



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Edward M. Kennedy
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, D.C. 20510-6300

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Dear Senator Kennedy:

Thank you for your December 5, 2003 letter expressing your concern about the Food and Drug Administration's (FDA or the Agency) July 2003 interim guidance relating to qualified health claims in dietary supplement and conventional food labeling. In your letter and accompanying legal memorandum, you stated your concern that the Agency intends to permit the use of claims based on "a lower standard of scientific evidence" and that the Agency has exceeded its statutory authority by modifying the current statutory standard.

We have reviewed your letter and legal memorandum but are unable to respond at this time to the specific legal arguments in your memorandum because FDA is involved in litigation related to these issues. See *Center for Science in the Public Interest et al. v. FDA*, No. 03-1962 (RBW) (D.D.C. filed September 24, 2003).

As you know, the Agency issued an advance notice of proposed rulemaking on November 25, 2003, soliciting comments on ways to manage qualified health claims, including the First Amendment concerns raised in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) and subsequent decisions. FDA is seeking comments in three broad areas:

- Alternatives for regulating health claims that do not meet the significant scientific agreement standard,
- Other issues related to health claims, and
- Dietary guidance statements on conventional food and dietary supplement labels.

We are forwarding your correspondence to the public docket so that your comments will be considered during our review of this issue.

Thank you again for contacting us about this matter. If you have further concerns or questions, please let us know.

Sincerely,

Amit K. Sachdev
Associate Commissioner
For Legislation

2003N-0496

C3 / ANS

Page 2 - The Honorable Edward M. Kennedy

bcc: HFW-10
HFW-1 (Sachdev, Barrett)
HFW-12 (Yanish, Eck, Ezzard, Hilton)
HFW-14 (McGarey)
HFS-22
HFA-305 (Division of Dockets Management)
GCF-1 (vpollard)

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5

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December 5, 2003

Mark McClellan, M.D., PhD.
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mark:

I'm writing to express my concern about the announcement by the Food and Drug Administration in July that the agency no longer intends to apply the strict standard under current law for approving health claims for food, and now intends to permit the use of claims based on a lower standard of scientific evidence. I'm concerned that the change will be a serious setback for public health and will encourage the use of unreliable and misleading labels on foods. I also believe that the agency is exceeding its statutory authority by modifying the current statutory standard, and will face long and contentious litigation because of it.

Congress passed the Nutrition Labeling and Education Act unanimously in 1990, and President Bush's father signed it into law to prevent the widespread use of unjustified health claims for foods. Under the 1990 Act, health claims can be approved only if supported by "significant scientific agreement." Products with claims not approved under that standard are misbranded as foods. Their intended use makes them drugs, and they must meet the stricter statutory standard for drug approval.

Under FDA's July announcement, the agency will assess the quality of evidence for a health claim, and will take no action against it if certain disclaimers are used. As a result, the agency will no longer apply either the significant scientific agreement standard or the higher drug approval standard that would apply but for the provisions of the 1990 Act to food products claimed to prevent or reduce the risk of disease. The new lower standard may well result in the use of health claims that are subsequently found to have little scientific support, or even no scientific support at all.

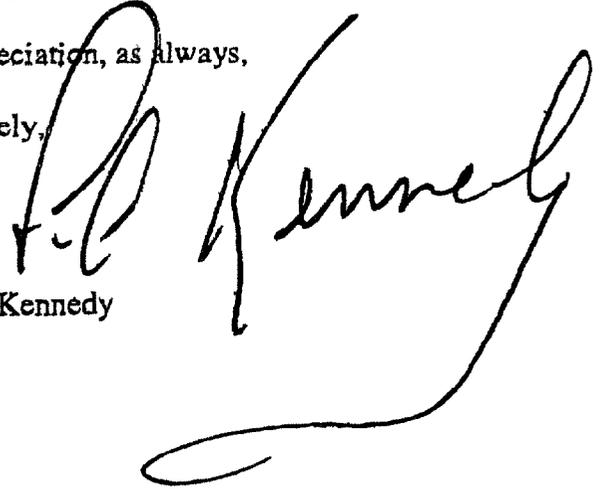
As the accompanying legal memorandum indicates, it is very likely that the change in policy exceeds the agency's authority under the 1990 Act, and I urge you to withdraw it. I hope very much that the agency will continue its announced research on how consumers understand disclaimers when used with health claims. After the research

Mark McClellan
December 5, 2003
Page 2

is completed, if the agency believes that it justifies a change in the standard, I'm confident that Congress will consider any change requested by the agency expeditiously.

