03-2520

# Congress of the United States

Washington, DC 20515

MAY 27 2003

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

Dear Dr. McClellan:

We are enclosing a comment in response to your March 13, 2003, request for comments on qualified health claims for foods (Public Docket No. 03N-0069). As described in the comment, we believe that Food and Drug Administration (FDA) has exceeded its authority in permitting health claims for foods that do not meet standard for such claims in the Nutrition Labeling and Education Act.

We also ask that you provide answers to the following questions:

1. Is it the position of the Food and Drug Administration that an agency's enforcement discretion authorizes the agency to refuse to enforce clear statutory standards for whole classes of products or regulated entities for indefinite periods of time and without any intention that the statutory standards will ultimately be met?

2. Is it the position of the Food and Drug Administration that, under the theory enunciated in the December 20 guidance document, the FDA could issue a similar document that announces that the agency will (a) no longer enforce the requirement that drugs be shown to be effective before they are promoted for specific uses, or (b) refuse to enforce the requirement if drug manufacturers meet some lower nonstatutory standard crafted by the agency?

3. Are there other statutory approval or review standards in the Federal Food, Drug, and Cosmetic Act that you believe the FDA could refuse to enforce under circumstances similar to those listed in the December 20 guidance?

4. If this action was motivated in part by concern that the FDA has been too slow in granting legitimate health claims for foods, please explain why the answer to this problem is to ignore a statutory standard rather than to improve the quality and speed of the approval process (as has been done for drugs).

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Thank you for your co-operation with these requests. Please provide your responses to these questions by June 13, 2003. If you have any questions, you may call Ann Witt on Mr. Waxman's staff (202-225-3976).

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

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

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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 (8th Cir. 1996) (enforcement discretion does not include agency decisions that effectively adopt permanent standards); Crowley Carribean 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 (7th 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."[2]

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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[2] 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
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