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Rockville, MD 20852

Docket No. 02N-0209/Request for Comments on First Amendment Issues

Introduction and Summary

I wish to respond to the comments of the Grocery Manufacturers of America and the National Food Processors Association that call on the Administration to curtail the Food and Drug Administration's (FDA) ability to regulate health claims under the Nutrition Labeling and Education Act (NLEA) of 1990. I have a long-standing commitment to advancing the public health and ensuring that health claims for foods are well-substantiated and scientifically valid. I am very concerned that the FDA, under pressure from the food industry, will respond to several recent judicial decisions that do not even involve the regulation of food in a manner that undermines the protections provided for in the NLEA.

History of Harm from Inadequately Regulated Claims

The legislative history of the NLEA demonstrates why it is essential that health claims for foods be permitted only in those instances in which the FDA has authorized the specific claim based upon a determination that it is supported by "significant scientific agreement." It also makes clear that attempts to end run that standard through the use of disclaimers and qualifiers

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on claims not supported by significant scientific agreement would undermine the NLEA's effectiveness.<sup>1</sup>

The health claims provisions of the NLEA, 21 U.S.C. § 403 (r), were passed in response to a proliferation of false or misleading claims linking consumption of a food to the prevention or reduced risk of a disease. Before 1984, the FDA read the Federal Food, Drug and Cosmetic Act (FDCA) as requiring that food products making health claims be regulated as new drugs requiring pre-market approval. At that time, the Agency's position was challenged when Kellogg began claiming that its All-Bran Cereal, when eaten as part of a low fat, high fiber diet, could help reduce the risk of certain forms of cancers. This statement was approved by the National Cancer Institute (NCI). The FDA took no regulatory action against this claim after the White House Office of Management and Budget forbade such action.<sup>2</sup>

However, soon thereafter, Kellogg added a similar claim to its Cracklin' Oat Bran cereal. That cereal contained 4 grams of fat per serving, a significant amount for a breakfast cereal and greater than the amount generally considered to constitute a low-fat food. The anti-cancer claim for this product was thus inconsistent with the NCI's position.

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<sup>1</sup> See, e.g., *FDA's Continuing Failure to Regulate Health Claims for Foods*, Hearings before the Human Resources and Intergovernmental Relations Subcommittee of the Committee of Government Operations, House of Representatives, 101st Cong. 2d Sess., Oct. 21 and Nov. 9, 1989 at 37 (Testimony of Robert Abrams, Attorney General of the State of New York).

<sup>2</sup> *FDA's Continuing Failure to Prevent Deceptive Health Claims for Food*, Twenty-Seventh Report by the Committee on Government Operations, 101<sup>st</sup> Cong. 2d Sess. (Nov. 14, 1990) at 22.

Other companies continued to "[flood] the marketplace with a barrage of false and misleading health claims."<sup>3</sup> Over time, claims became so egregious and commonplace that a 1989 cover story in *Business Week* magazine asked "Can Corn Flakes Cure Cancer?" The subhead read: "Of course not. But health claims for food are becoming ridiculous."<sup>4</sup>

As a result of the proliferation of false or misleading claims and the absence of effective federal regulation, a multi-state group of attorneys general was organized to take action. The states ultimately entered into agreements with several major food manufacturers to halt misleading claims.<sup>5</sup>

The Attorney General for the State of New York, Robert Abrams, later testified before a House Subcommittee about the need to permit only health claims based on strong scientific support. General Abrams testified that:

First, the specific health messages to be used must be drafted and approved by the FDA, and they must be permitted only where there is a consensus among scientific experts supporting such a claim. This has been the standard that the FDA has always applied to approving the marketing of new drugs. If health claims are permitted for food products, it should be the same standard there as well....[Permitting] FDA-drafted messages based upon a strong scientific consensus . . . will prevent manufacturers and advertisers from

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<sup>3</sup> *Id.*

<sup>4</sup> *Business Week*, Oct. 9, 1989.

