

**Congress of the United States**  
**House of Representatives**  
**Washington, D.C. 20515**

Mark B. McClellan, M.D., Ph.D.  
Commissioner of Food and Drugs  
5600 Fishers Lane  
Rockville, MD 20857

MAY 27 2003

Re: Docket No. 03N-0069

Dear Dr. McClellan:

We are submitting this comment to protest the recent "guidance" from the Food and Drug Administration that it will lower the scientific standard for approving "health claims" for foods to permit more claims based on less scientific evidence, a step long-sought by the food industry. In taking this action, the FDA has rejected the scientific standard required by its governing statute. This is not only a step backward for truthful, credible food labels, but an unprecedented assertion of authority on the part of the executive branch to ignore a specific congressional mandate.

The Nutrition Labeling and Education Act (NLEA), passed unanimously by Congress in 1990 under the first Bush Administration, requires FDA to disapprove a health claim on a food product unless the claim is supported by "significant scientific agreement." The NLEA was passed to stop the myriad of inadequately supported claims on foods that were confusing consumers and undermining the credibility of food labels.<sup>1</sup> Then-Secretary Louis Sullivan described the proliferation of misleading food claims before the passage of the NLEA as "a tower of Babel" for the consumer.

Despite the judgment of Congress that health claims for foods should be supported by "significant scientific agreement" and the unambiguous language of the law, the FDA's December guidance document states that the agency will no longer require companies to meet the statutory standard for health claims on foods and will instead take no action against such claims if they are supported by "the weight of the evidence." The agency admits that this lowered standard may result in the promotion of claims that are subsequently shown to lack scientific support. Moreover, the FDA has cited no legal basis for its refusal to enforce the statutory standard other than (1) "enforcement discretion," i.e., an agency's discretion not to prosecute every possible violation of the laws it administers, and (2) an unexplained reference to Pearson v.

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<sup>1</sup>136 Cong. Rec. H12953 (daily ed. Oct. 26, 1990) (remarks fo Rep. Waxman); H.R. Rep. No 538, 101<sup>st</sup> Cong., 2d Sess. 7.

Shalala, 164 F.3d 650 (D.C. Cir. 1999), a case that did not even consider the validity of the NLEA standard for health claims for conventional foods.

As authors of the NLEA, we strongly oppose this guidance document. The FDA's action is a serious setback for truthful advertising and an invitation for misleading claims on foods. The FDA's refusal to enforce the statutory standard for health claims threatens to return us to the deceptive and confusing food marketplace of the 1980s. Contrary to the FDA's assertions, the proliferation of health claims for foods that will in some cases be later shown to be false will almost certainly mislead and confuse consumers, undermining their health. It will also undermine the credibility of all food labels, which have become, under the NLEA, a powerful tool for educating consumers about healthy food choices.

We are particularly concerned about the FDA's purported use of "enforcement discretion" to permanently change a statutory standard. This approach is both a serious abuse of discretion and a precedent that could be used to undo a wide range of health and safety laws that currently protect Americans.

"Enforcement discretion" is an agency's discretion not to take an individual enforcement action and, when properly exercised, is unreviewable by any court. Heckler v. Chaney, 470 U.S. 821 (1985). It is typically used to allow an agency with limited enforcement resources to decide which types of violations should be given priority when allocating those resources. It is occasionally used to defer temporarily imposition of a regulatory requirement to allow companies sufficient time to come into compliance or to allow the agency time to revise a regulation. See e.g., Cutler v. Hayes, 549 F. Supp. (D.D.C. 1982); 65 Fed. Reg. 59855 (Oct. 6, 2000) (FDA notice announcing nonenforcement of standard for health claims on dietary supplements pending revision of regulations to comport with court decision).

It is a gross distortion of enforcement discretion to argue, as the FDA does, that this limited discretion authorizes an agency to issue a policy whose effect is to permanently lower a statutorily mandated approval standard. The Supreme Court, in the leading case on the limits of enforcement discretion, affirmed that an agency's discretion not to bring an enforcement action is not reviewable, but did not extend this principle to cases where the agency has "consciously and expressly adopted a general policy" that is so extreme as to amount to an abdication of its statutory responsibilities." Heckler v. Chaney, 470 U.S. at 833, n.4, citing Adams v. Richardson, 480 F. 2d 1159 (D.C. Cir. 1973) (en banc). See also Kenney v. Glickman, 96 F.3d 1118, 1123 (8<sup>th</sup> Cir. 1996) (enforcement discretion does not include agency decisions that effectively adopt permanent standards); Crowley Caribbean Transp. v. PEEA, 37 F.3d 671, 677 (D.C. Cir.1994) ("agency's pronouncement of a broad policy against enforcement poses special risks that it 'has consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities'"); Northern Indiana Public Service Co. v. FERC, 782 F.2d 730, 745 (7<sup>th</sup> Cir. 1986) (agency may not "essentially abandon its regulatory function . . . under the guise of unreviewable agency inaction"); Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 171 (D.D.C. 2000) ("agency decisions not to regulate an entire class of conduct, which are essentially policy choices" are reviewable and distinct from "individual

nonenforcement decisions" governed by Heckler v. Chaney ).

A subsequent FDA announcement made perfectly clear that this was no exercise of enforcement discretion, but a unilateral attempt by an administrative agency to change a statutory standard. On January 16, 2003, the FDA announced the formation of a task force assigned to report on "how the agency should apply the 'weight of the evidence' standard established under the consumer health information initiative for qualified health claims on conventional foods," and to "develop a framework of regulations that will give these principles the force and the effect of law."<sup>2</sup>

By explicitly refusing to enforce the statutory standard for approval of health claims and by purporting to establish a lower standard "with the force and effect of law," the FDA has "consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities." The statutory standard is clear on its face and has not been invalidated by any court of law. The FDA's decision to abandon the standard is an undeniable abdication of its statutory responsibilities.

The FDA's reference to Pearson v. Shalala provides no basis to refuse to enforce the NLEA standard for approving health claims for foods. In Pearson, the court found that four FDA regulations refusing to permit certain health claims for dietary supplements violated the First Amendment. Health claims for dietary supplements, however, are not authorized under the NLEA standard for approving health claims for foods. The Pearson court did not consider or decide the constitutionality of the NLEA standard for foods. Indeed, the guidance makes no attempt to argue that Pearson invalidated the statutory standard for conventional foods.

The reference to Pearson in the guidance document suggests that the FDA has taken it upon itself to determine that the NLEA standard for health claims on foods violates the First Amendment. If this is the basis for the December 20 guidance document, the agency has unequivocally exceeded its authority. It is an executive agency's responsibility to enforce and defend the laws passed by Congress. It is the responsibility of the judiciary, not the executive branch, to determine the constitutionality of those laws.

We therefore request that you order the FDA to rescind its December 20, 2002 guidance as an illegal assertion of authority. Because the guidance was issued without notice and comment or process of any kind, it can be rescinded immediately.

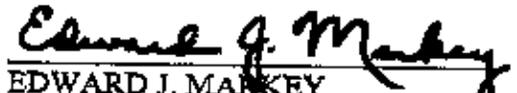
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<sup>2</sup> FDA News Release, "FDA task force on consumer health information for better nutrition established," January 16, 2003.

Signed.

  
 HENRY A. WAXMAN  
 United States House of Representatives

  
 BARBARA BOXER  
 United States Senate

  
 EDWARD J. MARKEY  
 United States House of Representatives

  
 JEFF BINGAMAN  
 United States Senate

  
 DAVID E. PRICE  
 United States House of Representatives