With respect and appreciation, as always,

Sincerely,

A large, handwritten signature in black ink, reading "E. M. Kennedy". The signature is written in a cursive style with a long, sweeping underline that extends to the right and then curves back down.

Edward M. Kennedy

MEMORANDUM ON FDA AUTHORITY on Health Claims for Food Products

As a legal basis for its July announcement, FDA cites only its "enforcement discretion," and refers to the decision of the U.S. Court of Appeals for the D.C. Circuit in Pearson v. Shalala, 164 F.3d 650 (1999). "Enforcement discretion," however, applies to an agency's discretion not to take an enforcement action in a particular case. It does not permit an agency to nullify a statutory standard. In the leading case on enforcement discretion, the Supreme Court held that a court may not review an agency's decision not to bring a specific enforcement action, but the Supreme Court did not extend this holding 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. 821, 833 n.4 (1985).

By abandoning both the statutory standard for approval of health claims and the statutory standard for approval of drugs, and by adopting a lower standard instead, the FDA has "consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities."

Pearson v. Shalala is no basis for refusing to enforce the standard for approving health claims for food and the standard for drug approval. The court in that case held that four FDA regulations refusing to permit certain specific health claims for dietary supplements violated the First Amendment. But the court did not invalidate the general regulatory standard for health claims on dietary supplements, which is the same as the statutory standard for health claims on food. In fact, the court required the agency to clarify the standard through guidance or rulemaking. Nor did it invalidate the statutory standard for food required by the Nutrition Labeling and Education Act. In fact, if the Pearson court had invalidated the Act's standard for health claims on food, there would be no statutory basis at all for a health claim on food, unless the food met the requirements for a new drug approval under the Federal Food, Drug, and Cosmetic Act.

The statutory "significant scientific agreement" standard for health claims on food is clearly permissible under the First Amendment. Before the 1990 Act, foods with health claims were treated as drugs that had to be proved "safe and effective" for their intended use, and the regulation of those claims did not violate the First Amendment. Wisconsin v. Mitchell, 509 U.S. 476, 489 (1993). The 1990 Act reduced the evidentiary standard on health claims for food and established the current standard of "significant scientific agreement." In effect, the Act permits additional speech about those products, and could not possibly violate the First Amendment under Wisconsin v. Mitchell.

The Supreme Court's decisions on commercial speech permit the prohibition of speech that is inadequately verified and may in fact be untrue, such as health claims that are not supported by significant scientific agreement. Those decisions required disclaimers for speech that is true but does not tell the whole story, e.g., Bates v. State Bar of Arizona, 433 U.S. 350 (1977), but no Supreme Court ruling requires the use of a disclaimer with respect to speech that simply may not be true. One federal district court

has recently cited Pearson and upheld the use of a health claim for which there was some scientific evidence, even though the overall weight and quality of the evidence did not support the claim, provided that a disclaimer was used, Whitaker v. Thompson, 248 F. Supp.2d. 1, 30-37 (D.D.C. 2000), but that result makes no sense.

The FDA reference to Pearson in its July announcement indicates that the agency itself has determined that the standard for health claims on food enacted in 1990 violates the First Amendment. That determination exceeds the FDA's authority. It is the responsibility of the judicial branch, not the executive branch, to determine the constitutionality of laws. If a law is found unconstitutional by the courts, it is the responsibility of Congress to decide whether and how to replace it.