<sup>5</sup> Marian Burros, *States Act to Fight False Ads on Foods*, *New York Times*, April 5, 1986.

giving a misleading spin to valid information or building a misleading statement on a kernel of truth.<sup>6</sup>

To exemplify the need for this requirement, General Abrams referred to a multi-state investigation involving claims that margarines and vegetable oils were responsible for specific decreases in cholesterol. He explained: "It is not at all clear that the scientific studies upon which these products rely prove the value of the particular products—".<sup>7</sup>

### Current Developments

These and other problems were eliminated by provisions in the NLEA that require that health claims be supported by "significant scientific agreement." The risks of rejecting the approach spelled out by Congress in the NLEA for food health claims was underscored recently by a National Academy of Sciences Institute of Medicine (IOM) report. The IOM urged the FDA and industry to be cautious about the use of claims based on preliminary evidence because it is difficult to predict whether such claims will be confirmed, and further testing may reveal unexpected consequences.<sup>8</sup>

The IOM explained that "[c]laims 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

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<sup>6</sup> Testimony of Robert Abrams, printed in *FDA's Continuing Failure to Regulate Health Claims for Foods*, Hearings before the Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Operations, House of Representatives 101<sup>st</sup> Cong. 2d Sess. Oct. 21 and Nov. 9, 1989 at 32.

<sup>7</sup> *Id.*, at 31.

<sup>8</sup> National Academy of Sciences, Institute of Medicine, *Evolution of Evidence for Selected Nutrient and Disease Relationships* (2002).

designed, typically large, clinical trials."<sup>9</sup> The IOM stated that further study of an "appealing hypothesis" may result in a finding that the nutrient actually causes harm. For example, although preliminary evidence suggested that beta-carotene could reduce the risk of lung cancer, clinical intervention trials later demonstrated that beta-carotene supplements actually increased the risk of lung cancer in smokers.<sup>10</sup>

Unlike the FDA, consumers cannot reasonably be expected to become experts in evaluating the evidence submitted to support a claim. Consumers rightly need to rely on the FDA to determine whether the preliminary research results should even be considered. It is unrealistic to expect consumers to develop personal expertise about the types of tests that should be conducted to establish the validity of a claim and how to evaluate such tests.

It should be noted that no judicial decision requires the FDA to abandon the "significant scientific agreement standard" in favor of a regulatory approach based on preliminary health claims accompanied by disclosures. Litigation in this area has involved dietary supplements, not foods, which are subject to a different regulation not at issue in the dietary supplement litigation.<sup>11</sup> Thus, if the agency proceeds with such plans, it is merely making a political decision. As former FDA Commissioner David Kessler, M.D., J.D. (appointed by the previous Bush Administration) recently stated in the *New York Times*, "I have great concerns that this

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<sup>9</sup> *Id.* at 58.

<sup>10</sup> *Id.* at 6.

<sup>11</sup> The U.S. Court of Appeals in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) held that the FDA must consider allowing preliminary health claims for dietary supplements if a disclosure could prevent any consumer deception that might result. However, this case did not involve the same statutory provision in the NLEA that pertains to foods and the agency is not compelled – and indeed may lack authority – to apply the Court's ruling in this case to food products.

[FDA proceeding] is simply an attempt to deregulate while doing it in the name of the First Amendment."<sup>12</sup>

Conclusion

Prior to the NLEA, consumers had little reason to trust health claims. The NLEA has restored this trust. But this trust will once again be in jeopardy if the FDA decides to approve health claims for foods in the absence of "significant scientific agreement." The FDA has the scientific expertise to evaluate studies and determine whether claims should be made. It should be free to make these decisions without political interference cloaked in a discussion of the First Amendment's protection of commercial speech.

Signed,



HENRY A. WAXMAN

Member of Congress

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<sup>12</sup> Gina Kolata, *Stung by Courts, FDA Rethinks its Rules*, New York Times, October 15, 2002, at F1.