, even if they had done so with a disclaimer noting that the evidence was not yet conclusive, the people most at risk of developing lung cancer (smokers and people exposed to asbestos) might have been induced to increase their consumption of a nutrient that in fact could have increased their risk of developing cancer. A qualified health claim based on the early evidence would have been not only misleading, suggesting a relationship that does not in fact exist, but also dangerous.

## **V. Conclusion**

In passing the NLEA, Congress was well aware of First Amendment concerns. Based on extensive hearings on abuses in food labeling, Congress concluded that unless claims met the ‘significant scientific agreement’ standard, consumers would be misled. The FDA’s and the food industry’s own research now convincingly demonstrate the appropriateness of Congress’ approach to regulating health claims. Therefore, the FDA should: (1) rescind its approval of all qualified health claims and (2) impose a moratorium on the approval of additional qualified health claims that do not meet the standards of the NLEA.

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<sup>23</sup> *Id.* at 28, 29, 57.

Respectfully submitted,

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Bruce Silverglade  
Director of Legal Affairs

A handwritten signature in black ink, appearing to read "Ilene R. Heller". The signature is cursive and somewhat stylized.

Ilene Ringel Heller  
Senior Staff Attorney